hfma
healthcare financial management association

Physician Fee Schedule Final Rule for 2024
Summary Part I

Medicare and Medicaid Program: 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider Enrollment Policies; and Basic Health Programs [CMS-1784-F]

On November 2, 2023, the Centers for Medicare & Medicaid Services (CMS) placed on public display a final rule relating to the Medicare physician fee schedule (PFS) for CY 2024[1] and other revisions to Medicare Part B policies. The final rule is scheduled to be published in the November 16, 2023 issue of the *Federal Register*. Policies in the final rule will go into effect on January 1, 2024, unless otherwise specified.

HFMA is providing a summary in three parts. Part I covers sections I through III.S (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 implementation of the evaluation and management (E/M) office/outpatient (O/O) complexity add-on code; telehealth services; care training services, services addressing health-related social needs; dental services; and Inflation Reduction Act (IRA) provisions relating to Part B drugs and biologicals.

Table of Contents – Part I

[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 the E/M O/O complexity add-on code, coding and payment for caregiving training services, community health integration services, social determinants of health risk assessment, and principal illness navigation services; and payment for dental services. CMS also finalizes policies for expansion of preventive vaccine administrations in the home and refinements in the process to evaluate requests for addition of services to the Medicare Telehealth Service List.

The final conversion factor (CF) for 2024 is $32.7442, which reflects the expiration of the 2.5 percent increase for services furnished in 2023[2]; the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act, the 1.25 percent increase provided by the CAA, 2023; and a budget neutrality (BN) adjustment of -2.18 percent. CMS notes that about 90 percent of the BN adjustment is attributable to the implementation of the O/O E/M visit complexity add-on code with all other valuation changes making up the other 10 percent. The final 2024 PFS CF is 3.4% lower than the 2023 CF.

[2] The CAA, 2023 provided an increase to PFS payments for 2023 of 2.5 percent.

Special-specific payments impact in most years is related to changes to RVUs for specific services, including RVUs for new and revised codes. For 2024, specialty level changes can be largely attributed to the implementation of the O/O E/M visit complexity add-on code, the Year 3 update to clinical labor pricing, and the adjustment to certain behavioral health services. These specialty impacts range from an increase of 3 percent for endocrinology and family practice; increase of 2 percent for clinical psychologist, clinical social worker, general practice, hematology/oncology, nurse practitioner, physician assistant, psychiatry and rheumatology; and a decrease of 4 percent for interventional radiology; and a decrease of 3 percent for nuclear medicine, radiology, physical/occupational therapy and vascular surgery. **These payment impacts, however, do not take into account the impact of the 2.50 and the 1.25 percent payment supplements for 2023 and 2024, as these are statutory changes that take place outside of BN requirements.** For example, if CMS specifies a -2 percent reduction for a given specialty, the combined effect of RVU changes with the net CF reduction from the CAA, 2023, would be roughly -3.25 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

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 2024, CMS makes note of issues it has discussed in prior final rules.

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

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

In the final rule, CMS received comments on the list of expected specialty assignments for low volume services. In general, CMS uses an average of the 3 most recent years of available Medicare claims data to determine the specialty mix assigned to each code. Codes with fewer than 100 allowed services in the Medicare claims data, however, are assigned an expected specialty that CMS identifies based on a list developed based on medical review and input from expert interested parties. Although CMS did not make any proposals related to the list of expected specialty assignments, CMS received a list of several dozen low volume HCPCS codes with recommended expected specialty assignments.

After its review, CMS finalized 59 additions to the list of expected specialties for low volume services identified in Table 1 of the final rule.

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

In the 2023 PFS final rule, CMS finalized its proposal to rebase and revise the Medicare Economic index (MEI) to reflect more current market conditions physicians faced in furnishing services. In the past, CMS has proposed and (subsequently finalized) implementation of the MEI into its payment calculations by holding the work RVUs constant and adjusting the PE RVUs, the MP RVUs, and the conversion factor to produce the appropriate balance in RVUs among the PFS components and payment rates for individual services. The most recent adjustments of this type were made for the 2014 RVUs, when the MEI was last updated.[3] 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 2024. CMS states, however, that it will continue to review more recently available data from the Census Bureau Services Annual Survey, the main source of data for the major components of the 2017-based MEI weights. It notes that 2022 data from the Services Annual Survey will be available later this year

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

and that it will evaluate these data and other data that may become available related to physician services' input expenses and will propose any changes to the MEI, if appropriate, in future rulemaking.

Many commenters supported CMS' continued delayed implementation of the rebased and revised MEI in the PFS ratesetting. One commenter stated the methodology for deriving the 2017-based MEI cost share weights is flawed because the U.S. Census Services Annual Survey data omits facility based physicians who account for 36 percent of physicians employed in the health sector. CMS replies there is currently no data source available that would provide a comprehensive collection of physician expense data for physicians that directly contract with hospitals or other healthcare settings. In addition, CMS notes that AMA is currently collecting data on physician expenses and that it will analyze these data when made available to CMS.

3. Changes to Direct PE Inputs for Specific Services

a. Standardization of Clinical Labor Tasks

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

CMS notes, as in previous years, that it will continue to display two versions of the Labor Task Detail public use file to facilitate rulemaking for 2024: 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.

For 2024, CMS finalized its proposal to update the prices of 16 supplies and two equipment items 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, the UltraView Universal DAB Detection Kit, which CMS established a price of $12.28 (an increase from $9.70) for the SL488 supply based on averaging the invoices received.
In response to comments, CMS made additional updates for the following supplies:

- Updated the pricing for the Ellipsys Vascular Access Catheter (SD351) supply item from $6,000 to $7,378.55 used in CPT code 36836. This was based on submission of 70 invoices that showed a bimodal pricing structure—$6,000 and $8,950. It did not agree with the commenter that the use of the angiography room (EL011) should be included in the equipment item instead of the current vascular ultrasound room (EL016).

- Added the WatchPAT device to its supply database priced at $98.20 based on submission of about 100 invoices. There are currently no HCPCS codes that currently include this device as a supply item, but CMS stated that it will add it to its database so that it can be used in future reviews of services that typically make use of this product.

See Table 17 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 eleven supplies from which it received information in time for the proposed rule. It cited two reasons including that the invoices had the same price as currently in the PE database (cited for extended external ECG patch, medical magnetic tape recorder) or that it was able to find the same supply item available for sale online at the current price or cheaper. CMS cited the latter reason for invoices received for laboratory supplies as well as supplies such as a surgical mask, gauze, and paper towels. CMS also notes that it avoids updating the price for common supply items like the surgical mask (used in 380 HCPCS codes) based on the submission of a single invoice as an invoice unrepresentative of current market pricing would have far-reaching effects across the PFS.

CMS also did not make changes to the following items in response to comments in the proposed rule:

- CMS received additional information and RUC workgroup recommendations regarding pricing discrepancies between the aggregated cost of some supply packs and the individual item components contained within. The sum of supply packs did not match the totals from the individual items. In response, CMS states that this issue would be better addressed in future rulemaking as this would have a substantial impact on the overall valuation of services, which were not incorporated into the proposed RVUs published as part of the 2024 proposed rule.

- CMS also received comments that identified several generic alternatives to the use of the skin adhesive (Dermabond) (SG007) supply noting that there are multiple skin adhesive products at different price points. CMS believes that this issue would be better addressed in future rulemaking noting that revisions to the skin adhesive supplies were incorporated into the recommendations from the April 2023 RUC meeting, and believes that these could also be addressed as part of the RUC review of these skin adhesive procedures for the upcoming 2025 cycle.

- CMS also notes that it continues to receive requests to implement separately billable alpha-numeric Leve II HCPCS codes to allow practitioners to be paid the cost of high cost disposable supplies per patient encounter instead of per CPT code. It states that this

option presents a series of potential problems that it has addressed previously and directs readers to the 2011 PFS final rule with comment period (75 FR 73251).

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 2024). CMS notes it will, of course, consider invoices submitted during the comment period following the publication of the proposed rule or during other times as part of its annual process.[4]

c. Clinical Labor Pricing Update

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

Similar to its approach in 2002, CMS primarily used Bureau of Labor Statistics (BLS) wage data to update its clinical labor pricing in 2022. It believed that BLS data is the most accurate source to use as a basis for clinical labor pricing and used the most recent BLS survey data available for its calculations of wage data (2019). For certain labor categories where BLS data were not available, CMS had to crosswalk or extrapolate the wages using supplementary data sources for verification. It used the median BLS wage data rather than the average or mean wage data for calculation of clinical labor rates. Based on comments received, CMS used the fringe benefits multiplier of 1.296 for employees in private industry based on a BLS release from June 17, 2021 (USDL-21-1094).

It also agreed with commenters that a multi-year transition would help smooth out the changes in payment resulting from the clinical labor pricing update and avoid potentially disruptive changes in payment and promote payment stability. CMS finalized the implementation of the clinical labor update over 4 years to transition from current prices to the final updated prices in 2025. CMS provides an example of how this transition would be implemented in Table 4 of the final rule (reproduced below). For 2024, the clinical labor pricing would be in Year 3 of the transition.

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

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

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, 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 2024 PFS proposed rule. In response to the proposed rule, CMS received the following comment related to the pricing of the cytotechnologist clinical labor type:

- Commenters recommended that CMS crosswalk the cytotechnologist clinical labor type to the BLS 29-9092 category (genetic counselors) at a rate of $0.85 to correct this pricing anomaly. They supported this request with data from the 2021 American Society of Clinical Pathologists Wage Survey of Medical Laboratories, in which the average cost of per minute for cytotechnologists was $0.86. CMS agreed with the updated crosswalk and updated the clinical labor pricing of the L045A clinical labor type from $0.76 to $0.85 based on this new information.

Thus, CMS finalizes the clinical labor prices as detailed in the proposed rule, aside from the Cytotechnologist (L045A) clinical labor type, These are detailed in Table 7 in the final rule (an extract is reproduced below).

Excerpt of Selected Labor Categories from Table 7: 2024 Clinical Labor Pricing						
Labor Code	**Labor Description**	**Source**	**2021 Rate Per Minute**	**Final Rate Per Minute**	**Y3 Phase-In Rate Per Minute**	**Total % Change**
L023A	Physical Therapy Aide	BLS 31-2022	0.23	0.28	0.268	22%
L026A	Medical/Technical Assistant	BLS 31-9092	0.26	0.36	0.335	38%
L032B	EEG Technician	BLS 29-2098	0.32	0.44	0.410	38%
L035A	Lab Tech/Histotechnologist	L0333A, L037B	0.35	0.60	0.534	70%
L037B	Histotechnologist	BLS 29-2010	0.37	0.64	0.573	73%
L037D	RN/LPN/MTA	L051A, BLS 29-2061, L026A	0.37	0.54	0.498	46%
L038B	Cardiovascular Technician	BLS 29-2031	0.38	0.60	0.545	58%
L042A	RN/LPN	L051A, BLS 29-2061	0.42	0.63	0.578	50%
L042B	Respiratory Therapist	BLS 29-1126	0.42	0.64	0.585	52%
L043A	Mammography Technologist	ASRT Wage Data	0.43	0.79	0.702	84%
L045A	Cytotechnologist	BLS 29-9092	0.45	0.85	0.750	89%
L046A	CT Technologist	ASRT Wage Data	0.46	0.78	0.703	70%
L047A	MRI Technologist	BLS 29-2035	0.47	0.76	0.688	62%
L050C	Radiation Therapist	BLS 29-1124	0.50	0.89	0.793	78%
L051A	RN	BLS 29-1141	0.51	0.76	0.698	49%
L051B	RN/Diagnostic Medical Sonographer	L051A, BLS 29-2032	0.51	0.77	0.705	51%

Technical Corrections to Direct PE Input Database and Supporting Files

CMS was notified of a technical error in its physician work time public use file for CPT code 86153 and finalizes it proposal to add the correct 20 minutes of intraservice work time for this code for 2024.

It received the following comments in response to the proposed rule:

- In response to comments, CMS made indicator changes for the assistant surgeon, co-surgeon, and team surgeon indicators for transcatheter valve procedures (CPT codes 33418 and 33419).
- Several commenters raised the topic of indirect PE allocation for the home PT/INR monitoring services described by HCPCS codes G0248 and G0249. They noted that CMS did not propose any changes to the crosswalk and request that the crosswalk remain as finalized for 2024. CMS notes the support and reiterates it did not propose any changes.
- CMS confirms that there were no technical errors for CPT code 97610 and that the lower valuation for this code is being affected by the ongoing clinical labor pricing transition.
- Commenter also questioned the pricing for supplies used for external counterpulsation therapy (HCPCS code G0166), but did not provide any proposals or provide any supply invoices or other data to support a change in pricing.

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

In 2023, CMS issued an RFI to solicit public comment on strategies to update PE data collection and methodology. CMS noted that it has explored issues related to indirect PE in previous rulemaking and has most recently contracted with the RAND corporation to examine this issue.[5] In general, stakeholders have raised the following concerns about CMS' current approach to indirect PE allocation:

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

- 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. Many commenters last year asked that CMS wait for the AMA to complete a refresh of AMA survey data. CMS is concerned that waiting for refreshed survey data would result in CMS using data nearly 20 years old to form indirect PE inputs to set rates for services on the PFS. In addition, CMS notes that some of the critical issues it has identified would not be addressed by an updated survey alone and may also require revisions to the PFS rates setting methodology.

b. Request for Information

CMS stated in the proposed rule that considering its ratesetting methodology and prior experiences implementing new data, it was issuing a follow-up solicitation for general information. CMS sought comments from interested parties on strategies to incorporate information that could address known challenges it experienced in implementing the initial AMA PPIS data. Its current methodology relies on the AMA PPIS data, legislatively mandated supplemental data sources (as required for oncology and hematology specialties), and in some cases crosswalks to allocate indirect PE as necessary for certain specialties and provider types.

It also sought to understand whether, upon completion of the updated PPIS data collection effort by the AMA, contingencies or alternatives that may be necessary and available to address lack of data availability or response rates for a given specialty, set of specialties, or specific service suppliers who are paid under the PFS.

In light of the considerations discussed above, CMS requested feedback on the following:

(1) If CMS should consider aggregating data for certain physician specialties to generate indirect allocators so that PE/HR calculations based on PPIS data would be less likely to over allocate (or under-allocate) indirect PE to a given set of services, specialties, or practice types. Further, what thresholds or methodological approaches could be employed to establish such aggregations?

(2) Whether aggregations of services, for purposes of assigning PE inputs, represent a fair, stable and accurate means to account for indirect PEs across various specialties or practice types?

(3) If and how CMS should balance factors that influence indirect PE inputs when these factors are likely driven by a difference in geographic location or setting of care, specific to individual practitioners (or practitioner types) versus other specialty/practice-specific characteristics (for example, practice size, patient population served)?

(4) What possible unintended consequences may result if CMS were to act upon the respondents' recommendations for any of highlighted considerations above?

(5) Whether specific types of outliers or non-response bias may require different analytical approaches and methodological adjustments to integrate refreshed data?

Most commenters stated that CMS should defer significant changes until the AMA PPIS results become available. It notes that the AMA RUC provided a set of responses, which many other commenters repeated in their separate responses. Their letters responded to all five prompts in the RFI with rationales that supported the assertion that CMS should not consider further changes until PPIS data collection and analysis is complete. CMS also notes that AMA's contractor, Mathematica, secured an endorsement for the PPIS updates prior to fielding the survey. CMS states that while this approach may possibly mitigate nonresponse bias, it may inject other types of bias in the validity and reliability of the information collected.

Other commenters did not recommend that CMS defer significant changes until the AMA PPIS results become available. In response, CMS notes that it remains important to reflect on the challenges with its current methodology and that it continues to seek alternatives that use verifiable, more objective data sets in the future to supplement or augment survey data used to establish PE RVUs for the PFS services.

CMS also received comments that it have a separate RFI that address topics regarding machine learning, AI, and software and explore a means outside of its annual rulemaking cycle. It also highlighted the AMA's efforts to develop Appendix S of the CPT Manual, which establishes a taxonomy for medical AI. In response, CMS notes that it is committed to fostering dialogue on a variety of issues, including how to incorporate new and evolving technologies most appropriately in both collection of PE data and the PE methodology itself.

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 2024, CMS received 10 nominations for potentially misvalued services.

(1). CPT code 59200 (Insertion cervical dilator)
CPT code 59200 was nominated as misvalued because the direct PE inputs do not include the supply item, Dilapan-S.[6] The stakeholder recommended adding 4 rods of Dilapan-S at $80.00 per unit, as a replacement item for the current PE supply item, laminaria tent (listed as 3 units at $4.0683 per unit). The current payment for CPT code is about $108.10 in the nonfacility setting, which is much less than the typical cost of the Dilapan-S supplies requested.

CMS did not propose to consider this code as potentially misvalued. CMS did not agree that the use of the Dilapan-S supply was typical for this service. CMS agreed with the nominator that this service is much more frequently reported in the Medicaid population and suggested that interested parties submit a request for new and separate Medicaid payments to Medicaid.

Several commenters suggested that CPT code 59200 should be reviewed. Commenters stated that the code is for a specific procedure for cervical dilation and other methods of cervical dilation are not described by this code. Commenters also pointed out that the current market price of the lamina tent has increased since the supply price was established in 2003 and it has been replaced by Dilapan-S.

After reviewing the comments, CMS is concerned that the code might not represent how the medical procedure is currently performed. CMS notes the code has not been reviewed in 20 years and would benefit from a review of physician work and PE inputs. CMS finalizes CPT code 59200 as potentially misvalued for 2024.

[6] This code was previously nominated as a misvalued code for the same reason, the direct PE inputs do not include the supply item, Dilapan-S.

(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 nominated as misvalued because it lacks separate direct PE inputs in the nonfacility setting. This service is only priced in the PFS in the facility setting at approximately $826.85 for the physician's professional services. The nominator claimed the service can be safely and effectively furnished in the nonfacility setting; it has a low profile risk similar to kyphoplasty furnished in the nonfacility setting. The nominator submitted a simple invoice to illustrate the high direct PE cost for CPT 27279 in the nonfacility setting.

CMS was 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 and sought comments on this nomination as a misvalued code.

Commenters had opposing opinions; some commenters believed the procedure had minimal risk and supported establishing a nonfacility payment for the procedure and others cited patient safety concerns and opposed establishing a nonfacility payment. CMS acknowledges the multiple perspectives for this service and because there isn't a consensus on whether these services can be safely and effectively be furnished in the nonfacility setting, it does not finalize CPT code as potentially misvalued for 2024.

CMS notes there is an increasing number of potentially misvalued code nominations requesting nonfacility rates for services. CMS acknowledges that the practice of medicine continues to evolve in ways that may support the transition of complex procedures into ambulatory settings. CMS will consider its policies for such services and also believes that these services would benefit from review by other interested parties, such as the AMA RUC and private payors.

(3). CPT codes 99221-99223 (Hospital Inpatient and Observation, Initial hospital care)
In the 2023 PFS final rule, CMS established new physician work times and new work RVUs for these codes. The nominator disagreed with these values because facility-based codes are always more intense than E/M services provided in other settings and the patients are always more seriously ill. The nominator recommended new work RVUs for these codes (Table 8). CMS proposed to maintain the values that were finalized for 2023 and not to nominate these codes as potentially misvalued.

Many commenters agreed with the nominator and suggested the work RVUs for these codes be restored to their pre-2023 values. CMS does not believe these codes are potentially misvalued and that the AMA RUC recommendations are still appropriate. For 2024, CMS does not finalize CPT codes 99221-99223 as potentially misvalued.

(4). CPT codes 36514 and 36516 (Therapeutic apheresis codes), CPT code 36522 (Photopheresis)
These codes were nominated as potential misvalued because of direct PE inputs. Specifically, for all three codes, the nominator stated that the direct PE of clinical labor L042A, "RN/LPN (labor rate of $0.525 per minute) was incorrect and should be changed to a more specific entry of "a therapeutic apheresis nurse specialist (RN)" (labor rate of about $1.06 to $1.14 per minute). The nominator also stated that supplies for CPT code 36514 were inaccurate. Specifically, the price

for PE supply SC085, “Tubing set, plasma exchange” should be $287.77 per item instead of $186.12 per item and supply item SC084, “Tubing set, blood warmer” should be $14.71 per item instead of $8.01 per item. Sample invoices, not actual invoices were submitted. CMS sought comments on whether or not these codes are potentially misvalued.

Several commenters supported the need to revalue these codes because they believed the current RN/LPN labor code is outdated and the codes need to reflect the new Therapeutic Apheresis Nurse Specialist labor category. Several commenters opposed the nomination of this codes as potentially misvalued and recommended reviewing these codes after the AMA PPIS survey is completed.

CMS is concerned that there may be a possible disparity with the clinical labor type for this service. Therefore, for 2024, CMS finalizes CPT codes 36514, 36516, and 36522 as potentially misvalued.

(5). CPT codes 44205 (Laparoscopy, surgical; colectomy, partial, with removal of terminal ileum with ileocolostomy) and 44204 (Laparoscopy, surgical; colectomy, partial, with anastomosis)
The nominator requested that payment for CPT code 44205 should be equivalent to CPT code 44054. Both codes are 90-day global codes and valued only in the facility setting. For 2023, CPT code 44204 has a total of 45.62 RVUs and CPT code 44205 has a total of 39.62. The direct PE entries for both codes are similar for supplies, equipment, and clinical labor but the number of usage minutes for clinical labor and equipment is higher for CPT code 44204.

CMS believed these two codes appear similar but have differences in their purpose, physician work times, and direct PEs. CMS did not think CPT code 44205 is misvalued and sought feedback on this nomination.
CMS did not receive any comments on this provision and does not finalize this codes as potentially misvalued.

(6). CPT codes 93655 (Intracardiac catheter ablation of an arrhythmia) and CPT code 93657 (Additional linear or focal intracardiac catheter ablation of the left or right atrium)
CMS notes these two add-on codes were part of its review of the cardiac ablation code family in 2022 and 2023 PFS final rules. The nominator believes that the appropriate work RVUs for both of these codes is 7.0 (AMA recommendation) and not the finalized value of 5.50. CMS proposed to maintain the values that were finalized for 2023 and not to nominate these codes as potentially misvalued.

A few commenters urged CMS to accept the AMA recommendation for these codes. CMS continues to believe that the current code valuations are correct and does not finalize these codes as potentially misvalued for 2024.

(7). CPT code 94762 (Noninvasive ear or pulse oximetry for oxygen saturation) and CPT code 95800 (Sleep study, unattended)
These codes were nominated as potentially misvalued due to outdated PE supply items. Table 9, in the final rule, list the nominator's recommendations for practice expense items for these codes. CMS sought comments as to whether or not these codes are potentially misvalued.

One commenter disagreed with the replacement of various PE items with alternative items. CMS concludes it cannot properly assess if these codes are potentially misvalued and suggests the original nominator and other parties resubmit their nomination with information providing additional clarity for future consideration. For 2024, CMS does not finalize these codes as potentially misvalued.

(8) CPT codes 0596T and 0597T (Insertion of temporary valve-pump in female urethra)
These temporary CPT category III codes are all contractor priced. The nominator stated the payment amounts determined by the Medicare Administrative Contractors (MACs) are inappropriately low and requests they become nationally priced. The nominator provided information about work time and nonfacility PE. CMS sought comments as to whether these temporary category III codes are potentially misvalued and whether or not they should remain contractor priced.

Several commenters supported nominating these codes as potentially misvalued. CMS notes that these are category III codes that describe new and low-volume services. Category III codes are generally contractor-priced under the PFS. CMS does not finalize these codes as potentially misvalued and they will remain contractor-priced codes. CMS encourages interested parties to engage with the MACs and provide accurate and appropriate cost data to inform the MACs payment for these services.

(9) CPT code 93000 (Electrocardiogram, routine ECG with at least 12 leads)
The nominator stated that the payment for CPT code 93000 should be increased to $36.64 to adequately compensate for PE item costs for EKG leads ($6.10), 5 minutes of a nurse visit ($21.19 crosswalked from CPT code 99211), and interpretation and report of EKG ($7.64 crosswalked from CPT code 93010). No invoices were provided. CMS did not support this methodology for determining Medicare payment and did not propose to nominate this code as potentially misvalued.

CMS did not receive any comments on this nomination. For 2024, CMS does not finalize CPT code 93000 as potentially misvalued.

(10) Nineteen therapy codes
The nominator stated that 19 therapy codes are potentially misvalued because the direct PE clinical labor minutes recommended from the RUC and the HCPAC might have had inappropriate multiple procedure payment reductions (MPPR) applied to their PE clinical labor time entries. CMS reviewed this information and is reconsidering the values established in the 2018 PFS final rule. CMS does not believe that MPPR should be applied to the clinical labor time entries and would like these recommendations to be re-reviewed. CMS proposed these 19 codes, listed below in Table 10, as potentially misvalued codes.

Numerous commenters supported CMS' proposal. For 2024, CMS finalizes these 19 therapy codes as potentially misvalued.

Table 10: 19 "Always Therapy" Service Codes Nominated for Potential Misvaluation	
HCPCS	**Long Descriptor**
97012	Application of mechanical traction
97014	Application of electrical stimulation
97016	Application of blood vessel compression device
97018	Application of hot wax bath
97022	Application of whirlpool therapy
97032	Application of electrical stimulation with therapist present, each 15 minutes
97033	Application of medication using electrical current, each 15 minutes
97034	Application of hot and cold baths, each 15 minutes
97035	Application of ultrasound, each 15 minutes
97110	Therapy procedure using exercise to develop strength, endurance, range of motion, and flexibility, each 15 minutes
97112	Therapy procedure to re-educate brain-to-nerve-to-muscle function, each 15 minutes
97113	Therapy procedure using water pool to exercises, each 15 minutes
97116	Therapy procedure for walking training, each 15 minutes
97140	Therapy procedure using manual technique, each 15 minutes
97530	Therapy procedure using functional activities
97533	Therapy procedure using sensory experiences
97535	Training for self-care or home management, each 15 minutes
97537	Training for community or work reintegration, each 15 minutes
97542	Evaluation for wheelchair, each 15 minutes
G0283	Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care

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

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

a. Changes to the Medicare Telehealth Services List

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

- Category 1 services are similar to services that are currently on the telehealth list. CMS also considers similarities in the telecommunications systems used to deliver the service.
- Category 2 services are not similar to services on the telehealth list. CMS requires evidence demonstrating the service furnished by telehealth improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part.[7]

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

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

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

CMS considers the following criteria when assessing whether there was a potential likelihood of a clinical benefit for a service and if the service should be added to the telehealth list on a Category 3 basis:

- Whether, outside of the PHE, there are increased concerns for patient safety if the service is furnished as a telehealth service.
- Whether outside the PHE, there are concerns about whether the provision of the service via telehealth is likely to jeopardize the quality of care.
- Whether all elements of the service could fully and effectively be performed by a remotely located clinician using two-way, audio/video telecommunications technology.

The 2024 Medicare telehealth services list, including the additions described later in this section, is included as Table 11 (the second Table 11) in the final rule and is also available on the CMS website at https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html. As discussed below, CMS also finalizes its proposal to simplify categorization of each service as either provisional or permanent. The telehealth services list categorizes services as either provisional or permanent and also whether the service is an audio-only service.

For 2025, requests must be received by February 10, 2024. CMS notes that information submitted as part of a request is subject to public disclosure, including discussion in the PFS proposed rule. Along with the telehealth list, information on submitting a request is available on the CMS website.

b. Requests to Add Services to the Medicare Telehealth Services List for 2024

CMS notes that the provisions of the Consolidated Appropriations Act, 2023 (CAA, 2023),[8] extends the telehealth policies enacted in the CAA, 2022[9] through December 31, 2024 if the PHE ends prior to that date.

CMS received several requests to permanently add services to the Medicare telehealth services list for 2024 (the first Table 11, reproduced with modifications below). CMS did not propose the permanent addition of any of these requests as Category 1 or Category 2 services; it did propose adding some of these services to the telehealth service list as Category 3 services.

[8] Section 4113 of Division FF, Title IV, Subtitle A of the CAA, 2023 (Pub.L. 117-328), December 29, 2022
[9] Pub.L. 117-103, March 15, 2022

Requests for Permanent Addition to the Medicare Telehealth List for 2024	
Code Family	**CPT codes**
Cardiovascular Procedures	93793
Cardiovascular and Pulmonary Rehabilitation	93797, 94625
Deep Brain Stimulation	95970, 95983, 95984
Therapy Services	90901, 97110, 97112, 97116, 97161-97164, 97530, 97550, 97663
Hospital Care and Emergency Department	99221-99236, 99238, 99239, 99281-99283
Health and Well-Being Coaching	0591T-0593T

Cardiovascular Procedures (CPT code 93793)
CPT code 93793 is for anticoagulant management for a patient taking warfarin. CMS did not consider the service as an inherently face-to face service that requires a patient to be present in order for the service to be furnished in its entirety.

In response to comments supporting this request, CMS reiterates that CPT code 93793 does not describe an inherently face-to-face service and is not a telehealth service. CMS finalizes its proposal not to add this service to the telehealth service list.

Cardiovascular and Pulmonary Rehabilitation (CPT codes 93797, 94625)
In 2022, CMS added these services to the telehealth list on a temporary, Category 3 basis. CMS noted that some of the evidence submitted supported this service as an eligible Medicare telehealth service. Ongoing discussions with interested parties have focused on the clinical benefits of patients receiving these services in the home.

Because these codes are will not have a statutory basis for coverage via telehealth in the beneficiary's home beginning January 1, 2025,[10] CMS proposed not to include these services permanently on the telehealth list on a Category 1 basis. CMS proposed to continue to include these services on the telehealth list through CY 2024. CMS finalizes these proposals.

Deep Brain Stimulation (CPT codes 95970, 95983, 95984)
CMS received requests to add these codes describing electronic analysis of implanted neurostimulators permanently to the Medicare telehealth list; these codes are currently on the telehealth list on a temporary, Category 3 basis. CMS believed there is not yet sufficient evidence to consider these services for permanent addition under the Category 2 criterion. CMS proposed not to include these services permanently on the telehealth list on a Category 1 basis. CMS proposed to continue to include these services on the telehealth list through CY 2024.

In response to comments, CMS clarifies that it believes these services may be safely furnished using only two-way interactive communications. However, the evidence has not demonstrated that the service, when furnished using only virtual interaction, would avoid a subsequent in-

[10] Under current law, beginning January 1, 2025, the beneficiary's home can be an originating site for Medicare diagnostic services for (1) diagnosis, evaluation, or treatment of a mental health disorder; or (2) a beneficiary with a diagnosed substance use disorder (SUD) for treatment of the SID or a co-occurring mental health disorder; or (3) monthly ESRD-related clinical assessments furnished to a beneficiary receiving home dialysis, beginning January 1, 2025.

person services. CMS is concerned that when the service is performed virtually, the beneficiary is not receiving the complete service. CMS finalizes its proposal; these codes remain as a Category 3 on the telehealth list.

Therapy Services (CPT codes 90901, 97110, 97112, 97116, 97161-97164, 97530, 97550, 97663)
CMS received a request to add the following codes on a Category 1 or 2 basis: Therapy Procedures (97110, 97112, 97116); Physical Therapy Evaluations (97161-97164); Therapy Personal Care (97530); Therapy Tests and Measurements (97750, 97763); and Biofeedback (90901). CMS reiterated it prior comments that these services do not meet the Category 1 criteria because they involve direct observation and/or physical contact between the practitioner and the patient and may be therapeutic in nature. These services also do not meet Category 2 criteria, because there isn't sufficient evidence to determine whether the service could be furnished remotely. CMS stressed that available evidence needs to address all elements of the service and not focus on any individual service within one specific clinical scenario.

CMS finalizes its proposal not to add these services to the telehealth list on a Category 1 or Category 2 basis. In response to comments, CMS notes it does not have the authority to expand the list of eligible Medicare telehealth practitioners to include therapists after 2024.

Hospital Care and Emergency Department Care (CPT codes 99221-99236, 99238, 99239, 99281-99283)
CMS continues to believe that telehealth Category 3 status is appropriate for these codes and proposed to continue these services on the telehealth service list though 2024.

In response to comments, CMS notes that the initial impetus for adding these codes to the telehealth service list was the unique circumstances of the COVID -19 PHE. Post the PHE, CMS expects further evidence to address the appropriateness of furnishing these services. CMS finalizes its proposal and will keep these services on the telehealth services list temporarily through 2024.

Health and Well-being Coaching (CPT codes 0591T-0593T)
CMS received a request to permanently add these Health and Well-being coaching services to the Medicare Telehealth Service List. CMS proposed to add these codes the telehealth list on a temporary basis for 2024. CMS believed the evidence submitted is evolving and suggested that these services could possibly meet the Category 2 criteria as additional evidence is obtained. CMS noted that the evidence needs to establish clinical benefit when delivered directly by or under the supervision of professionals who are Medicare telehealth practitioners.

Many commenters supported this request and provided additional information about the National Board of Health and Wellness Coaches and additional evidence of the clinical effectiveness of providing these services via telehealth. CMS reiterates that its evaluation of whether a service can be considered a Medicare telehealth service includes evidence that when the service is performed using only two-way interactive communications technology it is a substitute for face-to-face interactions between the telehealth practitioner and the patient. This review includes

ensuring that beneficiaries can receive all the elements and benefits of a service when that service is furnished via telehealth instead of in-person.

CMS notes the initial evidence and analysis appears anecdotal. It expects to see peer-reviewed literature, where the study population is typical of the Medicare population, and the methods focus on evaluating utilization and outcomes. CMS finalizes its proposal to add these services to the telehealth list on a temporary basis.

Addition of New Codes to the List (HCPCS code G0136)
CMS finalizes its proposal to permanently add HCPCS code G0136 (Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment (SDOH) tool, 5-15 minutes) to the telehealth list.

In response to requests to add Principal Illness Navigation (PIN) and Community Health Integration (CHI) services to the telehealth list, CMS states these services would not be considered potential Medicare telehealth services under section 1834(m) of the Act because they may not typically require a face-to-face interaction.

c. Clarifications and Revisions to the Process for Considering Changes to the Medicare Telehealth Services List

In the proposed rule, CMS reviewed its process for adding services to the Medicare Telehealth List, including the process used to add services on a temporary basis during the public health emergency (PHE). CMS believed that with the end of the PHE, clarifications and modifications to the process for reviewing requests for additions to the Medicare Telehealth List are needed. To reduce confusions about the telehealth list categories CMS proposed to replace the Category 1-3 status with permanent or provisional status for any service assigned to the telehealth list. As discussed below, CMS finalizes this proposal for 2024.

CMS emphasized the need for clinical evidence to support how the telehealth service is either clinically equivalent to a telehealth service already permanently on the list, or evidence from studies suggesting a clinical benefit sufficient for the services to remain on the list to allow time for confirmative studies. CMS noted that clinical evidence is sometimes missing from submissions. CMS believes that restatement of requirements with some proposed procedural requirements would facilitate submission of requests.

CMS finalizes its five step proposal for analysis for services under consideration for addition, or removal, or a change in status to the Medicare Telehealth Services List is summarized below. CMS notes that these changes will not change the timeline for requests related to the Medicare Telehealth List; requests for 2025 will still be due by February 10, 2024.

Step 1. *Determine whether the service is separately payable under the PFS*
Since Medicare telehealth services are limited to services separately payable under the PFS, CMS believes step 1 is necessary to answer this threshold question. CMS acknowledges that certain codes with non-payable or bundled (not separately payable) status under the PFS were temporarily included during the PHE to facilitate access to health care services. CMS believes

this step would lessen the administrative burden of the telehealth review process for both CMS and the public.

CMS finalizes if a submitted service is not separately payable under the PFS, it will not conduct any further review of the service. CMS will inform each submitter in the confirmation email it sends to each requestor whether the submission was complete, lacking required information, or outside the scope of issues for consideration to the telehealth service list.

Step 2. *Determine whether the service is subject to the provisions of section 1834 (m) of the Act*
Step 2 determines whether the service is, in whole or in part, inherently a face-to-face service. A service is subject to the provisions of section 1834(m) of the Act when at least some elements of the service, when delivered via telehealth, are a substitute for an in-person, face-to-face encounter, and all of the face-to-face elements of the service are furnished using an interactive telecommunications system as defined in §410.78(a)(3). CMS states that the scope of section 1834(m) of the Act is limited to services that would ordinarily be furnished with the furnishing practitioner and the patient in the same location.

CMS believes that step 2 is consistent with its longstanding policy that there is a range of services delivered using telecommunications technology and separately payable under the PFS that do not fall within the scope of Medicare telehealth services. These services generally include services that do not require the presence of, or involve interaction with the patient. CMS provides a list of examples including remote interpretation of diagnostic imaging tests, e-visits, and remote patient monitoring services that do not serve as a substitute for an in-person encounter.

CMS finalizes that if a submitted service does not meet the provisions of section 1834(m) of the Act, it will not conduct any further review of the service. CMS will inform each submitter in the confirmation email it sends to each requestor whether the submission was complete, lacking required information, or outside the scope of issues for consideration to the telehealth service list.

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)*
Step 3 determines 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.

For this step, CMS will review information submitted from providers demonstrating evidence of substantial clinical improvement in beneficiary populations that may benefit from the requested service when furnished via telehealth, including rural populations. CMS states that services are not equivalent when the clinical actions, or patient interaction, are not similar as an in-person visit. CMS notes that many submissions lack evidence indicating that some or all elements could be completed during a telehealth encounter without still requiring an in-person interaction with a patient to finish the complete service.

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*
Step 4 determines whether the service elements of a code that is being considered for addition to or removal from the Medicare Telehealth Services List maps to the service elements of a service that has permanent status of the telehealth list. CMS finalizes 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.

Section 1834(m)(4)(F)(i) of the Act defines telehealth services as professional consultations, office visits, and office psychiatry services (as identified as of July 1, 2000, by HCPCS codes 99241-99275, 99201-99215, 90804-90809, and 90862 and as subsequently modified by the Secretary) and any additional services specified by the Secretary. CMS has assigned Category 1 status to services that were included in the codes specified in the statute or added as successor codes. CMS finalizes that even if a code under review is not a successor code, it will consider whether the service is similar to professional consultations, office visits, and office psychiatry services already on the telehealth list on a permanent basis. CMS also finalizes that the step 4 analysis will be used to compare the candidate code to any permanent code that is on the list on a permanent basis, regardless of the previous Category status of the code.

CMS finalizes that any service satisfying Step 4, will be proposed for permanent addition to the telehealth list in the next PFS proposed rule. If Step 4 is not met, CMS will continue to Step 5.

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 notes this step is similar to the existing standards that applied when considering whether to add a code on a Category 2 basis. CMS reiterates this evidentiary standard of clinical benefit does not include minor or incidental benefits (81 FR 80194).

CMS finalizes that if there is enough evidence to suggest that further study may demonstrate that the service provided via telehealth is a clinical benefit, it 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.

Assignment of "Permanent" or "Provisional" Status to a Service and Changes in Status
CMS finalizes its proposal to replace the Category 1-3 taxonomy with "permanent" or "provisional" status. CMS will assign "permanent" status to any service when the service elements map to the service elements to a service on the telehealth list that has a permanent status. CMS will assign "provisional" status to a service that doesn't map to a service with permanent status but there is some evidence of clinical benefit analogous to the clinical benefit

of the in-person service when the service is provided via telehealth by an eligible Medicare telehealth physician or practitioner.

For a code with provisional status, CMS may assign permanent status in a future year or it may remove the service from the telehealth list because of patient safety concerns. CMS will address provisional status changes through regular annual telehealth submissions that provide new evidence or claims monitoring showing anomalous activity, or by patient safety considerations. CMS will review change in status by using all the proposed 5 steps.

Comments/Responses. Overall, commenters agreed with CMS' proposals. CMS notes it did not receive any proposals to delay or forgo the proposed changes. Some commenters requested more clarity about the timing of updates. Several commenters expressed concern that a static list may not keep pace with innovations.

In response, CMS notes that its flexibility to make subregulatory changes to the Telehealth Services List expired at the end of the PHE and changes to the list now require notice and comment rulemaking. CMS believes the revised process focuses on the need for evidence generation. CMS notes that whether a service has an appropriate valuation of whether a clinical action is appropriately described in the service are not open questions and should not be addressed in a submission. The question is whether audio-video communication can fully substitute for in-person interactions and still provide clinical benefit.

CMS disagrees with commenters that only Steps 1-3 are necessary. CMS states that Steps 1-3 only consider whether 1834(m) may apply, whereas Steps 4 and 5 help CMS decide whether there is a clinical benefit for a service when face-to-face interactions are substituted with two-way audio-video communications technology. CMS does not believe that Steps 4 and 5 threaten innovation and that the analysis differs from any substantial clinical improvement analysis.

d. Consolidation of the Categories for Services Currently on the Medicare Telehealth Services List

For 2024, CMS finalizes its proposal to redesignate any services on the Medicare Telehealth Services List on a Category 1 or 2 basis and will be on the list for 2024, to the permanent category. Any service currently added on a "temporary Category 2" or Category 3 basis will be assigned to the provisional category. CMS finalizes not to set any specific timing for reevaluation of services added to the telehealth list on a provisional basis. CMS notes it will not assign a provisional status when it believes it is improbable that a code would ever achieve permanent status.

Table 11 (the second Table 11) lists codes finalized for the Medical Telehealth Services list and includes the simplified categorization of each service as either provisional or permanent. The audio-only column designates those services that may be furnished using audio-only technology. This list is also available on the CMS website at https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.

Comments/Responses. Overall commenters expressed support for CMS' proposal. Some commenters requested a specific timeframe for provisional codes. Commenters also asserted that CMS should broaden its narrow interpretation of the requirements of section 1834(m) of the Act.

In response, CMS reiterates its has no plans to remove any provisional service from the telehealth list where evidence generation remains in-process and the individual code is subject to section 1834(m) of the Act. CMS will remove a provisional service if evidence demonstrates patient safety issues. CMS disagrees with commenters suggesting its interpretation of section 1834(m) is excessively narrow.

e. Implementation of Provisions of the CAA, 2023

In the proposed rule, CMS discussed the provisions of the CAA 2022[11] that extend certain Medicare telehealth flexibilities adopted during the PHE for 151 days after the end of the PHE. In the 2023 PFS final rule, CMS finalized implementation of the telehealth provisions in the CAA, 2022 through program instructions or other subregulatory guidance. These provisions extended the following policies for 151 days after the PHE ends:

- Allow telehealth services to be furnished in any geographic area and in any originating site setting, including the beneficiary's home;
- Allow certain services to be furnished via audio-only telecommunications systems;[12]
- Allow physical therapists, occupational therapists, speech-language pathologists and audiologists to furnish telehealth services;
- Allow continued payment for telehealth services furnished by FQHCs and RHCs using the methodology established during the PHE

The CAA, 2022 also delayed the in-person visit requirements for mental health services furnished via telehealth until 152 days after the end of the PHE.

Section 4113 of the CAA, 2023 further extended the previously-extended PHE-related telehealth policies and required CMS to extend telehealth flexibility that were extended under the CAA, 2022, through December 31, 2024. Similar to the CAA 2022, the CAA 2023 allows implementation of the relevant telehealth provisions through program instructions or other subregulatory guidance. As discussed below, CMS clarifies certain telehealth flexibilities that have been extended through December 31, 2024.

In-person Requirements for Mental Health Telehealth. CMS clarifies that the in-person requirements for telehealth services for purposes of diagnosis, evaluation, or treatment of a mental health disorder will be effective on January 1, 2025. CMS finalizes its proposal to revise the regulatory text at §410.78(b)(3)(xiv) and (b)(4)(iv)(D) to recognize the delay of the in-person requirements for mental health visits furnished by RHCs and FQHCs through telecommunication technology under Medicare until January 1, 2025.

[11] The CAA 2022 (Pub. L. 117-103) was enacted March 15, 2022.
[12] These services include certain behavioral health, counseling, and educational services that are listed on the Medicare Telehealth Services List available at https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.

In response to comments, CMS reiterates it is simply revising the regulations to conform to the requirements in the CAA 2023. CMS reminds providers that the in-person requirements for behavioral health services (§410.78(b)(3)(xvi) begins in 2025. The regulations describe two exceptions to the in-person requirements: (1) beneficiaries who already receive telehealth behavioral health services and have circumstances where in-person care may not be appropriate and (2) groups with limited availability for in-person behavioral health visits would have available the flexibility to arrange for practitioners to furnish in-person and telehealth visits with different practitioners.

Originating Site Requirements. CMS will not issue any program instructions or proposals to limit or modify telehealth originating sites in 2023 or 2024.

In response to comments, CMS states that its definition of home, both in general and for the originating site requirements, continues to include temporary lodging such as hotels and homeless shelters. As stated in the 2022 PFS final rule (86 FR 65059), for circumstances where the patient, for privacy or other personal reasons, chooses to travel a short distance from the exact home location during a telehealth service, the service is still considered to be furnished "in the home".

CMS received many comments expressing concerns about the expiring flexibility for telehealth practitioners to use 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. Commenters requested that CMS take steps to protect telehealth practitioners by adjusting enrollment requirements so that individual practitioners do not have to list their home addresses on enrollment forms. CMS appreciates these concerns and through 2024 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. CMS will consider this issue for future rulemaking and requests clear examples of how the enrollment process shows material privacy risks to inform future policy development.

Telehealth Practitioners. For 2024, the list of telehealth practitioners is the same as the list for 2023. Section 4121 of the CAA 2023 recognizes marriage and family therapists (MFT) and mental health counselors (MHC) as telehealth practitioners, effective January 1, 2024. CMS finalizes its proposal to amend §410.78(b)(2) to specify MFTs as described in proposed §410.53 and an MHC as described in proposed §410.54.

Audio-Only Services. Telehealth services specified on the Medicare Telehealth Services List as audio-only technology will remain covered through 2024.

f. Place of Service for Medicare Telehealth Services

In the 2023 PFS, CMS finalized that following the end of the calendar year in which the PHE ends, telehealth claims would no longer use modifier "95" (CPT telehealth modifier) and would only be billed with the POS indicators:

- POS "02" – Telehealth Provided Other than in Patient's Home (Patient is not located in their home when receiving health services or health related services through telecommunication technology) and
- POS "10" – Telehealth Provided in Patient's Home (Patient is in a location other than a hospital or other facility where the patient receives care in a private residence when receiving health services or health related services through telecommunication technology).

For 2024, CMS finalizes its proposal that claims billed with POS 10 will be paid at the non-facility PFS rate. CMS believes that behavioral health services that are furnished in a patient's home as an originating site have the same PE as services provided in-person. Claims billed with POS 2 will continue to be paid at the PFS facility rate. CMS believes the facility rate more accurately reflects the PE of these telehealth services. CMS clarifies that modifier '95' should be used when the clinician is in the hospital and the patient is in the home, as well as for outpatient therapy services furnished via telehealth by PT, OT, or SLP.

Commenters had diverse opinions about CMS' proposal. In response, CMS states that telehealth services that are not furnished in the patient's home will continue to be furnished in the same type of originating sites in which they were furnished prior to the PHE, such as hospitals or RHCs and the resource costs associated with these services will resemble those of services furnished in person in a facility setting. CMS believes that facility costs associated with furnishing the service would generally be incurred by the originating site, where the patient is located, and not by the practitioner at the distant site (81 FR 80199-80200). The statute requires Medicare to pay a fee to the site that hosts the patient. Thus, CMS believes that facility PE RVUs most accurately reflect the resource costs for telehealth services when the home is not the originating site.

CMS notes that beginning in 2025, most telehealth will be limited to the statutory restrictions under section 1834(m)4; only mental health telehealth and some ESRD-related home dialysis services will continue to be paid when furnished in the patient's home without geographic restrictions. Practitioners furnishing mental health services via telehealth will more typically be practicing in non-facility based settings, are more likely to have office-based practices, and incur non-facility resource cost. Therefore, CMS believes that paying with claims billed at POS 10 at the non-facility rate while continuing to pay for claims billed with POS 02 at the facility rate most accurately captures the resource costs inherent in these types of services.

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

To align with other telehealth-related flexibilities extended by CAA, 2023, CMS finalizes its proposal to remove the telehealth frequency limitations for 2024 on the following codes:

- 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.

CMS also sought information from interested parties on how practitioners have been ensuring that Medicare beneficiaries receive these services since the expiration of the PHE. This information will help CMS assess its frequency limitations for these codes.

Many commenters supported CMS' proposal; some commenters urged CMS to remove the frequency limitations permanently. CMS acknowledges the information it received in response to its comment solicitation and expects to address the frequency limitations in future rulemaking.

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

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

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

CMS is concerned that an abrupt transition to the pre-PHE policy that requires the physical presence of the supervising practitioner will disrupt current supervising practices and may present a barrier to access to many services furnished incident-to a physician's service. 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 2024. This policy aligns with the timeframe of extended provisions of the CAA, 2023.

In the proposed rule, CMS discussed how this additional time will allow collection of additional information for development of a permanent policy for direct supervision. CMS sought information on whether the flexibility to meet the immediately availability requirement for direct supervision through the use of real-time, audio/video technology should potentially be made permanent, including whether this should be allowed only for a subset of services. CMS was interested in input on potential patient safety or quality concerns when direct supervision occurs virtually and whether this flexibility would be more appropriate for certain types of services of certain types of auxiliary personnel.

CMS also discussed a potential approach for 2025 which would extend or permanently establish virtual presence flexibility for services that are valued under the PFS based on the presumption they are nearly always completely performed by auxiliary personnel. Services would include any

service wholly furnished incident to a professional service, as well as Level I office or other E/M visits for established patients and Level I ED visits.

Many commenters supported CMS' proposal; some commenters stated that this policy should become permanent and provided examples of specific services that should be allowed to be furnished with remote direct supervision. A few commenters supported CMS' potential approach for 2025 and others thought it was too restrictive. CMS acknowledges the comments it received and it expects to address this issue in future rulemaking.

Supervision of Residents in Teaching Settings
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 proposed to allow the teaching physician to have a virtual presence in all teaching settings when the service is furnished virtually (e.g., a 3-way telehealth visit, with all parties in separate locations) through 2024. CMS finalizes this proposal and it will continue exercising enforcement discretion to this policy through 2024.

In the proposed rule, CMS also sought comments and information about how telehealth services can be furnished in all residency training locations beyond 2024, including what clinical treatment situations are appropriate for the virtual presence of the teaching physician. CMS anticipates considering various types of teaching physician services, when it is appropriate for the teaching physician and resident to be co-located, and how virtual presence could support patient safety, particularly at-risk patients. CMS also invites data or other information on these issues.

In response to a comment, CMS clarifies that the policy continues to permit PFS payment when the teaching physician is present virtually only when the service is furnished virtually. In the example provided by a commenter, where the service is furnished with the resident in person at the same location with the patient and only the teaching physician is present virtually through real-time audio/video communications technology, the teaching physician is required to have a physical presence with the resident, unless the residency training location is outside a MSA. CMS acknowledges the comments it received in response to its solicitation and will consider these in future rulemaking.

CMS finalized its policy to allow teaching physicians to have a virtual presence in all teaching settings, only in clinical instances when the service is furnished virtually for all residency training locations through December 31, 2024. As finalized in the 2021 PFS final rule (84577-84581), the required physical presence of a teaching physician in order to bill under the PFS for their services at a residency training site that is located outside of a MSA, can be met through

interactive, audio/video real-time communications technology, and does not include audio-only technology.

b. Clarifications for Remote Monitoring Services

CMS has established payment for two code families describing remote monitoring services: Remote physiologic monitoring (RPM) (CPT codes 99453, 99453, 99457, and 99458) and Remote therapeutic monitoring (RTM) (CPT codes 98975- 99978, 98980, and 98981). In response to questions related to these codes, in the proposed rule, CMS clarified the appropriate use of these codes.
New vs. established patient requirements. In the 2021 PFS final rule, CMS finalized that when the PHE ends, it will require RPM services be furnished only to an established patient. Patients who received initial remote monitoring services during the PHE are established patients for purposes of the patient requirements.

In response to comments, CMS clarifies that only RPM services require an established patient relationship. CMS notes that it believes RTM services are similar to RPM services but it has not specified in rulemaking whether RTM services require an established patient relationship. CMS plans to clarify this policy in future rulemaking.

Data collection requirements. At the end of the PHE, CMS reinstated the 16-day monitoring requirement over a 30-day period. For 2024, CMS clarified the data collection requirements. In the proposed rule, CMS included codes CPT codes 99876-98978, 98980, and 98981 as codes with the data collection requirements. CMS states it inadvertently listed all the RTM codes and clarifies that the 16 day collection requirement does not apply to CPT codes 99457, 88458, 98980, and 98981.

CMS reiterated that remotely monitored monthly services should only be reported once during a 30-day period when reasonable and necessary. CMS clarified that only one practitioner can bill CPT codes 9956 and 99454, or CPT codes 98976 and 98977 during a 30-day period and only when at least 16 days of data have been collected on at least one medical device (defined in section 201(h) of the FFDCA). CMS also reiterated that even when multiple devices are provided, services with all the medical devices can be billed only once per patient per 30-day period and only when at least 16 days of data have been collected.

Use of RPM, RTM in conjunction with other services. CMS reiterated that practitioners may bill RPM or RTM, but not both RPM and RTM concurrently with the following care management services: Chronic care management (CCM)/transitional care management (TCM)/behavioral health integration (BHI), principal care management (PCM), and chronic pain management (CPM). RPM or RTM may be billed for the same patient with these care management services if the time or effort is not counted twice.

Other clarifications for appropriate billing. CMS clarified that when a beneficiary receives a procedure or surgery covered for payment as a global period, RPM services or RTM services may be furnished separately to the beneficiary and the practitioner would receive payment for the RTM or RPM services, separate from the global payment, if the other requirements for separate

payment during a global period are met. Specifically, a beneficiary receiving services during a global period and the practitioner may furnish RPM or RTM services and receive separate payment, as long as the remote monitoring services are (1) unrelated to the diagnosis for which the global period is performed and (2) the purpose of the remote monitoring addresses an episode of care that is separate and distinct from the episode of care for the global procedure (the remote monitoring services addresses an underlying condition that is not linked to the global procedure or service).

In response to comments, CMS clarifies that the policy prohibiting RPM or RTM services furnished during the global period only applies to billing practitioners who are receiving the global service payment. CMS finalizes that providing RTM or RPM services during the global period is permitted if the practitioner is not receiving global service payment because they did not furnish the global procedure.

c. Telephone Evaluation and Management Services

CPT codes 9941-99443 and 98966-98968 describe E/M and assessment and management services furnished via telephone. CMS notes that CPT codes 994410-99443 are telehealth services and will remain priced through 2024. CPT codes 98966-98967 are not telehealth services since they are provided by a qualified non-physician healthcare professional. CMS finalizes its proposal to continue payment for these codes through 2024.

3. Telehealth Originating Site Facility Fee Payment Amount Update

Section 1834 (m)(2)(B) of the Act established the initial Medicare telehealth originate site facility fee for telehealth services furnished from October 1, 2001 through December 31, 2002 at $20.00. For services furnished on or after January 1 of each subsequent year, the telehealth originating site fee is increased by the percentage increase in the MEI (Table 12). The final MEI increase for 2024 is 4.g percent; the final payment for HCPCS code Q3014 (Telehealth originating site facility fee) is $29.96.

4. Payment for Outpatient Therapy Services, Diabetes Self-Management Training, and Medical Nutrition Therapy when Furnished by Institutional Staff to Beneficiaries in Their Homes

In the proposed rule, CMS reviewed its pre-PHE policies for institutions billing for services furnished remotely by their employed practitioners when the practitioners do not bill for their own services. Using waiver authority, CMS implemented the Hospitals Without Walls (HWW) policy which allowed hospitals to reclassify patients' homes as part of the hospital. HWW allowed hospitals to bill for certain services furnished remotely to patients in their homes including outpatient therapy services, diabetes self-management training (DSMT), and medical nutrition therapy (MNT). In developing post-PHE guidance, CMS initially took the position that institutions billing for services furnished remotely by their employed practitioners (when the practitioners do not bill for their own services) would end with the PHE along with the HWW waivers.

Through 2024, CMS proposed to continue to allow institutional providers to bill for outpatient therapy, DSMT, and MNT services when furnished remotely in the same manner they would

have during the PHE. CMS sought comments on current practices for these services when billed, including how and to what degree they continue to be provided remotely to beneficiaries in their homes. In addition, CMS sought comments on whether these services may fall within the scope of Medicare telehealth at section 1834(m) of the Act or if there are other relevant authorities CMS might consider in future rulemaking. CMS also sought comments about whether DMST is only provided by practitioners authorized to furnish Medicare telehealth services or may be provided by other types of staff. CMS notes that in sub-regulatory guidance it indicated that it is exercising enforcement discretion in reviewing the telehealth eligibility status of the practitioner providing any part of remote DSMT so long as the persons were otherwise qualified to provide the service.[13]

In the proposed rule, CMS also discussed the billing and payment for telehealth services in institutional settings including when the services are furnished by practitioners who have reassigned their right to bill under and receive payment from the Medicare program to an institution. CMS noted that for Critical Access Hospitals (CAHs), where a practitioner has assigned their billing rights to the CAH, CMS makes payment for the practitioner's services under CAH method II.[14] Under method II, CMS makes payment for the telehealth service at the same rate for other in-person services (100 percent of the PFS payment amount). CMS sought comments on how telehealth services furnished under CAH method II arrangements are furnished, and whether they would be most accurately characterized in the context of section 1834(m) of the Act or services of the CAH under Method II.

Many commenters supported CMS' proposal to continue to allow institutional providers to provide remote outpatient PT, OT, SLP, DSMT, and MNT services in patients' homes through 2024. CMS acknowledges the information it received about current billing practices for these services and comments that these services are an invaluable resource to beneficiaries. With respect to whether these services fall without the scope of section 1834(m) of the Act, commenters had various opinion.

CMS finalizes its proposal with one amendment for modifiers, to allow outpatient hospitals and other providers of PT, OT, SLP, DSMT, ad MNT services that remain on the Telehealth Services List for 2024 to bill for these services when furnished remotely in the same was they have been during the COVID-19 PHE and through the end of 2023. This includes that for hospitals, beneficiaries' homes will no longer need to be registered as provider-based departments of the hospital to allow for hospitals to bill for these services. CMS states that its final subregulatory policy[15] requires all institutional providers that bill for therapy, DSMT, and/or MNT services, with the exception of Method II CAHs, to apply the 95 modifier on each applicable line if these services are furnished via telecommunication technology once hospitals that need to do so can update their systems. For CAHs opting for payment under Method II, these CAHs will continue to use the GT/GC modifier, as appropriate, when billing for their services furnished via telehealth.

---

[13] https://www.cms.gov/fo;es/document/frequently-asked-questions-cms-waivers-flexibilities-and-end-covid-19-public-health-emergency.pdf.
[14] Pub. 100-04, Chapter 4, Section 240.2
[15] This guidance can be found at https://www.cms.gov/files/document/hospitals-and-cahs-ascs-and-cmhcs-cms-flexibilities-fight-covid-19.pdf.

E. Valuation of Specific Codes

The final work RVUs, work time and other payment information for all the final payable codes in 2024 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 final 2024 valuation of specific codes:

Table 14	Work RVUs for New, Revised, and Potentially Misvalued Codes
Table 15	Direct PE Refinements
Table 16	Direct PE Refinements: Equipment Refinements Conforming to Changes in Clinical Labor
Table 17	Invoices Received for Existing Direct PE Inputs
Table 18	New Invoices
Table 19	No PE Refinements

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

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

2. Methodology for Establishing Work RVUs

CMS reviews its methodology for proposing work RVUs, including potential information sources and specific approaches.[16] CMS notes the importance of not only the RUC-recommended work and time values but also the accompanying rationales for setting those values.[17] CMS refers readers to its discussion of this subject in the 2017 PFS final rule (81 FR 80273-80274).

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

[16]Approaches include RUC survey data, building block, key reference code crosswalks, magnitude estimation, incremental difference applications, and time ratio calculations.
[17]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.

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 14 list the codes and final work RVUs, including all codes that CMS received recommendations from the RUC by February 10, 2023.

Several commenters recommended that CMS reinstitute the refinement panels. Commenters consider the refinement panel process to be an appeals process and its elimination discontinued CMS' reliance on outside interested parties to provide accountability through a transparent appeals process. CMS responds that the refinement panel was established to assist CMS in reviewing the public comments on CPT codes with interim final work RVUs and to balance the interests of the specialty societies with the budgetary and redistributive effects that would occur if CMS just accepted extensive increases in RUVs. CMS did not believe the refinement panel serves as the kind of 'appeals' process that interested parties envision. In addition, CMS does not believe the refinement panel was achieving its intended purpose and instead rehashed issues raised and previously discussed at the RUC meetings and considered by CMS.

3. Methodology for Direct PE Inputs to Develop PE RVUs

CMS reviews its methodology for proposing direct PE inputs, which include clinical labor, disposable medical supplies, and medical equipment. The RUC annually provides CMS with recommendations about PE inputs for new, revised, and potentially misvalued codes. Table 13 details CMS' refinements of the RUC's direct PE recommendations at the code specific level. Table 14 details proposed refinements in direct PE due to changes in the equipment time and the conforming changes in clinical labor time.

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

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

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

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

CMS received invoices for several existing and new supply and equipment items (see Tables 17 and 18). CMS encourages stakeholders to review these prices and if prices appear inaccurate it encourages stakeholders to submit invoices or other information to improve the pricing. CMS expects invoices received outside of the public comment period to be submitted by February 10th of the following year for consideration in future rulemaking (similar to the time for receiving RUC recommendations). CMS notes that in some cases it does not use the price listed on the invoice because it identifies publicly available alternative prices or information that suggests a different price is more accurate.

CMS reminds stakeholders that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services. CMS includes the number of invoices received and the number of nonfacility allowed services for procedures that use these equipment in Tables 17 and 18.

For 2024, CMS finalizes ten new and revised codes as services which meet the definition of "imaging services" for purposes of the OPPS cap[18]. This includes CPT code 76883 (Ultrasound, nerve(s), per extremity); 76984 and 76987-76989 (Intraoperative epicardial cardiac ultrasound for congenital heart disease); and 93584-93588 (Venography for congenital heart defect(s)).

Some commenters requested that CMS remove CPT code 92229 (Imaging of the retinal; point-of-care) from the OPPS cap list because it does not include an associated PC or physician interpretation and is primarily utilized in the physician office setting. Commenters thought it may still be appropriate for the technical components of CPT codes 92227 and 92228 to be on the OPPS Cap List. CMS appreciates this feedback. These comments are out of scope of this rule but CMS will consider these comments for future rulemaking.

4. Valuation for Specific Codes

This section discusses CMS' final decisions for 29 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.

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

Code Group Number and Name		Codes (CPT and HCPCS Codes)	CMS Proposed RVUs Agrees with RUC Recommendations		CMS Finalizes Its Proposed RUVS	
			Work	PE	Work	PE
1	Dorsal Sacroiliac Joint Arthrodesis	27278	Yes	Yes	Yes	Yes
2	Vertebral Body Tethering	22836-22838	Yes	Yes	Yes	Yes
3	Total Disc Arthroplasty	22587 & 22860	No	Yes	Yes	Yes
4	Phrenic Nerve Stimulation System	33276-33281 & 93150-93153	Yes	No	Yes	Yes
5	Posterior Nasal Nerve Ablation	30117, 30118, 31242, & 31243	No	No	Yes	Yes
6	Cystourethroscopy with Urethral Therapeutic Drug Delivery	52284	Yes	Yes	Yes	Yes
7	Transcervical RF Ablation of Uterine Fibroids	58580	Yes	No	Yes	Yes
8	Suprachoroidal Injection	67516	Yes	Yes	Yes	Yes
9	Skull Mounted Cranial Neurostimulator	61889, 61891, & 61892	Yes	Yes	Yes	Yes
10	Spinal Neurostimulator Services	63685 & 63688	Yes	Yes	Yes	Yes
		64596-64598	NA**	NA**	NA**	NA**
11	Neurostimulator Service-Bladder Dysfunction	64590 & 64595	Yes	No	Yes	Yes
12	Ocular Surface Amniotic Membrane Placement/Reconstruction	65778-65780	Yes	Yes	Yes	Yes
13	Fractional Flow Reserve with CT*	75580	Yes	No	Yes	Yes
14	Ultrasound Guidance for Vascular Access	76937	Yes	Yes	Yes	Yes
15	Neuromuscular Ultrasound	76881-76883	NA	No	NA	Yes
16	Intraoperative Ultrasound Services*	76998, 76984, 76987-769897	No	NA	Yes	NA
17	Percutaneous Coronary Interventions	92972	Yes	Yes	Yes	Yes
18	Auditory Osseointegrated Device Services	92622 & 92623	Yes	Yes	Yes	Yes
19	Venography Services	93584-93588	Yes	NA	Yes	NA

Code Group Number and Name		Codes (CPT and HCPCS Codes)	CMS Proposed RVUs Agrees with RUC Recommendations		CMS Finalizes Its Proposed RUVS	
			Work	PE	Work	PE
20	Post Operative Low-Level Laser Therapy*	97037	CMS finalizes non-covered status			
21	General Behavioral Health Integration Care Management	99484 & G0323	No	Yes	Yes	Yes
22	Advance Care Management	99497 & 99498	Yes	Yes	Yes	Yes
23	Pelvic Exam	9X036	NA	NA	Yes	Yes
24	Hyperthermic Intraperitoneal Chemotherapy (HIPEC)	96547 & 96548	NA**	NA**	NA**	NA**
25	Hyperbaric Oxygen Under Pressure	G0277	NA	No	NA	Yes
26	Remote Interrogation Device Evaluations-Cardiovascular*	G2006, 93297 & 93298	NA	Yes	NA	No
27	Caregiver Training Services*	96202, 96203, 97550-97552	Yes	Yes	Yes	Yes
28	Health-Related Social Needs:*		NA	NA	NA	NA
	Community Health Integration Services	G0019 & G0020				
	SDOH Risk Assessment	G0136				
	Principal Illness Navigation Services	G0023 & G0024; G0140 and G0146				
29	Maternity Services*	59400, 59410, 59425, 59426, 59430, 59510, 59610, 59614, 59618 & 59622	NA	NA	NA	NA
*Discussed in HFMA summary **Contractor Priced Codes						

(13) Fractional Flow Reserve with CT (FFRCT) (CPT code 7X005)

In 2018, CPT established four new Category III CPT codes for FFRCT: CPT codes 0501T-0504T. In 2018, under the OPPS, CMS began payment for CPT code 0503T. Under the PFS, payment was assigned contractor pricing. In the 2021 PFS final rule (85 FR 84630), CMS stated that FFRCT is similar to other technologies that use algorithms, artificial intelligence, or other

innovative forms of analysis to determine treatment, where the analysis portion of the service cannot be adequately reflected under the PE methodology. CMS requested information about direct PE expenses. In 2022, CMS stated that the costs in the physician office setting were similar to costs reflected under the PPS and finalized national pricing for CPT code 0503T based on a crosswalk to the technical component (TC) of CPT code 93457 (Catheter placement in coronary artery(s) for coronary angiography) (86 FR 65037-65042).

For 2024, CPT approved the replacement of the four Category III codes with one Category I code (75580) to report non-invasive estimate of FFRCT derived from augmentative software analysis of the dataset from a coronary computed tomography angiography). The RUC recommended including a software analysis fee for FFRCT listed as a supply input; this supply accounts for the overwhelming majority of the code's value.

In the proposed rule, CMS reiterated its prior concerns that the software algorithm in the analysis fee for CPT code 75580 is not well accounted for in the PE methodology. CMS recognizes that analysis fees are a type of cost for practitioners, but it has not traditionally recognized these analysis fees as forms of direct PE. CMS proposed to maintain the previous valuation crosswalk to the TC of CPT code 93457 for CPT code 75580. CMS proposed the RUC-recommended work RVU of 0.75 for the professional component of the code.

Many commenters approved CMS' proposal of the recommended work RYVs for the professional component of the code. A commenter disagreed with the proposed crosswalk to CPT code 93457 because they objected to CMS using data from the OPPS in establishing relative values for the PFS. CMS disagrees and believes it can use OPPS data in certain circumstances to inform payment under the PFS. Another commenter recommended that CMS accept the software as a direct practice expense. CMS reiterates its belief that the software analysis fee is not considered as a form of direct PE under the current methodology.

Several commenters recommended that CMS separately identify and pay for high-cost disposable supplies which would include the payment for the software analysis fee in CPT code 75580. CMS notes it has received similar prior recommendations and it continues to believe this option presents a series of potential problems regarding pricing high cost disposable supple items (discussed in the 2011 PFS, (75 FR 732451)

(16) Intraoperative Ultrasound Services (CPT codes 76998 & 76984-76989)
This code family is an example of the need to replace one code with multiple codes when it is used by a wide range of specialties. In 2018 CPT code 76998 was identified as a code with Medicare utilization of 20,000 or more; the code was used by eight specialties. Based on the variability of intraoperative ultrasound for each specialty with differences in the typical patient and physician work, it was decided that each specialty would submit an application for a new code. After the approval of additional codes CPT code 76998 is now for breast surgery.

(20) Post Operative Low-Level Laser Therapy (CPT code 97037)
In May 2022, the CPT Editorial Panel created CPT code 97037 to describe the application of low-level laser therapy for post-operative pain reduction. The RUC did not offer a recommendation and CMS did not realize this code was added to the CPT code set for 2024 until

after the publication of the proposed rule. CMS finalizes non-covered status (Procedure Status "N") for this code because NCD 270.6 states: The use of infrared and/or near infrared light and/or heat, including monochromatic infrared energy, is non-covered for the treatment, including the symptoms such as pain arising from these conditions, of diabetic and/or non-diabetic peripheral sensory neuropathy, wounds and/or ulcers of the skin and/or subcutaneous tissues. This service is noncovered by Medicare.

(25) Remote Interrogation Device Evaluation-Cardiovascular (HCPCS code G2066 & CPT codes 93297 and 93298)
CMS reviews the history of these codes. Because CMS did not agree with the RUC-recommended PE values, for 2020, CMS created HCPCS code G2066 and established contractor pricing for G2066 and CPT codes 93297 and 93298 were work-only codes. Payment concerns remained because of significant difference in payment for G2066.

For 2024, CMS finalizes its proposal to delete HCPCS code G2066 and its proposal to accept the RUC-recommended direct PE inputs for CPT codes 93297 and 93298. No recommendations were made for changes in the work RVUs.

Commenters stated that the RUC's recommendations included 4 minutes of clinical labor time for education/re-education tasks, however the equipment time assigned to these services was inadvertently recued by 11 minutes, in what appeared to be a clerical error. After reviewing this information, CMS agrees there appears to be a clerical error in the equipment minutes for EQ198. CMS finalizes an increase in the EQ198 equipment time to 29 minutes for CPT code 93297 and 65 minutes for CPT code 93298. CMS notes these refinements should correct the errors and align with what the RUC presumably intended to recommend.

(27) Payment for Caregiving Training Services (CPT codes 96202, 96203,97550-97552)

In the proposed rule, CMS reviewed the evolution of its understanding of caregiving training services. CMS did not establish payment for caregiving behavior management training codes (CPT codes 96202 and 96203) because these services were furnished exclusively to caregivers rather than the individual Medicare beneficiary. CMS did believe there could be circumstances where separate payment for services may be appropriate and in the 2023 PFS proposed rule requested public comment about these codes.[19] Public comments were generally supportive of separate payment for these codes and provided empirical support for these services. Commenters also noted that there are other services paid under the PFS that do not include direct contact with the patient but are still considered integral to the patient's care, including care management services.

After consideration of comments and review of payment policies for patient-centered care involving care coordination and team-based care, CMS believes that in certain circumstances caregivers can play a key role in developing and implementing a treatment plan established for the patient by the treating practitioner. In this context, CMS believes Caregiving Training

[19] 87 FR 69521-69523

Services (CTS) could be reasonable and necessary to treat the patient's illness or injury (section 1862(a)(1)(A) of the Act).

For 2024, CMS proposed the following for CTS services:

- Active payment status for CPT codes 96202 and 96203 (caregiver behavior management/modification training services) and CPT codes 97550-97552 (caregiver training services under a therapy plan of care established by a PT, OT, SLP).
- Payment may be made when the treating practitioner identifies a need to involve and train one or more caregivers to assist the patient in carrying out a patient-centered treatment plan.
- The treating practitioner must obtain the patient's (or representative's) consent for the caregiver to receive the CTS. The identified need for CTS and consent must be documented in the medical record.
- Require the full 60 minutes to be performed to report CPT code 96202. The add on code, 96203, may be reported once 75 minutes of total time is performed.

CMS sought comments on how the clinician and caregiver interactions would typically occur, including when the practitioner is dealing with multiple caregivers. CMS was also interested in how often these services would be billed considering the established treatment plan involving caregivers for the typical patient.

Comments/Responses. Most commenters supported the proposals. However, some commenters opposed the CTS proposals because these services are currently provided by organizations better equipped to provide CTS, such as home health agencies, home and community-based services, and non-profit organizations. Many commenters who opposed CTS suggested direct payment be made to caregivers.

CMS responds that the CTS, developed through the AMA CPT Editorial Panel's process, describes training services provided by a practitioner to effectuate the practitioner's treatment plan to improve a patient's treatment outcome. The available of these services should not prevent caregivers from seeking support or assistance from other organizations. In addition, CMS notes that the codes specify that the patient is not present during the service; this recognizes that both the practitioner's and the caregiver's attention is focused on the training. CMS clarifies that CTS does not affect patient eligibility for other Medicare services when reasonable and necessary. CMS also clarifies that under the statute, Medicare makes payments under the PFS only to enrolled physicians and other practitioners, not to caregivers.

The majority of commenters supported the proposal to require the patient's (or representative's consent for the caregiver to receive CTS. In response to specific recommendations related to how consent is obtained, CMS states it does not believe that the general consent to receive treatment is sufficient to make a patient aware of the unique circumstances under which CTS are furnished outside the patient's presence.

CMS acknowledges the additional information and comments it received about quality standards, teaching methods, and additional requirements for CTS. CMS will consider this information for any additional policy development in future rulemaking.

Final Rule Action: CMS finalizes as proposed that the patient's (or representative's) consent is required for the caregiver to receive CTS and that the consent must be documented in the patient's medical record.

i. Definition of a Caregiver
CMS has broadly defined a caregiver as a family member, friend, or neighbor who provides unpaid assistance to a person with a chronic illness or disabling condition.[20]

For CTS services, CMS proposed a caregiver is an individual who:

- Assists or acts as a proxy for a patient with an illness or condition of short or long-term duration (not necessarily chronic or disabling);
- Is involved on an episodic, daily, or occasional basis in managing a patient's complex health care and assistive technology activities at home; and
- Helps to navigate the patient's transitions between care settings.

For CTS, caregivers also refer to guardians who are the caregiver for minor children or other individuals who are not legally independent.

Comments/Responses. Many commenters did not support the proposes definition of caregiver. An overwhelming number of commenters requested that CMS use the definition of "family caregiver" used in the Recognize, Assist, Include, Support, and Engage (RAISE) Family Caregivers Act (Pub. L. 115-119). Commenters also requested that CMS remove the terms "layperson", "proxy", and/or "guardian" from our definition.

CMS agrees that the definition of "family caregiver" used in the RAISE Family Caregivers Act supports the CTS proposal. It will adopt both the RAISE definition and the CMS Outreach and Education definition (a family member, friend, or neighbor who provides unpaid assistance to a person with a chronic illness or disabling condition) as definitions of caregiver.

Final Rule Action: CMS finalizes a revised definition of caregiver to be "an adult family member or other individual who has a significant relationship with, and who provides a broad range of assistance to, an individual with a chronic or other health condition, disability, or functional limitation" and "a family member, friend, or neighbor who provides unpaid assistance to a person with a chronic illness or disabling condition".

CMS notes that it maintains that the caregiver population receiving these services on behalf of the patient should not also receive concurrent CTS under another Medicare benefit category or Federal program (88 FR 52323).

[20] https://www.cms.goc/outreach-and-education/outreach/partnerships.

ii. Patients Who Benefit from Care Involving Caregivers
CMS believes that a patient-centered treatment plan should account for the clinical circumstances where the treating practitioner believes the involvement of a caregiver is necessary to ensure a successful outcome and as appropriate, the patient agrees to caregiver involvement. In the proposed rule, CMS provided some examples of conditions where CTS may be reasonable and necessary including traumatic brain injury, autism spectrum disorders, dementia, and individuals with other intellectual or cognitive disabilities, physical mobility limitations, or use of assisted devices or mobility aids.

CMS also discussed the need to avoid potentially duplicative payments for CTS to a patient receiving similar services under another Medicare benefit category or Federal program. CMS did not expect CTS will overlap with any other coverage for patients who are dually eligible.

Comments/Responses. Many commenters suggested various physical and behavioral health conditions and circumstances where CTS may be reasonable and necessary. Commenters also detailed how these services could overlap with State-funded Medicaid consumer-directed programs and with Innovation Center models.

In response, CMS notes that the examples provided in the proposed rule were just illustrative and it acknowledges there are many circumstances where CTS may be reasonable and necessary to train a caregiver who assists in carrying out a treatment plan. CMS states it does not believe participation in Medicaid consumer-directed programs for dually eligible beneficiaries, or CMS' demonstration models would be duplicative of CTS codes because these are consumer-directed programs. Through the CTS codes, Medicare will pay the treating practitioner to train caregivers.

iii. Reasonable and Necessary CTS
CMS believes CTS could be reasonable and necessary when furnished based on an established individualized, patient-centered treatment plan or therapy plan of care accounting for the patient's specific medical needs, including but not limited to the examples discussed above.

As based on the code descriptors, treating practitioners may train caregivers in a group settings with other caregivers who are involved in care for patients with similar needs for assistance. Training for all of the caregivers for the patient can occur simultaneously; the applicable CTS codes would be billed once per beneficiary.

Responses/Comments. The majority of commenters thought CTS would be reasonable and necessary could be reasonable and necessary more than once a year for the same patient and provided to the same caregiver by the same provider. Many commenters requested payment be made per caregiver and not per beneficiary.

In response, CMS agrees that the medical necessity of CTS for the patient should determine the frequency of training. CTS should be considered reasonable and necessary when the treating practitioner determines a caregiver needs more training to ensure a successful patient treatment plan outcome; the documentation in the medical record needs to support the medical necessity of CTS. CMS reiterates that the caregiver training group codes (CPT code 96202, 96203, or 97552)

are used if more than one caregiver is trained at the same time; practitioners would not bill individually for each caregiver.

Final Rule Action: CMS finalizes its proposal for CTS with the following clarifications: the volume and frequency of CTS sessions furnished to caregivers by the treating practitioner for the same patient may be based on the treatment plan, as well as changes in the treatment plan, the patient's condition, or the patient's caregivers.

iv. Service Coding and Valuation

(a) Behavioral management/modification training for guardians/caregivers of patients with a mental or physical health diagnosis (CPT codes 96202 & 96203)

These two codes are used to report the total duration of face-to-face time spent by the physician or other qualified health professional providing group behavior management/modification training to guardians or caregivers of patients. According to the Summary of Recommendations submitted by the RUC, during the face-to-face service time, caregivers are taught how to structure the patient's environment to support and reinforce desired patient behaviors, to reduce the negative impacts of the diagnosis on the patient's daily life, and to develop highly structured technical skills to manage the patient's challenging behavior.

CMS notes that to be considered reasonable and necessary, this behavior/management modification training should be directly relevant to the person-centered treatment plan for the patient. Each behavior should be clearly identified and documented in the treatment plan and the caregiver should be trained in positive behavior management strategies.

CMS finalizes the proposed RUC-recommended work RVU of 0.43 for CPT code 96202 and 0.12 for CPT code 96203 and the RUC-recommended direct PE inputs for these codes. CMS requires the full 60 minutes of time to be performed to report CPT code 96202. The add-on code, CPT code 96203, may be reported once 75 minutes of total time is performed.

In response to a few commenters suggesting higher values for these services, CMS states it believes that the RUC recommendations that were based on extensive surveys with psychologists, psychiatrists and dieticians represents the best information for these codes. CMS notes that the RUC recommendation suggested that the RUC intends to review these services again soon.

(b) Caregiver training in strategies and techniques to facilitate the patient's functional performance (CPT codes 97550-97552)

These three codes are used to report the total duration of face-to-face time spent by the physician or other qualified health professional providing individual or group training to caregivers. The goals and outcomes of the sessions focus on interventions aimed at improving the patient's ability to successfully perform activities of daily living (ADL's), including ambulating, feeding, dressing, personal hygiene, and toileting.

CMS finalizes the proposed RUC-recommended work RVUs for these CPT codes: 1.00 for 97550, 0.54 for 97551, and 0.23 per identified patient service for 97552. The recommendation for 97552 is based on a median group size of five caregivers. CMS also finalizes s the RUC-

recommended direct PE inputs for these codes. CMS notes that the RUC recommendation suggested that the RUC intends to review these services again soon.

CMS finalizes its proposal to designate these codes as "sometimes therapy". This means that these codes are always furnished under a therapy plan of care when provided by PTs, OTs, and SLPs; but when they are furnished by physicians and NPPs outside a therapy plan of care they can be furnished under a treatment plan by physicians and NPPs.

In response to a few commenters suggesting higher values for these services, CMS states it believes that the RUC recommendations that were based on extensive surveys with PTs, OTs, and SLPs represents the best information for these codes. CMS notes that the RUC recommendation suggested that the RUC intends to review these services again soon.

(28) Services Addressing Health-Related Social Needs : Community Health Integration (CHI) services, SDOH Risk Assessment, and Principal Illness Navigation (PIN) Services)

a. Background

In the proposed rule, CMS discussed how it is working to better identify and value practitioners' work for the additional time and resources used to help patients with serious illnesses navigate the healthcare system or remove health-related social barriers that interfere with the practitioner's ability to implement a medically necessary plan of care. CMS believes this additional time and resources are not explicitly identified in current coding; this contributes to these activities being underutilized and undervalued. CMS believes the proposed new codes expressly identify and value these services and will promote activities and help distinguish them from care management services.

CMS also discussed how to better recognize through coding and payment policies, