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Physician Fee Schedule Proposed Rule for 2025 - Summary Part I

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 [CMS-1807-P]

On July 10, 2024, the Centers for Medicare & Medicaid Services (CMS) placed on public display a proposed rule relating to the Medicare physician fee schedule (PFS) for CY 2025[1] and other revisions to Medicare Part B policies. The proposed rule is scheduled to be published in the July 31, 2024 issue of the *Federal Register*. If finalized, policies in the proposed rule generally would take effect on January 1, 2025. **The 60-day comment period ends at close of business on September 9, 2024.**

HPA is providing a summary in three parts. Part I covers sections I through III.O (except for Section G: Medicare Shared Savings Program Requirements) and the Regulatory Impact Analysis. Part II will cover the Medicare Shared Savings Program Requirements. Part III will cover the updates to the Quality Payment Program.

Part I includes payment policies under the PFS including caregiver training services, the evaluation and management (E/M) office/outpatient (O/O) complexity add-on code; telehealth services; advanced primary care management services (APCM), global surgery payment, behavioral health services, dental services; preventive services, such as colorectal cancer and hepatitis B screening, and Inflation Reduction Act (IRA) provisions relating to Part B drugs and biologicals. The proposed rule contains several comment solicitations including on services addressing health-related social needs, building upon the MIPS Value Pathways (MVPs) framework to improve ambulatory specialty care, and strategies for implementing recurring updates to direct and indirect practice expense.

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[1] Henceforth in this document, a year is a calendar year unless otherwise indicated.

I. Introduction

The proposed rule would update the PFS payment policies that apply to services furnished in all sites by physicians and other practitioners. In addition to physicians, the PFS is used to pay a variety of practitioners and entities including nurse practitioners, physician assistants, physical therapists, radiation therapy centers, and independent diagnostic testing facilities (IDTFs). The proposed rule includes proposals for new coding and payment for caregiver training services, advanced primary care management services (APCM), and behavioral health services; payment refinements for improving global surgery payment accuracy; and maintaining limited telehealth flexibilities. In this proposed rule, CMS is also codifying policies established in revised guidance for the Medicare Part B Drug Inflation Rebate Program and proposing additional refinements. CMS also continues to defer changes to its practice expense methodology until it receives updated information from the American Medical Associations' (AMA) Physician Practice Information Survey and is able to assess that data along with ongoing work.

The proposed conversion factor (CF) for 2025 is $32.3562, which reflects the expiration of the temporary 2.93 percent increase for services furnished for most of 2024;[2] the 0.00 percent update

[2] The Consolidated Appropriations Act (CAA), 2023 provided a 1.25 percent increase for 2024 that was applied for services furnished from January 1, 2024 through March 8, 2024, and the CAA, 2024 provided a 2.93 percent increase (replaced the 1.25 percent), for services furnished from March 9, 2024 through December 31, 2024.

adjustment factor specified under section 1848(d)(19) of the Act, and a budget neutrality (BN) adjustment of +0.05 percent. The increase in the BN adjustment appears to be largely related to the proposed adjustments to the transfer of postoperative care for global surgical procedures.[3] The proposed 2025 PFS CF is -2.8 percent lower than the 2024 CF.

Specialty-specific payment impact in most years is related to changes to RVUs for specific services, including RVUs for new and revised codes. For 2025, specialty level changes can be largely attributed to changes to RVUs for specific services and the fourth and final year transition to updated clinical labor pricing. These specialty impacts range from an increase of 4 percent for clinical social worker, increase of 3 percent for clinical psychologist, increase of 2 percent for anesthesiology, and a decrease of 2 percent for diagnostic testing facility, interventional radiology, and vascular surgery. **These payment impacts, however, do not take into account the expiration of the temporary 2.93 percent increase for most of 2024, as this was a statutory change that took place outside of BN requirements.** For example, if CMS specifies a 2 percent reduction in Table 128 for a given specialty, the combined effect of RVU changes with the CF reduction would be roughly 5 percent.

II. Provisions of the Proposed Rule for PFS

A. Background

Since January 1, 1992, Medicare has paid for physician services under section 1848 of the Act, "Payment for Physicians' Services." The PFS relies on national relative values that are established for work, practice expense (PE), and malpractice (MP) for each service. These relative values are adjusted for geographic cost variations, as measured by geographic practice cost indices (GPCIs). The summation of these relative values or relative value units (RVUs) are multiplied by a conversion factor (CF) to convert them into a payment rate. This background section discusses the historical development of work, practice expense, and malpractice RVUs, and how the geographic adjustment and conversion factor are used to determine payment. The basic formula is the following:

Payment = [(RVU work x GPCI work) + (RVU PE x GPCI PE) + (RVU MP x GPCI MP)] x CF

B. Determinations of Practice Expense (PE) Relative Value Units (RVUs)

1. Practice Expense Methodology

CMS summarizes the history of the development of PE RVUs, the steps involved in calculating direct and indirect cost PE RVUs, and other related matters.

For 2025, CMS makes note of several issues in this section.

[3] CMS estimates that there will be a postoperative transfer of care 20 percent of the time with a corresponding 21 percent decrease in payment. This results in an increase in the budget neutrality adjustment to the conversion factor, which is redistributed across the PFS.

In accordance with the CAA, 2023 CMS incorporates the available utilization data for two new specialties, Marriage and Family Therapist (MFT) and Mental Health Counselor (MHC). CMS proposes to use PE/HR values from Licensed Clinical Social Workers as a proxy for these two specialties.

CMS notes that it is proposing mandatory use of the 54 and 55 modifiers when practitioners furnishing global surgery procedures share in patient care and intend only to furnish preoperative/intraoperative or postoperative portions of the total global procedure. It notes that, if implemented, this will likely increase the number of claims subject to the adjustment (discussed in more detail in section II.G of this proposed rule).

With respect to the formula for calculating equipment cost per minute, CMS notes in the 2021 Medicare PFS final rule it finalized its proposal to treat equipment life durations of less than 1 year as having a duration of 1 year for the purpose of its equipment price per minute formula. It notes that it continues to update the useful life of equipment items based on the American Hospital Associations' "Estimated Useful Lives of Depreciable Hospital Assets" guidelines (last updated in 2018).

CMS also recognizes that the annual maintenance factor used in the equipment calculation may not be precisely 5 percent for all equipment. In the absence of an auditable, robust data source, CMS does not believe it has sufficient information to propose a variable maintenance factor, though it continues to investigate ways of capturing such information.

2. Adjusting RVUs to Match PE Share of the Medicare Economic Index (MEI)

In the 2023 PFS final rule, CMS finalized its proposal to rebase and revise the Medicare Economic index (MEI) to reflect more current market conditions physicians faced in furnishing services. In the past, CMS has proposed and (subsequently finalized) implementation of the MEI into its payment calculations by holding the work RVUs constant and adjusting the PE RVUs, the MP RVUs, and the conversion factor to produce the appropriate balance in RVUs among the PFS components and payment rates for individual services. The most recent adjustments of this type were made for the 2014 RVUs, when the MEI was last updated.[4] In that update, CMS adjusted several steps in its PE RVU methodology to adjust the pool of direct and indirect PE costs for the revised MEI and recalibrate its relativity adjustment (steps 3, 10, and 18). In the 2023 PFS final rule, CMS finalized a delay of these adjustments to the PE pools in steps 3 and 10 and the recalibration of the relativity adjustment in step 18 for the rebased and revised MEI. It also sought comments on how best to incorporate the rebased and revised MEI into the PFS ratesetting and whether it would be appropriate to consider a transition to full implementation for potential future rulemaking. Many commenters expressed concern about the redistributive impacts of the implementation and also noted that the AMA intends to collect practice cost data from physician practices in the near future which could be used to derive cost share weights for the MEI and RVU shares.

[4] The 2014 PFS proposed rule (78 FR 43287 through 43288) and the final rule (78 FR 74236 through 74237) – steps 3, 10, and 18.

In light of AMA's intended data collection and CMS stated efforts to balance payment stability and predictability with incorporating new data through more routine efforts, CMS is not proposing to incorporate the 2017-based MEI in PFS ratesetting for 2025. CMS states, however, that it will continue to monitor the data available related to physician services' input expenses, but is not proposing to update the data underlying the MEI cost weights at this time.

3. Changes to Direct PE Inputs for Specific Services

a. Standardization of Clinical Labor Tasks

CMS states that it continues to work on revisions to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the pre-service, service, and post-service periods for each code. CMS believes this will increase the transparency of the information used to set PE RVUs, facilitate the identification of exceptions to the usual values, provide greater consistency among codes that share the same clinical labor tasks, and improve relativity of values among codes. In addition, CMS notes the advantage that as medical practice and technologies change over time, changes in the standards could be updated at once for all codes with the applicable clinical labor tasks, instead of waiting for individual codes to be reviewed.

CMS notes, as in previous years, that it will continue to display two versions of the Labor Task Detail public use file to facilitate rulemaking for 2025: one version with the old listing of clinical labor tasks, and one with the same tasks cross-walked to the new listing of clinical labor activity codes. These lists are available on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

b. Updates to Prices for Existing Direct PE Inputs

CMS notes that it completed its comprehensive 4-year market-based supply and equipment update in 2022; its contractor, StrategyGen, provided updated pricing recommendations for about 1,300 supplies and 750 equipment items.

(1) Public Submission of Invoices

For 2025, CMS proposes to update the prices of 17 supplies and one equipment item in response to the public submission of invoices. The proposed prices for these items were generally calculated following its standard methodology of averaging together the prices on the submitted invoices. This includes, for example, updating the pricing of the extended external ECG patch, medical magnetic tape recorder (SD339) from $260.35 to $292.50 based on 20 submitted invoices. See Table 16 in the proposed rule for details on the updated prices, CPT codes affected, and number of services impacted.

CMS does not update the price of another ten supplies for which it received information. It cited several reasons including that it needed additional information regarding the unit size of each supply included on the invoices, that it was able to find the same supply item available for sale

online at the current price or cheaper, or that the number of invoices provided was insufficient to support the significant price increase.

CMS notes it routinely accepts public submission of invoices as part of its process for developing payment rates for new, revised, and potentially misvalued codes. To be included in a given year's proposed rule, it generally needs to receive invoices by February (February 10th deadline in 2025). CMS notes it will, of course, consider invoices submitted during the comment period following the publication of the proposed rule or during other times as part of its annual process.[5]

CMS states it is concerned about the growing number of invoice submissions for use in updating supply and equipment pricing as these voluntary submissions represent a small subset of the total number of supply and equipment items in its database and may distort relativity across the fee schedule. It believes that it would be more efficient, and more accurate, to update supply and equipment pricing in a more comprehensive fashion, similar to the pricing update that took place from 2019 to 2022. **It welcomes comments on this general topic of more comprehensive updates to supply and equipment pricing, and may use these comments to inform future rulemaking.**

(2) Supply Pack Pricing Update

CMS notes that interested parties have identified numerous discrepancies between the aggregated cost of some supply packs and the individual item components contained within. For the 2024 rule cycle, the AMA RUC convened a workgroup and submitted recommendations to update pricing for a series of supply packs. Given the projected significant cost revisions in the pricing of supply packs and the fact that CMS did not propose to address this issue in the 2024 proposed rule, it deferred this issue for future rulemaking.

For 2025, CMS proposes to implement the supply pack pricing update and associated revisions as recommended by the RUC's workgroup. Specifically, CMS proposes to update the pricing for the "pack, cleaning and disinfecting, endoscope" (SA042) supply, the "pack, drapes, cystoscopy" (SA045) supply, the "pack, ocular photodynamic therapy" (SA049) supply, the "pack, urology cystoscopy visit" (SA058) supply, and the pricing of the "pack, ophthalmology visit (w-dilation)" (SA082) supply. CMS also proposes to delete the "pack, drapes, laparotomy (chest-abdomen)" (SA046) supply entirely. The proposed updated prices for these supply packs are listed in the valuation of specific codes section of the preamble under Table 16, CY 2025 Invoices Received for Existing Direct PE Inputs.

In accordance with the RUC workgroup's recommendations, CMS also proposes to create eight new supply codes, including components contained within previously existing supply packs. Aside from the SB056 supply, which is a replacement in several HCPCS codes for the deleted SA046 supply pack, all of these new supplies are not included as standalone direct PE inputs in any current HCPCS codes. CMS proposes to add:

[5] If outside of the comment period, interested parties can submit invoices to PE_Price_Input_Update@cms.hhs.gov.

- the kit, ocular photodynamic therapy (PDT) (SA137) supply at a price of $26.00 as a component of the SA049 supply pack;
- the Abdominal Drape Laparotomy Drape Sterile (100 in x 72 in x 124 in) (SB056) supply at a price of $8.049 as a replacement for the SA046 supply pack;
- the drape, surgical, legging (SB057) supply at a price of $3.284 as a component of the SA045 supply pack;
- the drape, surgical, split, impervious, absorbent (SB058) supply at a price of $8.424 as a component of the SA045 supply pack;
- the post-mydriatic spectacles (SB059) supply at a price of $0.328 as a component of the SA082 supply pack;
- the y-adapter cap (SD367) supply at a price of $0.352 as a component of the SA049 supply pack;
- the ortho-phthalaldehyde 0.55% (eg, Cidex OPA) (SM030) supply at a price of $0.554 as a component of the SA042 supply pack; and
- the ortho-phthalaldehyde test strips (SM031) supply at a price of $1.556 as a component of the SA042 supply pack.

The proposed new supply pack component items are listed in the valuation of specific codes section of the preamble under Table 17, CY 2025 New Invoices. CMS also proposes additional supply substitutions for selected CPT codes based on the recommendations of the RUC workgroup for the deleted SA046 supply pack.

The RUC workgroup also reviewed the issue of skin adhesives and identified several generic alternatives to using the skin adhesive (Dermabond) (SG007) supply. The workgroup stated that there are multiple skin adhesive products, at different price points, available that work similarly to Dermabond and requested that generic alternatives be used overall in place of brand names in the CMS direct PE database. CMS states, however, that it has no pricing information or submitted invoices for the four generic formulations of cyanoacrylate skin adhesive requested by the RUC, and thus it has not added them to its direct PE database for the 2025 proposed rule.

c. Clinical Labor Pricing Update

In the 2022 final rule, CMS finalized its proposal to update the clinical labor pricing for 2022 in conjunction with the final year of the supply and equipment pricing update. Clinical labor rates had not been updated in 20 years. The long delay since clinical labor pricing was last updated created a significant disparity between CMS' clinical wage data and the market average for clinical labor.

Similar to its approach in 2002, CMS primarily used Bureau of Labor Statistics (BLS) wage data to update its clinical labor pricing in 2022. It believed that BLS data is the most accurate source to use as a basis for clinical labor pricing and used the most recent BLS survey data available for its calculations of wage data (2019). For certain labor categories where BLS data were not available, CMS had to crosswalk or extrapolate the wages using supplementary data sources for verification. It used the median BLS wage data rather than the proposed average or mean wage data for calculation of clinical labor rates. Based on comments received, CMS used the fringe

benefits multiplier of 1.296 for employees in private industry based on a BLS release from June 17, 2021 (USDL-21-1094).

It also agreed with commenters that a multi-year transition would help smooth out the changes in payment resulting from the clinical labor pricing update and avoid potentially disruptive changes in payment and promote payment stability. CMS finalized the implementation of the clinical labor update over 4 years to transition from current prices to the final updated prices in 2025. CMS provides an example of how this transition would be implemented in Table 4 of the proposed rule (reproduced below). For 2025, the clinical labor pricing would be fully implemented.

Table 4: Example of Clinical Labor Pricing Transition		
Current Price	$1.00	
Final Price	$2.00	
Year 1 (2022) Price	$1.25	1/4 difference between $1.00 and $2.00
Year 2 (2023) Price	$1.50	1/3 difference between $1.25 and $2.00
Year 3 (2024) Price	$1.75	1/2 difference between $1.50 and $2.00
Final (2025) Price	$2.00	

For 2023, CMS finalized a change in the descriptive text of the L041A clinical labor type from "Angio Technician" to "Vascular Interventional Technologist". It also updated pricing of three clinical labor types for the Vascular Interventional Technologist, the Mammography Technologist, and the CT Technologist. The pricing for these clinical labor types is based on submitted data from the 2022 Radiologic Technologist Wage and Salary Survey.

For 2024, based on comments received from the proposed rule, CMS finalized an update in the clinical labor pricing of the cytotechnologist (L045A) clinical labor type from $0.76 to $0.85 based on submitted data from the 2021 American Society of Clinical Pathologists (ASCP) Wage Survey of Medical Laboratories (88 FR 78838).

For 2025, CMS did not receive new wage data or additional information for use in clinical labor pricing from interested parties prior to the publication of the 2025 PFS proposed rule. Thus, the proposed clinical labor pricing for 2025 is based on the prior year clinical labor pricing updated for year 4 or the final year of the transition.

Excerpt of Selected Labor Categories from Table 5: Proposed 2025 Clinical Labor Pricing					
Labor Code	**Labor Description**	**Source**	**2021 Rate Per Minute**	**Final Y4 Rate Per Minute**	**Total % Change**
L023A	Physical Therapy Aide	BLS 31-2022	0.23	0.28	22%
L026A	Medical/Technical Assistant	BLS 31-9092	0.26	0.36	38%
L032B	EEG Technician	BLS 29-2098	0.32	0.44	38%
L035A	Lab Tech/Histotechnologist	L0333A, L037B	0.35	0.60	70%
L037B	Histotechnologist	BLS 29-2010	0.37	0.64	73%
L037D	RN/LPN/MTA	L051A, BLS 29-2061, L026A	0.37	0.54	46%
L038B	Cardiovascular Technician	BLS 29-2031	0.38	0.60	58%

Excerpt of Selected Labor Categories from Table 5: Proposed 2025 Clinical Labor Pricing					
Labor Code	**Labor Description**	**Source**	**2021 Rate Per Minute**	**Final Y4 Rate Per Minute**	**Total % Change**
L042A	RN/LPN	L051A, BLS 29-2061	0.42	0.63	50%
L042B	Respiratory Therapist	BLS 29-1126	0.42	0.64	52%
L043A	Mammography Technologist	ASRT Wage Data	0.43	0.79	84%
L045A	Cytotechnologist	BLS 29-9092	0.45	0.85	89%
L046A	CT Technologist	ASRT Wage Data	0.46	0.78	70%
L047A	MRI Technologist	BLS 29-2035	0.47	0.76	62%
L050C	Radiation Therapist	BLS 29-1124	0.50	0.89	78%
L051A	RN	BLS 29-1141	0.51	0.76	49%
L051B	RN/Diagnostic Medical Sonographer	L051A, BLS 29-2032	0.51	0.77	51%

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

a. Background

CMS reviews the history and process it used to last update the "indirect" PE data inputs, such as office rent, IT costs, and other non-clinical expenses. The primary source for the indirect PE information is the Physician Practice Information Survey (PPIS) which was fielded by the AMA and last conducted in 2007 and 2008. In the 2010 PFS final rule, CMS finalized its proposal to phase-in the AMA PPIS data over a 4-year transition period. It uses these data to calculate the indirect PEs incurred per hour worked (or PE/HR) in developing the indirect PE RVUs. The PPIS survey data are used for almost all of the Medicare recognized specialties. Supplemental survey data is used for certain specialties as required by statute, such as oncology specialties, or because certain specialties, such as IDTFs, were not part of the PPIS. It notes that over time it has continued to review data and the PE methodology annually to evaluate the need for updates or refinements.

In 2023, CMS issued an RFI to solicit public comment on strategies to update PE data collection and methodology. CMS noted that it has explored issues related to indirect PE in previous rulemaking and contracted with the RAND corporation to examine this issue.[6] In general, stakeholders have raised the following concerns about CMS' current approach to indirect PE allocation:

- Relies on increasingly out-of-date sources, and there is a dearth of mechanisms to update empirical inputs.
- Exacerbates payment differentials that could possibly create inappropriate variation of reimbursement across ambulatory places of service.
- Does not reflect variation in PE across different types of services, different practice characteristics, or evolving business models.

[6] Burgette, Lane F., Jodi L. Liu, Benjamin M. Miller, Barbara O. Wynn, Stephanie Dellva, Rosalie Malsberger, Katie Merrell, et al. "Practice Expense Methodology and Data Collection Research and Analysis." RAND Corporation, April 11, 2018. https://www.rand.org/pubs/research_reports/RR2166.html.

Others have expressed concern that certain costs in CMS' current PE allocation methodology should be excluded or allocated in a different manner. Some stakeholders argue that the costs of disposable supplies, especially expensive supplies, and equipment are not relevant to allocating indirect PE; or that similarly, work in the facility setting (e.g., work RVUs for surgical procedures) is not relevant for allocating indirect PE.

CMS continues to have an interest in developing a roadmap toward more routine PE updates that better account for the changes in the health care landscape with updated data sources that support and enable ongoing refinements to its PE methodology.

b. Preparation for Incorporating Refreshed Data and Request for Information on Timing to Effectuate Routine Updates

In the 2024 PFS proposed rule, CMS continued to seek feedback and suggestions from stakeholders for an evidentiary basis to shape optimal PE data collection and methodological adjustments over time. CMS also sought to understand whether, upon completion of the updated PPIS data collection effort by the AMA, contingencies or alternatives may be necessary and available to address the lack of data availability or response rates for a given specialty, set of specialties, or specific service suppliers who are paid under the PFS.

Most commenters, in response to last year's RFI, stated that CMS should defer significant changes until the AMA PPIS results become available (88 FR 78841 to 78843). These were consistent with the AMA RUC letter submission from 2024 that CMS should not consider further changes to the underlying data or the methodology until PPIS data collection and analysis is complete. The AMA expects analysis, reporting, and documentation to be complete by the end of 2024, and the AMA would share data with CMS when results become available. Through its contractor, Mathematica, the AMA secured an endorsement for the PPIS updates from each State society, national medical specialty society, and others prior to fielding the survey (88 FR 78843).[7]

CMS remains uncertain about whether endorsements prior to fielding the survey may inject other types of bias in the validity and reliability of the information collected. It also believes that it remains important to reflect on the challenges with its current PE methodology, and to continue to consider alternatives that improve the stability and accuracy of the overall PE methodology. CMS notes that it 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. It continues to study possible alternatives, and would include analysis of updated PPIS data, as part of its ongoing work. **In the interim, CMS requests general information** from the public on ways that CMS may continue work to improve the stability and predictability of any future updates. Specifically, CMS requests feedback from interested parties regarding scheduled, recurring updates to PE inputs for supply and equipment costs.

[7] Refer to the AMA's summary of the PPIS, available at https://www.ama-assn.org/system/files/physician-practice-information-survey-summary.pdf

CMS believes that establishing a cycle of timing to update supply and equipment cost inputs every 4 years may be one means of advancing shared goals of stability and predictability. CMS would collect available data, including, but not limited to, submissions and independent third-party data sources, and propose a phase-in period over the following 4 years. It notes that this could have the unintended consequence of disproportionate effects of various supplies and equipment that have newly updated costs.

Further, CMS seeks feedback on possible mechanisms to establish a balance whereby its methodology would account for inflation and deflation in supply and equipment costs. It remains uncertain how economies of scale (meaning a general principle that cost per unit of production decreases as the scale of production increases) should or should not factor into future adjustments to the PE methodology. CMS also seek information about specific mechanisms that may be appropriate, and in particular, approaches that would leverage verifiable and independent, third- party data that is not managed or controlled by active market participants.

C. Potentially Misvalued Services under the PFS

1. Background

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the RVUs established under the PFS. Section 1848(c)(2)(K) requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the RVUs for these services.

In the 2012 PFS final rule (76 FR 73058), CMS finalized a process for the public to nominate potentially misvalued codes. The public and stakeholders may nominate potentially misvalued codes for review by submitting the code with supporting documentation by February 10th of each year. CMS reviews the information and in the following year's PFS proposed rule, discusses the nominated codes and indicates whether it is proposing the code as a potentially misvalued code. CMS finalizes its list of potentially misvalued codes in the final rule.

Nominations may be submitted to CMS via email or through postal mail.

- Email submissions should be sent to MedicarePhysicianFeeSchedule@cms.hhs.gov with the phrase "Potentially Misvalued Codes" and the referencing CPT code number(s) and/or CPT descriptor(s) in the subject line.
- Letters should be sent to the CMS, Mail Stop: C4-01-26, Security Blvd, Baltimore, MD 21244. Envelopes must be labeled "Attention: Division of Practitioner Services, Potentially Misvalued Codes."

2. Identification and Review of Potentially Misvalued Services

For FY 2025, CMS received 5 nominations for potentially misvalued services.

(1). CPT codes 22210, 22212, 22214, and 22216 (Osteotomy of spine codes)
These codes were nominated as misvalued for six reasons: (1) incorrect global period; (2) incorrect inpatient days; (3) incorrect intraservice work description; (4) overvalued intraservice

times; (5) changes in surgical practice; and (6) incorrect use of posterior osteotomy codes. Although the nominator provided limited evidence to support the first four assertions, CMS stated that the evidence supported changes in surgical practice and incorrect billing usage of posterior osteotomy codes. For example, according to the nominator isolated partial facetectomy and soft tissue release are already included in spinal fusion procedures and should not be separately billed with an osteotomy code.

CMS proposes to consider this code as potentially misvalued given that these codes were last valued almost 30 years ago, and given the identified billing practices. CMS believes that this code family would benefit from a comprehensive review by the RUC, and **it welcomes comments on a broader understanding of these codes, including input on current standing billing practices.**

(2). CPT code 27279 (Arthrodesis, sacroiliac joint, percutaneous or minimally invasive) with image guidance, includes bone graft when performed, and placement of fixation device)
CPT code 27279, a 90-day global service, was re-nominated as misvalued because it lacks separate direct PE inputs in the nonfacility setting. CMS states that it did not nominate this code as potentially misvalued in the 2024 PF final rule, mainly due to a lack of consensus on whether these services may be safely and effectively furnished in the nonfacility/office setting. Based on five studies submitted, the nominator asserts that the current medical literature provides evidence supporting the conclusion that percutaneous or minimally invasive SI joint arthrodesis (CPT code 27279) carries a complication rate that is acceptably low, comparable to other spinal procedures commonly performed in the office-based lab (OBL).CMS states, however, that upon reviewing the submitted information, these studies collectively report heterogeneous safety outcomes, with large variabilities in safety outcomes, and with several unreported outcomes.

CMS remains concerned about whether this surgical service can be safely and effectively furnished in the non-facility setting (for example, in the office-based surgical suite). Thus, CMS is not proposing to consider this code as potentially misvalued**. CMS seeks comments and additional studies from the broader medical community on whether this code should be priced under the PFS for the non-facility/office setting.**

(3). CPT code 95800 (Sleep study, unattended)
This code was renominated as potentially misvalued due to outdated PE supply and equipment items (nominated in the 2024 PFS proposed rule). This year, the nominator notes significant changes in the technologies available to perform home sleep apnea testing (HSAT) services, and in clinical practice. For example, the nominator states that the current practice utilizes disposable HSAT technology, such as the WatchPAT One device, more often than the reusable equipment currently included in the procedure's direct PE inputs. The nominator noted that the pandemic significantly altered the delivery of HSAT services, with many sleep physicians transitioning to single-use disposable sleep tests and that based on its internal data these disposable devices were used nearly 50 percent for this code in 2023. Table 6, in the proposed rule, list the nominator's recommendations for practice expense items for these codes.

CMS notes that the nominator's summary of their internal data on the use of disposable HSAT technology may not be generalizable and thus CMS is not proposing to consider this code as

potentially misvalued. **CMS seeks comments on whether this typical procedure described by CPT code 95800 now involves the use of a disposable HSAT device rather than reusable equipment.**

(4). CPT code 10021 (Fine needle aspiration biopsy, without imaging guidance; first lesion), CPT code 10004 (Fine needle aspiration biopsy, without imaging guidance; each additional lesion), CPT code 10005 (Fine needle aspiration biopsy, including ultrasound guidance; first lesion) and CPT code 10006 (Fine needle aspiration biopsy, including ultrasound guidance; each additional lesion)

This code family, as CMS notes, has been nominated several times in recent years (refers readers to the 2019 PFS final rule (83 FR 59517), the 2021 PFS final rule (85 FR 84602), and the 2020 PFS final rule (84 FR 62625). The commenter raised several concerns with these codes. For example, the commenter disagreed with the one-third reduction from its previous physician time and the 5 percent reduction in the work RVU for CPT 10021 stating that there was a change in intensity. It raised particular concern about CMS' choice for the RVU crosswalk for CPT code 36440 (Push blood transfusion, patient 2 years or younger), and believes this code is not comparable to fine needle aspiration in any respect other than service time. The nominator emphasized the differences in provider training, procedure risk, and patient population as well as the shift to facility setting, prompted by the reduced work RVUs, which could raise Medicare costs.

CMS notes, in response, that these codes underwent a thorough RUC survey and review process during the October 2017 and January 2018 RUC meetings. CMS is not proposing to consider these codes as potentially misvalued. **CMS welcomes comments on whether these codes should be re-reviewed.**

(5). Tympanostomy codes

CMS notes that it routinely interacts with interested parties, and has observed several new devices, related to tympanostomy, that could be beneficial for populations but are not currently included in its coding system. The new device is intended to deliver a tympanostomy tube (also referred to as a ventilation tube) through the tympanic membrane of the patient and is indicated to be used in office settings for pediatric patients 6 months and older. This device allows the tympanostomy service to be furnished to patients without general anesthesia and the service could therefore be performed in the office setting. CMS is concerned that the base code, CPT code 69433 *Tympanostomy (requiring insertion of ventilating tube), local or topical anesthesia*) (010-day global code) may serve as a sufficient base code, but may not adequately capture the additional physician work required when furnishing the service to a child and the cost of device.

CMS seeks comment on whether to establish a new G code and assign contractor pricing. It also seeks comment on whether it should establish an add-on payment for the service using inputs from CPT code 69433 as a crosswalk reference, plus direct costs from invoices for the surgical devices.

D. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

As background, the CAA, 2023 extended the availability of Medicare telehealth services to beneficiaries regardless of geographic location or site of service by temporarily removing such statutory restrictions under section 1834(m) of the Act until the end of 2024. Absent congressional action, the geographic location and site of service restrictions on Medicare telehealth services will once again take effect for services furnished beginning January 1, 2025. Although there are some important exceptions, including for behavioral health services and ESRD-related clinical assessments, most Medicare telehealth services will once again, in general, be available only to beneficiaries in rural areas and only when the patient is located in certain types of medical settings.

In this rule, CMS proposes changes to the Medicare Telehealth Services List, addresses frequency limitations on certain telehealth services, addresses the use of providers' home addresses, as well as telehealth issues on direct supervision and supervision of residents in teaching settings, among other proposed changes. These proposed policies are described below.

1. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

a. Changes to the Medicare Telehealth Services List

In the 2003 PFS final rule (67 FR 79988), CMS established a process for adding or deleting services from the Medicare telehealth list. CMS assigns requests to two categories: Category 1 and Category 2.

- Category 1 services are similar to services that are currently on the telehealth list. CMS also considers similarities in the telecommunications systems used to deliver the service.
- Category 2 services are not similar to services on the telehealth list. CMS requires evidence demonstrating the service furnished by telehealth improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part.[8]

In the 2021 PFS final rule (85 FR 84507), CMS created a third category for the Medicare telehealth list, Category 3.

- Category 3 services are services added to the telehealth services list during the PHE for which there is likely to be clinical benefit when furnished via telehealth, but there is not sufficient evidence available to consider adding the services under the Category 1 or Category 2 criteria. Services added as a Category 3 telehealth service would ultimately need to meet the Category 1 or Category 2 criteria to be permanently added to the telehealth service list.

[8] CMS provides the following examples of clinical benefit: ability to diagnose a medical condition in a patient population without access to in-person diagnostic services; treatment option for a patient population without access to in-person treatment options; reduced rate of complications; decreased rate of subsequent diagnostic or therapeutic interventions; decreased number of hospitalizations or physician visits; more rapid beneficial resolution of the disease process treatment; decreased pain, bleeding or other quantifiable symptom; and reduced recovery time.

In the 2024 PFS final rule, CMS consolidated these three categories and implemented a revised 5-step process for making additions, deletions, and changes to the Medicare Telehealth Services List beginning for 2025.

Step 1: Determine whether the service is separately payable under the PFS. Medicare telehealth services are limited to those services for which separate Medicare payments can be made under PFS. Specifically, the services (as identified by a HCPCS code), is a covered and separately payable service under the PFS (as identified by a payment status indicators, A, C, T, or R on its public use files).

Step 2. Determine whether the service is subject to the provisions of section 1834 (m) of the Act. This section of the Act provides for payment to a physician (or other practitioner) for services furnished via an interactive telecommunications system at the same amount that would have been paid if the service was furnished without the telecommunication system. CMS interprets this as that the service at issue, needs to be, in whole or in part, inherently a face-to-face service.

Step 3. Review the elements of the service as described by the HCPCS code and determine whether each of them is capable as being furnished using an interactive telecommunications system as defined in §410.78(a)(3). In this step, CMS considers whether one or more face-to-face component(s) of the service, if furnished via audio-video communications technology, would be equivalent to the service being furnished in-person.

Step 4. Consider whether the service elements of the requested service map to the service elements of a service on the list that has a permanent status described in previous final rulemaking. CMS states that any code that satisfies this criterion would require no further analysis and the code would be added to the telehealth list on a permanent basis.

Step 5. Consider whether there is evidence of clinical benefit analogous to the clinical benefit of the in-person service when the patient, who is located at a telehealth originating site, receives a service furnished by a physician or practitioner located at a distant site using an interactive telecommunications system. Under Step 5, CMS reviews the evidence submitted to determine the clinical benefit of a service and compare the clinical benefit of the service when provided in person to the clinical benefit of the service when provided via telehealth. CMS reiterates this evidentiary standard of clinical benefit does not include minor or incidental benefits (81 FR 80194). If there is enough evidence to suggest that further study may demonstrate that the service provided via telehealth is a clinical benefit, CMS will assign the code a "provisional" status on the telehealth list. When the clinical benefit of a service provided via telehealth is clearly analogous to the clinical benefit of the service provided in person, CMS will assign the code a "permanent" status.

b. Requests to Add Services to the Medicare Telehealth Services List for 2025

CMS received several requests to permanently add services to the Medicare telehealth services list for 2025 (Table 7 in the proposed rule, reproduced with modifications below). Many services were added to the Medicare Telehealth Services List on a temporary basis as discussed in the March 31st COVID–19 interim final rule with comment period (IFC) (85 FR 19235 through

19237) for the PHE for Covid-19, and CMS subsequently retained these services on a provisional basis. All of the received submissions were requests for addition on a permanent basis. CMS states that rather than selectively adjudicating only those services for which it received requests for potential permanent status, CMS will wait until it can complete a comprehensive analysis of all such provisional codes which it expects to address in future rulemaking

Requests for Permanent Addition to the Medicare Telehealth List for 2025	
Code Family	**CPT codes**
Cardiovascular Rehabilitation	93797, 93798
Caregiver Training	97550, 97551
Developmental Testing	96112, 96113
Diagnostic Audiologic Testing	92552, 92553, 92555-92557, 92563, 92565, 92567, 92568, 92570, 92587, 92588, 92625, 92626, 92627
Diagnostic CI Testing	92601, 92602, 92603, 92604
Health and Well Being Coaching	0591T, 0592T, 0593T
Intensive Cardiac Rehab	G0422, G0423
OT Evaluation	97165, 97166, 97167, 97168
Outpatient Pulmonary Rehab	94625, 94626
Physical therapy	97161-97163, 97164, 97110, 97112, 97116, 97530, and 97535.
Psych Testing	96130, 96136, and 96137
Radiation Treatment Management	77427
Speech, Language, and Voice Evaluation and Treatment	92507, 92508, 92521-92524, 96105, 92626, 92627, 96125, 97129, 97130
SGD Evaluation and Treatment	92607, 92608, 92609
Swallowing Evaluation and Treatment	92526, 92610, 92550

Continuous Glucose Monitoring (CPT code 95251)
CMS received a request to add this code to the Medicare Telehealth Services List and assign it permanent status. The service has not been previously added and removed. CMS concludes that this service does not meet the criteria described by Step 2 of the 5-step process, as it is not an inherently face-to-face service, as the patient does not need to be present for the service to be furnished in its entirety. This code describes sensor placement and monitoring over a 72-hour period. CMS is not proposing to add this service to the Medicare Telehealth Services List.

Cardiovascular and Pulmonary Rehabilitation; Health and Welling Being Coaching; Psychological Testing and Developmental Testing; Therapy/Audiology/Speech Language Pathology
CMS received requests to permanently add these codes (defined in Table above) to the Medicare Telehealth Services List. As noted previously, CMS is not proposing to revise the status of codes from provisional to permanent in this proposed rule because CMS intends to conduct a comprehensive review in future rulemaking.

Care Management
CMS received a request to permanently add General Behavioral Health Integration (CPT code 99484) and Principal Care Management (CPT codes 99424 – 99427) to the Medicare Telehealth

Services List. These services are not on the Medicare Telehealth Services List, nor have they been previously added and removed. CMS determines that these services do not meet the criteria described by Step 2 of the 5-step process as they are not inherently face-to-face services, and the patient need not be present for the services to be furnished in its entirety. Therefore, CMS is not proposing to add this service to the Medicare Telehealth Services List.

Posterior Tibial Nerve Stimulation for Voiding Dysfunction (CPT code 64566)
CMS received a request to permanently add this code to the Medicare Telehealth Services List, it is not currently on the list nor has it been previously added and removed. CMS concludes this service does not meet the criteria for addition described by Step 3 of the 5-step process that each of the elements of the service is capable of being furnished using an interactive telecommunications system. CPT Code 64566 describes a single treatment provided by a clinician who has direct contact with the patient and inserts an electrode into the skin overlying the posterior tibial nerve. Upon conclusion of the treatment, the clinician removes the electrode and examines and dresses the puncture wound. Providing these services would require in-person interaction. CMS is not proposing to add the service to the Medicare Telehealth Services List because it does not believe the service elements can be met in full using two-way audio-video telecommunications technology.

Radiation Treatment Management (CPT code 77427)
CMS received requests to permanently add and a request to remove this code from the Medicare Telehealth Services List. The request to remove this code citied the importance of in-person physical examination to ensure quality of care and stated that a telehealth modality presents patient safety concerns such as those related to the ability of the practitioner to address side effects of radiation therapy. CMS concludes that such concerns merit removing this item from the telehealth list and proposes to remove this code from the Medicare Telehealth Services List. **CMS solicits comment on these quality of care concerns.**

Home International Normalized Ratio (INR) Monitoring (G0248)
CMS received a request to permanently add this service on the Medicare Telehealth Services List; it is not currently on the list nor had it been previously added and removed. CMS proposes to add HCPCS code G0248 with provisional status because its clinical analyses of these services indicate that they can be furnished in full using two-way, audio and video technology. CMS states that adding this service on a provisional basis will allow additional time for the development of evidence of clinical benefit to determine whether it should be added with permanent status.

Caregiver Training
CMS received a request to permanently add Caregiver Training services, as described by HCPCS codes 97550 (Caregiver traing 1st 30 min) and 97551 (Caregiver traing ea addl 15) to the Medicare Telehealth Services List. CMS proposes to add these services to the Medicare Telehealth List with provisional status in addition to other currently payable caregiver training services codes (CPT codes 97550, 97551, 97552, 96202, 96203). These services were just added to the PFS in 2024 and adding these services on a provisional basis will allow additional time for the evidence development of clinical benefit for potential permanent addition to the Medicare Telehealth Services List.

Contingent upon finalizing the service code descriptions that CMS proposes in section II.E. of this proposed rule, CMS also proposes that HCPCS codes GCTD1-GCTD3 and GCTB1-GCTB2 be added to the Medicare Telehealth Services list for 2025 on a provisional basis. CMS believes that these codes are similar to other services already available on the Medicare Telehealth Services List, and that all elements of these services may be furnished when using two-way interactive communications technology.

c. Other Services Proposed for Addition to the Medicare Telehealth Services List

As discussed in Section II. E. of the proposed rule, CMS is proposing national rates for HCPCS codes G0011 (HIV PreP counsel, md 15-30m) and G0013 (HIV PrEP counsel, clin staff). CMS believes these services are similar to services currently on the Medicare Telehealth Services List, specifically HCPCS codes G0445 (High inten beh couns std 30m) and CPT code 99211 (Off/op est may x req phy/qhp) as these codes are the codes from which HCPCS codes G0011 and G0013 were unbundled. As similarity to services currently on the Medicare telehealth list is one of its criteria for permanent addition, CMS is proposing to add HCPCS codes G0011 and G0013 to the Medicare Telehealth Services List with a permanent status.

The services that CMS proposed to add to the Medicare Telehealth Services List are listed in Table 8 in the proposed rule (reproduced with modifications).

Services Proposed for Addition to the Medicare Telehealth List for 2025	
Code Family	**CPT codes/Proposed Status**
PrEP for HIV	G0011/Permanent G0013/Permanent
Home INR Monitoring	G0248/Provisional
Caregiver Training	97550/Provisional 97551/Provisional 97552/Provisional 96902/Provisional 96903/Provisional GCTD1/Provisional GCTD2/Provisional GCTD3/Provisional GCTB1/Provisional GCTB2/Provisional

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

In the past, CMS has included frequency restrictions on how often practitioners may furnish the service via Medicare telehealth for certain services on the Medicare Telehealth Services List. These included a limitation of 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. In establishing these limits, CMS cited concerns regarding the potential acuity and complexity of these patients.

CMS temporarily removed these frequency restrictions during the PHE for COVID-19 and applied enforcement discretion after expiration of the PHE during 2023. Medicare telehealth frequency limitations were suspended for 2024 for the following codes related to Subsequent Inpatient Visits, Subsequent Nursing Facility Visits, and Critical Care Consultation. CMS proposes to remove the frequency limitations for these same codes in 2025, as follows:

- Subsequent Inpatient Visit CPT Codes: 99231, 99232, and 99233;
- Subsequent Nursing Facility CPT Codes: 99307,99308, 99309, and 99310;
- Critical Care Consultation Services HCPCS Codes: G0508 and G0509.

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

In the 2022 PFS final rule (86 FR 65060), CMS finalized a policy to allow for audio-only services under certain circumstances and revised the regulation at §410.78(a)(3) to permit the use of audio-only equipment for telehealth services furnished to established patients in their homes for purposes of diagnosis, evaluation, or treatment of a mental health disorder (including substance use disorders) if the distant site physician or practitioner is technically capable of using an interactive telecommunications system as defined previously, but the patient is not capable of, or does not consent to, the use of video technology. CMS states that it established this policy in part because mental health services are different from most other services on the Medicare telehealth services list in that many of the services primarily involve verbal conversation where visualization between the patient and furnishing physician or practitioner may be less critical to the provision of the service.

CMS is proposing to revise the regulation at §410.78(a)(3) 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 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. Additionally, a modifier designated by CMS must be appended to the claim for these services to verify that these conditions have been met. These are CPT modifier "93" and, for RHCs and FQHCs, Medicare modifier "FQ" (Medicare telehealth service was furnished using audio-only communication technology). Practitioners have the option to use the "FQ" or the "93" modifiers or both where appropriate and true, since they are identical in meaning.

Under current statute, with the expiration of the PHE-related telehealth flexibilities on December 31, 2024, the patient's home is a permissible originating site only for services for the diagnosis, evaluation, or treatment of a mental health or substance use disorder, and for the monthly ESRD-related clinical assessments described in section 1881(b)(3)(B) of the Act.

f. Distant Site Requirements

In the 2024 PFS final rule, CMS received many comments expressing concerns about the expiring flexibility for telehealth practitioners to bill from their currently enrolled location

instead of their home address when providing services from their home. CMS also met with interested parties who were concerned that expiration of this flexibility poses a potential and imminent threat to the safety of the health care workforce. CMS finalizes, through 2024, that it would continue to permit the distant site practitioner to use their currently enrolled practice location instead of their home address when providing telehealth services from their home.

CMS states that it continues to hear from interested parties who have stressed the importance of continuing this flexibility for the safety and privacy of health care professionals. CMS proposes that through 2025 it will continue to permit the distant site practitioner to use their currently enrolled practice location instead of their home address when providing telehealth services from their home.

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

a. Direct Supervision via Use of Two-way Audio/Video Communications Technology

Prior to the PHE, direct supervision of diagnostic tests, services incident to physician services, and other specified services required the immediate availability of the supervising physician or other practitioner. CMS interpreted this "immediate availability" to mean in-person, physical availability and not virtual availability. During the PHE, CMS changed the definition of "direct supervision" to allow the supervising professional to be immediately available through a virtual presence using real-time audio/video technology for the direct supervision of diagnostic tests, physicians' services and some hospital outpatient services. CMS notes this temporary exception to allow immediate availability for direct supervision through a virtual presence also facilitated the provision of telehealth services by clinical staff of physicians and practitioner's incident to their own professional services. This allowed PT, OT, and SLP services provided incident to a physician to be provided and reimbursed. CMS finalized continuation of this policy through 2023.

In the 2024 PFS final rule, CMS extended this definition of direct supervision through December 31, 2024, to align the timeframe for the policy with other PH-related telehealth policies that were extended most recently under the CAA, 2023.

(1) Proposal to Extend Definition of "Direct Supervision" to include Audio-Video Communications Technology through 2025.

In the absence of evidence that patient safety is compromised by virtual direct supervision, CMS continues to be concerned about an abrupt transition to its pre-PHE policy that defines direct supervision to require the physical presence of the supervising practitioner. CMS notes that physicians and/or other supervising practitioners may need time to reorganize their practice patterns established during the PHE to reimplement the pre-PHE approach to direct supervision without the use of audio/video technology. In addition, CMS is concerned about quality of care and patient safety and, and the ability of the supervising practitioner to intervene if complication arise.

In light of these potential safety and quality of care implications, and exercising an abundance of caution, CMS is extending this flexibility for all services on a temporary basis only. CMS is proposing to continue to define direct supervision to permit the presence and "immediate availability" of the supervising practitioner through real-time audio and visual interactive telecommunications through December 31, 2025. **CMS seeks additional information regarding potential safety and quality of care concerns related to virtual direct supervision.**

(2) 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 described under § 410.26: (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). CMS notes that the service described by CPT code 99211 and the services that are identified with a PC/TC indicator of '5' as listed in the PFS Relative Value Files are services that are nearly always performed in entirety by auxiliary personnel.

CMS proposes an incremental approach whereby it will adopt without any time limitation the definition of direct supervision permitting virtual presence for services that are inherently lower risk: that is, 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.

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

3. Teaching Physician Billing for Services Involving Residents with Virtual Presence

In the 2021 PFS final rule, CMS established that after the end of the PHE, teaching physicians may meet the requirements to be present for the key or critical portions of services involving residents through a virtual presence, but only for services furnished in residency training sites outside an OMB-defined metropolitan statistical area (MSA). Within an MSA, for payment under the PFS, CMS finalized that teaching hospitals must have a physical presence during the key portion of the service provided by residents.

Again, given concerns about abrupt transitions to pre-PHE policies and in alignment with the telehealth policies extended under the CAA 2023, CMS proposes to continue its current policy to

allow teaching physicians to have a virtual presence for purposes of billing for services furnished involving residents in all teaching settings when the service is furnished virtually (e.g., a 3-way telehealth visit, with all parties in separate locations) through 2025. CMS notes that the teaching physician's virtual presence would continue to require real-time observation (not mere availability) and exclude audio-only technology. Documentation must demonstrate that the teaching physician was physically present or present through audio/video real-time communication technology at the time of the Medicare telehealth service, which includes documenting the specific portion of the service for which the teaching physician was present through audio/video real-time communication technology.

(a) Request for Information for Teaching Physician Services Furnished under the Primary Care Exception

The so-called primary care exception set forth at §415.174 permits the teaching physician to bill for certain lower and mid-level complexity physicians' services furnished by residents in certain types of residency training settings even when the teaching physician is not present with the resident during the services as long as certain conditions are met, including that the services are furnished by residents with more than 6 months of training in the approved residency program; and that the teaching physician directs the care of no more than four residents at a time, remains immediately available and has no other responsibilities while directing the care, assumes management responsibility for beneficiaries seen by the residents, ensures that the services furnished are appropriate, and reviews certain elements of the services with each resident during or immediately after each visit. For a more detailed description of the list of services currently allowed under the primary care exception policy, CMS refers readers to the 2021 PFS final rule (85 FR 84585 through 84590).

CMS has received feedback requesting that it permanently expand the list of services that can be furnished under the primary care exception to include all levels of E/M services and additional preventive services. These interested parties have suggested that including all levels of E/M services under the primary care exception could support primary care workforce development and improve patient continuity of care without compromising patient safety; and would increase the utilization of high value services, such as additional preventive services.
CMS requests information to help it consider whether and how best to expand the array of services included under the primary care exception in future rulemaking. This includes the following:

- Types of services that could be allowed under the primary care exception, specifically preventive services, and whether the currently required six months of training in an approved program is sufficient for residents to furnish these types of services without the presence of a teaching physician;
- Whether adding certain preventive services or higher level E/M services to the primary care exception would hinder the teaching physician from maintaining sufficient personal involvement in the care to warrant PFS payment for the services being furnished by up to four residents at any given time; and
- Whether the inclusion in the primary care exception of specific higher-level or preventive services would impede the teaching physician's ability to remain immediately available

for up to four residents at any given time, while directing and managing the care furnished by these residents.

4. Telehealth Originating Site Facility Fee Payment Amount Update

Section 1834 (m)(2)(B) of the Act established the initial Medicare telehealth originate site facility fee for telehealth services furnished from October 1, 2001 through December 31, 2002 at $20.00. For services furnished on or after January 1 of each subsequent year, the telehealth originating site fee is increased by the percentage increase in the MEI (Table 9). The proposed MEI increase for 2025 is 3.6 percent; the proposed payment for HCPCS code Q3014 (Telehealth originating site facility fee) is $31.04. The final facility fee update will be revised in the final rule.

E. Valuation of Specific Codes

The proposed work RVUs, work time and other payment information for all the proposed payable codes in 2025 are available on the CMS website under downloads for the PFS proposed rule at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

The following tables in the proposed rule provide additional details about the proposed 2025 valuation of specific codes:

Table 13	Work RVUs for New, Revised, and Potentially Misvalued Codes
Table 14	Direct PE Refinements
Table 15	Direct PE Refinements: Equipment Refinements Conforming to Changes in Clinical Labor
Table 16	Invoices Received for Existing Direct PE Inputs
Table 17	New Invoices
Table 18	No PE Refinements

1. Background: Process for Valuing New, Revised, and Potentially Misvalued Codes

CMS provides an overview of the process for establishing RVUs for the PFS. To establish RVUs CMS reviews available information including recommendations and supporting documentation from the RUC, the Health Care Professional Advisory Committee (HCPAC), public commenters, medical literature, Medicare claims data, comparison with other codes, and input from CMS and other federal government health care professionals.

