Physician Fee Schedule Final 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-F]

On November 1, 2024, the Centers for Medicare & Medicaid Services (CMS) placed on public display a final rule relating to the Medicare physician fee schedule (PFS) for CY 2025[1] and other revisions to Medicare Part B policies. The final rule is scheduled to be published in the December 9, 2024 issue of the *Federal Register*. Policies in the final rule generally would take effect on January 1, 2025.

HPA is providing a summary in three parts. Part I covers sections I through III.P (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 final rule contains an overview of comments CMS received from 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 final rule updates 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 final rule implements 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 final rule, CMS is also codifying policies established in revised guidance for the Medicare Part B Drug Inflation Rebate Program and making additional refinements. CMS also continues to defer changes to its practice expense methodology until it receives updated information from the American Medical Association's (AMA) Physician Practice Information Survey and is able to assess that data along with ongoing work.

The final conversion factor (CF) for 2025 is $32.3465, which reflects the expiration of the temporary 2.93 percent increase for services furnished for most of 2024,[2] the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act, and a budget neutrality (BN) adjustment of +0.02 percent. The increase in the BN adjustment appears to be largely related to the adjustments to the transfer of postoperative care for global surgical procedures.[3] The final 2025 PFS CF is 2.83 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, an increase of 3 percent for clinical psychologist, an increase of 2 percent for anesthesiology, and a decrease of 2 percent for diagnostic testing facility, interventional radiology, ophthalmology, 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 110 for a given specialty, the combined effect of RVU changes with the CF reduction would be roughly 5 percent.

II. Provisions of the Final 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

[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.
[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.

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.

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 finalizes its proposal to use PE per hour worked (or PE/HR) values from Licensed Clinical Social Workers as a proxy for these two specialties.

While CMS did not make any proposals associated with the list of expected specialty assignments for low volume services, CMS received comments from interested parties. Based on their review of the analysis submitted by commenters that examined whether the recommended specialty matches the dominant specialty in the claims data, CMS finalizes 75 additions to the list of expected specialty assignments for low volume services as identified in Table 1 in the final rule.

CMS notes that it is finalizing mandatory use of the -54 modifier 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. This will likely increase the number of claims subject to the adjustment (discussed in more detail in section II.L of this final 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 Association's "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 continues to believe it does not have sufficient information to use 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. Prior to this rule, CMS had 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.

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 did not propose 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.

Many commenters supported CMS' continued delayed implementation of the 2017-based MEI in PFS ratesetting and also urged CMS to delay consideration of other sources for the MEI until the AMA's efforts to collect practice costs data from physician practices have concluded. The AMA RUC stated that survey efforts concluded on August 31, 2024 and they are analyzing the data. Other commenters expressed a desire for alternatives should the data from the AMA Physician Practice Information Survey (PPIS) have low response rate for some specialties or prove insufficient. Another commenter urged CMS to implement the 2017-based MEI for PFS ratesetting as soon as possible and that the US Census Bureau's Service Annual Survey (SAS) data should be used determine the MEI in the future, rather than the PPIS, because it is reliable, regularly updated, and objectively collected.

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

[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.

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, 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 finalizes its proposal to update the prices of 17 supplies and one equipment item in response to the public submission of invoices. The 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. Based on wholesale acquisition cost (WAC) data submitted by a commenter, CMS also updated the supply pricing for esketamine described by the SH109 and SH110 supply codes. See Table 20 in the final 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 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

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

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.

(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 proposed to implement the supply pack pricing update and associated revisions as recommended by the RUC's workgroup. Specifically, CMS proposed 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 proposed to delete the "pack, drapes, laparotomy (chest-abdomen)" (SA046) supply entirely.

In accordance with the RUC workgroup's recommendations, CMS also proposed 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 Healthcare Common Procedure Coding System (HCPCS) codes for the deleted SA046 supply pack, none of these new supplies are included as standalone direct PE inputs in any current HCPCS codes. CMS proposed to add:

- 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.

While many commenters supported the proposed supply pricing update recommended by RUC, commenters expressed concern about the substantial decrease in the price of the urology cystoscopy visit pack (SA058) from $113.70 to $37.63. They recommended that CMS either delay the pricing update or phase-in the supply pack changes over a four-year period like it has done for other PE changes with significant distributive effects as this would allow independent urology practices to better prepare for the negative financial impact.

CMS agrees that the use of a phase-in transition period would be appropriate to allow practitioners to adjust to the pricing of these supplies. This would be consistent with CMS' policy used in the supply and equipment pricing update in the 2019 PFS final rule that established a 4-year transition period for very commonly used supplies and equipment. Based on this established policy, CMS finalizes the use of pricing transition for three supply packs as shown in Table 5 in the final rule (reproduced below):

Table 5: Supply Pack Pricing Transition

CMS_ CODE	HCPCS Codes	CMS_2024 Price	Recommend Price	Year 1 (CY 2025) Price	Year 2 (CY 2026) Price	Year 3 (CY 2027) Price	Final (CY 2028) Price
SA042	306	$19.43	$31.29	$22.40	$25.36	$28.33	$31.29
SA058	38	$113.70	$37.63	$94.68	$75.67	$56.65	$37.63
SA082	145	$3.91	$2.33	$3.52	$3.12	$2.73	$2.33

For the other supply packs, CMS finalizes each of them at their updated pricing for 2025 as proposed as these supplies are not commonly used and thus updating these prices in one year would not be financially disruptive. The updated pricing for existing direct PE inputs is shown in Table 20 and for new PE inputs in Table 21.

Several commenters noted that mathematical errors still remained for an additional 15 supply packs that needed mathematical correction by deconstructing the packs to determine the correct price through summing their individual components. These are shown in Table 6 in the final rule. CMS notes that it shares the concerns of the commenters regarding the accuracy in the pricing of these supply packs, but it has reservations about their potential for pricing disruptions. CMS further notes that many of these pricing updates would lead to drastic changes in pricing (increases and decreases) for these supply packs which are included in hundreds of HCPCS codes. It is not finalizing pricing updates for these additional 15 supply packs as requested by commenters citing the drastic shifts in overall PE for these codes and that the proposed rates did not appear in the proposed rule, thus not allowing opportunity for public comment. CMS states that it anticipates returning to this subject in future rulemaking and that should these supply pricing updates be proposed it would anticipate proposing the same pricing transition described above due to the number of potentially affected HCPCS codes.

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 did not add 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 believes 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 average 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 7 of the final rule (reproduced below). For 2025, the clinical labor pricing will be fully implemented.

Table 7: 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 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 8: 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%
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%

CMS received a variety of comments that included suggestions to freeze the final year of implementation, hold harmless the specialties most affected by the clinical labor pricing update, or cap payment cuts to individual codes in a single year to mitigate the financial impacts on physician payments. In response, CMS notes that to help smooth out changes in payment from clinical labor pricing it finalized the use of a 4-year transition in the 2022 PFS final rule. It also reminds readers that, as required by Protecting Access to Medicare Act of 2014 (PAMA), that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise decrease by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs are phased-in over a 2-year period.

d. Technical Corrections to Direct PE Input Database and Supporting Files

Several commenters, including the RUC, requested that CMS separately identify and pay for high-cost disposable supplies. They cited the outsized impact that high-cost disposable supplies

have within the current practice expense RVU methodology, which not only accounts for a large amount of direct practice expense for these supplies but also allocates a large amount of indirect practice expense. Commenters offered a couple of alternative solutions including:

- Requested that CMS separately identify and pay for high-cost disposable supplies priced more than $500 using appropriate HCPCS codes. CMS notes its prior discussion on this issue and reiterates that this option presents a series of potential problems in the context of broader challenges regarding its ability to price high-cost disposable supply items, referring readers to its discussion in the 2011 PFS final rule with comment period (75 FR 73251).

- Requested that high-cost disposable supplies priced more than $500 should be paid outside of the PFS, since PFS budget neutrality rules compound the challenge of appropriately valuing high-cost technology inputs without underpaying for physician professional services. One commenter recommended that CMS designate such services as office-based procedures under a new place of service designation and establish payment under the outpatient prospective payment system/ambulatory surgical center rulemaking instead of the PFS. CMS states that it has no current plans for such a policy, but will take it under consideration for potential future rulemaking.

CMS also made some technical corrections to the non-facility and facility PE RVUs for HCPCS codes G2251 and finalized an assistant at surgery payment policy indicator of "0" for CPT codes 37211, 37212, 37242, and 37197.

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 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,

[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,

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.

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

April 11, 2018. https://www.rand.org/pubs/research_reports/RR2166.html.

[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

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 requested general information from the public on ways that CMS may continue work to improve the stability and predictability of any future updates. Specifically, CMS requested feedback from interested parties regarding scheduled, recurring updates to PE inputs for supply and equipment costs.

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 sought 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 sought information about specific mechanisms that may be appropriate—in particular, approaches that would leverage verifiable and independent, third-party data that is not managed or controlled by active market participants.

CMS received numerous comments expressing concerns about CMS' current PE methodology, particularly highlighting its inadequacies in accommodating modern medical technologies and services, such as Software as a Medical Device (SaMD) and artificial intelligence (AI). They also supported more frequent updates and the incorporation of direct costs for software and innovative technologies. Many also supported the AMA's ongoing efforts to update the PPIS to PE calculations. CMS states that it will consider this information for future rulemaking.

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 finalizes its proposal to consider these codes 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.

Many commenters, including the RUC, supported this proposal. The AMA RUC noted that since the codes for osteotomy of the spine were last reviewed in 1995, these codes may benefit from updated descriptions and consideration of bundling with related procedures. They suggested options such as developing add-on codes for segment-specific osteotomies or integrating these into new deformity fusion codes. They further stated they will place the nominated osteotomy codes on the next Level of Interest (LOI) list for review at the January 2025 RUC meeting.

(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 PFS 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 finalizing its proposal to not to nominate this code as potentially misvalued**.**

Many commenters agreed with CMS and opposed creating a nonfacility/office payment rate for CPT code 27279 due to patient safety concerns and the lack of sufficient safety evidence. Specifically, they stated it would be challenging for a medical practice to consistently meet the sanitary requirements necessary to safely perform this procedure on an ongoing basis. Others stated that the procedure could be performed in an office or nonfacilty setting by referencing studies showing a low complication rate in OBL. CMS stated, however, that its review of the submitted studies was not persuasive.

(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 9, in the final 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 did not propose to consider this code as potentially misvalued. CMS sought comments on whether this typical procedure described by CPT code 95800 now involves the use of a disposable HSAT device rather than reusable equipment. After review of comments, CMS believes there is insufficient information at this time to demonstrate whether disposable or reusable HSAT devices are more commonly used than reusable HSAT equipment. Therefore, CMS is finalizing its proposal not to nominate CPT code 95800 as potentially misvalued.

(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 that these codes underwent a thorough RUC survey and review process during the October 2017 and January 2018 RUC meetings. CMS finalizes its proposal to not consider these codes as potentially misvalued.

The AMA RUC in its comments stated that these codes do not necessarily need to be re-evaluated but continues to believe there was an error in the utilization crosswalk for this code family during the 2019 review. CMS disagrees with this assessment and refers readers to its comments in the 2019 PFS final rule (83 FR 59517) and 2021 PFS final rule (85 FR 84602 through 84604). CMS further states that it welcomes the submission of new information regarding these services that was not part of the previous 2019 and 2021 reviews of the code family.

(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 sought comment on whether to establish a new G code and assign contractor pricing. It also sought 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.

Some commenters, including the RUC, stated that rather than developing new codes to describe tympanostomy tube delivery devices and/or systems, CMS should establish national pricing for Category III CPT code 0583T (*Tympanostomy (requiring insertion of ventilating tube), using an automated tube delivery system and iontophoresis local anesthesia)*. CMS disagrees and does not believe this code adequately reflects the work and PE for this procedure that uses innovative tympanostomy tube delivery devices.

Other commenters supported the creation of additional coding for these services. Specifically, they preferred that CMS establish a new G code, specifically an add-on G code with inputs based on CPT code 69433. CMS agrees and thus, for 2025, is finalizing the creation of a new add on G code, HCPCS code G0561 (*Tympanostomy* with *local or topical anesthesia and insertion of a ventilating tube when performed with tympanostomy tube delivery device, unilateral (List separately in addition to 69433) (Do not use in conjunction with 0583T)*) to be billed with 69433 in order to describe the additional resource costs associated with using the innovative tympanostomy tube delivery devices and/or systems falling under emerging technology and services categories. It is also finalizing contractor pricing for 2025.

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—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 finalizes changes to the Medicare Telehealth Services List and addresses frequency limitations on certain telehealth services, the use of providers' home addresses, and telehealth issues on direct supervision and supervision of residents in teaching settings, among other changes. These 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

CMS reviews the history of the process established for adding or deleting services from the Medicare Telehealth Services list. Its current structure was established in the 2024 PFS final rule as a 5-step process for making additions, deletions, and changes to the Medicare Telehealth Services List beginning for 2025. The steps are as follows:

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 service (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 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 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 11 in the final 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 submissions received 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.

In response to comments, CMS reiterates that this service is not an inherently face-to-face service. CMS finalizes its proposal not 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 did not propose to revise the status of codes from provisional to permanent in the proposed rule because CMS intends to conduct a comprehensive review in future rulemaking. Thus, CMS finalizes, as proposed, to maintain these services on the Medicare Telehealth Services List on a provisional basis.

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. CMS did not receive any comments on this proposal and finalizes, as proposed, not 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, which 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.

The commenter with the initial submission provided additional information to augment their argument that the patch containing the microneedle array can be applied by the patient themselves. CMS does not believe, however, that there is sufficient evidence to demonstrate, if the service was furnished using two-way audio-video telecommunications technology, that the clinician actions and patient interaction would be of similar content as an in-person visit.

CMS finalizes its proposal to not add CPT code 64566 to the Medicare Telehealth Services List.

Radiation Treatment Management (CPT code 77427)
CMS received requests to permanently add and a request to remove radiation treatment management (CPT code 77427) from the Medicare Telehealth Services List. The request to remove this code cited 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 proposed to remove this code from the Medicare Telehealth Services List.

Many commenters did not support CMS' proposal to remove Radiation Treatment Management from the Medicare Telehealth Service list. Specifically, they stated there have been no published safety incidents since this service has been able to be provided via Medicare telehealth and most of the side effects are minor dermatologic issues that can be treated via audio-visual technology. These commenters also discussed the medical decision-making used when determining if a patient's side effects are appropriate to be resolved in a telehealth encounter rather than in person. They also noted that since the visit portion of this is conducted weekly, this decision can be changed based on whether the patient is experiencing side effects and other clinical considerations.

CMS states that the points raised by the commenters regarding the lack of evidence of adverse patient safety outcomes and the importance of allowing clinical judgement are compelling. It also recognizes the ongoing patient safety concerns and welcomes any additional information regarding any adverse outcomes, as it becomes available. Thus, CMS is not finalizing its proposal and will retain radiation treatment management (CPT code 77427) on the Medicare Telehealth Servies List on a provisional basis.

Home International Normalized Ratio (INR) Monitoring (G0248)
CMS received a request to permanently add this service to the Medicare Telehealth Services List; it is not currently on the list nor had it been previously added and removed. CMS proposed 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.

Many commenters supported the CMS proposal and some suggested that this service be added to the Medicare Telehealth Services List on a permanent basis. These commenters clarified that as home INR services are primarily furnished by IDTFs, CMS should clarify that these suppliers are also able to bill for Medicare Telehealth services. They explain that these services are generally delivered by individuals considered to be clinical staff and practitioners under the PFS. In response, CMS states that based on the additional information provided about the entities who commonly bill these services and how they are currently delivered, it needs additional time to consider whether these services should be added to the Medicare Telehealth Services List.

Thus, CMS is not finalizing as proposed to add Home INR Monitoring (HCPCS code G0248) to the Medicare Telehealth Services List on a provisional basis.

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 finalizes its proposal 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.

CMS also finalizes its proposal that HCPCS codes G0541-G0543 and G0539-G0540 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.

Many commenters were in support of this proposal, with some recommending that CMS add these services to the Medicare Telehealth Services List on a permanent basis. CMS states that it may consider designating these services with permanent status after additional data is available.

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

As discussed in Section II.E of the final rule, CMS is finalizing 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 finalizes its proposal to add HCPCS codes G0011 and G0013 to the Medicare Telehealth Services List with a permanent status.

The services that CMS is adding to the Medicare Telehealth Services List are listed in Table 12 in the final rule (reproduced with modifications). In section II.I of the final rule, in response to commenters to add HCPCS G0560 to the Medicare Telehealth Services List, CMS finalizes this addition.

Services Finalized for Addition to the Medicare Telehealth List for 2025	
Code Family	**CPT codes/Status**
PrEP for HIV	G0011/Permanent G0013/Permanent
Caregiver Training	97550/Provisional 97551/Provisional 97552/Provisional 96202/Provisional 96203/Provisional G0541/Provisional G0542/Provisional G0543/Provisional G0539/Provisional G0540/Provisional
Safety Planning Interventions	G0560/Permanent

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

In the past, CMS 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 finalizes its proposal 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.

Commenters were mostly supportive of CMS' proposal to continue to suspend application of telehealth frequency limits on subsequent inpatient and nursing facility visits and critical care consultations through 2025. Others acknowledge the continued flexibility but express concern regarding the necessity of in-person care for patients in higher-acuity settings of care. In response, CMS states that continuing to suspend these frequency limitations on a temporary basis for 2025 will allow it more time to evaluate patient safety while preserving access.

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 finalizing its proposal 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. CMS clarifies in the final rule that no additional documentation, except for the appropriate modifier, is needed.

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.

Most commenters were supportive of this proposal. A few commenters requested the removal of the requirement that the distant site practitioner be able to furnish Medicare telehealth services via two-way, audio/video technology. This could be difficult, for example, in a rural area or areas without sufficient broadband infrastructure. CMS notes that Medicare telehealth services are generally analogous to, and must include the elements of, the in-person service and it believes that having the capability to use two-way, real-time, interactive audio and video communications is essential. CMS acknowledges in certain circumstances that patients may not want to use video in their homes because they do not want the practitioner to view their private, personal living space and thus is permitting a patient-driven choice to use audio-only technology in this instance.

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 finalized, 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 finalizes, as proposed, 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.

Commenters were in support of this proposal and highlighted the need for a permanent solution for practitioners who do not have an in-person practice location. Another commenter requested clarification regarding whether the practitioner's home address could be across a state line from the location of the beneficiary provided that the practitioner is licensed in both states. CMS states that it will consider the issues raised related to a permanent solution in future rulemaking. It defers to state law regarding licensure requirements for distant site Medicare telehealth practitioners. CMS notes, however, that a separate Medicare enrollment is required for each state in which the practitioner furnishes and intends to bill for covered Medicare services.

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 practitioners 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 PHE-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, patient safety, and the ability of the supervising practitioner to intervene if complications 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 finalizes its proposal 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 sought additional information regarding potential safety and quality of care concerns related to virtual direct supervision.

The majority of commenters supported extending this flexibility on a temporary basis for an additional year, and most requested that CMS make this flexibility permanent. A few commenters informed CMS of potential patient safety concerns and barriers to billing that it should consider before further extending or making this flexibility permanent.

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

CMS finalizes its proposal to adopt a definition of direct supervision that allows "immediate availability" of the supervising practitioner using audio/video real-time communications technology (excluding audio-only), but only for the following subset of incident-to services 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 finalizes 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 finalizing, as described above, to continue to define "immediate availability" to include real-time audio and visual interactive telecommunications technology only through December 31, 2025.

Commenters generally supported this policy and supported an incremental approach to making permanent the services that this definition applies to. They provided additional services for CMS to consider adopting permanently as inherently low risk for purposes of the policy permitting direct supervision through virtual presence, such as diagnostic tests, behavioral health, dermatology, therapy, registered dietitian nutritionists, cardiac rehabilitation, and pulmonary rehabilitation services. CMS states that it will consider adding to the services for which direct supervision can include virtual presence in future rulemaking.

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 finalizes its proposal 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.

The majority of commenters supported extending the policy described in this proposal through 2025. Several encouraged CMS to establish this policy permanently for in-person and telehealth services, within or outside of an MSA. Commenters also emphasized that teaching physicians should be allowed to determine when their virtual presence would be clinically appropriate, based on their assessment of the patient's needs and the competency level of the resident. CMS finalizes its policy, as proposed, and states that it will take the commenters' suggestions into consideration in future rulemaking.

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

The so-called primary care exception 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. These conditions include 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 requested 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.

Many commenters stated they support permanently expanding the array of services included under the primary care exception, specifically to include certain preventive and/or higher level E/M services. Other commenters requested that CMS consider expanding the primary care exception and definition of a "teaching setting" to include Rural Health Clinics (RHCs), Federally Qualified Health Centers (FQHCs) and Teaching Health Centers (THCs) that are reimbursed under Section 340H of the Public Health Service Act. Currently, the primary care exception does not apply to these centers, and commenters believe their inclusion would offer more training opportunities for residents and align payments for services provided at these centers with those furnished by residents under Medicare graduate medical education funding.

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. The final MEI increase for 2025 is 3.5 percent; the payment for HCPCS code Q3014 (Telehealth originating site facility fee) is $31.01. Table 13 shows the Medicare telehealth originating site facility fee and the corresponding MEI percentage increase for each applicable time period.

E. Valuation of Specific Codes

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

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

Table 17	Work RVUs for New, Revised, and Potentially Misvalued Codes
Table 18	Direct PE Refinements
Table 19	Direct PE Refinements: Equipment Refinements Conforming to Changes in Clinical Labor
Table 20	Invoices Received for Existing Direct PE Inputs
Table 21	New Invoices
Table 22	No PE Refinements

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

CMS provides an overview of the process for developing 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 developing work RVUs, including potential information sources and specific approaches.[8] CMS notes the importance of not only the RUC-recommended work and time values but also the accompanying rationales for setting those values.[9]

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 17 lists the codes and final work RVUs, including all codes that CMS received recommendations from the RUC by February 10, 2024.

Several commenters disagreed with the use of time ratio methodologies for work valuation. Commenters stated that treating all components for physician time (preservice, intraservice, postservice, and post-operative visits) as having identical intensity is incorrect, and inconsistently

[8]Approaches include RUC survey data, building block, key reference code crosswalks, magnitude estimation, incremental difference applications, and time ratio calculations.

[9]Time is parsed into pre-service, intra-service, and post-service components, summing to the total time for each 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.

applying it to only certain services under review creates inherent payment disparities in a payment system, which is based on relative valuation. Commenters further stated that in many scenarios, CMS selects an arbitrary combination of inputs rather than seeking a valid clinically relevant relationship that would preserve relativity. CMS disagrees and believes that the use of time ratios is one of several appropriate methods to identify potential work RVUs for particular RVU services. CMS notes, in particular, that this approach is helpful when alternative values recommended by RUC and other commenters do not account for survey information that suggests the amount of time involved in furnishing the service has changed significantly. CMS also reiterates that in addition to time ratios, it uses other methods (including estimates of work from CMS medical personnel and crosswalks to key references or similar codes) to validate work RVUs. For more details on its methodology for developing work RVUs, CMS refers readers to the discussion in the 2017 PFS final rule (81 FR 80272 through 80277).

3. Methodology for Direct PE Inputs to Develop PE RVUs

CMS reviews its methodology for establishing 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 18 details CMS' refinements of the RUC's direct PE recommendations at the code specific level. Table 19 details 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 that is performed outside of highly technical equipment rooms and is excluded from equipment time);
- 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 Outpatient Patient Payment System (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 in Tables 20 and 21 the number of invoices received and the number of nonfacility-allowed services for procedures that use this equipment.

For 2025, CMS finalizes seven new and revised codes as services which meet the definition of "imaging services" for purposes of the OPPS cap.[10] This includes CPT code 0868T (Hi-res gastric ep mapping); 0876T (Duplex scan hemo fstl lmtd); 74263 (CT colonography screening); 92137 (Cptrz oph img pst sg rta oct); and 93896-93898 (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 noted 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 sought 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.

In response to CMS' solicitation on CPT code 92229, some commenters requested that CMS remove this code from the OPPS cap list because it does not include an associated professional component (PC) or physician interpretation, and it is primarily utilized in the physician office setting. Commenters also argue that the Deficit Reduction Act of 2005 (DRA) is intended to apply to services typically performed in hospitals. CMS states that it will consider their input for future rulemaking, but notes that other ophthalmic codes on the OPPS cap list are typically performed in the physician office setting. CMS notes, however, that the amendments made to section 1848(b)(4) of the Act by section 5102(b)(1) of the DRA do not limit application of the OPPS cap to services typically performed in hospitals.

[10] As required by section 1848(b)(4)(A) of the Act, for imaging services furnished on or after January 1, 2007, CMS caps the technical component (TC) portion of the PFS payment amount for the year (prior to geographic adjustment) by the 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.

Some commenters expressed concerns that the application of the OPPS cap to CPT code 74263 (CT colonography screening) would be a significant barrier to imaging centers providing this service given the significant payment differential between the PFS payment amount and the OPPS payment amount. With the cap, the proposed 2025 PFS amount was about $460 less than the OPPS payment amount. These commenters suggested that CMS exempt screening services such as computed tomography colonography (CTC) from the OPPS cap. CMS notes that section 1848(b)(4)(B) of the Act specifically excludes diagnostic and screening mammography from the description of imaging services that are subject to the OPPS cap, and it does not have the statutory authority to exclude other services that are within the scope of the description of imaging services.

4. Valuation for Specific Codes

This section discusses CMS determinations for 40 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 final rule for more specific details.

Code Group Number and Name		Codes (CPT and HCPCS Codes)	CMS Proposed RVUs Agrees with RUC Recommendations		CMS Finalizes its Proposed RVUs	
			Work	PE	Work	PE
1	Skin Cell Suspension Autograft*	15011-15018	No**	N/A**	N/A**	N/A**
2	Hand, Wrist, & Forearm Repair & Recon*	25310, 2447, 25448, 26480	No	Yes	Yes	Yes
3	CAR-T Therapy Services*	38225-38227	Yes	No	No	No
		38228	Yes	Yes	Yes	Yes
4	Therapeutic Apheresis and Photopheresis	36514, 36516, & 36522	N/A	Yes	N/A	Yes
5	Intra-Abdominal Tumor Excision or Destruction	49186-49188	Yes	Yes	Yes	Yes
		49189-49190	No	Yes	Yes	Yes
6	Bladder Neck and Prostate Procedures*	53865, 53866	Yes	Yes	Yes	Yes
7	MRI-Monitored Transurethral Ultrasound Ablation of Prostate	51721, 55881, and 55882	Yes	Yes	Yes	Yes
8	Insertion of Cervical Dilator	59200	Yes	Yes	Yes	Yes
9	Guided High Intensity Focused Ultrasound*	61715	No	Yes	No	Yes
10	Percutaneous Radiofrequency Ablation of Thyroid	60660, 60661	Yes	Yes	Yes	Yes
11	Fascial Plane Blocks 64466, 64467, 64468, 64469, 64473, 64474, 64486, 64487, 64488, and 64489*	64467, 64468, 64469, 64474, 64487, 64488, and 64489	Yes	Yes	Yes	Yes
		64466, 64473, 64486	Yes	No	Yes	Yes
12	Skin Adhesives	64590, 64595, G0168, G0516-G0518	N/A	Yes	N/A	Yes

Code Group Number and Name		Codes (CPT and HCPCS Codes)	CMS Proposed RVUs Agrees with RUC Recommendations		CMS Finalizes its Proposed RVUs	
			Work	PE	Work	PE
13	Iris Procedures*	66680, 66682, & 66683	No	Yes	Yes	Yes
14	Magnetic Resonance Examination Safety Procedures*	76014, 76015	N/A	No	N/A	Yes
		76016, 76019,	Yes	No	Yes	Yes
15	Screening Virtual Colonoscopy*	74263	NA	N/A	NA	N/A
16	Ultrasound Elastography*	76981, 76982, & 76983	Yes	Yes	Yes	Yes
17	CT Guidance Needle Placement*	77012	Yes	No	Yes	Yes
18	Telemedicine Evaluation and Management (E/M) Services*	98000-98015	NA	N/A	NA	N/A
		98016	Yes	Yes	Yes	Yes
19	Genetic Counseling Services	96041	N/A	Yes	N/A	Yes
20	COVID Immunization Administration*	90480	Yes	Yes	No	No
21	Optical Coherence Tomography	92132-92134, 92137	Yes	Yes	Yes	Yes
22	Transcranial Doppler Studies	93886, 93888, 93892, 93893, 93896, 93897, 93898, & 93890	Yes	Yes	Yes	Yes
23	RSV Monoclonal Antibody Administration	96380 & 96381	Yes	Yes	Yes	Yes
24	Hyperthermic Intraperitoneal Chemotherapy	96547 and 96548	Yes	N/A	Yes	N/A
25	Laser Treatment – Skin*	96920, 96921, & 96922	No	No	Yes	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	N/A	Yes
27	Acupuncture - Electroacupuncture	97810, 97811, 97813, & 97814	Yes	Yes	Yes	Yes
28	New 365-Day Implantable Interstitial Glucose Sensor System*	G0564, G0565			N/A**	N/A**
29	Annual Alcohol Screening*	G0442, G0443	Yes	Yes	Yes	Yes
30	Annual Depression Screening	G0444	Yes	No		
31	Behavioral Counseling & Therapy*	G0445-G0447	Yes	No	Yes	Yes
32	Autologous Platelet Rich Plasma*	G0465	N/A	N/A	N/A	N/A

Code Group Number and Name		Codes (CPT and HCPCS Codes)	CMS Proposed RVUs Agrees with RUC Recommendations		CMS Finalizes its Proposed RVUs	
			Work	PE	Work	PE
33	Temporary Female Intraurethral Valve-Pump)*	0596T 0597T	N/A	N/A**	N/A	N/A**
34	PE-only replacement code for Heart Failure System*	G0555	N/A**	N/A**	N/A**	N/A**
35	Portable X-Ray	R0070-R0075	N/A**	N/A**	N/A**	N/A**
36	Non-chemotherapy Administration (updated policy)*	96401-96549	N/A	N/A	N/A	N/A
37	Hospital Inpatient or Observation (I/O) Evaluation and Management (E/M) Add-on for Infectious Diseases*	G0545	N/A	N/A	N/A	N/A
38	Preexposure Prophylaxis (PrEP) of Human Immunodeficiency Virus (HIV)	G0011, G0012, G0013	N/A	N/A	Yes	Yes
39	Opfolda	G0138	N/A	N/A	Yes	No
40	Direct Care Caregiver Training Services*	G0541, G0542, G0543	N/A	N/A	Yes	Yes
	Individual Behavior Management/Modification Caregiver Training*	G0539, G0540	N/A	N/A	Yes	Yes
41	RFI for Services Addressing Health-Related Social Needs*	G0019, G0222; G0023, G0024 G0140, G0146, G0136	N/A	N/A	N/A	N/A
* Discussed in HPA summary ** Contractor Priced Codes						

(1) Skin Cell Suspension Autograft (CPT codes 15011, 15012, 15013, 15014, 15015, 15016, 15017, and 15018)

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 sought 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 15013.

Many commenters supported CMS' proposal to contractor price these codes until reconsideration of the coding structure and re-survey is complete. The AMA RUC in their comment letter

confirmed that these codes will be re-reviewed in 2027. CMS reiterates its concerns, citing additional sources it reviewed since the proposed rule, about the service times, segmentation of the coding, and billing patterns of the add-codes based on the vignettes.

(2) Hand, Wrist, & Forearm Repair & Recon (CPT codes 25310, 25447, 25448, and 26480)
CMS disagrees with the RUC-recommended work RVUs for these codes; instead, CMS finalizes its proposed work RVUs based on the survey 25th percentile work RVU for these codes as it believes this more closely matches the increase in total work time. CMS finalizes the RUC-recommended direct PE inputs in this code family, without refinement.

Several commenters disagreed with CMS' proposed work RVUs for these codes with most suggesting that the RUC's recommendations of the survey median work RVU more accurately describes the physician work involved in furnishing these services. Commenters also disagreed with reductions in intensity for certain codes. CMS disagrees and believes that its use of survey 25th percentile is more accurate and more closely matches the increase in total work time.

(3) CAR-T Therapy Services (CPT codes 38225, 38226, 38227, and 38228)
In September 2023, CPT Editorial Panel deleted four category III codes (0537T-0540T) and approved the addition of four new codes (38225-38228) that describe only steps of the complex CAR-T Therapy process performed and supervised by physicians. CMS is not finalizing its proposal for CPT codes 38225, 38226, and 38227 and will instead continue to bundle payment under the PFS for CAR-T services. As commenters had pointed out, the predecessor codes for CAR-T services (0537T-0539T) are not separately payable under the OPPS and those codes similarly have a bundled status under the PFS. CMS notes that it will display the RUC-recommended work RVUs for these codes, however they will remain non-payable.

CPT code 38228 is the replacement code for Category III CPT code 0540T, which does not have bundled status, and therefore CMS is finalizing active pricing for CPT code 38228 at the proposed work RVU of 3.00 and with the proposed direct PE inputs.

(6) Bladder Neck and Prostate Procedures (CPT codes 53865 and 53866)
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 53865. It did not receive any comments on the issue of duplication. CMS, however, did receive updated invoices for the iTind device (SD366). Based on these four additional invoices, CMS is finalizing an increase in the pricing of the SD366 supply from the proposed $2,695 to $2,973.

(9) Guided High Intensity Focused Ultrasound (CPT code 61715)
CMS disagreed with the RUC-recommended work RVU of 18.95 for CPT code 61715 and instead proposed 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. Based on the clinical nature of the CPT code and its intensity relative to the various reference codes as described by many commenters, CMS does not finalize its proposed work RVU. Instead, CMS finalizes the RUC recommended work RVU of 18.95 and the recommended direct PE inputs.

(11) Fascial Plane Blocks (CPT codes 64466, 64467, 64468, 64469, 64473, 64474, 64486, 64487, 64488, and 64489)
CMS finalizes the RUC-recommended work RVU for all ten codes in this family. It disagreed with one of the RUC-recommended direct PE inputs for CPT codes 64466, 64473, and 64486. CMS disagreed that there was a rounding error in the CA019 clinical labor time and maintained the current 7 minutes of CA019 clinical labor time for these three codes. This refinement to the clinical labor time also results in small adjustments to RUC proposed equipment time for the stretcher and the 3-channel ECG. It finalizes the direct PE inputs, as proposed.

(13) Iris Procedures (CPT codes 66680, 66682, and 66683)
CMS disagrees with the RUC's recommended work RVUs based on 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 proposed 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 66683.

Almost all commenters opposed CMS' proposal for these codes and urged CMS to finalize the higher RUC recommended work RVUs. Many criticized the CMS methodology for relying too heavily on time and not enough on the overall intensity. CMS disagrees and finalizes the work RVUs for CPT codes 66680, 66682, and 66683 as proposed. It continues to believe that the use of time ratios is appropriate for identifying potential work RVUs for a particular service and disagreed that the intensity for CPT code 66680 has more than doubled. CMS also finalizes the direct PE inputs as proposed for all three codes in the family without refinement.

(14) Magnetic Resonance Examination Safety Procedures (CPT codes 76014, 76015, 76016, 76017, 76018, and 76019)
CMS finalizes the work RVU values for these codes as proposed (76014 and 76015 are PE only services). In response to comments, CMS makes various refinements to its proposed direct PE inputs. CMS finalizes the RUC recommended direct PE input of 2 minutes for clinical labor activity CA034 for CPT codes 76014, 76015, 76016, 76018, and 76019. For CPT code 76015, CMS is finalizing 21 minutes for clinical labor activity CA021 and 39 minutes for equipment code ED050. For CPT code 76019, CMS finalizes the inclusion of the RUC-recommended PE input for supply item SL082. All remaining direct PE inputs for CPT codes 76014, 76015, 76016, 76017, 76018, and 76019 are finalized as proposed.

(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 finalizes its proposal to assign an active payment status for CPT code 74263. The OPPS cap applies to this code, and payment for the TC of this service would be capped at the OPPS payment rate. Many commenters supported the proposal to assign active payment status to align with the expanded coverage proposal, though many expressed concerns with the application of the OPPS cap. CMS notes in section

III.K of the final rule that it does not have the statutory authority to waive the OPPS cap for this service.

(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 and finalizes the RUC-recommended work RVUs and direct PE inputs.

(17) CT Guidance Needle Placement (CPT code 77012)
CMS finalizes its proposal 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. CMS also finalizes the RUC-recommended work RVU of 1.50 as proposed.

Some commenters disagreed with its proposal to refine the equipment room time for the CT room (EL007) to maintain the current 9 minutes. They stated that the 9 minutes is appropriate for 35 of the 38 radiological supervision and interpretation codes performed in the angiographic room and for CPT code 76080 performed in the fluoroscopy room, but is not adequate for the two CPT codes 77012 and 75989 performed in the CT room. CMS states that it would serve the interests of relativity to increase the equipment time for the CT room without also addressing the equipment room time for other radiological supervision and interpretation procedures in a more comprehensive fashion.

(18) Telemedicine Evaluation and Management (E/M) Services (CPT codes 98000-980116)
CMS finalizes its proposal to assign CPT codes 98000-98015 a Procedure Status indicator of "I", meaning that there is a more specific code that should be used for purposes of Medicare. CMS does not believe there is a programmatic need to recognize the audio/video and audio-only telemedicine E/M codes for payment under 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 also finalizes its proposal to replace HCPCS code G2012 (e.g., virtual check-in) with CPT code 98016 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.

Many commenters, including specialty societies representing primary care and behavioral health practitioners, supported CMS' proposal and stated that they agreed with CMS' interpretation of section 1834(m) of the Act. Other commenters, including the AMA, disagreed with CMS' interpretation of Medicare telehealth services under section 1834(m) of the Act and stated that, as these codes describe a service that is definitionally not furnished in person, they would not be subject to the statutory restrictions. In response, CMS states that it did not find the comments put forth by the AMA and other commenters who opposed its proposal to be persuasive. They do not adequately address how or why the services described by the sixteen new telemedicine E/M codes are distinct from E/M services ordinarily furnished in person such that they are outside the

scope of section 1834(m) of the Act. Except for the service delivery modality, the new telemedicine E/M codes appear to describe the same services that are provided in person and billed under the existing office/outpatient E/M codes (99202-99215) and expressly referenced in section 1834(m)(4)(F)(i) of the Act as telehealth services

(20) COVID Immunization Administration (CPT code 90480)
In response to comments, CMS agrees with commenters and clarifies that payment for CPT code 90480 is already addressed under previously finalized policies associated with the Emergency Use Authorization (EUA) Declaration. Commenters requested that CMS not list the RVUs for CPT code 90480 in the PFS final rule until the EUA Declaration is rescinded as this policy is counter to population health initiatives and could result in stakeholder confusion. CMS further states that its proposal to assign separate pricing under the PFS for CPT code 90480 was an unintended error and it did not intend to cause any confusion. CMS is not finalizing the RUC-recommended work RVU and direct PE inputs for this code at this time.

(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.

After consideration of public comments, CMS finalizes the work RVUs and direct PE inputs for CPT codes 96920, 96921, 96922 as proposed with the exception of the finalized refinements of clinical staff time for the CA024 to 5 minutes and equipment times of 38, 40, and 46 minutes for the power table (EF031) and exam light (EQ168) equipment for CPT codes 96920, 96921, and 96922, respectively, to conform to the increased clinical staff time for CA024.

In the proposed rule, CMS sought comment on the difference in direct PE costs between the purchase and per-use rental of the laser. It also sought 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 model to limit overhead for purchase and maintenance of expensive equipment. CMS only received one comment on this issue, which encouraged CMS to remove the three pay-per-use excimer laser subscriptions from the list of supplies and stated that the equipment associated with these services can be purchased rather than leased. The commenter also expressed concern that that such a policy could alter

market dynamics, pushing more vendors to compel physician practices into subscription models. CMS states that while it understands that there may have been a change in business model, it does not believe a rental, subscription, or per-use fee of an equipment item that is still available to be purchased, as confirmed by the excimer laser vendor, and is already accounted for with CMS' equipment methodology is appropriate, especially given its implications for direct PE costs for these CPT codes.

(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 finalizes its proposal 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.

Several commenters disagreed with the CMS proposal of the HCPAC's recommended direct PE inputs. In particular, commenters questioned why it was appropriate to apply the MPPR first through the valuation of the direct PE inputs and then again during claims processing. In response, CMS states that it is a difficult task to properly value clinical labor, supply, and equipment inputs for these therapy services due to multiple billings being typical for the same patient on the same day. It has a longstanding policy such that in cases where multiple services are typically furnished to a beneficiary on the same day, it believes that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. At the same time, if CMS were to discount the clinical labor times too heavily by overlapping the MPPR, it runs the risk of under-allocating sufficient clinical labor to cover the typical case. It continues to believe that the direct PE inputs as recommended by the HCPAC are the most accurate values. Thus, CMS finalizes the direct PE inputs for the 19 CPT codes in the Physical Medicine and Rehabilitation family as proposed.

(28) Insertion, and Removal and Insertion of New 365-Day Implantable Interstitial Glucose Sensor System (HCPCS Codes G0564 and G0565)
In the 2023 PFS final rule (87 FR 6923), CMS revised national pricing for two Category III CPT codes that describe continuous glucose monitoring for a 180-day period. Category III CPT codes 0446T and 0448T describe the services related to the insertion, and removal and insertion of an implantable 180-day interstitial glucose sensor from a subcutaneous pocket. The implantable interstitial glucose sensors are part of systems that can allow real-time glucose monitoring, provide glucose trend information, and signal alerts for detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia).

Interested parties submitted a public comment in response to the 2025 PFS proposed rule that asked CMS to establish coding and payment similar to CPT codes 0446T and 0448T for services related to a newly FDA approved implantable 365-day continuous glucose monitoring system. The commenter stated that creating new coding will allow for continuity of this service during the manufacturer's transition from the 180-day monitoring service, as described by the current codes, to the new 365-day monitoring service.

CMS agrees with the commenters' request and establishes two new HCPCS codes to describe services related to the new 365-day monitoring services. HCPCS code G0564 and G0565. These will be contractor priced and effective January 1, 2025. CPT codes 0446T and 0448T should continue to be used to bill for the 180-day continuous glucose monitoring service.

(29) 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.

CMS finalizes the work RVUs for HCPCS codes G0442 and G0443 and the RUC-directed PE inputs for HCPCS codes G0442 and G0443 without refinement.

(31) *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 percent 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 finalizes 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 and finalizes its proposal, without modification.

(32) 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 Medicare Administrative Contractors (MACs) with some significantly below the cost of performing the service resulting in barriers to access.

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

While many commenters supported establishing national pricing for HCPCS code G0465 for 2025, they disagreed with the proposed crosswalk. CMS was persuaded by commenters that the higher work valuation would provide a more accurate crosswalk for HCPCS code G0465, as platelet-rich plasma may require more work and complexity in using these products. To ensure adequate valuation of both physician work and practice expense, CMS modifies its original proposal and instead is finalizing national pricing for HCPCS code G0465 for 2025 using a crosswalk to CPT code 15275 instead of CPT code 15271 because it believes this code more accurately reflects the work involved in furnishing the service described by HCPCS code G0465. Additionally, CMS finalizes an increase in the supply price of the 3C patch system (SD343) to $770.83, based on twelve submitted invoices.

(33) 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 on 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). Commenters were overwhelmingly in support of the CMS proposal. CMS finalizes creation of three new supply codes in the PE database to facilitate appropriate pricing by the MACs, as proposed.

(34) PE-only replacement code for Heart Failure System (G0555)
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 finalizes a new HCPCS code, with modifications to the descriptor to reflect comments received.

- G0555 *(Provision of replacement patient electronics system (e.g., system pillow, handheld reader) for home pulmonary artery pressure monitoring)*.

(36) 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 finalizes its proposal to update 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 describes requirements for these non-chemotherapy complex drugs or biologic agents to include the need for staff with advanced practice training and competency, such as, a physician or other qualified health care professional to monitor the patient during these infusions due to the incidence of severe adverse reactions. There are also special considerations for preparation, dosage, or disposal for these infusion drugs. CMS notes that these services do involve serious patient risk which requires frequent consults with a physician or other qualified healthcare professional.

(37) Hospital Inpatient or Observation (I/O) Evaluation and Management (E/M) Add-on for Infectious Diseases (HCPCS code G0545)

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 the COVID-19 PHE has ignited a hypervigilance for infectious diseases. For 2025, CMS finalizes its proposal to create a new HCPCS code G0545, with modifications to the HCPCS code descriptor to describe intensity and complexity inherent to hospital inpatient or observation care performed by a physician with specialized training in infectious diseases associated with a confirmed or suspected infectious disease.

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

- *HCPCS code G0545 (Visit complexity inherent to hospital inpatient or observation care associated with a confirmed or suspected infectious disease by an infectious diseases specialist, including disease transmission risk assessment and mitigation, public health investigation, analysis, and testing, and/or complex antimicrobial therapy counseling and treatment. (add-on code, list separately in addition to hospital inpatient or observation evaluation and management visit, initial, same day discharge, subsequent or discharge).*

CMS anticipates that this code would be reported by physicians with specialized infectious disease training. CMS does not believe it should limit the scope of codes with which this add-on HCPCS code could be billed based on visit level; or initial, same day discharge, or subsequent hospital inpatient or observation codes. Specifically, HCPCS code G0545 will be 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 G0545 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 finalizes 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 finalizes the same for HCPCS code G0545.

(40) 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 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 finalizes its proposal that the treating practitioner must obtain the patient's (or representative's) consent for the caregiver to receive the assessment. CMS also finalizes 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 clarifies that a caregiver is not required to have a caregiver-focused health risk assessment to participate in caregiver training services.

c. Proposals and New Coding

(A) Proposed Direct Care Caregiver Training Services

i. Coding

CMS finalizes its proposal 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 finalizes three new HCPCS codes with modifications to its descriptors:

- G0541 *(Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound care, and infection control) (without the patient present), face-to-face; initial 30 minutes);*
- G0542 *(Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound care, and infection control) (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service) (Use G0542 in conjunction with G0541))*; and

- G0543 *(Group caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound care, and infection control) (without the patient present), face-to-face with multiple sets of caregivers)).*

G0541 is for caregiver training for one person, first 30 minutes, and G0542 is to be used in conjunction with this for each additional 15 minutes in training. G0543 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. CMS also finalizes that caregiver training may be appropriate for circumstances when a beneficiary's caregiver needs training but the patient is under a home health plan of care, receiving at-home therapy, or receiving DME services for unrelated conditions.

Commenters were generally supportive of the creation of these codes. One commenter requested clarification on the definition of DME services and how wound dressings are involved in those services. CMS notes that it seeks to avoid potentially duplicative payment for services that are already paid for as part of another Medicare benefit. Payment to suppliers of DME items such as drug infusion pumps includes payment for supplies associated with use of the pump, such as wound dressings at the catheter site. DME suppliers are required to train the beneficiary or caregiver on use of supplies necessary for the effective use of the infusion pump, such as the dressings at the catheter site. Likewise, payment to suppliers of dressings covered under the Part B benefit for surgical dressings includes payment related to training the beneficiary or caregiver on how to use the dressings, including how to change them correctly. CMS clarifies, however, that the goal of paying for the direct care CTS for beneficiaries with wounds includes training related to all aspects of wound care, such as how to properly change dressings, use of different ointments, and turning the patient to prevent pressure. Therefore, CMS revises the direct care CTS code descriptors to replace the words "wound dressing changes" with "wound care."

ii. Valuation

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

- For G0541, CMS uses 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.
- For G0542, CMS uses 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.
- For G0543, CMS uses 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.

CMS notes that these codes could be conducted via telecommunications, as appropriate. CMS finalized addition of these codes to the Medicare Telehealth Services List (see Section II.D).

(B) Individual Behavior Management/Modification Caregiver Training Services

i. Coding

CMS finalizes its proposal 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 (88 FR 78818 for discussion of CPT 96202 and 96203). CMS finalizes the following two new HCPCS codes:

- G0539 *(Caregiver training in behavior management/modification for caregiver(s) of a patient with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face; initial 30 minutes)*; and
- G0540 *(Caregiver training in behavior management/modification for caregiver(s) of a patient with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service) (Use G0540 in conjunction with G0539)).*

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.

Commenters generally supported its proposals to establish these codes. Some comments requested the creation of broader caregiver training codes in the future. CMS states that it may consider commenters' recommendation for future rulemaking.

ii. Valuation

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

- For G0539, CMS uses 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.
- For G0540, CMS uses 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.

CMS notes that these codes could be conducted via telecommunications, as appropriate. CMS finalizes the addition of these codes to the Medicare Telehealth Services List (see Section II.D).

Some commenters supported CMS' valuation for HCPCS G0539 and G0540. A few commenters supported a crosswalk to CPT code 90832. CMS did not receive comments discussing supplies and equipment that would be typical for these codes. CMS believes its crosswalk to CPT codes 97550 and 97551 is more appropriate.

(C) Patient Consent

CMS finalizes its proposal 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 applies 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. Commenters were supportive of CMS' proposal to allow verbal consent for caregiver training services.

(41) 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))

In the 2024 PFS proposed rule, CMS issued 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 stated that it was 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 sought 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 noted 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 clarified that when it refers to "certified or trained auxiliary personnel" in the codes G0019, G0022, G0023, G0024, G0140, and G0146, this also includes CSWs. CMS sought 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 settings 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 was 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 sought 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 was 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 noted 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 finalizes new coding in other sections of the 2025 final rule that might be used to bill for managing fractures under a treatment plan, including the global post-operative add-on code, HCPCS code G0559. 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 was interested in hearing if the proposed global post-op add-on code could help resolve these issues.

A few commenters responded to CMS' RFI for fracture-related care. Overall, commenters agreed that care is commonly fragmented in osteoporosis and post-fracture care. Some commenters stated that services like APCM (G0559), CHI, or PIN do not accurately describe fracture liaison services. CMS states that it would take any comments and recommendation about how CHI, PIN, and SDOH risk assessment services are currently being used and how these services could be improved into consideration for future rulemaking.

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 continue 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 and 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 finalizes its proposal 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.

CMS received many comments on this issue with many in support of CMS' proposal. Others opposed the proposal based on arguments similar to those made in prior years that the O/O E/M visit complexity add-on code itself is ill-defined and the O/O E/M visit code set is appropriately valued. CMS disagrees and refers readers to the 2024 PFS final rule (88 FR 78972) where it discussed these concerns. A few commenters recommended that CMS allow the O/O E/M visit complexity add-on code (HCPCS code G2211) to be reported alongside other CPT codes, such as those describing other E/M services furnished to beneficiaries in other settings of care including nursing facilities, assisted living facilities, and the patient's home. CMS replies that it will consider in future rulemaking whether home or residence evaluation and management services bear unrecognized costs and whether HPCS code G2211 should be applicable to home or residence E/M visits.

Other commenters stated that CMS should continue to explore the appropriateness of restricting billing of HCPCS code G2211 to O/O E/M visits not billed with the payment modifier -25. These commenters stated that even if the visit is being reported in conjunction with another service, there still may be resource costs associated with longitudinal care that are not reflected in the payment for the O/O E/M visit or the other service. CMS replies that separately identifiable O/O E/M visits occurring on the same day as minor procedures (such as zero-day global procedures) have resources that are sufficiently distinct from the costs associated with furnishing stand-alone O/O E/M visits to warrant a different payment policy, and as such, it finalized that the O/O E/M visit complexity add-on code, HCPCS code G2211, is not payable when the O/O E/M visit is reported with payment modifier -25 (88 FR 78971). CMS states that it may consider additional changes to this policy for future rulemaking.

Many commenters also requested clarification as to whether HCPCS code G0402 (*Initial Preventive Physical Exam (IPPE))* was included as a preventive service billable alongside HCPCS code G2211. CMS confirms that the IPPE, known as the "Welcome to Medicare" preventive visit, is included in its policy because it is a Part B preventive service furnished in the office or outpatient setting.

Several commenters requested that CMS provide detailed medical necessity requirements and documentation guidelines related to reporting HCPCS code G2211. CMS notes that in response to interested party feedback requesting guidance about medical necessity and documentation requirements, it posted frequently asked questions at https://www.cms.gov/files/document/hcpcs-g2211-faq.pdf. It has not specified any additional medical record documentation requirements for this code, but notes that its medical reviewers may use the medical record documentation to confirm the medical necessity of the visit and the patient care relationship as appropriate. CMS states that it would expect that information included in the medical record or in the claims history for a patient/practitioner combination—such as diagnoses, the practitioner's assessment and medical plan of care, and/or other codes reported—could serve as supporting documentation for billing HCPCS code G2211. Practitioners should also consult their MAC regarding documentation requirements related to the underlying O/O E/M visit.

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.[11] Under section 1115A of the Act, the CMS Innovation Center may expand a model 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.

In this final rule, CMS incorporates 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 uses 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.[12]

As discussed below, for 2025, CMS establishes 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 final rule also includes a brief overview of comments CMS received in response to its 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.

2. Advanced Primary Care Management (APCM) Services (HCPCS codes G0556, G0557, and G0558)

a. Background

CMS observes 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

[11] 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.
[12] 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.

that define primary care. Based on this feedback, CMS continues to believe that it is important to establish codes that 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 23 in the final rule). CMS incorporated elements of these models into its policies for APCM services.

Commenters overwhelmingly supported the proposed coding and payment policies to recognize APCM services under this specific model of advanced primary care that incorporates lessons learned from the CMS Innovation Center's testing of advanced primary care models. A few commenters were concerned that CMS' proposed APCM coding and payment would duplicate work described by the existing Chronic Care Management and Principal Care Management codes, potentially creating confusion and administrative burden. Many commenters also recommended that cost sharing be eliminated for the proposed APCM services.

In response, CMS anticipates that these services will fulfil a need in primary care and care management. The agency also recognizes concerns about potential confusion with CCM and PC, it believes APCM codes are essential for improving payment accuracy and enabling practitioners to spend more time with patients. It would consider these issues in future rulemaking. With respect to cost sharing, CMS does not see how APCM services would fit within any of the benefit categories for preventive services under the Act at this time and it does not have other statutory authority that would allow it to remove or waive the applicable cost sharing for APCM services.

b. HCPCS G-Codes for APCM

CMS finalizes its proposal to create three new G codes (G0556, G0557, and G0558) 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.

G0556: *Advanced primary care management services for a patient with one chronic condition [expected to last at least 12 months, or until the death of the patient, which places the patient at significant risk of death, acute exacerbation/decompensation, or functional decline], or fewer, 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, 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.

G0557: *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 G0556 as appropriate*.

G0558: *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 G0556 as appropriate*.

CMS highlights the following 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 finalizes its proposal 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 also finalizes its proposal that unlike other coding to describe care management services, the code descriptors for HCPCS codes G0556, G0557, and G0558 would not be time-based.

CMS notes that although the service descriptors for APCM codes are the same, CMS finalizes its proposal that the APCM codes will be stratified into three levels based on certain patient characteristics that it believes are indicative of patient complexity and resources for providing services. Table 24, reproduced below, summarizes this stratification which is based on the advanced primary care model.

Table 24: Patient-Centered Risk Stratification for Billing APCM Codes		
Level 1 (G0556)	**Level 2 (G0557)**	**Level 3 (G0558)**
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).[13]

Level 1 APCM (G0556). CMS establishes 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 similar delineations based on the number of chronic conditions.

Level 2 APCM (G0557). This level includes 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 (G0558). This level incorporates people with \multiple chronic conditions *and* who have social risk factors. CMS will 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 sought 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.

[13] Sections 1902(a)(10)(E)(i) and 1905(p)(1) of the Act and §435.123. G0558 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.

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.[14]

Summary of Comments

1. Creation of Three New G Codes

Overall, commenters were supportive of CMS' proposal to create three new G codes (G0556, G0557, and G0558) to describe APCM services. They sought clarification on several issues:

- Type of practitioners that can furnish and be paid for APCM services - CMS clarifies that APCM services can be furnished by the types of Medicare-enrolled practitioners that are authorized under the statute to furnish and be paid for services performed by auxiliary personnel (which can include registered nurses and pharmacists) incident to their own professional services.
- Identification of the practitioner responsible for the patient's primary care – Commenters generally supported CMS' proposed approach. Other suggested attestation by the beneficiary of their main health care provider on Medicare.gov or a claims-based attribution method similar to the Medicare Shared Savings Program. CMS replies that, if needed, CMS may consider additional guardrails to prevent the submission of APCM services from more than one practitioner through future rulemaking.
- Specialties CMS would expect to furnish and bill for APCM services. CMS reiterates that a specialist who manages one or more of a patient's serious conditions is not necessarily the practitioner who is responsible for all of the patient's primary care. CMS notes that for the same patient it will make payment to only one practitioner for APCM services in any single month.

After consideration of public comments, CMS finalizes its proposals without modification to create three G-codes to describe APCM services effective January 1, 2025, which can be billed monthly following the initiating qualifying visit (see section II.G.2.c.(1) for more on the initiating visit) by the physician or practitioner (nurse practitioner, physician assistant, certified nurse midwife, or clinical nurse specialist) who intends to be responsible for the patient's primary care and serve as the continuing focal point for all needed health care services. CMS is not limiting APCM services to practitioners in specific specialties, but remains open to feedback about these policies from interested parties.

[14] Under the "lesser-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.

2. APCM services as a "designated care management service"

Commenters were overwhelmingly supportive of CMS' proposal to include APCM as a designated care management service, including its proposal to allow general supervision of auxiliary personnel for these services. CMS finalizes its proposal to add APCM services as a "designated care management service" under §410.26(b)(5) and, as such, these services can be provided by auxiliary personnel under the general supervision of the billing practitioner.

3. No Timeframe Restrictions for Billing

Most commenters were overwhelmingly supportive of CMS' proposal to not require the counting of clinical staff minutes spent furnishing APCM services to reach specific time-based thresholds for billing the proposed APCM codes, noting that doing so is both administratively burdensome and often results in practitioners providing services for which they are unable to bill and be paid. CMS agrees and notes that while these activities should be documented in the patient's medical record, it recognizes that documenting clinical staff minutes is unnecessarily administratively burdensome in this context. CMS finalizes its proposal without modification to establish APCM codes and descriptors that reflect all elements of service furnished during a month without specifying the amount of time that must be spent furnishing the services during the month; and without including time-related billing restrictions for the elements of the services.

4. Patient-Centered Risk Stratification for Billing APCM Codes

The majority of commenters supported CMS' approach and efforts to stratifying the APCM codes based on patient complexity and resource intensity. Several commenters, while in support, recommended various alternatives for stratification, including adding an additional level to the APCM service codes to account for patients with significant clinical complexity. A few suggested that six chronic conditions would be an appropriate threshold for this additional level and others suggested a four tier be added to the APCM service code levels based on the High Needs track of the ACO REACH Model to account for the resources needed to support patients with complex illness. CMS disagrees that an additional level is needed and believes that its proposed APCM code stratification strikes an appropriate balance between being overly specific in the creation of many categories (and thus creating confusion and administrative burdensome) and being overly simplistic (inadequate differentiation between variations in resource use). CMS finalizes, as proposed, the APCM service code levels.

5. Level 1 APCM Code Descriptor

One commenter notes that the code descriptor for HCPCS code G0556 does not mention the presence of a chronic condition, while the risk stratification for billing the code states "patients with one or fewer chronic conditions." CMS agrees and finalizes modifications to its proposed code descriptor for Level 1 APCM services to indicate the presence of one or fewer chronic conditions that are "expected to last at least 12 months or until the patient's death and or that place them at significant risk of death, acute exacerbation and or decompensation, or functional decline." This definition of "chronic condition" was already included for Level 2 and Level 3

APCM services. After consideration of public comments, CMS finalizes the code descriptor for HCPCS code G0556.

6. Level 2 APCM Code Descriptor

One commenter recommended that CMS add a modifier to be reported with the Level 2 APCM code to reflect social complexity and/or additional medical complexity for non-QMB beneficiaries. CMS replies that it believes its proposed coding approach appropriately balances coding specificity with administrative simplicity. CMS finalizes, as proposed, the code descriptor for HCPCS code G0557.

7. Level 3 APCM Code Descriptor

Several commenters appreciated CMS' recognition of social risk as a factor in health outcomes and health care delivery but were concerned about the proposed approach to use QMB status as a proxy indicator for patients with added social risk. Several commenters recommended that the requirements for Level 3 APCM include beneficiaries with at least one chronic condition and one unmet social determinants of health (SDOH) need. Others were concerned about practitioners' ability to determine a patient's QMB status and were concerned about additional operational burden. Many other commenters supported the use of QMB status as an appropriate indicator to identify beneficiaries with added social risk and called it a "good first approach." CMS replies that it believes that QMB status is a good indicator for patients with higher SDOH needs based on evidence from the Medicare Value-Based Purchasing Program, and is practical since CMS already records QMB status in its administrative data. The agency acknowledges, however, that there may be other ways to identify patients with SDOH needs and will consider those alternative methods through future rulemaking, as appropriate. CMS also notes practitioners already have access to QMB status, since practitioners have access to this information when verifying a patient's Medicare eligibility and because Medicare providers and suppliers are prohibited from billing QMBs for Medicare cost sharing. CMS finalizes its proposal to define Level 3 APCM services based on QMB status and two or more chronic conditions and finalizes the proposed code descriptor for HCPCS code G0558.

c. APCM Service Elements and Practice-Level Capabilities

Table 25 (reproduced below) lists all the elements within the scope of APCM. Additional details of each element are summarized in this section and discussed below.

Table 25: 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

Table 25: APCM Service Elements and Practice-Level Capabilities
• 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 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

Table 25: APCM Service Elements and Practice-Level Capabilities
• 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 sought 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.

Multiple commenters agreed that the proposed elements and requirements reflect the services consistent with effective APCM and that these standards are consistent with current CMS primary care models and demonstration projects. Several commenters also expressed appreciation for the references to caregivers in four of the proposed elements. Others expressed concern that small or independent practices may find it challenging and burdensome to meet some of the proposed service elements, which could exacerbate disparities in care and payment for patients at the highest risk. CMS in its response remains interested in the use of APCM services in settings such as small practices and in rural and underserved areas. It also encourages these providers to consider whether the care coordination and management services they are delivering would meet the requirements to bill for other care management services.

- Ways to align the APCM services with other Medicare programs and initiatives, such as the Medicare 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.

A number of commenters requested that CMS deem all ACO or alternative payment model (APM) participants as satisfying all service elements and requirements to bill the APCM codes by nature of their participation in such a program. In its reply, CMS clarifies that practitioners

participating in the ACO REACH Model, the Making Care Primary model, and the Primary Care First model would satisfy the proposed initiating visit, patient population-level management, and performance measurement APCM service elements and practice-level capabilities by virtue of meeting requirements of their model participation, and that CMS is not waiving any of the APCM service elements or requirements for practitioners in these models or the Shared Savings Program. CMS also clarifies that practitioners in practices participating in a Shared Savings Program ACO or in certain Innovation Center models (ACO REACH, Making Care Primary, Primary Care First) will satisfy the performance measurement element of the APCM services by meeting their respective program and model requirements.

(1) Beneficiary Consent

Consistent with other care management services, CMS finalizes its proposal 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 finalizes that the beneficiary's medical record would document the information provided and whether the beneficiary accepted or declined consent to receive APCM services.

Most commenters were generally supportive of CMS' proposal to require consent and the importance of beneficiaries understanding that cost sharing may apply for these services on an ongoing basis. Commenters also requested clarification on the frequency of consent, if patients with an existing consent for CCM would require a new consent for APCM, written versus verbal consent, and whether a standardized consent form would be available for use for APCM services. Others criticized the consent requirements as administratively burdensome and a substantial barrier to uptake of current CCM and PCM codes. CMS replies that while it understands the potential operational difficulty of obtaining and documenting consent, it believes consent is important to ensure beneficiaries understand their potential cost sharing responsibilities, especially for non-face-to-face services. CMS also clarifies that a beneficiary transitioning from CCM to APCM would require a new consent, though written consent is not necessary, and that a new consent to receive APCM services is required if there is a change in the practitioner who furnishes and bills for APCM services. CMS finalizes, as proposed, that patient consent needs to be obtained at initiation of APCM services and documented in the medical record.

(2) Initiating Visit

Also consistent with other care management services, CMS finalizes its proposal to require an initiating visit for APCM services only for new patients instead of for all beneficiaries receiving APCM services. CMS will 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.[15] CMS finalizes its proposal 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 Transitional Care Management (TCM) services. The initiating visit could be in-person or as a Medicare telehealth service.

CMS finalizes its proposal that an initiating visit is not 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[16] 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 sought 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." Commenters were overwhelmingly in favor of its proposals not to require initiating visits for established patients, and commenters agreed with the definitions proposed for established patients. CMS also finalizes a modification that the Medicare annual wellness visit can also serve as an initiating visit, so long as it is furnished by the practitioner who will furnish the APCM service.

(3) 24/7 Access and Continuity of Care

CMS finalizes its proposals, with modification, that APCM services generally include the same scope of service elements established for CCM and PCM services. For 24/7 Access to Care, CMS proposes that APCM services would provide 24/7 access for urgent needs to the care team/practitioner, including providing patients/caregivers with a way to contact health care professionals in the practice to discuss urgent needs 24/7. In response to comments, CMS clarifies that 24/7 access for urgent needs means reasonable after-hours care, when necessary. It also finalizes a modification that there need not be real-time 24/7 access to the patient's medical record. Instead, CMS will require that the after-hours responder must document and communicate their interaction with the patient to the primary care team/practitioner, and that interaction must be documented in the patient's medical record.

CMS finalizes its proposal that the "24/7 Access to Care" service element would require that practices 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 standard is similar to several requirements tested in CMS Innovation Center models. CMS notes that a practice does

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

not need to regularly deliver care in all these alternative ways but 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 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 finalizes its proposal that 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 with whom there is an established relationship. CMS discusses methods that practices have used for continuity of care including the use of practice management software to track improvements over time.

In response to comments, CMS explains that it is modifying 24/7 access to care requirement because it understands that real-time access to patient medical records may not always be feasible, especially for smaller practices that may rely on third parties for after-hours coverage. However, CMS reiterates that real-time access to the patient's medical record is a key component of advanced primary care, and it may revisit this issue in future rulemaking.

(4) Comprehensive Care Management

CMS finalizes its proposal 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 is "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.

Comments were overwhelmingly supportive and CMS finalizes the comprehensive care management service element as proposed.

(5) Patient-Centered Comprehensive Care Plan

CMS finalizes its proposal to adopt for APCM services the "Comprehensive Electronic Care Plan" service element it established 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.

In response to comments, CMS clarifies that a member of the care team could draft the care plan, as appropriate, and send it to the practitioner for review and approval. It also reminds commenters that the typical care plan elements which are based on those finalized in the 2020 PFS final rule (84 FR 62691) are not limited to the list. For example, it could include cultural and linguistic factors. CMS finalizes the patient-centered comprehensive care plan service element for APCM services as proposed.

(6) Management of Care Transitions

CMS finalizes its proposal for APCM services to adopt for APCM services the "Management of Care Transitions" service element it 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 simply requires the billing practitioner to "ensure timely exchange of electronic health information" with other practitioners and providers. CMS also finalizes 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.

After consideration of public comments, CMS finalizes the management of care transitions service element as proposed, but with clarification that practitioners should make reasonable efforts to provide timely follow-up communication after an ED visit or hospital discharge within 7 days when possible. Consistent with other APCM service elements, CMS requires that the efforts to reach the patient/caregiver and any interaction must be documented in the patient's medical record. CMS may consider revisions to this policy in future rulemaking.

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

For the APCM code descriptors, CMS finalizes its proposal 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." These are similar elements as established for CCM and PCM with some modifications. CMS also finalizes more detail about the communication documented in the patient's medical record as including "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.

Most commenters were generally supportive of the CMS proposal. One commenter was concerned that this proposal does not incentivize specialists and other clinicians to coordinate with primary care practitioners. CMS agrees with commenters that specialists furnishing consultations in conjunction with primary care practitioners are an essential element of advanced primary care services. CMS therefore clarifies in this final rule that the interprofessional consultation codes (CPT codes 99446-99449 and 99451) can be billed concurrently with APCM services. CMS finalizes the practitioner, home- and community-based care coordination service element as proposed.

(8) Enhanced Communications Opportunities

CMS finalizes its proposal 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." These are similar elements as established for CCM and PCM with some modifications. 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 did not propose timeframe restrictions for this element, which includes access to certain CTBS, such as the time restrictions between a virtual check-up and an E/M visit.

Many commenters supported the emphasis in its proposal on technology integration. Another commenter recommended that CMS eliminate the requirement to offer digital E/M services and virtual check-ins, since these may not be appropriate for certain specialized populations. In its

reply CMS clarifies that virtual check-ins and digital online assessment and management and E/M visits (or e-visits) are not specific requirements of this service element, but rather, are listed as examples. Several commenters requested clarification on the documentation required for this proposed service element. CMS states that it would not expect that the presence of enhanced communications opportunities and capabilities would be documented in each patient's medical record except to the extent that they are used to furnish APCM services. Rather, if the patient has an interaction with a care team member via an enhanced communication tool or service, CMS expects that the interaction to be documented in the patient's medical record. By billing for APCM services, the practitioner is attesting that the APCM service meets the requirements specified in the code descriptor. After consideration of public comments, CMS finalizes the enhanced communications opportunities service element as proposed.

(9) Patient Population-Level Management

CMS finalizes its proposal 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 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 Medicare 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.

Several commenters requested clarification on how to document that a practice meets the Patient Population-Level Management requirement. In response, CMS states that it would not expect that the practice-level requirements would be documented in each patient's medical record except to the extent they are used in furnishing APCM services to a specific patient, in which case CMS would expect the service to be documented in the patient's medical record. For example, if a practitioner calls a patient after a hospitalization and reviews medication changes, a record of what transpired during that conversation should be included in that patient's medical record. CMS finalizes the "Patient Population-Level Management" service element as proposed.

(10) Performance Measurement

CMS finalizes its practice-level requirement of performance measurement of primary care quality, total cost of care, and meaningful use of Certified Electronic Health Record Technology (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 finalizes its proposal 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.[17] A MIPS eligible clinician can report to MIPS as an individual, subgroup, group, APM 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.[18] 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 APM 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 received several comments supporting the practice-level performance measurement requirement, and a few commenters appreciated that CMS was using an existing reporting pathway via the Value in Primary Care MVP for practices to meet the performance measurement requirement. CMS replies that it chose this pathway because of the flexibility it offers practitioners in reporting on quality metrics that align with their patient populations and because the measures focus on the clinical theme of promoting quality care for patients in order to reduce the risk of diseases, disabilities, and death.

A few commenters indicated that it may be difficult or expensive for some practitioners to meet the MIPS Promoting Interoperability performance category requirements, so the electronic data sharing and integration requirements of the Value in Primary Care MVP should be removed or delayed. CMS reiterates that there are practitioners who would not be MIPS-eligible clinicians for various reasons—for example, they would have earned QP status based on meeting threshold levels of participation in an Advanced APM, they are newly enrolled in Medicare, or they bill a

[17] CMS finalized "The Value in Primary Care" MIPS Value Pathway in the 2024 PFS final rule (88 FR 80042-80047).
[18] §414.1375(b) and §414.1365(c)(4)(i)

low volume of Medicare services. These practitioners could bill for APCM services if they meet the service elements and practice-level requirements to do so, but these practitioners would not be required to meet the performance measurement requirement for APCM services through reporting the Value in Primary Care MVP to MIPS.

Several commenters requested that participants in other CMS Innovation Center models be able to meet the performance measurement requirement by meeting requirements of their model participation, and not have to report the Value in Primary Care MVP. CMS states that it specifically identified the Shared Savings Program, the ACO REACH model, the Primary Care First model, and the Making Care Primary model, as APMs in which their participation would meet performance measurement requirements. CMS states that at this time, the performance measurement requirements of other APMs are not sufficiently aligned with the Value in Primary Care MVP.

Several commenters requested clarification on how APCM services and the performance measurement requirements could be implemented by Medicare Advantage or other payers. CMS notes that it designed the APCM code set, including the practice-level performance measurement requirement, for purposes of payment under FFS Medicare. To the extent that other payers, including Medicare Advantage organizations, Medicaid State plans, or commercial payers, decide to use the APCM codes, CMS encourages them to adopt requirements that align with CMS in the interest of efficiency and burden reduction for practitioners. CMS finalizes the "Performance Measurement" requirement as proposed.

d. Duplicative Services and Concurrent Billing Restrictions

CMS does not finalize its concurrent billing restrictions, except with respect to the one practitioner who is furnishing APCM services. APCM services could not be billed by the same practitioner within the same month with these other services: CCM, PCM, TCM, interprofessional consultation, remote evaluation of patient videos/images, virtual check-in, and e-visits. In response to comments, CMS modifies its proposed policy and will allow these other specified care management services to be billed by a practitioner other than the practitioner furnishing APCM services to the same beneficiary. The table below lists the duplicative services (Table 26 provides additional information). Since CMS has intentionally designed the elements of APCM services to track closely with the elements of several other care management services and CTBS codes, it believes these services are substantially duplicative of APCM services

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

Services Duplicative of APCM Services	
Online Digital E/M (e-Visit)	CPT Codes 98970 - 98972, 99421- 99423

CMS sought comments on potential overlap between APCM services and other services, including, but not limited to, care management, care coordination, and other CTBS. Most commenters agreed that CCM and TCM were duplicative with APCM if performed by the same practitioner. Many did not agree with CMS' proposed concurrent billing restrictions by a practitioner in the same practice as a practitioner who is furnishing APCM services for the patient. For example, one commenter stated that a patient may be receiving APCM services from their primary care practitioner but receiving PCM from their cardiologist who works for the same practice and was concerned the proposed concurrent billing restriction would impede the beneficiary's care. CMS agrees and believes that specialists should still be able to furnish these care management services concurrently to patients receiving APCM from another practitioner, when medically reasonable and necessary. Thus, CMS is not finalizing the concurrent billing restrictions, except with respect to the one practitioner who is furnishing APCM services.

CMS also 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 APCM services. CMS believes these services, when appropriate, may complement APCM services rather than overlap or duplicate APCM services. CMS indicates that nearly all commenters were supportive of its proposal to allow concurrent billing of BHI, CHI, PIN, PIN-PS, and the SDOH Risk Assessment with APCM services. Some commenters expressed that RTM and RPM should not be included within the APCM codes, but rather billed separately as complementary, non-duplicative services.

CMS agrees with commenters that RTM and RPM services are complementary to APCM services, and do not represent duplication of services, as long as time and effort involved in furnishing these services are not counted more than once, requirements to bill the other services are met, and the services are medically reasonable and necessary.

After consideration of public comments, CMS finalizes its proposal to allow concurrent billing for BHI, CHI, PIN, PIN-PS, the SDOH Risk Assessment, RPM, and RTM services in the same month as APCM services.

e. Valuation of APCM Services – G0556, G0557, and G0558

To value the APCM services, CMS uses the current valuation and utilization of the codes incorporated into the 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 the valuation of these codes and future related codes.

Table 27, reproduced below, summarizes the valuation of the APCM services. Detailed information about the calculation of these values is provided in the final rule.

Code	Short Descriptor	Reference Codes	CMS Work RVU	Approximate National Non-Facility Rate
G0556	APCM for patients with up to one chronic condition	99490	0.25	$15
G0557	APCM for patients with multiple (two or more) chronic conditions	99490, 99439, 99487,99489	0.77	$50
G0558	APCM for QMBs enrollees with multiple chronic conditions	Relative increase from G0557	1.67	$110

CMS sought feedback on whether these proposed values appropriately reflect the resources in furnishing these services, and requested other sources of data would help it assess the valuation for APCM.

Commenters generally suggested that the proposed valuation for APCM services underestimated the time and resources involved in providing the activities required under APCM such as 24/7 access to care, patient population-level management, and performance management. CMS generally agreed with commenters that these services may be undervalued, given the time and resources that are necessary for the provision of advanced primary care, but it also recognized there could be a wide range of potential resource costs, especially during the initial use of the codes. CMS also received comments that were in favor of its proposed valuations. One commenter recommended that it finalize these valuations as proposed, even if the code descriptors and associated payment rates need to be refined in the future as interested parties gain experience with the new codes and provide feedback. CMS agrees with commenters that the valuation of these services is likely to be an iterative process, and it may revisit its valuation of these codes in future rulemaking.

For the proposed valuation of G0556, CMS was persuaded by commenters that the proposed rate for G0556 would not fully capture the relative resource costs involved in providing continuous, ongoing care management through an advanced primary care model of care delivery. CMS agrees with commenters that the methodology suggested of increasing HCPCS code G0556 to the equivalent of three units of 99490 divided over 12 months would better account for the work and PE involved in furnishing APCM services. This represents a work RVU of 0.25. CMS recognizes this is a relatively modest increase in valuation for G0556, and it may revisit the valuation of this and other APCM codes in future rulemaking.

CMS finalizes the valuation of G0557 and G0558, as proposed, with work RVU values of 0.77 and 1.67, respectively.

3. Request for Information: Advanced Primary Care Hybrid Payment

In the 2025 PFS proposed rule, CMS discussed 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 noted 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 recognize advanced primary care and reflect the resources involved in furnishing longitudinal care. CMS requested 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 requested that respondents provide objective, empirical and actionable evidence and to cite this evidence within their responses (the detailed questions can be found in our proposed rule summary).

CMS provides only a short description of the comments received from this detailed RFI. Most commenters responding to the Advanced Primary Care RFI were generally optimistic about the future of advanced primary care but cautioned that fee-for-service payments are still necessary for certain services. While several commenters expressed concern about administrative burden, many commenters also noted that capacity building investments could provide significant support to providers new to longitudinal care. CMS states that it will continue to review feedback in response to the Advanced Primary Care Hybrid Payment RFI as it pertains to future rulemaking.

Regulatory Impact

CMS estimates the following utilization for these codes: approximately 300,000 claims for G0556, 1.3 million claims for G0557, and 400,000 claims for G0558. 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 policy 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 beneficiary's risk of having a heart attack or stroke over 10 years, and provision of 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.[19]

CMS concludes that 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.[20] CMS does not believe the resources for these activities are appropriately reflected in current policies and establishes codes to describe a separately billable ASCVD risk assessment and CVD-focused risk management.

a. ASCVD Risk Assessment (G0537)

CMS finalizes its proposed ASCVD risk assessment code, HCPCS code G0537 with modification. The code descriptor now reads *"Administration of a standardized, evidence-based Atherosclerotic Cardiovascular Disease (ASCVD) Risk Assessment for patients with ASCVD risk factors, 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 finalizes that the ASCVD risk assessment must 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. 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 did not propose any specific ASCVD risk assessment tool. Elements of the ASCVD risk assessment include:

[19] 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.
[20] 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.

- 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 AHA Prevent Tool. The tool must not introduce discriminatory bias.

CMS finalizes its proposal that G0537 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 finalizes 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 uses this crosswalk to also establish direct PE inputs.

Many commenters requested that the ASCVD risk assessment not be required to be furnished on the same date as the associated E/M visit since practitioners may not have the necessary laboratory data on the same date as the E/M visit. CMS agrees with commenters so it is not finalizing the requirement that the ASCVD risk assessment must be performed on the same date as the associated E/M visit. CMS also received comments requesting changes in the requirement that the ASCVD risk assessment can only be furnished "not more often than every 12 months" per beneficiary in cases where a different practitioner may need to furnish the risk assessment to furnish appropriate ASCVD risk management services. For example, if a beneficiary's primary care practitioner conducted the ASCVD risk assessment and they were determined to be at high risk for a future ASCVD diagnosis, the primary care practitioner may feel the need to refer the beneficiary to a cardiologist to finish ASCVD risk management services. CMS also agrees with commenters about this concern. It finalizes that the ASCVD risk management service can be furnished not more often than once every 12 months per practitioner per beneficiary. CMS finalized the code descriptor to align with these changes.

b. Atherosclerotic Cardiovascular Disease Risk Management Services (G0538)

CMS finalizes, with modifications, its ASCVD risk assessment code. The HCPCS code G0538 now reads –*"Atherosclerotic Cardiovascular Disease (ASCVD) risk management services with the following required elements: patient is without a current diagnosis of ASCVD, but is determined to be at intermediate, medium, or high risk for CVD 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 finalizes that the elements of ASCVD risk management service includes:

- 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 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 does not 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 finalizes 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 finalizes 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 finalizes 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 finalizes that HCPCS G0538 has a work RVU of 0.18. This 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 also finalizes this crosswalk to establish direct PE inputs.

CMS received many comments requesting clarification on whether concurrent billing of other services would be allowed with G0538, such as care management services and Self-Measured

Blood Pressure (99473-99474). CMS replies that concurrent billing with G0538 would be allowed during the same month if time and effort are not counted more than once, requirements to bill both services are met, and the services are medically reasonable and necessary. CMS also received additional information about the current clinical practice metrics for identifying patients at medium to high risk of CVD. Many standardized, evidence-based risk assessment tools use different percentage ranges that may fall outside of the proposed ">15 percent in the next 10 years." CMS in response acknowledges that clinical practice evolves over time and the categorization of risk percentiles into categories of risk may also evolve as risk prediction tools and clinical guidelines are refined. For these reasons, CMS will remove the risk management threshold percentile from the code description for G0538 services given that the intent of the Million Hearts® model was to identify patients commonly considered to be at intermediate (or medium) or high risk of ASCVD for G0538 services.

H. Supervision of Outpatient Therapy Services in Private Practices, Certification of Therapy Plans of Care with a Physician or NPP Order, and KX Modifier Thresholds

1. Supervision of Outpatient Therapy Services in Private Practices

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 facilities, outpatient hospitals, SNFs and comprehensive outpatient rehabilitation facilities (CORFs), *et cetera*), 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 change 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 policy 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 finalizes its proposal 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 allows 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).

Commenters overwhelmingly supported CMS' proposal to change the required level of supervision of PTAs and OTAs in PT and OT private practices from direct to general supervision. Among other reasons, commenters cited potential benefits including increase patient access to therapy services, alignment with State laws and practice acts and reduced administrative burden.

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, *et cetera*) 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, *et cetera*) 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 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 believes 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 finalizes its proposal to carve out an exception to the physician signature requirement at §424.24(c) by adding a new paragraph (c)(5). The 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 policy, 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.

Commenters were generally supportive as they believed this change would reduce the administrative burden for therapists and physicians/NPPs, as well as encouraging more timely and efficient care delivery.

CMS requested 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).

Many commenters supported having a 10-business day window of opportunity for the physician or NPP to provide modification to the plan of care. Others did not support the 10-business day window as the NPP may not be able to respond within 10 days. Many also urged CMS to clarify that physician/NPP modifications to therapy POCs are only applied on a prospective basis and asked it to guarantee payment for those therapist services provided prior to the modification, as otherwise therapists could wait 10 days before providing therapy services to avoid nonpayment for a modification. CMS replies on this issue that it agrees with commenters that payment should be made for such therapy services if all applicable payment requirements, including medical necessity, are met.

Additionally, CMS solicited comment as to whether there should be a 90-calendar day time 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 sought 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).

Some commenters opposed the 90-day limitation, arguing it was too short and suggested a 6-month limit as more reasonable. One commenter stated a 90-day limit to physician referrals would pose significant problems for certain patients whose physicians write referrals for therapy at the same time they order surgery, and by the time the patient is able to start therapy the referral could be older than 90 days. CMS stated that it would take these comments into consideration for future rulemaking.

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 revises the headings of paragraphs (c) introductory text and (c)(1)(i) to include the term "occupational therapy" after physical therapy. CMS also replaces the term speech pathology with the accepted term speech-language pathology in 42 CFR 424.24(c)(1)(i), and adds 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 increases the 2024 KX modifier threshold amount by the most recent forecast of the 2017-based MEI, which is estimated to be 3.5 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 threshold amount of $2,410 for physical therapy and speech-language pathology services combined and $2,410 for occupational therapy services for 2025.

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 expenses incurred 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 Medicare implementation 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 finalizes its proposal, with modification, to establish separate coding and payment under the PFS describing safety planning interventions. Specifically, CMS finalizes HCPCS code G0560 as a standalone code, rather than an add-on code as proposed, to be billed in units of 20 minutes. It also finalizes that this code would need to be personally performed by the billing practitioner for 2025. In response to a comment, CMS also finalizes adding this code to the Medicare Telehealth List. The descriptor for HCPCS code G0560 is the following:

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

CMS values HCPCS code G0560 based on the valuation of CPT code 90839 *(Psychotherapy for crisis)*, which describes 60 minutes. CMS assumes 20 minutes for HCPCS code G0560, resulting in a final work RVU value of 1.09 (one-third of the work value assigned to CPT code 90839).

Many commenters recommended that CMS finalizes this code as a standalone code, rather than an add-on code. They noted the practitioners need a way to capture time spent performing safety planning interventions beyond the initial 20 minutes. Others pointed out the in settings such as emergency departments, crisis centers, and primary care, SPI will be conducted on its own at times and at other times, SPI will be provided in addition to services such as psychotherapy or E/M services. CMS agrees that there may be times when SPI may need to be furnished as a standalone service, that more time may be needed to complete safety planning interventions and that one 20-minute code may not accurately reflect the resource costs involved in furnishing these services. Thus, CMS finalizes HCPCS code G0560 as a standalone code that can be billed in 20-minute increments.

Several commenters believed that there was sufficient evidence to support trained clinical staff providing this service under the supervision of the billing practitioner and that this restriction would severely limit uptake and access for beneficiaries. CMS notes that it did not receive specific feedback on the nature of the training that would be needed but would consider these issues in future rulemaking. Thus, CMS finalizes, as proposed, that this code would need to be personally performed by the billing practitioner. CMS reminds commenters that the billing practitioner could be any practitioner who is authorized to furnish services for the diagnosis and treatment of mental illness, including Clinical Social Workers, Mental Health Counselors, Marriage and Family Therapists, Clinical Psychologists, as well as physicians and NPPs.

CMS also received comments on the code descriptor with some pointing out that the proposed code descriptor reads as if the code is specific to safety planning to prevent an impending suicidal crisis and they suggested that the code descriptor should be broader to recognize "warning signs" and that it should be more specific related to "contacting professionals." CMS agrees and modifies the descriptor to include: "recognizing warning signs of an impending substance-use related crisis," "contacting mental health or substance use disorder professionals or agencies," and adding "or risky substance use," as suggested.

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

CMS finalizes its proposal 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 G code is

- HCPCS code G0544: *Post discharge telephonic follow-up contacts performed in conjunction with a discharge from the emergency department for behavioral health or other crisis encounter, per calendar month.*

CMS finalizes its proposal 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 G0560 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 G0544. 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 finalizes its proposal, with modification, that the treating practitioner would be required to obtain verbal (or written) beneficiary consent either prior to or during the initial phone call in furnishing the services described by G0544, 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 clarifies and modifies several aspects of its proposal in response to comments. It clarifies that HCPCS code G0544 can be billed by practitioners in any instance in which the beneficiary has been discharged following a crisis encounter, including discharge from psychiatric inpatient care, or crisis stabilization. In addition, CMS clarifies that the services described by this code can be provided by auxiliary personnel incident to the services of the billing practitioner. In response to a comment about obtaining beneficiary consent in advance of furnishing the service related to cost sharing, CMS agrees that it may not be possible to obtain consent before performing the service and thus finalizes to allow patient consent either prior to, or during the initial phone call.

2. Digital Mental Health Treatment (DMHT)

CMS finalizes its proposal to establish Medicare payment to billing practitioners for digital mental health treatment (DMHT) devices furnished incident to professional behavioral health

services used in conjunction with ongoing behavioral health care treatment under a behavioral health treatment plan of care. In this 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 topics: 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 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.[21]

[21] https://store.samhsa.gov/product/advisory-digital-therapeutics-management-and-treatment-behavioral-

CMS finalizes its proposal to create three new HCPCS codes for DMHT devices modeled on coding for RTM services for 2025. The first code (G0552) 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:

- G0552 *(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 has been cleared under section 510(K) of the FD&C Act or granted De Novo authorization by FDA and classified under 21 CFR 882.5801
- 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 behavioral health treatment under a plan of care by the billing practitioner;
- Billing practitioner diagnoses the patient with a mental health condition and prescribes or orders the DMHT device

The patient could then use the DMHT device at home or 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 finalizes contractor pricing for code G0552. This code is not payable in cases where the billing practitioner incurs no cost in acquiring and furnishing the DMHT device, or a patient procures the DMHT device independent of the practitioner. Payment may only be made for DMHT devices for mental health treatment in accordance with the use indicated in their FDA classification under 21 CFR 882.5801.

CMS also finalizes its proposal to establish payment for two additional new codes. These codes and their descriptions (modified based on public comments) are:

- G0553 *(First 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing information related to the use of the DMHT device, including patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month)*, and

- G0554 *(Each additional 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing information related to the use of the DMHT device, including patient observations and patient specific inputs in a calendar month and requiring at*

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least one interactive communication with the patient/caregiver during the calendar month. (List separately in addition to HCPCS code G0553)).

Under this proposal, G0552 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. G0553 and G0554 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 G0552, CMS finalizes contractor pricing. CMS notes that the invoice prices received on these devices vary considerably and the agency does not believe it can appropriately price all the DMHT devices for which it proposes to make payment. For G0553 CMS finalizes a direct crosswalk to CPT code 98980 (remote therapeutic monitoring first 20 minutes), which is assigned a work RVU of 0.62. For G0554, CMS finalizes its proposal 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 0.61.

Overall, most commenters expressed general support for the proposed coding, but several dozen expressed either opposition or recommended significant refinements. Commenters expressed wide-ranging views about how broadly CMS should define DMHT devices for payment under HCPCS code G0552. For a detailed discussion of this issue, see pages 591-593 of the display copy of this final rule. In brief, CMS finalizes payment under HCPCS code G0552 for DMHT devices furnished incident to professional behavioral health services used in conjunction with ongoing behavioral health treatment under a behavioral health treatment plan of care. Specifically, CMS finalizes that DMHT devices under this payment policy must be cleared under section 510(k) of the FD&C Act or granted De Novo authorization by FDA and in each case must be classified under 21 CFR 882.5801 for mental or behavioral health treatment.

Commenters generally supported the two HCPCS codes G0553 and G0554 for treatment management related to a patient's therapeutic use of a DMHT device, but recommended that CMS acknowledge that many DMHT devices do not collect patient data. Many commenters recommended that CMS distinguish the treatment management codes from existing RTM codes by revising the descriptors for HCPCS codes G0553 and G0554 to replace the words: "reviewing data generated from the DMHT device from" with "reviewing information related to the use of the DMHT device, including." CMS agrees and finalizes the code descriptors for these codes, accordingly.

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 health care professional to

request the opinion and/or treatment advice of a consulting physician or qualified health care professional with specific specialty expertise without the need for the patient's face-to-face contact with the consulting physician or qualified health care 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.

In this rule, CMS finalizes six 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 finalizes six new G codes:

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

- G0551 *(Interprofessional telephone/Internet/electronic health record referral service(s) provided by a treating/requesting practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, 30 minutes).*

With respect to patient consent, CMS finalizes its proposal to require the treating practitioner to obtain the patient's consent in advance of these services, which should be documented by the treating practitioner in the medical record (similar to what is required for the CPT interprofessional consultation codes). This ensures 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 finalizes its proposal to value the six 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 Code	Work RVU	Crosswalk
G0546	0.35	99446
G0547	0.7	99447
G0548	1.05	99448
G0549	1.40	99449
G0550	0.70	99451
G0551	0.70	99452

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

Commenters overwhelmingly supported interprofessional consultations provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness. CMS finalizes HCPCS codes G0546-G0551, as proposed.

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 sought 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 the 2025 PFS proposed rule solicitation, CMS sought feedback on substance use disorder (SUD) facilities, community-based crisis stabilization, urgent care centers, and Certified Community Behavioral Health Clinics (CCBHCs).

SUD facilities. CMS was 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 Medicare patients or patients who are dually eligible, whether bundled payment could better facilitate billing for these services, and its potential impact on underserved areas.

Several commenters stated they believe that freestanding SUD facilities and other entities that furnish IOP services serve an important function in their communities and thus should have a sustainable payment structure because of their vital role in treatment engagement. Among other suggestions, several commenters urged CMS to enable payment for freestanding facilities that furnish IOP services, as well as for other levels of care along the continuum of SUD treatment and recovery (including Level 0.5 early intervention and screening, Level 1 outpatient treatment, Level 2.5 high-intensity outpatient treatment (previously partial hospitalization (PHP)), and Level 2.7 medically managed intensive outpatient treatment) to facilitate greater access to and continuity of SUD care. CMS replies that it may consider input for potential policy proposals through future rulemaking.

Community-based Crisis Stabilization. In addition, CMS sought 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 also sought 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.

Commenters stated that innovative approaches such as crisis stabilization units have helped communities improve coordination of emergency psychiatric care, and help alleviate the overall load on the mental health care system and emergency psychiatric boarding. Another commenter stated that payment for mental health and SUD services in these settings would greatly expand access to care in the midst of the ongoing overdose epidemic and mental health crisis. Another commenter stated that the definition of crisis stabilization, as well as "sobering care," can vary from state to state, and noted that variations can include: acceptance of involuntary admissions, referring parties (law enforcement, EMS, walk-in, *et cetera*), length of stay, environment, staffing levels and qualifications, etc. CMS replies that it may consider this input for potential policy proposals through future rulemaking.

Urgent Care Center. CMS was 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 sought 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 identifies and defines the scope of services furnished in such settings, whether the existing code set accurately describes and values 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.

One commenter suggested that CMS create a payment structure in which urgent care centers are differentially compensated. In response to its question about the existing place of service codes, they stated that the current place of service (POS) definitions are inadequately differentiated, especially if CMS wishes to encourage proliferation of the type of urgent care centers that can provide suitable alternatives to EDs. Another commenter expressed concern that it is essential to preserve the fundamental right for patients to seek emergency care when they think they are experiencing a medical emergency. CMS replies that it may consider this input for potential policy proposals through future rulemaking.

*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?

Several commenters stated that they understand that CCBHCs can bill Medicare if they are registered as a different provider type such as an office or CMHC but noted that Medicare does not cover all required CCBHC services. They also noted that CCBHCs are already certified per federal and state Medicaid criteria and to the extent Medicare were to allow CCBHCs as a Medicare provider, they encouraged alignment of any potential future Medicare CCBHC conditions of payment with existing Medicaid and state certification requirements. CMS replies that it may consider this input for potential policy proposals through future rulemaking.

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 that 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).

The deadline for submissions of additional clinical scenarios for potential consideration for 2025 rulemaking was February 10, 2024. CMS received thirteen timely submissions. CMS partnered with the Agency for Healthcare Research and Quality (AHRQ) to review requests for coverage of dental services in additional clinical scenarios.

2. Additions to Current Policies Permitting Payment for Dental Services Inextricably Linked to Other Covered Services

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 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; thus for 2024, CMS did not add either of these conditions to its list of clinical scenarios where it will pay for dental services. In the CY 2025 PFS proposed rule, CMS further summarized AHRQ's clinical review, and re-iterated its position that the agency does not consider dental services inextricably linked to services related to the treatment of SCD and hemophilia. In the proposed rule, CMS solicited public comment on its conclusion, and received nine comments in response. CMS indicates that the information commenters provided did not support a finding that dental services are inextricably linked to a covered medical service for SCD or that the standard of SCD care would be compromised without dental services, or that the standard of SCD care would require dental services to be performed in conjunction with treatments for SCD. The agency came to the same conclusion with regard to the information commenters provided for hemophilia. Thus, the agency in this final rule is not expanding the examples of clinical scenarios under §411.15(i)(3)(i) to include additional covered medical services for SCD or hemophilia.

In circumstances where CMS finds an inextricable link between dental services and the medical condition under consideration, CMS' existing rules allow Medicare to cover certain dental

services when furnished in either inpatient or outpatient settings.[22] In the 2025 PFS proposed rule, CMS discussed 13 public submissions providing disease-specific scenarios under which CMS could potentially cover dental services.

Dental Services Linked to ESRD. CMS reviews the evidence base indicating 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.[23] 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. Thus, in the 2025 PFS proposed rule, CMS proposed 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. The agency also proposed 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.

CMS indicated the agency received 54 comments in response to these proposals, all of which were supportive. Some commenters also supported Medicare paying for permitted dental services with stage 4 and stage 5 chronic kidney disease (CKD). In light of public comments and the research conducted by AHRQ, CMS concludes that the clinical evidence supports that medically necessary dental care is inextricably linked to, and substantially related, and integral to the clinical success of dialysis services in the treatment of ESRD because an oral or dental infection can present a substantial risk to the success and outcomes of these procedures (including the risk of systemic infection, bloodstream infections, sepsis, and death). Thus, the agency is finalizing its proposal that Medicare Part A and Part B payment can be made for certain dental services, such as a dental or oral examination performed as part of a comprehensive workup prior to dialysis services in the treatment of ESRD, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, dialysis services in the treatment of ESRD, and will add a new paragraph (F) at §411.15(i)(3)(i) to codify this change.[24] In light of the paucity of clinical evidence, CMS makes no corresponding change with respect to Medicare beneficiaries with CKD.

[22] These include 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, and services that are ancillary to these dental services, such as x-rays, administration of anesthesia, and use of the operating room.

[23] AHRQ produced a rapid response report to evaluate the evidence base establishing whether or not a similar relationship exists for dental services and patients with CKD, but found the clinical evidence lacking.

[24] CMS leaves determination of the frequency with which these services will be covered to the discretion of the Medicare Administrative Contractors (MACs).

3. Request for Comment on 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.

In the 2025 PFS NPRM, CMS acknowledged the benefits of dental services for beneficiaries with diabetes who also have a diagnosis of periodontitis, but indicated that the agency did not regard such dental services as inextricably integral to the clinical services directly treating diabetes, and the agency did not propose to revise its regulations to permit dental services to be paid when linked to the provision of services to treat patients with diabetes. However, CMS did solicit additional comment and information that could more definitively establish such a relationship between dental services and other clinical services used in the treatment of diabetes, as well as information on how periodontal disease services are provided, the duration of such services, and how such services might be coded for billing purposes.

As with ESRD, AHRQ produced a rapid response report related to the possible linkage between dental services and treatment modalities and services for diabetes patients, which documented "a complex relationship between diabetes and oral health," leading CMS to conclude that additional investigation is needed to ascertain the connections between dental services and clinical outcomes for beneficiaries with diabetes. Further, none of the public comments received (n=23) documented specific services for the treatment of diabetes to which dental services are inextricably linked. Thus, in this final rule, CMS is not expanding the coverage of dental services to Medicare beneficiaries with diabetes.

4. Request for Comment on 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.

In prior rulemaking, 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. 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. Like in the prior section,

CMS provided detailed requests for the type of information commenters could provide for CMS to change its conclusion, and CMS further reiterated its request for additional evidence and information in the 2025 PFS proposed rule.

As with ESRD and diabetes, AHRQ produced a rapid response report summarizing the evidence regarding the possible linkage between dental services and treatment modalities for patients with autoimmune diseases; the findings from the report were inconclusive, but suggested future avenues of research. In addition, CMS received 22 comments from the public on this topic. CMS asserts that none of the comments established that dental services were "inextricably linked" to clinical services treating autoimmune diseases, and thus CMS in this rule does not expand Medicare coverage of dental services to this population.

5. Implementation of Payment for Dental Services Inextricably Linked to Other Specific Covered Services

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 health care provider has included appropriate documentation in the medical record to support or justify the medical necessity of the service or item. In the 2025 PFS proposed rule, CMS proposed that, effective January 1, 2025, the KX modifier would be required on claims for dental services inextricably linked to covered medical services.[25]

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. In the 2025 PFS proposed rule, CMS sought 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. Thus, CMS sought 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.

[25] Use of the KX modifier signifies 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 that coordination of care between the medical and dental practitioners has occurred.

CMS indicates that most commenters supported its proposal to require the KX modifier for claims submission of dental services inextricably linked to covered medical services on both the dental claim format 837D and the professional claim format 837P. Comments were also supportive of CMS' recommended use of the GY modifier as discussed above. "Many commenters" supported CMS's proposal to require diagnoses codes on dental claims beginning January 1, 2025, although some commenters suggested a delay in these requirements would help ease implementation issues.

In light of comments received, CMS is finalizing its proposals to require the KX modifier on professional, dental, and institutional claims, and diagnosis codes on professional claims, but is delaying the requirement until July 1, 2025. CMS is also finalizing the use of the GY modifier as discussed above.

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. The 2025 PFS NPRM was the second consecutive year that CMS requested public comment on how to price dental services.

CMS states that several commenters indicated that the best source of data for pricing dental services would be national benchmark prices, such as those in the FAIR Health database, to help support and inform interim contractor pricing for dental claim reimbursement. A few commenters also mentioned CMS should require MACs to update payment rates annually using the Medicare Economic Index. CMS does not indicate that it is taking any particular action in response to these comments, but will consider them in the development of future payment policies for dental services.

6. Miscellaneous Comments (no summary)

7. Request for Information: Services Associated with Furnishing Oral Appliances Used for the Treatment of 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.

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 (K1027)[26] was

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

established effective April 1, 2022, to describe custom fabricated oral appliances without a fixed mechanical hinge.

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 K1027 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). But in the CY 2025 PFS proposed rule (89 FR 61764 through 61765) CMS included a Request for Information (RFI) to help determine if oral appliances used to treat obstructive sleep apnea can withstand repeated use (furnished as rental equipment for use by successive patients) and thus could be classified as durable medical equipment (DME). Specifically, CMS sought information regarding details that may inform or support a future proposal regarding a code assignment for services related to oral sleep apnea appliances under the Medicare physician fee schedule.

CMS indicates that it received 400 comments in response to this RFI. The agency received comments responding to some or all of the RFI questions from approximately 209 stakeholders, with an additional 191 comments that indirectly addressed the RFI questions. CMS is not responding to comments or information received in this final rule, but will consider these comments for future rulemaking.

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 for graft application procedures. However, it did not finalize this policy. CMS indicated 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. CMS did not make a specific proposal for changing how skin substitutes are paid under the PFS. CMS indicated 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 finalizes that billing and payment codes that describe products currently referred to as skin substitutes will not be counted for purposes of identifying refundable drugs for calendar quarters in 2025. In section III.I. of this final rule, CMS is also finalizing 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.

Several public commenters raised objections to paying for all skin substitute products as supplies, including that assessing the costs of skin substitute products within the PE RVU methodology is challenging due to variability in usage in these products (size, intended use, composition). Many commenters expressed their support for separate payment under the ASP+6 percent methodology. Another commenter recommended an alternative option of applying a maximum fee-for-service price of $150 per square centimeter that would be applicable to all skin substitute product. CMS states it will consider the suggestions and concerns raised by commenters to help inform future payment policies for skin substitutes and for future rulemaking.

L. Strategies for Improving Global Surgery Payment Accuracy

1. Background

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 valued based on estimates inconsistent with the number and kind of services actually 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[27] prohibited 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 nine years to obtain accurate data about the number and level of post-operative visits. CMS also discusses the responses received in response

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

to a RFI in the 2023 PFS 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 frequently as the number assumed 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 finalizes its proposals, with modifications

(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 policies will help align payment with the way surgical procedures are currently performed as evidenced in the Medicare data and help improve payment accuracy.

2. 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 in 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.[28] 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.

3. Strategies to Address Global Package Valuation

CMS recognizes that it is precluded under section 1848(c)(8)(A) of the Act from revisiting the policy CMS established in the 2015 PFS final rule to revalue all 10-day and 90- day global packages to 0-day global packages (79 FR 67582 through 67591). Further, CMS notes that transitioning all global packages to 0-day global periods could take several years and require substantial CMS resources (see 2014 PFS final rule (77 FR 44737 through 44738) for previous discussion). CMS has also considered revaluing 10-day and 90-day global packages to reflect the observed number of post-operative visits furnished to patients based on data collected over nearly a decade and notes that this approach would be quicker to implement, assuming there would be straightforward ways to revalue the services with the data. However, interested parties have continued to express uncertainty about the validity of claims-based counts of post-operative visits. This uncertainty stems in part from CMS not having complete information surrounding the use of the transfer of care modifiers since they are not currently routinely used.

For 2025, CMS focuses on different aspects of its policy objectives for global packages and policies (as discussed in greater detail later in this section), which are not mutually exclusive, to obtain information and allow for more accurate payment to reflect time and resources spent on post-operative care associated with the current global packages. CMS states it will continue to assess and monitor for potential future opportunities to improve its payment approach for the global packages more broadly.

Commenters were generally supportive of its ongoing efforts to pay more accurately for global surgical services. Many commenters requested that CMS update the values of the global surgical packages to reflect the revalued E/M visits with the full increase of work and physician time for the inpatient hospital and observation care visits (CPT codes 99231-99233, 99238, and 99239), and office visits (CPT codes 99202-99215) for each CPT code with a global period of 10 days

[28] Group practice as defined at 42 CFR 411.352

and 90 days, in addition to updating the practice expense inputs. Several commenters suggested referring the 90-day global packages to the RUC for revaluation. A few commenters objected to the policy of global surgical packages entirely advocating revaluation by shifting 10-day and 90-day global periods to 0-day global periods or aligning work RVUs with the amount of post-operative care typically provided to patients. CMS also received feedback from commenters specific to the provision of RPM and RTM during the global period. These commenters advocated allowing separate billing and payment for RPM and RTM during the global period by the physician who performed the procedure.

In its response, CMS notes that it considers improving the accuracy of global surgical package valuation and payment as a crucial, ongoing process and views its proposals in the 2025 PFS rulemaking cycle as steps in this direction. With respect to comments that CMS should increase the valuation of the global surgical packages based on the previously revalued E/M visits, CMS views this topic as outside the scope of its proposals, but refers readers to the most recent discussion in the 2020 PFS final rule (84 FR 62858). CMS states that it appreciates the commenters' support and insight describing the use of RPM and RTM in the post-operative global period and may consider those comments for future rulemaking.

4. 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".[29]

As indicated in the PFS Relative Value files, the payment for the global package is adjusted based on the modifier used.[30] 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.

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

CMS' analysis of 2022 Medicare claims data found that these modifiers were rarely used except for ophthalmology global practice, primarily with 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 in conjunction 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 finalizes its proposal, with modifications, to broaden the applicability of the transfer of care modifier for the 90-day global packages. Beginning with services furnished in 2025, modifier -54 is required for all 90-day global surgical packages in any case when a practitioner plans to furnish only the surgical procedure portion of the global package (including both formal and other transfers of care). CMS is not finalizing any change regarding the use of modifier -55 and modifier -56 for 2025; modifiers -55 and -56 will continue to be billed exclusively in cases where there is documented formal transfer of care.

Some commenters supported the proposal regarding the use of transfer of care modifier, while others expressed concerns regarding the proposed policy and intent for expanding the scope for transfer of care modifier reporting. Others expressed concern regarding the oversight and monitoring of modifier use and whether their use could result in more frequent auditing by the Recovery Audit Contractor (RAC), MACs or in consideration of the False Claims Act. CMS acknowledges the concerns raised by commenters regarding the applicability of the transfer of care modifiers. CMS is finalizing the requirement that in instances when a practitioner only intends to perform the procedure and does not intend to provide the post-operative care, that the appropriate modifier (modifier -54) be applied. With respect to audit issues, CMS states that it will continue to monitor these concerns by monitoring claims data and may address them in future rulemaking, if needed.

There was particular confusion about how modifier -55 should be appropriately used and documented under the CMS proposal. After consideration of the comments received, CMS is not finalizing any changes to current policy with regard to the use of modifier -55 or modifier -56. Because of policy for 2025 remains unchanged for formal transfers of care, CMS does not expect the practitioner 'receiving' the patient through an informal transfer of care to use modifier -55. Practitioners other than the proceduralist and, if applicable, those outside the proceduralist's group practice, can continue to separately bill for post-operative services without the need to report a modifier. CMS states that it will continue to assess the full range of modifiers for future consideration.

5. 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 sought 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.

CMS received a few comments on this topic. Commenters stated that the current component percentages published in the PFS were developed using magnitude estimation and cross-specialty scaling. These commenters stated they did not believe that any reverse engineering of work and time can be performed to develop a better percentage of pre-, intra- and post-operative work than what is currently published in the PFS.

CMS disagrees and notes the development of the component percentages occurred three decades ago and that both PFS global surgical procedures and relative valuations have since changed. The agency also notes that series of analytic reports from RAND have found that fewer post-operative visits are provided to patients compared to the number of visits reflected in the valuation of global packages, with variation across procedure services in the share of visits assumed to occur during global periods (as noted in the Physician Time File) versus the number of visits actually furnished. CMS also notes that data from claims-based reporting of post-operative visits could be used to exclude post-operative visit RVUs from total global package valuation on a code-by-code level.

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 sought 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. CMS did not receive public comments in response to this comment solicitation and did not comment further on any actions the agency may take.

6. Post-operative Care Services Add-on Code

CMS acknowledges that when a practitioner sees a patient post-operatively, that practitioner may not have been 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 finalizes its proposal, with modification, to establish an add-on code, HCPCS code G0559, 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. CMS modifies its proposed policy such that G0559 may be billed by a practitioner of the same specialty as the proceduralist who is not in the same group practice as the proceduralist.

For post-operative care services, CMS finalizes the add-on code, G0559, with modifications to the code descriptor - (Post-operative follow-up visit complexity inherent to evaluation and management services addressing surgical procedure(s), provided by a physician or qualified health care professional who is not the practitioner who performed the procedure (or in the same group practice) and is of the same or of a different specialty than the practitioner who performed the procedure, within the 90-day global period of the procedure(s), once per 90-day global period, when there has not been a formal transfer of care and requires the following required elements, when possible and applicable:

- Reading available surgical note to understand the relative success of the procedure, the anatomy that was affected, and potential complications that could have arisen due to the unique circumstances of the patient's operation.
- Research the procedure to determine expected post-operative course and potential complications (in the case of doing a post-op for a procedure outside the specialty).
- Evaluate and physically examine the patient to determine whether the post-operative course is progressing appropriately.
- Communicate with the practitioner who performed the procedure if any questions or concerns arise. (List separately in addition to 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 G0559:

- 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.

CMS clarifies that practitioners can bill the G-code when applicable, regardless of whether the proceduralist billed for the procedure with or without transfer of care modifier -54. CMS specifically proposed the G-code to capture the work involved when a practitioner may not know the patient's surgical history. It expects that this code would be billed only once per practitioner during the 90-day global period for the global package because it expects the patient to typically see one practitioner, either a specialist or their primary care physician for post-operative care.

Comments were mixed with respect to a new add-on code to capture the time and resources spent by a practitioner who is assuming post-operative care for a patient. Some commenters stated that the add-on code would support patient flexibility to seek follow-up care from practices other than those who performed the surgery. Several commenters thought this policy would help address inadequate payment for post-operative care delivered by clinicians and primary care physicians. Other commenters voiced strong general opposition to the add-on code, viewing CMS' rationale as ignoring the expertise, training and continuity necessary to perform appropriate follow-up care for some procedures. Some commenters supported the add-on code though some stated that the proposed code descriptor was ambiguous, poorly defined, and requested clarification regarding when it could be billed and that it should not be limited to the office/outpatient E/M visits.

CMS states that it appreciates commenters' concerns regarding the proposed add-on HCPCS code G0559 and lack of clarity surrounding when and by whom it can be billed. To help clarify any confusion, CMS states that HCPCS code G0559 would be reported by a physician or other practitioner who did not perform the surgical procedure within a global package but provided a related post-operative visit during the global period despite the absence of a formal transfer of care agreement. CMS states that it understands that there may be instances where there is no formal coordination (i.e., to require billing of the transfer of care modifier -55) or no coordination at all between the proceduralist and the practitioner who provides post-operative care and expects that HCPCS code G0559 would be used in those instances. CMS is also finalizing HCPCS code G0559 with modification such that it may be billed by a practitioner of the same specialty as the proceduralist who is not in the same group practice as the proceduralist. It recognizes that in some clinical scenarios, it is possible that post-operative care would be furnished only by a particular specialty. The add-one code should not be billed by another practitioner in the same group practice as the practitioner who performed the surgical procedure.

7. Valuation for G0559 Add-on Code

For valuing G0559, 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 G0559 is only

half of the work assigned for CPT code 90785. CMS finalizes a work RVU of 0.16; CPT code 90785 has no direct PE inputs and CMS finalizes the same for G0559.

Several commenters stated that the proposed work RVU and work time for HCPCS code G0559 was not sufficient to accurately reflect assessment of certain post-operative patients. One commenter stated the complexity of post-operative work for patients in some setting, such as tertiary care centers, may often exceed the "typical" post-operative work in other settings. CMS replies that this code can only be valued to reflect the typical work time and resources for this service.

8. Regulatory Impact

CMS' regulatory impact estimate 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 applies 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 estimates 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 add-on code, HCPCS code G0559. CMS anticipates that uptake of this code will be low initially, consistent with initial uptake of other new services finalized under the PFS.

III. Other Provisions

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[31] 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.[32]

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

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

[32] 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.

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 apply.[33] 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.

Selected Comments/Responses. In the final rule, CMS reports that the manufacturer of Leukine agreed that the agency lacked sufficient information to increase the applicable percentage for adjuvant uses of Leukine, and it will reapply in a future rulemaking cycle. Commenters also provided various rationales to change the applicable percentage for certain drugs; CMS does not finalize any changes to the applicable percentage for any drug, including those used in pediatrics, ophthalmology, cell and gene therapies, or drugs with multiple indications.

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.

[33] See 42 CFR 414.940(e).

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 finalizes its proposal to use the date on which the drug is first paid under Part B. To effectuate this policy, CMS adds this situation to the three existing exclusions in the definition refundable single-dose container or single-use package drug at §414.902; it also restructures that section of the regulation. The agency modifies the regulatory text at §414.902, which describes the 18-month exclusion for drugs subject to an NCD. In order to use consistent terminology throughout the definition of refundable drug under that section, CMS substitutes "date the drug was first marketed (as reported to CMS)" for "date of first sale as reported to CMS".

(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 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.

CMS proposed including 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.

It also proposed amending 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 noted that the proposal would be consistent with the description of single-dose container in the October 2018 FDA guidance. Specifically, it proposed 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".

Final Action. CMS finalizes the proposals without modification.

Selected Comments/Responses. The agency disagrees with those commenters who claimed the proposals would increase administrative burden on providers. In response to a request that it publish a complete list of NDC codes for drugs that meet the definitions of single-dose

containers or single-use packages, as well as multiple-dose containers, on at least a quarterly basis, CMS says that would not be operational feasible at this time.

One commenter questioned how refunds will be calculated when a drug subject to the discarded drug refund policy no longer meets the definition of refundable drug mid-way through a quarter, such as when a single source drug becomes a multiple source drug. In response, CMS says a refundable drug that becomes multiple source drug mid-way through a quarter would be a multiple source drug for the entire quarter and would not meet the definition of refundable drug for the quarter. This policy would apply provided that both the original product (e.g., reference listed drug) and one or more therapeutically equivalent products are marketed and sold in the same quarter.

Similarly, if all therapeutically equivalent products are no longer sold or marketed and only the reference listed drug remains (which was previously classified as a multiple source drug), the reference listed drug would be reclassified as a single source drug. However, if the reference listed drug is no longer sold or marketed and only one therapeutically equivalent product remains, the therapeutically equivalent product would continue to be classified as a multiple source drug because it was approved by the FDA under an *abbreviated* new drug application (ANDA).

(3) Skin Substitutes

As was the case in 2023 and 2024, billing and payment codes that describe products currently referred to as skin substitutes will not be counted for purposes of identifying refundable drugs for calendar quarters in 2025. CMS 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 proposed requiring 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 would 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 to the proposed rule included 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.

Final Action. CMS finalizes its proposals for the required use of the JW and JZ modifiers.

Selected Comments/Responses. The agency disagrees with comments complaining of additional burden, noting that policies on the use of these modifiers are not new; it refers readers to the discussion in the 2023 PFS final rule (87 FR 69711 through 69720), in which it codified the JW modifier policy that had been in place since 2017. A commenter was concerned about claims denials due to Medicare's Medically Unlikely Edits (MUEs) because MUEs set the maximum number of units of a drug or service that can be reported on a claim—with respect to both administered and discarded units. In the case of Tecvayli®[34] the MUE limit is 480 billing units, which could lead to claims denials if two vials of Tecvayli, each containing 306 billing units per vial, are used. In response, CMS clarifies effective October 1, 2024, the limit in the MUE file is 612 units to accommodate claims for two vials.

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 are available.[35] 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.

[34] Teclistamabcqyv, HCPCS code J9380
[35] 75 FR 73461 through 73465.

CMS finalizes its proposed 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 will 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 will be considered "available" and negative or zero manufacturer's ASP data will be considered "not available" in calculating a payment limit. The single comment received on this issue was supportive.

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 proposed calculating 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 proposal is finalized without modification.

The policy is intended to fill a gap to address this specific set of circumstances relating to negative or zero manufacturer's ASP data. CMS reiterates that the policy is not intended to supersede existing policy 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 proposed 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.

The proposal is finalized without modification.

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 proposed setting 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.

The proposal is finalized without modification.

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 proposed setting 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[36]) 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-

[36] See 42 CFR 414.902.

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.

Final Action. Based on stakeholder input, CMS finalizes the second alternative approach. It will set the payment limit for a biosimilar for which negative or zero ASP data are reported for all NDCs equal to the sum of the following until at least one NDC for the biosimilar has positive manufacturer's ASP data for a quarter:

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

The agency will not consider the manufacturer's ASP data of other biosimilars with the same reference product.

CMS believes the policy it adopts in this final rule codifies a clear and simple payment methodology for these circumstances and accurately and fairly pays for these drugs and biosimilars. It disagrees with those who claim the original policy proposal would have caused disruptions in the biosimilar market or led to withdrawal of patient treatment options. It also believes this policy approach is most consistent with statutory requirements under section 1847A(c)(5)(B) of the Act, which requires use of a manufacturer's ASP data from the most recent calendar quarter for which such data are available for quarterly updates to a drug's ASP payment limit.

Some commenters questioned the agency's statutory authority to set payment limits for biosimilars for which ASP data is not available using pricing data associated with other biosimilar products. They argued section 1847A(b)(8) of the Act[37] (i) requires the calculation of ASP-based payment for biosimilars to be particular to each biosimilar product even when ASP data is not available for a given quarter and (ii) prohibits the proposed blending of manufacturer ASP data. CMS notes section 1847A(b)(8) does not address circumstances in which ASP data is not available for the calculation of a biosimilar's payment limit for a given quarter, which CMS believes it must address. Additionally, the approach finalized closely follows the statutory methodology.

[37] Section 1847A(b)(8) establishes the methodology for calculating the payment limit of biosimilars when manufacturer's ASP data is available.

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 proposed that MACs develop prices for the drugs consistent with section 20.1.3 in Chapter 17 of the Medicare Claims Processing Manual for developing payment limits for covered drugs when CMS does not supply the payment allowance limit on the ASP drug pricing file. 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.

The proposal is finalized without modification.

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 finalizes its proposal to clarify any payment methodology for radiopharmaceuticals furnished in the physician office setting used by any MAC before the enactment of the MMA, which includes invoice pricing, may continue to be used by MACs. CMS will consider suggestions submitted by commenters should it address this payment issue in future rulemaking.

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 proposed to include orally and enterally administered compounded formulations of immunosuppressive drugs with active ingredients. The active ingredients would have to be derived from FDA-approved drugs where approved labeling includes an indication for preventing or treating the rejection of a transplanted organ or tissue, or for use in conjunction with immunosuppressive drugs to prevent or treat rejection of a transplanted organ or tissue. Alternatively, a MAC, in processing the claim, could determine the formulation 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.

The proposal is finalized without modification.

b. Immunosuppressive Refill Policy and Supplying Fee

CMS proposed 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 did 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).

The proposed changes are finalized without modification.

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 proposed clarifying existing policy that blood clotting factors must be self-administered to qualify for the furnishing fee. It proposed to 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.

Final Action. As it had proposed, the agency revises §410.63(b) to clarify existing CMS policy that blood clotting factors must be self-administered. Additionally, in response to comments, it clarifies that therapies that enable the body to produce clotting factor and do not directly integrate into the coagulation cascade are not themselves clotting factors for which the furnishing fee applies. It also finalizes its proposed clarification at §410.63(c) 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.

Selected Comments/Responses. Clarification was sought for an exception to the rules for eligibility of the furnishing fee in cases where a patient needs a blood clotting factor for hemophilia and surgery while in the hospital, which would be a significant reduction. CMS directs readers to §410.63(c)(1), which provides that a furnishing fee of $0.14 per unit of clotting factor is paid to entities that furnish blood clotting factors unless the costs associated with furnishing the clotting factor are paid through another payment system, for example, hospitals that furnish clotting factor to patients during a Part A covered inpatient hospital stay. Some commenters asserted that CMS' interpretation limiting section 1842(o)(5) of the Act to self-administered clotting factors is unlawful because there is nothing in the language of that section or the legislative history of the MMA that indicates congressional intent to require self-administration for the furnishing fee. The agency disagrees, arguing that section 1842(o)(5) specifically contemplates blood clotting factors are self-administered. The furnishing fee takes into account the costs associated with supplying the clotting factor, including patient training necessary for self-administration of such factors. Thus, it believes payment for furnishing of a product would be inappropriate for a product that cannot be self-administered and requires significant medical supervision.

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

Stakeholders asked CMS to 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 proposed 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 28 of the final 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.

Final Action. The proposals are finalized with a modification to delay their implementation until July 1, 2025.

Selected Comments/Responses. While commenters generally supported the proposals, concerns were expressed about the time needed for FQHCS and RHCs to implement systems changes to incorporate the change in billing practices; some commenters requested a transition period of up to a year. As noted above, the final rule provides until July 1, 2025, for facilities to come into compliance, and FQHCs and RHCs may continue to bill the general care management HCPCS code G0511 until that date. CMS says it will also provide additional information through subregulatory guidance. Some commenters worried that reimbursement rates for some of the unbundled services were inadequate, which could jeopardize sustainability of and access to facilities and those services; they asked the agency to ensure rates reflect actual costs of furnishing the services. CMS believes the rates do reflect the costs of providing the services and notes that the policy permits 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.

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 finalizes its proposals, without modification, 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. (See section II.G. above for a fuller description of the codes.) CMS says the new HCPCS codes will encompass a broader range of services and simplify the billing and documentation requirements, as compared to existing care management codes.

- G0556. 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.
- G0557. 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.
- G0558, which is similar to G0557 with the exception that the patient must be a Qualified Medicare Beneficiary.

Some commenters requested that CMS waive coinsurance requirements for APCM services furnished to patients of FQHCs and RHCs, but the statute does not afford that discretion to the agency. In response to requests for clarification on billing for community heath integration (CHI) and principal illness navigation (PIN) services, CMS believes CHI and PIN services are additive to APCM services as long as time and effort are not counted more than once, requirements to bill the other services are met, and the services are medically reasonable and necessary.

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 tried developing 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. The agency sought 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.

CMS will consider the feedback received in evaluating improvements to these payment systems.

3. Services Using Telecommunications Technology

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

c. Services Furnished Through 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 proposed, for 2025, 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.

CMS finalizes its proposal without modification. Thus, for RHC and FQHC services furnished using telecommunication technologies in 2025, RHCs and FQHCs may continue to bill those services by reporting HCPCS code G2025 on the claim, including services furnished using audio-only communications technology. The agency will continue to calculate the payment amount based on the average amount for all PFS telehealth services on the telehealth list, weighted by volume. CMS says it will continue to monitor and analyze information made available in order to develop, propose, and finalize more permanent policy in future rulemaking, particularly given the potential for congressional action.

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 proposed to delay the requirements for an additional year until January 1, 2026.

The proposal is finalized without modification.

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. Its proposal 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 is finalized without modification. The 2025 geometric mean per diem costs and payment rates for hospital-based IOPs, as finalized in the 2025 OPPS/ASC final rule, are as follows:

2025 APC	Group Title	PHP and IOP APC Geometric Mean Per Diem Costs*	Payment Rates**
5861	Intensive Outpatient (3 services per day) for hospital-based IOPs	$272.46	$269.19
5862	Intensive Outpatient (4 or more services per day) for hospital-based IOPs	$413.50	$408.55

* Table 136 of the 2025 OPPS/ASC final rule shows the 2025 PHP and IOP APC geometric mean per diem costs.
** The 2025 payment rates are from Addendum A to the 2025 OPPS/ASC final 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 proposed allowing RHCs and FQHCs to bill for the administration of Part B preventive vaccines at the time of service, and the policy would apply to all four Part B preventive vaccines: pneumococcal, influenza, hepatitis B, and COVID-19 vaccines.

CMS finalizes the policy as proposed.

Claims will initially be paid like other Part B vaccine and vaccine administration claims: vaccine products will be paid at 95 percent of their AWP, and vaccine administration will 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.

CMS reiterates that 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. RHCs and FQHCs may begin billing for preventive vaccines and their administration at the time of service, for dates of service beginning on or after July 1, 2025.

Selected Comments/Responses. Commenters welcomed the proposals but sought clarification on a number of points. CMS will release cost reporting instructions and subregulatory guidance before the July 1, 2025 effective date of this policy, which will contain additional billing

instructions for RHCs and FQHCs to bill Medicare Part B for preventive vaccines and their administration at the time of service. A commenter objected to additional burden of both tracking payments received from vaccine administration claims and reconcile vaccine costs on their cost reports. CMS acknowledges there will be additional burden.

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, and it proposed removing them. Commenters universally supported the proposal, which CMS finalizes effective with cost reporting periods ending after December 31, 2024.

7. Rebasing of the FQHC Market Basket

CMS rebases and revises the FQHC market basket that is used in the annual update to FQHC operating and capital cost structures for freestanding FQHC facilities. The base year is moved from 2017 to 2022. The 2022-based FQHC market basket is a fixed-weight, Laspeyres-type price index. The updated base year is 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 rebased and revised market basket, including the development of cost categories and weights. The final 2025 FQHC update is based on the four-quarter moving-average percent change of the 2022-based FQHC market basket through the second quarter of 2024.

Based on IGI's third quarter 2024 forecast with historical data through the second quarter of 2024, the 2022-based FQHC market basket increase factor for 2025 is 4.0 percent. The 2017-based FQHC market basket percentage increase is 4.1 percent for 2025 based on IGI's third quarter 2024 forecast (with historical data through the second quarter of 2024), which CMS explains is attributable to the lower wages and salaries cost weight for FQHC Provider Wages and Salaries and Clinical Staff Wages and Salaries.

CMS includes a productivity adjustment to the 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, which is 0.6 percent. This results in a 2025 productivity-adjusted proposed 2022-based FQHC market basket update of 3.4 percent.

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

Cost Category	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

a. Payment 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 final 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 will 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 must include documentation to support the medical necessity of the item or service. The agency will provide additional instruction and education through subregulatory guidance on the use of KX and GY modifiers on claims submitted for dental services that are inextricably linked to covered medical services.

b. Medical and Dental Visits Furnished on the Same Day

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 sought 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.

Commenters universally supported an exception to the multiple visit policy for dental visits to permit RHCs and FQHCs to bill for both a medical visit and a dental visit for a patient on the same day. CMS agrees, and it will clarify in subregulatory guidance that RHCs and FQHCs can bill separately for dental services that are inextricably linked to other covered Medicare services on the same day a medical visit is furnished by an RHC or FQHC practitioner.

9. "Grandfathered" Technical Refinement

CMS finalizes its proposal 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)

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.

a. Basic Requirements (§491.9(a))

CMS proposed to clarify a number of requirements for RHCs and FQHCs, including that they must provide primary care services Additionally, 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 proposed 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, which it finalizes without modification.

Selected Comments/Responses. Many commenters were in favor of the proposal because it permitted tailoring services to meet the unique needs of their patient populations and addressing shortages in access to specialty services in rural areas to reduce health disparities and improve health outcomes. Other commenters were concerned that the proposal as applied to FQHCs could negatively impact health and safety. After consulting with HRSA[38], CMS agrees with the commenters and finalizes the policy change only with respect to RHCs and withdraws it for FQHCs. CMS does not believe withdrawing this proposal for FQHCs will negatively impact patient care because there are safeguards in place under section 330 of the Public Health Service Act to ensure that a standard of primary care services is provided in FQHCs. However, the same safeguards do not apply in the context of RHCs, which are overseen by CMS.

The policy will 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 to offer a range of primary health care services to ensure patient access to necessary care at the earliest possible point of contact.

b. Mental Diseases (§491.9(a)(2)(ii))

Under section 1861(aa)(2)(K) of the Act, RHCs may not be a rehabilitation agency or a facility which is primarily for the care and treatment of mental diseases. CMS proposed codifying this statutory policy to clarify the requirements and intent of the RHC program. Commenter reaction was mixed; many opposed the proposal because adding it to the CfCs may increase confusion among providers who may see this as imposing more restrictions on the types of services RHCs may furnish, preventing them from meeting the needs of the communities they serve, disincentivizing them from delivering behavioral health services, and inadvertently creating obstacles to accessing behavioral health services. The agency is concerned about unintended negative impacts on access to outpatient care and withdraws its proposal.

c. Laboratory Requirements (§491.9(c)(2))

By statute,[39] 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

[38] HRSA oversees requirements for FQHCs and look-alike FQHCs to provide services that meet the full spectrum of healthcare needs in the communities they serve, including primary care services.
[39] Section 1861(aa)(2)(G) of the Act

of some of these tests, CMS proposed removing hemoglobin and hematocrit (H&H) from that list of laboratory services that RHCs must perform directly.

One commenter noted that 82 percent of RHCs indicated that the lab requirement for the "examination of stool specimens for occult blood" was no longer frequently ordered or considered the best clinical practice and thus should also be excluded from the required labs that RHCs must provide. CMS agrees with the comment.

The proposal is finalized with one modification: CMS also removes the current requirement that RHCs directly provide "examination of stool specimens for occult blood."

D. Clinical Laboratory Fee Schedule: 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 required by statute was January 1, 2019 through June 30, 2019. While the second data reporting period was originally scheduled to be conducted January 1, 2020 through March 31, 2020, a series of subsequent statutory amendments (most notably the Consolidated Appropriations Act, 2023, and the Further Continuing Appropriations and Other Extensions Act, 2024) 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.

In the 2025 PFS proposed rule, CMS proposed to conform its regulations to the then applicable statutory amendments. However, the Continuing Appropriations and Extensions Act, 2025 (CAEA, 2025) (Pub. L. 118-83) was passed on September 26, 2024, after the publication of the proposed rule and close of the comment period. The CAEA eliminated the data reporting requirements between January 1, 2020, and December 31, 2025, established a new reporting period beginning January 1, 2026, and ending March 31, 2026, and lastly, required data reporting every three years thereafter. It did not modify the data collection period. The CAEA delayed the scheduled payment reductions by an additional year (they will now start in CY 2028), and establishes a payment update of 0 percent for 2025. CMS indicates that the CAEA 2025 is "prescriptive, leaving us no room for interpretation, and as such, is self-implementing."

As a result, in this rule CMS is finalizing the self-implementing conforming changes to the data reporting and phase-in of payment reductions at 42 CFR part 414, subpart G in accordance with section 221 of the CAEA, 2025. CMS is revising the definitions of both the "data collection period" and "data reporting period" at §414.502 to specify that for the data reporting period of

January 1, 2026, through March 31, 2026, the data collection period is January 1, 2019, through June 30, 2019. The agency is also finalizing revisions to §414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017, and is required every 3 years beginning January 1, 2026. Finally, related to the requirements for the phase-in of payment reductions CMS is revising §414.507(d) to indicate that for CY 2024 and CY 2025, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2023 and 2024 respectively, and for CYs 2026 through 2028, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

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 three 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 makes 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. Changes to MDPP Conditions of Coverage (§410.79)

CMS finalizes its proposal to make the following conforming changes to §410.79(b), *Conditions of Coverage*, to align with the 2024 CDC DPRP Standards:[40]

- 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 revises the definition for the MDPP "online" delivery mode to include 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. Chatbots and AI forums do not count as Live Coach interaction.

Commenters were generally supportive of the proposed policy, with support received for aligning conditions of coverage with the 2024 CDC DPRP Standards definitions. CMS notes it is currently allowing an exception to the once per lifetime requirement for MDPP beneficiaries to restart their MDPP program if their services were interrupted by the PHE for COVID-19 (85 FR 19230,19283).

2. 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 finalizes its proposal, with modifications, to revise its requirement to allow more flexibility

[40]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

to document the weight of the MDPP beneficiary. Specifically, CMS revises §410.79(e)(3)(iii)(C) to provide that self-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 one (1) or two (2) date-stamped photo(s) 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 one photo, this photo must show the beneficiary's weight on the scale with the beneficiary visible in their home. If choosing to submit two photos, one photo must show the beneficiary's weight on the digital scale, the second photo must show the beneficiary visible in their home. All 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.

Similar to comments submitted in response to previous rules (FR 88 79249, 88 FR 78818), commenters expressed concern about the burden on the lifestyle coaches, suppliers, and beneficiaries of requiring a date-stamped photo of weight due to technology difficulties and/or inexperience, risk of injury, and HIPAA compliance for photo storage. While many commenters supported the new option to allow two photos instead of just one to self-report weight in an MDPP distance learning session, some commenters misinterpreted the proposed regulatory language, commenting that CMS was requiring two photos instead of one, thus doubling the amount of photo collection. In response to comments, CMS revises the regulation text in the final rule to reflect that beneficiaries can choose to submit one or two (2) photos for self-reporting weight for an MDPP distance learning session. If a beneficiary is able to capture both themself and their weight on the digital scale in one photo, then they can choose to submit only one photo, or they can choose to submit two photos (one showing their weight on the scale and one showing them visible in their home), if this is more convenient. CMS states that its intention was to add flexibility in self-reporting of weight for MDPP distance learning sessions, not to limit it.

CMS also states that the submission of video or photos remains necessary to ensure program integrity in MDPP. In situations in which beneficiaries may be unable to self-report their weight according to the MDPP conditions of coverage, suppliers may consider collecting weight measurements from the MDPP beneficiary in-person.

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

CMS finalizes its proposal 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 MACs in processing claims for same day make-up sessions in MDPP, CMS finalizes its proposal 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 amends 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.

Commenters were all supportive of the proposed policies to remove the MDPP bridge payment and to allow MACs to process claims for an MDPP make-up session held on the same day as a regularly scheduled session. CMS finalizes the changes to the provision to remove the MDPP bridge payment as proposed. To allow MACs to process claims for MDPP make-up sessions held on the same day as a regularly scheduled session, CMS is finalizing with a technical correction to change CPT modifier 79 to CPT modifier 76. Upon further review of modifier 79 and the associated description, CMS is making a technical correction to finalize in § 414.84(c)(4) that Modifier 76 (repeat services by same physician) to be appended to any claim for G9886 or G9887 to identify an MDPP make-up session that was held on the same day as a regularly scheduled MDPP session.

4. Aligning Language with Previous Rulemaking

CMS finalizes its proposed 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

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act, enacted 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.[41] 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 of 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 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 the proposed version of this rule, CMS proposed 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. Allowing 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 proposed a

[41] P.L. 115-271, section 2005.

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.

Specifically, CMS proposed 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."

Final Action. CMS finalizes its proposal to permanently allow OTPs to furnish periodic assessments using audio-only telecommunications beginning January 1, 2025, so long as all applicable requirements are met and the use of these technologies is permitted under the applicable SAMHSA and DEA requirements.

Selected Comments/Responses. Many commenters supported this proposal, citing several reasons—for example, that it would significantly expand access to care, especially for patients living in rural regions, racial or ethnic minorities, tribal populations, and others. Commenters also shared that audio-only telecommunication is often the most accessible form of communication for those with limited access to high-speed broadband internet service, those with lower incomes, and others. Some agreed with CMS that audio-only services could be delivered by OTPs in a manner that would not diminish safety or quality of care. As one commenter noted, if OTPs are concerned about issues that arise during a patient's periodic assessment, they could ask the patient to be seen in person.

One commenter urged CMS to not restrict audio-only flexibilities for periodic assessments to specific circumstances. The commenter further stated that restricting audio-only flexibilities to cases where only patients lack access to video-based technologies overlooks scenarios where providers might also face limitations (for example, in emergency situations). In response, CMS says there could be limited circumstances where a provider is unable to access audio-video communications technology, but that allowing audio-only communications technology in situations where a patient does not have access to two-way audio-video communications technology is critical to safeguarding the medical needs of the patient and ensuring that an appropriate modality of care is selected for the patient's condition and circumstance.

The agency does not believe it would be appropriate for audio-only periodic assessments to be performed on the basis that the provider does not have access to audio-video communications technology. OTPs should possess the technical capability to use an interactive telecommunications system (that is, with audio-only and audio-video capabilities) to ensure services are a comparable and appropriate substitute for services ordinarily provided in person.

b. 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.

Earlier this year, SAMHSA 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).[42] SAMHSA also updated full examination requirements for initiation of treatment with methadone at §8.12(f)(2)(v)(A), now permitting audio-visual 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. When audio-visual technologies are not available or their use is not feasible for a patient, it is acceptable to use audio-only devices, but only when the patient is in the presence of a licensed practitioner who is registered to prescribe controlled medications.

To be consistent with SAMHSA's recent reforms, CMS proposed 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. 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

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

the extent that the use of such telecommunications technology is permitted under the applicable DEA and SAMHSA regulations and guidance at the time the services are furnished.

CMS did not propose to extend the flexibility to audio-only telecommunications for these intake activities for treatment with methadone, as it is not currently permitted by SAMHSA and the DEA. Methadone is characterized as a Schedule II controlled substance—that is, 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 audio-visual 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, reciting reasons and data presented in the proposed rule.

Final Action. CMS finalizes its proposal 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 if the OTP determines that an adequate evaluation of the patient can be accomplished via an audio-visual telehealth platform.

Specifically, it revises 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) to separately list flexibilities for intake activities furnished via communications technology.[43] The existing flexibility for the initiation of treatment with buprenorphine is moved to paragraph (vi)(A)(*1*). New paragraph (vi)(A)(*2*) states 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.

Selected Comments/Responses. Many comments expressed strong support of this proposal for several reasons. For example, commenters shared that many individuals face geographic or social challenges to engaging in OUD treatment, and others may have an immediate need for treatment with methadone but face barriers to initiating treatment due to the need to coordinate transportation, childcare, work schedules, or other complicating factors.

Multiple commenters agreed with CMS on the necessity of requiring audio-video telecommunications when initiating treatment with methadone. Specifically, commenters concurred that methadone is distinct from buprenorphine, given both its risk for sedation and

[43] CMS also added and reserved a new paragraph (vi)(B).

complex pharmacokinetics. Using audio-visual telecommunications for methadone treatment initiation would address potential safety concerns by allowing the OTP to monitor the patients via audio-video telecommunications technology, while still increasing access to care and maintaining care quality.

One commenter said that while extending the PHE telecommunications flexibilities is important, controlled substances should not be prescribed without an initial in-person visit. CMS agrees that there could be limited instances where it may not be appropriate for an OTP to initiate treatment with methadone via audio-visual communication technology for a particular patient without an in-person visit. However, the agency restates that existing evidence has demonstrated initiating OUD treatment via audio-visual communications technology can be done in a manner that maintains quality of care and safety for patients. For example, some research has not found significant differences in clinical outcomes (for example, OUD-related emergency department visits or severity of an OUD) between patients receiving telemedicine inductions into treatment versus in-person examinations. CMS notes that the proposal to allow OTPs to initiate methadone treatment via audio-video communication technology is not a requirement; OTPs may still choose to see the patient in person instead. CMS also defers to program requirements established by SAMHSA and the DEA concerning when these communication technology services can be furnished before they can be billed for under the Medicare OTP benefit.

A few commenters, including some representing tribal populations, requested that CMS consider extending flexibilities to allow initiation of treatment with methadone via audio-only telecommunications. CMS says it is important to align with guidance by SAMHSA and the DEA. SAMHSA allows a specific exception for the use of audio-only initiation of treatment with methadone pursuant to §8.12(f)(2)(v)(A)—when the patient is *in the presence of a licensed practitioner* who is registered to prescribe (including dispense) controlled medications,[44] and when audio-visual technologies are not available or their use is not feasible for a patient. If these specific exceptions are met, CMS will allow the intake add-on code to be billed for audio-only telecommunications for initiation of treatment with methadone, consistent with SAMHSA requirements at §8.12(f)(2)(v)(A).

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.

[44] CMS says the licensed practitioner would need to be present in the same room as the patient and be available to conduct the visual component of the examination, which would be required to satisfy the requirement for telehealth initiation of treatment with methadone which is through an audio-visual examination.

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 §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 from earlier this year[45] made major reforms to 42 CFR part 8, governing requirements for OTPs in providing medications for the treatment of OUD and many other services. These changes reflect new paradigms of care for OUD since 42 CFR part 8 was published more than 21 years ago. 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."[46] 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 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. 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

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

[46] 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."

OUD treatment. The agency recognizes that 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 could increase the risk of a patient leaving OUD treatment prematurely or that pose barriers to treatment engagement. It also acknowledges that coding already exists under the PFS that accounts for the resources involved in conducting these types of assessments.

For these reasons, CMS proposed 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 to 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.

Specifically, CMS proposed 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).[47] 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.

When OTPs bill the intake add-on code (G2076, which is for new patients), OTPs would not be required to perform SDOH risk assessments in a *specific* manner.[48] 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 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.

[47] G0136 (*Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5–15 minutes, not more often than every 6 months*) 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.

[48] 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.

Final Action. CMS finalizes its proposal to update the payment rate for OTP intake activities (HCPCS code G2076) by adding in the value of the non-facility rate for SDOH risk assessments (G0136). In response to comments, it is also updating the payment rate for periodic assessments by OTPs (HCPCS code G2077) by also adding in the value of the non-facility rate for SDOH risk assessments (G0136). The current 2024 non-facility rate for G0136 is $18.97, which will be added to the current 2024 payment rates for the intake add-on code ($201.73) and periodic assessments add-on code ($123.96) for approximate final payment rates of $220.70 (HCPCS code G2076) and $142.93 (HCPCS code G2077), and updated by the MEI and GAF.

CMS reiterates that:

- Intake activities, periodic assessments, and SDOH risk assessments conducted during intake and periodic assessments must continue to relate to the diagnosis or treatment of an OUD and be consistent with SAMHSA requirements under §8.12(f)(4); and
- HRSNs identified through SDOH risk assessments 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.

Selected Comments/Responses. CMS received many comments supporting its proposal, agreeing that recent regulatory reforms to OUD treatment finalized by SAMHSA necessitate additional resources for OTPs. Commenters also noted that some accrediting organizations require HRSNs to be assessed as part of a patient's initial assessment and that establishing payment for intake activities to account for these assessments may further incentivize these assessments as standard practice at OTP intakes.

One commenter encouraged CMS to make SDOH risk assessments optional as part of intake activities for both the OTP and beneficiary as there may be some circumstances that prevent OTPs from being able to administer an SDOH risk assessment during intake activities, such as a patient being under the influence or unable to answer questions. While CMS agrees that there could be circumstances that impact OTPs being able to effectively assess the patient and perform an SDOH risk assessment, OTPs must perform initial assessment services consistent with SAMHSA certification requirements at §8.12(f)(4)(i) that already largely reflect these types of SDOH risk assessment activities. CMS reiterates that it did not propose to require that OTPs perform SDOH risk assessments in a specific manner, stating OTPs are best suited to evaluate when and how to appropriately conduct assessments after considering clinical and situational circumstances of the patient.

CMS had also proposed revising the current descriptor for the intake add-on code G2076 for consistency with revisions to §8.12(f)(4)(i) and to reflect furnishing an SDOH risk assessment. A commenter suggested referring to an "appropriately licensed practitioner" in alignment with SAMHSA regulations, rather than "a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician or qualified personnel." CMS agrees and finalizes the following for G2076:

- *Intake activities, including initial medical examination that is conducted by an appropriately licensed practitioner and 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, housing, and other recovery support services that a patient needs and wishes to pursue, conducted by an appropriately licensed/credentialed personnel (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to each primary code.

In response to CMS' questions in the proposed rule, multiple commenters stated that establishing payment for SDOH risk assessments should not just be limited to intake activities and offered several suggestions. Commenters highlighted several concerns, including the following:

- There may be circumstances preventing OTPs from administering SDOH screenings at intake;
- Patients may not be willing to answer sensitive SDOH questions at the time of intake since it takes time for patients to establish trust with their providers;
- Intake activities in OTP settings involve a mix of multiple assessments and medical evaluations that are time-intensive, so additional assessments furnished may require multiple treatment sessions to complete; and
- The recovery process for patients with an OUD is rarely linear, and patients with an OUD often face changes in their SDOHs throughout treatment.

CMS says it was made aware of various information through comments—for example, that these types of assessments take additional time and, in some cases, cannot be completed in full at the time of intake. Thus, CMS is persuaded by commenters that multiple SDOH risk assessments may be needed to address unmet HRSNs that impact OUD treatment outcomes when a patient is being treated at an OTP, so these types of assessments should not be limited to only intake activities that are payable under the Medicare OTP benefit for new patients. Thus, CMS finalizes payment for SDOH risk assessments during periodic assessments in addition to intake activities.

Specifically, CMS updates payment for periodic assessments (HCPCS code G2077) by adding in the value of the non-facility rate for SDOH risk assessments described by HCPCS code (G0136) and revises the code descriptor for G2077 as follows:[49]

- *Periodic assessment; assessing periodically by an OTP practitioner and includes a review of MOUD dosing, treatment response, other substance use disorder treatment needs, responses and patient-identified goals, and other relevant physical and psychiatric treatment needs and goals; assessment may be informed by administration of a standardized, evidence-based Social Determinants of Health Risk Assessment to identify unmet health-related social needs, or the need and interest for harm reduction interventions and recovery support services (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to each primary code).*

[49] In the public inspection version of this rule, leading up to the revised descriptor, CMS erroneously said it was for G2076 rather than G2077.

In response to a question about whether these payment updates will have an impact on budget neutrality, CMS said that the Medicare OTP benefit is wholly separate from services paid under the PFS and physician services, and for which payment is made under section 1848 of the Act, and is not subject to budget neutrality rules or limitations.

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.

In this RFI in the proposed rule, CMS sought comment on several specific issues 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.

CMS says commenters submitted "an abundance of information" on the types of service provider entities in the community that OTPs interact with, examples of operational processes in OTP settings related to these activities, the types of referral services OTPs refer patients to, etc. The agency says it is "persuaded by commenters" that these types of services have been integrated into OTP settings for a long period of time, are critical to treatment and recovery, and warrant additional payment under the Medicare OTP benefit. CMS believes that it now has enough information to establish coding and payment for coordinated care and referral activities as well as for patient navigational and peer recovery support services in this final rule—specifically for community health integration services (CHI), principal illness navigation services (PIN), and principal illness navigation services-peer support (PIN-PS).

Final Action: CMS is finalizing creation of a new code for coordinated care and/or referral services (G0534[50]) based on a crosswalk to the 2024 PFS non-facility rate of the community

[50] "*Coordinated care and/or referral services, such as to adequate and accessible community resources to address unmet health-related social needs, including harm reduction interventions and recovery support services a patient needs and wishes to pursue, which significantly limit the ability to diagnose or treat an opioid use disorder; each additional 30 minutes of services (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to each primary code*"

health integration base HCPCS code G0019,[51] but divided by two to represent each additional 30 minutes of services furnished (2024 PFS non-facility rate of G0019 = $80.56; divided by two = $40.28). Basing HCPCS code G0534 on each additional 30 minutes of services furnished would allow for a smaller unit of billing (30 minutes versus 60 minutes per calendar month for HCPCS code G0019). CMS lists numerous reasons for this, such as lowering the time threshold needed to bill for coordinated care and/or referral services as it learned how often these services are furnished in OTP settings. The agency expect OTPs to furnish services coded with G0534 when an OTP coordinates care or provides referral or linkage services to adequate and accessible community resources or community-based organizations that address a patient's identified unmet HRSN, or need and interest for harm reduction interventions and recovery support services, which may limit the ability of an OTP to diagnose or treat a patient's OUD.

CMS makes associated revisions in regulation:

- To the definition of an opioid use disorder treatment service at §410.67(b) in a new paragraph (x) to account for these type of "coordinated care and/or referral services, provided by an OTP to link a beneficiary with community resources to address unmet health-related social needs or the need and interest for harm reduction interventions and recovery support services that significantly limit the ability to diagnose or treat a patient's opioid use disorder."
- By adding paragraph (G) in §410.67(d)(4)(i) to specify that for the "coordinated care and/or referral services described in paragraph (x) of the definition of OUD treatment service at § 410.67(b), an adjustment will be made when each additional 30 minutes of these services are furnished," to the bundled payment.

CMS also finalizes the creation of a new code for patient navigational services (G0535[52]) based on a crosswalk to the 2024 PFS non-facility rate of the PIN base HCPCS code G0023,[53] but divided by two to represent each additional 30 minutes of services furnished (PFS non-facility rate of HCPCS code G0023 = $80.56; divided by two = $40.28). CMS based HCPCS code G0535 on each additional 30 minutes of services for similar reasons as mentioned for G0534—that is, administrative simplification for providers, to lower the billing threshold, and to more easily be billed alongside the weekly bundled payment for an episode of care. CMS expects OTPs to bill for HCPCS code G0535 when an OTP provides directly or by referral to patient navigational services that help the patient with an OUD navigate multiple settings of care.

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[51] "*Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address social determinants of health (SDOH) need(s) that significantly limit the ability to diagnose or treat problem(s) addressed in an initiating visit.*"

[52] "*Patient navigational services, provided directly or by referral; including helping the patient to navigate health systems and identify care providers and supportive services, to build patient self-advocacy and communication skills with care providers, and to promote patient-driven action plans and goals; each additional 30 minutes of services (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to each primary code*"

[53] "*Principal illness navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator; 60 minutes per calendar month, in the following activities*"

CMS is also finalizing the creation of a new code for peer recovery support services (G0536[54]) based on a crosswalk to the 2024 PFS non-facility rate of the principal illness navigation – peer support base code HCPCS code G0140[55] but divided by two to represent each additional 30 minutes of services furnished (2024 PFS non-facility rate of HCPCS code G0140 = $80.56; divided by two = $40.28), for reasons cited above. CMS expects OTPs to bill for G0536 when individuals either with knowledge of an OUD, or with lived experience of an OUD, provide support, coaching, mentorship, or inspiration to patients with an OUD to meet various MOUD treatment and recovery goals. Revisions are also finalized to the definition of opioid use disorder treatment service at §410.67(b) by adding paragraph (xi) to account for patient navigational services and/or peer recovery support services, when provided directly by an OTP or through referral. Conforming amendments are added in a new paragraph (H) to §410.67(d)(4)(i) to specify the adjustment to the bundled payment for patient navigational services and/or peer recovery support services when each additional 30 minutes of these services are furnished.

CMS also revises §410.67(d)(4)(ii) and (iii) to update the adjustment to the bundled payment for the three new codes—coordinated care and/or referral services (G0534), and patient navigational services (G0535) and/or peer recovery support services (G0536)—by the GAF and MEI, consistent with other adjustments to the bundled payment.

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.[56] CMS reviews the regulatory history of 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 finalizing new payment for injectable buprenorphine and nalmefene hydrochloride products furnished by OTPs.

[54] "*Peer recovery support services, provided directly or by referral; including leveraging knowledge of condition or lived experience to provide support, mentorship, or inspiration to meet OUD treatment and recovery goals; conducting a person-centered interview to understand the patient's life story, strengths, needs, goals, preferences, and desired outcomes; developing and proposing strategies to help meet person-centered treatment goals; assisting the patient in locating or navigating recovery support services; each additional 30 minutes of services (provision of the services by a Medicare- enrolled Opioid Treatment Program); List separately in addition to each primary code*"

[55] "*Principal illness navigation - peer support by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a certified peer specialist; 60 minutes per calendar month, in the following activities*"

[56] 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."

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.

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 proposed 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 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)(1) 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 was 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 proposed 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)*

As proposed, 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 codes G2215 and 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. The ASP+0 for Opvee in the fourth quarter of 2023 was $92.033 for a carton of two 2.7-mg nasal sprays, the amount that would be used to price the drug component of GOTP1.

CMS also proposed 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 proposed 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 proposed to update the non-drug component for the adjustment of GOTP1 annually based on the GAF and 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 proposed 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 Part B 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.

Final Action. CMS finalizes its proposal to create a new adjustment to the bundled payment for nalmefene nasal spray, but with a new HCPCS code of G0532 (replaces the placeholder code GOTP1).

Selected Comments/Responses. Many commenters supported the proposal. Some stated that both the proposed coding and payment methodology for the add-on code of take-home supplies of

nalmefene nasal spray would be consistent with Medicare pricing provisions in section 1847A of the Act and CMS' method for pricing similar opioid antagonist medications under the Medicare OTP benefit.

One commenter asked CMS to consider any interaction of this proposal on treatments currently covered under Medicare Part D, since nalmefene nasal spray may be available by prescription through Medicare Part D. CMS says it does not seek to influence whether a Medicare beneficiary receives this emergency medication through either Medicare Part B or D, but is required to ensure that no duplicative payments are made under Medicare Part B or Part D for items and services furnished by an OTP. CMS reiterates its expectation that if the OTP bills for G0532, it 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. 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 proposed to establish payment for the weekly and monthly formulations for Brixadi, using the existing payment methodology for implantable and injectable medications at §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 (ASP+0), if ASP is used, and 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 since many OTPs purchase directly from drug manufacturers, thereby limiting the markup from distribution channels.

For the monthly version, CMS proposed 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 ASP+0 payment limits of Sublocade® and monthly Brixadi (add 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+0 amounts for monthly Brixadi (J0578) and the two HCPCS codes for Sublocade® (Q9991 and Q9992) ($1524.855 and $1768.775, respectively) are comparable, as reflected in the fourth calendar quarter of 2023);
- 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 proposed to calculate the nondrug component of HCPCS code G2069 consistent with the methodology at §410.67(d)(2)(ii). It also proposed 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 proposed 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.
- 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*).
- 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.

Final Action. CMS finalizes its proposal to establish coding and payment for the weekly and monthly injectable buprenorphine, but with a new HCPCS code of G0533 for the weekly version (not the placeholder code GOTP2).

In response to a comment, rather than averaging each product's ASP+0 to calculate the drug component as proposed, CMS finalizes the calculation using a volume-weighted ASP of all NDCs for both products using the calculation described in section 1847A(b)(6) of the Act. This would better reflect the utilization of drugs in clinical practice by accounting for the sales volume of each NDC for both products. Based on the data used for the October 2024 ASP pricing file (sales from the second calendar quarter of 2024), the drug component of the bundle for monthly injectable buprenorphine using the proposed calculation would be approximately $1,726.26. However, volume-weighting the ASP for all the NDCs crosswalked to HCPCS codes for monthly Brixadi and Sublocade would increase the payment of the drug component to approximately $1,797.29. CMS will use this revised payment approach to address the commenter's concerns, to more closely reflect the market variables, including the volume of sales in each calendar quarter. The agency says it will continue to monitor utilization to ensure

Medicare beneficiaries continue to have access to these medications and will propose additional refinements as needed through future rulemaking.

Selected Comments/Responses. Multiple commenters supported CMS' efforts to expand access to a new, innovative injectable buprenorphine product for MOUD treatment, stating it would bolster efforts to combat the opioid epidemic. Many also expressed support for the payment approach to create a new weekly bundled payment code to reflect the weekly formulation of Brixadi and to update the existing bundled payment for monthly injectable buprenorphine to account for the monthly formulation of Brixadi.

One commenter asked CMS to consider any interaction of this proposal on treatments currently covered under Medicare Part D. CMS notes that injectable buprenorphine can only be given if administered by an authorized healthcare provider and therefore is not available for self-administration and prescription through the Medicare Part D benefit.

One commenter provided reasons for opposing the proposed monthly payment methodology for Brixadi of adding the payment limits of Brixadi and Sublocade together under the same drug component in the existing monthly bundled payment (HCPCS code G2069) for injectable buprenorphine and averaging their two ASP+0 values. For example, the commenter noted that if the payment rate of the existing bundled payment were to decrease, it may incentivize OTPs to prescribe one type of medication over the other. While acknowledging there are certain clinical differences in the drugs, CMS describes why it does not believe the drugs were significantly clinically different from each other to support creating a separate bundled payment for monthly Brixadi.

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 clarified in the proposed version of this rule 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.

A few public comments were submitted on this topic, which were pleased with the clarification. One commenter requested that CMS consider the population of patients who may receive opioid antagonist and/or agonist medications for chronic pain management and may be given naloxone for safety reasons. CMS responds that it understands how OTPs may treat patients with multiple diagnoses; those diagnosis codes may also be reflected on claims as OTPs should be coding appropriately per ICD-10-CM diagnosis coding guidelines. However, it reiterates that services paid to OTPs under Medicare Part B must be for the treatment of OUD.

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 Services (§§410.10, 410.57, 401.64, 410.152)

CMS reviews the history for the payment rates for Part B vaccines (*i.e.*, influenza, pneumococcal, hepatitis B virus (HBV),[57] 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 that 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

[57] 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).

products ends.[58] Effective January 1 of the year following the end of the EUA declaration, the administration payment for COVID-19 vaccine would align with the payment rate for the other Part B vaccines. The current payment rates for the CPT codes that describe administration of COVID-19 vaccines are available on the CMS COVID-19 Vaccines website.[59] 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. In the 2025 PFS NPRM, CMS proposed to update the vaccine administration payment rates (G0008, G0009, and G0010) by the 2025 final MEI increase factor, 3.5 percent. In this final rule, CMS is finalizing these rate increases as proposed.

In August of 2023, the CPT Editorial Panel approved five new COVID-19 vaccine product codes, and a new vaccine administration code (90480) for reporting the administration of any COVID-19 vaccine. CMS indicates that the Medicare payment rate for COVID-19 vaccine administration will be contingent on whether or not the Emergency Use Authorization for Drugs and Biologicals with respect to COVID-19 is terminated on or before December 31, 2024 (see following table, adapted from Tables 51 and 52 in this final rule).

CY 2025 Part B Payments for Preventive Vaccine Administration				
Category of Part B Product Administration	Part B Payment Amount (Unadjusted), EUA Continues into CY 2025	Part B Payment Amount (Unadjusted), EUA Ends on or Before 12/31/24	Annual Update	Geographic Adjustment
Influenza, Pneumococcal, Hepatitis B[1]	$33.71	$33.71	MEI	GAF
COVID-19[2]	$44.95	$33.71	MEI	GAF
In-home additional payment for Part B Vaccine Administration (M0201)[4]	$39.90	$39.90	MEI	GAF
COVID-19 Monoclonal Antibodies (post-exposure)[3,4,5]	N/A	Payment under applicable payment system	---	---
COVID-19 Monoclonal Antibodies (pre-exposure)[3,4]	N/A	TBD	N/A	---
Intravenous Infusion: Health Care Setting	$450	---	N/A	GAF

* Rate for COVID-19 Vaccine would be $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.

[58] https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines
[59] https://www.cms.gov/medicare/medicare-part-b-drug/average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.

[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 final rule, there are no monoclonal antibodies approved or authorized for the treatment or for post-exposure prophylaxis of COVID-19.
[6] The CY 2025 percentage increase of the 2017-based MEI is 3.5 percent based on historical data through the 2nd quarter of 2024.

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

a. Background

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

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,[60] the agency 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 51 and 52 in this final rule (modified version reproduced above) reflect the potential alternative payment amounts for Part B preventive vaccine administration for 2025. CMS is finalizing these rates for 2025.

[60] Section 1861(s)(10) of the Act

2. Revised Payment Policies for Hepatitis B Vaccine Administration

a. Background

In the 2025 PFS NPRM, CMS proposed 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. CMS noted 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 B as well as a physician's order, and thus cannot be roster billed by mass immunizers. CMS proposed to eliminate these requirements.

b. Revisions to Payment Policies for Hepatitis B Vaccinations

Under the CMS 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.

The finalized payment rates for G0010, with the annual update applied for 2025, are specified in Tables 51 and 52 (adapted in the table above) of this final rule.

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.

Given its proposal to expand coverage for hepatitis B vaccination in section III.M of the 2025 PFS proposed rule, CMS also proposed 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, and proposed 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).

CMS indicates that commenters "overwhelmingly supported" its proposals related to hepatitis B vaccines and their administration. CMS is finalizing the proposed changes (eliminating the risk

assessment and the physician's order; updating the payment rate; and making payments for hepatitis B vaccines and their administration in FQHCs and RHCs consistent with payments for other Part B vaccines), effective for dates of service on or after July 1, 2025. CMS will 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, and will make changes 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.

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 sets forth 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. 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.

At the time of publication of the 2025 PFS proposed rule, CMS had not yet covered or paid for any drugs or biologicals (hereinafter, referred to as drugs) under the benefit category of additional preventive services. On 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; the NCD was finalized on September 30, 2024.[61]

b. 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

[61] *https://www.cms.gov/medicare/coverage/prep*

payment authorities.[62] 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, which in this final rule it refers to as the "payment limit.". In the proposed rule CMS proposed a fee schedule for DCAPS drugs (89 FR 61931) that uses existing Part B drug pricing mechanisms. CMS proposed 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 proposed to update the fee schedule quarterly, on the same schedule as the ASP pricing file, which is updated each calendar quarter.

CMS proposed to establish a DCAPS fee schedule using the following pricing mechanisms to determine the payment limit for DCAPS drugs under Part B:

> (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 proposed 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 proposed that the otherwise applicable coinsurance would not apply to DCAPS drugs. CMS proposed to publish the payment limits for DCAPS drugs along with other separately payable Part B drugs on the ASP pricing file.

CMS indicates that commenters were generally supportive of its proposed fee schedule for DCAPS drugs. However, in response to public comments, in this final rule CMS is changing its proposed DCAPS drug pricing calculation. CMS had originally proposed to average together all NDCs of a drug if a drug is available in generic and brand formulations to determine the payment limit. In light of commenters' feedback, CMS is now finalizing a DCAPS drug pricing

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

policy to treat brand and generic drugs in a similar manner to the description in the Medicare Claims Processing Manual, Chapter 17, sections 20.1.3 and 20.4. Under this approach, when calculating the price for multiple-source DCAPS drugs using NADAC or FSS other government agencies (OGA) pricing, CMS will use the lesser price of: the median of all generic forms of the drug; or the lowest brand name product. Apart from this change, CMS is finalizing its proposed DCAPS drug pricing policies, and is amending §410.152 by adding paragraph (o) to establish the applicable fee schedule and the pricing methodologies used to determine the payment limits for DCAPS drugs under Part B. In addition, to highlight that coinsurance does not apply to DCAPS drugs, CMS will publish the payment limits for DCAPS drugs along with other separately payable Part B drugs on the ASP pricing file.

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

Until this final rule, there has been no Medicare policy regarding payment for the administration of DCAPS drugs or the supplying of DCAPS drugs by suppliers and providers. CMS proposed 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 category 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed that such administration or supplying would be considered an additional preventive service.

In the proposed rule, CMS noted that with regard to the July 12, 2023 Proposed NCD for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention, CMS proposed 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).

CMS states that many commenters were supportive of the agency's proposals to set payment limits for DCAPS drug supplying fees that are similar to the supplying fees for other Part B-covered drugs dispensed from a pharmacy, indicating that commenters appreciated the agency's efforts to align payments across health care settings and to allow for consistency among similar payments in Part B. CMS discusses a few comments in detail, and provides responses, but does not explicitly indicate how it is finalizing its proposals with respect to administration and supplying fees for DCAPS drugs – it appears that the agency is finalizing its proposals without modification.

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, in the 2025 PFS proposed rule, CMS proposed 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. CMS described those payment limits in section III.H.3.b of the proposed rule, and proposed to codify them at §410.152(o)(1). CMS proposed to codify this RHC/FQHC DCAPS policy in regulation as well, at a new §405.2464(h).

CMS indicates that commenters supported this DCAPS policy for RHCs and FQHCs. After consideration of public comments, in this final rule CMS is finalizing these policies as proposed. Finalized DCAPS fee schedule information can be found in section III.H.3.b. of this final rule. DCAPS drugs and the services to administer and supply them are paid at 100 percent of the Medicare payment amount, that is, the amounts on the DCAPS fee schedule, in RHCs and FQHCs, and they are paid on a claim-by-claim basis. CMS is codifying this RHC/FQHC DCAPS policy in regulation 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 final rule establishes 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 finalized codification includes some modifications to the policies established in guidance. CMS also proposed new policies, which it finalizes with modifications. The modifications are described below in the relevant finalized policies discussed in this section of the summary.

Medicare Part B Drug Inflation Rebate Program:

- CMS will 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 will 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 is 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 will 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 will 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 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 establishes 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 adds 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 is 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 will identify the payment amount benchmark period as the first calendar year in which the drug has at least one quarter of AMP reported, which will 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 will 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 will 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 will 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 does not finalize its proposal to estimate the number of 340B units that will be excluded.
- CMS describes the 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 establishes 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 adds 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 is severable from part 428 (§428.10).

The applicability date finalized for these policies for Part B rebatable drugs is 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 policies (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 B-I1 and B-I2 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. Figure B-I3 illustrates how rebates for quarters in calendar year 2025 will be calculated for drugs billed under a NOC code during calendar quarter July 1, 2021 and assigned to a unique billing and payment code on April 1, 2024.

Table 53 of the final rule (reproduced below) shows summary timelines for inflation rebate amount reports and deadlines.

Table 53: Summary of Proposed Part B and D Drug Inflation Rebate Amount Reports and Deadlines[a]

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

MILESTONE	TIMING/DEADLINE
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
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 codifies definitions of terms in a manner that is consistent with the meanings given them 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).[63] Definitions for new terms based on policies described in the proposed rule (and finalized in this rule) are added, and modifications (described below) are made to some definitions in response to comments received.

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.[64] CMS codifies its definition of that term without modification. Policies in section 30.1 of the Part B Revised Guidance to identify Part B rebatable drugs are also codified without change. CMS will:

- 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
- 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.

The term "individual who uses such a drug or biological" means 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 Product Categories

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

[63] 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

[64] Qualifying biosimilar biological products are biosimilars that, during a temporary 5-year period, have an average sales price that is less than the reference biological product. See section 1847A(b)(8)(B)(iii) of the Act.

- Skins substitutes. (CMS notes these products will not be subject to the beneficiary coinsurance adjustment.)
- Units of separately payable radiopharmaceuticals. (CMS notes these products will 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 will 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[65] 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 finalizes its proposal, without modification, 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 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.

CMS will 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 will 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 will 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 will separately sum the total allowed charges billed

[65] 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.

under the grouped billing and payment code and the unique billing and payment code, and identify the individuals on those claims. It will 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 will 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.[66]

CMS finalizes its proposal, without modification, to use the payment amount in quarterly pricing files to determine if a Part B rebatable drug should have an adjusted beneficiary coinsurance; this will be used only to determine whether there should be a coinsurance adjustment and will not impact the applicability or calculation of inflation rebates. Thus, an adjusted beneficiary coinsurance amount will 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, 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 will not be subject to the inflation-adjusted beneficiary coinsurance.

[66] 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.

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 finalizes its proposal, without modification, to codify the rebate calculation established in the Part B Revised Guidance. The estimated amount will equal 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 will 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 codifies the policy from section 50.13 of the Part B Revised Guidance under which it apportions the Part B rebate amount among manufacturers by multiplying 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.

A commenter identified at least one circumstance where the majority of ASP units for an NDC in a billing and payment code are packaged into a payment amount that includes another item or service and are not separately payable. The commenter believes that units attributed to that NDC should not be used to apportion rebate liability. In the circumstance raised by the commenter, the NDCs in the bundled code are also in the non-bundled code; thus, the ASP reporting for the NDCs will be applied to only the non-bundled code, since the bundled code is not separately payable. CMS will use this information to apportion liability since CMS cannot determine how many units by NDC are being administered in the bundled versus non-bundled code.

Apportionment of the Part B Rebate Amount when Reported Units for NDCs within a Billing and Payment Code Are Missing, Negative, or Equal to Zero

Where ASP data are missing, including when the number of units sold is zero or negative, CMS considered a number of different policy approaches to apportion the Part B rebate amount, and it finalizes the following policies:

(1) Scenarios in which All NDCs Within a Billing and Payment Code Have Negative, Zero, or Missing ASP Units (§427.301(c)(1))

If there are multiple NDCs in a grouped billing and payment code and the manufacturer-reported ASP units for *all* NDCs are either missing, negative, or equal to zero but there is a positive rebate amount, CMS finalizes the following policies:

- For NDCs that were sold or marketed during the applicable calendar quarter and for which all NDCs assigned to the grouped billing and payment code lack manufacturer-reported ASP data for the applicable calendar quarter, CMS will equally apportion a positive rebate amount to each NDC with missing ASP units that were marketed or sold during the applicable calendar quarter by *dividing* the total rebate amount for the grouped billing and payment code *by* the total number of NDCs sold or marketed during the applicable calendar quarter within the billing and payment code; and
- For NDCs (i) that were not sold or marketed during the applicable calendar quarter and lack manufacturer-reported ASP units for the applicable calendar quarter, (ii) with negative manufacturer-reported ASP units for the applicable calendar quarter, and (iii) with manufacturer-reported ASP units equal to zero for the applicable calendar quarter, CMS will apportion a $0 rebate amount to each respective NDC. If all NDCs assigned to the grouped billing and payment code are described in clauses (i), (ii) and/or (iii), no rebate will be assessed for that billing and payment code.

(2) Scenarios in which Some (But Not All) NDCs Have Negative, Zero, or Missing ASP Units (§427.301(c)(2))

When there are multiple NDCs in a grouped billing and payment code and the manufacturer-reported ASP units for *some but not all* NDCs assigned to the grouped billing and payment code are either missing, negative, or equal to zero but there is a positive rebate amount, CMS finalizes the following policies:

- For NDCs that were not sold or marketed during the applicable calendar quarter and that lack manufacturer-reported ASP units during the applicable calendar quarter, for NDCs that have negative manufacturer-reported ASP units for the applicable calendar quarter, and for NDCs that have manufacturer-reported ASP units equal to zero for the applicable calendar quarter, CMS will apportion a $0 rebate amount to each respective NDC; and
- For NDCs that were sold or marketed during the applicable calendar quarter and lack manufacturer-reported ASP units for the applicable calendar quarter, and for NDCs that were sold or marketed during the applicable calendar quarter and for which respective NDCs have positive manufacturer-reported units, CMS will apportion rebate amounts as follows:
    - Assign to NDCs that were sold or marketed during the applicable calendar quarter and lack manufacturer-reported ASP units for the applicable calendar quarter the number of ASP units equal to the lowest positive number of manufacturer-reported ASP units for any NDC in the grouped billing and payment code;
    - Determine the total billing units sold for each NDC assigned to the billing and payment code (by multiplying the number of units reported by a manufacturer in

ASP data submissions at the NDC-11 package level by the number of billing units per NDC-11 reporting unit);
- For all NDCs of each individual manufacturer assigned to the billing and payment code, sum the total billing units for such NDCs sold during the applicable calendar quarter;
- Sum the 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;
- Divide (i) the sum of the total billing units for such NDCs sold during the applicable calendar quarter by (ii) the sum of the 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 and multiplying that quotient by the total rebate amount.

ii. Calculation of the Per Unit Part B Drug Rebate Amount

(1) Identification of the Specified Amount for the Applicable Calendar Quarter

CMS finalizes its proposal 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 with modifications. Specifically, the first applicable calendar quarter for a Part B rebatable drug will be the later of (i) the third full calendar quarter after the payment amount benchmark quarter or (ii) the calendar quarter beginning January 1, 2023. (CMS had proposed to identify the first applicable calendar quarter for a Part B rebatable drug as the earliest applicable calendar quarter that follows the payment amount benchmark quarter.)

CMS also adds a new §427.302(b)(2) to state that for a Part B rebatable drug that was billed under a NOC code during the calendar quarter beginning July 1, 2021, or the third full calendar quarter after the effective date of the drug's assigned billing and payment code other than a NOC code, whichever is later, the first applicable calendar quarter will be the first full calendar quarter that follows the payment amount benchmark quarter.

CMS will:
- Use the most updated price information reported by manufacturers to compare whether 106 percent of WAC or 106 percent of ASP is less, and 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, 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, use that negative or zero ASP amount 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 finalizes its proposal to codify policies from section 50.3 of the Part B Revised Guidance as follows:

Date of FDA License/Approval	First Marketed Date	Payment Amount Benchmark Quarter
On or before 12/01/2020	On or before 12/01/2020	The July 1, 2021 calendar quarter
On or before 12/01/2020	After 12/01/2020	The third full calendar quarter after the drug's was first marketed date
After 12/01/2020	After 12/01/2020	The third full calendar quarter after the drug's was first marketed date

Special Rules	
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
Part B rebatable drug that is no longer considered a selected drug for a price applicability period	The calendar quarter beginning January 1 of the last year of the price applicability period for the selected drug

CMS will 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 will 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 will identify the first marketed date from alternative public sources, such as National Institutes of Health's DailyMed.

In the final rule, CMS indicates it will also use the earliest approval or licensure date for any FDA application associated with any NDC ever assigned to the billing and payment code. The reason for this modification is to address a scenario where an NDC previously assigned to a billing and payment code had a first marketed date in June 1992 (that is, before December 1, 2020), but the FDA applications with NDCs currently in the billing and payment code were approved after December 1, 2020. A billing and payment code in this scenario will have a first marketed date in 1992 and a first approval date before December 1, 2020, and thus will have a payment amount benchmark quarter of July 1, 2021 through September 30, 2021.

(2) Identification of Payment Amount in the Payment Amount Benchmark Quarter

CMS finalizes its proposal, without modification, to codify the methodology established in section 50.2 of the Part B Revised Guidance to identify the payment amount in the payment amount benchmark quarter for the Part B rebatable drug. It will 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 55 in 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 equals 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 equals 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 finalizes its proposal to 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.

Additionally, CMS will 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 finalizes its proposals 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. It makes modifications in the final rule with respect to identifying the Benchmark Period CPI-U. CMS will use the first month of the first full calendar quarter after a drug's first marketed date as the benchmark period CPI-U for drugs first approved or licensed on or before December 1, 2020, and with a first marketed date after December 1, 2020. Similarly, it will use the first month of the first full calendar quarter after a drug is assigned a billing and payment code other than a NOC code as the benchmark period CPI-U for a Part B rebatable drug that was billed under a NOC code during the calendar quarter beginning July 1, 2021, or the third full quarter after such drug's first marketed date, whichever is later.

iii. Determination of Total Number of Billing Units (§427.303)

CMS finalizes its proposal 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; however, the final rule includes a number of modifications to that proposal.

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.
- In the final rule, CMS clarifies that Part B drugs that are billed as compounds are not Part B rebatable drugs because they are reported with HCPCS code J7999, which is a NOC code. Similarly, Part B drugs that are billed as compounds are excluded from the calculation of the average total allowed charges used to exclude drugs and biological products with average total allowed charges below the applicable threshold.

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.

Units of Drugs Acquired Through the 340B Program. 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 (MPNs) or both to identify these suppliers and the claims submitted with those identifiers. CMS finalizes its proposal to continue this approach for professional claims with dates of service during 2024 with some clarifying modifications.

CMS notes that if NPIs and MPNs are not available from these suppliers and claims, it will use other fields available in the HRSA 340B Office of Pharmacy Affairs Information System (OPAIS), such as name and address. The agency also states that it will remove units in all professional claim lines for dates of service during 2023 that were billed with the "JG" or "TB" modifiers.

Additionally, for institutional claims with dates of service during 2023, in addition to removing units in all institutional claim lines that were billed with the "JG" or "TB" modifiers, CMS will

remove units in institutional claims from critical access hospitals covered entities and Maryland waiver hospital covered entities billing separately payable claim lines for drugs acquired under the 340B Program with those dates of service. CMS notes that separately payable drugs acquired under the 340B Program billed by non-excepted off-campus PBDs in 2023 can be identified with the "JG" or "TB" modifier and will be excluded from rebate calculations.

The final rule extends these 340B policies for institutional claims with dates of service from January 1, 2024 through December 31, 2024. The regulations also specifically exclude separately payable billing units in claim lines for institutional claims that are billed with the "TB" modifier for claims with dates of service on or after January 1, 2025, from rebate calculations.

Units with a Medicaid Drug Rebate. For Medicaid Rebate billing units, CMS finalizes its proposal, without modification, 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.

Units that Are Packaged into the Payment Amount and Not Separately Payable. The agency reiterates that it identifies billing units only for separately payable claim lines for Part B rebatable drugs. Thus, billing units that are packaged into the payment amount for an item or service and are not separately payable are excluded. Examples includes drugs for which payment is packaged under the OPPS, or the Ambulatory Surgical Center (ASC) payment system, or those furnished in FQHCs or RHCs. Claim lines for drugs for which payment is bundled under the ESRD PPS would not have a Medicare allowed amount that is greater than zero and those units will also be excluded.

Units When a Drug is No Longer a Part B Rebatable Drug. CMS codifies its policy in section 50.8.4 of the Part B Revised Guidance. As finalized, the billing units of a drug that is no longer a Part B Rebatable Drug furnished on and after the first day of the calendar month in which the therapeutically equivalent drug was first sold or marketed during the applicable calendar quarter are excluded. CMS may consult with FDA where there is ambiguity as to whether a new product is therapeutically equivalent.

Units Furnished to Medicare Advantage Enrollees. CMS did 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 finalizes its proposal to establish a new policy to address the interaction between Part B inflation rebates and billing units of discarded drugs with one modification. CMS will exclude billing units of discarded drugs for which a discarded drug refund is owed from Part B inflation rebates. Specifically, it will exclude billing units of a refundable single-dose container or single-use package drug for which a discarded drug refund is owed, 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 will 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.

The proposal originally based the exclusion on whether a refund had been paid; however, under the final policy, the exclusion is based on whether the refund is owed.

iv. Adjustments for Changes to Billing and Payment Codes

CMS finalizes its proposal, without modification, to codify policies under section 50.9 of the Part B Revised Guidance for instances where a drug's code dose description changes. It will 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)

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 56 of the final 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	Part B rebatable biosimilar biological product
First four consecutive calendar quarters	25%	75%	75%

Second four consecutive calendar quarters	10%	50%	75%
Subsequent calendar quarters	2%	25%	Not applicable

CMS will not fully waive the rebate amount owed because it 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. It also believes the relief under the policies is adequate.

i. Reducing the Rebate Amount for Part B Rebatable Drugs Currently in Shortage

CMS codifies its policies in section 50.11 of the Part B Revised Guidance which reduce 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 decrease the amount of the reduction over time. The agency will use the shortage lists maintained by the FDA Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER) to determine whether a Part B rebatable drug or biological is currently in shortage during a calendar quarter.

To calculate the reduced total rebate amount for a Part B rebatable drug currently in shortage, CMS will 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, if any NDC-10 assigned to the HCPCS code(s) is currently in shortage, CMS will apply the rebate reduction to all of the NDCs under the relevant HCPCS code(s).

CMS will 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 finalizes its proposal 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 will treat the subsequent shortage as a new shortage and will apply the applicable percent reduction for the first 4 consecutive calendar quarters.

The final rule includes a modification to clarify the starting point for the application of the rebate reduction. CMS will apply the greatest rebate reduction to the first applicable calendar quarter that a drug or biological product is described as currently in shortage regardless of whether the drug meets the definition of a Part B rebatable drug or whether a rebate amount is owed for that applicable period, starting with the calendar quarter that begins January 1, 2023. The preamble illustrates the application of this policy; see for example Table 57.

ii. Reducing the Rebate Amount for Part B Rebatable Biosimilars When There is a Severe Supply Chain Disruption

CMS finalizes its proposal to codify the provisions of section 50.12 of the Part B Revised Guidance with a modification described below. CMS considers severe supply chain disruptions as distinct from current drug shortages identified on FDA's drug shortage lists in providing a rebate reduction for an eligible biosimilar biological product. The agency is not required by statute to consult the FDA shortage lists for severe supply chain disruptions, and it does not believe manufacturer reports to FDA on drug and biological product discontinuances and manufacturing interruptions (referred to as 506C notifications) or other information voluntarily reported by manufacturers to FDA to be dispositive as to the existence of a severe supply chain disruption. Thus, manufacturers must provide CMS with sufficient information for the agency to determine if there is a severe disruption and the timing of that disruption.

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 will provide a time-limited standard reduction of 75 percent in the total rebate amount for the Part B rebatable biosimilar. Manufacturers must submit a rebate reduction request that specifies each NDC-11 and HCPCS code to which the request applies. The request must be submitted within 60 days of the first day of the natural disaster/other unique or unexpected event. The modification in the final rule is a clarification that CMS will apply a rebate reduction (initial or extension) regardless of whether a biosimilar biological product meets the definition of a Part B rebatable drug during that applicable calendar quarter or whether a rebate amount is owed for such biosimilar biological product for that applicable calendar quarter.

For example, if CMS grants a severe supply chain disruption rebate reduction request for a Part B biosimilar biological product for 4 calendar quarters, it will apply the rebate reduction beginning with the first applicable calendar quarter for which the reduction request was granted, regardless of whether the biosimilar biological product meets the definition of a Part B rebatable drug or is subject to a rebate amount in that calendar quarter. Table 58 in the final rule illustrates the application of a severe supply chain disruption reduction. CMS notes that if the reduction is applied to 4 applicable calendar quarters in which there is no rebate amount to reduce, the manufacturer could still apply for an extension of the reduction, which will apply to the fifth through eighth applicable calendar quarters.

If CMS grants the request for an NDC-11, the rebate reduction will apply to all the NDC-11s under the relevant HCPCS code, and the disruption is deemed to apply to the calendar quarter involved and the three succeeding calendar quarters. The total rebate amount owed by a

manufacturer will be reduced by 75 percent for those four calendar quarters, and the manufacturer may 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 provides three more examples in Table 59 in the final rule (shown below):

TABLE 59: Application of Severe Supply Chain Disruption Reduction for a Part B Rebatable Biosimilar Biological Product other than a Plasma-Derived Product that is Currently in Shortage on an FDA Shortage List

	Example 1	Example 2	Example 3
1Q2024	Not applicable	25% (shortage reduction)	75% (severe supply chain disruption reduction)
2Q2024	75% (severe supply chain disruption reduction)	75% (severe supply chain disruption reduction)	75% (severe supply chain disruption reduction)
3Q2024	75% (severe supply chain disruption reduction)	75% (severe supply chain disruption reduction)	75% (severe supply chain disruption reduction)
4Q2024	75% (severe supply chain disruption reduction)	75% (severe supply chain disruption reduction)	75% (severe supply chain disruption reduction)
1Q2025	75% (severe supply chain disruption reduction)	75% (severe supply chain disruption reduction)	25% (shortage reduction)
2Q2025	25% (shortage reduction)	10% (shortage reduction)	25% (shortage reduction)

Note: This table illustrates the application of the initial severe supply chain disruption reduction. A manufacturer may still apply for a rebate reduction extension request. Example 1 illustrates the application of the rebate reduction when a severe supply chain disruption precedes a shortage, and the severe supply chain disruption rebate reduction request is submitted less than 60 days before the end of a calendar quarter. Example 2 illustrates the application of the rebate reduction when a severe supply chain disruption rebate reduction request is submitted less than 60 days before the end of a calendar quarter for a non-plasma-derived Part B rebatable biosimilar biological product that is currently in shortage during the same calendar quarter. Example 3 illustrates the application of the rebate reduction when a severe supply chain disruption rebate reduction request is submitted at least 60 days before the end of a calendar quarter for a non-plasma-derived Part B rebatable biosimilar biological product that is currently in shortage during the same calendar quarter.

CMS will 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 will be kept confidential if allowed under law; information indicated as a trade secret or confidential commercial or financial information will 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 finalizes its proposed requirements for Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments in §§427.500 through 427.505.

i. Reports of Rebate Amounts and Suggestion of Error

CMS codifies the definition of the term "date of receipt" from section 60.1 of the Part B Revised Guidance. It means the calendar day following the day on which CMS makes the Rebate Report available to the manufacturer. For example, a Rebate Report made available 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.

Manufacturers of a Part B rebatable drug will be provided a Preliminary Rebate Report, which indicates 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 is due 30 days after receipt of the Rebate Report.

All rebate amounts are subject to reconciliation. One regular reconciliation will 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 will be due for any outstanding rebate amount 30 days after receipt of a report with a reconciled rebate amount.

The Preliminary Rebate Report includes (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 may submit to CMS a "Suggestion of Error" within 10 calendar days after receipt of the Preliminary Rebate Report. CMS believes 10 days is sufficient because these submissions are limited to mathematical errors; 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 will be provided to manufacturers no later than 6 months after the end of the applicable calendar quarter; they will include similar information as the Preliminary Rebate Report and include recalculations based on Suggestion of Error submissions.

ii. Reconciliation of a Rebate Amount

CMS finalizes its proposed policies, with a minor modification, to reconcile the rebate amount, which involves 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, such as 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 will 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 will be collected upon reconciliation; overpayments will be refunded. The final rule includes a modification to the contents of the Rebate Report; it will include the payment amount benchmark quarter in addition to the payment amount in the payment amount benchmark quarter and the corresponding cross-reference at §427.302(c) to identify both the benchmark period and the price in the benchmark period within the report information.

CMS establishes 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 will provide the manufacturer information about the preliminary reconciliation of the rebate amount at least one month before issuing the reconciled rebate amount, and manufacturers may, within 10 days of receipt of the preliminary reconciliation, suggest to CMS that the preliminary rebate amount contains mathematical errors. The reconciled rebate amount will 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 is not available. The 3-year limit does not apply if the manufacturer misreported information.

iii. Rebate Report for Applicable Calendar Quarters in 2023 and 2024

CMS finalizes its proposal, without modification, 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 will provide 30 calendar days for manufacturers to submit Suggestion of Errors with respect to the Preliminary Rebate Reports.

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

g. Enforcement of Manufacturer Payment of Rebate Amounts (§427.600)

CMS finalizes its proposal whereby 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 will be in addition to the rebate amount owed. Several commenters argued that CMS lacks authority to impose CMPs for reconciled amounts in the Drug Inflation Rebate Programs. CMS disagrees citing the authority under section 1847A(i)(7) of the Act for violations of obligations under section 1847A(i)(1) for the Part B Drug Inflation Rebate Program and the authority under section 1860D-14B(e) of the Act for violations of obligations under section 1860D-14B(a).

CMS will send written notice of its decision to impose a CMP, which will 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 will be 125 percent of the rebate amount for the applicable calendar quarter due at the applicable payment deadline. The CMP will 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 apply to CMPs imposed under the Part B Drug Inflation Rebate Program. However, the scope of appeals is 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 will be assessed before the next reconciliation process, and they must 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 may impose a separate civil money penalty for the increase to the rebate amount due for the applicable quarter. CMS will 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 reserves 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 finalizes its proposal, without modification, 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 are 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 is a distinct, severable provision, and do not affect similar provisions in the Part D Drug Inflation Rebate Program.

Some commenters disagreed that each regulatory provision in part 427 is severable and distinct; they believe the Part B inflation rebate regulations should be treated as a single, integrated proposal. CMS disagrees, citing provisions in the Administrative Procedures Act. The agency argues its intent is clear by including the severability provision. It also believes that if one provision within part 427 were held invalid, it does not follow that all of the program requirements under that part are also invalid.

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 codifies 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);[67] it also adds new definitions based on policies finalized in the rule.

The definition of National Drug Code (NDC) is modified sightly from its proposed definition. Specifically, references to the package size and type in the definition of NDC have been omitted for purposes of the Part D Drug Inflation Rebate Program because provisions of the Part D Drug Inflation Rebate program generally apply at the NDC-9 level.

CMS gives 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.

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 codifies the policy in section 30 of the Part D Revised Guidance to use specified FDA resources, such as the "Orange Book"[68] and NDC Directory, to determine whether a generic drug meets the definition of a Part D rebatable drug. CMS will consider historical information from NDC Directory files, such as discontinued, delisted, and expired listings. It will 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 defines 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

[67] 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

[68] FDA Orange Book: https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-productstherapeuticequivalence-evaluations-orange-book.

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 finalizes its proposal to codify policies in section 30.2 of the Part D Revised Guidance to identify drugs and biologicals for purposes of this exclusion with modifications for Part D rebatable drugs that have been billed as a compound. It will also exclude units of a Part D rebatable drug when those units are billed as compounded, and in calculating gross covered prescription drug costs for the drug or biological, it will exclude PDE records that indicate indicating the drug or biological was billed as a compound.

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 codifies 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 inflation rebate amount will 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), 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 will 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 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.

ii. Calculation of the Per Unit Part D Drug Rebate Amount

The per unit Part D drug inflation rebate amount is 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 finalizes its proposal, without modification, 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 will be the earliest applicable period that follows the payment amount benchmark period.

(2) Identification of the Payment Amount Benchmark Period

CMS finalizes the policies it will use to identify the payment amount benchmark period for a Part D rebatable drug.

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	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	The first calendar year in which such drug has at least one quarter of AMP reported
Part D rebatable drug that is no longer considered a selected drug for a price applicability period	The last calendar year of the price applicability period for the selected drug

For drugs lacking AMP data during the payment amount benchmark period, CMS will 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 will 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. This could occur when one manufacturer acquires a Part D rebatable drug from another manufacturer. However, that policy was not operationally feasible, and it sought comment on several alternative approaches to address this concern. In the final rule, CMS selects the approach under which it identifies the payment amount benchmark period and calculates the benchmark period manufacturer price of a new NDC-9 of a Part D rebatable drug by using other information reported by a manufacturer under the MDRP for the Part D rebatable drug. This information could include the base date AMP if it is reported for a calendar quarter that overlaps with (i) the January 1, 2021 through September 30, 2021 period or (ii) the first calendar year following the drug's first marketed date.

CMS will also apply this policy to rebate calculations beginning with the applicable period that began on October 1, 2022, including the calculation of the benchmark period manufacturer prices (§428.207(d)), the identification of the benchmark period CPI-U (§428.207(e)), and in situations where manufacturers do not report units to the Medicaid Drug Programs systems (§428.207(g)) (described below).

The agency will monitor the extent to which manufacturers obtain a new NDC-9 for the same Part D rebatable drug that could result in inappropriately resetting the payment amount benchmark period or otherwise affect the calculation of the benchmark period manufacturer price.

Where a Part D rebatable drug is no longer a selected drug under the IRA Drug Price Negotiation Program, the payment amount benchmark period will be reset as the last calendar year of the price applicability period for the selected drug.

These policies will apply to rebate calculations beginning with the applicable period that began on October 1, 2022.

(3) Calculation of the Benchmark Period Manufacturer Price

The agency finalizes its proposal 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 finalizes its proposal 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, will be the CPI-U for January 2021. For a subsequently approved drug, the benchmark period CPI-U will 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 will 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 will be the CPI-U for January of the calendar year in which such drug has at least one quarter of AMP reported. For Part D rebatable drugs that are no longer selected drugs for a price applicability period, the benchmark period CPI-U is the CPI-U for January of the last calendar year of such price applicability period.

(5) Calculation of the Inflation-Adjusted Payment Amount

CMS will 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 finalizes it proposal 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 will 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 will 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 finalizes its proposal 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. The determination will be based on information reported to CMS by Part D plan sponsors on the Part D PDE records for the 12-month applicable period. Specifically, the total number of units will 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 will 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 will 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. However, CMS will not perform additional adjustments to reduce the effect of outliers not resolved through the Part D payment reconciliation process at this time.

CMS will 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. In the final rule, CMS will also exclude PDE records for Part D rebatable drugs that were billed as compounds when determining the total number of units of each Part D rebatable drug dispensed under Part D and covered by Part D sponsors. Similarly, CMS will exclude PDE records for drugs and biologicals billed as a compound when calculating gross prescription drug costs.

(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 will 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 proposed to estimate the number of 340B units that will be excluded. The estimation would have been based on a calculated percentage that reflects the portion of 340B purchasing relative to total

sales. CMS would have set the percentage, which it referred 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.

Many commenters expressed strong objections to the estimation policy because they believed it is highly doubtful that the 340B units excluded via the estimation percentage would be reasonably correct and would likely underestimate the number of 340B units. They note the statute requires CMS to exclude all 340B units.

CMS does not finalize the proposal. Instead, CMS will "explore the establishment" of a Part D claims repository to identify 340B units from data elements submitted to CMS by covered entities from 340B-identified Part D claims for removal of 340B units starting January 1, 2026. The exploration will include the development of detailed policies and requirements related to the repository for future rulemaking on this topic and the exclusion of 340B units, including requirements for covered entities to report retrospectively, at a minimum, the date of service, the prescription or service reference number, the fill number, and the dispensing pharmacy NPI for all covered Part D drugs billed to Medicare.

CMS also confirms that it is not currently pursuing a policy to require a 340B claims indicator be included on the PDE record at the time of dispensing to identify drugs purchased under the 340B Program that were dispensed under Medicare Part D.

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 finalizes its proposal, without modification, 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. Under this policy, CMS will compare the *total* rebate amount calculated to the alternative *total* rebate amount.

The agency will first determine the inflation rebate amount for the new formulation of the Part D rebatable drug and then it will 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 will 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 codifies its policy in section 40.4 of the Part D Revised Guidance to calculate the alternative inflation rebate amount. The agency will 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 60 of the final rule (reproduced below) summarizes policies on reducing the total rebate amount owed by a manufacturer in each of these cases.

TABLE 60: Determination of Rebate Reduction Amount for Part D Rebatable Drugs

	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

CMS finalizes its proposals for reducing the rebate amount for Part D rebatable drugs currently in shortage as proposed, with the addition of a provision to clarify the starting point for the application of the rebate reduction (described below).

The rebate amount owed will not be fully waived.

To calculate the reduced total rebate amount for a Part D rebatable drug currently in shortage, CMS will 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 will 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.

While CMS will generally apply the shortage reduction starting with the first applicable period that a drug or biological covered under Part D is described as currently in shortage, it acknowledges that for a drug or biological that has been granted a rebate reduction for a severe supply chain disruption, or for a generic drug that has been granted a rebate reduction for a likely shortage, it will delay the start of the applicable percent reduction for being in shortage until after the conclusion of the severe supply chain disruption reduction or likely to be in shortage reduction if the shortage continues. Table 61 of the final rule (shown below) illustrates the policy.

TABLE 61: Application of Shortage Reduction

	Applicable period 1	Applicable period 2	Applicable period 3
In shortage on FDA shortage list	Yes	Yes	Yes
Meets definition of Part D rebatable drug	No	Yes	Yes
Owes a >$0 rebate	No	No	Yes
Applicable percent reduction applied for a Part D rebatable drug other than a plasma-derived product or generic	25%	10%	2%
Applicable percent reduction for a Part D rebatable plasma-derived product or generic Part D rebatable drug	75%	50%	25%

Note: CMS would "start the clock" for rebate reductions with applicable period 1. The highest percent reduction would thus apply to applicable period 1, regardless of how many days the Part D rebatable drug is in shortage during this applicable period. In this example, the 25 percent reduction (for a drug other than a generic or plasma derived product) or 75 percent reduction (for a generic drug or plasma-derived product) would apply to applicable period 1, even though there would be no rebate amount to which it applies.

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 will apply the shortage reduction as if there were 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 will treat

the subsequent shortage as a new shortage and 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 finalizes its proposal to codify the provisions of section 40.5.2 of the Part D Revised Guidance with a modification (described below). 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 will provide a time-limited standard reduction of 75 percent to the total rebate amount for the Part D rebatable drug or biosimilar. Manufacturers must submit a rebate reduction request that would specify each NDC-11 to which the request applies. The request must 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, the rebate reduction will apply to the entire generic Part D rebatable drug or biosimilar at the NDC-9 level. The disruption is 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 will be reduced by 75 percent for the applicable period. In the final rule, CMS modifies its proposal to clarify that the application of a rebate reduction (initial or extension) applies regardless of whether a generic drug or biosimilar meets the definition of a Part D rebatable drug during that applicable period or whether a rebate amount is owed for such generic Part D drug or biosimilar for that applicable period. In other words, CMS will apply the 75 percent reduction in the total rebate amount even if there is no rebate amount owed to reduce. Table 62 in the final rule (shown below) provides an illustration.

TABLE 62: Application of Severe Supply Chain Disruption Reduction

	Applicable period 1	Applicable period 2	Applicable period 3
Meets definition of Part D rebatable drug	No	Yes	Yes
Owes a > $0 rebate	No	No	Yes
Applicable percent reduction applied	75%	0%	0%

Note: CMS would "start the clock" with applicable period 1 if the request was granted for applicable period 1. In this example, the 75% reduction would apply to applicable period 1, even though there would be no rebate amount in the applicable period to which the reduction applies.

The manufacturer may request a second consecutive applicable period reduction if it provides new supporting documentation; that rebate reduction extension request and any new supporting documentation must be submitted at least 60 calendar days before the start of that second applicable period. A manufacturer may 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 will apply a 75 percent reduction in the rebate amount to the entire applicable period in lieu of the reduction under the shortages policy.

CMS will 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 will 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 finalizes its proposal, with a modification, 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 must 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 will reduce the likelihood of the drug appearing on an FDA shortage list. The rebate reduction request must 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 will 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. In the final rule, CMS modifies its proposal to clarify that CMS will apply a likely to be in shortage rebate reduction to the applicable period in which the request was submitted or the following applicable period, depending on the timing of the submission of the request. CMS will not delay the application of the reduction until the generic drug meets the definition of a Part D rebatable drug or until a rebate amount is owed for such drug. Table 64 in the final rule provides an illustration.

Similar requirements established for the cases described above for severe supply chain disruptions will 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 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 finalizes its proposed requirements for Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments in §§428.400 through 428.405.

CMS codifies the definition of the term "date of receipt" from section 50.1 of the Part D Revised Guidance. It means 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 finalizes its proposals for Rebate Reports and Suggestion of Error submissions with a modification to the content of the Rebate Reports described below.

CMS will provide manufacturers a Preliminary Rebate Report, which will 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 will be due 30 days after receipt of the Rebate Report.

All rebate amounts are subject to two regular reconciliations, which 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 is due for any outstanding rebate amount 30 days after receipt of a report with a reconciled rebate amount.

The Preliminary Rebate Report will 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 will 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 will also include the NDC for the initial drug; the inflation rebate amount ratio for the initial drug; and the alternative rebate amount. Under the final rule, Preliminary Rebate Reports will also include the payment amount benchmark period and benchmark period manufacturer price.

Manufacturers may 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 will be provided to manufacturers no later than 9 months after the end of the applicable period; they will include the same data elements as the Preliminary Rebate Report and also 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 finalizes its proposals for reconciliation of rebate amounts with modifications.

CMS will reconcile the rebate amount, which involves 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. As modified in the final rule, the reconciliation will include an updated payment amount benchmark period and the price in the benchmark period within the report information. Additionally, updates to inputs included in the reconciliation calculations will include newly reported information, in addition to the restated AMP. The agency believes the modifications will clarify how it will conduct the reconciliation process, including where AMP data are missing when CMS issues a Rebate Report for a Part D rebatable drug.

A report of a reconciled rebate amount will 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 will be collected upon reconciliation; overpayments will be refunded.

CMS finalizes 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) will capture a majority of the updates and the second (with 37 months of claims run-out) will capture the rest.

For each reconciliation, CMS will 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 will include the same

information outlined for the Rebate Report, updated with more recent data. Manufacturers may, 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 will 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 will limit the scope of the reconciliation to the specific information that is the basis for the reconciliation; it will 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.

CMS 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 does not apply if the manufacturer misreported information.

iii. Rebate Reports for the Applicable Periods Beginning October 1, 2022, and October 1, 2023

CMS finalizes its proposal, without modification, to issue a Preliminary Rebate Report for each of these applicable periods no later than December 21, 2025. It will provide 30 calendar days for manufacturers to submit Suggestion of Errors with respect to the Preliminary Rebate Reports.

Under this policy, there will 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 will be reconciled twice. The first reconciliation occurs 9 months after issuance of the Rebate Report to include 13 months of claims run-out and payment data, and the second will occur 24 months after the first reconciliation and include 37 months of claims run-out and payment data.

f. Enforcement of Manufacturer Payment of Rebate Amounts (§428.500)

A manufacturer may 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 will be in addition to the rebate amount owed.

CMS will send written notice of its decision to impose a CMP, which will 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.

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 will be 125 percent of the rebate amount at the applicable payment deadline for the applicable period. The CMP will 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 will 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 will be assessed before the next 12- or 36-month reconciliation, and must 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 apply to CMPs imposed under both the Part B and Part D Drug Inflation Rebate Programs. However, the scope of appeals is 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 reserves 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 adds 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 are severable from part 428. Thus, the invalidity or unenforceability of those invalid provisions will 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 is a distinct, severable provision, and does 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

In the 2025 PFS proposed rule, CMS described that as part of the Center for Medicare and Medicaid Innovation (CMMI) comprehensive specialty strategy to test models, 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 MIPS under the PFS. MIPS eligible clinicians have been able to report on MVPs beginning with the 2023 MIPS performance period. 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.

In the 2025 PFS proposed rule, CMS sought comment on various aspects of the potential ambulatory specialty care model. In this final rule, CMS does not review any of the comments received in response to the RFI, but states that the agency will consider those comments for future rulemaking, technical assistance, and work related to the design of a future ambulatory specialty model.

K. Expand Colorectal Cancer Screening

Statutes, regulations and a National Coverage Determination (NCD) describe Medicare Part B coverage for colorectal cancer (CRC) screening tests.[69] 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

[69] Sections 1861(s)(2)(R), 1861(pp), 1862 (a)(1)(H) and 1834(d) of the Act, §410.37 and NCD 210.3.

organizations.[70] CMS finalizes its proposal 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 policies 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 it 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.[71] In addition, several organizations, including the 2017 U.S. 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 joint public comments from the American College of Gastroenterology, American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy, who commented that barium enema is not recommended as a CRC screening modality.

CMS finalizes its proposal to remove barium enema as a colorectal screening test under 42 CFR 410.37(a)(1)(iv).

Commenters supported CMS' proposal to exercise its authority to remove coverage for barium enema procedures from the CRC screening regulations at §410.37. They agreed that barium enema procedures no longer meet modern clinical standards, are no longer recommended in clinical guidelines, and would not be an appropriate CRC screening test given the advancement of alternatives.

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.[72] The USPSTF recommends screening CTC

[70] Section 1861(pp)(1)(D) of the Act and §410.37(a)(1)(v).
[71] 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.
[72] USPSTF June 2016 Revised Final Recommendation Statement,

frequency every five years. The ACS guidelines also recommend screening CTC frequency every five years. CMS also discusses the recommendations of the US MSTF of Colorectal Cancer and the online resource RadiologyInfo.[73]

CMS finalizes its proposal to add CTC as a covered CRC screening test at §410.37. CMS finalizes its description of 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 establishes 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.[74] 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.

The majority of commenters supported CMS' proposal to exercise its authority to add coverage for the CTC procedure for CRC screening in regulations at §410.37. The commenters acknowledged that adding CTC is a significant advancement in preventive care and ensures equity in prevention and early detection of colon cancer. CMS agrees and states that it strives to offer a variety of appropriate CRC screening options to ensure greater access.

The majority of commenters supported CMS' proposal to codify in regulatory text that Medicare Part B pays for a screening CTC if it is ordered in writing by the beneficiary's attending physician, physician assistant, nurse practitioner, or clinical nurse specialist. One commenter suggested that Medicare beneficiaries should be able to refer themselves directly for a CTC without the requirement for an order from a clinician. In response to this comment, CMS states that unlike mammography, there are multiple options for CRC screening. Thus, CMS expects that the patient and their clinician will make the appropriate choice in CRC screening for the individual, which includes considerations of the risks, burdens and tradeoffs for each covered test

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.

[73] RadiologyInfo Website: https://www.radiologyinfo.org.

[74] Section1833(a)(1)(Y) and section 1833(b)(1) of the Act

or procedure.

The majority of commenters also supported CMS' proposed frequency limitations of coverage for CTC. One commenter, while supporting expanding screening to include CTC, requested CMS reconsider the limitations on time between screenings. CMS replies that the frequency limitations of coverage for CTC average risk and high risk individuals described in its provision are in alignment with clinical evidence-based recommendations. CMS finalizes the frequency limitations to coverage, as proposed, with one minor editorial modification for grammatical clarity in paragraph § 410.37(i)(1) adding the words "was performed" after the word colonography in the phrase "59 months have passed following the month in which the last screening computed tomography colonography…".

Most commenters supported CMS' proposal to add CTC to the definition of CRC screening methods and because CTC has been given Grade A by the USPSTF. Part B coinsurance and deductibles will be eliminated for the preventive screening procedure. The commenters stated that by reducing or eliminating financial barriers, it enhances patient access to these cancer screening tools without the burden of out-of-pocket costs. CMS reminds commenters that CTC will continue to require Part B coinsurance and deductible when furnished as a diagnostic or other non-preventive/ screening procedure.

CMS finalizes its proposals related to coverage for CTC.

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 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 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.[75]

CMS finalizes its proposal 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-

[75] https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs.

based biomarker CRC screening test returns a positive result. The revision also states that in the instance of a follow-on colonoscopy as part a complete CRC screening the frequency limitations for CRC screening will not apply.

All commenters supported CMS' proposal to revise the regulatory text at §410.37(k) to state the instance of the follow-on colonoscopy in the context of a complete colorectal cancer screening shall not apply to the frequency limitations for colorectal cancer screenings. Commenters stated that this regulatory text is clearer and recognizes, outside the context of a complete colorectal cancer screening, the instance of a screening colonoscopy is factored into the calculation of frequency limitations of other covered CRC screening tests and procedures in addition to a subsequent screening colonoscopy. CMS finalizes §410.37(k) with editorial modification of the regulatory text at §410.37(k) for additional clarity, replacing one of the sentences with the following, "A follow-on screening colonoscopy in the context of a complete colorectal cancer screening is not subject to the frequency limitations for colorectal cancer screening in §410.37(g)(2) or (3)."

Several commenters requested that CMS exercise its authority in section 1861(pp)(1)(D) of the Act to expand its approach to a "complete CRC screening" to also add CTC along with the Medicare covered blood-based biomarker CRC screening test and the Medicare covered non-invasive stool-based CRC screening test within the definition of a "complete CRC screening." CMS disagrees with commenters that requested a further expansion of a complete colorectal cancer screening to include CTC. CTC is a visualization procedure along with colonoscopy and flexible sigmoidoscopy whereas stool-based and blood-based CRC screening tests are non-visualization tests. CMS further expands that the follow-up screening colonoscopy after a positive non-visualization test is necessary to confirm the presence of polyps and/or cancer. A follow-up colonoscopy after an abnormal finding from a CTC would be considered a diagnostic colonoscopy to biopsy or remove visualized polyps and/or cancer.

Two commenters requested that CMS exercise the same authority in section 1861(pp)(1)(D) of the Act to add coverage for the newly FDA-approved CRC screening test using multi-target mRNA stool. CMS replies that the first multi-target mRNA stool CRC screening test received FDA approval in May 2024. Medicare currently covers multi-target stool DNA CRC screening tests in regulations at §410.37, but not multi-target mRNA tests as a CRC screening test. CMS has accepted a formal NCD reconsideration request and added it to the public facing NCD CMS believes that the NCD process will provide an opportunity for public participation and for CMS to consider additional relevant scientific and medical information. However, CMS states that if an mRNA stool test is covered through a reconsideration of the NCD, such a test would qualify as an additional non- invasive stool-based colorectal cancer screening test. CMS notes that the blood-based biomarker test just received FDA approval in July 2024 and met the coverage criteria set forth in NCD 210.3 and therefore became coverable on the same day of FDA approval.

After consideration of public comments, CMS finalizes the proposals made in the 2025 PFS proposed rule to update and expand colorectal cancer screening and reduce barriers to access to CRC cancer prevention, early detections and improved health outcomes.

Regulatory Impact

CMS anticipates this policy to update and expand coverage for CRC screening will result in 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 72 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.[76]

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, with the earliest date of compliance actions to no earlier than January 1, 2023—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. Through December 31, 2023, compliance actions were limited to a non-compliance notice.
- 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), 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.
- 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.

[76] 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.

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 that they 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.[77]

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, 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.

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, 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 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

[77] 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.

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 versions 2017071 and 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

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
- Lack of three-way (or multi-party) communication between the prescriber, the LTC facility, and the pharmacy under NCPDP SCRIPT standard version 2017071. CMS walks through a few examples and improvements under NCPDP SCRIPT standard version 2023011.

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).

In the proposed version of this rule, CMS proposed 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 such beneficiaries 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 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.

Final Action. CMS is finalizing its proposals 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.

Selected Comments/Responses. Many commenters supported the proposal, reiterating reasons already mentioned. One commenter noted that this proposal would prevent a large number of waiver applications.

A few commenters expressed their concerns about conducting EPCS in LTC facilities, noting the difficulty prescribers experience working with multiple EHRs in different facilities and the necessary workarounds when the technology has not been adopted uniformly. Some stated that not all LTC facilities have EHRs because LTC facilities were excluded from funding in the Health Information Technology for Economic and Clinical Health Act (HITECH Act), enacted as part of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5, Feb. 17, 2009). Commenters offered some suggestions for closing this gap.

In response, CMS notes that the EPCS Program assesses compliance with requirements for electronic prescribing using information from the PDE data and does not measure electronic communication within LTC facilities. If prescribers are prescribing from their own health IT systems, they do not need the LTC facility to have EPCS functionality to be compliant with the

CMS EPCS Program, because compliance is measured based on the prescriber sending the prescriptions to the pharmacy electronically using the appropriate standards. Nevertheless, CMS encourages LTC facilities to adopt EPCS capabilities with NCPDP SCRIPT standard version 2023011 as soon as possible to simplify the communication between prescribers and LTC facilities. If prescribers are unable to conduct electronic prescribing of controlled substances due to circumstances beyond their control, they may apply for a waiver per §423.160(a)(5)(iii).

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 as 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 and Prevention (CDC) for infants at birth, completing the vaccination series by 16 months of age.[78] 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.[79] 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.

CMS finalizes its proposal 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 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 includes 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

[78] CDC, 2024. Vaccine safety: Hepatitis B vaccines. Retrieved from. *https://www.cdc.gov/vaccinesafety/vaccines/hepatitis-b-vaccine.html*

[79] 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

hepatitis B virus because of current or previous infection or vaccination, nor does it increase the risk for adverse events.

All the commenters supported the proposals to expand access to the hepatitis B vaccines in order to increase utilization as it addresses concerns about disparities in access to the vaccine for people with Medicare. Some commenters noted that only four preventive vaccines are covered under Medicare Part B, but also recognized that CMS does not have the authority to add new ACIP-recommended vaccines to Part B coverage. CMS replies that additional legislation would be necessary to expand the scope of coverage under Part B for these additional vaccines.

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 the final 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 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.

Regulatory Change

CMS proposed 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 did not include alternative blood product treatments in its proposal and sought comment on 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.

Upon further review and feedback from interested parties, CMS determined that all prehospital blood transfusions (PHBTs), which refer to the administration of low titer O+ and OWBT, packed red blood cells (PRBCs), plasma, or a combination of PRBCs and plasma, should independently qualify as ALS2 procedures; the administration of low titer O+ whole blood transfusion should not be the only PHBT that independently qualifies as an ALS2 procedure, as CMS had proposed in the 2025 PFS proposed rule (89 FR 62004).

CMS thus finalizes its proposed policy, with modifications, to add the administration of low titer O+ whole blood to the list of procedures that independently qualify as an ALS2 procedure and finalizes a policy to change the definition of ALS2 at §414.605 by including all PHBTs in the list of procedures that independently qualify as an ALS2 procedure. Specifically, the list of ALS2 procedures in the definition at §414.605 now includes, as a new number 8, prehospital blood transfusion, which includes the administration of low titer O+ and O- whole blood; the administration of packed red blood cells; the administration of plasma; or the administration of a combination of packed red blood cells and plasma.

O. Medicare Parts A and B Overpayment Provisions of the Affordable Care Act (ACA) (§§401.305(a)(2), 401.305(b)(1), (2), and (3))

1. Background

Overview. In the proposed rule referred to by CMS as the "December 2022 Overpayment Proposed Rule,"[80] 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 the 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.

After considering the public comments from the December 2022 Overpayment Proposed Rule, CMS, in the 2025 PFS Propose Rule, issued a statement that the agency was retaining the Parts A and B proposals published in that December 2022 Overpayment Proposed Rule and was also making additional proposals to revise regulations at §401.305(b) regarding the deadline for reporting and returning overpayments.

[80] 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).

Statutory Background. Section 1128J(d) of the Act, added by the ACA, requires a person[81] 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 that appropriate actor of the reason for the overpayment. The statute specifies the deadline by which the overpayment is to be reported and returned[82] and if an overpayment is retained after the deadline, the overpayment constitutes an obligation for purposes of the False Claims Act (FCA). The term overpayment is defined by statute as funds that a person receives under title XVIII or XIX of the Act (the Medicare and Medicaid statutes, respectively) to which that person, after reconciliation, is not entitled. Section 1128J(d)(4) of the Act also applies the definition for "knowing" and "knowingly" that are applied in the False Claims Act.[83]

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",[84] 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",[85] 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).

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,

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[81] The term "person" is defined in section 1128J(d)(4)(C) of the Act as including (for purposes of Medicare Parts C and D) a Medicare Advantage organization (MAO) defined in section 1859(a)(1) of the Act and a Part D sponsor defined in section 1860D-41(a)(13) of the Act.

[82] 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.

[83] Under section 3729(b)(1) of title 31, United States Code (the False Claims Act), knowing and knowingly "(A) mean that a person, with respect to information (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud;".

[84] 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)

[85] Full title is "Medicare Program; Reporting and Returning of Overpayments" (81 FR 7654)

CMS impermissibly established False Claims Act liability for mere negligence.[86] 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 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).

2. Updates to Regulations

a. Medicare Parts A and B – Amending the Standard for When an Overpayment Is Identified (§401.305(a)(2))

CMS is finalizing, as proposed in the December 2022 Proposed Rule, to change the standard for an "identified overpayment" to the knowledge standard derived from the FCA standard, which provides that a provider or supplier has identified an overpayment if it has actual knowledge of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment.

Selected Comments/Responses. Some commenters believe that the proposed language is ambiguous and recommend the adoption of clear and practical guidance with examples of acting in reckless disregard or deliberate ignorance. CMS points out that the FCA language is supported by FCA caselaw and examples and that the inquiry is a fact-specific inquiry as to whether a person has the requisite knowledge to have identified an overpayment for purposes of §401.305(a)(2). Many commenters raised concerns about time needed to investigate, calculate, and report and return certain overpayments. In response, CMS is finalizing (as discussed below) a suspension of the applicable requirements for 180 days to conduct a timely, 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.

Commenters were also concerned that the agency's expectations for quantifying overpayments and the time needed to calculate overpayments were unclear. In response, CMS is clarifying (through its finalized proposals discussed below) that, for purposes of section 1128J of the Act, "a person has identified an overpayment when the person (1) has actual knowledge of an overpayment; (2) acts in deliberate ignorance of the truth or falsity of information regarding the overpayment; or (3) acts in reckless disregard of the truth or falsity of information regarding the

[86] 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).

overpayment." In cases for which the provider or supplier is actively investigating a potential overpayment, the 60-day period for reporting and returning the overpayment begins when the provider or supplier has actual knowledge of the overpayment. In cases for which the provider or supplier acts in deliberate ignorance or reckless disregard of the existence of the overpayment, the 60-day period begins on the date of such deliberate ignorance or reckless disregard. Also, CMS clarifies that the 60 days to report and return overpayment applies even if the person has not yet calculated the precise amount of the overpayment. The overpayment, though, must be calculated within the 60-day deadline. If the person believes there may be other related overpayments, the deadline for the initially identified overpayment may be suspended (as discussed below) for up to 180 days for a timely, good faith investigation to determine the existence of related overpayments, including calculating the aggregate amount of the initially identified overpayment and related overpayments uncovered by the investigation.

b. Medicare Parts A and B Overpayment Provisions (§§401.305(b)(1), (b)(2), (b)(3))

In addition to CMS' earlier proposals, in the 2025 PFS Proposed Rule, CMS made the following proposals (all of which the agency is finalizing in this rule) to revise regulations at §401.305(a)(2) and (b)(1), (2), and (3) regarding the deadline for reporting and returning overpayments.

Existing §401.305(b)(1) specifies when a person who has received an overpayment must report and return an overpayment. CMS finalized its proposal to amend this paragraph to reference revised §401.305(b)(2), as well as to reference newly-added §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 finalized, as proposed, 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.

As finalized, §401.305(b)(3) will specify the circumstances under which the deadline for reporting and returning overpayments will be suspended to allow time for providers to investigate and calculate overpayments. The deadline to report and return an overpayment will 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 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 notes that these finalized proposals were in response to many of the comments received on the December 2022 Overpayment Proposed Rule, which expressed concern about the agency's December 2022 proposal to remove the term "quantified" from the original regulatory text. Other commenters had 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 proposed (and is finalizing) to codify this allowance into regulation at §401.305(b)(3)(ii).

Selected Comments/Responses. Several commenters expressed concern over the timeframes and potential obligations being imposed on providers or suppliers and requested further clarifications. In response, CMS clarifies that the up to 180-day suspension of the 60-day period is available after a person has identified an overpayment, i.e., when a person has identified an overpayment but has not yet completed a good-faith investigation to determine the existence of related overpayments. Further, CMS explains that §401.305(b)(3) does not impose an independent obligation to investigate related overpayments when a person has actual knowledge of an overpayment, but the FCA or other laws may impact when a person has an obligation to investigate overpayments. Under §401.305(b)(3) if a person has actual knowledge of an overpayment but no reason to believe there are other related overpayments then there is no obligation to investigate such other overpayments.

P. Medicare Parts C and D Overpayment Provisions of the Affordable Care Act (ACA) (§§422.326(c) and 423.360(c))

Statutory and Regulatory Background. As discussed in section III.O above, section 1128J(d) of the Act, added by the ACA, requires a person[87] 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 that appropriate actor of the reason for the overpayment. The statute specifies the deadline by which the overpayment is to be reported and returned and if an overpayment is retained after the deadline, the overpayment constitutes an obligation for purposes of the False Claims Act (FCA). The term overpayment is defined by statute as funds that a person receives under title XVIII or XIX of the Act (the Medicare and Medicaid statutes, respectively) to which that person, after reconciliation, is not entitled. Section 1128J(d)(4) of the Act also applies the definition for "knowing" and "knowingly" that are applied in the False Claims Act.[88]

[87] The term "person" is defined in section 1128J(d)(4)(C) of the Act as including (for purposes of Medicare Parts C and D) a Medicare Advantage organization (MAO) defined in section 1859(a)(1) of the Act and a Part D sponsor defined in section 1860D-41(a)(13) of the Act.

[88] Under section 3729(b)(1) of title 31, United States Code (the False Claims Act), knowing and knowingly "(A) mean that a person, with respect to information (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud;".

CMS describes (as discussed above) that pursuant to this statutory authority it promulgated its Part C and D Final Overpayment Rule,[89] which provided that an overpayment is identified by an MAO or Part D sponsor when the MAO or part D sponsor has determined, or should have determined through reasonable diligence, that it received the overpayment.

Related Litigation. As discussed in section III.O above, a group of MAOs in *UnitedHealthcare Insurance Co. v. Azar*[90] challenged the reasonable diligence standard applied under the Part C and D final Overpayment Rule. The District Court held that the standard impermissibly made a provider liable for mere negligence and noted that the FCA (which is referred to under section 1128J(d) of the Act as the enforcement mechanism for that section) imposes liability for false claims that are submitted "knowingly," which is defined under the FCA.

Revised Part C and D Final Overpayment Rule. In response to the litigation, CMS proposed in December 2022[91] to amend the Parts C and D Overpayment Rule (§§422.326(c) and 423.360(c)) to replace the reference to "reasonable diligence" with language that references the FCA definition of the terms "knowing" and "knowingly," consistent with the application of the FCA definition of those terms pursuant to section 1128J(d)(4) of the Act. As revised, an MAO or Part D sponsor has identified an overpayment if it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment.

In this final rule, the agency finalizes its changes to §§422.326(c) and 423.360(c), as proposed.

Selected Comments/Responses. A commenter raised concerns that the agency's proposed revisions go beyond the plain meaning of the statute, but CMS disagrees. The agency acknowledges that section 1128J(d)(4) of the Act defines "knowing" and "knowingly" for purposes of section 1128J(d) by applying the FCA definitions, but that those terms are not actually used in that section. However, the agency believes that Congress did not intend to create a lower knowledge standard for Medicare overpayments than what otherwise exists for the FCA and reasons that such an interpretation would allow MAOs and Part D sponsors to deliberately ignore and recklessly disregard overpayments.

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.

[89] The Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs (79 FR 29844) was published on May 23, 2014.
[90] *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 (2022).
[91] The 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 (87 FR 79452).

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 payment rates for 2025 using 2023 Medicare utilization. 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 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 CF for 2025 is $32.3465, 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 +0.02 percent. As noted previously, the increase in the BN adjustment appears to be largely related to the adjustments to the transfer of postoperative care for global surgical procedures. The 2025 anesthesia conversion factor is $20.3178, 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 108 and 109 from the final rule, reproduced below.

Table 108: Calculation of the 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	0.02 percent (1.0002)	
2025 Conversion Factor		**$32.3465**

Table 109: Calculation of the 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	0.02 percent (1.0002)	
2025 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	0.65 percent (1.0065)	
2025 Conversion Factor		**$20.3178**

Table 110 (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 110. 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 110 for a given specialty, the combined effect of RVU changes with the CF reduction would be roughly 5 percent.[92]

2025 PFS Impact Discussion

The most widespread specialty impacts of RVU changes in most years are 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 adjustments to transfer of postoperative care for global surgical procedures. These specialty impacts range from an increase of 4 percent for clinical social worker, an increase of 3 percent for clinical psychologist, an increase of 2 percent for anesthesiology, and a decrease of 2 percent for diagnostic testing facility, interventional radiology, ophthalmology, and vascular surgery. The specialties with significant increases largely

[92] CMS displays the combined impact percentage in Table 110 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.

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 110 (reproduced below) shows the estimated 2025 combined impact on total allowed charges by specialty of all the RVU and other changes. CMS also provides an additional impact table (Table 111 in the final rule) that includes a facility/non-facility breakout of payment changes.

Table 110: 2025 Final 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	$218	0%	-1%	0%	-1%
Anesthesiology	$1,591	1%	1%	0%	2%
Audiologist	$74	0%	0%	0%	0%
Cardiac Surgery	$166	0%	0%	0%	-1%
Cardiology	$6,117	0%	0%	0%	0%
Chiropractic	$656	0%	1%	0%	1%
Clinical Psychologist	$737	3%	1%	0%	3%
Clinical Social Worker	$854	3%	1%	0%	4%
Colon And Rectal Surgery	$151	0%	0%	0%	0%
Critical Care	$333	0%	0%	0%	0%
Dermatology	$3,885	0%	0%	0%	0%
Diagnostic Testing Facility	$942	0%	-2%	0%	-2%
Emergency Medicine	$2,440	0%	0%	0%	0%
Endocrinology	$517	0%	0%	0%	0%
Family Practice	$5,515	0%	0%	0%	0%
Gastroenterology	$1,453	0%	0%	0%	0%
General Practice	$379	0%	0%	0%	0%
General Surgery	$1,602	0%	0%	0%	0%
Geriatrics	$222	0%	0%	0%	1%
Hand Surgery	$265	-1%	-1%	0%	-1%
Hematology/Oncology	$1,579	0%	-1%	0%	-1%
Independent Laboratory	$561	0%	0%	0%	0%
Infectious Disease	$555	0%	0%	0%	0%
Internal Medicine	$9,491	0%	0%	0%	0%
Interventional Pain Mgmt	$839	0%	0%	0%	0%
Interventional Radiology	$445	0%	-2%	0%	-2%
Multispecialty Clinic/Other Phys	$152	0%	0%	0%	0%
Nephrology	$1,706	0%	0%	0%	0%

Table 110: 2025 Final 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**
Neurology	$1,333	0%	0%	0%	0%
Neurosurgery	$706	0%	0%	0%	0%
Nuclear Medicine	$50	0%	0%	0%	0%
Nurse Anes / Anes Asst	$1,056	0%	1%	0%	1%
Nurse Practitioner	$7,029	0%	0%	0%	0%
Obstetrics/Gynecology	$565	0%	0%	0%	-1%
Ophthalmology	$4,667	-1%	-1%	0%	-2%
Optometry	$1,361	0%	0%	0%	-1%
Oral/Maxillofacial Surgery	$64	0%	0%	0%	0%
Orthopedic Surgery	$3,426	-1%	0%	0%	-1%
Other	$58	0%	-1%	0%	-1%
Otolaryngology	$1,155	0%	0%	0%	0%
Pathology	$1,187	0%	0%	0%	0%
Pediatrics	$55	0%	0%	0%	0%
Physical Medicine	$1,127	0%	0%	0%	0%
Physical/Occupational Therapy	$5,905	0%	0%	0%	0%
Physician Assistant	$3,699	0%	0%	0%	0%
Plastic Surgery	$303	0%	0%	0%	-1%
Podiatry	$1,928	0%	0%	0%	0%
Portable X-Ray Supplier	$79	0%	1%	0%	1%
Psychiatry	$867	1%	0%	0%	1%
Pulmonary Disease	$1,269	0%	0%	0%	0%
Radiation Oncology and Radiation Therapy Centers	$1,538	0%	0%	0%	0%
Radiology	$4,557	0%	0%	0%	0%
Rheumatology	$520	0%	-1%	0%	0%
Thoracic Surgery	$297	0%	0%	0%	-1%
Urology	$1,617	0%	0%	0%	0%
Vascular Surgery	$998	0%	-2%	0%	-2%
Total	$90,861	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 110:

- 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 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 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 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 Provisions

The expected impacts of some of the 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 119, 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 119: Description of MIPS Eligibility Status for 2025 Performance Period/2027 MIPS Payment Year Using the 2025 PFS Final 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) meet group eligibility or 2) opt-in eligibility criteria)	Opt-in Eligible; Do not opt-in	178,216	$5,517
	Group Eligible; Did not Report	405,945	$9,502
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.			

Table 119: Description of MIPS Eligibility Status for 2025 Performance Period/2027 MIPS Payment Year Using the 2025 PFS Final Rule Assumptions**			
Eligibility Status	**Predicted Participation Status in MIPS Among Clinicians***	**Number of Clinicians**	**PFS allowed charges ($ in mil)*****
MIPS Eligible Clinicians			
** 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 final 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' 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 120 and 126 displayed in the final 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. The decrease in the size of the budget neutral pool results in a decrease in the size of its positive payment adjustment increases.

Table 120 & 126: 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%
Final Policies Model						
1) Solo	18,867	32.41%	21.94%	45.65%	1.55%	-6.42%

Table 120 & 126: 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 ****
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 scores 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 final 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 in the MIPS program. Given these limitations and others, there continues to be considerable uncertainty around CMS' estimates.

D. Alternatives Considered

The final 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 final rule, CMS is finalizing its proposal to broaden the applicability of the transfer of care modifier -54 for the 90-day global packages as proposed. Beginning with services furnished in 2025, modifier -54 is required for all 90-day global surgical packages in any case when a practitioner plans to furnish only the surgical procedure portion of the global package (including both formal and other transfers of care). CMS is not finalizing any changes regarding the use of modifier -55 and modifier -56 for 2025. Modifiers -55 and -56 will continue to be billed exclusively in cases where there is a documented formal transfer of care. Additionally, CMS is finalizing a global surgical add-on code, HCPCS code G0559, 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,[93] 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 final rule, CMS finalizes its proposal 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 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.

[93] 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.

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 final rule, CMS sets 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 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.

CMS 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 provisions 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 final 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 this 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 $129.28 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 final rule. For each facility that reviews the rule, the estimated cost is $1034.24 (8.0 hours x $129.28) and the total cost of reviewing this regulation is about $7.2 million ($1034.24 x 6,980 reviewers on this year's final rule).