2. Methodology for Establishing Work RVUs

CMS reviews its methodology for proposing work RVUs, including potential information sources and specific approaches.[9] CMS notes the importance of not only the RUC-recommended work and time values but also the accompanying rationales for setting those values.[10]

[9]Approaches include RUC survey data, building block, key reference code crosswalks, magnitude estimation, incremental difference applications, and time ratio calculations.
[10]Time is parsed into pre-service, intra-service, and post-service components, summing to the total time for each

CMS discusses the methodology it uses for adjusting work RVU and/or time, including the methodology used when it believes there is overlap between a service typically furnished on the same day as an E/M service. The work RVU for a service is the product of the time involved with furnishing the service multiplied by the work intensity. CMS notes that the pre-service and post-service time have a long-established intensity of work per unit time (IWPUT) of 0.0224; thus, 1 minute of pre-service or post-service time equates to 0.0224 of a work RVU. Using this information, when CMS is concerned about overlap between a service and an E/M service, it generally removes 2 minutes of pre-service time and 2 minutes of post-service time from the procedure which results in removing a work RVU of 0.09 (4 minutes x 0.0224 IWPUT).

CMS discusses its ongoing concern that many codes reviewed by the RUC have recommended work RVUs that do not appear to account for significant changes in the reduction in time. In addition to using its standard methodologies such as survey data, crosswalk to key reference or similar codes, CMS uses the relationship between the old time values and the new time values to help identify alternative work RVUs based on changes in time components. CMS states that a decrease in time does not always equate to a one-to-one linear decrease in work RVUs but absent a rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs.

Table 13 list the codes and proposed work RVUs, including all codes that CMS received recommendations from the RUC by February 10, 2024.

3. Methodology for Direct PE Inputs to Develop PE RVUs

CMS reviews its methodology for proposing direct PE inputs, which include clinical labor, disposable medical supplies, and medical equipment. The RUC annually provides CMS with recommendations about PE inputs for new, revised, and potentially misvalued codes. Table 14 details CMS' refinements of the RUC's direct PE recommendations at the code specific level. Table 15 details proposed refinements in direct PE due to changes in the equipment time and the conforming changes in clinical labor time.

CMS notes that, on average, in any case where the impact on the direct cost for a particular refinement is $0.35 or less, the refinement has no impact on the PE RVUs. CMS notes that nearly half of the refinements result in changes under the $0.35 threshold and are unlikely to result in a change to the RVUs.

Common CMS refinements to RUC recommendations are related to or triggered by the following:

- Changes in work component times (e.g., intra-service time, postoperative visit levels);
- Changes in equipment time (e.g., pre-service clinical task is performed outside of highly technical equipment rooms and is excluded from equipment time);

service. To assist in the development of pre-service time recommendations, the RUC created standardized pre-service time packages. There are pre-service time packages for services typically furnished in the facility setting and pre-service packages for services typically furnished in the nonfacility setting.

- Clinical labor task times that are inconsistent with standard times in the CMS direct PE input database or overlap with associated E/M visit clinical labor time;
- Recommended items that are not direct PE inputs (e.g., items that are not clinical labor, disposable supplies or medical equipment or cannot be allocated to individual services or patients);
- New supply or equipment items (e.g., when invoices lack sufficient information);
- Clinical labor time in the facility setting (i.e., facility payment is separate); and
- Application of the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap.

CMS received invoices for several existing and new supply and equipment items (see Tables 16 and 17). CMS encourages stakeholders to review these prices and if prices appear inaccurate it encourages stakeholders to submit invoices or other information to improve the pricing. CMS expects invoices received outside of the public comment period to be submitted by February 10th of the following year for consideration in future rulemaking (similar to the time for receiving RUC recommendations). CMS notes that in some cases it does not use the price listed on the invoice because it identifies publicly available alternative prices or information that suggests a different price is more accurate.

CMS reminds stakeholders that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services. CMS includes the number of invoices received and the number of nonfacility allowed services for procedures that use this equipment in Tables 16 and 17.

For 2024, CMS proposes seven new and revised codes as services which meet the definition of "imaging services" for purposes of the OPPS cap[11]. This includes CPT code 0868T (Hi-res gastric ep mapping); 0876T (Duplex scan hemo fstl lmtd); 74263 (CT colonography screening); 9X059 (Cptrz oph img pst sg rta oct); and 93X94-93X96 (Vasoreactivity study, emboli detection, and venous-arterial shunt detection performed with transcranial Doppler study of intracranial arteries).

In the 2024 PFS final rule (88 FR 78894), CMS notes that commenters requested that CMS remove CPT code 92229 (Imaging of retina for detection or monitoring of disease; point-of-care autonomous analysis and report, unilateral or bilateral) from the OPPS cap list because it does not include an associated PC or physician interpretation and it is primarily utilized in the physician office setting. **CMS is seeking comment on the appropriateness of applying the OPPS cap to services such as this for which the interpretation component is not captured by work RVUs, and the service is not split into technical and professional components.** CMS states that it is more broadly evaluating how services involving assistive technologies are most accurately valued.

[11] As required by section 1848(b)(4)(A) of the Act, for imaging services furnished on or after January 1, 2007, CMS caps the TC portion of the PFS payment amount for the year (prior to geographic adjustment) by the Outpatient Patient Payment System (OPPS) payment amount for the service (prior to geographic adjustment). CMS then applies the PFS geographic adjustment to the capped payment amount. Section 1848(b)(4)(B) of the Act includes X-ray, ultrasound (including echocardiography), nuclear medicine (including PET), magnetic resonance imaging, computed tomography and fluoroscopy as imaging services. Diagnostic and screening mammography are excluded.

4. Valuation for Specific Codes

This section discusses proposal for 39 code groups (listed in the table below). Highlights of some of CMS' discussions are summarized; the numbering is consistent with the preamble format. The reader is referred to the proposed rule for more specific details. **CMS seeks comments on the work values, direct PE inputs, or both, for all these code groups.**

Code Group Number and Name		Codes (CPT and HCPCS Codes)	CMS Proposed Work RVUs Agrees with RUC Recommendations	CMS Proposed Direct PE RVUs Agrees with RUC Recommendations
1	Skin Cell Suspension Autograft*	15XX1-15XX8	No**	N/A**
2	Hand, Wrist, & Forearm Repair & Recon*	25310, 2447, 2X005, 26480	No	Yes
3	CAR-T Therapy Services*	3X018-3X020	Yes	No
		3X021	Yes	Yes
4	Therapeutic Apheresis and Photopheresis	36514, 36516, & 36522	N/A	Yes
5	Intra-Abdominal Tumor Excision or Destruction	4X015-4X017	Yes	Yes
		4X018-4X019	No	Yes
6	Bladder Neck and Prostate Procedures*	5XX05, 5XX06	Yes	Yes
7	MRI-Monitored Transurethral Ultrasound Ablation of Prostate	5X006, 5X007, and 5X008	Yes	Yes
8	Insertion of Cervical Dilator	59200	Yes	Yes
9	Guided High Intensity Focused Ultrasound*	6XX00	No	Yes
10	Percutaneous Radiofrequency Ablation of Thyroid	6XX01, 6XX02	Yes	Yes
11	Fascial Plane Blocks 6XX07, 6XX08, 6XX09, 6XX10, 6XX11, 6XX12, 64486, 64487, 64488, and 64489*	6XX08, 6XX09, 6XX10, 6XX12, 64487, 64488, and 64489	Yes	Yes
		6XX07, 6XX11, 64486	Yes	No
12	Skin Adhesives	64590, 64595, G0168, G0516-G0518	N/A	Yes
13	Iris Procedures*	66680, 66682 & 6X004	No	Yes
14	Magnetic Resonance Examination Safety Procedures*	7XX00, 7XX01	N/A	No
		7XX02, 7XX03, 7XX04 7XX05	Yes	No
15	Screening Virtual Colonoscopy*	74263	NA	N/A
16	Ultrasound Elastography*	76981, 76982, & 76983	Yes	Yes
17	CT Guidance Needle Placement*	77012	Yes	No
18	Telemedicine Evaluation and Management (E/M) Services*	9X075-9X090	N/A	N/A
		9X091	Yes	Yes

Code Group Number and Name		Codes (CPT and HCPCS Codes)	CMS Proposed Work RVUs Agrees with RUC Recommendations	CMS Proposed Direct PE RVUs Agrees with RUC Recommendations
19	Genetic Counseling Services	9X100	N/A	Yes
20	COVID Immunization Administration	90480	Yes	Yes
21	Optical Coherence Tomography	92132-92134, 9X059	Yes	Yes
22	Transcranial Doppler Studies	93886, 93888, 93892, 93893, 93X94, 93X95, 93X96, & 93890	Yes	Yes
23	RSV Monoclonal Antibody Administration	96380 & 96381	Yes	Yes
24	Hyperthermic Intraperitoneal Chemotherapy	96547 and 96548	Yes	N/A
25	Laser Treatment – Skin*	96920, 96921, & 96922	No	No
26	Physical Medicine and Rehabilitation*	97012, 97014, 97016, 97018, 97022, 97032-97035, 97110, 97112, 97113, 97116, 97140, 97530, 97533, 97535, 97537, 97542, G0283	N/A	Yes
27	Acupuncture - Electroacupuncture	97810, 97811, 97813, & 97814	Yes	Yes
28	Annual Alcohol Screening*	G0442, G0443	Yes	Yes
29	Annual Depression Screening	G0444	Yes	No
30	Behavioral Counseling & Therapy*	G0445-G0447	Yes	No
31	Autologous Platelet Rich Plasma*	G0465	N/A	N/A
32	Temporary Female Intraurethral Valve-Pump)*	0596T 0597T	N/A**	N/A**
33	PE-only replacement code for Heart Failure System*	GMEM1	N/A**	N/A**
34	Portable X-Ray	R0070-R0075	N/A**	N/A**
35	Non-chemotherapy Administration (updated policy)*	96401-96549	N/A	N/A
36	Hospital Inpatient or Observation (I/O) Evaluation and Management (E/M) Add-on for Infectious Diseases*	GIDXX	N/A	N/A
37	Preexposure Prophylaxis (PrEP) of Human Immunodeficiency Virus (HIV)	G0011, G0012, G0013	N/A	N/A
38	Opfolda	G0138	N/A	N/A
39	Direct Care Caregiver Training Services*	GCTD1, GCTD2, GCTD3	N/A	N/A

Code Group Number and Name		Codes (CPT and HCPCS Codes)	CMS Proposed Work RVUs Agrees with RUC Recommendations	CMS Proposed Direct PE RVUs Agrees with RUC Recommendations
	Individual Behavior Management/Modification Caregiver Training*	GCTB1, GCTB2	N/A	N/A
40	RFI for Services Addressing Health-Related Social Needs*	G0019, G0222; G0023, G0024 G0140, G0146, G0136	N/A	N/A
*Discussed in HPA summary **Contractor Priced Codes				

(1) Skin Cell Suspension Autograft (CPT codes 15XX1, 15XX2, 15XX3, 15XX4, 15XX5, 15XX6, 15XX7, and 15XX8)
CMS disagrees with RUC-recommended work RVUs for these codes and is proposing contractor-pricing for these CPT codes until reconsideration of the coding structure and re-survey is complete. It notes, in particular, that the survey median intraservice times for these codes contradict numerous publicly available sources that describe much lower times for this service or specific service parts. Overall, CMS expressed expansive concerns with the coding structure of the code family and the total physician time that results when these codes are billed multiple times on the same date of service for the typical patient. **CMS also seeks comments on several issues** including whether the segmentation of the harvest, preparation, and application is necessary when these are sequential service parts of one episode of care, and could be simplified by having just two codes that encompass all three service parts; the base and add-on codes' incremental square centimeters; and the recommended global period for CPT code 15XX3.

(2) Hand, Wrist, & Forearm Repair & Recon (CPT codes 25310, 25447, 2X005, and 26480)
CMS disagrees with the RUC-recommended work RVUs for these codes; instead, CMS proposes the survey 25th percentile work RVU for these codes as this more closely matches the increase in total work time. CMS proposes the RUC-recommended direct PE inputs in this code family, without refinement.

(3) CAR-T Therapy Services (CPT codes 3X018, 3X019, 3X020, and 3X021)
In September 2023, CPT Editorial Panel deleted four category III codes (0537T-0540T) and approved the addition of four new codes (3X018-3X021) that describe only steps of the complex CAR-T Therapy process performed and supervised by physicians. CMS proposes the RUC-recommended work RVUs for these codes. CMS proposes the RUC-recommended direct PE inputs for CPT code 3X021. RUC recommended contractor-pricing for the 3X018-3X020, but CMS states that contractor pricing can only be applied at the whole code level, not to a single component of the valuation. **CMS is treating these codes as having no recommended direct PE values and is seeking comment on direct PE values for them.**

(6) Bladder Neck and Prostate Procedures (CPT codes 5XX05 and 5XX06)
CMS agrees with the RUC-recommended work and direct PE inputs for these codes. CMS notes, however, possible duplications in two of the supply items within CPT 5XX05. **CMS seeks**

comments on whether a total of three SB027 impervious staff gowns and two SB024 pairs of sterile gloves would be typical and necessary when providing this procedure.

(9) Guided High Intensity Focused Ultrasound (CPT code 6XX00)
CMS disagrees with the RUC-recommended work RVU of 18.95 for CPT code 6XX00 and instead proposes a work RVU of 16.60 based on a crosswalk to CPT code 61626, which describes a similar tumor destruction service that has similar time and intensity values to this service.

(11) Fascial Plane Blocks (CPT codes 6XX07, 6XX08, 6XX09, 6XX10, 6XX11, 6XX12, 64486, 64487, 64488, and 64489)
CMS proposes the RUC-recommended work RVU for all ten codes in this family, but disagrees with one of the RUC-recommended direct PE inputs for CPT codes 6XX07, 6XX11, and 64486. CMS disagrees that there is a rounding error in the CA019 clinical labor time and proposed to maintain the current 7 minutes of CA019 clinical labor time for these three codes. This refinement also results in small adjustments to equipment time for the stretcher and the 3-channel ECG.

(13) Iris Procedures (CPT codes 66680, 66682, and 6X004)
CMS disagrees with the RUC's recommended work RVUs as the suggestion there has been a tremendous increase in intensity as compared to how these services have historically been valued. It also notes that the RUC recommended values do not maintain relativity with the other 90-day global period codes. CMS proposes the following reductions in the RUC-recommended work RVUs for these codes: 7.97 instead of 10.25 for CPT code 66680; 8.74 instead of 10.87 for CPT code 66682; and 10.67 instead of 12.80 for CPT code 6X004.

(14) Magnetic Resonance Examination Safety Procedures (CPT codes 7XX00, 7XX01, 7XX02, 7XX03, 7XX04, and 7XX05)
CMS makes various refinements to the direct PE inputs. Among other changes, CMS reduced the clinical labor CA021 activity (Perform procedure/service – NOT directly related to physician work time) from 27 minutes to 14 minutes. This also results in a decrease in equipment time for the Technologist PACS workstation from 45 minutes to 32 minutes.

(15) Screening Virtual Colonoscopy (CPT code 74263)
CMS is updating and expanding coverage for colorectal cancer screening and adding coverage for the computed tomography colonography procedure. CMS is assigning an active payment status for CPT code 74263.

(16) Ultrasound Elastography (CPT codes 76981, 76982, and 76983)
This code is an example of a change in utilization of one code resulting in the entire code family being resurveyed. CMS accepts the RUC-recommended work RVUs and direct PE inputs.

(17) CT Guidance Needle Placement (CPT code 77012)
CMS proposes to refine the equipment time for the CT room (EL007) to maintain the current time of 9 minutes. This is the standard time CMS uses for 38 other radiological supervision and interpretation procedures and it would not serve the interests of relativity to increase the equipment

time for this one code without addressing the time for the other radiological supervision and interpretation procedures.

(18) Telemedicine Evaluation and Management (E/M) Services (CPT codes 9X075, 9X076, 9X077, 9X078, 9X079, 9X080, 9X081, 9X082, 9X083, 9X084, 9X085, 9X086, 9X087, 9X088, 9X089, 9X090, and 9X091)
CMS proposes to assign CPT codes 9X075-9X090 a Procedure Status indicator of "I", meaning that there is a more specific code that should be used for purposes of Medicare. In this case, the practitioner could use the existing office/outpatient E/M codes currently on the Medicare telehealth services list when billed with the appropriate POS code. CMS is proposing to replace HCPCS code G2012 (e.g., virtual check-in,) with CPT code 9X091 and accept the RUC-recommended work RVU and direct PE inputs. CMS believes that maintaining separate coding for purposes of Medicare payment could create confusion.

(25) Laser Treatment - Skin (CPT codes 96920, 96921, and 96922)
CMS reviews the history of these codes. It disagrees with the RUC-recommended values for these codes and believes they are too high relative to the decreases in physician work times, absent any rationale for why the relative intensity of these procedures has increased. CMS bases the work RVUs on crosswalks to other codes.

CMS also makes refinements to the direct PE inputs. In particular, CMS disagrees with the RUC-recommended proposal to include a pay-per-use excimer laser as a supply item to replace the excimer laser listed as an equipment item. It notes that it has repeatedly stated in past rulemaking that rental licensing fees are typically considered forms of indirect PE under its methodology. It also does not believe that CPT codes 96920 through 96922 should be valued based on a significantly more expensive pay-per-use rental version of the excimer laser when the same treatment is cheaper and available as a purchasable form of equipment.

CMS seeks comment on the difference in direct PE costs between the purchase and per-use rental of the laser. It also seeks comments on this broader issue and is interested in feedback from interested parties on the payment disparity between this equipment as a per-use or rental versus how it currently accounts for the purchase of equipment using the standard equipment formula. CMS notes that it understands that both manufacturers and physicians may be inclined to shift to a per-use or rental business models to limit overhead for purchase and maintenance of expensive equipment.

(26) Physical Medicine and Rehabilitation (CPT codes 97012, 97014, 97016, 97018, 97022, 97032, 97033, 97034, 97035, 97110, 97112, 97113, 97116, 97140, 97530, 97533, 97535, 97537, and 97542 and HCPCS code G0283)
CMS reviews the history of these codes. In the 2024 PFS proposed rule, CMS received public nomination on these 19 physical medicine and rehabilitation codes as potentially misvalued. There was a particular concern that the direct PE clinical labor minutes already reflected multiple procedure payment reductions (MPPR), which were duplicative of the CMS MPPR policy implemented in the claims processing system. CMS reviewed the clinical labor times and concluded that a payment reduction should not have been applied in some instances. The RUC's

Health Care Professionals Advisory Committee (HCPAC) revised these codes for PE only, with no work review, at the January 2024 RUC meeting for inclusion in the 2025 PFS proposed rule.

The HCPAC, based on its calculations, determined that many of the standard clinical labor times should be divided by 2.25 to account for the MPPR and used the standard equipment time formula in most cases. Representatives from the American Physical Therapy Association (APTA) and the American Occupational Therapy Association (AOTA) believe that the HCPAC has inappropriately recommended too few equipment times for these procedures. CMS proposes to accept the direct PE inputs recommended by the HCPAC for all 19 codes in the Physical Medicine and Rehabilitation code family. CMS notes that this topic may warrant additional review, particularly related to equipment times, to ensure that this family of codes is properly valued.

(28) Annual Alcohol Screening (HCPCS codes G0442 and G0443)
CMS agrees with the RUC-recommended increase in the work RVU for HCPCS code G0443 *(Brief face-to-face behavioral counseling for alcohol misuse)* from 0.45 to 0.60 based on the time and intensity of this service in preventing alcohol misuse. It also believes that codes in the adjacent Behavioral Counseling & Therapy code family (G0445, G0446, G0447) may benefit from additional review in the future to recognize the intensity of these services. CMS states that this review highlights an important consideration on how best to implement and maintain payment for preventive services and it may address this issue more comprehensively in future rulemaking.

(30) *Behavioral Counseling & Therapy (HCPCS codes G0445, G0446, and G0447)*
This is an example of a service that was reviewed by the RUC because they were services with Medicare utilization of 10,000 or more that had increased by at least 100% from 2015 through 2020. The specialty societies surveyed these codes but did not obtain the required number of survey responses even after a resurvey. Given the insufficient number of survey responses, the RUC determined it would be most appropriate to maintain the current work RVU values and flagged these codes for review in 3 years. CMS proposes the RUC-recommended work RVU of 0.45 for each of these codes. CMS does not agree with RUC-recommended direct PE inputs for these codes and makes refinements.

(31) Autologous Platelet Rich Plasma (HCPCS code G0465)
CMS reviews the history of this code. It was created in 2022 and assigned contactor pricing. In 2023, CMS reviewed this code but did not establish national pricing as it did not have sufficient information. At that time, CMS updated its supply database for the 3C patch system (SD3434) at a price of $678.57 based on an average of the submitted invoices. Interested parties have continued to request national pricing due to inconsistent payment rates from MACs with some significantly below the cost of performing the service resulting in barriers to access.

Due to these concerns, CMS is establishing national pricing for HCPCS code G0465 for 2025 using a crosswalk to CPT code 15271. It also using the direct PE inputs from this code with the additional inclusion of the 3C patch system (SD343) that it priced in 2023. **CMS seeks comment regarding its selection of the crosswalk as well as general comments and available studies regarding the valuation of this code.**

(32) Temporary Female Intraurethral Valve-Pump (CPT codes 0596T and 0597T)
These codes are Category III codes, which are contactor priced under the PFS, meaning that each MAC can establish pricing or the code within its jurisdiction. This results in variability in payment. CMS continues to hear concerns about payment inconsistencies for these codes and is recommending that the MACs establish more consistency in pricing, enabling the appropriate inclusion of the Vesiflo system in the code's PE valuation. To aid in this process, CMS is adding three new supplies to its direct PE database: the inFlow Measuring Device at a price of $140 (SD370), the inFlow Valve-Pump Device at a price of $495 (SD371), and the inFlow Activator Kit at a price of $1,250 (SD372). **CMS welcomes additional comments from the broader medical community regarding the usage of this service, particularly concerning its safety and effectiveness, as well as potential factors contributing to its low utilization.**

(33) PE-only replacement code for Heart Failure System (GMEM1)
Interested parties have expressed concern about the lack of coding and a billing mechanism when practitioners incur costs replacing identified components of the CardioMEMS™ Heart Failure System used in the physician service described by CPT code 33289. They have highlighted the critical importance of the device for heart failure patients who require close monitoring of weight and blood pressure to prevent fluid buildup around the heart. Given that these components are crucial for system functionality and there is no existing coding framework to address their replacement, CMS believes that establishing appropriate coding and payment mechanisms can facilitate the provision of these services more effectively in the office and hospital settings.

CMS proposes assigning contractor pricing to this PE-only code for 2025. CMS is proposing a new HCPCS code

- GMEM1 *(Provision of replacement patient electronics system (for example, system pillow) for home pulmonary artery pressure monitoring including provision of materials for use in the home and reporting of test results to physician or qualified health care professional).*

CMS seeks feedback from interested parties on its contractor pricing approach with the aim of establishing national pricing through future rulemaking that can be billed under the OPPS and PFS specifying an ongoing care visit for the CardioMEMS™ Heart Failure System along with the provision of the replacement part. CMS requests direct costs from invoices for the replacement component, utilization estimates, potential indicators, and any additional direct PE inputs.

(35) Non-chemotherapy Administration
CMS discusses concerns that it has received from several external parties that 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, including drugs furnished to treat, for example, rheumatology related conditions. In response to this concern, CMS is proposing updated policy based largely on the 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 stating 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.

CMS notes that CPT guidance describe 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. CMS notes that these services do involve serious patient risk which requires frequent consults with a physician or other qualified healthcare professional.

CMS seeks comment on its proposal to revise its claim processing manual to better reflect how complex non-chemotherapeutic drug administration infusion services are furnished and billed.

(36) Hospital Inpatient or Observation (I/O) Evaluation and Management (E/M) Add-on for Infectious Diseases (HCPCS code GIDXX)

CMS notes that interested parties have continued to engage with it and provide recommendations to recognize the increased work associated with diagnosis, management, and treatment of infectious diseases that may not be adequately accounted for in current hospital inpatient or observation E/M codes. CMS believes the timing is appropriate since COVID-19 PHE has ignited a hypervigilance for infectious diseases. For 2025, CMS is proposing 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.

The full proposed descriptor for the hospital I/O E/M visit complexity add-on code is the following:

- *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).*

CMS anticipates that HCPCS code GIDXX would be reported by physicians with specialized infectious disease training. CMS does not believe it should limit the scope of codes with which this proposed add-on HCPCS code could be billed based on visit level; or initial, same day discharge, or subsequent hospital inpatient or observation codes. Specifically, CMS proposes HCPCS code GIDXX as an add-on code (ZZZ global period) separately reportable in addition to CPT codes 99221-99223 and 99231-99236.

Based on feedback from commenters on the 2022 PFS proposed rule comment solicitation regarding infectious diseases (86 FR 65125 through 65126) and feedback from interested parties, HCPCS code GIDXX would include the following service elements related to (1) diseases transmission risk assessment and mitigation; (2) public health investigation, analysis, and testing; and (3) complex antimicrobial therapy counseling & treatment.

CMS proposes a work RVU of 0.89 based on a crosswalk for HCPCS code G2211 (Visit complexity inherent to evaluation and management. HCPCS code G2211 has no direct PE inputs, and CMS is proposing the same for HCPCS code GIDXX.

To help inform whether its proposed descriptor is appropriate and reflects the typical service, CMS seeks comment on the typical amount of time infectious disease physicians spend on the proposed service elements and the relative intensity compared to similar service elements of other CPT codes. CMS also seeks comment on any potential barriers for infectious disease physicians to use the initial and subsequent day hospital inpatient or observation codes, CPT codes 99221 through 99223 and 99231 through 99233, for consultations if they meet the coding requirements for time and/or medical decision making (MDM). CMS states that understanding the barriers to utilizing these codes is important, as these codes will serve as the base codes for HCPCS code GIDXX, and will need to be billed by the infectious disease physician prior to billing HCPCS code GIDXX.

(39) Payment for Caregiving Training Services

a. Background

CMS reviews the payment of caregiving training services. In the 2024 PFS final rule, CMS finalized the assignment of payable status for caregiver behavior management/modification training (CTS) services (CPT codes 96202 and 96203) and caregiver training services under a therapy plan of care established by a PT, OT, SLP (CPT codes 97550-97552) without the patient present. Payment can be made for CTS services when the treating practitioner identifies a need to involve and train one or more caregivers to assist the patient in carrying out the treatment plan. Because the CTS services are provided outside the patient's presence, the treatment physician must obtain the patient's (or representative) consent for the caregiver to receive the training. This must be documented in the medical record. CMS is proposing to apply these principles to the newly proposed CTS coding described below.

CMS continues to obtain questions and requests from interested parties and provides clarification and a proposal related to caregiver assessment.

b. Caregiver Assessment

CMS clarifies that when reasonable and necessary, assessing the caregiver's skills and knowledge for the purposes of caregiver training services could be included in the service described by CPT code 96161 *(Administration of caregiver-focused health risk assessment instrument (eg, depression inventory) for the benefit of the patient, with scoring and*

documentation, per standardized instrument) to determine if caregiver training services are needed. CMS also notes that CPT code 96161 is currently on the Medicare Telehealth list.

CMS provides examples of when this service may be reasonable and necessary. These examples include assessment of maternal depression in the active care of infants, assessment of parental mental health as part of evaluating a child's functioning, and assessment of caregivers as part of care management for adults whose physical or cognitive status renders them incapable of independent living and dependent on another adult caregiver, among others.

CMS proposes that the treating practitioner must obtain the patient's (or representative's) consent for the caregiver to receive the assessment. CMS also proposes that the definition of "caregiver" specified in the 2024 PFS final rule (88 FR 78917) will be the same for caregiver training services and the caregiver-focused health risk assessment.

CMS seeks comment on these proposals and clarifications.

c. Proposals and New Coding

(A) Proposed Direct Care Caregiver Training Services

i. Coding

CMS proposes to establish new coding and payment for caregiver training for direct care services and supports. Unlike other caregiver training codes that are currently paid under the PFS, the caregiver training codes for direct care services and support focus on specific clinical skills aimed at the caregiver effectuating hands-on treatment, reducing complications, and monitoring the patient. This could include, for example, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control. CMS believes that CTS may be reasonable and necessary when they are integral to a patient's overall treatment and furnished after the treatment plan is established. The CTS needs to be congruent with the treatment plan and designed to effectuate the desired patient outcomes.

CMS proposes three new HCPCS codes:

- 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))*
- 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).

GCTD1 is for caregiver training for one person, first 30 minutes, and GCTD1 is to be used in conjunction with this based for each additional 15 minutes in training. GCTD3 is to be used for multiple sets of caregivers in a group training. CMS notes that each training activity should be clearly identified and documented in the treatment plan. This would not be billable for patients under home health plan of care, receive at-home therapy, or receiving DME services for involved medical equipment and supplies.

CMS seeks additional information from commenters about potential service overlaps and potential examples of direct care services to receive caregiver training to inform its final policy.

ii. Valuation

CMS proposes the following direct crosswalks to other CPT codes for valuation of work RVUs and direct PE inputs.

- For GCTM1, CMS proposes a direct crosswalk to CPT Code 97550 (Caregiver traing 1st 30 min) with a work RVU of 1.0. This code has an intraservice time of 30 minutes, and the physician work is of similar intensity to its proposed GCTM1.
- For GCTM2, CMS proposes a direct crosswalk to CPT Code 97551 (Caregiver traing ea addl 15) with a work RVU of 0.54. This code has an intraservice time of 17 minutes, and the physician work is of similar intensity to its proposed GCTM2.
- For GCTM3, CMS proposes a direct crosswalk to CPT Code 97552 (Group caregiver training) with a work RVU of 0.23. This code has an intraservice time of 9 minutes, and the physician work is of similar intensity to its proposed GCTM3.

CMS notes that these codes could be conducted via telecommunications, as appropriate. CMS is proposing to add these codes to the Medicare Telehealth Services List (see Section II.D). **CMS seeks comments in its valuation proposals for these codes.**

(B) Individual Behavior Management/Modification Caregiver Training Services

i. Coding

CMS proposes to establish new coding and payment for caregiver behavior management and modification training that could be furnished to the caregiver(s) of an individual patient. Current CPT coding (CPT 96202 and 96203) allows for caregiver training service to only be furnished in a group setting with multiple sets of caregivers of multiple beneficiaries (please reference 88 FR 78818 for discussion of CPT 96202 and 96203). CMS proposes the following two new HCPCS codes:

- 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)).*

Consistent with other CTS codes, CMS believes that behavior management/modification training for caregivers may be reasonable and necessary when they are integral to a patient's overall treatment and furnished after the treatment plan is established. The CTS needs to be congruent with the treatment plan and designed to effectuate the desired patient outcomes. Each treatment activity should be clearly identified and documented in the treatment plan. **CMS seeks comments on these new codes.**

ii. Valuation

CMS proposes the following direct crosswalks to other CPT codes for valuation for work RVUs and direct PE inputs.

- For GCTB1, CMS proposes a direct crosswalk to CPT Code 97550 (Caregiver traing 1st 30 min) with a work RVU of 1.0. This code has an intraservice time of 30 minutes, and the physician work is of similar intensity to its proposed GCTM1.
- For GCTB2, CMS proposes a direct crosswalk to CPT Code 97551 (Caregiver traing ea addl 15) with a work RVU of 0.54. This code has an intraservice time of 17 minutes, and the physician work is of similar intensity to its proposed GCTB2.

CMS notes that these codes could be conducted via telecommunications, as appropriate. CMS is proposing to add these codes to the Medicare Telehealth Services List (see Section II.D). **CMS seeks comments in its valuation proposals for these codes.**

(C) Patient Consent

CMS proposes that consent for CTS can be provided verbally by the patient (or representative). This would align consent requirements with other services paid under the PFS that may be furnished without the patient present, such as certain care management services. This proposal would apply to CPT codes 97550, 97551, 97552, 96202, and 96203, as well as any caregiver training services HCPCS codes finalized in this year's rule, and any subsequently created caregiver training service codes. **CMS seeks comment on this proposal.**

(40) Request for Information for Services 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))

CMS is issuing 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 states that it is interested in better addressing the social needs of beneficiaries and requesting information on the codes it created and finalized beginning in 2024 to fully encompass what interested parties and commenters believe should be included in the coding and payment recently established. Specifically, CMS seeks overall comment on the following areas:

- Any related services that may not be described by the current coding that it finalized in the 2024 PFS final rule and that are medically reasonable and necessary "for the diagnosis or treatment of illness or injury".
- Barriers to furnishing the services addressing health-related social needs, and if the service described by the codes it established are allowing practitioners to better address unmet social needs that interfere with the practitioners' ability to diagnose and treat the patient (e.g., rural and tribal communities, residents of the U.S. Territories, individuals with disabilities, individuals with limited English proficiency, or other populations who experience specific unmet social needs).
- How to improve the accuracy of valuation and payment for these services and what else it could consider to be included in this newly established code set.
- Ways to identify specific services and to recognize possible barriers to improved access to these kinds of high-value, potentially underutilized services by Medicare beneficiaries.

CMS notes that clinical social workers (CSWs) can bill Medicare directly for services they personally perform for the diagnosis or treatment of mental illness but are not authorized by statute to bill for services that are provided by auxiliary personnel incident to their professional services. Since CHI and PIN codes are typically provided by auxiliary personnel supervised by the billing practitioner, CSWs could serve as the auxiliary personnel. CMS clarifies that when it refers to "certified or trained auxiliary personnel" in the following codes: G0019, G0022, G0023, G0024, G0140, G0146, this also includes CSWs. CMS seeks additional information on this topic, including the following:

- Other types of auxiliary personnel, other certifications, and/or training requirements that are not adequately captured in current coding and payment for these services.
- 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 (e.g., in setting such as, community mental health centers, community health clinics including FQHCs and RHCs, tribal health centers, migrant farmworker clinics, or facilities located in and serving rural and geographically isolated communities)

CMS is also interested in hearing more about community-based organizations (CBOs) and their collaborative relationships with billing practitioners. The new codes for CHI and PIN services recognized CBOs and their role in providing auxiliary personnel under the general supervision of the billing practitioners. CMS is seeking comment on the following topics:

- 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.
- Comment on CBOs' roles, the extent to which practitioners are contracting with CBOs, incident to billing, and auxiliary personnel employed by CBOs under general supervision of practitioners serving and located in rural, tribal and geographically isolated communities, including the U.S. Territories.
- Coding Z codes on claims associated with billing for CHI, PIN, and SDOH risk assessment codes across provider types including practitioners in geographically isolated communities (for example, rural, tribal, and island communities)

CMS is also interested in understanding more clearly how often evidence-based care for persons with fractures, for example, is not provided and the reasons for this, and how recent or new PFS codes, or their revaluation, might help resolve specific barriers to its provision. It notes that the PFS currently includes many codes that pay for various components of care to manage patients with fractures over a course of treatment, such as transitional care management (TCM) and other care management services, evaluation and management visits (including the inherent complexity add-on for office/outpatient visits), principal illness navigation services, community health integration services, and the social determinants of health risk assessment.

CMS is proposing new coding in other sections of the 2025 proposed rule that might be used to bill for managing fractures under a treatment plan, including the global post-operative add-on code, HCPCS code GPOC1. Interested parties have indicated a systemic disconnect on which provider and/or specialty is responsible for osteoporosis diagnosis and treatment, and that global surgical periods focus on acute fracture recovery rather than addressing osteoporosis. CMS is interested in hearing if the proposed global postop add-on code could help resolve these issues.

F. Evaluation and Management (E/M) Visits

In the 2024 PFS final rule (88 FR 78970 through 78982), CMS finalized separate payment for the Office/Outpatient (O/O) Evaluation and Management (E/M) visit complexity add-on code.

- HCPCS code G2211 *(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)).*

CMS explained that it is the relationship between the patient and the practitioner that is the determining factor for when the add-on code should be billed. The add-on code captures the inherent complexity of the visit that is derived from the longitudinal nature of the practitioner and patient relationship.

Commenters continues to express concern about CMS' policy to exclude payment for the visit complexity add-on code when the O/O E/M base code is reported with Modifier -25 because some preventive services such as the annual wellness visit (AWV) or a preventive vaccine are often provided on the same day as a separately identifiable O/O E/M visit, appropriately billed

with Modifier -25. Practitioners state that this is disruptive to the way such care is usually furnished and contrary to CMS' policy objective for establishing the add-on payment

In response to these concerns, CMS proposes to 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 AWV, vaccine administration, or any Medicare Part B preventive service furnished in the office or outpatient setting. CMS states that allowing payment for the O/O E/M visit complexity add-on code in this scenario would support its policy aims, which include paying for previously unaccounted resources inherent in the complexity of all longitudinal primary care office visits.

G. Enhanced Care Management

1. Background

The CMS Center for Medicare and Medicaid Innovation (CMS Innovation Center) has recently reviewed selected innovative payment and service delivery models and found evidence of enhanced care delivery in selected areas such as care coordination and team-based care.[12] Under section 1115A of the Act, CMS Innovation Center models may be expanded through rulemaking if it is expected either to reduce spending without compromising the quality of care or enhance the quality of care without increasing spending.

CMS proposes to incorporate key payment and service delivery models from Innovation Center models into permanent coding and payment under the PFS for "advanced primary care". To recognize the resources involved in providing advanced primary care, CMS proposes to use The National Academies of Sciences, Engineering and Medicine (NASEM) definition of 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" to recognize the resources involved in providing advanced primary care.[13]

As discussed below, for 2025, CMS proposes to establish coding and payment for advanced primary care management (APCM) services for practitioners who provide services using an advanced primary care delivery model when the practitioner is the continuing focal point for all needed health care services and is responsible for all primary care services. This proposed rule also includes a Request for Information (RFI) to obtain feedback on how it should consider additional payment policies, including bundling of additional primary care services, that recognize the delivery of advanced primary care services.

[12] Accelerating Care Delivery Transformation — The CMS Innovation Center's Role in the Next Decade Authors: Elizabeth Fowler, PhD, JD, Noemi Rudolph, MPH, Kate Davidson, LCSW, MSW, Bruce Finke, MD, Shannon Flood, Susannah M. Bernheim, MD, MHS, and Purva Rawal, PhD Author Info & Affiliations Published October 18, 2023. NEJM Catal Innov Care Deliv 2023;4(11). https://doi.org/10.1056/cat.23.0228.
[13] NASEM. 2021. Implementing high-quality primary care: Rebuilding the foundation of health care. Washington, DC: The National Academies Press. https://doi.org/10.17226/25983.

2. Advanced Primary Care Management (APCM) Services (HCPCS codes GPCM1, GPCM2, and GPCM3)

a. Background

CMS discusses that despite paying separately for care management services, there has been limited use of these services and Medicare still overwhelming pays for primary care through office/outpatient (O/O) E/M visits. In the 2024 PFS final rule, CMS finalized the O/O E/M visit complexity add-on code (G2211) for use by practitioners furnishing services as the continuing focal point for all the patient's needed health care services. CMS received feedback that the current coding and payment under the PFS still does not recognize the broad range of elements that define primary care. Based on this feedback, CMS continues to believe that it is important to establish codes to better describe advanced primary care management services.

CMS summarizes several CMS Innovation Center models, including the Comprehensive Primary Care Plus (CPC+) and Primary Care First (PCF) models, designed to address payment for care management services and communication technology-based services (CTBS) (Table 19 in the proposed rule). CMS incorporated elements of these models into its proposals for APCM services.

b. Proposed HCPCS G-Codes for APCM

CMS proposes to create three new G codes (GPCM1, GPCM2, and GPCM3) to describe APCM services that incorporate care management services and CTBS. CMS notes these codes include some of the language from the Chronic Care Management (CCM) and Principal Care Management (PCM) services.

GPCM1: *APCM services provided by clinical staff and directed by a physician or other qualified health professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the following elements as appropriate*:

- Consent;
    - Inform the patient of the availability of the service; that only one practitioner can furnish and be paid for the service during a calendar month; of the right to stop the services at any time (effective at the end of the calendar month); and that cost sharing may apply.
    - Document in the patient's medical record that consent was obtained.
- Initiation during a qualifying visit for new patients or patients not seen within 3 years;
- Provide 24/7 access for urgent needs to care team/practitioner, including providing patients/caregivers with a way to contact health care professionals in the practice to discuss urgent needs regardless of the time of day or day of week;
- Continuity of care with a designated member of the care team with whom the patient is able to schedule successive routine appointments;
- Deliver care in alternative ways to traditional office visits to best meet the patient's needs, such as home visits and/or expanded hours;
- Overall comprehensive care management;

    - Systemic needs assessment (medical and psychosocial)
    - System-based approaches to ensure receipt of preventive services;
    - Medication reconciliation, management and oversight of self-management.
- Development, implementation, revision, and maintenance of an electronic patient-centered comprehensive care plan;
    - Care plan is available timely within and outside the billing practice as appropriate to individuals involved in the beneficiary's care, can be routinely accessed and updated by care team/practitioner, and copy of care plan to patient/caregiver.
- Coordination of care transitions between and among health care providers and settings, including referrals to other clinicians and follow-up after an emergency department (ED) visit and discharges from hospitals, skilled nursing facilities (SNFs) or other health care facilities as applicable:
    - Ensure timely exchange of electronic health information with other practitioners and providers to support continuity of care.
    - Ensure timely follow-up communication (direct contact, telephone, electronic) with the patient and/or caregiver after an ED visit and discharges from hospitals, SNFs, or other health care facilities, within 7 calendar days of discharge, as clinically indicated.
- Ongoing communication and coordinating receipt of needed services from practitioners, home- and community-based service providers, community-based social service providers, hospitals, and SNFs (or other health care facilities), and document communication regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors, in the patient's medical record;
- Enhanced opportunities for the beneficiary and any caregiver to communicate with the care team/practitioner regarding the beneficiary's care through the use of asynchronous non-face-to-face consultation methods other than telephone, such as secure messaging, email, internet, or patient portal, and other CTBS, including remote evaluation of pre-recorded information and interprofessional telephone/internet/EHR referral service(s), to maintain ongoing communication with patients, as appropriate;
    - Ensure access to patient-initiated digital communications that require a clinical decision, such as virtual check-ins and digital online assessment and management and E/M visits (or e-visits).
- Analyze patient population data to identify gaps in care and offer additional interventions, as appropriate;
- Risk stratify the practice population based on defined diagnoses, claims, or other electronic data to identify and target services to patients;
- Be assessed through performance measurement of primary care quality, total cost of care, and meaningful use of Certified EHR Technology.

GPCM2: *APCM services for a patient with multiple (two or more) chronic conditions expected to last at least 12 months; or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, provided by clinical staff and directed by a physician or other qualified health professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the elements included in GPCM1 as appropriate.*

GPCM3: *APCM services for a patient that is a Qualified Medicare Beneficiary with multiple (two or more) chronic conditions expected to last at least 12 months; or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, provided by clinical staff and directed by a physician or other qualified health professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the elements included in GPCM1 as appropriate*.

CMS highlights the following proposed requirements for these codes:

- APCM services are furnished per calendar month;
- Physicians and NPPS, including nurse practitioners (NPs), physician assistants (PAs, certified nurse midwives (CNMs) and clinical nurse specialists (CNSs) could bill for APCM services.
- The practitioner who bills for APCM services intends to be responsible for the patient's primary care and serves as the continuing focal point for all needed health care services.
    - CMS notes that in contrast to the O/O E/M visit complexity add-on code HCPCS G2211 (88 FR 78971), APCM codes can be used by a practitioner's management of one or more serious conditions without additional services. APCM requires the practitioner to also be responsible for all primary care services and the focal point for all needed care.
- These code descriptors would not be time-based and do not include timeframe restrictions for billing certain CTBS (e.g., there are no restrictions related to virtual check-in services).
- All the elements described in the code descriptors are not required to be furnished during any given calendar month for which the service is billed.
    - Although specific minutes spent furnishing these services are not required, CMS expects that any APCM services would be described in the medical record, and as appropriate, its relationship to the clinical problem they are intended to resolve and the treatment plan.
- Although all the elements of the APCM service must not be furnished, the billing practitioner and auxiliary personnel must have the ability to furnish every service element and furnish these elements as is appropriate for any individual patient during any given calendar month.

CMS proposes that APCM services would be considered a "designated care management service" and could be provided by auxiliary personnel under the general supervision of the billing practitioner.

CMS seeks feedback on these code descriptors, including whether there are elements of other care management services that should be removed or altered.

CMS notes that although the service descriptors for APCM codes are the same, CMS proposes that the APCM codes would be stratified into three levels based on certain patient characteristics that it believes are indicative of patient complexity and resources for providing services. Table

20, reproduced below, summarizes this stratification which is based on the advanced primary care model.

Table 20: Patient-Centered Risk Stratification for Billing APCM Codes		
Level 1 (GPCM1)	**Level 2 (GPCM2)**	**Level 3 (GPCM3)**
Patients with one or fewer chronic conditions	Patients with two or more chronic conditions	Patients with two or more chronic conditions and who are Qualified Medicare Beneficiaries (QMB).[14]

Level 1 APCM (GPCM1). CMS proposes this level because the use of non-face-to-face interactions is important for patients with relatively few health needs. CMS believes that patients with one or fewer chronic conditions require less time and resources than patients with two or more conditions. CMS notes that based on 2010 Medicare claims data, the difference in annual expenditures per beneficiary between patients with one or fewer chronic conditions and those with two or three chronic conditions was $3,673. In addition, current care management codes have similarly delineation based on the number of chronic conditions.

Level 2 APCM (CPCM2). CMS proposes that this level include patients with two or more chronic conditions because this corresponds to the frequency of chronic conditions in the Medicare population; four in five Medicare beneficiaries have two or more chronic conditions.

Level 3 APCM (CPCM3). CMS proposes this level because it incorporates people with both multiple chronic conditions and social risk factors. CMS proposes to use a patient's QMB status to identify beneficiaries with social risk factors that generally require relatively greater resource requirements to furnish advanced primary care. **CMS seeks comments on whether QMB status is an appropriate indicate to identify beneficiaries with added social risk, and whether there is an equivalent marker of social risk for use in commercial markets that might be a possible alternative identifier.**

In addition, CMS notes that patients with QMB status are not responsible for the Medicare cost-sharing associated with covered Part A or B services, including for any APCM services. States generally cover such cost-sharing on behalf of QMBs, although many states use a "lesser-of" policy through which states pay less than the full cost sharing amounts.[15] **CMS seeks comments from States on how they would cover cost-sharing for the APCM bundle, considering the "less-of" policies**.

[14] Sections 1902(a)(10)(E)(i) and 1905(p)(1) of the Act and §435.123. The proposed CPCM3 would not include those QMBs who are in the Medicare Part B Immunosuppressive Drug benefit, which provides coverage of immunosuppressive drugs based on eligibility requirements described in §407.55, because such individuals would not qualify for Medicare coverage of the services described in this proposed rule.

[15] Under the "less of" policy, a State caps its payment of Medicare cost-sharing at the Medicaid rate for a particular service. For example, if the Medicaid rate for a service is $100, of which $20 is beneficiary coinsurance, and the Medicaid rate for the service is $90, the state would only pay $10. If the Medicaid rate is $80 or lower, the state would make no payment.

c. APCM Service Elements and Practice-Level Capabilities

Table 21 lists all the elements within the scope of APCM. Additional details of each element are summarized in this section and discussed below. **CMS seeks comments on all these proposed requirements.**

Table 21: APCM Service Elements and Practice-Level Capabilities
Consent • Inform the patient of the availability of APCM services; that only one practitioner can furnish and be paid for these services during a calendar month; of the right to stop services at any time (effective at the end of the calendar month); and that cost sharing may apply* (may be covered by supplemental health coverage) • Document in patient's medical record that consent was obtained
Initiating Visit for New Patients (separately paid) • Initiation during a qualifying visit for new patients • An initiating visit is not needed: (1) if the beneficiary is not a new patient (has been seen by the practitioner or another practitioner in the same practice within the past three years) or (2) if the beneficiary received another care management service (APCM, CCM, or PCM) within the previous year with the practitioner or another practitioner in the same practice.
24/7 Access to Care and Care Continuity • Provide 24/7 access for urgent needs to care team/practitioner with real-time access to patient's medical information, including providing patients/caregivers with a way to contact health care professionals in the practice to discuss urgent needs regardless of the time of day or day of week • Continuity of care with a designated member of the care team with whom the patient is able to schedule successive routine appointments • Deliver care in alternative ways to traditional office visits to best meet the patient's needs, such as home visits and/or expanded hours, as appropriate
Comprehensive Care Management Overall comprehensive care management may include, as applicable • Systematic needs assessment (medical and psychosocial) • System-based approaches to ensure receipt of preventive services • Medication reconciliation, management and oversight of self-management
Patient-Centered Comprehensive Care Plan Development, implementation, revision, and maintenance of an electronic patient-centered comprehensive care plan which is available timely within and outside the billing practice as appropriate to individuals involved in the beneficiary's care, can be routinely accessed and updated by care team/practitioner, and copy of care plan to patient/caregiver
Management of Care Transitions (for example, discharges, ED visit follow-up, referrals, as applicable) • Coordination of care transitions between and among health care providers and settings, including transitions involving referrals to other clinicians, follow-up after an emergency department visit, or follow-up after discharges from hospitals, SNFs, or other health care facilities, as applicable • Ensure timely exchange of electronic health information with other practitioners and providers to support continuity of care. • Ensure timely follow-up communication (direct contact, telephone, electronic) with the patient and/or caregiver after ED visits and discharges from hospitals, SNFs, or other health care facilities, within 7 calendar days of discharge, as clinically indicated
Practitioner, Home-, and Community-Based Care Coordination Ongoing communication and coordinating receipt of needed services from practitioners, home- and community- based service providers, community-based social service providers, hospitals, and SNFs (or other health care facilities), as applicable, and document communication regarding the patient's

Table 21: APCM Service Elements and Practice-Level Capabilities
psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors in the patient's medical record
Enhanced Communication Opportunities • Enhanced opportunities for the beneficiary and any caregiver to communicate with the care team/practitioner regarding the beneficiary's care through the use of asynchronous non-face-to-face consultation methods other than telephone, such as secure messaging, email, internet, or patient portal, and other communication technology-based services, including remote evaluation of pre-recorded patient information and interprofessional telephone/internet/EHR referral service(s), to maintain ongoing communication with patients, as appropriate • Ensure access to patient-initiated digital communications that require a clinical decision, such as virtual check-ins and digital online assessment and management and E/M visits (or e-visits)
Patient Population-Level Management • Analyze patient population data to identify gaps in care and offer additional interventions, as appropriate • Risk stratify the practice population based on defined diagnoses, claims, or other electronic data to identify and target services to patients • A practitioner who is participating in a Shared Savings Program ACO, REACH ACO, Making Care Primary, or Primary Care First satisfies this requirement
Performance Measurement Be assessed on primary care quality, total cost of care, and meaningful use of CEHRT, which can be met in several ways: • For MIPS-eligible clinicians, by registering for and reporting the Value in Primary Care MVP** • A practitioner who is part of a TIN participating in a Shared Savings Program ACO satisfies this requirement through the ACO's reporting of the APM Performance Pathway • A practitioner who is participating in a Shared Savings Program ACO, REACH ACO, Making Care Primary, or Primary Care First satisfies this requirement through the quality reporting, assessment and performance requirement and other program and model requirements.
* Medicare beneficiaries who are enrolled in the QMB eligibility group do not have any Medicare cost-sharing responsibility for copays, deductibles, and coinsurance. ** See discussion in section II.G.2.c.(10) of this proposed rule for a description of the timeline of MIPS reporting. For APCM services billed in 2025, practitioners would register to report the MVP in 2025, and report the MVP in 2026 for the 2025 performance year/2027 MIPS payment year. For more details, see the 2024 MIPS Quick Start Guide, available at *https://qpp.cms.gov/mips/reporting-options-overview*.

CMS seeks comments on the following:

- Whether the proposed elements and requirements are appropriately reflective of care management for advanced primary care and if there are elements that should be modified or reviewed.
- Ways to align the APCM services with other Medicare programs and initiatives, such as the Shared Savings Program, ACO REACH, and advanced primary care models and the QPP. CMS seeks to create a way that is low burden for practitioners to furnish APCM services by recognizing ways in which they may meet APCM billing requirements as part of these programs and initiatives.

(1) Beneficiary Consent

Consistent with other care management services, CMS proposes to require the billing practitioner to inform the beneficiary about APCM services, the application of Medicare cost-sharing; and the requirement for a one-time beneficiary consent for APCM services. The beneficiary should

be informed that by providing APCM services, the practitioner intends to assume responsibility for all of the patient's primary care services and serve as the focal point for all needed health care services. The information provided to the beneficiary should also indicate that only one practitioner can furnish and be paid for APCM services during a calendar month; that APCM services do not limit a beneficiary from receiving other Medicare covered services from other practitioners; and that the beneficiary can stop the APCM services at any time (effective at the end of the month). CMS proposes that the beneficiary's medical record would document the information provided and whether the beneficiary accepted or declined consent to receive APCM services.

CMS seeks feedback on these proposed requirements, including how best to educate patients and beneficiaries on the benefits of APCM and whether a CMS-provided template to facilitate patient consent would be helpful. CMS also seeks feedback on whether CMS should require practitioners to revisit consent for APCM services on an ongoing basis with patients.

(2) Initiating Visit

Also consistent with other care management services, CMS proposes to require an initiating visit for APCM services only for new patients instead of for all beneficiaries receiving APCM services. CMS proposes to use the CPT definition of "new patient" which is a person who did not receive any professional services from the physician or other qualified health care professional or another practitioner in the same group practice within the previous 3 years.[16] CMS proposes that the same services that serve as the initiating visit for CCM services could serve as the initiating visit for APCM, including a Level 2 through 5 E/M visit, initial preventive physician exam (IPPE), or TCM services. CMS also proposes the initiating visit could be in-person or as a Medicare telehealth service.

CMS proposes that an initiating visit would not be required for "established patients" in advance of furnishing APCM services: (1) if the beneficiary is not a "new patient" (has been seen by the practitioner or another practitioner in the same practice with in the past three years) or (2) if the beneficiary received another care management service[17] within the previous year with the practitioner or another practitioner in the same practice. CMS notes that an initiating visit may still be needed even when not required, and the billing practitioner can always provide and bill for medically necessary visits before initiating APCM services.

CMS discusses how these proposals are also consistent with standards in the Shared Savings Program and CMS Innovation Center patient attribution standards in ACO REACH, Making Care Primary, and Primary Care First.

CMS seeks comments on these proposals, including whether additional services could serve as the initiating visit and whether a different period of time would be more appropriate to define a "new patient".

[16] CPT Professional 2024 page 4. AMA, 2023.
[17] Care management services include CCM services (CPT codes 99487, 99489-99491, 99439, 99437) or PCM services (CPT codes 99425-99427).

(3) 24/7 Access and Continuity of Care

CMS proposes that APCM services include the same scope of service elements established for CCM and PCM services with some modifications. For 24/7 Access to Care, CMS proposes that APCM services would provide 24/7 access for urgent needs to the care team/practitioner with real-time access to patient's medical records, include providing patients/caregivers with a way to contact health care professionals in the practice to discuss urgent needs 24/7. CMS states that access to primary care, informed by health IT, makes the right care at the right time possible and potentially avoids costly urgent and emergent care.

CMS proposes the "24/7 Access to Care" service element would require that practices would maintain the capability to deliver care in alternative ways to traditional office visits, such as e-visits, phone visits, home visits, and/or expanded hours. This proposed standard is similar to several requirements tested in CMS Innovation Center models. CMS notes it is not proposing that a practice would need to regularly deliver care in all these alternative ways but would need to demonstrate the practice has the capability.

CMS states that practices can achieve 24/7 access to care through call coverage by a practitioner with health IT system access. CMS discusses the use of nurse call lines or answering services working to provide the initial point of contact with escalation as appropriate. In addition, some successful practices expand hours, add urgent care service or partner with other practices or existing urgent providers to manage and coordinate care after regular office hours.

For Continuity of Care, CMS proposes the service element would be to provide continuity of care with a designed member of the care team with whom the patient is able to schedule successive routine appointments. CMS believes continuity of care refers to the ability of patients to receive care from practitioners who know them and there is an established relationship. CMS discusses methods that successful practices have used for continuity of care including the use of practice management software to track improvements over time.

(4) Comprehensive Care Management

CMS proposes to include the same scope of service elements established for CCM and PCM services with some modifications. Instead of "care management for chronic conditions", the APCM service element would be "overall comprehensive care management" which may include, as applicable, systematic assessment of the patient's medical, functional, and psychosocial needs; system-based approaches to ensure timely receipt of all recommended preventive care services; medication reconciliation; and oversight of patient self-management of medications. CMS notes this care management standard is similar to several requirements tested in the CMS Innovation Center models, including the CPC+ model.

CMS discusses how successful practices differentiate between longitudinal care management for the highest risk cohort of patients and episodic care management to identify patients who have acute or urgent needs for short-term, problem-focused care management services after a triggering event such as a hospital discharge.

(5) Patient-Centered Comprehensive Care Plan

CMS proposes for APCM services similar elements for the "Comprehensive Electronic Care Plan" service element for CCM and PCM but with modifications to specify that the care plan is "patient-centered". CMS states that longitudinal care management includes personalized care planning which results in a care plan that is a mutually agreed-upon document that outlines the patient's health goals, needs, and self-management and is accessible to all team members providing care. The care plan should be patient-friendly, accessible to the patient, and limit use of unfamiliar medical jargon and acronyms. CMS notes that patients receiving longitudinal care management should have a personalized care plan developed in a joint, open-ended conversation between the patient and care team. In addition, personalized care planning is a dynamic process and the care plan document should be updated at regular intervals.

CMS notes that a comprehensive care plan typically includes the following elements: problem list; expected outcome and prognosis; measurable treatment goals; cognitive and functional assessment; symptom management; planned interventions; medical management; environmental evaluation; caregiver assessment; interaction and coordination with outside resources and practitioners and providers; requirements for periodic review; and when applicable, revision of the care plan.

(6) Management of Care Transitions

CMS proposes for APCM services similar elements as established for CCM and PCM with some modifications. Instead of requiring practices facilitate communication of relevant patient information through electronic exchange of continuity of care documents, CMS proposes to simply require the billing practitioner to "ensure timely exchange of electronic health information" with other practitioners and providers. CMS also proposes that the care team/practitioner would follow up with the patient and/or caregiver within 7 days after each ED and hospital discharge. This standard is similar to several requirements tested in CMS Innovation Center models. CMS discusses several processes for data exchange and timely follow-up.

(7) Practitioner, Home, and Community-Based Care Coordination

CMS continues to propose for APCM services similar elements as established for CCM and PCM with some modifications. For the APCM code descriptors, CMS proposes to specify that the "ongoing communication and coordinating receipt of needed services" is not only with home- and community-based service providers, but also with "practitioners", "community-based social service providers, hospitals, and SNFs (or other health care facilities), as applicable." CMS also proposes to add more detail about the communication documented in the patient's medical record to include "the patient's psychosocial strengths and needs, and functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors."

CMS discusses how coordinated referral management with specialty groups and other community or health care organizations ensures referrals are properly managed and coordinated. CMS notes that a collaborative care agreement with clear and agreed-upon expectations improves the process. CMS provides examples of care coordination including interprofessional

consultation service codes which are covered by Medicare. CMS also stresses the need for addressing health-related social needs (HRSNs) for high-risk patients.

(8) Enhanced Communications Opportunities

CMS continues to propose for APCM services similar elements as established for CCM and PCM with some modifications. Specifically, CMS proposes to add "internet and patient portal" as examples of asynchronous non-face-to-face consultation methods and to specify that the practitioner would provide "other CTBS services, including remote evaluation of prerecorded patient information and interprofessional telephone/internet/EHR referral services to maintain ongoing communication with patients, as appropriate" as well as specify "access to patient-initiated digital communications that require a clinical decision, such as virtual check-ins and digital online assessment and management and E/M visits". CMS believes that providing asynchronous non-face-to-face consultation methods and other CTBS are an essential element of care under an advanced primary model of care. CMS is not proposing timeframe restrictions for this proposed element, which includes access to certain CTBS, such as the time restrictions between a virtual check-up and an E/M visit.

(9) Patient Population-Level Management

CMS proposes that all practices providing APCM would have capabilities for population-based, data-driven approaches to manage preventive and chronic care for their patient population and to plan and implement strategies to improve care and outcomes. CMS notes these proposed patient population-level management standards are similar to several requirements tested in CMS Innovation Center models, including the CPC+ model. CMS discusses how data and risk stratification allows practitioners to identify beneficiaries for longitudinal care management, promote follow-up care, and develop strategies to address the needs of patients who are at increased risk.

CMS notes that this Patient Population-Level Management requirement would be met for practitioners billing for APCM services through a TIN that is participating in an ACO in the Shared Savings Program, as these ACOs must meet eligibility requirements for population management. Similarly, the ACO REACH, Making Care Primary, and Primary Care First models all require their participants to engage in population health management.

(10) Performance Measurement

CMS proposes a practice-level requirement of performance measurement of primary care quality, total cost of care, and meaningful use of CEHRT. CMS discusses several performance measurement requirements tested in CMS Innovation Center models.

For a practitioner who is a MIPS eligible clinician (defined in §414.1305), CMS proposes that these practitioners can satisfy the performance measurement requirement by registering and reporting the Value in Primary Care MVP for the performance year in which they bill for APCM services.[18] A MIPS eligible clinician can report to MIPS as an individual, subgroup, group, APM

[18] CMS finalized "The Value in Primary Care" MIPS Value Pathway in the 2024 PFS final rule (88FR 80042-

Entity, or in any combination of these four participation options. A practitioner who is part of a TIN that is participating as a Shared Savings Program ACO or a REACH ACO, or a Primary Care First or Making Care Primary practice would meet these requirements by these programs' quality reporting, accountability for total cost of care, and other program and model requirements.

MIPS-eligible clinicians who report the MVP are also required to report the Promoting Interoperability (PI) performance category measures and attestations through the performance period in which they bill for APM services.[19] CMS believes the use of CEHRT or remote access to the care plan is fundamental to providing APCM services. These requirements are similar to several tested in CMS Innovation Center models.

CMS discusses practitioners who are not MIPS eligible clinicians. CMS recognizes that there are many practitioners who are not MIPS eligible clinicians for a year because they achieve Qualifying APM Participant (QP) status based on their levels of participation in an Advanced APM. CMS states that based on Advanced APMs requirements, practitioners with QP status are engaging in performance measurement consistent with advanced primary care. CMS notes that practitioners who are not MIPS eligible clinicians because they are newly enrolled in Medicare could technically bill for APCM services and are only excluded from MIPS for one year. CMS does not believe that clinicians who bill a low volume of Medicare services and are not MIPS eligible clinicians would be unlikely to bill for APCM services since they would likely invest in the necessary infrastructure.

CMS seeks feedback on the following:

- How to align the APCM services with other Medicare programs and initiatives?
- Whether there are areas of duplication within the APCM service elements and practice capabilities that it should consider addressing?
- How to appropriately align the time period for which the practitioner bills the monthly APCM code with the calendar year reporting period covered by the MVP, and how it would verify and enforce the performance measurement requirement of the APCM service.

d. Duplicative Services and Concurrent Billing Restrictions

CMS proposes that APCM services could not be billed by the same practitioner or another practitioner within the same practice for the same patient concurrent with these other services: CCM, PCM, TCM, interprofessional consultation, remote evaluation of patient videos/images, virtual check-in, and e-visits. The table below lists the proposed duplicative services (Table 22 provides additional information). Since it has intentionally designed the proposed elements of APCM services to track closely with the elements of several other care management service and CTBS codes, CMS believes these services are substantially duplicative of APCM services.

80047).

[19] §414.1375(b) and §414.1365(c)(4)(i)

Proposed Services Duplicative of APCM Services	
Care Management Services	
Chronic Care Management (CCM)	CPT Codes 99487, 99489 - 99491, 99439, 99437
Principal Care Management (PCM)	CPT Codes 99424 - 99427
Transitional Care Management (TCM)	CPT Codes 99495, 99496
Communication Technology-Based Services (CTBS)	
Interprofessional Internet Consultation (IPC)	CPT Codes 99446 – 99449, 99451, 99452
Remote Evaluation of Patient Videos/Images	HCPCS Code G2250
Virtual Check-In	HCPCS Code G2251, G2252
Online Digital E/M (e-Visit)	CPT Codes 98970 - 98972, 99421- 99423

CMS considered whether other care management services such as Behavior Health Integration (BHI), services addressing HRSNs (Community Health Integration (CHI) and Principal Illness Navigation (PIN), and/or other CTBS (Remote Physiologic Monitoring and Remote Therapeutic Monitoring) would be duplicative of the proposed APCM services. CMS believes these services, when appropriate, may complement APCM services rather than overlap or duplicate APCM services.

CMS seeks comments on potential overlap between APCM services and other services, including but not limited to care management, care coordination, and other CTBS. For the services with potential overlap, CMS is interested in the degree of overlap and whether any overlap depends on whether the same or different practitioner reports the services. The Advanced Primary Care RFI (discussed in the next section) requests information about whether to incorporate additional service elements into the APCM, valuation of the APCM codes, and whether, and if so, how to incorporate E/M services into future coding.

e. Valuation of APCM Services – GPCM1, GPCM2, and GPCM3

To value the APCM services, CMS uses the current valuation and utilization of the codes incorporated into the proposed APCM codes. CMS acknowledges this methodology does not account for changes to utilization of APCM that may occur due to the differences in the billing and documentation requirements for APCM services when compared to the requirements for care management services and CTBS. CMS also discusses that currently CTBS are not typically billed for a patient in the same month as care management services. CMS anticipates that as it receives more information about how these codes are used, it will refine these codes and future related codes.

Table 23, reproduced below, summarizes the proposed valuation of the APCM services. Detailed information about the calculation of these values is provided in the proposed rule.

Table 23: Proposed APCM Bundled Codes and Proposed Valuation							
Code		**Crosswalk Codes**	**Work RVU**	**PE RVU**	**MP RVU**	**Total RVU**	**Approximate National Payment***
GPCM1	Patients with up to one chronic condition	99490	0.17	0.14	0.01	0.31	$10

Table 23: Proposed APCM Bundled Codes and Proposed Valuation							
Code		**Crosswalk Codes**	**Work RVU**	**PE RVU**	**MP RVU**	**Total RVU**	**Approximate National Payment***
GPCM2	Patients with two or more chronic conditions	99490, 99439, 99487,99489	0.77	0.72	0.05	1.54	$50
GPCM3	QMBs enrollees with multiple chronic conditions	Relative increase from GPCM2	1.67	1.57	0.12	3.36	$110
*The 2025 proposed CF is $32.36.							

CMS seeks feedback on whether these proposed values appropriately reflect the resources in furnishing these services. CMS seeks comments on ideas for other sources of data to help assess the APCM services valuation, including data to help identify the best approach to reflect the proposed CTBS elements incorporated into the APCM monthly bundle.

3. Request for Information: Advanced Primary Care Hybrid Payment

CMS discusses the experience of the Innovation Center with primary care models and what happens when primary care services are paid with hybrid payments, a mix of fee-for-service and population-based payments. CMS notes these models have not met the criteria for expansion but the findings suggest advanced primary care may reduce unnecessary utilization and improve diabetes care and cancer screening rates. CMS believes that advanced primary care is a fundamental component of accountable care and acknowledges the need to increase the capability of primary care clinicians to promote longitudinal and accountable relationships with beneficiaries through incentives and flexibilities to manage quality and total cost of care.

CMS is exploring ways to strengthen the primary care infrastructure within FFS Medicare. CMS is working to increase access to advanced primary care through the creation and ongoing refinement of specific billing and coding under the PFS that better recognizes advanced primary care and incorporates the resources involved in furnishing longitudinal care. CMS requests input on a broader set of questions based on five foundational components:

- Streamlined Value-Based Care Opportunities
- Billing Requirements
- Person-Centered Care
- Health Equity, Clinical, and Social Risk
- Quality Improvement and Accountability

Whenever possible, CMS requests respondents provide objective, empirical and actionable evidence and to cite this evidence within their responses.

(1) Streamlined Value-Based Care Opportunities

CMS seeks feedback about how to scale the proposed payment for APCM into larger units and incorporate population-based variability in resources to develop a hybrid payment system within the PFS.

- How can CMS better support primary care clinicians and practices who may be new to population-based and longitudinal care management?

- What are the primary barriers to providing particular strategies or supports needed for pediatric clinicians and practices?
- How can CMS ensure that potential future advanced primary care payment will not induce clinicians to leave effective accountable care relationships and clinician networks that already produce positive results? Additionally, how can CMS support growth over time in existing effective accountable care relationships and clinician networks?
- Should CMS evolve the proposed APCM services into an advanced primary care payment that includes E/M and other relevant services, or maintain a separate code set for APCM?
- If E/M services are bundled together for advanced primary care payments, how can CMS ensure that there is not a disincentive for primary care clinicians to continue to provide E/M visits, or increase accountability to E/M visits as warranted?
- As many codes depend on E/M visits (for example, as the base code for an add-on code, or to initiate specific care management activities), how should CMS consider the downstream impacts of incorporating E/M visits into advanced primary care payments?
- Should CMS consider incorporating other CTBS services into advanced primary care hybrid payments, such as Remote Physiologic Monitoring and/or Remote Therapeutic Monitoring?
- Should CMS consider incorporating other services that involve comprehensive care management and care coordination, such as Behavioral Health Integration, End-Stage Renal Disease Monthly Capitation Payment (ESRD MCP), Assessment/Care Planning for Cognitive Impairment, and/or Advance Care Planning?
- Should CMS consider incorporating other services while the patient is under care of home health agencies or hospices, such as Care Plan Oversight?
- Newly finalized HCPCS codes are eligible for use by other payers, including commercial insurers, state Medicaid agencies, and others. CMS notes that value-based alignment is a key goal. If the APCM codes are finalized, they would be eligible for use by these other payers as well. To what extent are other payers interested in adopting the APCM codes? Are there any other changes that would be necessary for other payers to adopt the codes?
- CMS has historically used information presented by the Relative Value Scale Update Committee to determine PFS payment rates. Are there other sources of data on the relative value of primary care services that CMS should consider when setting hybrid payment rates?

(2) Billing Requirements

CMS seeks feedback about how advanced primary care hybrid payments can balance program integrity concerns and provide high-quality care, payment stability, and reduce clinician burden.

- How can CMS reduce the potential burden of billing for population-based and longitudinal care services?
- Are there particular types of items or services that should be excluded from the advanced primary care bundle?
- Are there particular services paid under the PFS today that should be included in the advanced primary care bundle?

- Care management activities are currently billed monthly. What episode lengths should CMS consider when thinking about an advanced primary care bundle of services for hybrid payment? Include evidence to support the proposed episode length.
- Should CMS attribute the advanced primary care clinical episode to a single clinician, or consider weighted attribution and payment for multiple entities or clinicians? How could weighted attribution and payment work? What rules or processes should CMS consider to attribute the episode?
- Care management coding and payment have historically required an initiating visit prior to starting monthly billing, to ensure that the services are medically reasonable and necessary and consistent with the plan of care. Are there other ways that CMS could ensure the clinician billing APCM is responsible for the primary care of the Medicare beneficiary?
- Care management coding and payment require beneficiary cost sharing. Has beneficiary cost sharing been a barrier to practitioners providing such services?
- Consistent with the initiating visit requirement in the APCM proposal, should CMS require the billing of specific qualifying services for billing of an advanced primary care bundle that is larger in scale and scope than APCM?
- Are there Health IT functions beyond what is proposed for APCM services that clinicians should be required to have to bill for an advanced primary care bundle? What should CMS consider in the design of the advanced primary care bundle to effectively incorporate Health IT standards and functionality, to support interoperability and the aims of advanced primary care?
- Should CMS limit the types of non-physician clinicians that can bill for an advanced primary care bundle that is larger in scale and scope than APCM? If so, include evidence to support the restriction.
- How should CMS reconcile instances where an advanced primary care bundle is billed, but primary care services are then billed for and provided by separate entities?

(3) Person-Centered Care

CMS seeks feedback on how advanced primary care code(s) could be structured to both increase efficiency and promote high value services.

- What activities that support the delivery of care that is coordinated across clinicians, support systems, and time should be considered for payment in an advanced primary care bundle that are not currently captured in the PFS?
- How can CMS structure advanced primary care hybrid payments to improve patient experience and outcomes?
- How can CMS structure advanced primary care hybrid payments to ensure appropriate access to telephonic and messaging primary care services?
- What is the best reporting structure to ensure that targeted services are delivered without causing undue or excessive documentation?
- How can CMS facilitate coordination between primary care clinicians that bill for advanced primary care bundles and specialists to reduce costs and improve patient outcomes?

(4) Health Equity, Social and Clinical Risk
CMS seeks feedback about how to develop a simple payment structure that ensures the risk adjustment method incentives the appropriate coding of patient conditions and needs.

- What non-claims-based indicators could be used to improve payment accuracy and reduce health disparities, and how can CMS ensure that they are collected uniformly and documented consistently without unduly increasing administrative burden?
- What risk factors, including clinical or social, should be considered in developing payment for advanced primary care services?
- How can CMS account for apparent changes in risk that are due to changes in coding patterns rather than changes in health status?
- What risk adjustments should be made to proposed payments to account for higher costs of traditionally underserved populations?
- What indicators are used to capture added social risk in commercial insurance? Should CMS consider using these?
- What metrics should be used or monitored to adjust payment to ensure that health disparities are not worsened as an unintended consequence?
- How can CMS ensure that advanced primary care hybrid payment increases access to health care services for patients without a usual source of primary care?
- Are there steps CMS can take to ensure advanced primary care billing and coding is utilized for dually eligible beneficiaries, and by safety net providers?
- Should CMS incorporate Community Health Integration and/or Principal Illness Navigation services and payment into an advanced primary care bundle?

(5) Quality Improvement and Accountability
CMS seeks feedback on how to develop a payment system in which practitioners are engaged in a relationship with their patients where there are responsible for the quality and cost of care.

- How can CMS ensure clinicians will remain engaged and accountable for their contributions to managing the beneficiary's care?
- What are key patient-centered measures of quality, outcomes and experience that would help ensure that hybrid payment enhances outcome and experience for patients?
- How could measures of quality, outcomes, and experience guard against and decrement in access or quality?
- As described in the APCM proposal, reporting of the "Value in Primary Care" MVP would be an APCM service element for MIPS eligible clinicians beginning in 2026. Since this MVP contains measures focused on both the total cost and quality of care, would its inclusion as an APCM service element be sufficient to count as "accountable care?" If not, what other service delivery or quality reporting would be expected in "accountable care?"
- What should CMS consider so that that advanced primary care bundles could be used to promote accountable care across payers, both commercial and Medicaid?
- What quality measures are other payers using to drive improvements in primary care?
- What utilization measures are other payers using to drive improvements in primary care?

- What patient experience measures are other payers using to drive improvements in primary care?
- Should CMS consider flexibilities for smaller practices to bill the advanced primary care bundle? Should CMS consider flexibilities for entities exempt from MIPS to bill the advanced primary care bundle?
- Would clinicians be willing to take on more accountability to further reduce the frequency and/or administrative burden of billing?
- For APCM services, are there other key practice-level elements of the service that should be considered for advanced primary care practices to bill for advanced primary care?

Regulatory Impact

CMS estimates the following utilization for the proposed codes: approximately 300,000 claims for GPCM1, 1.3 million claims for GPCM2, and 400,000 claims for GPCM3. It anticipates that APCM services would result in slight reductions in utilization of existing care management services and CTBS during 2025 as compared to 2024. Specifically, CMS estimates an approximate 11.4 percent reduction from 2024 across the 20 service codes incorporated into the APCM services. CMS believes that the cost impact of this proposal is negligible and therefore it is not necessary to adjust the conversion factor under the PFS budget neutrality requirement.

4. Cardiovascular Risk Assessment and Risk Management

CMS discusses the design and results from CMS Innovation Center's Million Hearts® Cardiovascular Disease (CVD) Risk Reduction (referred to as the Million Hearts® model). The model's goals were to decrease the incidence of first-time heart attacks and strokes among medium and high-risk Medicare beneficiaries over five years and reduce spending on cardiovascular events. The model incorporated calculation of a beneficiaries' risk of having a heart attack or stroke over 10 years and cardiovascular care management services to high-risk patients. The evaluation of the model found reduced rate of death from any cause for this population by four percent and reduced the risk of death from a cardiovascular event (heart attack or stroke) by eleven percent.[20]

CMS concludes the Million Hearts model demonstrates the benefit of determining a beneficiary's risk of CVD and providing recommendations for lifestyle modifications. This is consistent with guidelines from the American Heart Association (AHA) recommendations for using atherosclerotic CVD (ASCVD) risk assessment tools in determining treatment decisions for patients without a prior history of CVD and providing recommendations for life style modifications.[21] CMS does not believe the resources for these activities are appropriately reflected in current policies and proposes to establish codes to describe a separately billable ASCVD risk assessment and CVD-focused risk management.

[20] Evaluation of the Million Hearts CVD Risk Reduction Model. Final Report. August 2023. Mathematica. https://www.cms.gov/priorities/innovation/data-and-reports/2023/mhcvdrrm-finalannevalrpt.
[21] Arnett DK et al. 2019 ACC/AHA Guideline on the Primary Prevention of CVD: A Report of the ACC/AHA Task Force on Clinical Practice Guidelines. Circulation. 2019 Sep 10;140(11):e596-e646.

a. ASCVD Risk Assessment (GCDRA)

CMS proposes an ASCVD risk assessment code, HCPCS code GCDRA – *Administration of a standardized, evidence based ASCVD Risk Assessment for patients with ASCVD risk factors on the same date as an E/M visit, 5-15 minutes, not more often than every 12 months*. ASCVD refers to a review of the individual's demographic factors, modifiable risk factors for CVD, and risk enhancers for CVD.

CMS proposes that the ASCVD risk assessment must be furnished by the practitioner on the same day they furnish an E/M visit and to incorporate the findings of the risk assessment into the patient's diagnosis and treatment plan established during the visit. CMS states that an ASCVD risk assessment is reasonable and necessary for a patient who has at least one predisposing condition for CVD that may put them at increased risk for future ASCVD diagnosis. Examples of predisposing conditions include obesity, a family history of CVD, high blood pressure, and high cholesterol. CMS proposes that the risk assessment would not be separately billable for patients with a CVD diagnosis or with a history of a heart attack or stroke.

CMS is not proposing any specific ASCVD risk assessment tool. Proposed elements of the ASCVD risk assessment would include:

- Current (from the last 12 months) laboratory data (lipid panel) for inputs needed for the risk assessment tool.
- Administration of a standardized, evidence-based ASCVD risk assessment tool that has been tested and validated through research and includes the following domains:
    - The output must include a 10-year estimate of the patient's ASCVD risk and this output must be documented in the medical record
    - Demographic factors such as age and sex
    - Modifiable risk factors for CVD such as blood pressure and cholesterol control, smoking history, physical activity, obesity and alcohol and other drug use.
    - Possible risk enhancers such as a family history of CVD and pre-diabetes.
    - Billing practitioners may assess for additional domains if the tool used requires additional domains. Examples of tools include the ACC ASCVD Risk Assessment Estimator and the ACC Prevent Tool. The tool must not introduce discriminatory bias.

CMS proposes that GCDRA has a duration of 5 to 15 minutes for the administration of the risk assessment tool and be billed no more than once every 12 months. CMS proposes a work RVU of 0.18. This proposal is based on a direct crosswalk to HCPCS Code G0136 (*Administration of a standardized, evidence-based SDOH assessment, 5-15 minutes, not more often than every 6 months*). CMS proposes to use this crosswalk to also establish direct PE inputs.

CMS seeks comments about these proposals and how to educate clinicians about these proposed codes.

b. Atherosclerotic Cardiovascular Disease Risk Management Services (GCDRM)

CMS proposes an ASCVD risk assessment code, HCPCS code GCDRM – *ASCVD risk management with the following required elements: patient is without a current diagnosis of ASCVD but is determined to be at medium or high risk for CVD (>15 percent in the next 10 years) as previously determined by the ASCVD risk assessment: ASCVD-Specific care plan established, implemented, revised, or monitored that addresses risk factors and risk enhancers and must incorporate shared decision-making between the practitioner and the patient; clinical staff time directed by physician or other qualified health care professional; per calendar month*.

CMS proposes that the elements of ASCVD risk management service would include:

- ASCVD Specific Risk Management, which may include:
    - Promoting receipt of preventive services (including tobacco cessation counseling, diabetes screening, diabetes self-management);
    - Medication management (including aspirin or statins to maintain or decrease risk of CVD);
    - Ongoing communication and care coordination via certified EHR technology; and
    - Synchronous, non-face-to-face communication methods must be offered.
- ASCVD-Specific, Individualized, Electronic Care Plan
    - Must address modifiable risk factors and risk enhancers specific to CVD, as applicable, such as: blood pressure and cholesterol control; smoking, alcohol, and other drug use status, history, and cessation; physical activity and nutrition; and obesity; and
    - Plan must be established, implemented, and monitored and must incorporate shared decision-making between the practitioner and the patient.

CMS states there is no minimum service time requirements in a month but each of the proposed elements must be addressed to bill for the service, unless an element is not medically indicated or necessary for that specific patient. For example, smoking cessation would not be addressed for a patient who doesn't use tobacco. The medical record must include documentation of each service element.

Physicians and NPPs who can furnish E/M services could bill for ASCVD risk management. CMS proposes that these services would be considered a "designated care management service" and could be provided by auxiliary personnel under the general supervision of the billing practitioner.

CMS proposes that patient consent must be obtained before starting ASCVD risk management, the patients must be informed about applicable Medicare cost-sharing, and must be documented in the medical record. CMS proposes that ASCVD risk management services could be billed no more often than once per calendar month, and that payment is limited to one practitioner per beneficiary per month. Patients must be determined to be at medium or high risk for CVD (>15 percent in the next 10 years) as previously determined by the ASCVD risk assessment and must not have a current diagnosis of CV disease or have a history of heart attack or stroke.

CMS proposes that GCDRM has a work RVU of 0.18. This proposal is based on a direct crosswalk to CPT Code 99211 (*O/O E/M for an established patient that may not require the presence of a physician or other qualified health care professional*). CMS proposes to use this crosswalk to also establish direct PE inputs.

5. Strategies for Improving Global Surgery Payment Accuracy

CMS pays for approximately 4,100 physicians' services as global surgery packages (referred to as "global packages"). Global packages are valued to include all services provided during a specified period of days (0-, 10-, or 90-day global packages) by a physician or another practitioner is the same group practice for a specific surgical procedure. In the 2015 PFS final rule, CMS discussed its concerns with the accuracy of the valuation and payment of global surgery packages including concerns that the packages were not valued based on estimates consistent with the number and kind of services being performed (79 FR 67582-67591). Multiple OIG reports suggested that practitioners perform fewer post-operative visits than expected and included in the valuation of global packages. In the 2015 PFS final rule, CMS finalized a policy to transition all 10-day and 90-day global packages to 0-day global packages and to allow any post-operative visits to be billed as standalone visits by any practitioner who furnished them. Amendments made by section 523 of the Medicare Access and CHIP Reauthorization Act of 2015[22] prohibit CMS under section 1848(c)(8)(A) of the Act from implementing this finalized policy. In addition, section 188(c)(8)(B) required CMS, beginning in 2017, to collect data on the number and level of post-operative visits typically provided to patients during 10- and 90-day global periods and to use this data and any other data beginning in 2019 to improve the accuracy of global package valuation.

CMS reviews the work it has done over the past 9 years to obtain accurate data about the number and level of post-operative visits. CMS also discusses the responses received in response to a RFI in the 2023 proposed rule about strategies for revaluing these service; information on how changes to health care delivery and payment may impact the accuracy of global package payments; and possible impact of changes to global packages on health care access for beneficiaries. Some commenters generally disagreed with the finding that post-operative visits are not performed as frequency as the assumed number in the global surgery packages; these comments were based on anecdotal assertions rather than data. Some commenters supported eliminating 10-day global packages. Commenters have not proposed specific alternative strategies to revalue global surgical packages.

CMS has also reviewed the billing requirements and payment policies for the global packages and believes there are opportunities for clarification or revision of related policies and billing instructions. Specifically, as discussed below, CMS proposes:

(1) to revise its transfer care policy for global packages and

(2) to develop an add-on code that accounts for resources involved in post-operative care provided by a practitioner who did not furnish the surgical procedure.

CMS believes these proposals will help align payment with the way surgical procedures are currently performed as evidenced in the Medicare data and help improve payment accuracy.

[22] MACRA; Pub. L, 114-10, enacted April 16, 2015)

a. Clarifying the Scope of Global Surgical Packages

CMS has valued global packages to include the surgical procedure and services furnished during the global period based on the scenario when the services are furnished by the practitioner who performs the surgery (referred to as the proceduralist) or by another practitioner in the same group as the proceduralist.

Under current payment policy, certain services furnished during the global period by the proceduralist or by another practitioner is the same group practice may be separately billed and, in some cases, require an appropriate modifier:

- Initial decision for surgery: E/M service billed with modifier -57 (Decision for Surgery);
- E/M services unrelated to the procedure: billed with modifier -24 (Unrelated E/M Service During a Global Period);
- Other services unrelated to the procedure (including underlying condition treatment, diagnostic tests, distinct procedures) not including care for complications/returns to the operating room: no modifier required;
- Failure of a less extensive procedure requiring a more extensive procedure: no modifier required;
- Organ transplant immune suppressive therapy: no modifier required; and
- Critical care services unrelated to surgery: billed with modifier -FT if in the post-operative period.

In general, except when there is a formal transfer of care, a practitioner other than the proceduralist or a practitioner in the same group practice as the proceduralist can bill separately for an E/M visit during the global period, including post-operative E/M visits related to the procedure. Under CMS' current transfer of care policy, transfer of care modifiers must be reported when a formal transfer of care arrangement is documented by both proceduralist and another practitioner providing the related post-operative visits. CMS' analysis of claims data indicates these modifiers are rarely used and when used they are predominately for ophthalmologic procedures.

CMS reiterates that under its current policy, the scope of the global package extends to services furnished by the entire group practice of the proceduralist, including services furnished by practitioners in the group practice with a different specialty from the proceduralist.[23] Without a modifier to indicate otherwise, during the global period, all E/M services furnished to the patient by the proceduralist or another practitioner in the same group practice as the proceduralist are presumed to be related to, and included in the payment for the global package.

CMS recognizes that there may be multiple practitioners in the same or different specialties in the same group practice and **seeks comments on how its policies should apply to practitioners in a range of specialties within the same group practice**. **CMS also seeks comment on how remote monitoring and other types of technologies represent new resource costs and/or produce efficiencies and effectiveness of post-operative care.**

[23] Group practice as defined at 42 CFR 411.352

b. Expand Applicability of Transfer of Care Modifiers

Under current policy, transfer of care modifiers are required to be appended to the global package code when billing for services that are within the scope of the global package only when the proceduralist and one or more other practitioners who are not in the same group practice as the proceduralist formally document their agreement to provide distinct portions of the global package. CMS defines a formal documented transfer of care agreement as "a letter or an annotation in the discharge summary, hospital record, or ASC record".[24]
As indicated in the PFS Relative Value files, the payment for the global package is adjusted based on the modifier used.[25] The following transfer of care modifiers describe the different portions of the global package:

- Modifier -54 Surgical Care Only: appended to the global package code to indicate that the proceduralist performed only the surgical portion of the global package.
- Modifier -55 Post-operative Management Only: appended to the global package code to indicate that the practitioner performed only the post-operative management portion of the global package.
- Modifier -56 Pre-operative Management Only: appended to the global package code to indicate that the practitioner performed only the pre-operative management portion of the global package.

CMS' analysis of 2022 Medicare claims data identified these modifiers were rarely used except for ophthalmology global practice, primarily cataract-related procedures. In addition, there were more claim lines billed with modifier -54 that there are corresponding lines with modifier -55 and modifier -56 is rarely used. CMS concludes these observations suggest that the overwhelming concentration of reported transfer of care modifiers is with ophthalmology procedures and there is a potential mismatch in billing for formal transfer of care between proceduralists and other practitioners providing post-operative care.

Beginning for services furnished in 2025, CMS proposes to broaden the applicability of the transfer of care modifiers for the 90-day global packages. CMS proposes to require the use of the appropriate transfer of care modifiers (modifier -54, -55, or -56) for all 90-day global surgery packages in any case when a practitioner plans to furnish only a portion of a global package. This policy includes but not limited to when there is a formal, documented transfer of care under current policy or an informal, non-documented but expected, transfer of care. 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 E/M service unrelated to the global package; modifier-24 would still be required. CMS believes this proposed policy would prevent duplicative payment for post-operative care because the global package payment would be adjusted based on the appended modifier.

CMS seeks comments on the following:

[24] CMS Manual System, Pub 100-04 Medicare Claims Processing, Transmittal 11287
[25] The PFS Relative Value files are available at https://www.cms.gov/medicare/payment/fee-schedules/physician/pfs-relative-value-files.

- 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.
- Whether it should consider proposing these changes for the 10-day global packages in future rulemaking.

c. Payment for Global Packages

CMS is interested in identifying a procedure-specific, data-driven method for assigning shares to portions of the global payment package and **seeks comments on the following issues related to the payment for global packages:**

- How best to determine the appropriate payment proportions for the three portions of the global package?
- Potential approaches to revise these payment allocations and how they could be established to better reflect current medical practice and conventions for post-operative follow-up care?
- Recommendations from interested parties, including the AMA RUC, on what allocation percentages should be, based on how the global package codes are valued and any other relevant information.

In its review of the percentages assigned to the portions of the global payment package, CMS identified the following four codes that did not have any assigned percentages in its files even though they are identified as global packages:

- CPT code 77750 – Infusion of instillation of radioelement solution (includes 3-month follow-up care),
- CPT code 77761 – Intracavitary radiation source applic simple,
- CPT code 77762 - Intracavitary radiation source applic intermed, and
- CPR code 77763 - Intracavitary radiation source applic complex.

CMS believes that the MACs have local edits in place to ensure appropriate payment for these services when billed with the transfer of care modifiers.

CMS seeks comments on whether these codes are appropriately categorized as 90-day global package codes and if they are, what the assigned percentages should be for the pre-operative, surgical care, and post-operative portions of the service.

d. Post-operative Care Services Add-on Code

CMS acknowledges that when a practitioner sees a patient post-operatively, they may not be involved in creating the surgical plan and may not have access to the operative notes to know the appropriate needs for the post-operative care. CMS proposes to establish an add-on code that would account for resources involved in post-operative care for a global package provided by a practitioner who did not furnish the surgical procedure and does not have a formal transfer of care. The add-on code should not be billed by another practitioner in the same group practice as the practitioner who performed the surgical procedure, or in the same specialty as the practitioner who performed the surgical procedure.

For post-operative care services, CMS proposes 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 the O/O E/M visit, new or established).

CMS notes that it would consider using any newly available CPT code to describe services similar to those described in future rulemaking.

CMS proposes the following requirements for billing GPOC1:

- The code would be reported by a physician or other practitioner who did not perform the surgical procedure and provides related post-operative visits despite the absence of a formal transfer of care.
- The code would only be reported with an O/O E/M visit for a new of established patient
    - The medical record would document the relevant surgical procedure (to the extent it can be identified).
- The code could only be billed once during the 90-day global period
    - CMS proposes to assign a ZZZ global period payment indicator to allow the code to be billed during the post-operative time frame that applies to the surgical procedure and with an E/M visit.

For valuing GPOC1, CMS believes that CPT code 90785 (Interactive complexity (List separately in addition to the code for primary procedure)) serves as an appropriate reference code. CMS notes that CPT code 90785 was created to capture additional work that occurs during diagnostic psychiatric evaluation, psychotherapy, psychotherapy performed with an E/M services and group psychotherapy sessions, and the service refers to specific communication factors that complicate the delivery of a psychiatric/psychotherapy procedure. CMS believes the work for GPOC1 is only half of the work assigned for CPT code 90785. CMS proposes a work RVU of 0.16; CPT code 90785 has no direct PE inputs and CMS proposes the same for GPOC1.

CMS seeks comments on the typical time and intensity spend over and above a separately billed E/M visit when providing post-operative care to a patient when the practitioner did not perform the surgical procedure.

Regulatory Impact

CMS regulatory impact is based only on 90-day high volume and/or high cost codes. This is a relatively small set of codes (approximately 180) and accounts for about 73 percent of total Medicare 90-day procedure volume. From this select group of global surgical codes, CMS estimates the transfer of care modifier (modifier -54) will be employed 20 percent of the time. CMS proposes to apply the payment reduction associated with modifier -54 for the postoperative care and apply it to the utilization estimates for the associated procedures. For example, for CPT code 27447 (Total knee arthroplasty), CMS proposes there will be a postoperative transfer of care 20 percent of the time with a corresponding 21 percent decrease in payment. CMS notes that the impact of this reduction in spending associated with this policy results in an increase in the budget neutrality adjustment to the conversion factor, which is redistributed across the PFS.

CMS estimates a utilization of approximately 40,000 total claims in 2025 for the proposed add-on codes, HCPCS code GPOC1. CMS anticipates that uptake of this code will be low initially, consistent with initial uptake of other new services finalized under the PFS.

H. Supervision of Outpatient Therapy Services

1. Supervision of Outpatient Therapy Services in Private Practice

CMS notes that over the past several years and again more recently, it has heard from interested parties that the direct supervision requirements in the private practice setting are problematic for OTPPs and PTPPs who must remain on-site and immediately available when Medicare patients are treated in order to bill for therapy services furnished by their supervised OTAs and PTAs. These interested parties have requested that CMS revise its requirement for PTPPs and OTPPs to provide direct supervision of OTAs and PTAs to align with the general supervision policies for OTs and PTs that work in Medicare institutional settings that provide therapy services (for example, rehabilitation agencies, outpatient hospitals, SNFs and comprehensive outpatient rehabilitation facilities (CORFs), etc.), to allow for the general supervision of their therapy assistants. These interested parties note that this policy has had a disproportionate impact on small practices in rural and underserved areas.

CMS believes that a change from direct to general supervision would allow OTPPs and PTPPs the flexibility to better accommodate patients' availability and act to ensure access to necessary therapy services. This would also better align CMS' supervision policies for OTPPs and PTPPs with the majority of state-established supervision levels for therapy assistants providing occupational therapy and physical therapy services. This will parallel the 44 States that allow general supervision of PTAs and the 49 States that allow general supervision of OTAs (most often described as requiring the PT or OT to be in touch via telecommunication).

Thus, CMS proposes to revise its regulations at §§410.59(a)(3)(ii) and (c)(2) and 410.60(a)(3)(ii) and (c)(2) to allow for general supervision of OTAs and PTAs by OTPPs and PTPPs, when the OTAs and PTAs are furnishing outpatient occupational and physical therapy services, respectively. For the States with more restrictive supervision levels, such as direct supervision, those therapy services are always furnished to the extent that is permitted under State law. CMS

notes that while it is proposing to allow for general supervision by OTPPs and PTPPs of their OTAs/PTAs, an OTPP or PTPP would still be required to provide direct supervision to unenrolled OTs and PTs, respectively, in accordance with §§410.59(c)(2) and 410.60(c)(2).

2. Certification of Therapy Plans of Care with a Physician or NPP Order

Certification of Therapy Plans of Care
The current regulations at 42 CFR 424.24(c) require that a physician, nurse practitioner (NP), physician assistant (PA), or clinical nurse specialist (CNS) who has knowledge of the case sign the initial certification for the patient's plan of treatment. These regulations require recertification at least every 90 days, and the plan or other documentation in the patient's medical record must indicate the continuing need for physical therapy, occupational therapy, or speech-language pathology services. The physician, nurse practitioner, clinical nurse specialist, or physician assistant who reviews the plan must recertify the plan by signing the medical record.

Over the past two years, representatives of several therapy-related organizations have requested that CMS reduce the administrative burden involved with attempting to obtain signed plans of treatment from the physician/NPP. They expressed concern that therapists are held accountable for the action or inaction of physicians/NPPs who may be overwhelmed with paperwork. These interested parties report that therapists make exhaustive efforts to obtain the physician/NPP's signature – some reporting that they contact physician offices (via phone, email, or fax, etc.) more than 30 times. Without the required signature, the therapist will not meet the conditions to be paid for the services they deliver. These interested parties have suggested that CMS amend its regulation at §424.24(c) to permit the presumption of a physician/NPP signature for purposes of certification and recertification in cases where a signed written order or referral from the patient's physician/NPP is on file and there is written documentation in the patient's medical record to substantiate the method and date (such as a fax, email, etc.) that the therapist forwarded the plan of care to the physician/NPP.

After reviewing its current regulatory requirements and considering the suggestions of interested parties, CMS believes it would be appropriate to propose to amend the regulation at § 424.24(c) for those cases when a patient has a signed and dated order/referral from a physician/NPP for outpatient therapy services. Rather than characterizing this proposal as a "presumption," CMS takes the view that when the patient's medical record includes a signed and dated written order or referral indicating the type of therapy needed, CMS (and its contractors) would treat the signature on the order or referral as equivalent to a signature on the plan of treatment. CMS believe this would be reflective of the intent of the ordering/referring physician/NPP when that order/referral is on file in the patient's medical record and that it would be consistent with the initial certification required under section 1835(a) of the Act for providers of therapy services and CMS' current policy for therapy in the private practice setting.

As such, CMS proposes to carve out an exception to the physician signature requirement at §424.24(c) by adding a new paragraph (c)(5). The proposed policy would be an exception to the physician signature requirement for purposes of an initial certification in cases where a signed and dated order/referral from a physician, NP, PA, or CNS is on file and the therapist has documented evidence that the plan of treatment has been delivered to the physician, NP, PA, or CNS within 30 days of completion of the initial evaluation. However, at this time, CMS is not

proposing and does not intend to establish an exception to the signature requirement for purposes of recertification of the therapy plan of treatment. CMS believes that physicians and NPPs should still be required to sign a patient's medical record to recertify their therapy treatment plans, in accordance with §424.24(c)(4), to ensure that a patient does not receive unlimited therapy services without a treatment plan signed and dated by the patient's physician/NPP.

Under its proposal, CMS or its contractors would be able to treat the physician/NPP signature on the order or referral as equivalent to a signature on the plan of treatment for purposes of the initial certification if that physician/NPP has not signed and returned the patient's plan of treatment to the therapist within 30 days of the initial evaluation, but only in cases where the patient's physician/NPP has signed and dated the written order or referral and indicated the type of therapy needed, and that written order or referral is on file in the medical record.

CMS solicits comments to gather more information about the need for a regulation that would address the amount of time for changes to plans of treatment. Its current regulations currently allow for changes to the treatment plan by the physician/NPP without time restrictions. Interested parties have suggested that CMS allow physicians/NPPs to have just ten business days from the date of receipt of a plan of care to modify that plan of care (in the case of a patient with an order for the therapy services). Additionally, CMS solicits comment as to whether there should be a 90 calendar daytime limit on the order/referral for outpatient therapy services in cases where the order/referral is intended to be used in relation to the proposed regulatory amendment for the initial certification of the treatment plan. CMS also seeks feedback about whether this limit, or one of a different duration, should be incorporated into the regulatory provision proposed above for §424.24(c)(5).

CMS clarifies that it is not proposing to amend §424.27 for CORF physical therapy, occupational therapy, and speech-language pathology treatment plans to align with its proposed amendments at §424.24 because section 1861(cc) of the Act and regulation at 42 CFR 410.105(c) require these treatment plans to be established by a physician.

Clarification and Technical Revision to Requirements for medical and other health services furnished by providers under Medicare Part B (§424.24)

In accordance with the statute and §424.24(b), Medicare Part B pays for outpatient physical therapy and speech-language pathology services furnished by providers only if a physician certifies the content specified in § 424.24(c)(1) or (4). CMS recognizes that it may not be clear that §424.24(c) applies to the occupational therapy services furnished by providers, since occupational therapy services are currently only explicitly mentioned in the recertification requirements at § 424.24(c)(4).

Due to the foregoing concerns, CMS proposes to revise the headings of paragraphs (c) introductory text and (c)(1)(i) to include the term "occupational therapy" after physical therapy. CMS also proposes to replace the term speech pathology with the accepted term speech-language pathology in 42 CFR 424.24(c)(1)(i), and proposes to add the term "occupational therapist" to 42 CFR 424.24(c)(3)(ii) between physical therapist and speech-language pathologist.

3. KX Modifier Thresholds

For 2025, CMS proposes to increase the 2024 KX modifier threshold amount by the most recent forecast of the 2017-based MEI, which is estimated to be 3.6 percent, based on the IHS Global, Inc. (IGI) forecast based on historical data through the second quarter of 2024. This results in a per beneficiary proposed threshold amount of $2,410 for physical therapy and speech-language pathology services combined and $2,410 for occupational therapy services for 2025; CMS would use more recent data for the final rule, if available.

Section 1833(g)(7)(B) of the Act describes the targeted medical review (MR) process for PT, SLP, and OT services. The threshold for targeted MR is $3,000 until 2028, when it will be updated by the percentage increase in the MEI. The preamble describes the factors used to identify and conduct targeted MR; requirements for billing the KX modifier; and how the agency tracks beneficiary incurred expenses for the year.

I. Advancing Access to Behavioral Health Sciences

1. Safety Planning Interventions and Post-Discharge Telephonic Follow-up Contacts

a. Background

In the 2024 PFS proposed rule, 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, such as safety planning interventions and/or telephonic post-discharge follow-up contacts. Several commenters suggested that CMS encourage wider implementation under Medicare of the Safety Planning Intervention (SPI) and the Post-Discharge Telephonic Follow-up Contacts Intervention (FCI).

Safety planning interventions involve a patient working with a clinician to develop a personalized list of coping strategies and sources of support that the person can use in the event of experiencing thoughts of harm to themselves or others. The basic components of a safety plan include the following: (1) recognizing warning signs of an impending suicidal crisis or actions that increase the risk of suicide; (2) employing internal coping strategies; (3) utilizing social contacts and social settings as a means of distraction from suicidal thoughts and/or taking steps to reduce the risk of suicide; (4) utilizing family members, significant others, caregivers, and/or friends to help resolve the crisis; (5) contacting mental health professionals, crisis services, or agencies; and (6) making the environment safe, including restricting access to lethal means, as applicable.

FCI is a specific protocol of services for individuals with suicide risk involving a series of telephone contacts between a provider and patient in the weeks and sometimes months following discharge from the emergency department and other relevant care settings, that occurs when the person is in the community and is designed to reduce the risk for subsequent adverse outcomes. FCI calls are typically 10-20 minutes in duration and aim to encourage use of the Safety Plan (as needed in a crisis) and updating it to optimize effectiveness, expressing psychosocial support,

and helping to facilitate engagement in any indicated follow-up care and services. CMS notes that this service would not be within the scope of Medicare telehealth services as these services are specifically structured to be delivered via audio-only phone calls and are not a substitute for an in-person service.

b. Safety Planning Interventions (SPI)

CMS proposes to establish separate coding and payment under the PFS describing safety planning interventions. Specifically, CMS proposes to create an add-on G-code that would be billed along with an E/M visit or psychotherapy when safety planning interventions are personally performed by the billing practitioner in a variety of settings. The proposed G-code is HCPCS code GSPI1:

- 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)*

CMS proposes to value HCPCS code GSPI1 based on the valuation of CPT code 90839 *(Psychotherapy for crisis)*, which describes 60 minutes. CMS assumes 20 minutes for HCPCS code GSPI1, resulting in a proposed work RVU value of 1.09 (one-third of the work value assigned to CPT code 90839).

CMS seeks comments on several issues:

- whether clinical staff who meet the definition of auxiliary personnel defined at 42 CFR 410.26(a)(1) or who are employed by a hospital could participate in furnishing this service under the supervision of the billing practitioner in certain settings with the relevant training needed to perform the service as well as what sort of training would be needed;
- whether 20 minutes accurately captures the typical amount of time spent with a patient on safety planning interventions, including all six elements of the SPI;
- whether these interventions typically occur in the context of an encounter, such as an E/M visit or psychotherapy, or whether there may be times when they may be furnished as a standalone service; and
- whether CMS should consider allowing this code to be billed on its own and information on which clinician types might be most likely to bill such a code on its own.

c. Post-Discharge Telephonic Follow-up Contacts Intervention (FCI)

CMS proposes to create a monthly billing code to describe the specific protocols involved in furnishing post-discharge follow-up contacts that are performed in conjunction with a discharge from the emergency department for a crisis encounter, as a bundled service describing four calls in a month, each lasting between 10-20 minutes. The proposed G- code is

- 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.*

CMS proposes to price this service based on direct crosswalk to CPT code 99426 *(Principal care management; first 30 minutes of clinical staff time directed by a physician or other qualified healthcare professional),* which is assigned a work value of 1.00 work RVUs. CMS notes several billing considerations:

- Can be billed in conjunction with proposed HCPCS code GSPI1 for the same patient.
- Billing practitioners would need to meet a threshold of at least one real-time telephone interaction with the patient in order to bill HCPCS code GFCI1. Unsuccessful attempts to reach the patient would not qualify.
- Billing practitioner could not count time or effort more than once for the purposes of

CMS proposes that the treating practitioner would be required to obtain verbal (or written) beneficiary consent in advance of furnishing the services described by GFCI1, which would be documented by the treating practitioner in the medical record (similar to care management and other non-face-to-face services paid under the PFS). Obtaining advance consent would include: (1) ensuring that the patient is aware that Medicare cost sharing applies to these services; (2) furnishing and receiving the necessary information to enable the patient to receive these services (for example, obtaining the patient's telephone number(s)); and (3) confirming that the patient consents to the contacts.

CMS seeks comments on whether it should consider finalizing a specified duration that HCPCS code GFCI1 could be billed) following discharge, for example, allowing this code to be billed for up to two months following discharge or whether a longer duration would be appropriate, the number of calls per month, the billing structure (for example, four calls for each discharged patient), and any other relevant feedback).

2. Digital Mental Health Treatment (DMHT)

CMS proposes Medicare payment to billing practitioners for digital mental health treatment (DMHT) devices furnished incident to or integral to professional behavioral health services used in conjunction with ongoing behavioral health care treatment under a behavioral health treatment plan of care. In this proposed rule CMS uses the term "digital mental health treatment (DMHT) device" to include the term "digital computerized behavioral therapy (CBT)" it used in prior rulemaking and in general to refer to software devices cleared by the Food and Drug Administration (FDA) that are intended to treat or alleviate a mental health condition, in conjunction with ongoing behavioral health care treatment under a behavioral health treatment plan of care, by generating and delivering a mental health treatment intervention that has a demonstrable positive therapeutic impact on a patient's health.

a. Background

CMS reviews the history and payment of software enabled devices that capture and record or transmit data and the challenges associated with fitting these services into the existing benefit structure under the PFS. In particular, CMS reviews its policies on payment for remote physiologic monitoring (RPM), remote therapeutic monitoring (RTM) and supply of a device for cognitive behavioral therapy (CBT) monitoring. For this last service, CMS is allowing for contractor pricing as there are no invoices for devices specific to the cognitive behavioral therapy monitoring described by the CPT code created for this purpose.

CMS notes the particular challenges presented in setting appropriate pricing under the PFS for these technologies as they rely primarily on software, licensing, and analysis fee, with minimal costs in equipment and hardware. These are not well accounted for in its practice expense methodology, which is why CMS has relied on a crosswalk methodology to approximate relative resources for these kinds of services.

In the 2024 PFS proposed rule, CMS requested information on a variety of specific questions: distribution and delivery models; practitioners and auxiliary staff involved in furnishing services; collection of data; defining an episode of care; how to code these products and services; scientific and clinical evidence to support reasonable and necessary determinations; Medicare benefit category; improving access to services for underserved populations; and protecting privacy and confidentiality. Public commenters indicated that CMS has existing authority to pay for digital therapeutics as durable medical equipment (DME) or incident to a physician service. These commenters suggested that CMS should continue to use its authority to code and pay for digital therapeutics that are cleared by the FDA consistent with other prescription medical devices.

b. Payment for Digital Mental Health Treatment (DMHT) Devices

CMS emphasizes that its proposed coding and payment policy only applies to DMHT devices that have been cleared by the FDA. It notes that many digital platforms and applications are marketed as behavioral health and wellness intervention, but few have evidence demonstrating improved behavioral health outcomes.[26]

CMS proposes to create three new HCPCS codes for DMHT devices modeled on coding for RTM services for 2025. The first code (GMBT1) would be billable by physicians and practitioners who are authorized to furnish services for the diagnosis and treatment of mental illness for furnishing a DMHT device. Specifically, the code is as follows:

- GMBT1 *(Supply of digital mental health treatment device and initial education and onboarding, per course of treatment that augments a behavioral therapy plan)*

CMS notes several billing requirements for the code to be payable:

- DMHT device must be FDA cleared;

[26] https://store.samhsa.gov/product/advisory-digital-therapeutics-management-and-treatment-behavioral-health/pep23-06-00-001.

- Billing practitioner must incur the cost of furnishing the DMHT device to the beneficiary;
- Furnishing of the device must be incident to the billing practitioner's professional services in association with ongoing treatment;
- Billing practitioner must diagnose the patient and prescribe or order the DMHT device; and
- DMHT device must have demonstrated a reasonable assurance of safety and effectiveness (as determined by the FDA)

The patient could then use the DMHT device at home or perhaps in an office or other outpatient setting, if that is how the device has been cleared by the FDA for use under 21 CFR 882.5801. CMS proposes proposing contractor pricing for code GMBT1 and **seeks comment on what national pricing methodology it might consider, including what potential crosswalks would be appropriate.**

CMS also seeks comment about other parameters that it should consider regarding the services described by GMBT1:

- whether payment should be made if the practitioner furnishes a digital device that has not been cleared by FDA for mental health treatment for a specific use, even if the digital device has been cleared by the FDA for another specific use;
- whether payment should be made for DMHT devices cleared by the FDA not only under 21 CFR 882.5801 but also under other regulations;
- whether and how payment might be limited if a patient discontinues use of the DMHT device before completing a course of treatment; and
- whether and how payment might be limited to a set number of DMHT devices per calendar month per patient.

CMS also proposes to establish payment for two additional new codes. These proposed codes are

- 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);* and
- 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).*

Under this proposal, GMBT1 requires that the billing practitioner who diagnosed the patient and prescribed or ordered the DMHT device or that billing practitioner's clinical staff must monitor the patient's therapeutic response to the DMHT device and adjust the behavioral health therapy

plan as needed. GMBT2 and GMBT3 should only be billed when there is ongoing use of the DMHT device and should not be billed in cases where the patient discontinues use of the DMHT device.

For GMBT2 CMS proposes a direct crosswalk to CPT code 98980 (remote therapeutic monitoring first 20 minutes), which is assigned a work RVU of .62. For GMBT3, CMS proposes to value this code based on a crosswalk to CPT code 98981 (remote therapeutic monitoring each additional 20 minutes), which is assigned a work RVU of .61. CMS believes that the work and PE described by these crosswalk codes are analogous to the services described in GMBT2 and GMBT3, respectively.

3. Interprofessional Consultation Billed by Practitioners Authorized by Statute to Treat Behavioral Health Conditions

a. Background

In the 2019 PFS final rule (83 FR 59489), CMS finalized payment for six CPT codes regarding interprofessional consultations (99451, 99452, 99446, 99447, 99448, 99449). These codes are intended to allow a patient's treating physician or other qualified healthcare professional to request the opinion and/or treatment advice of a consulting physician or qualified healthcare professional with specific specialty expertise without the need for the patient's face- to-face contact with the consulting physician or qualified healthcare professional. These interprofessional consultation codes are currently limited to being billed by practitioners who can independently bill Medicare for E/M visits. As such, they cannot be billed by clinical psychologists, clinical social workers, marriage and family therapists, or mental health counselors because these practitioners cannot independently bill Medicare for E/M visits.

CMS proposes new codes that would allow clinical psychologists, clinical social workers, marriage and family therapists, and mental health counselors to bill for interprofessional consultations with other practitioners whose practice is similarly limited, as well as with physicians and practitioners who can bill Medicare for E/M services and would use the current CPT codes to bill for interpersonal consultations.

b. Coding

To further expand access to behavioral health services, CMS proposes payment for six new G codes:

- GIPC1 *(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),*
- GIPC2 *(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)

- GIPC3 *(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),*
- GIPC4 *(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),*
- GIPC5 *(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
- GIPC6 *(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).*

With respect to patient consent, CMS proposes to require the treating practitioner to obtain the patient's consent in advance of these services, which would be documented by the treating practitioner in the medical record (similar to what is required for the CPT interprofessional consultation codes). This would include ensuring that the patient is aware that Medicare cost sharing applies to these services, including informing the patient that there may be cost sharing for two services (one for the treating/requesting practitioner's service and another for the consultant practitioner's service).

c. Valuation

CMS proposes to value the six proposed new G codes based on crosswalks to the six CPT codes for interprofessional consultations for practitioners who can independently bill Medicare for E/M visits (CPT codes 99451, 99452, 99446, 99447, 99448, 99449).

New Proposed Code	Work RVU	Crosswalk
GIPC1	0.35	99446
GIPC2	0.7	99447
GIPC3	1.05	99448
GIPC4	1.40	99449
GIPC5	0.70	99451
GIPC6	0.70	99452

CMS is not proposing any direct PE inputs for these codes since there are none assigned to the six CPT codes describing interprofessional consultation services.

4. Comment Solicitation on Payment for Services Furnished in Additional Settings, including Freestanding SUD Treatment Facilities, Crisis Stabilization Units, Urgent Care Centers, and Certified Community Behavioral Health Clinics (CCBHCs)

In the CY 2024 OPPS final rule (88 FR 81809 through 81858), CMS finalized payment for Intensive Outpatient Program Services (IOP) services furnished in HOPDs, CMHCs, FQHCs, RHCs, and Opioid Treatment Programs (OTPs). CMS is seeking comment on whether IOP services are furnished in other settings in order to determine whether potential coding and payment for IOP services under the PFS would facilitate these services being billed in additional settings.

In this solicitation, CMS seeks feedback on substance use disorder (SUD) facilities, community-based crisis stabilization, urgent care centers, and Certified Community Behavioral Health Clinics (CCBHCs).

SUD facilities. CMS is interested in feedback on the extent to which freestanding SUD facilities employ practitioner types who can supervise auxiliary personnel and bill Medicare for their services, the extent to which SUD facilities see patients with Medicare or that are dually eligible, whether bundled payment could better facilitate billing for these services, and its potential impact on underserved areas.

Community-based Crisis Stabilization. In addition, CMS seeks comment on entities that offer community-based crisis stabilization, including 24/7 receiving and short-term stabilization centers, that provide immediate access to voluntary and/or involuntary care, without the need for a referral. It is seeking comment on the kinds of services these units provide (e.g., similar to psychotherapy for crisis codes (CPT codes 90839 and 90840), the extent to which the definition of crisis stabilization unit varies by State, the extent these units employ practitioner types who can supervise auxiliary personnel and bill Medicare for their services, the extent to which these facilities see patients with Medicare or that are dually eligible, and its potential impact on underserved areas.

Urgent Care Center. CMS is also interested in how entities such as urgent care centers can play a role in addressing some of the capacity issues in emergency departments in treating non-emergent urgent care needs such as common conditions like allergic reactions, lacerations, sprains and fractures, and common respiratory illnesses (for example, flu or RSV). Specifically, CMS seeks feedback on the types of services alternative settings to EDs need to offer, whether the "Urgent Care Facility" Place of Service code (POS 20) adequately identify and define the scope of services furnished in such settings, whether the existing code set accurately describe and value services personally performed by professionals and costs incurred by the facility in these settings, and how potential strategies to reduce overcrowding and wait times in EDs advance equity in access to health care services.

*Certified Community Behavioral Health Clinics (CCBHCs).*Lastly, CMS seeks comment regarding Certified Community Behavioral Health Clinics (CCBHCs). It is interested in feedback on what kinds of services CCBHCs provide and whether that includes services, services for the treatment of substance use disorders, psychotherapy, behavioral health integration, community health integration, or principal illness navigation services to patients with either Medicare or another payer; how CCBHCs could bill Medicare under the PFS and its impact on underserved areas; the extent to which CCBHCs see patients with Medicare or who are dually eligible for Medicare and Medicaid; and whether CCBHCs employ practitioner types who can supervise auxiliary personnel and bill Medicare for their services?

J. Medicare Parts A and B Payment for Dental Services

1. Background

Section 1862(a)(12) of the Act generally precludes payment under Medicare Parts A or B for any expenses incurred for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth (collectively referred to by CMS as "dental services"). In the 2023 PFS final rule (87 FR 69663 through 69688), CMS identified clinical scenarios where payment is permitted under both Medicare Parts A and B for certain dental services where the services are not considered to be in connection with dental services. In these instances, the services are inextricably linked to and substantially related to the clinical success of other covered medical services.

In the 2023 PFS final rule (87 FR 69682, 69685, 69687), CMS established a process for the public to submit additional dental services that may be inextricably linked to other covered services for its consideration and review. For there to be an inextricable link between the dental service and the other covered service, the standard of care is such that the practitioner would not proceed with the procedure or service without performing the dental service(s). Medicare evidence supporting this standard should:

1. Provide support that the provision of certain dental services leads to improved healing, improved quality of surgery outcomes, and the reduced likelihood of readmission and/or surgical revisions because an infection has interfered with the integration of the medical implant and/or interfered with the medical implant to the skeletal structure;
2. Be clinically meaningful and demonstrate that the dental services result in a material difference in terms of the clinical outcomes and success of the procedure such that the dental services are inextricably linked to other covered services; and
3. Be compelling to support that certain dental services would result in clinically significant improvements in quality and safety outcomes.

This evidence should include at least one of the following:

1. Relevant peer-reviewed medical literature and research/studies regarding the medical scenarios requiring medically necessary dental care;
2. Evidence of clinical guidelines or generally accepted standards of care for the suggested clinical scenario;

3. Other ancillary services that may be integral to the covered services; and/or
4. Other supporting documentation to justify the inclusion of the proposed medical clinical scenario requiring dental services (87 FR 69686).

The deadline for submissions of additional clinical scenarios for potential consideration for 2025 rulemaking was February 10, 2024. CMS received thirteen submissions representing dozens or hundreds of organizations.

CMS has partnered with the Agency for Healthcare Research and Quality (AHRQ) to review requests for coverage of dental services in additional clinical scenarios. AHRQ is conducting "rapid response reports," instead of comprehensive assessments, to better address "the public's immediate dental needs."

2. Sickle Cell Disease and Hemophilia

For 2024, CMS received requests to add sickle cell disease (SCD) and hemophilia as disease states where dental services are inextricably linked to covered medical services to treat these conditions. CMS has not added either of these two disease states to its list of clinical scenarios where Medicare could cover dental services. However, CMS has since partnered with AHRQ to review available clinical evidence regarding the relationship between dental services and SCD or hemophilia medical services. AHRQ's rapid response reports are available at: https://effectivehealthcare.ahrq.gov/products/sickle-cell-dental/research and https://effectivehealthcare.ahrq.gov/products/hemophilia-dental/research.

AHRQ found the body of evidence evaluating dental services before, during, or after the treatment of these conditions lacking in primary clinical data and is currently limited to available guidelines. CMS is not making any changes to add either of these conditions to its list of clinical scenarios where it will pay for dental services. However, CMS will consider conducting additional evaluations as new studies emerge that examine the impact of dental services on SCD and hemophilia.

3. Submissions Received Through the Public Submission Process

In circumstances where CMS finds an inextricable link between dental services and the medical condition under consideration, CMS' existing rules allow Medicare to cover the following services when furnished in either inpatient or outpatient settings:

- Dental or oral examinations performed as part of a comprehensive workup in either the inpatient or outpatient setting.
- Medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to or contemporaneously with any of the above services.
- Services that are ancillary to these dental services, such as x-rays, administration of anesthesia, and use of the operating room.

Dental Services Linked to ESRD. CMS concludes the evidence base indicates that evaluation for and treatment of oral infection leads to improved outcomes and reduced risk of mortality for individuals with ESRD receiving covered dialysis services. Dental services to diagnose and treat

infection prior to dialysis services in the treatment of ESRD represent a clinically analogous scenario to dental services for which Medicare payment under Parts A and B is currently permitted when furnished in the inpatient or outpatient setting, such as prior to organ transplant.

The clinical evidence supports that medically necessary dental care may similarly advance the clinical success of dialysis services in the treatment of ESRD because an oral or dental infection can present substantial risk to the success and outcomes of these procedures (including the risk of systemic infection, bloodstream infections, sepsis, and death). For this reason, CMS proposes to pay for medically necessary dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered dialysis services when used in the treatment of ESRD. It also proposes to cover medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to or contemporaneously with Medicare-covered dialysis services when used in the treatment of ESRD.

Dental Services Integral to Specific Covered Services to Treat Diabetes. CMS recognizes that evidence submitted by interested parties demonstrates that an individual with both a diagnosis of diabetes and a diagnosis of periodontitis who in turn receives periodontal treatment services may experience improvements in markers for HbA1c, which is a key target outcome for the patient population with diabetes. However, the interaction between these diagnoses and the potential improvements due to periodontal treatment services does not appear to align with the framework CMS has established to pay for dental services inextricably linked to covered services.

Under CMS' framework, the delivery of certain dental services is integral to the successful completion of or outcomes related to the covered medical services. The studies that have been provided to CMS through submissions have not identified any specific covered services for the treatment of diabetes to which dental services are inextricably linked. Rather, the studies indicate that the primary treatment of periodontal disease in patients with diabetes generally leads to better outcomes in the management of the patients' diabetes. While the research makes the case that the dental services are medically necessary for patients with diabetes, medical necessity alone does not permit payment for dental services given the broad statutory prohibition on payment for dental services.

At this time, CMS is not making any proposal to revise its regulations to permit dental services to be paid when linked to the provision of services to treat patients with diabetes. That said, CMS provided detailed information that commenters could provide that may lead CMS to change its conclusion. CMS is committed to continuing to explore the potential inextricable relationship between dental services and covered medical services utilized in treatment for individuals with diabetes.

Dental Services Integral to Treating Systemic Autoimmune Diseases Requiring Immunosuppressive Therapies. When an individual has an autoimmune disease, the immune system malfunctions and may mistakenly attack healthy cells, tissues, and organs. There are over 100 autoimmune diseases, including Type 1 diabetes, multiple sclerosis, lupus, rheumatoid arthritis, and inflammatory bowel disease.

Requestors asking to add dental services linked to treating autoimmune diseases asserted that immunosuppressive therapies have similar effects as those of toxic chemotherapy utilized in the treatment of cancer. These treatments are analogous to the clinical examples finalized in 2024 PFS rulemaking for dental services inextricably linked to covered medical services in the treatment of cancer. The requestors state that the covered services upon which immunocompromised patients depend (for example, immunosuppressive therapy) should not proceed until a dental or oral exam is performed to address the oral complications and/or clear the patient of an oral or dental infection.

CMS disagreed and said that the level of immunosuppression for systemic autoimmune disease has different characteristics versus therapies utilized in chemotherapy used in the treatment of cancer. For example, the usage of monoclonal antibodies in the treatment of autoimmune disease may not render the same level of immunosuppression and subsequent susceptibility to infection as chemotherapy used in the treatment of cancer. Like in the prior section, CMS provided detailed requests for the type of information commenters could provide for CMS to change its conclusion. However, at this time, CMS is not making any changes to the regulations to add clinical scenarios involving treatment of autoimmune diseases to those where Medicare will cover related dental services.

4. Operational Issues

KX and GY Modifiers: Currently, the KX modifier is submitted on a Medicare Part B claim to indicate that the service or item is medically necessary and that the healthcare provider has included appropriate documentation in the medical record to support or justify the medical necessity of the service or item. CMS is proposing that, effective January 1, 2025, the KX modifier would be required on claims for dental services inextricably linked to covered medical services.

Use of the KX modifier will signify that the billing practitioner believes that:

- The dental service meets the established payment criteria;
- The practitioner has included appropriate documentation in the medical record to support or justify the medical necessity of the service or item and that demonstrates the inextricable linkage to covered medical services; and
- Coordination of care between the medical and dental practitioners has occurred.

CMS is allowing optional use of the KX modifier for dates of services in 2024. Additional instruction and education regarding voluntary use of the KX modifier is expected to be provided through sub-regulatory guidance.

The GY modifier signifies that a service is not covered because it is outside of the scope of Medicare coverage authorized by the statute. Denial modifiers should be used when physicians, practitioners, or suppliers want to indicate that the item or service is statutorily non-covered. **CMS is seeking comment on whether to recommend the usage of the GY modifier on the 837D or 837P dental claim format in instances where a Medicare claim denial is sought for**

purposes of submission to third party payers or when the service does not fit within a Medicare benefit category and is statutorily excluded from coverage.

837D Claim Form: CMS anticipates that its systems will be able to process claims submitted using the dental claim form 837D by January 1, 2025. Consistent with the statutory and regulatory requirements, the 837D claim form will require a diagnosis code for billed services to be paid. However, interested parties have indicated that, in current dental practice, claims processing systems do not require the submission of a diagnosis code on claims for dental services. **For this reason, CMS is requesting comments on whether to delay implementation of the 837D to give clinicians and billing entities additional time to change their workflows and transition to using the 837D form.**

Payment for Dental Services: Medicare covered dental services are currently contractor priced. MACs have requested information that would support their efforts to assign payment amounts. CMS seeks to facilitate the sharing of available pricing information with the MACs and has requested comment on specific information to inform appropriate payment for dental services.

This is the second consecutive year that **CMS is requesting public comment** on how to price dental services. In this comment solicitation, CMS suggests:

- Using publicly available data (such Fair Health cost data) that are available for purchase but may not directly inform payment amounts in a manner useful for Medicare payment.
- Fee schedules used by state governments, discount fee schedules or discount dental programs.

5. Oral Appliances Used for Obstructive Sleep Apnea

Among other requirements, a product cannot be considered durable medical equipment (DME) and covered by Medicare unless it can withstand repeated use. Different types of oral appliances are fabricated and furnished by licensed dentists as a treatment for obstructive sleep apnea.

The following two HCPCS Level II codes were established effective January 1, 2006, for these devices:

- E0485 - Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment.
- E0486 - Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment.

A very limited subset of custom fabricated oral appliances used to treat obstructive sleep apnea (HCPCS code E0486) have been Medicare covered by the Durable Medical Equipment Medicare Administrative Contractors (DME MACs). The DME MACs consider these devices to be DME because of the presence of a fixed mechanical hinge.

An additional HCPCS code was established effective April 1, 2022, to describe custom fabricated oral appliances without a fixed mechanical hinge:

- K1027 - Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment.

The DME MACs have not covered any of the prefabricated devices because of lack of medical evidence that they are an effective therapy for obstructive sleep apnea. They have not covered K107 because devices without mechanical hinges do not qualify as DME.

For several years, manufacturers of products without fixed mechanical hinges that dentists use in custom fabricating oral appliances have raised concerns regarding why their versions of the custom fabricated oral appliances have not been classified as DME. CMS responded that these oral appliances do not seem to be the kind of equipment that can withstand repeated use (i.e., could potentially be rented and used by successive patients).

CMS does not believe these oral appliances would be subject to the dental services exclusion as the devices are not being used in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth. As oral appliances are not dental services, they also cannot be covered as dental services inextricably linked to covered medical services.

However, CMS does state that the statute permits Medicare coverage of services furnished by physicians. Dentists are included in the statutory definition of a physician. For this reason, CMS is seeking information on a future proposal regarding a code assignment for the services a dentist may provide to fabricate an oral sleep apnea appliance that may be paid under the PFS. CMS is requesting details and information on specific questions related to patient eligibility (among them is differentiating snoring that is a nuisance from the medical condition of sleep apnea), time of services and other considerations.

CMS further notes that individuals could consider nominating codes related to oral sleep apnea appliances for consideration under the misvalued code process described earlier. Nominations may be submitted to CMS in one of two ways:

- Via email to: MedicarePhysicianFeeSchedule@cms.hhs.gov, with the phrase "Potentially Misvalued Codes" and the referencing CPT code number(s) and/or the CPT descriptor(s) in the subject line.
- U.S. Post to: Centers for Medicare & Medicaid Services, Mail Stop: C4–01–26, 7500 Security Blvd., Baltimore, Maryland 21244. Envelopes containing the nomination letters must be labeled "Attention: Division of Practitioner Services, Potentially Misvalued Codes."

Nominations for consideration in the next annual rule cycle must be received by February 10, 2025.

K. Payment for Skin Substitutes

In the 2023 PFS proposed rule, CMS had initially proposed to bundle skin substitutes into its PFS practice expense payments with the graft application procedures. However, it did not finalize this policy. CMS indicates that it would be appropriate to take a phased approach over multiple rulemaking cycles to examine how to appropriately incorporate skin substitutes as supplies under the PFS ratesetting methodology.

In the 2024 PFS final rule, CMS solicited comments on different approaches CMS could use to identify appropriate practice expense (PE) direct costs for skin substitute products, such as reviewing various sources for price information, including performing market research, reviewing invoices submitted by interested parties, or cost information on Medicare claims. It did not contain a specific proposal for changing how skin substitutes are paid under the PFS. CMS indicates that continuing this dialogue with interested parties will help inform potential policy changes for future rulemaking.

CMS also notes an increase in HCPCS Level II coding request applications for newly developed skin substitute products and is considering broadly all of its relevant payment policies. Such policies, for example, include the discarded drug refund policy and the Part B drug inflation rebate policy and how these policies may align with the usage and payment for skin substitute products

Similar to last year, for 2025, CMS proposes that billing and payment codes that describe products currently referred to as skin substitutes would not be counted for purposes of identifying refundable drugs for calendar quarters in 2025. In section III.I. of this proposed rule, CMS is also proposing to codify existing policy by including products currently referred to as skin substitutes on the list of product categories that are not considered Part B rebatable drugs.

III. Other Provisions of the Proposed Rule

A. Drugs and Biological Products Paid Under Medicare Part B

1. Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs to Provide Refunds with Respect to Discarded Amounts (§§414.902 and 414.940)

a. Background

Section 1847A(h) of the Act requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug (hereafter referred to as "refundable drug"). The refund amount is the amount of discarded drug that exceeds an applicable percentage, which must be at least 10 percent, of total charges for the drug in a given calendar quarter. In the 2023 PFS final rule, CMS finalized a number of policies, including requiring billing providers and suppliers to report the JW modifier for all separately payable drugs with discarded drug amounts from single use vials or single use packages payable under Part B, beginning January 1, 2023, and to report the JZ modifier for all such drugs with no discarded amounts beginning no later than July 1, 2023. CMS published the JW Modifier and JZ

Modifier Policy Frequently Asked Questions (FAQ) document[27] addressing the correct use of these modifiers.

CMS also excluded the following categories of drugs from this policy:

- Radiopharmaceuticals and imaging agents (including contrast agents);
- Drugs where the FDA label indicates that filtration must occur prior to dilution and administration where the preparation process results in large amounts of wastage; and
- New drugs that have been paid by Medicare Part B for less than 18 months.

CMS sends reports for each calendar quarter, on an annual basis, to each manufacturer of a refundable drug. It finalized the manner in which the refund will be calculated. In December 2023, it issued preliminary reports based on available claims data from the first two quarters of 2023 to provide manufacturers information regarding estimated discarded amounts of refundable drugs prior to the initial refund report.[28]

CMS also finalized a policy for drugs with unique circumstances permitting the agency, through notice and comment rulemaking, to increase the applicable percentage to 35 percent; CMS applied it for drugs reconstituted with a hydrogel and with variable dosing based on patient-specific characteristics. A dispute resolution process through which manufacturers may challenge refund calculations was adopted, and enforcement provisions (including manufacturer audits, provider audits, and civil money penalties required by statute) were established in regulations.

In the 2024 PFS final rule, CMS finalized the date of the initial refund report to manufacturers, the date for subsequent reports, the method of calculating refunds for discarded amounts in lagged claims data, the method of calculating refunds when there are multiple manufacturers for a refundable drug, increased applicable percentages for certain drugs with unique circumstances, and a future application process by which manufacturers may apply for an increased applicable percentage for a drug, which would precede proposals to increase applicable percentages in rulemaking. It also finalized that drugs separately payable under Part B from single-dose containers furnished by a supplier who is not administering the drug are required to be billed with the JZ modifier, since CMS believes it is unreasonable to collect discarded drug data from beneficiaries.

b. Application for Increased Applicable Percentage

As noted above, CMS established an application process for manufacturers to request an increased applicable percentage for an individual drug with unique circumstances. Applications must be submitted by February 1 of the year before the year the increased applicable percentage would apply. Additionally, CMS adopted a deadline of August 1 for the FDA-approval of the drug and the deadline for notifying and submitting the FDA-approved label to CMS of September 1 of the year before the year in which the increased applicable percentages would

[27] https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifierfaqs.pdf.

[28] More information about discarded drugs, including the discarded drug refund and the JW and JZ modifier policy, is available at https://www.cms.gov/medicare/payment/part-b-drugs/discarded-drugs.

apply.[29] The applicant must provide a written request comprising FDA-approved labeling for the drug; justification for the consideration of an increased applicable percentage based on such unique circumstances; and justification for the requested increase in the applicable percentage.

For 2025, CMS received one application for an increased applicable percentage of 72 percent from the manufacturer of Leukine® (sargramostim), which is a leukocyte growth factor that is primarily used in hematological malignancies to increase white blood cell counts. The applicant did not submit FDA-approved labeling for the drug for the particular adjuvant uses described in the application due to ongoing cancer vaccine adjuvant trials; the estimated completion dates for the Phase III clinical trials vary from March 2025 to March 2029. The drug would be used as a vaccine adjuvant in oncology indications, specifically in stimulating the immune response of dendritic cells when used alongside these vaccines, and doses of the drug when used in this manner are much smaller than the dosages for indications in the FDA approved labeling.

CMS will require additional information before proposing an increased applicable percentage for these particular adjuvant uses of Leukine; claims data from the first quarter of 2023 through the first quarter of 2024 found the percentage of units discarded for the HCPCS code for Leukine (J2820) ranged from 1.2 percent to 3.8 percent, which is below the applicable percentage of 10 percent. The agency notes the applicant may reapply when more information becomes available.

c. Clarifications for the Definition of Refundable Single-dose Container or Single-use Package Drug

(1) Exclusions for Drugs for which Payment Has Been Made under Part B for Fewer than 18 Months

A drug approved or licensed by the FDA on or after November 15, 2021, and for which payment has been made under Part B for fewer than 18 months is excluded from the definition of refundable drug. The 18-month period begins on the first day of the calendar quarter following the date of first sale as reported to CMS for the first National Drug Code (NDC) assigned to the HCPCS code. The agency uses the first date of sale because it is more operationally feasible than identifying the date when the first Part B claim was paid for a new drug.

However, in a situation where the first date of sale as reported to CMS does not adequately approximate the first date of payment under Part B due to an applicable NCD (e.g., Leqembi®), CMS proposes to use the date on which the drug is first paid under Part B. To effectuate this proposal, CMS would add this situation to the three existing exclusions in the definition refundable single-dose container or single-use package drug at §414.902; it also proposes to restructure that section of the regulation.

(2) Clarification for Identifying Single-dose Containers

CMS has learned that some drug product labeling does not specify the package type terms (e.g., whether the product is supplied in a single-dose or single-use package or a multiple-dose preparation) nor does it include explicit discard statements. This may occur in drugs, including

[29] See 42 CFR 414.940(e).

drugs contained in ampules, that were approved prior to October 2018 because at that time, FDA issued guidance on the selection of the appropriate package terms to address bacterial and viral infections among patients resulting from improper use of single-dose containers such as vials, ampules, and prefilled syringes.

In the proposed rule, CMS proposes to include 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.

CMS proposes to amend the definition of refundable single-dose container or single-use package drug to include drugs contained in ampules and for which there is no discard statement. It notes this proposal would be consistent with the description of single-dose container in the October 2018 FDA guidance. Specifically, it proposes to include "single-patient-use container" as a package type term in §414.902 and to add three types of products that may be considered refundable single-dose container or single-use package drugs:

- A product furnished from a single-dose container or single-use package based on FDA-approved labeling or product information.
- A product furnished from an ampule for which product labeling does not have discard statement or language indicating the package type term, like "single-dose container," "single-use package," "multiple-dose container," or "single-patient-use container".
- A product 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".

(3) Skin Substitutes

As it did for 2023 and 2024, CMS again proposes that billing and payment codes that describe products currently referred to as skin substitutes would not be counted for purposes of identifying refundable drugs for calendar quarters in 2025. It plans to revisit the issue in future rulemaking.

d. Discarded Amounts

In the CY 2024 PFS final rule (88 FR 79062), CMS finalized a policy that drugs separately payable under Part B from single-dose containers that are furnished by a supplier who is not administering the drug must be billed with the JZ modifier; the JW modifier is not used on these claims. Stakeholders have requested additional clarification on how to bill for discarded amounts from single-dose containers when there are amounts discarded during preparation by the billing supplier who is not administering the drug.

In response, CMS now 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 patient. Discarded units should be billed using the JW modifier in the same way as a drug that is administered incident-to physician service. However, if no amounts

were discarded during the preparation process before supplying the drug to the patient, the supplier would report the JZ modifier. The preamble includes the following 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.

2. Payment Limit Calculation When Manufacturers Report Negative or Zero Average Sales Price (ASP) Data (§414.904)

a. Background

Generally, CMS calculates payment limits for Part B drugs on a quarterly basis using the manufacturer's ASP. For each NDC, in most cases, the manufacturer's ASP is a positive dollar value, along with a positive number of units sold, which CMS refers to as "positive manufacturer's ASP data." Manufacturers may also report "negative or zero manufacturer's ASP data," which occurs when 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. This could occur because of lagged discounts, units returned to the manufacturer, drug shortages, discontinuation of a drug, or other reasons unknown to CMS.

CMS previously finalized a policy for situations where ASP data for some, but not all, NDCs in a multiple source drug billing and payment code are not available for the calculation of an ASP payment limit; it updates payment limits based on the manufacturer's ASP reported for the most recent quarter for which data is available.[30] If ASP data are not available for some but not all NDCs in a multiple source drug billing and payment code prior to the publication deadline for quarterly payment limits, and that unavailability of the manufacturer's ASP data significantly changes the quarterly payment limit for the billing and payment code when compared to the prior quarter's payment limit, CMS calculates the payment limit by carrying over the most recent available manufacturer's ASP price from a previous quarter for an NDC, adjusted by the weighted average of the change in the manufacturer's ASPs for the NDCs that were reported for both the most recently available previous quarter and the current quarter.

CMS proposes policies to address payment for separately payable Part B drugs when the reported manufacturer's ASP for at least one NDC within the billing and payment code (that is, HCPCS code) of the drug is negative or zero. It would consider these ASP data to be "not available" for purposes of calculating payment limits when negative or zero manufacturer's ASP data is reported. Thus, positive manufacturer's ASP data would be considered "available" and negative or zero manufacturer's ASP data would be considered "not available" in calculating a payment limit.

[30] 75 FR 73461 through 73465.

b. Single and Multiple Source Drugs when Negative or Zero Manufacturer's ASP Data Is Reported for Some, But Not All NDCs (§414.904(i))

In cases where manufacturers report negative or zero manufacturer's ASP data, CMS proposes to calculate a payment limit using only NDCs with positive manufacturer's ASP data for that drug; this policy would apply to both single source drugs, including biosimilar biological products, and multiple source drugs.

The agency notes that this proposal is intended to fill a gap to address this specific set of circumstances relating to negative or zero manufacturer's ASP data; it is not intended to supersede existing policy it previously established for multiple source drugs for which the absence of ASP data would result in a significant change (i.e., a 10 percent or greater change) in the ASP payment limit compared to the payment limit of the previous quarter.

c. Multiple Source Drugs with Only Negative or Zero Manufacturer's ASP Data

In cases where a manufacturer reports 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, CMS proposes to carry over all positive manufacturer's ASP data from the most recently available previous quarter with 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. CMS would calculate the payment limit for the applicable quarter using data from the most recent calendar quarter for which there is positive manufacturer's ASP data.

d. Single Source Drugs with Only Negative or Zero Manufacturer's ASP Data, Excluding Biosimilar Biological Products

For single source drugs that have negative or zero manufacturer's ASP data reported for all NDCs associated with a billing and payment code for that drug, CMS proposes to set the payment limit for a quarter at the lesser of the following:

- 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 is based on 106 percent of the WAC, that payment limit would be carried over.)
- 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.)

This methodology would be used until at least one NDC for the drug has positive manufacturer's ASP data for a future quarter.

e. Biosimilars with Only Negative or Zero Manufacturer's ASP Data

Where 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), and positive manufacturer's ASP data is available for another biosimilar(s) with the same reference biological

product for the given quarter, CMS proposes to set the payment limit for the given quarter equal to the sum of the following:

- The volume-weighted average of the positive manufacturer's ASP data from all other biosimilars with the same reference biological product, and
- 6 percent (or 8 percent for qualifying biosimilar biologicals[31]) of the amount determined under section 1847A(b)(4) of the Act (i.e., payment for single source drugs or biologicals) for the reference biological product for the given quarter.

This methodology would apply 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.

If negative or zero manufacturer's ASP data is reported for all NDCs for a biosimilar for a given quarter and either (i) no other biosimilars have been approved for the same reference product or (ii) no other biosimilars with the same reference product report positive manufacturer's ASP data for the given quarter, CMS would set the payment limit for the given quarter equal to the sum of the following:

- 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) of the amount determined under section 1847A(b)(4) of the Act for the reference biological product for the given quarter.

CMS would apply this methodology until at least one NDC for the biosimilar has positive manufacturer's ASP data for a quarter.

CMS also considered two alternative approaches:

1. The volume-weighted ASP calculation for the biosimilar would include the ASP data and billing units sold of its reference product for a given quarter along with those of the other biosimilars that reference the same reference product in the volume-weighted average calculation. Under this alternative, the payment limit would equal the sum of the volume-weighted average of the positive manufacturer's ASP data from all other biosimilars with the same reference product and the reference product plus 6 or 8 percent, as appropriate, of the amount determined under section 1847A(b)(4) of the Act for the reference biological product for the given quarter.
2. Base the payment limit of the biosimilar on the volume-weighted average of its own most recent available positive manufacturer's ASP data from a previous quarter and either 6 or 8 percent, as appropriate, of the amount determined under section 1847A(b)(4) of the Act for the reference biological product for the given quarter.

f. Discontinued Drugs

For single and multiple source drugs for which negative or zero manufacturer's ASP data is reported for all NDCs and for which all relevant applications have a marketing status of "discontinued" on the FDA website, CMS proposes that MACs develop prices for the drugs consistent with section 20.1.3 in Chapter 17 of the Medicare Claims Processing Manual for

[31] See 42 CFR 414.902.

developing payment limits for covered drugs when CMS does not supply the payment allowance limit on the ASP drug pricing file. Noting that very few claims are paid for drugs after their discontinuation, CMS believes it is not a good use of agency resources to set payment limits for them.

3. Payment of Radiopharmaceuticals in the Physician Office

MACs set payment limits for radiopharmaceuticals furnished in settings other than hospital outpatient departments based on methodologies in place before the enactment of the MMA in November 2003. This results in variations in payments by MACs. CMS clarifies that MACs may use any payment methodology used by any MAC before enactment of the MMA, which includes invoice pricing, for radiopharmaceuticals furnished in the physician office setting.

4. Immunosuppressive Therapy (§§410.30 and 414.1001)

a. Compounded Immunosuppressive Drugs with Oral or Enteral Routes of Administration

Stakeholders note that compounded formulations of immunosuppressive drugs are not included in the immunosuppressive therapy benefit category because these formulations are not approved by the FDA. Examples include azathioprine, cyclophosphamide, and tacrolimus. Compounded formulations are important for patients with dysphagia or with enteral feeding tubes; they are also used for many pediatric patients.

CMS proposes to include orally and enterally administered compounded formulations of immunosuppressive drugs with active ingredients. The drug would have been approved for marketing by FDA and determined by a MAC, in processing the claim, to be reasonable and necessary for the specific purpose of preventing or treating the rejection of a patient's transplanted organ or tissue, or for use in conjunction with immunosuppressive drugs for the purpose of preventing or treating the rejection of a patient's transplanted organ or tissue. In making such a determination, the MACs could consider factors such as authoritative drug compendia, current medical literature, recognized standards of medical practice, and professional medical publications.

b. Immunosuppressive Refill Policy and Supplying Fee

CMS proposing two changes to its policies for pharmacy supplying fees and refills for immunosuppressive drugs. First, it would allow payment of a supplying fee for a prescription of a supply of up to 90 days as opposed to the current 30-day limit. It does not propose any changes to the supplying fee amount at this time and will continue the current fee schedule regardless of days' supply dispensed.

Second, it would allow payment of refills for immunosuppressive drugs based on the individual circumstance of the beneficiary (subject to state law).

5. Blood Clotting Factors (§410.63)

CMS discusses gene therapy to treat hemophilia A or B and the differences between that therapy and infusion of blood clotting factors. Gene therapy for hemophilia is administered by a one-time, single dose intravenous infusion, and personnel and equipment must be immediately available to treat infusion-related reactions. Close monitoring is required for at least three hours after the end of the infusion. They are not "typically administered by a patient in their home." Gene therapies prompt the body to make clotting factors but are not clotting factors themselves.

Thus, gene therapies for hemophilia are eligible for payment as Part B drugs or biologicals as part of (or incident to) a physician's service. "Incident to" coverage is limited to drugs that are not usually self-administered and the physician generally must incur a cost for the drug and must bill for it. Stakeholders questioned whether gene therapies could be considered blood clotting factors and thus be eligible for the furnishing fee associated with blood clotting factors. CMS believes gene therapies could not qualify for the furnishing fee available for blood clotting factors in part because payment is available under the PFS for the administration of the therapies.

CMS proposes to clarify existing CMS policy that blood clotting factors must be self-administered to qualify for the furnishing fee. It would amend 410.63(c) to specify 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.

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

1. Background

RHCs and FQHCs are paid a single rate for face-to-face encounters. The RHC is paid an "all-inclusive rate" (AIR) while the FQHC is paid a prospective payment system (PPS) amount. Both the RHC AIR and FQHC PPS payment rates were designed to reflect the cost of all services and supplies that an RHC or FQHC furnishes to a patient in a single day. The rates are not adjusted for the complexity of the patient health care needs, the length of the visit, or the number or type of practitioners involved in the patient's care.

2. General Care Management Services in RHCs and FQHCs

a. Background

CMS explains its recent history of providing payment for care management services in addition to the AIR or FQHC PPS payment. As much of the care provided in the care management services is provided outside of a face-to-face visit, CMS indicates it should be paid separate and apart from the AIR or FQHC PPS payment for a face-to-face visit. CMS has over the years expanded on the scope of care management services that could be billed under HCPCS code G0511 by RHCs and FQHCs, including most recently remote physiologic monitoring (RPM), remote therapeutic monitoring (RTM), community heath integration (CHI), principal illness navigation (PIN), and PIN – peer support services. The agency also clarified RHCs and FQHCs

may bill HCPCS code G0511 multiple times in a calendar month, as long as all of the requirements are met and resource costs are not counted more than once.

In the 2024 PFS final rule (88 FR 79076 through 79079), CMS revalued HCPCS code G0511 by using a weighted average of utilization in the physician office setting of its composite codes. The agency took the weighted average of the base code and add-on code pairs, in addition to the individual base codes for all of the services that comprise HCPCS code G0511. CMS used the most recently available utilization data from the services paid under the PFS in the physician office setting, explaining that the physician office setting was an appropriate proxy for utilization of these services in the absence of actual data because it most closely aligns with the types of primary care services furnished in RHCs and FQHCs.

b. Proposed Payment Policy for General Care Management Services (§405.2464(c))

Stakeholders asked that CMS allow them to bill for each of the care management services comprising HCPCS code G0511 when they are furnished in RHCs and FQHCs. They expressed concern about a lack of transparency for the services billed using this code, and they believe it would not pose an undue burden to bill for each of those services.

CMS proposes to require RHCs and FQHCs, beginning in 2025, to bill the individual codes that make up the general care management HCPCS code G0511. (The current list of base and add-on codes that make up G0511 are listed in Table 24 of the proposed rule.) Under the proposal, CMS would also allow RHCs and FQHCs to bill the add-on codes for additional time spent once the minimum threshold of time was met to account for a complete encounter. If finalized, HCPCS code G0511 would no longer be paid when billed by RHCs and FQHCs.

c. New Codes for Advanced Primary Care Management (APCM) Services.

CMS states that effective primary care is essential for improving access to healthcare, for the health and well-being of individuals, families, and communities, and for achieving health equity. It seeks to foster advances in primary care in a number of ways, including improving payment policies.

In this rule, CMS proposes to establish coding and make payment under the PFS for a newly defined set of APCM services described and defined by three new HCPCS G-codes to reflect the effectiveness and growing adoption of the advanced primary care approach to care. CMS says the proposed new HCPCS codes would encompass a broader range of services and simplify the billing and documentation requirements, as compared to existing care management codes.

- GPCM1. Advanced primary care management services provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month.
- GPCM2. Advanced primary care management services for a patient with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute

exacerbation/decompensation, or functional decline, provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month.

- GPCM3, which is similar to GPCM2 with the exception that the patient must be a Qualified Medicare Beneficiary.

For all three proposed G-codes, the APCM services would have the following elements, as appropriate: (i) Provision of patient information and receipt of consent; (ii) Initiation during a qualifying visit; (iii) 24/7 access to care team for urgent needs; (iv) Continuity of care with designated APCM team member; (v) Use of home visits and other alternatives in lieu of traditional office visits; (vi) Overall comprehensive care management; (vii) Use of electronic patient-centered comprehensive care plan; (viii) Coordination of care transitions; (ix) Ongoing communication and coordination of needed services; (x) Beneficiary and caregiver communication to APCM care team via secure messaging, email, patient portals, etc.; (xi) Analysis of patient population data to identify gaps in care; (xii) Risk stratify the practice population; and (xiii) Performance measures for quality, total cost of care and meaningful use of Certified EHR Technology.

d. Request for Information – Aligning with Services Paid Under the PFS

Because RHCs and FQHCs may not bill under the PFS for RHC or FQHC services and individual practitioners working at RHCs and FQHCs cannot bill under the PFS for RHC or FQHC services while working at the RHC or FQHC, CMS has tried to develop payment policies for RHCs and FQHCs that complement the new services for care coordination under the PFS so RHC and FQHC resource costs are aligned for those services. **CMS seeks comment** on how to improve transparency and predictability regarding which HCPCS codes are considered care coordination services, with the goal being to classify care coordination services in the PFS in a way that makes it automated in the downstream effect on RHCs and FQHCs.

3. Telecommunication Services

a. Background

The COVID-19 PHE telehealth flexibilities and special payment rules for RHC and FQHC services furnished to Medicare beneficiaries by telehealth expire December 31, 2024, absent congressional intervention. For example, waiver of the in-person requirements under Medicare for mental health services furnished through telehealth under the PFS and for mental health visits furnished by RHCs and FQHCs via telecommunications technology will expire on that date as well as the use of payment rates that are similar to the national average payment rates for comparable telehealth services under the PFS.

b. Direct Supervision via Use of Two-way Audio/Video Communications Technology

Services and supplies furnished incident to physicians' services are generally required to be furnished under direct physician supervision. Direct supervision means the physician must be

immediately available to provide assistance and direction throughout the time the incident to service or supply is being furnished to a beneficiary. During the COVID-19 PHE, CMS modified the definition of direct supervision in this context to include the use of a virtual supervisory presence through the use of interactive audio and video telecommunications technology.

In the 2024 PFS final rule, CMS extended this definition of direct supervision for RHCs and FQHCs through December 31, 2024; it aligned the timeframe of this policy with many of the previously discussed PHE-related telehealth policies that were extended under provisions of the CAA, 2023. For RHCs and FQHCs, CMS continued to define "immediately available" as including real-time audio and visual interactive telecommunications through December 31, 2024. Commenters were very supportive of this policy, noting that direct supervision has become increasingly challenging.

CMS proposes to extend this policy for another year. Thus, for RHCs and FQHCs, the presence of the physician (or other practitioner) would include virtual presence through audio/video real-time communications technology (excluding audio-only) through December 31, 2025.

c. Telecommunications Technology

One of the COVID-19 PHE flexibilities was to permit an RHC or FQHC mental health visit to include encounters furnished through interactive, real-time, audio/video telecommunications technology or audio-only interactions in cases where beneficiaries are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder. This authority expires December 31, 2024.

CMS is concerned that terminating this 4-year flexibility would disrupt access to services from RHC and FQHC practitioners, which would exacerbate access issues for underserved populations and could fragment care. CMS proposes, on a temporary basis, to allow payment for non-behavioral health visits furnished via telecommunication technology, and it would facilitate payments using an approach that closely aligns with the mechanisms mandated by the statute that end December 31, 2024.

Under the proposal, RHCs and FQHCs would continue to bill for RHC and FQHC services furnished using telecommunication technologies by reporting HCPCS code G2025 on the claim, including services furnished using audio-only communications technology. CMS would continue to calculate the payment amount based on the average amount for all PFS telehealth services on the telehealth list, weighted by volume for those services reported under the PFS.

d. In-person Visit Requirements for Remote Mental Health Services Furnished by RHC and FQHCs

The CAA, 2021, require a beneficiary to receive an in-person, non-telehealth service 6 months before initiation of the telehealth mental health services; additionally, CMS established a requirement for subsequent periodic in person, non-telehealth services every 12 months. These

requirements were delayed because of the COVID-19 PHE and subsequent legislation; CMS proposes to delay the requirements for an additional year until January 1, 2026.

4. Intensive Outpatient Program Services (IOP)

Section 4124(c)(1) of the CAA, 2023 set the payment rate for IOP services furnished by RHCs and FQHCs at the amount that would have been paid for those services had they been covered outpatient department services furnished by a hospital. In the 2024 OPPS/ASC final rule (88 FR 81841), CMS finalized two payment rates, a 3-service per day rate and a 4 or more services per day rate, for IOP services for hospitals and CMHCs. However, for RHCs and FQHCs it only established a 3-service per day payment rate.

CMS has reconsidered its policy for RHCs and FQHCs, and it now proposes to provide a payment rate for 4 or more services per day in an RHC/FQHC setting at the higher payment rate applied to hospital outpatient department settings. The proposed 2025 geometric mean per diem costs and payment rates for hospital-based IOPs, as proposed in the 2025 OPPS/ASC proposed rule, are as follows:

2025 APC	Group Title	Proposed PHP and IOP APC Geometric Mean Per Diem Costs*	Proposed Payment Rates**
5861	Intensive Outpatient (3 services per day) for hospital-based IOPs	$279.97	$270.77
5862	Intensive Outpatient (4 or more services per day) for hospital-based IOPs	$428.39	$414.33

* Table 68 of the 2025 OPPS/ASC proposed rule shows the proposed 2025 PHP and IOP APC geometric mean per diem costs.
** The 2025 proposed payment rates are from Addendum A to the 2025 OPPS/ASC proposed rule.

5. Payment for Preventive Vaccine Costs in RHCs and FQHCs

By statute, payment for pneumococcal, influenza and COVID-19 vaccines and their administration are paid at 100 percent of reasonable cost when administered in RHCs and FQHCs. Thus, for RHCs, costs associated with these vaccines and their administration are not included in determining the AIR or subject to the payment limit, and for FQHCs, these costs are not included under the FQHC PPS.

The hepatitis B vaccine is not exempt from the RHC/FQHC payment limit of 80 percent of reasonable costs; thus, payment for a hepatitis B vaccine and its administration is included in the FQHCs PPS rate and the RHC AIR. However, because hepatitis B vaccines and their administration are considered a Part B preventive service, no coinsurance or deductible applies.

CMS proposes to allow RHCs and FQHCs to bill for the administration of Part B preventive vaccines at the time of service; this proposal would apply to all four Part B preventive vaccines: pneumococcal, influenza, hepatitis B, and COVID-19 vaccines. Claims would initially be paid like other Part B vaccine and vaccine administration claims: vaccine products would be paid at 95 percent of their AWP, and vaccine administration would be paid according to the National Fee Schedule for Medicare Part B Vaccine Administration. The fee schedule's locality-adjusted

payment rate files for 2024 can be found on the CMS Vaccine Pricing website at https://www.cms.gov/medicare/payment/all-fee-service-providers/medicare-part-b-drug-average-sales-price/vaccine-pricing.

RHC or FQHC providers may bill HCPCS code M0201 for an in-home additional payment for Part B preventive vaccine administration, if the home visit meets all the requirements of both (i) part 405, subpart X, for RHCs and FQHCs services provided in the home, and (ii) §410.152(h)(3)(iii) for the in-home additional payment for Part B preventive vaccine administration.

Payments for these services received at the time they are furnished in RHCs and FQHCs will have to be annually reconciled with the facilities' actual vaccine and vaccine administration costs, including the in-home additional costs, on their cost reports. CMS proposes that RHCs and FQHCs begin billing for preventive vaccines and their administration at the time of service, for dates of service beginning on or after July 1, 2025.

6. Productivity Standards

Productivity standards for RHCs were first established on March 1, 1978 (43 FR 8260), and updated on December 1, 1982 (47 FR 54163 - 54165), to help determine the average cost per patient for Medicare reimbursement in RHCs. Section 130 of the CAA, 2021 restructured the payment limits for RHCs beginning April 1, 2021. CMS believes productivity standards for RHCs are outdated and no longer necessary; it proposes to remove them.

7. Proposed Rebasing of the FQHC Market Basket

CMS is proposing to rebase and revise the FQHC market basket that is used in the annual update to FQHC operating and capital cost structures for freestanding FQHC facilities. The proposed 2022-based FQHC market basket is a fixed-weight, Laspeyres-type price index. CMS is proposing to move the base year from 2017 to 2022. The updated base year will primarily be based on Medicare cost report data for FQHCs for 2022 (i.e., for cost reporting periods beginning on and after October 1, 2021, and before October 1, 2022). The preamble provides an extensive description of the development of the proposed rebased and revised market basket, including the development of cost categories and weights. The final 2025 FQHC update would be based on the four-quarter moving-average percent change of the proposed 2022-based FQHC market basket through the second quarter of 2024 (based on the final rule's statutory publication schedule); those data are not available at this time.

Based on IGI's first quarter 2024 forecast with historical data through the fourth quarter of 2023, the proposed 2022-based FQHC market basket increase factor for 2025 is 4.0 percent, which is the same projection CMS calculated when using the 2017-based FQHC market basket.

CMS proposes to continue to include a productivity adjustment to the proposed 2022-based FQHC market basket, based on the most recent estimate of the 10-year moving average of changes in annual private nonfarm business (economy-wide) total factor productivity (TFP) through 2023. Using IGI's first quarter 2024 forecast, the productivity adjustment for 2025 is

projected to be 0.5 percent, which results in a proposed 2025 productivity-adjusted proposed 2022-based FQHC market basket update of 3.5 percent.

The below table shows the impact from changing to a 2022-based FQHC market basket. In no year would the change be more than 0.1 percentage point and the average for the historical and projected period is unchanged.

CY	Proposed 2022-Based FQHC Market Basket % Change	2017-Based FQHC Market Basket % Change
Historical Data		
2021	2.4	2.4
2022	2.2	2.3
2023	4.3	4.3
2024	5.0	5.1
Average: 2021–2024	**3.5**	**3.5**
Forecast		
2025	4.0	4.0
2026	3.3	3.3
2027	2.9	2.9
2028	2.8	2.9
Average 2025 –2028	**3.3**	**3.3**

The below table shows how the major cost weights would change from moving to a 2022-based FQHC market basket.

Cost Category	Proposed 2022-Based FQHC Market Basket Cost Weight	2017-Based FQHC Market Basket Cost Weight
Total	**100.0**	**100.0**
Compensation	**68.5**	**72.6**
Practitioner Compensation	**24.8**	**28.5**
Wages and Salaries	20.5	23.1
Employee Benefits	4.3	5.4
Clinical Staff Compensation	**15.3**	**16.9**
Wages and Salaries	12.4	13.6
Employee Benefits	2.9	3.3
Non-Health Staff Compensation	**28.4**	**27.2**
All Other Products (Rx, utilities, medical equipment, medical supplies, and miscellaneous products)	**9.8**	**8.5**
All Other Services (Professional, scientific, technical, administrative, facility support, and all other services)	**14.5**	**12.6**
Capital-Related Costs (Fixed assets and movable equipment)	**7.2**	**6.4**

8. Clarification for Dental Services Furnished in FQHCs

CMS has previously established policies for coverage of dental services. Generally, payment may not be made under Parts A and B for dental services unless those services are (1) furnished in either the inpatient or outpatient setting and (2) inextricably linked to, and substantially related and integral to the clinical success of, other covered services. Stakeholders have commented that

CMS should ensure that policy changes for FQHCs are analogous to any changes made under the PFS for coverage of and payment for authorized dental services.

In response, CMS clarifies that dental services exactly as described in section II.J of this proposed rule and furnished in an RHC or FQHC are RHC and FQHC visits; thus, they can be paid under the RHC AIR methodology or FQHC PPS. CMS would update the FQHC qualifying visit list as appropriate. RHC or FQHC practitioners would report the KX modifier on the RHC or FQHC claim for payment purposes if they believe the dental services furnished are inextricably linked to a covered service and would include documentation to support the medical necessity of the item or service.

Generally, under current policy, if an RHC or FQHC patient has a medically-necessary face-to-face visit with an RHC or FQHC practitioner, and is then seen by another RHC or FQHC practitioner (including a specialist) for further evaluation of the same condition on the same day, or is then seen by another RHC or FQHC practitioner (including a specialist) for evaluation of a different condition on the same day, the multiple encounters would constitute a single RHC or FQHC visit. Both visits would be payable as a single visit regardless of the length or complexity of the visit, whether the second visit is a scheduled or unscheduled appointment, or whether the first visit is related or unrelated to the subsequent visit. However, under certain circumstances multiple visits on the same day may be paid separately for each visit; these circumstances include when the patient suffers an illness or injury subsequent to the first visit that requires additional diagnosis or treatment on the same day, when the patient has a medical and a mental health visit on the same day, or when an RHC patient has an initial preventive physical exam and a separate medical and/or mental health visit on the same day.

CMS seeks comment on whether the multiple visits policy should apply to patients who have an encounter with an RHC or FQHC practitioner and a dentist on the same day or whether a subsequent encounter with a dentist should be considered an exception to this policy and be paid as a separate billable visit.

9. "Grandfathered" Technical Refinement

CMS proposes to strike the term "grandfathered" in its regulations and to instead use the term "historically excepted."

C. RHCs and FQHCs Conditions for Certification or Coverage (CfCs) (491.9)

1. Provision of Services

Noting that there are approximately 5,462 Medicare-certified RHCs and 11,853 Medicare-certified FQHCs, CMS describes the important role they play in ensuring access to comprehensive health care services in underserved areas and emphasizes the need to support these facilities. CMS proposes to clarify a number of requirements for RHCs and FQHCs, including that they must provide primary care services and that RHCs may not be a rehabilitation agency or a facility which is primarily for the care and treatment of mental diseases.

Under current guidance, RHCs may not be primarily engaged in specialized services, and primarily engaged means more than 50 percent of the total hours of an RHC's operation furnishing RHC services. CMS proposes to abandon its practice of determining or enforcing an RHC's standard of being primarily engaged in furnishing primary care services through the survey process. The proposal would permit RHCs to provide more outpatient-specialty services within the practitioners' scope of practice to meet the needs of the patient population, such as internal medicine, pediatrics, geriatrics, obstetrics and gynecology, cardiology and other specialties. However, CMS expects RHCs and FQHCs to offer a range of primary health care services to ensure patient access to necessary care at the earliest possible point of contact.

Comment is sought on a number of issues, including the impact of this proposal on access to primary care services, behavioral health services, and specialty care services. CMS is also interested in the types of behavioral health services offered by RHCs, the types of practitioners who furnish these services, barriers RHCs face that limit their ability to furnish these services, and standards or criteria to evaluate whether an RHC is operating as a facility that is primarily for the care and treatment of mental diseases.

2. Laboratory Requirements

By statute,[32] RHCs must provide routine diagnostic services directly (i.e., they must be furnished at the RHC, by RHC personnel), including clinical laboratory services. Section 491.9(c)(2) lists six specific diagnostic laboratory tests that RHCs must provide directly: chemical examinations of urine by stick or tablet method or both (including urine ketones), hemoglobin or hematocrit, blood glucose, examination of stool specimens for occult blood, pregnancy tests, and primary culturing for transmittal to a certified laboratory. Citing concerns about the administrative burden of some of these tests, CMS proposes to remove hemoglobin and hematocrit (H&H) from that list of laboratory services that RHCs must perform directly. These tests are typically performed as part of a comprehensive blood count (CBC); they are not ordered separately. Patients will be sent to hospitals equipped with a full-service laboratory for CBCs and similar tests. It also proposes to revise paragraph (c)(2)(vi) (i.e., primary culturing for transmittal to a certified lab) to reflect current practice for microbiology specimens. CMS says that primary culturing is an outdated microbiology practice that is no longer performed due to modern lab techniques and proposes to substitute the following description, "collection of patient specimens for transmittal to a certified laboratory for culturing."

Comment is sought on the impact of removing H&H from the list of laboratory services that RHCs must perform directly on access to those services, especially in rural areas. CMS also seeks feedback on alternative basic lab services RHCs should provide to meet the needs of underserved rural communities.

[32] Section 1861(aa)(2)(G) of the Act

D. Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-in of Payment Reductions

1. Revised Data Reporting Period and Phase-In of Payment Reductions

Under regulations implementing the Protecting Access to Medicare Act (PAMA), CMS required "applicable laboratories" to collect the rates they were paid by private payer rates from January 1, 2016 through June 30, 2016 (the data collection period) and report those rates to CMS between January 1, 2017 and March 31, 2017 (the data reporting period). The weighted median private payer rate for each code became the CLFS payment amount effective January 1, 2018 except the statute limited reductions to 10 percent annually for 2018 through 2020.

The second data collection period is January 1, 2019 through June 30, 2019. While the second data reporting period was originally January 1, 2020 through March 31, 2020, a series of subsequent statutory amendments delayed the next reporting period until January 1, 2025 through March 31, 2025 without changing the date of the second data collection period. These statutory amendments also limited the reduction in payment to 0 percent for 2021, 2022, 2023 and 2024 and 15 percent for each year 2025 through 2027.

CMS proposes to conform its regulations to the latest statutory amendments.

E. Medicare Diabetes Prevention Program (MDPP)

CMS' Medicare Diabetes Prevention Program Expanded Model (MDPP) was established in 2017 as an in-person "additional preventive service" under Medicare. MDPP is the expansion of CMMI's DPP model test that ran from 2012 to 2016. MDPP 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, requires no Medicare cost sharing, and is available once per lifetime to eligible beneficiaries.

Organizations seeking to participate in MDPP must enroll in Medicare separately, even if they are already enrolled in Medicare for other purposes. Organizations could begin enrolling in Medicare as MDPP suppliers on January 1, 2018, with MDPP services furnished beginning April 1, 2018. The CDC's National DPP Diabetes Prevention Recognition Program (DPRP) recognizes eligible organizations that furnish the National DPP through its evidence-based DPRP Standards, which are updated every 3 years.

MDPP is a non-pharmacological behavioral intervention consisting of at least 22 intensive sessions using a CDC-approved National DPP curriculum. The sessions are furnished over 12 months by a trained coach who provides training on relevant topics for weight control and diabetes risk reduction. Suppliers may use the CDC-developed PreventT2 curriculum or an alternate CDC-approved curriculum.

CMS proposes the following changes to MDPP regulations, summarized in greater detail below:

- Revise and add definitions to provide greater flexibility, including for virtual sessions;

- Revise its requirement to allow more flexibility to document the weight of the MDPP beneficiary.
- Eliminates the use of MDPP bridge payment to reduce the potential for fraud, waste, and abuse.
- Allow payment for same day make-up sessions in MDPP

1. Proposed Changes to MDPP Conditions of Coverage (§410.79)

CMS proposes to make the following conforming changes to §410.79(b), *Conditions of Coverage*, to align with the 2024 CDC DPRP Standards:[33]

- Add a new term for MDPP, "in-person with a distance learning component," defined as "MDPP sessions that are delivered in person by trained Coaches where participants have the option of attending sessions via MDPP distance learning."
- Add a new term "combination with an online component," defined as "sessions that are delivered as a combination of online (non-live) with in-person or distance learning."
- Remove the "combination delivery" term as this definition is no longer needed with the addition of "in-person with a distance learning component," which includes any combination of in-person and distance learning sessions.
- Modify the current term and definition for "online delivery" to "online" to align with both the MDPP "distance learning" term and CDC DPRP "online (non-live)" term.
- Add that "MDPP make-up sessions may only use in-person of distance learning delivery."

CMS provides additional detail on the MDPP "online" delivery mode. Specifically, CMS proposes to revise the definition for the MDPP "online" delivery mode to provide that sessions that are delivered 100 percent through the internet via phone, tablet, or laptop in an asynchronous (non-live) classroom where participants are experiencing the content on their own time without a live (including non-artificial intelligence (AI)) Coach teaching the content. These sessions must be furnished in a manner consistent with the DPRP Standards for online sessions. Live Coach interaction must be offered to each participant during weeks when the participant has engaged with content. E-mails and text messages can count toward the requirement for live Coach interaction if there is bi-directional communication between the Coach and participant. Chat bots and AI forums do not count as live Coach interaction.

2. Proposed Changes to Alternatives to the Requirement for In-person Weight Measurement (§410.79(e)(3)(iii)

As part of MDPP's Emergency Policy that was finalized in the 2021 PFS final rule, CMS allowed for virtual weight collection (88 FR 79249). Based on feedback from interested parties, CMS proposes to revise its requirement to allow more flexibility to document the weight of the MDPP beneficiary. Specifically, CMS proposes revising §410.79(e)(3)(iii)(C) to provide that self-

[33]Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures

reported weights can be obtained in the following two ways:

(1) Live, synchronous online video technology, such as video chatting or video conferencing, wherein the MDPP Coach observes the beneficiary weighing themselves and views the weight indicated on the at-home digital scale, or
(2) The MDPP supplier receives 2 date-stamped photos or a video recording of the beneficiary's weight, with the beneficiary visible on the scale, submitted by the MDPP beneficiary to the MDPP supplier.

The photo or video must clearly document the weight of the MDPP beneficiary as it appears on their digital scale on the date associated with the billable MDPP session. If choosing to submit 2 photos, one photo must show the beneficiary's weight on the digital scale, the second photo must show the beneficiary visible in their home, and both photos must be date-stamped.

To reduce confusion as MDPP suppliers transition to the new CDC DPRP recognition for "in-person with a distance learning component," CMS is clarifying that MDPP suppliers can have and maintain either CDC's "in-person" or the new "in-person with a distance learning component" CDC DPRP code. The 2024 CDC DPRP Standards, implemented in June 2024, introduced and defined the new "in-person with a distance learning component" modality and associated code. CMS believes that aligning terminology would reduce administrative burden to MDPP suppliers and allow them to streamline CDC DPRP data submission (that is, they will not have to submit data for two CDC organization codes). MDPP suppliers will not be required to switch to this new code if they already have an in-person code; it is only being made available for their convenience.

3. Proposed Changes to Medicare Payment for MDPP Services (§414.84 (a), (c), (d), and (e))

CMS proposes to amend Medicare payment for MDPP services (§414.84 (e)) to remove the MDPP bridge payment. The MDPP bridge payment was introduced in the 2018 PFS final rule and is defined as follows: "Bridge payment means a one-time payment to an MDPP supplier for furnishing its first MDPP session to an MDPP beneficiary who has previously received one or more MDPP services from a different MDPP supplier" (81 FR 80470). CMS believes this payment structure is no longer necessary in MDPP's 2024 FFS payment structure for attendance and could introduce the potential for fraud, waste, and abuse.

In addition, at §414.84(c), to facilitate Medicare Administrative Contractors (MACs) in processing claims for same day make-up sessions in MDPP, CMS proposes to require MDPP suppliers to append an existing claim modifier to any claim for G9886 or G9887 that indicates a make-up session that was held on the same day as a regularly scheduled MDPP session. CMS believes this new requirement would contribute minimal additional complexity to the payment structure while creating a flexibility that would have value for the program, particularly for beneficiaries in the core phase of MDPP who may not have transportation to 2 in-person sessions in one week or have the flexibility to make time on more than one day per week for a distance learning session.

Lastly, with the removal of §414.84(d), CMS proposes to amend the current §414.84(e) to be the new §414.84(d). It is also removing from the new §414.84(d) the reference to updating the MDPP bridge payment.

CMS seeks comment on these proposals.

4. Aligning Language with Previous Rulemaking

CMS proposes minor edits throughout §§410.79, 424.205, and 414.84 to update outdated references and align with previous rulemaking pertaining to MDPP terminology, payment structure, and requirements.

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

1. Background

Section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act, P.L. (P.L. 115-271, October 24, 2018) 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. The 2020 PFS final rule implemented Medicare coverage and provider enrollment requirements and established a methodology for determining the bundled payments for episodes of care for the treatment of OUD furnished by OTPs, along with new codes and bundled payments for weekly episodes of care that included the following: methadone, oral buprenorphine, implantable buprenorphine, injectable buprenorphine or naltrexone, and nondrug episodes of care; and add-on codes for intake and periodic assessments, take-home dosages for methadone and oral buprenorphine, and additional counseling.

Since then, CMS has made several refinements and expansions under the Medicare OTP benefit—for example, adopting new add-on codes for take home supplies of nasal naloxone and injectable naloxone as well as a new add-on code and payment for a higher dose of nasal naloxone. The agency also implemented various telecommunications flexibilities, including to allow OTPs to furnish individual and group therapy and substance use counseling via two-way interactive audio-video telecommunications and, when audio-video telecommunications are not available to the beneficiary, via audio-only telephone calls.

In the 2024 PFS rule, CMS made further modifications, allowing periodic assessments to be furnished audio-only through the end of 2024 when video is not available to the extent that use of audio-only communications technology is permitted by the Drug Enforcement Administration (DEA) and the Substance Abuse and Mental Health Services Administration (SAMHSA). At that time, CMS noted that extending these flexibilities another year would allow the agency time to further consider this issue, including whether periodic assessments should continue.

In this proposed rule, CMS proposes several modifications to the policies governing Medicare coverage and payment for OUD treatment services furnished by OTPs.

2. Telecommunication Flexibilities for Periodic Assessments and Initiation of Treatment with Methadone

a. Proposal to Allow Periodic Assessments to be Furnished via Audio-only Telecommunications on a Permanent Basis

Building on several temporary telecommunication flexibilities previously finalized for periodic assessments furnished by OTPs, and to better align coverage for those assessments with other telehealth services furnished under the PFS for mental health disorders, CMS proposes a permanent extension—to allow OTPs to furnish periodic assessments using audio-only communications technology when video is not available on a permanent basis beginning January 1, 2025. This would allow periodic assessments to be furnished via audio-only when video is not available to the extent that use of audio-only communications technology is permitted under the applicable SAMHSA and DEA requirements at the time the service is furnished, and all other applicable requirements are met.

CMS believes permanently extending this flexibility would meaningfully promote access to care for the Medicare population, as supported by the agency's analysis of claims data showing the proportion of telephonic audio-only visits increases with the age of the patient, with 17 percent of visits delivered via audio-only interaction for patients 41-60 years of age, 30-percent for patients 61 to 80 years of age, and 47 percent of visits for patients over 81 years of age. Those more likely to be offered and use audio-only telemedicine services, rather than audio-video services, are Medicare beneficiaries who are older than 65 years old, racial/ethnic minorities, dual-enrollees in Medicare and Medicaid, living in rural areas, experiencing low broadband access, low-income, and/or for whom English is not their primary language.

While Tribal populations, including American Indian and Alaska Natives (AI/AN), have the highest rates of OUD prevalence among Medicare beneficiaries, one-third of these populations do not have adequate access to high-speed broadband and continue to rely on audio-only visits. Telemedicine flexibilities have been shown to be feasible and effective for rural patients with an OUD, helping improve treatment retention, especially for rural patients who are older and covered by Medicare. Telephone-based (that is, audio-only) therapy provided by SUD programs has been found to be one of the most common modes of telehealth for treatment of OUD. CMS says that permanently extending this flexibility could help prevent disruptions to care in OTP settings that may regularly provide periodic assessments via audio-only telehealth to Medicare beneficiaries.

Thus, CMS proposes to revise paragraph (vii) of the definition of "Opioid treatment services" at §410.67(b) to remove the references to the "Public Health Emergency, as defined in §400.200 of this chapter" and "through the end of CY 2024," in order to reflect that this flexibility would be implemented on a permanent basis. CMS would continue to state that "in cases where a beneficiary does not have access to two-way audio-video communications technology, periodic assessments can be furnished using audio-only telephone calls if all other applicable requirements are met."

CMS welcomes comments on this proposal to permanently extend this audio-only flexibility for periodic assessments.

b. Proposal to Allow OTPs to Use Audio-Visual Telecommunications for Initiation of Treatment with Methadone

SAMHSA regulations have historically required a complete physical evaluation before a patient begins treatment at an OTP. However, after the declaration of the PHE for COVID-19, the DEA and SAMHSA jointly issued flexibilities for prescribing controlled substances via telehealth to ensure patient therapies would remain accessible. OTPs were exempted from the requirement to perform an in-person physical evaluation for any patient who would be treated by the OTP with buprenorphine if a program physician, primary care physician, or authorized healthcare professional under the supervision of a program physician determines that an adequate evaluation of the patient can be accomplished via telehealth through an audio-video or audio-only evaluation. At the time, this applied exclusively to patients with an OUD being treated at an OTP with buprenorphine, not to new patients initiating treatment with methadone; new OTP patients starting treatment with methadone would need to still receive an in-person physical evaluation prior to the OTP prescribing methadone.

To align with the SAMHSA and DEA policies, in the 2023 PFS final rule, CMS revised the regulation in paragraph (vi) of the definition of "Opioid treatment services" at §410.67(b) to allow the OTP intake add-on code to be furnished via two-way audio-video communications technology when billed for the initiation of treatment with buprenorphine, to the extent authorized by DEA and SAMHSA at the time the service is furnished. CMS also permitted the use of audio-only communication technology to initiate treatment with buprenorphine in cases where audio-video technology is not available to the beneficiary. Consistent with SAMHSA and DEA requirements at that time, CMS noted that this exemption applied exclusively to OTP patients treated with buprenorphine and did not apply to new patients treated with methadone.

SAMHSA recently finalized and codified this flexibility on a permanent basis at 42 CFR 8.12(f)(2)(v)(B), so that OTPs may use audio-visual or audio-only platforms when evaluating patients who are being admitted for treatment at the OTP with Schedule III medications (such as buprenorphine).[34] In that same rule, SAMHSA made reforms to full examination requirements for initiation of treatment with methadone at §8.12(f)(2)(v)(A), now permitting audiovisual telehealth initiation for any new patient who will be treated by the OTP with methadone if a practitioner or primary care provider determines that an adequate evaluation of the patient can be accomplished via an audio-visual telehealth platform.

To be consistent with SAMHSA's recent reforms, CMS proposes to allow the OTP intake add-on code (HCPCS code G2076) to be furnished via two-way audio-video communications technology when billed for the initiation of treatment with methadone, to the extent authorized by DEA and SAMHSA at the time the service is furnished. Under this proposal, the initiation of treatment with methadone using telecommunications technology would be considered an intake activity for purposes of paragraph (vi) of the definition of "Opioid treatment services" at §410.67(b) only to the extent that the use of such telecommunications technology is permitted

[34] "Medications for the Treatment of Opioid Use Disorder," 89 FR 7528, February 2, 2024.

under the applicable DEA and SAMHSA regulations and guidance at the time the services are furnished.

At this time, CMS is not proposing to extend the flexibility to allow the use of audio-only telecommunications for these intake activities for treatment with methadone, as these flexibilities are not currently permitted by SAMHSA and the DEA. Methadone is characterized as a Schedule II controlled substance, which means that it still has higher potential for misuse with potential physical dependence. Unlike buprenorphine, which is a Schedule III controlled substance, methadone is a full agonist and does not have a "ceiling effect" that provides more protective overdose factors when taking additional doses of the drug. Thus, use of audio-visual telecommunications for initiation of treatment with methadone would balance potential safety concerns associated with methadone, such as its higher potential for misuse and risk for sedation in patients presenting with mild somnolence which may be easier to identify via an audio-visual telehealth platform, while still allowing patients the flexibility of initiating treatment via (audiovisual) telehealth at an OTP.

CMS believes this proposal may meaningfully improve access to care, promote positive health outcomes, and advance health equity among Medicare beneficiaries. Data indicate that expanded use of telehealth and flexibilities for the provision of Medications for Opioid Use Disorder (MOUD) during the COVID-19 pandemic was associated with improved care retention and a reduction in medically treated overdoses among Medicare beneficiaries. Similarly, telehealth initiation for buprenorphine to treat OUD was associated with improved treatment retention in a subset of states. Many of these benefits associated with telehealth flexibilities for initiating treatment with other MOUDs can be potentially replicated by allowing initiation of treatment with methadone via audio-visual telecommunications. Additionally, CMS believes this proposal would meaningfully impact health equity, since individuals from Black, AI/AN, and Hispanic populations are significantly less likely to initiate treatment for a SUD. During the COVID-19 pandemic, the odds of initiating treatment for a SUD increased for most age, race, ethnicity, and socioeconomic status subgroups, which may have been explained by increases in treatment initiation occurring through telehealth. Thus, promoting flexibilities for telecommunication modalities of treatment initiation in regards to methadone may provide additional options for accessing treatment, especially for populations who often experience barriers in beginning treatment.

Specifically, CMS proposes to revise the regulations for intake activities at paragraph (vi) within the definition of "opioid use disorder treatment service" at § 410.67(b) to add a new paragraph (vi)(A) within the description of intake activities to separately list flexibilities for intake activities furnished via communications technology (adding and reserving a new paragraph (vi)(B)). The language related to the existing flexibilities for the initiation of treatment with buprenorphine would be moved to paragraph (vi)(A)(1). In the definition of "opioid use disorder treatment service" at §410.67(b), CMS proposes at paragraph (vi)(A)(2) that services to initiate treatment with methadone may be furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements, if an OTP determines that an adequate evaluation of the patient can be accomplished through audio-video communication technology.

3. Proposals Related to Reforms to 42 CFR Part 8

Going back to the 2020 PFS rule, CMS reviews its implementation of payment and coverage for OUD treatment services, such as substance use counseling by a professional (to the extent authorized under state law) and individual and group therapy with a physician, psychologist or other mental health professional to the extent authorized under state law. These services were included within the definition of OUD treatment services at §410.67(b), with payment for these services incorporated as part of the non-drug component at §410.67(d)(2)(ii), with subsequent revisions and additions.

For example, CMS previously finalized adjustments to the bundled payment for an episode of care, such as intake activities and periodic assessments, noting that both initial and periodic assessments are required under SAMHSA regulations and are integral services for the establishment and maintenance of OUD treatment for a beneficiary at an OTP. CMS codified definitions at §410.67(b) to include initial medical examination services required under 42 CFR 8.12(f)(2), initial assessment services required under §8.12(f)(4), and periodic assessment services including those required under §8.12(f)(4). Services under §8.12(f) are required services as part of federal opioid treatment standards for OTPs, as regulated by SAMHSA. CMS also defined an "opioid treatment program" at §410.67(b) as an entity that is an OTP as defined in §8.2 (or any successor regulation) that meets the applicable requirements for an OTP.

The previously cited SAMHSA regulation[35] made major reforms to 42 CFR part 8, governing requirements for OTPs in providing medications for the treatment of OUD and many other services, reflecting new paradigms of care for OUD and an understanding that OUD is a chronic condition. CMS provides many examples, including that SAMHSA redefined comprehensive treatment at §8.2 to specify that treatment at OTPs includes "the continued use of MOUD provided in conjunction with an individualized range of appropriate harm reduction, medical, behavioral health, and recovery support services."[36] As another example, per §8.12(f)(5)(iii), OTPs must provide directly or through referral to adequate and reasonably accessible community resources, vocational training, education, and employment services for patients who request such services or for whom these needs have been identified and mutually agreed-upon as beneficial by the patient and program staff.

Beyond the changes at 42 CFR part 8, there have been recent activities under the PFS and in other CMS programs to address the social determinants of health (SDOH), which often affect the

[35] "Medications for the Treatment of Opioid Use Disorder," 89 FR 7528, February 2, 2024.
[36] In 42 CFR 8.2, SAMHSA now defines harm reduction as "practical, evidence-based strategies, including: overdose education; testing and intervention for infectious diseases including counseling and risk mitigation activities forming part of a comprehensive, integrated approach to address human immunodeficiency virus (HIV), viral hepatitis, sexually transmitted infections, and bacterial and fungal infections; distribution of opioid overdose reversal medications; linkage to other public health services; and connecting those who have expressed interest in additional support to peer services." It defines recovery support services as including "community-based recovery housing, peer recovery support services, social support, linkage to and coordination among allied service providers and a full range of human services that facilitate recovery and wellness contributing to an improved quality of life. The services extend the continuum of care by strengthening and complementing substance use disorder (SUD) treatment interventions in different settings and stages."

diagnosis and treatment of a patient's medical problem. CMS reviews many of these efforts as well as the administration goals and research findings that prompted them.

a. Proposal to Establish Payment for Social Determinants of Health Risk Assessments

CMS says the recent refinements to initial assessments under §8.12(f)(4)(i) likely necessitate additional resource costs for OTPs to comply with the opioid treatment standards for assessing various SDOHs—for example, education, vocational training, employment, economic, legal, housing—that impact a patient's health-related social needs (HRSNs), and to identify a patient's goals for harm reduction interventions and needs for recovery support services as they relate to the treatment of an OUD. The agency recognizes the paradigm for OUD treatment and care has evolved rapidly since implementation of the Medicare OTP benefit in 2020 and that providers have increasingly incorporated interventions to address HRSNs that increase the risk of a patient leaving OUD treatment prematurely or that pose barriers to treatment engagement. It also additionally acknowledges that coding already exists under the PFS that accounts for the resources involved in conducting these types of assessments.

For these reasons, CMS is proposing 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 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. There are multiple standardized, evidence-based SDOH risk-assessment tools; if an OTP furnishes SDOH risk assessments as part of initial assessments under §8.12(f)(4)(i), CMS would expect the assessment tools would allow the OTP to identify more specific individual-level HRSNs as part of the care plan, including giving consideration to potential harm reduction and recovery support services needs.

CMS is proposing 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 (HCPCS code G0136). CMS believes G0136 may serve as a reasonable proxy to reflect the value and resources required for the type of assessment service activities that OTPs are required to provide according to SAMHSA requirements under §8.12(f)(4)(i), including an assessment to identify a patient's unmet HRSNs or the need for harm reduction intervention and recovery support services that are critical to the treatment of an OUD. **CMS seeks comment** on whether these types of SDOH assessments ordinarily complement the type of community coordination activities that OTPs perform.

CMS provides evidence showing that healthcare providers who screen for SDOH in their settings have found that patients who screen positive for a HRSN were significantly more likely to have a history of substance use or mental illness compared to patients who did not have an HRSN. For example, one review found that between 50 to 90 percent of patients in publicly funded OTPs were unemployed. SDOH and their contribution to unmet HRSNs have heavily impacted prescription opioid misuse and abuse and the rates of drug overdoses. Many of these SDOH factors have impaired treatment retention and completion rates. Those with lower levels of educational attainment and who are unemployed are less likely to complete SUD treatment, and

individuals who are experiencing homelessness are significantly less likely to remain in treatment. Therefore, screening for the SDOH and identifying these unmet HRSNs as part of intake assessments may help OTPs link patients with an identified social need to appropriate resources that can impact the diagnosis of an OUD or address barriers to treating an OUD.

As stated above, CMS is proposing to update the adjustment to the bundled payment for an episode of care for intake activities (G2076) by adding in the value of the non-facility rate for SDOH risk assessments (G0136: *Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5–15 minutes, not more often than every 6 months*), which currently has a non-facility rate of $18.66 under the PFS. The 2024 payment rate for the intake add-on code (G0276) is $201.73. Adding the value of a crosswalk to the 2024 non-facility rate of $18.66 would result in a payment rate of approximately $220.39. CMS believes incorporating the value of G0136 into the intake activities adjustment would be the most appropriate, since the assessment activities related to SDOH are more likely to occur during intake assessments when a new patient is admitted to an OTP. However, **CMS seeks comment** on the frequency with which these SDOH risk assessments occur, and whether it would be more appropriate if these assessments occur when OTPs furnish periodic assessments per G2077.

When OTPs bill the intake add-on code (G2076), OTPs would not be required to perform SDOH risk assessments in a specific manner.[37] However, they must continue to perform initial assessment services consistent with SAMHSA certification requirements at §8.12(f)(4)(i), which now largely reflect these types of SDOH risk assessment activities, and abide by other applicable requirements under the Medicare OTP benefit at §410.67. This also means that for the purposes of Medicare payment, if SDOH risk assessments are furnished, they must be related to the diagnosis or treatment of OUD, and any HRSNs identified through SDOH risk assessments performed should be documented in the patient's medical record to indicate how assessing and addressing the HRSN relates to the treatment and diagnosis of an OUD.

In light of these proposed changes, CMS is proposing to revise the current descriptor for the intake add-on code for consistency with revisions to §8.12(f)(4)(i) and to reflect furnishing an SDOH risk assessment:
G2076 (*Intake activities, including initial medical examination that is a complete, fully documented physical evaluation and initial assessment conducted by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician or qualified personnel that includes preparation of a care plan, which may be informed by administration of a standardized, evidence-based Social Determinants of Health Risk Assessment to identify unmet health-related social needs, and that includes the patient's goals and mutually agreed-upon actions for the patient to meet those goals, including harm reduction interventions; the patient's needs and goals in the areas of education, vocational training, and employment; and the medical and psychiatric, psychosocial, economic, legal,*

[37] If OTPs do furnish these assessment services, CMS encourages OTPs to adopt evidence-based, validated tools that (1) are already available (for example, the CMS Accountable Health Communities tool, the Protocol for Responding to and Assessing Patients Assets, Risks and Experiences (PRAPARE), and instruments identified for Medicare Advantage Special Needs Population Health Risk Assessment); (2) include the domains of food insecurity, housing insecurity, transportation needs, and utility difficulties; (3) can be furnished in a manner appropriate for the patient's educational, developmental, and health literacy level; and (4) are culturally and linguistically appropriate.

housing, and other recovery support services that a patient needs and wishes to pursue, conducted by qualified personnel (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure).

b. RFI on Payment for Coordinated Care and Referrals to CBOs that Address Unmet HRSNs, Provide Harm Reduction Services, and/or Provide Recovery Support Services

As mentioned above, SAMHSA's recent reforms to 42 CFR part 8 finalized new definitions for harm reduction and recovery support services, which are included in the services OTPs may provide. The Medicare OTP benefit already pays for some of these services, such as take-home supplies of opioid antagonist medications for emergency treatment of known or suspected opioid overdose, overdose education in conjunction with opioid antagonist medications, and social support via group therapy.

However, CMS 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. A referral is an important aspect of following up on unmet HRSNs identified during an initial assessment service or SDOH risk assessment. OTPs often have collaborative agreements with providers outside of the OTP. **CMS is seeking comment** to understand how OTPs are currently coordinating care and making referrals to CBOs that address unmet HRSNs, provide harm reduction services, or provide recovery support services.

The agency cites various research findings, such as evidence that SUD treatment facilities establishing relationships with community-based peer support services, educational and employment agencies, housing agencies, and other organizations have been able to better support a patient's engagement in SUD treatment. **CMS says it is interested in** additional information related to the following:

- How community-based resources and coordination of these services with MOUD provided by OTPs would impact access to treatment for Medicare beneficiaries who may face barriers in accessing treatment, such as those in rural areas, racial/ethnic minorities, living with a disability, dual-enrollees in Medicare and Medicaid, and low-income, or other populations who may face barriers in accessing treatment.
- The types of entities, service providers, and organizations that OTPs may interact with on a regular basis to address a patient's unmet HRSNs and needs or goals related to harm reduction and recovery support services—for example, if these entities would typically include housing or transportation agencies, local support groups, syringe service programs, etc.
- The types of collaborative arrangements that OTPs typically have with these CBOs, including how frequently OTPs coordinate care or make referrals to these CBOs for patients with an OUD, the types of circumstances that warrant such interaction, and the workflows originating from the initial SDOH assessment to identify these HRSNs to a beneficiary successfully receiving referred services.
- When these coordinated activities or referrals occur in the process of furnishing care to a beneficiary—during SUD counseling session services, initial or periodic assessments, therapy sessions, or as part of other services.

- When Medicare billing for OTP intake activities (G2076), periodic assessments (G2077), additional therapy/counseling (G2080), and/or the non-drug component code (G2074), if OTPs are already accounting for these coordinated care and referral services as part of those codes.
- Payment for these types of coordinated care or referral services—specifically on the resource costs that OTPs must expend to coordinate or make referrals to community-based services that address HRSNs, harm reduction, or recovery support needs.
- Whether existing coding properly describes these services, or whether there are elements unique to OTPs that require new coding.
- If any of the following codes may describe the type of coordinated care or referral activities that OTPs may provide, or if there are other codes that more precisely match the type of coordinated care or referral activities at OTPs:
    - Community health integration (G0019, G0022),
    - Principal illness navigation (G0023, G0024, G0140, G0146),
    - Chronic care management (99437, 99439, 99490, 99491),
    - Complex chronic care management (99487, 99489),
    - Principal care management (99424, 99425, 99426, 99427), or
    - Other codes, including any other relevant codes used by other payers.
- Whether OTPs already receive funding for these types of coordinated care or referral services from other public or private sources, and if additional payment would be duplicative or unnecessary.

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

Section 1861(jjj)(1)(A) of the Act establishes Medicare payment for opioid agonist and antagonist treatment medications that are FDA-approved under section 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA) for use in the treatment of OUD and as part of OUD treatment services under the OTP benefit. Section 1834(w)(2) of the Act granted CMS the authority to establish multiple bundled payments.[38] CMS reviews the regulatory history of it establishing and modifying OTP bundled payments for an episode of care, based on both a drug and non-drug component. In this rule, CMS is proposing new payment for injectable buprenorphine and nalmefene hydrochloride products furnished by OTPs.

a. Coding and Payment for a New Nalmefene Hydrochloride Product, Opvee®

In May 2023, the FDA approved the first nalmefene hydrochloride (nalmefene) nasal spray (under the brand name Opvee®), which is indicated for the emergency treatment of known or suspected opioid overdose. This is the first FDA approval of a nasal spray for nalmefene hydrochloride for health care and community use. It is intended for immediate administration as emergency therapy. Nalmefene acts as an opioid receptor antagonist and, when administered quickly, can reverse the effects of an opioid overdose.

[38] CMS provides this direct quote that the "Secretary may implement this subsection through one or more bundles based on the type of medication provided (such as buprenorphine, methadone, naltrexone, or a new innovative drug), the frequency of services, the scope of services furnished, characteristics of the individuals furnished such services, or other factors as the Secretary determine appropriate."

Opvee delivers 2.7 milligrams of nalmefene in a single spray into the nasal cavity. After the first dose, if the patient does not respond, or responds and then relapses into respiratory depression, additional doses may be administered every 2 to 5 minutes until emergency medical assistance arrives. Compared to naloxone, which has a half-life of approximately 2 hours and also rapidly reverses the effects of an opioid overdose, nalmefene has a half-life of 11 hours, which means it remains in the body much longer and thus reduces the need for multiple treatments to prevent recurring symptoms.

CMS is proposing to make payment for Opvee under the Medicare OTP benefit, recognizing that expanding access to such overdose reversal medications is a critical component to confronting the opioid crisis. The agency then cites various numbers about opioid overdose deaths to emphasize the importance of expanding access to overdose reversal medications.

Although nalmefene is not yet on the list of drugs for the treatment of OUD, it was approved by the FDA under section 505(b)(2) authority, is an opioid antagonist, and is on the list of overdose reversal drugs approved by the FDA. Thus, CMS believes nalmefene is consistent with its definition of OUD treatment service at §410.67(d), which describes opioid antagonist medications that are approved by the FDA under section 505 of the FFDCA for the emergency treatment of known or suspected opioid overdose at paragraph (viii). Therefore, CMS believes it is appropriate to propose new payment for nalmefene, as it would align with existing authority under §410.67(b) that recognizes opioid antagonist medications that treat known or suspected opioid overdose as an OUD treatment service.

CMS proposes a new adjustment to the bundled payment for Opvee with a code of GOTP1: [*Take-home supply of nasal nalmefene hydrochloride; one carton of two, 2.7 mg per 0.1 mL nasal sprays (provision of the services by a Medicare-enrolled Opioid Treatment Program); (List separately in addition to each primary code)*].

CMS would price this new add-on code based on the established methodology under the OTP benefit for determining the adjustment for take-home supplies of opioid antagonist medications at §410.67(d)(4)(i)(E), including both a drug component and a non-drug component. The amount of the drug component would be determined using the methodology for pricing the drug component of an episode of care at §410.67(d)(2)(i), which tends to use ASP data when available (with certain exceptions). Consistent with the approach used to price the drug component for nasal naloxone (HCPCS code G2215, G1028), CMS would apply the ASP payment methodology set forth in section 1847A of the Act, except that payment amounts would not include any add-on percentages if either ASP or WAC is used. CMS says ASP provides a transparent and public benchmark for manufacturers' actual pricing as it generally reflects the manufacturers' actual sales prices to all purchasers and is the only pricing methodology that includes off-invoice rebates and discounts. Therefore, CMS believes ASP to be the most market-based approach to set drug prices, including for the new nalmefene nasal product.

The drug component would be priced based on an assumption of a typical dosage for this new product to be a carton containing two 2.7 mg nasal sprays. CMS would, therefore, multiply the payment amount of 100 percent of the volume-weighted ASP reported for 2.7 mg of nalmefene by two in order to reflect a carton of two nasal spray devices. **CMS seeks comment** on whether

this amount reflects the typical maintenance dosage for this drug when administered. The payment limit for Opvee in the April 2024 ASP pricing file is $92.033, which reflects a carton of two 2.7-mg nasal sprays.

CMS also proposes to include a non-drug component for GOTP1 that would include payment for overdose education, which is an important component of overdose prevention, based on the 2020 Medicare payment rate for CPT code 96161 (*Administration of caregiver-focused health risk assessment instrument (e.g., depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument*) and updated to reflect the MEI updates that have been applied since that time. This is consistent with the payment methodology for naloxone and the language in §410.67(d)(4)(i)(E). Since CMS is proposing to establish payment for Opvee through an adjustment to the bundled payment, and since Opvee is also considered an opioid antagonist medication, it is also proposing to update the non-drug component for the adjustment of GOTP1 annually based on the Geographic Adjustment Factor (GAF) and the Medicare Economic Index (MEI).

Consistent with established criteria for opioid antagonist medications at §410.67(d)(4)(i)(E), payment for Opvee would be limited to one add-on code (GOTP1) every 30 days. However, similar to flexibilities established for naloxone, CMS is proposing to allow exceptions where the beneficiary overdoses and uses the initial supply of nalmefene dispensed by the OTP to the extent that it is medically reasonable and necessary to furnish additional nalmefene. If an additional supply of Opvee is needed within 30 days, OTPs would have to document in the medical record the reason for the exception.

CMS expects that if the OTP provides reasonable and necessary medications for an OUD as part of an episode of care, the OTP will take measures to ensure that there is no claim for payment for these drugs other than as part of the OTP bundled payments. Thus, Opvee billed by an OTP as an add-on to the bundled payment should not be reported to or paid under a Medicare Part D plan.

b. Coding and Payment for New Injectable Buprenorphine Product Brixadi®

Buprenorphine is another medication for the treatment of OUD for which the Secretary may establish payment. Buprenorphine is a partial opioid agonist that is FDA approved to treat OUD, as it can diminish the effects of opioid withdrawal symptoms and cravings. It is a schedule III substance, meaning it has low to moderate potential for physical dependence.

Beginning with the 2020 PFS rule, CMS has established weekly bundles for various forms (e.g., injectable, oral) of buprenorphine (HCPCS G0268-G2072, G2079). The payments for the drug component and non-drug component are added together to create the bundled payment amount. CMS reviews the payment methodologies used for the various buprenorphine codes.

In May 2023, the FDA approved a new drug application (NDA) under section 505(b)(2) of the FFDCA for another extended-release buprenorphine injection—Brixadi®—for subcutaneous use to treat moderate to severe OUD. Clinical data suggest it likely contributes to high rates of treatment retention, reductions in opioid withdrawal and cravings, and fewer levels of illicit opioid use. Brixadi is available in two formulations:

- A weekly injection (containing 50 mg of buprenorphine per mL) that can be used in patients who have started treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine-containing products, and
- A monthly injection (containing 356 mg of buprenorphine per mL) for patients already being treated with buprenorphine.

The weekly and monthly formulations of the drug are available at varying doses, including lower doses that may be appropriate for those who do not tolerate higher doses of extended-release buprenorphine that are currently available.

CMS reviews evidence showing that buprenorphine is associated with decreasing the risk for overdose, opioid-related mortality, and all-cause mortality, particularly long-acting injectable forms. The most common reasons for not receiving SUD treatment include financial barriers in affordability and coverage. CMS says establishing coverage and payment for a new medication to treat OUD may provide more MOUD treatment options, reduce financial barriers to accessing medication, and aid health equity efforts among Medicare beneficiaries.

CMS is proposing to establish payment for the weekly and monthly formulations for Brixadi, using the existing payment methodology for implantable and injectable medications §410.67(d)(2)(i)(A). This regulation specifies that payment is determined using the methodology set forth in section 1847A of the Act, except that the payment amount must be 100 percent of the ASP, if ASP is used; and the payment must be 100 percent of the WAC, if WAC is used. The payment amount would be limited to 100 percent of ASP without a 6-percent add-on percentage since many OTPs purchase directly from drug manufacturers, thereby limiting the markup from distribution channels.

To establish the two different payments for the weekly and monthly injectable buprenorphine formulations of Brixadi. For the monthly version, CMS proposes the following:

- Crosswalk the monthly formulation of Brixadi (J0578: *Injection, buprenorphine extended release (brixadi), greater than 7 days and up to 28 days of therapy*) to the drug component of the existing bundled payment for injectable buprenorphine, HCPCS code G2069.
- Average the payment limits of Sublocade® and monthly Brixadi by adding their two payment limits together and dividing the sum by two, in order to update the payment for the drug component of existing HCPCS code G2069, since CMS does not expect that a beneficiary would receive two different types of buprenorphine monthly medication injections simultaneously from an OTP.

CMS notes that bundling the monthly formulation of Brixadi into the existing HCPCS code (G2069) for injectable buprenorphine would be appropriate and no more administratively complex for OTPs since G2069 is already billed on a monthly basis. Sublocade, which is already reflected in the drug component of G2069, is administered on a monthly basis to beneficiaries, as would be the monthly formulation of Brixadi, so OTPs could continue to bill G2069 once each month when either monthly Brixadi or Sublocade is administered.

CMS says that, in all, bundling the monthly formulation of Brixadi into its current injectable buprenorphine coding under the OTP benefit would be appropriate for several reasons, including:

- The costs for furnishing these drugs, as shown by similar ASP payment limits for monthly Brixadi (J0578) and the two HCPCS codes for Sublocade® (Q9991 and Q9992) ($1616.346 and $1874.902, respectively) are comparable, as reflected in the April 2024 ASP file);
- The average maintenance dosage for Sublocade (100 mg) is comparable to the median monthly dosage for Brixadi (96 mg); and
- Both drugs have similar frequencies and costs of administration (on a monthly basis) with a fee paid to the OTP for one administration of an injection once a month.

CMS proposes to calculate the nondrug component of HCPCS code G2069 consistent with the methodology at §410.67(d)(2)(ii). It also proposes to change the code descriptor for HCPCS code G2069 to take out references to a "weekly bundle" to make it clear that the code is to be billed on a monthly basis. Specifically, the code descriptor for HCPCS code G2069 would state: (*Medication assisted treatment, buprenorphine (injectable) administered on a monthly basis; bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)*).

Consistent with current guidance in Chapter 39 of the Medicare Claims Processing Manual, CMS would still expect that HCPCS code G2069 "would be billed for the week during which the injection was administered and that HCPCS code G2074, which describes a bundle not including the drug, would be billed during any subsequent weeks that at least one non-drug service is furnished until the injection is administered again, at which time HCPCS code G2069 would be billed again for that week."

For the weekly formulation of Brixadi, CMS proposes to calculate a new bundled payment for HCPCS code GOTP2 as follows:

- For the drug component, crosswalk to the weekly Brixadi formulation described by HCPCS code J0577 (*Injection, buprenorphine extended release (brixadi), less than or equal to 7 days of therapy*), which would also be based on the payment methodology at §410.67(d)(2)(i)(A) for implantable and injectable medications, consistent with the existing monthly injectable buprenorphine bundle.[39]
- For the non-drug component, consistent with the methodology utilized for the monthly bundle of injectable buprenorphine (G2069), continue to pay for substance use counseling, individual and group therapy, and toxicology testing that are included in the non-drug components for each of the bundled payments reflecting an episode of care, but include the Medicare non-facility rate for administration of an injection in the determination of the non-drug component payment rate based on CPT code 96372 (*Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular*).

[39] CMS lists numerous reasons why a bundled payment amount for the weekly formulation should be separate from the monthly formulation.

- Consistent with the payment amounts for the non-drug component of other bundled payments for an episode of care, update the value of the non-drug component for GOTP2 by the GAF and MEI.

5. Clarification to Require an OUD Diagnosis on Claims for OUD Treatment Services

CMS reviews statutory provisions implementing Medicare coverage for "opioid use disorder treatment services," defining them as items and services that are furnished by an opioid treatment program for the treatment of opioid use disorder, and specifying payments to OTPs for opioid use disorder treatment services. CMS interpreted these provisions to mean that services paid to OTPs under Medicare Part B must be for the treatment of opioid use disorder, as reflected for coverage and payment in §410.67.

In August 2023, an Office of Inspector General (OIG) report (A-09-22-03005) found that Medicare made over $1.3 million in payments to 70 OTPs for OUD treatment services that were claimed without an OUD diagnosis:

- 39 percent were for alcohol dependence, uncomplicated (F1020),
- 7 percent were for cocaine dependence, uncomplicated (F1420), and
- 5 percent were for generalized anxiety disorder (F411).

As a result of these findings, OIG recommended that CMS "develop billing requirements for OTPs to include OUD diagnosis codes on claims for OUD treatment services to indicate that enrollees have OUD diagnoses and consider working with MACs to implement a system edit to ensure that OTP payments are made for enrollees only when OUD diagnosis codes are included on claims." In its response, CMS said that the lack of an OUD diagnosis code on a claim is not conclusive evidence of an improper claim because an OUD diagnosis code is not required for payment when an OTP submits a claim for OUD treatment services; however, CMS agreed to explore ways to educate providers about including an OUD diagnosis on claims. CMS has since found that only a small number of OTPs do not append an OUD diagnosis code to claims. However, it does intend to ensure that payments made to OTPs are in alignment with statutory requirements, which is that payments made must be for services furnished for the treatment of an OUD.

Therefore, CMS is clarifying that all claims submitted to Medicare, on Form CMS-1450 for institutional providers, and on Form CMS-1500 for professional providers, or the electronic equivalents, under the OTP benefit must include an OUD diagnosis. These diagnosis codes must apply to HCPCS G-codes representing both the bundled payments (G2067 through G2075) and add-on codes to the bundled payments (G2076-G2080, G2215-G2216, G1028, and G0137). Applicable diagnosis codes for an OUD that must be submitted on claims include ICD-10-CM codes in the F11 range for "disorders related or resulting from abuse or misuse of opioids." CMS plans to issue additional guidance on appending these diagnosis codes to claims.

G. Medicare Shared Savings Program

This section is summarized in Part II of the HPA summary of the PFS.

H. Medicare Part B Payment for Preventive Vaccine Administration Services (§§410.10, 410.57, 410.152)

CMS reviews the history for the payment rates for Part B vaccines (i.e., influenza, pneumococcal, hepatitis B virus (HBV),[40] and COVID-19 vaccines) and their administration.

In the 2022 PFS final rule, CMS finalized a uniform payment rate of $30 for the administration of an influenza, pneumococcal or HBV vaccine (HCPCS codes G0008, G0009, and G0010, respectively). In the 2023 PFS final rule, CMS finalized it would maintain a payment rate of $40 for the administration of COVID-19 vaccines through the end of the calendar year in which the March 27, 2020 Emergency Use Authorization (EUA) declaration for drugs and biological products ends.[41] Effective January 1 of the year following the EUA declaration ends, the administration payment for COVID-19 vaccine would align with the payment rate for the other Part B vaccines. As of this writing, the COVID-19 EUA remains in effect. The current payment rates for the CPT codes that describe administration of COVID-19 vaccines are available on the CMS COVID-19 Vaccines website.[42] In the 2023 PFS final rule, CMS finalized an annual update to the payment amount for the administration of Part B preventive vaccines based upon the percentage increase in the MEI and also finalized the use of the GAF to adjust the payment for geographic cost differences.

1. In-Home Additional Payment for Administration of COVID-19 Vaccines

a. Background

In the 2022 PFS final rule, CMS finalized add-on payment (HCPCS code M0201) for in-home COVID-19 vaccine administration, under specific circumstances. In the 2024 PFS final rule, CMS finalized it would continue this additional payment; this payment is adjusted for the percentage increase in the MEI and the GAF to reflect geographic cost differences.

The following requirements apply when billing for HCPCS code M0201:[43,44]

- The patient has difficulty leaving the home to get the vaccine, with "difficulty leaving the home" meaning any of the following:
    - They have a condition, due to an illness or injury, that restricts their ability to leave home without a supportive device or help from a paid or unpaid caregiver;
    - They have a condition that makes them more susceptible to contracting a pandemic disease like COVID-19; or
    - They are generally unable to leave the home, and if they do leave home, it requires a considerable and taxing effort.

[40] Section 1861(s)(10)(B) of the Act specifies that the hepatitis B vaccine and its administration is only covered for those who are at high or immediate risk of contracting hepatitis B (§410.63).
[41] https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines
[42] https://www.cms.gov/medicare/medicare-part-b-drug/average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.
[43] https://www.cms.gov/medicare/covid-19/medicare-covid-19-vaccine-shot-payment
[44] https://www.cms.gov/files/document/vaccine-home.pdf.

- The patient is hard-to-reach because they have a disability or face clinical, socioeconomic, or geographical barriers to getting a COVID-19 vaccine in settings other than their home. These patients face challenges that significantly reduce their ability to get vaccinated outside the home, such as challenges with transportation, communication, or caregiving.
- The sole purpose of the visit is to administer the COVID-19 vaccine. Medicare will not pay the additional amount if the provider or supplier furnished another Medicare covered service in the same home on the same date.
- A home can be a private residence, temporary lodging (e.g., a hotel or motel, campground, hostel, or homeless shelter); an apartment in an apartment complex or a unit in an assisted living facility[45] or group home; a patient's home that is made provider-based to a hospital during the PHE for COVID-19; or communal spaces of a multi-unit living arrangement or communal living arrangement.
- A home cannot be an institution which meets the requirements of sections 1861(e)(1), 1819(a)(1), or 1919(a)(1) of the Act (relating to hospitals, skilled nursing facilities, and most Medicaid nursing facilities).

Additionally, HCPCS code M0201 may only be billed once per individual home per date of service. Medicare pays the additional payment amount for up to a maximum of five vaccine administration services per home unit or communal space within a single group living location, but only when fewer than ten Medicare patients receive a COVID-19 vaccine dose on the same day at the same group living location.

If more than one Medicare beneficiary lives in the same individual home, the additional payment for COVID-19 vaccine administration in the home is limited to one time in that home on that day. Any additional COVID-19 vaccine administration services for other individuals in that same home would be paid at the generally applicable rate, without the additional in-home add-on payment amount.

b. Payment

In the 2024 PFS final rule, CMS finalized its proposal to maintain the additional payment for the administration of a COVID-19 vaccine in the home. CMS noted that since the statutory authority to regulate Part B is identical for all four preventive vaccines,[46] it also extended this in-home additional payment to the administration of the other three preventive vaccines in the Part B vaccine benefit—influenza, pneumococcal and HBV. The additional payment for in-home administration of these additional vaccines would need to meet the current payment requirements.

Due to the uncertainty surrounding the future of the EUA declaration for drugs and biological products for COVID-19, Tables 45 and 46 in the proposed rule reflect the potential alternative payment amounts for Part B preventive vaccine administration for 2025. If the EUA declaration continues to be in effect on January 1, 2025, CMS proposes that the payment rates in Table 45

[45] Assisting living facilities participating in the CDC's Pharmacy Partnership for Long-Term Care Program are considered a home when the residents are vaccinated through this program.
[46] Section 1861(s)(10) of the Act

(reproduced below) will apply. If the EUA declaration is terminated before January 1, 2025, CMS proposes that the payment rates in Table 46 will apply. The annual update for all vaccine administration services will be made available in the 2025 PFS final rule.

Table 45: CY 2025 Part B Payments for Preventive Vaccine Administration if the EUA Declaration for Drugs and Biologicals with Respect to COVID-19 Continues into CY 2025

Category of Part B Product Administration	Part B Payment Amount (Unadjusted)	Annual Update[6]	Geographic Adjustment
Influenza, Pneumococcal, Hepatitis B Vaccines[1,4]	$33.74	MEI	GAF
COVID-19 Vaccine[2,4]	$44.99*	MEI	GAF
In-Home Additional Payment for Part B Vaccine Administration (M0201)[4]	$39.94	MEI	GAF
COVID-19 Monoclonal Antibodies (for Treatment or Post-Exposure Prophylaxis) [3,4,5]	N/A	N/A	N/A
COVID-19 Monoclonal Antibodies (for Pre-Exposure Prophylaxis)[3,4]			
Intravenous Infusion: Health Care Setting	$450**	N/A	GAF

* Rate for COVID-19 Vaccine would $33.74 if the EUA declaration is terminated before January 1, 2025.

**Rate for Intravenous Infusion: Health Care Setting is TBD if the EUA declaration is terminated before January 1, 2025.

[1] HCPCS Codes G0008, G0009, G0010.

[2] CPT code 90480.

[3] *https://www.cms.gov/monoclonal*.

[4] Beneficiary coinsurance and deductible are not applicable.

[5] As of the issuance of the CY 2025 PFS proposed rule, there are no monoclonal antibodies approved or authorized for the treatment or for post-exposure prophylaxis of COVID-19

[6] The proposed CY 2025 percentage increase of the 2017-based MEI is 3.6 percent based on IGI's first quarter of 2024 forecast with historical data through the 4th quarter of 2023.

2. Revised Payment Policies for Hepatitis B Vaccine Administration

a. Background

In section III.M of this proposed rule, CMS proposes to improve access and utilization of hepatitis B vaccines by expanding the list of individuals who are at high or intermediate risk of contracting hepatitis B at §410.63. In the 2013 PFS final rule, CMS amended the regulations to include those diagnosed with diabetes mellitus in the list of groups at high risk of contracting hepatitis B. CMS notes the current unique coverage and payment requirements related to the hepatitis B vaccine under Part B include a required assessment of a patient's risk of contracting hepatitis Bas well as a physician's order, and thus cannot be roster billed by mass immunizers.

b. Revisions to Payment Policies for Hepatitis B Vaccinations

As note earlier, section III.M of the proposed rule would expand the range of Medicare enrollees with coverage under Part B for hepatitis B vaccines and their administration. Under the new proposal, an assessment of an individual's vaccination status could now be made without the

clinical expertise of a physician and a doctor's order would no longer be necessary for the administration. This change in policy would also allow mass immunizers to use the roster billing process to submit Medicare Part B claims for hepatitis B vaccines and their administration. CMS would make revisions to its Medicare Benefit Policy Manual and Medicare Claims Processing Manual, accordingly.

The payment rates for G0010, with the annual update applied for 2025, will be made available at the time of publication of the 2025 PFS final rule. Tables 45 and 46 in section III.H.1.f of this proposed rule provide the 2025 projected payment rates for G0010.

c. Revisions to Payment Policies for Hepatitis B Vaccinations in Rural Health Clincs (RHCs) and Federally Qualified Health Centers (FQHCs)

Even though hepatitis B vaccines and their administration are deemed preventive services for which coinsurance (and deductible in RHCs) is waived, hepatitis B vaccines are still currently paid differently than other Part B vaccines in RHCs and FQHCs. Due to the statutory differences, pneumococcal, influenza and COVID-19 vaccines and their administration are paid at 100 percent of reasonable cost in RHCs and FQHCs—that is, they are paid separately from the FQHC PPS or the RHC All-Inclusive Rate (AIR) methodology—while hepatitis B vaccines and their administration are paid as part of the FQHC PPS or the RHC AIR, which means that they are paid through changes to the facilities' capitated rate.

In light of the proposal to expand coverage for hepatitis B vaccination in section III.M of this proposed rule, CMS proposes to use its authority at section 1833(k) of the Act to align payment for hepatitis B vaccinations in RHCs and FQHCs with the payment for pneumococcal, influenza and COVID-19 vaccinations in those settings. That is, CMS proposes to pay for hepatitis B vaccines and their administration in RHCs and FQHCs at 100 percent of reasonable cost, separate from the FQHC PPS and the RHC AIR methodology, for all populations identified for coverage at §410.63(a). If this policy is finalized, then effective January 1, 2025, RHCs and FQHCs would bill for Part B hepatitis B vaccines in the same manner as they currently bill for pneumococcal, influenza and COVID-19 vaccines, that is, on their cost report.

To implement this proposal regarding payment for hepatitis B vaccines and their administration in RHCs and FQHCs, CMS also proposes to amend the regulations at §405.2466(b)(1)(iv), to add hepatitis B vaccines to the list of vaccines covered in RHCs and FQHCs at 100 percent of reasonable cost. CMS would also make change to guidance in the Medicare Benefit Policy Manual, Chapter 13, and Medicare Claims Processing Manual, Chapter 9, as well as any necessary operational systems updates needed to implement these changes.

d. Regulations Concerning Hepatitis B Vaccines and their Administration

CMS notes that since it is proposing to revise §410.63(a), it does not believe additional regulation text changes are needed to conform to the coverage proposal.

3. Payment for Drugs Covered as Additional Preventive Services (§410.152)

a. Statutory Background

Section 101 of the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 (Pub. L. 110-275) added section 186(ddd)(1) and (2) of the Act to effectuate "improvements to coverage of preventive services" in the Medicare program. Under this section, Medicare Part B covers "additional preventive services" that identify medical conditions or risk factors 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.

Section 101 of MIPPA also added section 1833(a)(1)(W) of the Act, which provides requirements for payment of additional preventive services. In particular, section 1833(a)(1)(W)(ii) requires that the amount paid for the provision of all other additional preventive services is 100 percent of the lesser of the actual charge for the service, or the amount determined under a fee schedule established by the Secretary for purposes of this subparagraph. This payment authority under this section (1833(a)(1)(W)(ii)) has not been utilized yet as CMS has not yet covered any additional preventive services that would require use of that payment authority.

Specifically, CMS has not yet covered or paid for any drugs or biologicals (hereinafter, referred to as drugs) under the benefit category of additional preventive services. In July 12, 2023, CMS released a Proposed NCD for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention. This proposed NCD announced CMS' intention to cover and pay for those drugs under section 1861(ddd) of the Act's additional preventive services authority, and a decision on the NCD is forthcoming.

b. Proposed Fee Schedule for Drugs Covered as Additional Preventive Services (DCAPS)

As discussed above, the authority at section 1833(a)(1)(W)(ii) of the Act provides for payment for additional preventive services, including drugs. This authority differs, however, from the authority used to pay drugs that are separately paid as drugs and biologicals under other Part B payment authorities.[47] Payment for most drugs separately payable under Part B is generally made according to the Average Sales Price (ASP) methodology. These provisions do not apply to drugs covered as additional preventive services (hereinafter, DCAPS); thus, other requirements do not apply, including requirements for manufacturers to report ASP to CMS on a quarterly basis. CMS emphasizes that DCAPS drugs that are also covered under Part B for non-preventive indications (that is, are also used for diagnosis or treatment) would be subject to ASP reporting requirements.

CMS is using its authority in section 1833(a)(1)(W)(ii) to determine payment based on a fee schedule. Specifically, CMS is proposing a fee schedule for DCAPS drugs that uses existing Part

[47] Section 1833(a)(1)(S) of the Act and outlined at section 1842(o)(1)(C) of the Act

B drug pricing mechanisms. Accordingly, CMS proposes that the payment limit for a DCAPS drug would be determined using the ASP methodology or, if ASP data is not available for a particular drug, to use an alternative pricing mechanism, as described below. CMS proposes to update the fee schedule quarterly, on the same schedule as the ASP pricing file, which is updated each calendar quarter.

CMS would establish a DCAPS fee schedule using the following pricing mechanisms to determine the payment limit for DCAPS drugs under Part B, 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 National Average Drug Acquisition Cost (NADAC) prices for the drug;
(3) If ASP data and NADAC prices are not available, the payment limit would be calculated using the Federal Supply Schedule (FSS) prices for the drug; and
(4) If ASP data, NADAC prices, and FSS prices are not available, the payment limit would be the invoice price determined by the MAC.

CMS proposes to amend §410.152 by adding paragraph (o) to establish the fee schedule and the pricing methodologies used to determine the payment limit for DCAPS drugs under Part B. In addition, CMS highlights that the coinsurance does not apply to DCAPS drugs. CMS proposes to publish the payment limits for DCAPS drugs along with other separately payable Part B drugs on the ASP pricing file.

CMS invites comment on the proposed fee schedule for drugs paid as additional preventive services.

c. Payment for Supplying and Administration of Drugs under the Additional Preventive Services Benefit

There is no existing policy regarding payment for the administration of DCAPS drugs or the supplying of DCAPS drugs by suppliers and providers. CMS proposes administration and supplying fees for DCAPS drugs that mirror existing policies under the PFS and Part B drug payment. CMS anticipates that an NCD that adds drugs to the additional preventive services benefit would include coverage for the supplying or administration of the drug, as appropriate, and those fees would therefore be considered payment for additional preventive services as well. Therefore, CMS proposes payment limits for the supply and administration of DCAPS drugs to be included on the DCAPS fee schedule.

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, to allow for consistency among similar payments in Part B. Specifically, CMS proposes that it will establish 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. 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 that it would determine the payment limit for administration of a DCAPS drug provided incident to a physician service via a crosswalk to an existing, corresponding drug administration code under the PFS. The exact detail codes and corresponding crosswalks would be included on the published fee schedule once DCAPS drugs are finalized for coverage via the NCD process. The fee schedule would be published quarterly on the CMS website and implemented in the Medicare claims processing systems.

No cost sharing would apply for the administration or supplying of DCAPS drugs, because CMS is proposing that such administration or supplying would be considered an additional preventive service. CMS proposes to codify these policies at the newly added §410.152(o).

CMS notes that with regard to the July 12, 2023 Proposed NCD for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention, in section II.E.4.b of this proposed rule, CMS proposes 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).

d. Payment for Drugs Covered as Additional Preventive Services in RHCs and FQHCs

In this section, CMS clarifies that drugs covered as additional preventive services, and any accompanying administration and supplying fees, are not subject to cost-sharing in RHCs and FQHCs. Since DCAPS drugs and the services to administer and supply them are all considered additional preventive services, as explained in the previous section, they are paid at 100 percent of the Medicare payment amount in RHCs and FQHCs and they are paid on a claim-by-claim basis.

In addition, CMS proposes DCAPS drugs, when administered and supplied in an RHC or FQHC, as well as any administration and supply fee for those drugs, would be paid according to the fee schedule payment limits. Those payment limits are described earlier in section III.H.3.b, and if finalized as proposed, they would be codified at §410.152(o)(1). CMS proposes to codify this RHC/FQHC DCAPS policy in regulation as well, at a new §405.2464(h).

I. Medicare Prescription Drug Inflation Rebate Program

1. Background

Drug manufacturers must pay rebates to Medicare if prices for certain Part B drugs increase faster than the rate of inflation for a calendar quarter beginning with the first quarter of 2023; they are also required to pay rebates to Medicare if prices for certain Part D drugs increase faster than the rate of inflation over a 12-month period, starting with the 12-month period that began October 1, 2022. Drugs for which inflation rebates are required are referred to as Part B rebatable drugs and Part D rebatable drugs, respectively. As authorized by the IRA, CMS initially implemented these provisions through program guidance.

a. Overview of Proposals

The proposed rule would establish two new parts (parts 427 and 428, respectively, of title 42, Code of Federal Regulations) to codify policies established in the revised guidance for the Medicare Part B Drug Inflation Rebate Program and the Medicare Part D Drug Inflation Rebate Program (collectively referred to as the "Medicare Prescription Drug Inflation Rebate Program"). The codification would include some modifications to the policies established in guidance as well as the following new policies:

Medicare Part B Drug Inflation Rebate Program:

- CMS would compare the payment amount in the quarterly pricing files published by CMS to the inflation-adjusted payment amount for a given quarter when determining whether the criteria for a coinsurance adjustment are met (§427.201(b)).
- For a Part B rebatable drug first approved or licensed by the FDA on or before December 1, 2020 but with a first marketed date after December 1, 2020, the payment amount benchmark quarter for such drug would be the third full calendar quarter after the drug's first marketed date (§427.302(c)(3)).
- For a Part B rebatable drug that was billed under a Not Otherwise Classified (NOC) code during the calendar quarter beginning July 1, 2021, or the third full calendar quarter after such drug's first marketed date, whichever is later, the payment amount benchmark quarter would be the third full calendar quarter after the drug is assigned a billing and payment code other than a NOC code (§427.302(c)(4)).
- CMS would remove 340B units for professional claims with dates of service during 2024 (in addition to 2023) submitted by Medicare suppliers that participate in the 340B Program, by using National Provider Identifiers (NPIs) and/or Medicare Provider numbers to identify these suppliers and the claims submitted with such identifiers (§427.303(b)(1)(i)).
- CMS would remove units of refundable single-dose container or single-use package drugs subject to discarded drug refunds from the calculation of rebate amounts in the reconciliation process (§427.303(b)(5)).
- CMS describes the proposed method and process for reconciliation of a rebate amount for a Part B rebatable drug, including the circumstances that may trigger a reconciliation (§427.501).

- CMS would establish a civil money penalty (CMP) process for manufacturers of a Part B rebatable drug that fail to pay the rebate amount in full by the payment deadline for such drug for such applicable calendar quarter (§427.600).
- CMS would add a severability provision such that if any provision of part 427 were held invalid or unenforceable by its terms, or as applied to any person or circumstance, that provision would be severable from part 427 (§427.10).

Medicare Part D Drug Inflation Rebate Program:

- If a Part D rebatable drug first approved or licensed by the FDA on or before October 1, 2021, does not have AMP data reported under section 1927(b)(3) of the Act for any quarters during the period beginning on January 1, 2021 and ending on September 30, 2021, CMS would identify the payment amount benchmark period as the first calendar year in which the drug has at least one quarter of AMP reported, which would be no earlier than 2021 (§428.202(c)(3)).
- For a Part D rebatable drug first approved or licensed after October 1, 2021 (i.e., a subsequently approved drug) for which there are no quarters during the first calendar year beginning after the drug's first marketed date for which AMP has been reported under section 1927(b)(3), the payment amount benchmark period would be the first calendar year in which the drug has at least one quarter of AMP reported (§428.202(c)(4)).
- For claims with dates of service on or after January 1, 2026, and with respect to an applicable period, CMS would exclude from the total number of units used to calculate the total rebate amount for a Part D rebatable drug those units of the Part D rebatable drug for which a manufacturer provided a discount under the 340B Program. To determine the total number of units for which a manufacturer provided a discount under the 340B Program, CMS would use data reflecting the total number of units of a Part D rebatable drug for which a discount was provided under the 340B Program and that were dispensed during the applicable period. CMS could apply adjustment(s) to these data as needed (§428.203(b)(2)).
- CMS describes the proposed method and process for reconciliation of a rebate amount for a Part D rebatable drug, including the circumstances that may trigger reconciliation (§428.401).
- CMS would establish a CMP process to address when a manufacturer of a Part D rebatable drug fails to pay the rebate amount in full by the payment deadline for such drug for such applicable period (§428.500).
- CMS would add a severability provision such that if any provision of part 428 were held invalid or unenforceable by its terms, or as applied to any person or circumstance, that provision would be severable from part 428 (§428.10).

The proposed applicability date for these proposals for Part B rebatable drugs would be all calendar quarters beginning with January 1, 2023 and for Part D rebatable drugs all applicable periods beginning with October 1, 2022.

Section 1871(e)(1)(A) of the Act prohibits the retroactive application of substantive changes to Medicare regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability unless (i) retroactive application is required to comply with statutory requirements or (ii) failure to apply those substantive changes retroactively would be

contrary to the public interest. CMS has determined that the retroactive application of its proposals (if any) is both consistent with the authority granted under the IRA and necessary to implement statutory requirements for calculations involving invoice pricing.

b. Timeline of Key Dates for the Medicare Prescription Drug Inflation Rebate Program

The IRA permitted delayed reporting and invoicing of rebate amounts for applicable calendar quarters in 2023 and 2024 for Part B rebatable drugs and the first two applicable periods for Part D rebatable drugs. Figures 1 and 2 in the preamble provide example timelines for how rebates will be calculated for applicable calendar quarters and one applicable period in calendar year 2025; they also show how rebate periods and components of the rebate calculation may shift based on the marketing and approval dates for a rebatable drug or biological product.

Table 47 (reproduced below) shows summary timelines for inflation rebate amount reports and deadlines.

MILESTONE	TIMING/DEADLINE
Part B Rebate – CMS must invoice manufacturers not later than 6 months after each calendar quarter	
Preliminary Rebate Report sent to Manufacturers	Not later than 5 months after the end of the calendar quarter
Manufacturer Reviews	Manufacturer Suggestion of Error must be submitted to CMS not later than 10 calendar days following receipt of the Preliminary Rebate Report
Rebate Report sent to Manufacturers	Not later than 6 months after the end of the calendar quarter
Manufacturer Rebate Amount Due (if applicable)	Not later than 30 calendar days after receipt of the Rebate Report
Preliminary Reconciliation Rebate Report sent to Manufacturers	Not later than 11 months after receipt of the Rebate Report
Manufacturer Reviews	Manufacturer Suggestion of Error must be submitted to CMS not later than 10 calendar days following receipt of the Preliminary Reconciliation Rebate Report
Reconciliation Rebate Report sent to Manufacturers	Not later than 12 months after receipt of the Rebate Report
Manufacturer Reconciled Rebate Amount Due (if any)	Not later than 30 calendar days after receipt of the Reconciliation Rebate Report
Part D Rebate – CMS must invoice manufacturers not later than 9 months after the end of each applicable period	
Preliminary Rebate Report sent to Manufacturers	Not later than 8 months after the end of the applicable period
Manufacturer Reviews	Manufacturer Suggestion of Error must be submitted to CMS not later than 10 calendar days following receipt of the Preliminary Rebate Report
Rebate Report sent to Manufacturers	Not later than 9 months after the end of the applicable period

MILESTONE	TIMING/DEADLINE
Manufacturer Rebate Amount Due (if applicable)	Not later than 30 calendar days after receipt of the Rebate Report
First Reconciliation Preliminary Rebate Report sent to Manufacturers	Not later than 11 months after the receipt of the Rebate Report
Manufacturer Reviews	Manufacturer Suggestion of Error must be submitted to CMS not later than 10 calendar days following receipt of the First Reconciliation Preliminary Rebate Report
First Reconciliation Rebate Report sent to Manufacturers	Not later than 12 months after the receipt of the Rebate Report
Manufacturer Reconciled Rebate Amount Due (if any)	Not later than 30 calendar days after receipt of the First Reconciliation Rebate Report
Second Reconciliation Preliminary Rebate Report sent to Manufacturers	Not later than 35 months after the receipt of the Rebate Report
Manufacturer Reviews	Manufacturer Suggestion of Error should be submitted to CMS not later than 10 calendar days following receipt of the Second Reconciliation Preliminary Rebate Report
Second Reconciliation Rebate Report sent to Manufacturers	Not later than 36 months after the receipt of the Rebate Report
Manufacturer Reconciled Rebate Amount Due (if any)	Not later than 30 calendar days after receipt of the Second Reconciliation Rebate Report

[a] *The months referred to in these timelines represent calendar months. This means, for example, that if a Preliminary Rebate Report is issued on August 15, 2027, the Rebate Report could be issued up until September 30, 2027.*

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

a. Definitions (§427.20)

CMS proposes to codify definitions of terms consistent with the meanings given in section 1847A(i) of the Act or established in the revised Medicare Part B Drug Inflation Rebate Guidance (referred to in this summary as the Part B Revised Guidance);[48] it also proposes new definitions based on policies described in the proposed rule.

b. Determination of Part B Rebatable Drugs (§§427.100 through 427.101)

i. Identification of Part B Rebatable Drugs

A Part B rebatable drug is a single source drug or biological product for which payment is available under Part B; it includes a biosimilar biological product (biosimilar) but excludes a qualifying biosimilar biological product.[49] CMS proposes to codify its definition of that term as

[48] Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Revised Guidance, Implementation of Section 1847A(i) of the Social Security Act; December 14, 2023. https://www.cms.gov/files/document/medicare-part-binflation-rebate-program-revised-guidance.pdf

[49] Qualifying biosimilar biological products are biosimilars that, during a temporary 5-year period, have an average

well as policies in section 30.1 of the Part B Revised Guidance to identify Part B rebatable drugs. CMS would (1) identify the applicable billing and payment code for each single source drug or biological product, including biosimilars, for which payment is made under Part B and (2) exclude 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.

CMS also proposes to define the term "individual who uses such a drug or biological" to mean a unique Medicare Part B beneficiary who was furnished the Part B drug or biological that was covered under Part B during the applicable calendar quarter, identified using final action claims data with dates of service during the calendar year involved and with allowed charges greater than zero.

ii. Excluded Products

As noted above, qualifying biosimilar biological products are excluded from the definition of Part B rebatable drug. The following would also be excluded from that definition:

- Single-source drugs or biological products that are within the same billing and payment code as of October 1, 2003.
- Drugs and biologicals billed using a billing and payment code that represents a NOC code drug or biological product or claims for such drugs and biological products when no other billing and payment code is applicable.
- Skins substitutes. (CMS notes these products would not be subject to the beneficiary coinsurance adjustment.)
- Units of separately payable radiopharmaceuticals. (CMS notes these products would not be subject to the beneficiary coinsurance adjustment.)
- Drugs with low average Medicare Part B total allowed charges (i.e., those below the "applicable threshold").
- Vaccines, including monoclonal antibodies that are used for pre-exposure prophylaxis of COVID-19. For monoclonal antibodies used for treatment or post-exposure prophylaxis of COVID-19, which are covered and paid for under vaccine benefit category under section 1861(s)(10) of the Act, CMS would exclude these products from the definition of Part B rebatable drugs for applicable quarters through the end of the calendar year in which the EUA declaration[50] for drugs and biological products is terminated.
- Generic drugs (i.e., Part B drugs approved under an Abbreviated New Drug Application (ANDA) submitted under 505(j) of the Federal Food, Drug, and Cosmetic (FD&C) Act.

iii. Drugs and Biological Products with Average Total Allowed Charges Below the Applicable Threshold

CMS proposes to codify policies in section 30.2 of the Part B Revised Guidance to identify drugs and biologicals for purposes of this exclusion. This includes policies for the calculation of the applicable threshold, which is $100 for all four calendar quarters in 2023, as adjusted for

sales price that is less than the reference biological product. See section 1847A(b)(8)(B)(iii) of the Act.

[50] EUA Declaration refers to the March 27, 2020, Emergency Use Authorization (EUA) Declaration for Drugs and Biological Products under section 564 of the Food, Drug, and Cosmetic (FD&C) Act.

inflation by CPI-U for each subsequent year (i.e., for all four calendar quarters of such year) and rounded to the nearest multiple of $10.

It would identify average total allowed charges for a year per individual by summing the allowed charges from final action claims greater than $0 and dividing the summed amount by the number of individuals who use such a drug or biological. For drugs and biological products assigned to more than one billing and payment code, it would do the calculation for all billing and payment codes.

CMS may move a drug or biological product from a grouped billing and payment code to a unique billing and payment code under certain circumstances, such as when the agency initially assigns a brand name drug to the same billing and payment code as its reference drug for a period of time, or when the drug was previously a multiple source drug but is now a single source drug that was moved to its own billing and payment code. Where this occurs for a full year, CMS proposes to calculate the average total allowed charges per individual per year for the drug, using allowed charges and the number of individuals who used the drug or biological product based on claims for the previously grouped billing and payment code during the year.

In instances where a single source drug or biological was initially billed under a grouped billing and payment code (other than a NOC code) and was later billed under a unique billing and payment code for some of the year, CMS would separately sum the total allowed charges billed under the grouped billing and payment code and the unique billing and payment code, and identify the individuals on those claims. It would then sum the total allowed charges under both billing and payment codes across the full year and divide by the total number of individuals (de-duplicated for those individuals identified under both the previously grouped billing and payment code and the unique billing and payment code).

Where a single source drug or biological product is assigned to more than one billing and payment code during a year and the average total allowed charges for a year per individual that uses such drug or biological product are less than the applicable threshold, CMS proposes to exclude all assigned billing and payment codes for such single source drug or biological product for that applicable calendar quarter.

c. Inflation-Adjusted Beneficiary Coinsurance Adjustment and Adjusted Medicare Payment for Part B Rebatable Drugs with Price Increases Faster than Inflation (§§427.200 through 427.201)

Per the statute, if the payment amount for a Part B rebatable drug or biological exceeds the inflation-adjusted payment amount, beneficiary coinsurance will be 20 percent of the inflation-adjusted payment amount for such quarter. The applicable beneficiary coinsurance percentage is shown for each HCPCS code in the pricing files that are posted on the CMS website.[51]

[51] https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files; https://www.cms.gov/medicare/payment/prospective-payment-systems/hospitaloutpatient/addendum-a-b-updates; and https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgicalcenter-asc/asc-payment-rates-addenda.

CMS proposes to use the payment amount in quarterly pricing files to determine if a Part B rebatable drug should have an adjusted beneficiary coinsurance; this would be used only to determine whether there should be a coinsurance adjustment and would not impact the applicability or calculation of inflation rebates. Thus, an adjusted beneficiary coinsurance amount would apply only when the payment amount for a Part B rebatable drug exceeds the inflation-adjusted payment amount in a given quarter. CMS points to differences in the statutory language governing when beneficiary coinsurance should be adjusted (based on the payment amount) and how to determine rebate amounts (based on the specified amount). The agency's intent is to hold beneficiaries harmless when the payment amount is calculated differently from the specified amount.

Additionally, it proposes that the calculation to determine the adjusted Medicare payment (if applicable) will not be adjusted for sequestration, and drugs not identified as Part B rebatable drugs would not be subject to the inflation-adjusted beneficiary coinsurance.

d. Determination of the Rebate Amount for Part B Rebatable Drugs (§§427.300 through 427.304)

i. Calculation of the Total Part B Rebate Amount To Be Paid by Manufacturers

CMS proposes to codify the rebate calculation established in the Part B Revised Guidance. The estimated amount would be equal to the product of 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 biological product for an applicable calendar quarter. The estimated amount would be reduced in the case of shortages or a severe disruption in the supply chain of the drug or biological. It could also be reduced under the reconciliation process.

In calculating the rebate owed by manufacturers for a rebatable drug with more than one manufacturer, CMS proposes to codify the policy from section 50.13 of the Part B Revised Guidance under which it multiplies the total rebate amount calculated for the billing and payment code by the following quotient:
Sum of the individual manufacturer's billing units sold during the applicable calendar quarter for all NDCs of the manufacturer assigned to the billing and payment code, as reported in the ASP data submissions *divided by* Sum of all manufacturers' total billing units sold during the applicable calendar quarter for all NDCs of the Part B rebatable drug assigned to the billing and payment code, as reported in the ASP data submissions.

Where ASP data are missing, including when the number of units sold is zero or negative, **CMS seeks comment** on the following possible policies:

(1) Scenarios in which All NDCs Within a Billing and Payment Code Have Negative, Zero, or Missing ASP Units

If there are NDCs of multiple manufacturers in a billing and payment code, to determine the respective rebate amount when the manufacturer-reported ASP units for all NDCs are either

negative, zero, or missing but there is a positive rebate amount calculated for the Part B rebatable drug, CMS proposes to: (1) apportion a $0 rebate amount when the reported units for all NDCs are missing for NDCs not marketed or sold during the applicable calendar quarter, negative, and/or zero; and (2) equally apportion a positive rebate amount to each NDC with missing units when the NDCs were marketed or sold during the applicable calendar quarter.

If the NDCs within a billing and payment code have a mix of negative units, zero units, missing units for NDCs marketed or sold during the applicable calendar quarter, or missing units for NDCs not marketed or sold during the applicable calendar quarter, CMS says it would apportion a $0 rebate amount to the NDCs with missing units that are not marketed or sold during the applicable calendar quarter, NDCs with negative units, and NDCs with zero units. It would also equally apportion the positive rebate amount across all NDCs with missing units that are marketed or sold during the applicable quarter.

CMS also considered (1) using the reported ASP units from the calendar quarter before the applicable calendar quarter; (2) using an average of units sold based on sales data for several calendar quarters prior to the applicable calendar quarter (such as 4 quarters); and (3) validating ASP data based on review of AMP data in combination with one of the alternative proposed policies to determine inflation rebate amounts. **CMS seeks comment** on its proposals and the alternatives it considered.

(2) Scenarios in which Some (But Not All) NDCs Have Negative, Zero, or Missing ASP Units

When some (but not all) manufacturers' NDCs within a billing and payment code report negative, zero, or missing ASP units, CMS would:

- Treat any NDCs with missing units that are not marketed or sold during the applicable calendar quarter, negative units, or zero units as not having any sales for the applicable calendar quarter and apportion a $0 rebate amount to them;
- Treat NDCs with missing units that are marketed or sold during the applicable calendar quarter as though they had the same units as that of the NDC with the lowest positive units; and
- Apportion rebate amounts across NDCs with missing units that are marketed or sold during the applicable calendar quarter and NDCs with positive units based on the share of ASP units sold as provided under section 50.13 of the Part B Revised Guidance.

CMS is considering the following alternative policies: (1) reviewing historical ASP data to identify the most recent calendar quarter with positive ASP units for any of the NDCs with negative, zero, or missing units in the applicable calendar quarter and allocation of financial responsibility across NDCs with positive ASP units in that quarter (excluding NDCs without positive units in that quarter); (2) using an average of units sold based on sales data for several calendar quarters prior to the applicable quarter (e.g., an average of the previous four calendar quarters); (3) apportioning rebates based on units at the NDC-9 level rather than the NDC-11 level; and (4) apportioning rebates to only those manufacturers within a HCPCS code that reported positive ASP units for the applicable calendar quarter.

ii. Calculation of the Per Unit Part B Drug Rebate Amount

(1) Identification of the Specified Amount for the Applicable Calendar Quarter

CMS proposes to codify the methodology established in section 50.2 of the Part B Revised Guidance for calculating the specified amount for the applicable calendar quarter. It proposes that the first applicable calendar quarter for a Part B rebatable drug will be the earliest applicable calendar quarter that follows the payment amount benchmark quarter. To clarify a number of issues, CMS proposes:

- To use the most updated price information reported by manufacturers to compare whether 106 percent of WAC or 106 percent of ASP is less, and would use the lower value for the specified amount.
- If all NDCs in the HCPCS code have neither manufacturer-reported ASP nor WAC price data available for the applicable calendar quarter, CMS would use WAC price data from other public sources, if available, to calculate 106 percent of WAC.
- If negative or zero manufacturer ASP data is reported for all NDCs for a given quarter, that negative or zero ASP amount would be used to compare 106 percent of WAC to 106 percent of ASP to determine the lower value for use as the specified amount.

To identify the payment amount benchmark quarter, CMS proposes to codify policies from section 50.3 of the Part B Revised Guidance as follows:

Date of FDA License/Approval	**Payment Amount Benchmark Quarter**
On or before December 1, 2020	The July 1, 2021 calendar quarter
After December 1, 2020	The third full calendar quarter after the day on which the drug was first marketed
Special Rules	
Drugs first approved or licensed on or before December 1, 2020 that lack ASP or WAC data for the calendar quarter beginning July 1, 2021 because they were not marketed or sold	The third full calendar quarter after the day on which the drug was first marketed
Part B rebatable drug billed under a NOC code during the July 1, 2021 calendar quarter, or the third full calendar quarter after such drug's first marketed date, whichever is later	The third full calendar quarter after the Part B rebatable drug is assigned a billing and payment code other than a NOC code

CMS would use the earliest first marketed date of any NDC ever marketed under any FDA application under which any NDCs that have ever been assigned to the billing and payment code for that Part B rebatable drug as of the applicable calendar quarter have ever been marketed. The earliest first marketed date would apply to all NDCs within a billing and payment code and to all products and package sizes marketed under the same FDA approved application. If the date of first sale is missing from ASP data, CMS proposes to identify the first marketed date from alternative public sources, such as National Institutes of Health's DailyMed.

(2) Identification of Payment Amount in the Payment Amount Benchmark Quarter

CMS proposes to codify the methodology established in section 50.2 of the Part B Revised Guidance and would use the published payment limit for the billing and payment code for the applicable payment amount benchmark quarter determined in accordance with section 1847A of the Act to identify the payment amount in the payment amount benchmark quarter for the Part B rebatable drug by billing and payment code. The policies are summarized in the following table (based on Table 49 of the preamble):

Specified Amount		**Payment Amount in the Payment Amount Benchmark Quarter**	
Purpose in Rebate Calculation	**Pricing Methodology Under 1847A(i)(3)(A)(ii)(I)**	**Purpose in Rebate Calculation**	**Pricing Methodology Under 1847A(i)(3)(C)(i)**
Part B amount under 1847A(i)(3)(A)(ii)(I) for the calendar quarter in which a rebate may be assessed	• Lesser of ASP+6% or WAC+6% • For biosimilars, 100% of ASP for the biosimilar + 6% of the lesser of ASP or WAC for the reference biological product	Part B published payment limit for the payment amount benchmark quarter, which is generally the quarter beginning July 1, 2021	Various Part B pricing provisions consistent with section 1847A of the Act

The rebate amount would equal the product of (i) the number of billing units in the applicable calendar quarter and (ii) the difference between the specified amount and the inflation adjusted payment. The inflation-adjusted payment amount would equal the product of (i) the payment amount in the payment amount benchmark quarter and (ii) the quotient of the rebate period CPI-U divided by the benchmark period CPI-U.

If a Part B rebatable drug was previously billed under a grouped billing and payment code during the benchmark quarter and later billed under a unique billing and payment code, the agency would identify the grouped billing and payment code payment limit CMS used for the payment amount in the payment amount benchmark quarter and use that payment limit for the benchmark quarter.

Under its proposals, CMS would not apply a sequestration reduction to the payment amount in the payment amount benchmark quarter as part of the methodology to calculate a Part B inflation rebate amount.

CMS proposes to codify policies under §§50.5, 50.6 and 50.7 of the Part B Revised Guidance to identify the Benchmark Period CPI-U, to identify the Rebate Period CPI-U, and to determine the inflation-adjusted payment amount.

iii. Determination of Total Number of Billing Units

CMS proposes to codify policies in section 50.8 of the Part B Revised Guidance to determine the number of billing units for each Part B rebatable drug by HCPCS code. Billing units include the

number of billing units for the HCPCS code of the Part B rebatable drug furnished during the relevant calendar quarter but exclude the following billing units:

- Drugs for which the manufacturer provides a 340B discount, identified on the claims line by the "JG" or "TB" modifiers which all 340B covered entities are required to use. (Hospitals reporting the "JG" modifier must use the "TB" modifier beginning January 1, 2025.)
- Drugs for which the manufacturer could have paid a Medicaid rebate, such as for QMBs, SLMBs, and full dually eligible beneficiaries.
- Drugs that are packaged into the payment amount for an item or service and are not separately payable.
- Drugs that are no longer Part B rebatable drugs. Billing units of these drugs will be excluded 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.

CMS will determine the total number of units for each HCPCS code by identifying claims lines for those codes for dates of service in the calendar quarter after excluding units as described above; this process will be done at least 3 months after the end of a calendar quarter to allow time for claims to be submitted, processed, and finalized.

For 340B billing units, CMS excludes separately payable billing units in claim lines for professional claims with dates of service during 2023 from suppliers that are 340B covered entities. CMS uses NPI numbers, Medicare Provider Numbers or both to identify these suppliers and the claims submitted with those identifiers. CMS proposes to continue this approach for professional claims with dates of service during 2024.

For Medicaid Rebate billing units, CMS proposes to codify its policy of including billing units for Part B rebatable drugs furnished to dual eligibles who do not qualify for cost-sharing assistance (i.e., SLMB Only, Qualified Disabled and Working Individuals (QDWI), and Qualifying Individuals (QI) beneficiaries) in the total number of billing units. CMS considered excluding all units furnished to dually eligible individuals but rejected the policy because too many billing units would be excluded.

CMS does not propose to establish a policy on treatment of Medicare Advantage units in the calculation of Part B inflation rebates because of significant operational complexities. It may establish policy on this issue in future rulemaking.

New Policy for Units Subject to Discarded Drug Refunds. CMS proposes a new policy to address the interaction between Part B inflation rebates and billing units of discarded drugs. It proposes to exclude billing units of discarded drugs that are subject to discarded drug refunds from Part B inflation rebates. Specifically, it proposes to exclude billing units of a refundable single-dose container or single-use package drug subject to discarded drug refunds, from the calculation of rebate amounts during the reconciliation process except for calendar quarters in calendar year 2023. For calendar quarters in calendar year 2023, CMS proposes to exclude billing units of a refundable drug subject to discarded drug refunds from the calculation of the rebate amount before the agency issues the Rebate Report to the manufacturer.

iv. Adjustments for Changes to Billing and Payment Codes

CMS proposes to codify policies under section 50.9 of the Part B Revised Guidance for instances where a drug's code dose description changes. It would apply a conversion factor and use the benchmark quarter's payment amount, the payment amount benchmark quarter, and the benchmark quarter CPI-U of the prior billing and payment code to calculate the per unit Part B rebate amount. The preamble contains an example.

e. Reducing the Rebate Amount for Part B Rebatable Drugs in Shortage and When There Is a Severe Supply Chain Disruption (§§427.400 through 427.402)

i. Reducing the Rebate Amount for Part B Rebatable Drugs Currently in Shortage

By statute, CMS must reduce or waive the rebate amount owed by a manufacturer for a Part B rebatable drug with respect to a calendar quarter in two cases:

- When a Part B rebatable drug is described as currently in shortage on a shortage list in effect under section 506E of the FD&C Act at any point during the applicable period; and
- When CMS determines there is a severe supply chain disruption during the applicable quarter for a Part B rebatable biosimilar biological product.

Under the Part B Revised Guidance, CMS reduces the total rebate amount for a Part B rebatable drug that is currently in shortage based on the length of time the drug is in shortage during a calendar quarter and decreases the amount of the reduction over time. It applies the same policy for severe drug supply chain disruptions. Table 50 of the proposed rule (reproduced below) summarizes policies on reducing the total rebate amount owed by a manufacturer in each of these cases.

	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	
First four consecutive calendar quarters	25%	75%	75%
Second four consecutive calendar quarters	10%	50%	75%
Subsequent calendar quarters	2%	25%	Not applicable

As proposed, the rebate amount owed would not be fully waived. CMS is concerned about incentivizing manufacturers to delay taking appropriate steps to resolve a drug shortage or severe

supply chain disruption to avoid an obligation to pay rebates, and it believes the relief it proposes is adequate.

To calculate the reduced total rebate amount for a Part B rebatable drug currently in shortage, CMS proposes to use the following formula: Reduced Total Rebate Amount = total rebate amount multiplied by (1 minus applicable percent reduction) multiplied by (percentage of time drug was currently in shortage during the calendar quarter) added to the total rebate amount multiplied by (1 minus percentage of time drug was currently in shortage during the calendar quarter).

Because drugs and biologicals on the FDA shortage lists are maintained at the NDC-10 level, and Part B drug inflation rebates are calculated at the HCPCS level, CMS proposes if any NDC-10 assigned to the HCPCS code(s) is currently in shortage, CMS would apply the rebate reduction to all of the NDCs under the relevant HCPCS code(s).

CMS proposes to count the number of days the Part B rebatable drug is currently in shortage in a calendar quarter and divide by the total number of days in that calendar quarter.

If the drug's status changes from currently in shortage to resolved during a calendar quarter and then changes to currently in shortage during one or more of the subsequent three calendar quarters, CMS proposes to apply the shortage reduction as if there was a continuous shortage beginning with the quarter in which the drug has re-entered a shortage and move to the percent reduction applicable for the second four consecutive quarters. When the status of the drug changes from currently in shortage to resolved and either remains in resolved status or is removed from the list for at least 4 full consecutive calendar quarters and then subsequently reemerges on a shortage list, CMS would treat the subsequent shortage as a new shortage and would apply the applicable percent reduction for the first 4 consecutive calendar quarters.

ii. Reducing the Rebate Amount for Part B Rebatable Biosimilars When There is a Severe Supply Chain Disruption

CMS proposes to codify the provisions of section 50.12 of the Part B Revised Guidance. If CMS determines there is a severe supply chain disruption for a biosimilar during the calendar quarter caused by a natural disaster or other unique or unexpected event, it would provide a time-limited standard reduction of 75 percent in the total rebate amount for the Part B rebatable biosimilar. Manufacturers would have to submit a rebate reduction request that would specify each NDC-11 and HCPCS code to which the request applies. The request would have to be submitted within 60 days of the first day of the natural disaster/other unique or unexpected event.

If CMS grants the request for an NDC-11, CMS proposes that the rebate reduction would apply to all the NDC-11s under the relevant HCPCS code, and that the disruption would be deemed to apply to the calendar quarter involved and the three succeeding calendar quarters. The total rebate amount owed by a manufacturer would be reduced by 75 percent for those four calendar quarters, and the manufacturer could request a second four-calendar quarter reduction (i.e., the fifth through eighth consecutive quarters) if it provides new supporting documentation.

If there are multiple events causing severe supply chain disruptions during the same four calendar quarters for the same Part B rebatable biosimilar, and the manufacturer submits multiple rebate reduction requests for the same product, CMS will grant only one rebate reduction for that Part B rebatable biosimilar for those 4 consecutive calendar quarters.

If a Part B rebatable biosimilar that is "currently in shortage" experiences a severe supply chain disruption, the manufacturer may request a severe supply chain disruption rebate reduction. If granted, CMS will apply a 75 percent reduction to the rebate amount for the duration of four consecutive calendar quarters (i.e., the quarter in which the event that caused the severe supply chain disruption occurred and the three subsequent calendar quarters) in lieu of the reduction under the shortages policy.

CMS proposes to review rebate reduction requests and rebate reduction extension requests within 60 calendar days of receipt of all documentation, beginning with the October 1, 2024 calendar quarter. Rebate reduction requests and rebate reduction extension requests will be accepted upon completion of the Paperwork Reduction Act (PRA) process. Information in manufacturer requests would be kept confidential if allowed under law; information indicated as a trade secret or confidential commercial or financial information would be protected from disclosure if CMS determines the information meets the requirements set forth under Exemption 3 or 4, or both, of the Freedom of Information Act (FOIA).

f. Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments (§§427.500 through 427.505)

CMS proposes to codify the definition of the term "date of receipt" from section 60.1 of the Part B Revised Guidance. It would mean the calendar day following the day in which the Rebate Report was posted via the TPA's online portal; for example, a Rebate Report posted to the portal on June 30, 2026 would have a date of receipt of July 1, 2026, which would also be day one of the 30-calendar-day payment period.

i. Reports of Rebate Amounts and Suggestion of Error

CMS proposes to provide manufacturers of a Part B rebatable drug a Preliminary Rebate Report, which would indicate the preliminary rebate amount, followed by a Rebate Report to all manufacturers of a Part B rebatable drug, even if the amount due is $0. The Rebate Report is also the invoice for the rebate amount due, if any, for each NDC that has been assigned to a billing and payment code for a product determined to be a Part B rebatable drug for the applicable calendar quarter. Payment would be due 30 days after receipt of the Rebate Report.

All rebate amounts would be subject to reconciliation. One regular reconciliation would be conducted within 12 months of the Rebate Report to determine whether the rebate amount should be adjusted due to updated claims and payment data used in the calculation of the rebate amount. Payment would be due for any outstanding rebate amount 30 days after receipt of a report with a reconciled rebate amount.

The Preliminary Rebate Report would include (i) the NDC(s) and billing and payment code for the Part B rebatable drug, (ii) the total number of billing units; (iii) the payment amount in the payment amount benchmark quarter; (iv) the applicable calendar quarter specified amount; (v) the applicable benchmark period and rebate period CPI-Us; (vi) the inflation-adjusted payment amount; (vii) the amount, if any, by which the specified amount exceeds the inflation-adjusted payment amount for the Part B rebatable drug for the applicable calendar quarter; (viii) any applied reduction for shortages or severe supply chain disruption; and (ix) the rebate amount due.

Manufacturers would be able to submit to CMS a "Suggestion of Error" within 10 calendar days after receipt of the Preliminary Rebate Report. Comments on the initial guidance argued for more than 10 days to review the report, but CMS believes 10 days is sufficient. These submissions are limited to mathematical errors because the statute waives judicial review of the determination of units, whether a drug is a Part B rebatable drug, and the calculation of the rebate amount.

Rebate Reports would be provided to manufacturers no later than 6 months after the end of the applicable calendar quarter; they would include similar information as the Preliminary Rebate Report and would include recalculations based on Suggestion of Error submissions.

ii. Reconciliation of a Rebate Amount

CMS proposes policies to reconcile the rebate amount, which would involve recalculating the rebate amount for an applicable calendar quarter at regular intervals to include updated information about key data elements included in the calculation of the rebate amount, including total units; the payment amount in the payment amount quarter; and any applied reductions for drug shortages or severe supply chain disruptions.

A report of a reconciled rebate amount would identify the difference between the rebate amount due as specified on the Rebate Report and the reconciled rebate amount. In order to prevent duplicate payments, only net rebate amounts due would be collected upon reconciliation; CMS would refund overpayments.

CMS proposes a 12-month reconciliation period for the Part B rebate program, which it believes provides sufficient time to capture the majority of data updates. CMS does not believe a second or longer restatement process is needed for Part B rebatable drugs because the ASP and claims run-out periods correspond with sufficient claims run-out and ASP restatement timing for Part B.

The preamble provides great detail on the reconciliation process. Of note, CMS would provide the manufacturer information about the preliminary reconciliation of the rebate amount at least one month before issuing the reconciled rebate amount, and manufacturers could, within 10 days of receipt of the preliminary reconciliation, suggest to CMS that the preliminary rebate amount contains mathematical errors. The reconciled rebate amount would be provided to the manufacturer 12 months after the Rebate Report was issued for an applicable calendar quarter.

CMS also reserves the right to recalculate a rebate amount if the agency (i) identifies a mathematical or other error in the Rebate Report or (ii) determines that information used to

calculate the rebate amount was inaccurate due to manufacturer misreporting. It also clarifies that it retains the discretion not to initiate recalculation of the rebate amount in these situations, which are outside of the regular reconciliation process. An agency error must be identified within 3 years of the date of receipt of the reconciled rebate amount for the applicable calendar quarter; otherwise, recalculation due to agency error would not be available. The 3-year limit would not apply if the manufacturer misreported information.

iii. Rebate Report for Applicable Calendar Quarters in 2023 and 2024

CMS proposes to consolidate the Preliminary Rebate Reports and Rebate Reports for 2023 and 2024 into two reports: one report for the four applicable calendar quarters in 2023 and one report for the four applicable calendar quarters in 2024. It also proposes to provide 30 calendar days for manufacturers to submit Suggestion of Errors with respect to the Preliminary Rebate Reports.

g. Enforcement of Manufacturer Payment of Rebate Amounts (§427.600)

A manufacturer could be subject to a CMP if it fails to pay a rebate amount due by any payment deadline for (i) a Rebate Report, (ii) a reconciled rebate amount greater than the rebate amount in the Rebate Report, or (iii) in calendar years 2023 and 2024, a Rebate Report and a reconciled rebate amount greater than the amount reflected in the Rebate Report, if applicable, for the applicable calendar quarters. The CMP would be in addition to the rebate amount owed.

CMS proposes to send written notice of its decision to impose a CMP, which would include the basis for the determination, the basis for the penalty, the amount of the penalty, the date the penalty is due, the manufacturer's right to a hearing, and information about where to file the request for a hearing.

The amount of the CMP would be 125 percent of the rebate amount for the applicable calendar quarter due at the applicable payment deadline. The CMP would be calculated based on the outstanding rebate amount due at the payment deadline, which is 30 calendar days after the date of receipt of a Rebate Report that contains any rebate amount due.

The existing appeals procedures for CMPs would apply to CMPs imposed under the Part B Drug Inflation Rebate Program. However, the scope of appeals would be limited to determinations relating to whether the rebate payment was made by the payment deadline and the calculation of the penalty amount. Judicial review of specific data inputs or calculations related to the underlying Rebate Report and reconciliation is precluded under section 1847A(i)(8) of the Act.

Once assessed, a CMP remains in effect even if the outstanding rebate amount is paid. CMPs would be assessed before the next reconciliation process, and they would have to be paid in full within 60 days of the later of the date of the CMP notice or, if the determination is appealed, the date of the final decision of the Departmental Appeal Board upholding the CMP, in whole or in part.

If a reconciled rebate amount results in an increase to the rebate amount due, CMS could impose a separate civil money penalty for the increase to the rebate amount due for the applicable

quarter. CMS would not impose another CMP if the reconciled rebate amount results in a reduction to the rebate amount due.

CMS clarifies that payment of the CMP does not eliminate or postpone the requirement to pay any outstanding rebate amount due, including any rebate amount due following a reconciliation. Readers are cautioned that CMS may refer manufacturers to the Department of Justice, Department of the Treasury, and/or the Department of Health and Human Services Office of Inspector General for further review and investigation.

If a manufacturer declares bankruptcy and, as a result of the bankruptcy, fails to pay either the full rebate amount owed or the total sum of CMPs imposed, the government would reserve the right to file a proof of claim with the bankruptcy court to recover the unpaid rebate amount and/or CMPs owed by the manufacturer.

h. Severability (§427.10)

CMS proposes to add a severability provision. If any provision of part 427 were to be held invalid or unenforceable by its terms, or as applied to any person or circumstance, those provisions would be severable from part 427. Thus, the invalidity or unenforceability of those invalid provisions would not affect the remainder of part 427 or any other part of the Medicare regulations or the application of such provision to other persons not similarly situated or to other dissimilar circumstances.

CMS intends that each of the provisions of Part B Drug Inflation Rebate Program would be a distinct, severable provision, and would not affect similar provisions in the Part D Drug Inflation Rebate Program.

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

a. Definitions (§428.20)

CMS proposes to codify definitions of terms consistent with the meanings given in section 1860D-14B of the Act or established in the revised Medicare Part D Drug Inflation Rebate Guidance (referred to in this summary as the Part D Revised Guidance);[52] it also proposes new definitions based on policies described in the proposed rule.

CMS would give the term "manufacturer" the definition applied under the Medicaid Drug Rebate Program (MDRP). CMS intends that manufacturer identification in the Medicare Part D Inflation Rebate Program, including communications and rebate liability, will be consistent with the policies and practices adopted under §447.502 for purposes of manufacturer obligations under the MDRP.

[52] Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Revised Guidance, Implementation of Section 1860D-14B of the Social Security Act; December 14, 2023. https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-revised-guidance.pdf

b. Determination of Part D Rebatable Drugs (§§428.100 through 428.101)

i. Identification of Part D Rebatable Drugs

A Part D rebatable drug is a covered Part D drug that, as of the first day of the applicable period involved, is a brand name drug, a biological product (including a biosimilar), or a generic drug that meets certain sole source criteria. CMS proposes to codify the policy in section 30 of the Part D Revised Guidance to use specified FDA resources, such as the "Orange Book"[53] and NDC Directory, to determine whether a generic drug meets the definition of a Part D rebatable drug. CMS proposes to clarify it that considers historical information from NDC Directory files, such as discontinued, delisted, and expired listings. CMS would determine whether a covered Part D generic drug meets the definition of a Part D rebatable drug based on the status of the drug on the first day of the applicable period. CMS understands that the status of the drug could change during an applicable period.

CMS also proposes to define the term "individual who uses such a drug or biological" to mean a unique Medicare Part D beneficiary who was dispensed the Part D drug or biological that was covered by their Part D plan sponsor during the applicable period, identified using Prescription Drug Event (PDE) data with dates of service during the applicable period and with gross covered prescription drug costs (as defined in §423.308) greater than zero.

ii. Drugs and Biologicals with Average Annual Total Cost Under Part D Below the Applicable Threshold

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 an applicable period per individual who uses such a drug or biological product is less than $100 per year, as adjusted for inflation by CPI-U for each subsequent applicable period. CMS proposes to codify policies in section 30.2 of the Part D Revised Guidance to identify drugs and biologicals for purposes of this exclusion. It intends to calculate the average annual total cost based on gross covered drug costs for the Part D rebatable drug at the NDC-9 level, using PDE data with gross covered drug costs greater than zero that are available for the drug with dates of service during that applicable period.

c. Determination of the Rebate Amount for Part D Rebatable Drugs (§§428.200 through 428.204)

i. Calculation of the Total Rebate Amount To Be Paid by Manufacturers

CMS proposes to codify the rebate calculation methodology described in section 40 of the Part D Revised Guidance, which provides that the total Part D drug inflation rebate amount is equal to the per unit Part D drug inflation rebate amount multiplied by the total number of units of a Part D rebatable drug dispensed under Part D and covered by Part D plan sponsors. The Part D drug

[53] FDA Orange Book: https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-productstherapeuticequivalence-evaluations-orange-book.

inflation rebate amount would be reduced in the case of shortages or a severe disruption in the supply chain of the drug or biological. It could also be reduced under the reconciliation process.

In the case of a new formulation of a Part D rebatable drug (i.e., one that is a line extension of a Part D rebatable drug that is an oral solid dosage form), CMS proposes that the total Part D drug inflation rebate amount is equal to the per unit Part D drug inflation rebate amount for the initial drug divided by the annual manufacturer price (AnMP) for that initial drug for the applicable period.

Part D rebatable drugs that are missing average manufacturer price (AMP) data for the entire duration of the applicable period would be excluded from the calculation of the total rebate amount. This can occur where a Part D rebatable drug is marketed by a manufacturer that is not required to report pricing and drug product data under the MDRP, which means the manufacturer does not currently report information needed for CMS to calculate Part D drug inflation rebates. CMS clarifies that this proposed exclusion relates only to the calculation of the rebate amount; it does not affect the determination of whether a drug or biological meets the definition of a Part D rebatable drug. **It welcomes comment** on how to address this issue.

ii. Calculation of the Per Unit Part D Drug Rebate Amount

The per unit Part D drug inflation rebate amount would be calculated by determining the amount by which the AnMP for a Part D rebatable drug exceeds the inflation-adjusted payment amount for such drug for the applicable period. To do this, CMS must calculate the AnMP for the drug, identify the payment amount benchmark period and calculate the benchmark period manufacturer price for the drug, identify the benchmark period CPI-U, and calculate the inflation-adjusted payment amount for the drug.

(1) Calculation of the AnMP for the Applicable Period

CMS proposes to use the AMP reported by manufacturer to the Medicaid Drug Programs system for each calendar quarter of the applicable period, as well as the manufacturer's total number of units that are used to calculate the monthly average manufacturer price under the MDRP for each Part D rebatable drug for each month of the applicable period. The AnMP for a Part D rebatable drug for an applicable period equals the sum of the products of (1) the AMP for the Part D rebatable drug reported for each calendar quarter of the applicable period, and (2) the total units of such drug reported for each of the corresponding calendar quarters of the applicable period divided by the total units of the Part D rebatable drug reported for the 4 calendar quarters in the applicable period.

The first applicable period for a Part D rebatable drug would be the earliest applicable period that follows the payment amount benchmark period.

(2) Identification of the Payment Amount Benchmark Period

CMS proposes to identify the payment amount benchmark period for a Part D rebatable drug as follows:

Date of FDA License/Approval	Payment Amount Benchmark Period
On or before October 1, 2021	January 1, 2021 through September 30, 2021
After October 1, 2021	The first calendar year beginning after the day on which the drug was first marketed
Special Rules	
Drugs first approved or licensed on or before October 1, 2021 that lack AMP data for the payment amount benchmark period of January 1, 2021, through September 30, 2021 because they were not marketed or sold	The first calendar year in which such drug has at least one quarter of AMP reported, but no earlier than calendar year 2021
Drugs first approved or licensed after October 1, 2021 that lack AMP data for the payment amount benchmark period because they were not marketed or sold	The first calendar year in which such drug has at least one quarter of AMP reported

For drugs lacking AMP data during the payment amount benchmark period, CMS would look to the first calendar year beginning after the drug's first marketed date and if no AMP was reported to the MDRP for such NDC-9 for that 4-quarter period, CMS would then identify the payment amount benchmark period as the first calendar year in which such drug has at least one quarter of AMP reported.

CMS had established a policy to prevent manufacturers from resetting the payment amount benchmark period (and therefore the benchmark period manufacturer price) by obtaining a new NDC-9 for the Part D rebatable drug; it would use the benchmark period manufacturer price of the earliest NDC-9 of the Part D rebatable drug. However, the policy is not operationally feasible. **CMS seeks comments** on the following alternative policies for calculating the benchmark period manufacturer price when AMP is missing:

- If a new NDC-9 of an existing Part D rebatable drug is reported to the MDRP, CMS would calculate the benchmark period manufacturer price for such NDC-9 using the base date AMP reported to the MDRP by a manufacturer for the Part D rebatable drug, if that base date AMP was reported for a calendar quarter that overlaps with the applicable payment amount benchmark period (i.e., the time periods shown in the first two rows of the table above) for that Part D rebatable drug.
- In cases where the manufacturer did not report AMP for the Part D rebatable drug to the MDRP for the applicable payment amount benchmark period but AMP data are available either for the NDC-9 or for another NDC-9 within the same dosage form and strength, require the manufacturers to submit to CMS AMP data for that drug for the applicable payment amount benchmark period.
- CMS would use a reasonable proxy metric to calculate the benchmark period manufacturer price for a new NDC-9 of an existing Part D rebatable drug that lacks AMP data for the applicable payment amount benchmark period.

Comment is also sought on other policies that CMS should consider to prevent manufacturers from inappropriately resetting the payment amount benchmark period by obtaining a new NDC-9

for an existing Part D rebatable drug. If finalized, CMS would apply the policies described above to rebate calculations beginning with the applicable period that began on October 1, 2022.

Where a Part D rebatable drug is no longer a selected drug under the IRA Drug Price Negotiation Program, CMS proposes that the payment amount benchmark period will be reset as the last calendar year of the price applicability period for the selected drug.

(3) Calculation of the Benchmark Period Manufacturer Price

As noted previously, CMS proposes to use the AMP reported by manufacturers to the Medicaid Drug Programs system for each calendar quarter of the applicable period, as well as the manufacturer's total number of units that are used to calculate the monthly average manufacturer price under the MDRP for each Part D rebatable drug for each month of the payment amount benchmark period. The benchmark period manufacturer price is the sum of the products of (1) the AMP for the Part D rebatable drug reported for each calendar quarter of the payment amount benchmark period, and (2) the total units reported for each of the corresponding calendar quarters of the payment amount benchmark period divided by the total units of the Part D rebatable drug reported for the 3 calendar quarters in the payment amount benchmark period.

(4) Identification of the Benchmark Period CPI-U

CMS proposes that the benchmark period CPI-U for a Part D rebatable drug first approved or licensed by the FDA on or before October 1, 2021, would be the CPI-U for January 2021. For a subsequently approved drug, the benchmark period CPI-U would be the CPI-U for January of the first calendar year beginning after the drug's first marketed date.

In the case of a Part D rebatable drug first licensed or approved on or before October 1, 2021, for which there are no quarters during the period beginning on January 1, 2021, and ending on September 30, 2021, for which AMP has been reported to the MDRP, the benchmark period CPI-U would be the CPI-U for January of the calendar year in which the drug has at least one quarter of AMP reported. For a subsequently approved drug for which there are no quarters during the first calendar year beginning after the drug's first marketed date for which AMP has been reported to the MDRP, the benchmark period CPI-U would be the CPI-U for January of the calendar year in which such drug has at least one quarter of AMP reported.

(5) Calculation of the Inflation-Adjusted Payment Amount

CMS proposes to calculate the inflation-adjusted payment amount for a Part D rebatable drug by dividing the applicable period CPI-U by the benchmark period CPI-U and then multiplying the quotient by the benchmark period manufacturer price.

(6) Situations in which Manufacturers Do Not Report Units under Section 1927(b)(3)(A)(iv)

CMS proposes to codify the policy in section 40.1.2 of the Part D Revised Guidance for cases where there are one or more quarter(s) in the payment amount benchmark period or applicable period for which a manufacturer has not reported its total number of units used to calculate the

monthly average manufacturer price under the MDRP for a Part D rebatable drug but has reported AMP to the Medicaid Drug Programs system. In these cases, CMS would calculate the benchmark period manufacturer price or AnMP, as applicable, using data only from quarter(s) with those reported units.

Additionally, if there are no quarters of the payment amount benchmark period or applicable period for which a manufacturer has reported units, but the manufacturer has reported AMP for at least one quarter of the period, CMS would use the average of the AMP over the calendar quarters of the payment amount benchmark period or applicable period for which AMP is reported to calculate the benchmark period manufacturer price or AnMP, respectively.

iii. Determination of the Total Number of Units Dispensed Under Part D

CMS proposes to codify policies in the Part D Revised Guidance to determine the total number of units of each Part D rebatable drug dispensed under Part D and covered by Part D sponsors based on information reported to CMS by Part D plan sponsors on the Part D PDE records for the 12-month applicable period. The total number of units would be determined from the quantity dispensed field on the PDE record for each Part D rebatable drug with gross covered prescription drug costs greater than zero, and CMS proposes to crosswalk the information from the PDE record to a drug database that provides the unit type for an NDC.

CMS reviews PDE records for outliers in the quantity dispensed field of Part D PDE records as part of the annual reconciliation process between CMS and plan sponsors. The agency intends to rely on this process to resolve outliers that would otherwise impact the Part D drug inflation rebate amount calculated. Due to timing differences between this annual payment reconciliation process between the agency and plan sponsors and the issuance of Part D Rebate Reports, the Rebate Report will not reflect the resolution of unit outliers identified through the Part D payment reconciliation process. However, CMS intends to conduct a reconciliation of the rebate amount with additional PDE run-out, and the reconciled rebate amounts will reflect the resolution of any unit outliers corrected by Part D plan sponsors through the Part D payment reconciliation process.

CMS would subtract from the total number of units any units of a generic drug dispensed on or after the date that the generic drug no longer meets the definition of a Part D rebatable drug, as well as units acquired through the 340B Program. **Comment is sought** on whether other units should be excluded from the calculation of the rebate amount.

(1) Removal of Units When a Generic Drug Is No Longer a Part D Rebatable Drug

Determinations of whether a generic drug no longer meets the definition of a Part D rebatable drug would be done monthly using the FDA Orange Book and the NDC directory to determine whether a therapeutically equivalent drug was marketed.

(2) Exclusion of 340B Acquired Units from Part D Rebatable Drug Requirements

Per the statute, beginning with plan year 2026, CMS must exclude units for which manufacturers provided a 340B discount from the total number of units for a Part D rebatable drug with respect to an applicable period. CMS does not have access to data on which units dispensed under Part D and covered by Part D plan sponsors were purchased under the 340B Program. Thus, it proposes to estimate the number of 340B units that will be excluded. The estimation would be based on a calculated percentage that reflects the portion of 340B purchasing relative to total sales. CMS would set the percentage, which it refers to as the "estimation percentage," to equal the total number of units purchased by covered entities under the 340B Program for an NDC-9, divided by the total units sold of that NDC-9.

CMS would use data from HRSA's Prime Vendor Program (PVP) to identify the total number of units purchased under the 340B Program for an NDC-9, which would be the numerator of the estimation percentage. Recognizing that not all covered entities use the PVP, **CMS seeks comment** on how to account for potential underreporting. CMS proposes to use the total number of units that are used to calculate the monthly AMP and which manufacturers are required to report to CMS under the MDRB for each covered outpatient drug to determine the denominator of the estimation percentage.

The agency acknowledges that the proposed numerator represents 340B units dispensed in multiple settings, whereas the denominator represents units typically dispensed only in the retail community pharmacy setting. **CMS seeks evidence** that demonstrates how 340B dispensing rates differ between the retail community pharmacy setting versus multiple settings; it may consider adjusting the estimation percentage to reflect variation between the percentage of 340B units dispensed in multiple settings and the percentage of 340B units dispensed in only the retail community pharmacy setting. **Comments are also sought** 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.

Additional Comment Solicitations. **CMS seeks comment** on the following policies for excluding 340B units from Part D rebatable drug requirements:

- The establishment of a Part D claims repository to identify 340B units. Covered entities would provide to CMS certain data elements from 340B-identified Part D claims for submission to the repository. Feedback is sought on how CMS could confirm the completeness and accuracy of each submission and on methods to review and ensure the accuracy of reported data.
- Require covered entities to enroll in a repository and submit certain data elements from 340B-identified claims for all covered Part D drugs billed to Medicare to the repository. The elements would include date of service, the prescription or service reference number, the fill number, and the dispensing pharmacy NPI.
- Require covered entities to submit the data elements within 3 months of the end of a calendar quarter, and providing covered entities additional time to submit data to reflect a revision to the 340B determination of claims with dates of service throughout an applicable period.

iv. Treatment of New Formulations of Part D Rebatable Drugs

To determine the total rebate amount to be paid by manufacturers of new formulations of Part D rebatable drugs, CMS proposes to take the greater of (1) the total rebate amount for the applicable period for the Part D rebatable drug that is a line extension, or (2) the alternative total rebate amount. This proposal differs from the policy in the Part D Revised Guidance that compared the *per unit* rebate amount to the alternative *per unit* rebate amount. CMS proposes to compare the *total* rebate amount calculated to the alternative *total* rebate amount.

The agency would first determine the inflation rebate amount for the new formulation of the Part D rebatable drug and then it would calculate an alternative inflation rebate amount consistent with the formula applied under the MDRP (under section 1927(c)(2)(C) of the Act for line extension drugs under Medicaid). To identify the initial drug for the new formulation, CMS would use information from the Medicaid Drug Program system and identify new formulations based on manufacturer reporting of drugs as new formulations and related pricing and product data in that system.

CMS proposes to codify its policy in section 40.4 of the Part D Revised Guidance to calculate the alternative inflation rebate amount. The agency would determine an inflation rebate amount ratio for the initial drug identified by the manufacturer by dividing the inflation rebate amount for that initial drug for the applicable period by the AnMP for that initial drug for the applicable period.

d. Reducing the Rebate Amount for Part D Rebatable Drugs in Shortage and When There Is a Severe Supply Chain Disruption or Likely Shortage (§§428.300 through 428.303)

By statute, CMS must reduce or waive the rebate amount owed by a manufacturer for a Part D rebatable drug with respect to an applicable period in three cases:

- When a Part D rebatable drug is described as currently in shortage on a shortage list in effect under section 506E of the FD&C Act at any point during the applicable period;
- 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
- 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 such shortage list during a subsequent applicable period.

Under the Part D Revised Guidance, CMS reduces the total rebate amount for a Part D rebatable drug that is currently in shortage based on the length of time the drug is in shortage during an applicable period and decreases the amount of the reduction over time. Table 51 of the proposed rule (reproduced below) summarizes proposed policies on reducing the total rebate amount owed by a manufacturer in each of these cases.

	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 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

i. Reducing the Rebate Amount for Part D Rebatable Drugs Currently in Shortage

As proposed, the rebate amount owed would not be fully waived. CMS is concerned about incentivizing manufacturers to delay taking appropriate steps to resolve a drug shortage or severe supply chain disruption to avoid an obligation to pay rebates, and it believes the relief it proposes to codify is adequate. To calculate the reduced total rebate amount for a Part D rebatable drug currently in shortage, CMS proposes to use the following formula:

Reduced Total Rebate Amount = total rebate amount *multiplied by* (1 minus applicable percent reduction) *multiplied by* (percentage of time drug was currently in shortage during the applicable period) *added to* the total rebate amount *multiplied by* (1 minus percentage of time drug was currently in shortage during the applicable period).

To determine the percentage of time a Part D rebatable drug was currently in shortage during the applicable period, CMS proposes to count the number of days the drug is currently in shortage in an applicable period and divide by the total number of days in that applicable period.

If the Part D rebatable drug changes from currently in shortage to resolved during an applicable period and then changes to currently in shortage in the next applicable period, CMS proposes to apply the shortage reduction as if there was a continuous shortage and move to the percent reduction applicable for the second applicable period. When the status of the drug changes from currently in shortage to resolved and either remains in resolved status or is removed from the list for at least one applicable period and then subsequently reemerges on a shortage list, CMS would treat the subsequent shortage as a new shortage and would apply the applicable percent reduction for the first applicable period.

ii. Reducing the Rebate Amount for Generic Part D Rebatable Drugs and Biosimilars When There Is a Severe Supply Chain Disruption

CMS proposes to codify the provisions of section 40.5.2 of the Part D Revised Guidance. If CMS determines there is a severe supply chain disruption for a generic Part D rebatable drug or biosimilar during an applicable period caused by a natural disaster or other unique or unexpected event, it would provide a time-limited standard reduction of 75 percent to the total rebate amount for the Part D rebatable drug or biosimilar. Manufacturers would have to submit a rebate reduction request that would specify each NDC-11 to which the request applies. The request would have to be submitted within 60 days of the first day of the natural disaster/other unique or unexpected event.

If CMS grants the request for an NDC-11, CMS proposes that the rebate reduction would apply to the entire generic Part D rebatable drug or biosimilar at the NDC-9 level, and that the disruption would be deemed to apply to the applicable period in which the event that caused the severe supply chain disruption occurred or began, or the following applicable period if the request is submitted less than 60 calendar days before the end of an applicable period. The total rebate amount owed by a manufacturer would be reduced by 75 percent for the applicable period.

The manufacturer could request a second consecutive applicable period reduction if it provides new supporting documentation; that rebate reduction extension request and any new supporting documentation would have to be submitted at least 60 calendar days before the start of that second applicable period. A manufacturer could only receive one extension of the rebate reduction per generic Part D rebatable drug or biosimilar.

If there are multiple events causing severe supply chain disruptions during the same applicable period for the same Part D rebatable generic drug or biosimilar, and the manufacturer submits multiple rebate reduction requests for the same product, CMS will grant only one rebate reduction for that Part D rebatable generic or biosimilar for the applicable period.

If a Part D rebatable generic drug or biosimilar that is "currently in shortage" experiences a severe supply chain disruption, the manufacturer may request a severe supply chain disruption rebate reduction. If granted, CMS would apply a 75 percent reduction in the rebate amount to the entire applicable period in lieu of the reduction under the shortages policy.

CMS proposes to review rebate reduction requests and rebate reduction extension requests within 60 calendar days of receipt of all documentation, beginning with the applicable period that begins on October 1, 2024. Rebate reduction requests and rebate reduction extension requests will be accepted upon completion of the PRA process. Information in manufacturer requests would be kept confidential if allowed under law; information indicated as a trade secret or confidential commercial or financial information would be protected from disclosure if CMS determines the information meets the requirements set forth under Exemption 3 or 4, or both, of the FOIA.

iii. Reducing the Rebate Amount for Generic Part D Rebatable Drugs Likely To Be in Shortage

CMS proposes to codify the provisions of section 40.5.3 of the Part D Revised Guidance to provide a time-limited standard reduction of 75 percent to the total rebate amount for a generic Part D rebatable drug that is likely to be in shortage.

The manufacturer would have to submit a written request to CMS that demonstrates the generic Part D rebatable drug is likely to be in shortage, the manufacturer is taking actions to avoid the potential drug shortage, and the reduction of the rebate amount would reduce the likelihood of the drug appearing on an FDA shortage list. The rebate reduction request would have to be submitted to CMS before the start of the next applicable period in which the manufacturer believes the generic Part D rebatable drug is likely to be in shortage. If the rebate reduction request is granted, CMS would reduce the total rebate amount owed by a manufacturer by 75 percent for the manufacturer's generic Part D rebatable drug for the applicable period in which the request was submitted or the following applicable period, depending on the timing of the submission of the request.

Similar requirements established for the cases described above apply for a rebate reduction request for a generic Part D rebatable drug that is likely to be in shortage, including with respect to the timing for the submission of the request, the agency's proposed period to review requests, the ability to request only one extension of the request, a prohibition on multiple requests for the same generic drug, and the confidentiality of information submitted with the request.

e. Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments (§§428.400 through 428.405)

CMS proposes to codify the definition of the term "date of receipt" from section 50.1 of the Part D Revised Guidance. It would mean the calendar day following the day in which a report of a rebate amount is made available to the manufacturer of a Part D rebatable drug by CMS. For example, if CMS issues a Rebate Report on June 30, 2026, then July 1, 2026, will be the date of receipt and day one of the 30-calendar-day payment period.

i. Reports of Rebate Amounts and Suggestion of Error

CMS proposes to provide manufacturers a Preliminary Rebate Report, which would indicate the preliminary rebate amount, followed by a Rebate Report to all manufacturers of a Part D rebatable drug, even if the amount due is $0. The Rebate Report is also the invoice for the rebate amount due, if any, for each Part D rebatable drug for the applicable period. Payment would be due 30 days after receipt of the Rebate Report.

All rebate amounts would be subject to two regular reconciliations, which would occur 12 months and 36 months after the Rebate Report is issued to determine whether the rebate amount should be adjusted due to updated claims and drug pricing data used in the calculation of the rebate amount. Payment would be due for any outstanding rebate amount 30 days after receipt of a report with a reconciled rebate amount.

The Preliminary Rebate Report would be provided to manufacturers at least one month before the issuance of the Rebate Report for an applicable period. CMS says this would be roughly 8 months after the end of the applicable period unless otherwise specified. Information in a Preliminary Rebate Report would include (i) the NDC(s) for the Part D rebatable drug, (ii) the total number of billing units for the applicable period; (iii) the benchmark period manufacturer price; (iv) the AnMP for the Part D rebatable drug for the applicable period; (v) the applicable benchmark period and applicable period CPI-Us; (vi) the inflation-adjusted payment amount; (vii) the amount, if any, of the excess AnMP for the Part D rebatable drug for the applicable period; (viii) any applied reduction for shortages or severe supply chain disruption; and (ix) the rebate amount due. For new formulations, the information would also include the NDC for the initial drug; the inflation rebate amount ratio for the initial drug; and the alternative rebate amount.

Manufacturers would be able to submit to CMS a "Suggestion of Error" within 10 calendar days after receipt of the Preliminary Rebate Report. These submissions are limited to mathematical errors because the statute waives judicial review of the determination of units, whether a drug is a Part D rebatable drug, and the calculation of the rebate amount. CMS also notes that it is not providing an administrative dispute resolution process.

Rebate Reports would be provided to manufacturers no later than 9 months after the end of the applicable period; they would include the same data elements as the Preliminary Rebate Report and would include recalculations due to errors, including those contained in Suggestion of Error submissions that CMS approved.

The agency may use an online portal administered by a CMS contractor to afford manufacturers the ability to access to their Rebate Report, to submit a Suggestion of Error and to pay a rebate amount due.

ii. Reconciliation of a Rebate Amount

CMS proposes policies to reconcile the rebate amount, which would involve recalculating the rebate amount for an applicable period at regular intervals to include updated information about key data elements included in the calculation of the rebate amount, including total units, the benchmark period manufacturer price, the payment amount in the payment amount benchmark period, the AnMP, and updated data on line extension calculations.

A report of a reconciled rebate amount would identify the difference between the rebate amount due as specified on the Rebate Report and the reconciled rebate amount. In order to prevent duplicate payments, only net rebate amounts due would be collected upon reconciliation; CMS would refund overpayments.

CMS proposes two reconciliation periods—the first at 12 months and the second at 36 months—after an applicable period. CMS believes the first reconciliation (with 13 months of claims run-out) would capture a majority of the updates and the second (with 37 months of claims run-out) would capture the rest.

For each reconciliation, CMS proposes to provide the manufacturer information about the preliminary reconciliation of the rebate amount at least one month before issuing the reconciled rebate amount for the applicable period. The preliminary reconciliation would include the same information outlined for the Rebate Report, updated with more recent data. Manufacturers could, within 10 days of receipt of the preliminary reconciliation, suggest to CMS that the preliminary reconciliation of the rebate amount contains a mathematical error.

The reconciled rebate amount would be provided to the manufacturer 12 months and 36 months after the Rebate Report was issued for an applicable period.

CMS also reserves the right to recalculate a rebate amount if the agency (i) identifies a mathematical or other error in the Rebate Report or (ii) determines that information used to calculate the rebate amount was inaccurate due to manufacturer misreporting. If CMS reconciles data due to an instance of agency error or manufacturer misreporting, CMS proposes to limit the scope of the reconciliation to the specific information that is the basis for the reconciliation; it would not update or otherwise revise any other data elements in the Rebate Report or the report of the reconciled rebate amount unless the correction directly impacts additional data fields.

It also clarifies that it retains the discretion not to initiate recalculation of the rebate amount in these situations that are outside of the regular reconciliation process. An agency error must be identified within 5 years of the date of receipt of the reconciled rebate amount for the applicable period; otherwise, recalculation due to agency error would not be available. The 5-year limit would not apply if the manufacturer misreported information.

iii. Rebate Reports for the Applicable Periods Beginning October 1, 2022, and October 1, 2023

CMS proposes to issue a Preliminary Rebate Report for each of these applicable periods no later than December 21, 2025. It also proposes to provide 30 calendar days for manufacturers to submit Suggestion of Errors with respect to the Preliminary Rebate Reports.

Under this approach, there would be 13 months of claims run-out for the Rebate Report for the applicable period beginning October 1, 2022; thus, CMS intends to conduct a single reconciliation 21 months after issuance of the Rebate Report for this applicable period.

For the applicable period beginning October 1, 2023, the rebate amount would be reconciled twice. The first reconciliation would occur 9 months after issuance of the Rebate Report to include 13 months of claims run-out and payment data, and the second would occur 24 months after the first reconciliation and would include 37 months of claims run-out and payment data.

f. Enforcement of Manufacturer Payment of Rebate Amounts (§428.500)

A manufacturer could be subject to a CMP if it fails to pay a rebate amount due by any payment deadline for (i) a Rebate Report, (ii) a reconciled rebate amount greater than the rebate amount in the Rebate Report, or (iii) in calendar years 2023 and 2024, a Rebate Report and a reconciled rebate amount greater than the amount reflected in the Rebate Report, if applicable, for the applicable period. The CMP would be in addition to the rebate amount owed.

CMS proposes to send written notice of its decision to impose a CMP, which would include the basis for the determination, the basis for the penalty, the amount of the penalty, the date the penalty is due, the manufacturer's right to a hearing, and information about where to file the request for a hearing.

CMS proposes that CMPs may be calculated at several points in time associated with missing a payment deadline for the rebate amount due reflected in the Rebate Report or missing a payment deadline associated with any rebate amount determined after a reconciliation to be greater than the amount invoiced in the Rebate Report. The amount of the CMP would be 125 percent of the rebate amount at the applicable payment deadline for the applicable period. The CMP would be calculated based on the outstanding rebate amount due at the payment deadline, which is 30 calendar days after the date of receipt of a Rebate Report that contains any rebate amount due.

Once assessed, a CMP remains in effect even if the outstanding rebate amount is paid. CMS would not modify a CMP from a prior missed payment deadline based on changes to the rebate amount due following reconciliation, including where the rebate amount is reduced following reconciliation. However, a separate CMP could be imposed for the failure by a manufacturer to provide an inflation rebate for the applicable period for the increase to the rebate amount due by reason of reconciliation.

CMPs would be assessed before the next 12- or 36-month reconciliation, and would have to be paid in full within 60 days of the later of (i) the date of the CMP notice or (ii) the date of the final decision of the Departmental Appeal Board upholding the CMP, in whole or in part.

CMS clarifies that payment of the CMP does not eliminate or postpone the requirement to pay any outstanding rebate amount due, including any rebate amount due following a reconciliation. Readers are cautioned that CMS may refer manufacturers to the Department of Justice, Department of the Treasury, and/or the Department of Health and Human Services Office of Inspector General for further review and investigation.

The existing appeals procedures for CMPs would apply to CMPs imposed under both the Part B and Part D Drug Inflation Rebate Programs. However, the scope of appeals would be limited to CMS determinations relating to whether the rebate payment was made by the payment deadline and the calculation of the penalty amount. Judicial review of specific data inputs or calculations related to the underlying Rebate Report and reconciliation is precluded under section 1860D-14B(f) of the Act.

If a manufacturer declares bankruptcy and, as a result of the bankruptcy, fails to pay either the full rebate amount owed or the total sum of civil money penalties imposed, the government would reserve the right to file a proof of claim with the bankruptcy court to recover the unpaid rebate amount and/or civil monetary penalties owed by the manufacturer.

g. Severability (§428.10)

As it did for the Part B Drug Inflation Rebate Program, CMS proposes to add a severability provision for the Part D Drug Inflation Rebate Program. If any provision of part 428 were to be held invalid or unenforceable by its terms, or as applied to any person or circumstance, those provisions would be severable from part 428. Thus, the invalidity or unenforceability of those invalid provisions would not affect the remainder thereof or any other part of the Medicare regulations or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances.

CMS intends that each of the provisions of Part D Drug Inflation Rebate Program would be a distinct, severable provision, and would not affect similar provisions in the Part B Drug Inflation Rebate Program.

J. RFI: Building Upon the MIPS Value Pathways (MVPs) Framework to Improve Ambulatory Specialty Care

1. Background

CMS describes how Medicare beneficiaries are increasingly seeing more specialists more often, while the frequency of seeing their primary care clinicians has remained relatively constant. The Center for Medicare and Medicaid Innovation (CMMI) has created a comprehensive specialty strategy to test models, and as part of that strategy CMMI is considering a model for specialists in ambulatory settings that would use the MVP framework. Participants under the model would not receive a MIPS payment adjustment, but would instead receive a payment adjustment based on (1) a set of clinically relevant MVP measures on which they would be required to report and (2) comparing the participant's final score against a pool of other model participants of the same specialty type and clinical profile who are required to report on the same clinically relevant MVP measures.

Reporting on MVPs is a reporting option under the Merit-based Incentive Payment System (MIPS) under the PFS. MIPS eligible clinicians have been able to report on MVPs beginning with the 2023 MIPS performance period. CMS describes that MVPs are intended to provide MIPS eligible clinicians with a cohesive subset of measures and activities on which to report, which are related to a specific specialty or condition. There are 16 MVPs that are reportable for the 2024 performance period.[54]

CMS believes that there are benefits to using the MVP framework for an ambulatory specialty care model, including that it provides a means for reporting a set of measures and activities that allows for meaningful comparisons to be made across similar providers. Also, the agency believes that a payment methodology for the model that is based on MVPs could address concerns that have been raised about the MIPS program, such as by testing ways to enhance incentives that allow for more specific comparisons between clinicians of the same type who are providing similar services. CMS describes that an ambulatory specialty care model could focus

[54] Information on the 16 MVPs is under sections IV.A.4 and Appendix 3 of the rule.

on a subset of MVPs in the initial years of implementation and the number of MVPs included in the model could be increased over time.

2. Solicitation of Public Comments

CMS seeks comments on various aspects of the potential ambulatory specialty care model, including on the possible approach of having mandatory participation of relevant specialty care providers. Any such mandatory model would be proposed through notice and comment rulemaking. The agency expects that the model would not be implemented before 2026. Specifically, CMS requests feedback on the following.

a. Participant definition

Participants in the model could be limited to MIPS eligible clinicians[55] with specific ambulatory-based specialties for a specific clinical focus area. The model would need to determine which clinicians are specialists and subspecialists practicing in the clinical area. Each MVP provides measures and activities for a range of specialties and subspecialties in a clinical area or topic. CMS describes several factors to consider for participation identification, including (i) the need for such identification to be based on data sources already accessible by CMS, (ii) the need to identify non-physician clinician types that practice within a specialty or subspecialty but may not be so categorized within existing data systems, and (iii) the possibility of considering additional provider characteristics such as those associated with disparities in access to specialty care (such as solo clinicians, those practicing in a rural area, or those serving a higher proportion of Medicare and Medicaid dually eligible individuals, etc.). CMS seeks feedback on the following:

- How should it identify single specialty and multispecialty groups while accounting for regular clinician turnover? Which data sources and methodologies should CMS use to consider identifying specialists and subspecialists that could participate in the model?
- Should (and if so, how should) the agency consider different identification approaches for identifying clinician specialist types on the individual level versus practice/group level?
- What characteristics of clinicians or practices warrant additional policy flexibilities or exemption from participation in a mandatory ambulatory specialty model? What flexibilities should be considered?
- How should CMS collect unbiased comparison group data on quality and costs for evaluation purposes? Would mandating a control group to report MVPs be appropriate?
- How can CMS support a multispecialty group's ability to successfully participate in MIPS and the model if a portion of its clinicians are reporting separate measures under the model; and what steps could CMS take to reduce administrative burden from separate reporting?

[55] §414.1305

b. MVP Performance Assessment

MVP participants are assessed across the 4 MIPS performance categories (1) Quality,[56] (2) Cost,[57] (3) Improvement Activities (IAs),[58] and (4) Promoting Interoperability (PI).[59] CMS requests the following feedback on incorporating measures and activities from MVP performance categories into an ambulatory specialty model:

- How CMS should select measures and activities if it were to reduce the measures and activities in an MVP for clinicians participating in the model to the most relevant measures and activities specific to a specified specialty or subspecialty. CMS lists the following prioritization approaches for consideration and comment (and asks for any other measure selection principles): (i) measures with a performance gap, (ii) measures with meaningful benchmarks, (iii) measures that are reliable in the model context given sample size, (iv) measures that are evidence-based and strongly linked to outcomes or an outcome measure, (v) measures that capture an adequate number and representativeness of clinicians intended by the model, and (vi) measures that drive specialty integration with primary care and meaningful involvement with accountable entities.
- Any specific measure focus areas or objectives that should be prioritized across MVPs (i.e., equity, population health, PRO-PMs, patient-reported experience measures).
- Measures within the Advancing Care for Heart Disease MVP and the Rehabilitative Support for Musculoskeletal Care MVP that could be subset in order to apply to general cardiology and physical medicine and rehabilitation, respectively.
- What role the ambulatory specialty model could have in testing potential new measures, such as relevant PRO-PMs, by gathering data for consideration in future MVP measure sets.
- Strategies that could be tested to obtain patient and family feedback on care coordination for the clinical focus areas.
- Types of peer engagement that specialists would consider valuable to enhance their performance within a given subspecialty or clinical topic.

c. Payment Methodology

Currently, CMS compares each MIPS eligible clinician's MIPS final score against the performance threshold for the payment year and against others in a single comparison pool to determine which clinicians will receive a positive, neutral, or negative payment adjustment. The payment adjustment is applied to Part B payments during the payment year, which occurs two years after the MIPS performance period.[60] CMS believes that an ambulatory specialty care

[56] As of the 2024 performance period, MVP participants must report at least 4 quality measures, including at least 1 outcome measure or 1 measure designated "high priority" if an outcome measure is not available within an MVP. Quality measures must meet case minimums to be scored.
[57] Each MVP identifies relevant and applicable cost measures, which are calculated by CMS using administrative claims data. MVP participants are score on all cost measures included in the MVP that they select and report.
[58] MVP participants must report IAs included in a given MVP while meeting overall IA reporting requirements for the performance period.
[59] MVP participants are required to report the entire MIPS PI measure set, including required attestations.
[60] CMS describes that for the 2022 performance period/2024 payment year (for which MVPs were not a reporting option), over 624,000 clinicians received MIPS payment adjustments based on MIPS participation; 14 percent received negative adjustments, 7 percent received neutral adjustments, and 79 percent received positive adjustments

model could promote payment adjustments that are more reflective of the range of performance of similar clinicians caring for individuals in a given clinical area, which could drive quality improvement. CMS seeks feedback on:

- How a model for applicable specialists could improve the comparison of similar specialists to determine future Part B payment adjustments.
- The range of upside and downside risk (measured by the range of possible payment adjustments to future Part B claims) that could be used to incentivize increased and meaningful participation of specialists in APMs, care transformation, and strengthened integration between primary and specialty care.
- Model design features that CMS should consider in designing an ambulatory specialty care model that increases risk over time to qualify the model for Advanced APM status.

d. Care Delivery and Incentives for Partnerships with Accountable Care Entities and Integration with Primary Care

CMS would like to incentivize partnerships between specialist clinicians, accountable care entities, and primary care clinicians and therefore seeks input on the following:

- Model design features not discussed that would incentivize primary and specialty providers to improve how individuals experience care coordination.
- How to encourage specialists and accountable care entities to collaborate to optimize patient outcomes and ensure efficient resource use.
- How CMS can identify specialists who are most engaged with an accountable care entity in care management, coordination, and improvement activities.
- Ways the model can define expectations and performance metrics for specialists, beyond what exists in the current MVP measure sets, to promote collaboration with ACOs and primary care, including levers (such as MIPS' IAs) that could be used to support such coordination.
- Characteristics CMS should consider in the model design to account for variations between ACOs (i.e., whether the ACO is physician-owned or hospital-owned or a low or high revenue ACO, whether an ACO identifies as an integrated delivery system, differences in regional and local healthcare landscapes, and other characteristics).
- How the model could address concerns about increased consolidation and ensure that integration efforts do not reduce competition.
- How risk categorization of ACOs might influence the design of incentive structures of model participants engaging with ACOs and adjustments that could be necessary to accommodate different risk levels.

e. Health Information Technology (HIT) and Data Sharing

CMS describes that clinicians ask for more timely and expansive data feedback under MIPS to enable improvement efforts. The agency requests feedback on:

with a maximum positive adjustment of 8.26 percent.

- Specific issues CMS should consider when determining whether additional HIT requirements may be necessary beyond those currently specified in the MVP framework for specialists participating in the potential model.
- Investments in HIT or information exchange that would be the most beneficial to help specialists succeed in the model.
- Experiences with the integration of HIT systems, highlighting interoperability issues for seamless data exchange between systems.
- How CMS should structure HIT and data sharing requirements under the model to align with, build upon, and leverage advances in federal interoperability policy.
- The data or metrics that are important to clinicians for monitoring performance and improving patient outcomes. Data or metrics that CMS should publicly share.
- Additional resources or support CMS could provide to help clinicians understand data (enhancing data's usability, effectiveness, and frequency of updates) for clinicians to gather actionable insights and to enable data-driven referrals.
- Supports the model could provide to decrease burden from data collection and reporting.

f. Health Equity

CMS reviews several CMMI initiatives to further health equity. Several MVPs include equity-focused measures. MVPs also provide scoring flexibilities for certain special status designations, which may include clinicians caring for historically underserved beneficiaries. To understand potential health equity impacts of a potential ambulatory specialty care model, CMS requests feedback on the following:

- How CMS could support participants in the model that may serve a higher proportion of underserved patients (such as small practices or clinicians in rural areas).
- How the model could support participant efforts to identify health disparities within their practices, identify actionable equity goals, and design and implement strategies to improve disparities.
- How the model could work with primary care focused models to improve health disparities.
- How the model could encourage clinicians to collect and use HRSN screening and follow-up data on patients within the model.
- How measure stratification among patient subgroups or use of composite health equity measures could improve how participants identify and quantify disparities in care and outcomes related to ambulatory specialty care.

g. Multi-payer Alignment

CMS requests feedback on:

- Opportunities to reduce clinician burden between the described potential model, other CMMI models, and beyond the models through multi-payer alignment, in areas such as performance measurement, quality measurement, and reporting requirements.
- How the model could align with value-based care approaches that focus on specialty integration in MA, Medicaid, and commercial payers; and model components and payment incentives that could be aligned with other payers to support improvement.

- Ways CMS could align with other payer approaches to equity and disparity reduction, including alignment on definitions, methods, and requirements for equity-related data collection.
- Technical assistance that CMS could provide to support alignment and reduce burden.

K. Expand Colorectal Cancer Screening

Statutes, regulations and a National Coverage Determination (NCD) describe Medicare Part B coverage for colorectal cancer (CRC) screening tests.[61] The statute and regulations authorize the Secretary to add other tests and procedures for colorectal screening with such frequency and payment limitations as the Secretary finds appropriate based on consultation with appropriate organizations.[62] CMS proposes to exercise this authority to update and expand coverage for CRC screenings by:

- Removing coverage for the barium enema procedure in regulations at §410.37;
- Adding coverage for the computed tomography colonography (CTC) procedure in regulations at §410.37; and
- Expanding a "complete colorectal cancer screening" in §410.37(k) to include a follow-on screening colonoscopy after a Medicare covered blood-based biomarker CRC screening test (NCD 210.3).

CMS believes that these proposals support health equity and the goal of increasing CRC screening.

1. Remove Coverage of the Barium Enema

Appropriate organizations have provided feedback to CMS that although coverage for a barium enema was reasonable and necessary for CRC screening when in was initially covered in the 1998 PFS final rule, the barium enema no longer meets clinical standards, is no longer recommended in clinical guidelines, and would not be an appropriate CRC screening test given the alternatives. The June 2106 and the May 2021 USPSTF revised Final Recommendation Statements did not include the barium enema as a CRC screening method in their revised Final Recommendation Statements.[63] In addition, several organizations, including the 2017 US Multi-Society Task Force of Colorectal Cancer (MSTF) and the 2018 American Cancer Society (ACS) guidelines do not support barium enema as a screening option. During the 2023 PFS, CMS received a joint public comments from the American College of Gastroenterology, American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy commented that barium enema is not recommended as a CRC screening modality.

CMS proposes to remove barium enema as a colorectal screening test under 42 CFR 410.37(a)(1)(iv).

[61] Sections 1861(s)(2)(R), 1861(pp), 1862 (a)(1)(H) and 1834(d) of the Act, §410.37 and NCD 210.3.
[62] Section 1861(pp)(1)(D) of the Act and §410.37(a)(1)(v).
[63] USPSTF June 2016 Revised Final Recommendation Statement, https://www.uspstf/recommemdation/colorectal-cancer-screening-june-2016. USPSTF January 2021 Revised Final Recommendation Statement, https://www.uspreventiveservisestaskforce.org/uspstf/recommendation/colorectal-cancer-screening.

2. Coverage for the CT Colonography (CTC)

The USPSTF included CTC procedure as a CRC screening method in their June 2016 and May 2021 revised Final Recommendation Statements.[64] The USPSTF recommends screening CTC frequency of every 5 years. The ACS guidelines also recommend screening CTC frequency every 5 years. CMS also discusses the recommendations of the US MSTF of Colorectal Cancer and the online resource RadiologyInfo.[65]

CMS proposes to add CTC as a covered CRC screening test at §410.37. CMS proposes to describe CTC as a test that uses X-rays and computers to produce images of the entire colon (including image processing and a physician's interpretation of the results of the procedure). Medicare Part B will pay for a screening CTC if it is ordered in writing by the beneficiary's attending physician, physician assistant, nurse practitioner, or clinical nurse specialist.

CMS proposes the following limitations of coverage for CTC:

- For an individual age 45 or over who is not at high risk of CRC, payment may be made for a screening CTC performed after at least 59 months have passed following the month in which the last screening CTC or 47 months have passed following the month in which the last screening flexible sigmoidoscopy or screening colonoscopy was performed.
- For an individual who is a high risk for CRC, payment may be made for a screening CTC performed after at least 23 months have passed following the month in which the last screening CTC or the last screening colonoscopy was performed.

Congress eliminated Part B coinsurance and deductibles for covered preventive services recommended with a grade A or B by the USPSTP.[66] CTC will require no Part B coinsurance nor deductible when furnished as a CRC screening procedure. As a diagnostic or other non-preventive/screening procedure, CTC will continue to require Part B coinsurance and deductible.

3. Expand the definition of "complete colorectal cancer screening"

CMS recognizes there are several advantages to choosing a non-invasive CRC screening test as a first step compared to a screening colonoscopy, including the relative ease of administration and reducing the experience of burdensome preparation and invasive procedures. CMS discusses the feedback it has received that blood-based biomarker test would be appropriate as a covered non-invasive stool-based tests within a complete CRC screening context.

NCD 210.3 requires that Blood-based Biomarker Tests for CRC screening must have FDA market authorization with an indication for CRC screening. In addition, proven test performance characteristics for a blood-based screening test include both sensitivity greater than or equal to 74 percent and specificity greater than or equal to 90 percent in the detection of CRC compared to

[64] USPSTF June 2016 Revised Final Recommendation Statement, https://www.uspreventiveservicetaskfroce.org/uspstf/recommendation/colorectal-cancer-screening-june02016. USPSTF January 2021 Revised Final Recommendation Statement, https://www.uspreventiveservisestaskforce.org/uspstf/recommendation/colorectal-cancer-screening.
[65] RadiologyInfo Website: https://www.radiologyinfo.org.
[66] Section1833(a)(1)(Y) and section 1833(b)(1) of the Act

the recognized standard (accepted as colonoscopy at this time), as minimal threshold levels. Based on the pivotal studies included in the FDA labeling, CMS believes that this NCD provides for coverage for tests that meet the NCD requirements. Because blood-based biomarker tests will be paid under the Clinical Laboratory Fee Schedule (CLFS) they will not require beneficiary cost sharing.[67]

CMS proposes to revise the regulatory text describing a complete CRC screening at §410.37(k) to state that CRC screening test include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based CRC screening test or a Medicare covered blood-based biomarker CRC screening test returns a positive result. The proposed revision will also state that in the instance of a follow-on colonoscopy as part a complete CRC screening the frequency limitations for CRC screening will not apply.

Regulatory Impact

CMS anticipates the proposal to update and expand coverage for CRC screening will result is some additional utilization, but that utilization will be offset, by avoided utilization of alternative tests as well as benefits and savings resulting from increased prevention and early detection which reduces the utilization of more invasive treatments. In 2022, only 71 claims were paid for a barium enema. CMS expects the utilization of CTC for CRC screening will be modest. In addition, a 2015 study concluded that CTC is 29 percent less expensive than colonoscopy.[68]

L. Requirements for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD Plan

1. Previous Regulatory Action

Section 2003 of the SUPPORT Act generally mandated that the prescribing of a Schedule II, III, IV, or V controlled substance under Medicare Part D be done electronically beginning January 1, 2021, subject to exceptions specified by HHS. In the 2021-2024 PFS final rules, CMS finalized detailed policies for its Electronic Prescribing for Controlled Substances (EPCS) Program requirements specified in section 2003 of the SUPPORT Act. Some of the highlights of those provisions include the following:

- 2021 PFS final rule: Using the NCPDP SCRIPT standard version 2017071 with an effective date of January 1, 2021, and a compliance date of January 1, 2022 (85 FR 84807).
- 2022 PFS final rule: Requiring prescribers to electronically prescribe at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs, except in cases where an exception or waiver applies (86 FR 65366), with the earliest date of compliance actions to no earlier than January 1, 2023 (86 FR 65364)—except for prescriptions written for a beneficiary in a long-term care (LTC) facility, the earliest date of compliance actions was no earlier than January 1, 2025 (86 FR 65364-65365); through

[67] https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs.
[68] Pyenson, B., Pickhardt, P.J. Sawhney, T.G. et al. Medicare cost of CRC: CTC vs. optical colonoscopy. Abdom Imaging 40, 2977-2976 (2016). https://doi.org/10.1007/s00261-015-0538-1.

December 31, 2023, compliance actions were limited to a non-compliance notice (86 FR 65370).

- 2023 PFS final rule: Extending the noncompliance action of sending notices to non-compliant prescribers through 2024, changing the data sources used to identify the geographic location of prescribers for purposes of the recognized emergency exception at §423.160(a)(5)(iii) (87 FR 70011-70012), and using the Prescription Drug Event (PDE) data from the current evaluated year (instead of the preceding year) when CMS determines whether a prescriber qualifies for an exception based on issuing 100 or fewer Part D controlled substance prescriptions per calendar year (87 FR 70009-70011).
- 2024 PFS final rule: Clarifying through the cross reference in §423.160(a)(5) to refer to the standards in §423.160(b) so the CMS EPCS Program will automatically adopt the electronic prescribing standards there as they are updated and modifying calculations as part of the 70 percent compliance threshold.

2. Timeline for Including Prescriptions Written for Beneficiaries in LTC Facilities in CMS EPCS Program Compliance Calculation

a. Background

As previously mentioned, the 2022 PFS rule finalized a policy to extend to January 1, 2025 the date on or after which CMS will pursue compliance actions against prescribers based on Part D controlled substance prescriptions those prescribers write for beneficiaries in LTC facilities. Prescribers who work in LTC facilities or who provide care to residents in LTC facilities faced technological barriers that other prescribers did not face—for example, that the NCPDP SCRIPT standard version 2017071 lacked appropriate guidance for EPCS in LTC facilities.[69]

In response to that proposed rule, public comments requested that CMS exempt prescribers writing Part D controlled substance prescriptions for beneficiaries in LTC facilities from having to conduct EPCS until after NCPDP SCRIPT standard version 2022011 was adopted. CMS was not persuaded to further delay commencing compliance actions to await publication of the NCPDP SCRIPT standard version 2022011, while acknowledging that three-way communication was not as seamless in the NCPDP SCRIPT standard version 2017071 as it may be in upcoming versions. Even so, three-way communication was still possible with some modifications to EPCS, and therefore, CMS did not believe it would be appropriate to adopt a further delay on this basis alone (86 FR 65364).

Although CMS did not propose any policy changes regarding the NCPDP SCRIPT standard version in the 2024 PFS proposed rule, it received public comments requesting clarification on when the new NCPDP SCRIPT standard version would be adopted and the implications for measuring EPCS compliance in LTC. In response, in the 2024 PFS final rule (88 FR 79286), CMS acknowledged that it had not finalized the proposal regarding the NCPDP SCRIPT standard version 2022011 that was proposed in the CY 2024 Medicare Advantage and Part D Policy and Technical Changes proposed rule and that some prescribers prescribing for

[69] At that time, NCPDP was in the process of creating a new version of the SCRIPT standard that would be better suited for use by prescribers serving LTC facilities, which would allow willing partners to enable three-way communication between the prescriber, LTC facility, and pharmacy.

beneficiaries in LTC facilities have adopted EPCS, but that others have waited for the standard to be updated. CMS said that if the requirement to use an updated version of the NCPDP SCRIPT standard is finalized for a date after January 1, 2025, it may explore whether a waiver is appropriate for prescribers who are not compliant solely as a result of prescriptions they have written for beneficiaries in LTC facilities, or whether the compliance start date should be revisited.

In the "Medicare Program; Medicare Prescription Drug Benefit Program; Health Information Technology Standards and Implementation Specifications" final rule (89 FR 51242 through 51247, hereafter referred to as the June 2024 Part D and Health IT Standards final rule), CMS finalized at §423.160(b)(1) the requirement that Part D sponsors, prescribers and dispensers, when electronically transmitting prescriptions and prescription-related information for covered Part D drugs for Part D eligible individuals, must comply with a standard in 45 CFR 170.205(b). Taken in conjunction with the standards and expiration date adopted by the Office of the National Coordinator for Health Information Technology (ONC) in the June 2024 Part D and Health IT Standards final rule, §423.160(b)(1) will require use of NCPDP SCRIPT standard version 2023011, which ONC is adopting at 45 CFR 170.205(b)(2), beginning January 1, 2028, and retire use of NCPDP SCRIPT standard version 2017071, which ONC previously adopted at 45 CFR 170.205(b)(1) and to which it is applying an expiration date of January 1, 2028. Thus, the NCPDP SCRIPT standard version 2023011 will be required for the CMS EPCS Program by January 1, 2028.

As both NCPDP SCRIPT standard version 2017071 and NCPDP SCRIPT standard version 2023011 will be adopted at 45 CFR 170.205(b) and unexpired as of the effective date of the June 2024 Part D and Health IT Standards final rule, entities subject to the requirement at §423.160(b)(1) may use either version of the NCPDP SCRIPT standard during the transition period beginning July 17, 2024, the effective date of the June 2024 Part D and Health IT Standards final rule, and ending December 31, 2027.

b. Barriers to Electronic Prescribing of Controlled Substances for Beneficiaries in LTC and the Role of Three-Way Communication in the NCPDP SCRIPT Standard

In this proposed rule, CMS reiterates its understanding of the challenges of conducting EPCS in the LTC setting, including:

- Prescribers being responsible for covering multiple LTC facilities, each with different electronic health record (EHR) systems;
- Reliance on LTC nursing staff to communicate prescriptions to the pharmacy on behalf of the prescriber; and
- With respect to NCPDP SCRIPT standard version 2017071, lack of three-way (or multi-party) communication between the prescriber, the LTC facility, and the pharmacy.

CMS walks through a few examples of these challenges.

c. Timeframe for Including Prescriptions Written for Beneficiaries in LTC in the CMS EPCS Program Compliance Calculation

In response to the proposal in section III.B.4. of the 2025 Medicare Advantage and Part D Policy and Technical Changes proposed rule (88 FR 78489) to require NCPDP SCRIPT standard version 2023011 and retire NCPDP SCRIPT standard version 2017071, CMS received multiple public comments requesting reconsideration of the current January 1, 2025, compliance date for when prescriptions written for covered Part D drugs for Part D eligible individuals in a LTC facility will be included in the CMS EPCS Program compliance calculation. Commenters requested aligning the CMS EPCS Program compliance date for prescriptions written for beneficiaries in LTC with the date that NCPDP SCRIPT standard 2023011 will be required, which CMS indicated it would consider (89 FR 51247).

CMS proposes to revise §423.160(a)(5) to state 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 prescriptions written for a beneficiary in a LTC facility would commence on or after January 1, 2028.

As of the effective date of the June 2024 Part D and Health IT Standards final rule (July 17, 2024), Part D sponsors, prescribers and dispensers, when electronically transmitting prescriptions and prescription-related information for covered Part D drugs for Part D eligible individuals, may use NCPDP SCRIPT standard version 2023011. However, as discussed, there will be a transition period where both NCPDP SCRIPT standard version 2023011 and NCPDP SCRIPT standard version 2017071 may be used. ONC finalized an expiration date for NCPDP SCRIPT standard version 2017071 of January 1, 2028 (rather than January 1, 2027, as proposed), in part due to commenters' concern about implementing the new standard in LTC facilities (89 FR 51247).

CMS also recognizes the administrative burden prescribers could potentially face when implementing EPCS for prescriptions written for covered Part D drugs for Part D eligible individuals in LTC facilities using NCPDP SCRIPT standard version 2017071, particularly with the lack of guidance. By delaying the inclusion of prescriptions written for covered Part D drugs for Part D eligible individuals in LTC facilities in the CMS EPCS Program compliance threshold calculation to January 1, 2028, it would align CMS EPCS Program compliance calculations to the date by which the NCPDP SCRIPT standard version 2017071 is retired and the new NCPDP SCRIPT standard version 2023011 is required. This would provide sufficient time for prescribers and pharmacies to adopt the new standard.

CMS considered an alternative to permit prescribers to apply for a waiver for circumstances beyond their control, rather than modify the date. In 2022, approximately 4.7 percent (4.5 million) of Part D Schedule II, III, IV, and V controlled substance prescriptions were written for beneficiaries in LTC facilities, with roughly 52 percent (2.4 million) not meeting the CMS EPCS Program standards for e-prescribing. If CMS kept the existing start date of January 1, 2025, as in the current regulatory text at § 423.160(a)(5) for the CMS EPCS Program, at least 6,800 additional prescribers could become non-compliant. In that case, thousands of prescribers could

become non-compliant and potentially apply for a waiver, even though by the 2028 measurement year, many would be compliant because, beginning January 1, 2028, NCPDP SCRIPT standard version 2023011 will be the required standard for prescribing and dispensing Part D drugs to Part D eligible individuals, which will facilitate EPCS in LTC.

If CMS' proposal is finalized, it encourages prescribers who write Schedule II, III, IV, or V controlled substance prescriptions for covered Part D drugs for Part D eligible individuals in LTC facilities to use the additional time to prepare for when such prescriptions would be included in the CMS EPCS Program compliance threshold calculation.

The agency seeks comment on its proposals to extend to January 1, 2028 (from January 1, 2025) the date after which prescriptions for covered Part D drugs for Part D eligible individuals in LTC facilities would be included in the CMS EPCS Program compliance threshold calculation and that related non-compliance actions would commence on or after January 1, 2028. CMS also seeks comment on how NCPDP SCRIPT standard version 2023011 is expected to improve prescribers' ability to conduct EPCS to pharmacies dispensing covered Part D drugs to Part D eligible individuals in LTC facilities.

M. Expand Hepatitis B Vaccine Coverage

Hepatitis B vaccines are currently covered as a Medicare Part B benefit under section 1861(s)(10)(B) of the Act. Medicare beneficiaries who are at high or intermediate risk of contracting hepatitis B can receive hepatitis B vaccines, with no cost to the beneficiary. The statute expressly authorizes the Secretary to determine who is at high or intermediate risk of contracting hepatitis B by issuing regulations. This definition was last updated in the 2013 PFS final rule (77 FR 69363). Beneficiaries with coverage under Medicare Part D whose level of risk falls outside high or intermediate may have their vaccine covered under the Part D benefit. CMS believes that Medicare coverage of hepatitis B vaccination is too limited and outdated in light of more recent information about the risks of contracting hepatitis B.

CMS provides a detailed discussion of the evidence supporting expanding those considered high or intermediate risk as well a history of its past regulatory changes. It notes that since 1991, hepatitis B vaccination has been recommended by the Advisory Group for Immunization Practices (ACIP) and the Centers for Disease Control (CDC) for infants at birth, completing the vaccination series by 16 months of age.[70] CMS notes that the age cohorts who have received the completed series have low to no risk of contracting the hepatitis B virus, as evidenced by the rate of zero acute hepatitis B virus infections for the 0 – 19 age group.[71] No other age group has reached a rate of zero acute hepatitis B virus infections. Based on this information, CMS considers the population of people who have completed the vaccination series to be at low risk of contracting the hepatitis B virus. Individuals who remain unvaccinated against hepatitis B are at intermediate risk, at minimum, of contracting hepatitis B virus.

[70] CDC, 2024. Vaccine safety: Hepatitis B vaccines. Retrieved from. *https://www.cdc.gov/vaccinesafety/vaccines/hepatitis-b-vaccine.html*
[71] CDC. Viral hepatitis. 2021 viral hepatitis surveillance report. Atlanta, GA: U.S. HHS, CDC; 2023. Retrieved from https://www.cdc.gov/hepatitis/statistics/2021surveillance/hepatitis-b/figure-2.4.htm

CMS proposes to revise §410.63(a)(2), Intermediate Risk Groups, by adding a new paragraph (a)(2)(iv) to include individuals who have not previously received a completed hepatitis B vaccination series or whose vaccination history is unknown. CMS states that it includes the latter group in this proposal because the CDC has stated that it is not harmful to receive either extra doses or a repeat vaccination series. CMS notes that §410.63(a)(3) provides an exception to individuals considered intermediate or high risk of contracting hepatitis B. This includes individuals who have undergone a prevaccination screening and have been found to be currently positive for antibodies to hepatitis. CMS proposes this exception as these individuals would not benefit from the vaccine, but states that it is not harmful to vaccinate people who are immune to hepatitis B virus because of current or previous infection or vaccination, nor does it increase the risk for adverse events.

N. Low Titer O+ Whole Blood Transfusion Therapy During Ground Ambulance Transport

Ambulance Fee Schedule Background

Since April 1, 2002, payment for ambulance services has been made under the ambulance fee schedule (AFS), which consists of a base rate for the level of service, a separate payment for mileage to the nearest appropriate facility, a geographic adjustment factor (GAF), and other applicable adjustment factors. The levels of service for ground ambulance transports include basic life support (emergency); basic life support (non-emergency); advanced life support, level 1 (ALS1) (emergency); ALS1 (non-emergency); advanced life support, level 2 (ALS2); paramedic intercept; and specialty care transport. Payment for an ambulance service is made at the lesser of the actual billed amount or the AFS amount. AFS rates are adjusted annually based on an inflation factor. The AFS also incorporates two permanent add-on payments and three temporary add-on payments to the base rate and/or mileage rate.

In this proposed rule, CMS provides a detailed history of the Emergency Medical Services (EMS) system and the administration of low titer O+ whole blood transfusions, otherwise referred to as whole blood transfusion therapy (WBT). Low titer O+ whole blood contains low levels of antibodies that patients of any blood type can receive and is provided in EMS settings to significantly increase these patients' chances of survival. CMS notes that not all ground ambulance transports providing WBT may already qualify for the higher level of ALS2 payment and its does not have the authority to provide an additional payment, such as an add-on payment for the administration of WBT.

Proposed Regulatory Change

CMS proposes to modify the definition of ALS2 at §414.605 by adding the administration of low titer O+ whole blood transfusion to the current list of seven ALS2 procedures as a new number 8. CMS would also reflect this change in the Medicare Benefit Policy Manual, Chapter 10, Ambulance Services, section 30.1.1, Definition of Ground Ambulance Services. Under this proposal, a ground ambulance transport that provides WBT would itself constitute an ALS2-level transport.

CMS states that it is not including alternative blood product treatments in its proposal and seeks comment whether it should add alternative blood product treatments, such as the

administration of packed red blood cells or plasma, to the list of ALS2 procedures. CMS also invites comment on its overall proposal.

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

1. Background

In the proposed rule referred to by CMS as the "December 2022 Overpayment Proposed Rule,"[72] CMS proposed to amend its regulations regarding the standard for an "identified overpayment" under Medicare Parts A, B, C, and D to align the regulations with the statutory language in section 1128J(d)(4)(A) of the Act. This would align terms "knowing" and "knowingly" to have the same meaning given those terms in the Federal False Claims Act (the False Claims Act) at 31 U.S.C. 3729(b)(1)(A). This would also remove the reference to the "reasonable diligence" standard.

CMS, however, has not yet finalized its proposals with respect to overpayments under Medicare Parts A and B in the December 2022 Overpayment Proposed Rule. Instead, after considering the public comments , CMS is retaining the Parts A and B proposals published in that rule and is now making additional proposals to revise existing regulations at §401.305(b) regarding the deadline for reporting and returning overpayments.

CMS notes that it continues to review the comments received on its December 2022 Overpayment Proposed Rule, and plans to respond both to those comments and the comments CMS receives on its new proposals when it publishes the 2025 PFS final rule.

2. Provisions of the Proposed Regulation (Preamble)

Section 6402(a) of the Patient Protection and Affordable Care Act (Pub. L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) (collectively known as the Affordable Care Act), established section 1128J(d) of the Act. This requires a person who has received an overpayment to report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, and to notify the Secretary, State, intermediary, carrier or contractor to which the overpayment was returned in writing of the reason for the overpayment. The statute defines the term "overpayment" as any funds that a person receives or retains under title XVIII or XIX of the Act to which the person, after applicable reconciliation, is not entitled under such title. The term "person" is defined to include providers and suppliers, a Medicare Advantage organization (MAO), and a Part D Plan (PDP) sponsor.

The statute specifies that the overpayment be reported and returned by the later of: (1) the date which is 60 days after the date on which the overpayment was identified; or (2) the date any corresponding cost report is due, if applicable. Any overpayment retained by a person after the

[72] Full title is Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications", which appeared in the December 27, 2022 Federal Register. (87 FR 79452).

deadline for reporting and returning an overpayment is an obligation (as defined in 31 U.S.C. 3729(b)(3)) for purposes of the False Claims Act, 31 U.S.C. 3729.

The terms "knowing" and "knowingly" have the meaning given those terms in the False Claims Act at 31 U.S.C. 3729(b)(1)(A), which defines the terms "knowing" and "knowingly" to include information about which a person "has actual knowledge," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information."

a. Regulations Promulgated Under Section 1128J(d) of the Act

CMS reviews the regulations promulgated under section 1128J(d) of the Act. In May 2014, CMS published a final rule, referred to as the "Parts C and D Overpayment Final Rule",[73] which provided, among other things, that an MAO or PDP sponsor has identified an overpayment when the MAO or PDP sponsor has determined, or should have determined through the exercise of reasonable diligence, that the MAO or PDP sponsor has received an overpayment. In February 2016, CMS published a final rule referred to as the "Parts A and B Overpayment Final Rule",[74] with similar language with respect to overpayment and the exercise of "reasonable diligence" of Parts A and B.

As noted previously, in the December 2022 Overpayment Proposed Rule, CMS proposed to amend the existing regulations for Medicare Parts A and B, as well as Parts C and D, regarding the standard for an "identified overpayment" to align the regulations with the statutory language in section 1128J(d)(4)(A) of the Act. If finalized, these regulations would assign the meaning of the terms "knowing" and "knowingly" in the False Claims Act at 31 U.S.C. 3729(b)(1)(A) to its regulations for purposes of Medicare overpayments. As proposed in the December 2022 Overpayment Proposed Rule, this would remove the existing "reasonable diligence" standard and adopt by reference the False Claims Act definition of "knowing" and "knowingly" as set forth at 31 U.S.C. 3729(b)(1)(A).

b. Relevant Litigation

In *UnitedHealthcare Insurance Co. v. Azar*, a group of MAOs challenged the Parts C and D Overpayment Final Rule, and the District Court held, in relevant part, that by requiring MAOs to use "reasonable diligence" in searching for and identifying overpayments, CMS impermissibly established False Claims Act liability for mere negligence.[75] The District Court noted that "(t)he False Claims Act—which the ACA refers to for enforcement—imposes liability for erroneous ('false') claims for payment submitted to the government that are submitted 'knowingly' … a term of art defined in the FCA to include false information about which a person 'has actual

[73] Full title is Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" (79 FR 29844)
[74] Full title is "Medicare Program; Reporting and Returning of Overpayments" (81 FR 7654)
[75] UnitedHealthcare Ins. Co. v. Azar, 330 F. Supp. 3d 173, 191 (D.D.C. 2018), rev'd in part on other grounds sub nom. UnitedHealthcare Ins. Co. v. Becerra, 16 F.4th 867 (D.C. Cir. 2021), cert. denied, 142 S. Ct. 2851 (U.S. June 21, 2022) (No. 21-1140).

knowledge,' 'acts in deliberate ignorance of the truth or falsity of the information,' or 'acts in reckless disregard of the truth or falsity of the information.'" Id. at 190.

Although the court's ruling applied only to Medicare Part C, to provide for consistency in Medicare regulations related to reporting and returning overpayments, in the December 2022 Overpayment Proposed Rule, CMS proposed to amend the regulations at current §401.305(a)(2) to remove the reference to "reasonable diligence" and replace it with language incorporating the terminology of section 1128J(d)(4)(A) of the Act by ascribing the terms "knowing" and "knowingly" the same meaning given those terms in the False Claims Act at 31 U.S.C. 3729(b)(1)(A).

c. Provisions of Proposed Regulations

In addition to CMS' earlier proposals, which remain under consideration, CMS makes the following new proposals. Existing §401.305(b)(1) specifies when a person who has received an overpayment must report and return an overpayment. CMS proposes to amend this paragraph to reference revised §401.305(b)(2), as well as to reference newly-proposed §401.305(b)(3). Existing §401.305(b)(2) specifies the circumstances under which the deadline for returning overpayments will be suspended. Overpayments must be reported no later than the date which is 60 days after the date on which the overpayment was identified or the date any corresponding cost report is due, if applicable. However, the deadline for returning a reported overpayment will be suspended under specified circumstances, including the acknowledgement of receipt of a submission to the OIG Self-Disclosure Protocol or the CMS Voluntary Self-Referral Disclosure Protocol, or under specified conditions if a person requests an extended repayment schedule as defined in §401.603. CMS proposes a technical modification to the introductory language in §401.305(b)(2) to acknowledge that this section might be applicable after the suspension described in new §401.305(b)(3) is complete.

The new proposed §401.305(b)(3) would specify the circumstances under which the deadline for reporting and returning overpayments would be suspended to allow time for providers to investigate and calculate overpayments. The deadline to report and return an overpayment would be suspended if: (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. If the proposed conditions are met, the deadline for reporting and returning the initially identified overpayment and related overpayments that arise from the same or similar cause or reason as the initially identified overpayment will remain suspended until the earlier of the date that the investigation of related overpayments has concluded and the aggregate amount of the initially identified overpayments and related overpayments is calculated, or the date that is 180 days after the date on which the initial identified overpayment was identified.

CMS provides the following example to elucidate a hypothetical circumstance. Assume that, on day 1, a person identifies an overpayment arising from a physician's failure to properly document the medical record to support the coding of a specific claim, and the person has reason

to believe that this may be a common practice of the physician, so there could be more affected claims. At this point, the person has up to 180 days to conduct and conclude a good faith investigation to determine whether related overpayments that arise from the same or similar cause or reason as the initially identified overpayment exist. If the person does NOT conduct an investigation, or the investigation is not timely or not conducted in good faith, the identified overpayment must be reported and returned by day 60. If the person does conduct a timely, good faith investigation, suspension of the report and return obligation under §401.305(b)(3) begins on day 1. The suspension ends when the investigation is concluded and the initially identified overpayment and related overpayments, if any, are calculated, or by day 180, whichever is earlier. The overpayment must be reported and returned within 60 days after either completion of the investigation or day 180, whichever is earlier. However, the suspensions described in §401.305(b)(2) may also be applicable. For example, if the person is reporting the overpayment to the OIG Self-Disclosure Protocol, as provided for in §401.305(b)(2) the overpayment return requirement may be further suspended in accordance with that provision.

CMS states that it made these proposals because many of the comments received on the December 2022 Overpayment Proposed Rule expressed concern that it proposed to remove the term "quantified" from the original regulatory text. CMS believes its proposals address this concern. Other commenters expressed concern that the December 2022 Overpayment Proposed Rule proposals removed a perceived 6-month time period to investigate all overpayments that was referenced in an example in the preamble to the original 2016 Parts A and B Overpayment Rule. Acknowledging this concern, CMS proposes to codify this allowance into regulation at proposed §401.305(b)(3)(ii).

IV. Updates to the Quality Payment Summary – HPA Summary Part III

This section is summarized in Part III of the HPA summary of the PFS.

V. Regulatory Impact Analysis

A. RVU Impacts

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, CMS makes adjustments to preserve budget neutrality.

CMS states that its estimates of changes in Medicare allowed charges for PFS services compare payment rates for 2024 with proposed payment rates for 2025 using 2023 Medicare utilization for all years. The payment impacts reflect averages for each specialty based on Medicare utilization. The payment impact for an individual physician would be different from the average, based on the mix of services the physician provides. As usual, CMS asserts that the average change in total revenues would be less than the impact displayed here because physicians furnish services to both Medicare and non-Medicare patients and specialties may receive substantial Medicare revenues for services that are not paid under the PFS. For instance, independent

laboratories receive approximately 83 percent of their Medicare revenues from clinical laboratory services that are not paid under the PFS.

Prior to 2015, the annual update to the PFS conversation factor (CF) was previously calculated based on a statutory formula (the Sustainable Growth Rate methodology that was largely overridden each year by Congressional action). MACRA established the update factor for calendar years 2015 and beyond and amended section 1848(d) of the Act. This provision requires an update of 0.0 percent for 2025, before applying any other adjustments. To calculate the proposed 2025 conversion factor, CMS had to remove the temporary payment increases of 1.25 percent provided by the CAA, 2023 that applied to services furnished from January 1, 2024 through March 8, 2024, and the 2.93 percent payment increase from the CAA, 2024 (replaced the 1.25 percent increase) that applied to services furnished from March 9, 2024 through December 31, 2024. It also takes into account an RVU budget neutrality (BN) adjustment.

The proposed CF for 2025 is $32.3562, which reflects the expiration of the temporary 2.93 percent increase for services furnished from March 9, 20024 through December 31, 2024, the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act, and a BN adjustment of +0.05 percent. As noted previously, the increase in the BN adjustment appears to be largely related to the proposed adjustments to the transfer of postoperative care for global surgical procedures. The 2025 proposed anesthesia conversion factor is $20.3340, which reflects the same adjustments and an additional adjustment due to an update to the practice expense and malpractice risk factor for anesthesia specialty. See Tables 126 and 127 from the proposed rule, reproduced below.

Table 126: Calculation of the Proposed 2025 PFS Conversion Factor		
2024 Conversion Factor		**$33.2875**
Conversion Factor without CAA, 2024 (2.93 Percent Increase for CY 2024)		$32.3400
2025 Statutory Update Factor	0.00 percent (1.0000)	
2025 RVU Budget Neutrality Adjustment	0.05 percent (1.0005)	
2025 Conversion Factor		**$32.3562**

Table 127: Calculation of the Proposed 2025 Anesthesia Conversion Factor		
2024 National Average Anesthesia Conversion Factor		**$20.7739**
Conversion Factor without CAA, 2024 (2.93 Percent Increase for CY 2024)		$20.1826
2025 Statutory Update Factor	0.00 percent (1.0000)	
2025 RVU Budget Neutrality Adjustment	0.05 percent (1.0005)	
2025 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	0.70 percent (1.0070)	
2025 Conversion Factor		**$20.3340**

Table 128 (included at the end of this section) shows the estimated impact of changes in the components of the RVUs on total allowed charges, by specialty. This regulatory impact table, however, **does not** include any changes in spending which result from finalized policies that are

not subject to the budget neutrality adjustment, and therefore, have a neutral impact across all specialties. Specifically, the 2.93 percent temporary payment increase for 2024 is a statutory change that took place outside of budget neutrality requirements. Thus, the combined effect of RVU changes and the CF is much larger than what CMS displays in Table 128. There is a decrease of almost 3 percent to the PFS CF from the statutory changes that would apply to all specialties. If, for example, CMS specifies a 2 percent reduction in Table 128 for a given specialty, the combined effect of RVU changes with the CF reduction would be roughly 5 percent.[76]

2025 PFS Impact Discussion

The most widespread specialty impacts of RVU changes in most years is related to changes to RVUs for specific services, including RVUs for new and revised codes. For 2025, this includes changes to RVUs for specific services, the fourth and final year transition to updated clinical labor pricing, and/or the proposed adjustments to transfer of postoperative care for global surgical procedures. These specialty impacts range from an increase of 4 percent for clinical social worker, increase of 3 percent for clinical psychologist, increase of 2 percent for anesthesiology, and a decrease of 2 percent for diagnostic testing facility, interventional radiology, and vascular surgery. The specialties with significant increases largely benefit from increases in values for particular services and those specialties with significant decreases are negatively affected by updated clinical labor pricing as they rely primarily on supply/equipment items for their practice expense costs.

Column F of Table 128 (reproduced below) shows the estimated 2025 combined impact on total allowed charges by specialty of all the proposed RVU and other changes. CMS also provides an additional impact table (Table 129 in the proposed rule) that includes a facility/non-facility breakout of payment changes.

Table 128: 2025 Proposed Rule Estimated Impact on Total Allowed Charges by Specialty

(A)	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F)* Combined Impact
Allergy/Immunology	$207	0%	0%	0%	0%
Anesthesiology	$1,488	1%	1%	0%	2%
Audiologist	$70	0%	0%	0%	0%
Cardiac Surgery	$155	0%	0%	0%	0%
Cardiology	$5,748	0%	0%	0%	0%
Chiropractic	$616	0%	1%	0%	1%
Clinical Psychologist	$680	3%	1%	0%	3%
Clinical Social Worker	$794	3%	1%	0%	4%
Colon and Rectal Surgery	$143	0%	1%	0%	0%
Critical Care	$309	0%	0%	0%	1%

[76] CMS displays the combined impact percentage in Table 128 to the nearest whole number so adjusting these numbers for the decrease of 2.93 percent could be off as much as +/- 0.5 percentage points.

Table 128: 2025 Proposed Rule Estimated Impact on Total Allowed Charges by Specialty					
(A)	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F)* Combined Impact
Dermatology	$3,717	0%	0%	0%	0%
Diagnostic Testing Facility	$875	0%	-2%	0%	-2%
Emergency Medicine	$2,240	0%	0%	0%	0%
Endocrinology	$491	0%	1%	0%	1%
Family Practice	$5,133	0%	0%	0%	1%
Gastroenterology	$1,372	0%	0%	0%	0%
General Practice	$341	0%	0%	0%	0%
General Surgery	$1,484	0%	0%	0%	0%
Geriatrics	$193	0%	1%	0%	1%
Hand Surgery	$251	-1%	0%	0%	-1%
Hematology/Oncology	$1,501	0%	0%	0%	0%
Independent Laboratory	$512	0%	0%	0%	0%
Infectious Disease	$513	0%	0%	0%	0%
Internal Medicine	$8,771	0%	0%	0%	1%
Interventional Pain Mgmt	$792	0%	0%	0%	0%
Interventional Radiology	$418	0%	-2%	0%	-2%
Multispecialty Clinic/Other Phys	$142	0%	0%	0%	0%
Nephrology	$1,571	0%	1%	0%	1%
Neurology	$1,252	0%	0%	0%	0%
Neurosurgery	$658	0%	0%	0%	0%
Nuclear Medicine	$47	0%	0%	0%	0%
Nurse Anes / Anes Asst	$987	0%	1%	0%	1%
Nurse Practitioner	$6,531	0%	0%	0%	0%
Obstetrics/Gynecology	$531	0%	0%	0%	-1%
Ophthalmology	$4,469	-1%	-1%	0%	-1%
Optometry	$1,280	0%	0%	0%	-1%
Oral/Maxillofacial Surgery	$57	0%	0%	0%	0%
Orthopedic Surgery	$3,239	-1%	0%	0%	-1%
Other	$54	0%	0%	0%	0%
Otolaryngology	$1,095	0%	0%	0%	0%
Pathology	$1,090	0%	0%	0%	0%
Pediatrics	$51	0%	0%	0%	1%
Physical Medicine	$1,054	0%	0%	0%	0%
Physical/Occupational Therapy	$5,607	0%	0%	0%	0%
Physician Assistant	$3,472	0%	0%	0%	0%
Plastic Surgery	$280	0%	0%	0%	-1%
Podiatry	$1,780	0%	0%	0%	0%
Portable X-Ray Supplier	$69	0%	1%	0%	1%

Table 128: 2025 Proposed Rule Estimated Impact on Total Allowed Charges by Specialty					
(A)	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F)* Combined Impact
Psychiatry	$795	1%	0%	0%	1%
Pulmonary Disease	$1,188	0%	0%	0%	1%
Radiation Oncology and Radiation Therapy Centers	$1,458	0%	0%	0%	0%
Radiology	$4,273	0%	0%	0%	0%
Rheumatology	$496	0%	0%	0%	0%
Thoracic Surgery	$277	0%	0%	0%	0%
Urology	$1,532	0%	-1%	0%	-1%
Vascular Surgery	$937	0%	-2%	0%	-2%
Total	$106,413	0%	0%	0%	0%
* **HPA note** – The combined impact numbers CMS displays in Column F **do not** take into account the 2.93 percent payment increase for 2024 as this was a statutory change that took place outside of budget neutrality requirements. Thus, there is a decrease of almost 3 percent to the PFS CF that would apply to all specialties. If a 2 percent reduction is shown for a given specialty, the combined effect of RVU changes with the CF reduction from the CAA, 2024 would be roughly 5 percent. Note: The allowed charges shown in the table are the Medicare PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary).					

The following is an explanation of the information for Table 128:

- Column A (Specialty): Identifies the specialty for which data is shown.
- Column B (Allowed Charges): The aggregate estimated PFS allowed charges for the specialty based on 2023 utilization and 2024 rates. Allowed charges are the Medicare fee schedule amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all specialties to arrive at the total allowed charges for the specialty.
- Column C (Impact of Work RVU Changes): This column shows the estimated 2025 impact on total allowed charges of the proposed changes in the work RVUs, including the impact of changes due to potentially misvalued codes.
- Column D (Impact of PE RVU Changes): This column shows the estimated 2025 impact on total allowed charges of the proposed changes in the PE RVUs.
- Column E (Impact of MP RVU Changes): This column shows the estimated 2025 impact on total allowed charges of the proposed changes in the MP RVUs.
- Column F (Combined Impact): This column shows the estimated 2025 combined impact on total allowed charges of all the changes in the previous columns.

B. Impacts of Other Proposals

The expected impacts of some of the proposed changes in this rule (other than those associated with changes in RVUs or the update factor) are discussed in previous sections of this summary. This includes the effect of changes related to payment for dental services linked to specific covered medical services, supervision of outpatient therapy services in private practices,

advanced primary care management services, strategies for improving global surgery payment accuracy, drugs and biological products paid under Medicare Part B, immunosuppressive therapy, RHCs and FQHCs, clinical laboratory fee schedule, modifications to the MSSP, Medicare Part B payment for preventive vaccine administrative services, Medicare Diabetes Prevention Program Expanded model, Medicare Prescription Drug Inflation Rebate Program, the expansion of Hepatitis B Vaccine coverage, among others.

C. Changes Due to the Quality Payment Program

CMS estimates that approximately 38 percent of the nearly 1.8 million clinicians billing to Part B (686,645) will be assigned a MIPS score because others will be ineligible for or excluded from MIPS. Table 136, reproduced below, provides the details of clinicians' MIPS eligibility status for 2027 MIPS payment year (2025 MIPS performance year). CMS notes it is difficult to predict whether clinicians will elect to opt-in to participate in MIPS.

Table 136: Description of MIPS Eligibility Status for CY 2025 Performance Period/2027 MIPS Payment Year Using the 2025 PFS Proposed Rule Assumptions**

Eligibility Status	Predicted Participation Status in MIPS Among Clinicians*	Number of Clinicians	PFS allowed charges ($ in mil)***
MIPS Eligible Clinicians			
Required eligibility (always subject to a MIPS payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria)	Reported to MIPS	105,843	$29,530
	Did not Report to MIPS	40,813	$11,951
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low-volume threshold in all 3 criteria)	Had a group submission	533,473	$13,108
Opt-In eligibility (only subject to a positive, neutral, or negative adjustment because the individual or group exceeds the low-volume threshold in at least 1 criterion but not all 3, and they elect to opt-in to MIPS)	Opted-in to MIPS	6,516	$350
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**686,645**	**$54,564**
Not MIPS Eligible			
Potentially MIPS eligible (not subject to payment adjustment for non-participation; could be eligible for one of two reasons: 1)	Opt-in Eligible; Do not opt-in	178,216	$5,517
	Group Eligible; Did not Report	405,945	$9,502

Table 136: Description of MIPS Eligibility Status for CY 2025 Performance Period/2027 MIPS Payment Year Using the 2025 PFS Proposed Rule Assumptions**			
Eligibility Status	**Predicted Participation Status in MIPS Among Clinicians***	**Number of Clinicians**	**PFS allowed charges ($ in mil)*****
MIPS Eligible Clinicians			
meet group eligibility or 2) opt-in eligibility criteria)			
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	129,806	$795
Excluded for other reasons (Non-eligible clinician type, newly enrolled)	Not applicable	60,471	$501
Qualified Participant (QP)***	Not applicable	359,816	$17,602
Total Number of Clinicians Not MIPS Eligible		1,134,254	$33,916
Total Number of Clinicians (MIPS and Not MIPS Eligible)		1,820,899	$88,481
* Participation excludes facility-based clinicians who do not have scores in the 2022 MIPS submission data. ** Allowed charges estimated in 2022 dollars. Low-volume threshold is calculated using allowed charges. MIPS payment adjustments are applied to the paid amount. *** CMS' QP estimate differs from that reported in section VII.E.17.b of this proposed rule because, for purposes of establishing the population used in its modeling, CMS estimates an absolute number of QPs rather than a range.			

In the aggregate, CMS estimates that for the 2027 payment year, it would redistribute about $458 million in payment adjustments on a budget neutral basis. CMS estimates that the median positive payment adjustment is about 1.31 percent and the median negative payment adjustment is -1.48 percent. The overall proportion of clinicians receiving a positive or neutral payment adjustment is expected to be 84.5 percent, and 15.5 percent of clinicians are expected to receive a negative adjustment. This increase in the number of MIPS eligible clinicians expected to receive a positive payment adjustment is largely due to CMS' proposed change to the cost scoring methodology. Beginning with the CY 2025 MIPS payment year, the additional MIPS payment adjustment for exceptional performance was no longer available.

The table below combines elements of Tables 137 and 143 displayed in the proposed rule and shows the impact of payments by practice size, including proportion of eligible clinicians with a negative, neutral, or positive payment adjustment. It also shows the median positive or negative payment adjustment by practice size. CMS notes that as the proportion of MIPS eligible clinicians receiving a negative payment adjustment decreases the budget neutral funds available for redistribution also decrease The decrease in the size of the budget neutral pool results in a decrease in the size of its positive payment adjustment increases.

Table 137 & 143: CY 2025 Final Score Estimates and Median Positive and Negative Payment Adjustment, by Practice Size						
Practice Size*	**Total Number of MIPS Eligible Clinicians**	**Percent Eligible Clinicians with Positive Payment Adjustment**	**Percent Eligible Clinicians with Neutral Payment Adjustment**	**Percent Eligible Clinicians with Negative Payment Adjustment**	**Median Positive Payment Adjustment****	**Median Negative Payment Adjustment ****
Baseline						
1) Solo	18,867	31.05%	22.00%	46.95%	2.06%	-9.00%
2) 2-15	71,908	60.47%	14.97%	24.56%	1.82%	-4.69%
3) 16-99	150,377	64.79%	10.32%	24.89%	1.65%	-1.25%
4) 100+	445,493	74.84%	4.32%	20.84%	1.59%	-0.88%
Overall	686,645	69.93%	7.23%	22.84%	1.65%	-1.10%
Proposed Policies						
1) Solo	18,867	32.41%	21.94%	45.65%	1.55%	-6.42%
2) 2-15	71,908	64.29%	14.78%	20.93%	1.46%	-5.88%
3) 16-99	150,377	72.41%	9.98%	17.61%	1.35%	-1.44%
4) 100+	445,493	83.28%	4.13%	12.59%	1.28%	-1.08%
Overall	686,545	77.51%	7.02%	15.47%	1.31%	-1.48%

* Practice size is defined as the number of NPIs in a TIN

** The median positive payment adjustment is defined as the medium payment adjustment among clinicians with a final score above the performance threshold. The median negative adjustment has a final score below the performance threshold.

For payment year 2025, QPs will receive a lump-sum APM Incentive Payment equal to 3.5 percent of their estimated aggregate paid amounts for covered professional services furnished during 2024. As a result of changes made by the CAA, 2024, the APM Incentive payment will be equal to 1.88 percent for payment year 2026. Beginning in performance year 2026, as required by statute, there will be two separate PFS conversion factors, one for items and services furnished by a QP, and the other for other items and services (the nonqualifying APM conversion factor). Specifically, the update to the PFS CF for services that are furnished by clinicians who achieve QP status for a year will be 0.75 percent, otherwise it will be 0.25 percent.

Limitations of CMS Analysis

Importantly, CMS describes several limitations to the analysis underlying the tables. It notes that because many score are clustered near the performance threshold of 75 points, minor variations in clinicians' final scores relative to its estimations could have significant impacts on the proportion of clinicians receiving a positive or negative payment adjustment. The scoring model results presented in the proposed rule assume that 2022 Quality Payment Program data submissions and performance are representative of modeled performance. Likewise, CMS states that it is difficult to predict whether clinicians will elect to opt-in to participate into the MIPS program. Given these limitations and others, there continues to be considerable uncertainty around CMS' estimates.

D. Alternatives Considered

The proposed rule contains a range of potential policies, and CMS provides a discussion of alternatives considered for some of these policies.

1. Alternatives Considered Related to Strategies for Improving Global Surgery Payment Accuracy

As discussed in section II.G of the proposed rule, CMS proposes to broaden the applicability of the transfer of care modifiers for the 90-day global packages. CMS is proposing to require the use of the appropriate transfer of care modifier (modifier -54, -55, or -56) for all 90-day global surgical packages in any case when a practitioner (or another within the same group practice) expects to furnish only a portion of a global package. Additionally, CMS is proposing a global surgical add-on code, HCPCS code GPOC1, which it expects will be billed during the postoperative period of 90 days following the procedure. CMS anticipates that this code will be billed by a physician or practitioner who is seeing the patient for a visit during the post\-operative period and did not furnish the surgical procedure. CMS states that it analyzed a few different policy options to best achieve its goal of improving the payment accuracy of the global packages. These included:

- Revaluing the 10- and 90-day global packages on the PFS utilizing its findings and data under the MACRA requirement to improve payment accuracy on the fee schedule (precluded from doing so, however, under MACRA).
- Revaluing services specifically included in the RAND study,[77] which looked at claims for which reporting of follow up visits was requested.
- Requiring separate billing, which would result in separate payments for the procedures and postoperative visits in global packages, based on its current research and analysis of how practitioners may be furnishing care described by global packages.
- Revising all global surgical packages in a phased approach starting with the subset of packages described above and gradually revising other global packages over time.

2. Alternatives Considered Related to the Supervision of Outpatient Therapy Services in Private Practices

As discussed in section II.H of this proposed rule, CMS proposes to allow for the general supervision of occupational therapy assistants (OTAs) and physical therapist assistants (PTAs), by OTs and PTs in private practice (OTPPs and PTPPs, respectively) who are enrolled as suppliers in Medicare. Currently, and since 2005, OTPPs and PTPPs are required to provide direct supervision of their OTAs and PTAs, which requires the OTPP/PTPP to be immediately available to furnish assistance and direction throughout the performance of the procedure in the

[77] Mulcahy, Andrew W., Harry H. Liu, Teague Ruder, Susan L. Lovejoy, Katie Merrell, and Ateev Mehrotra, Using Claims-Based Estimates of Post-Operative Visits to Revalue Procedures with 10- and 90-Day Global Periods. Santa Monica, CA: RAND Corporation, 2021. https://www.rand.org/pubs/research_reports/RR3035-1.html.

office suite or in the patient's home when Medicare patients are treated in order to bill for therapy services furnished by their supervised OTAs and PTAs.

In developing its proposal to allow for general supervision in these private practice settings, CMS considered the possibility of allowing for virtual direct supervision by the OTPP/PTPP instead. The OTPP or PTPP could meet the virtual direct supervision requirement by being immediately available to engage via audio/video technology (excluding audio-only).

3. Alternatives Considered for the Quality Payment Program

CMS states that the performance threshold is a critical factor affecting the distribution of payment adjustments in the Quality Payment Program. In this proposed rule, CMS proposes to set the performance threshold to 75 points for the CY 2025 MIPS performance period/CY 2027 MIPS payment year. CMS considered setting the performance threshold at 86 points, as a possible alternative. In its analysis of the alternative performance threshold of 86, CMS results show that a substantial higher proportion of MIPS eligible clinicians would receive a negative payment adjustment under this alternative compared with its proposal.

E. Impact on Beneficiaries

CMS believes that its proposed health equity benchmark adjustment (HEBA) would mainly provide upward adjustments to benchmarks and likely result in increased participation from new ACOs with a particular focus on coordinating care for beneficiaries in underserved communities. This change is expected to increase assignment to the Shared Savings Program by roughly 500,000 beneficiaries per year.

It also believes that several changes to the quality payment program are expected to have a positive effect on beneficiaries. For example, CMS states that the MVP and subgroup proposals, if finalized, will lead to meaningful feedback to beneficiaries on the type and scope of care provided. Beneficiaries could also use the publicly reported information on clinical performance in subgroups to inform their decisions on selection of clinicians and multispecialty groups. It also believes that several of the proposed new quality measures include patient-reported outcome-based measures, which may be used to help patients make more informed decisions about treatment options.

F. Estimating Regulatory Costs

Because regulations impose administrative costs on private entities, CMS estimates the cost associated with regulatory review, such as the time needed to read and interpret the proposed rule. CMS assumes that the total number of unique reviewers for this year's rule will be comparable to the number of unique commenters on last year's proposed rule. CMS also assumes that each reviewer reads approximately 50 percent of the rule and estimates that the cost of reviewing this rule is $123.06 per hour, including overhead and fringe benefits. In addition, CMS assumes that it would take about 8 hours for the staff to review half of this proposed rule. For each facility that reviews the rule, the estimated cost is $984.48 (8.0 hours x $123.06) and the total cost of reviewing this regulation is about $21.7 million ($984.48 x 22,019 reviewers on last year's proposed rule).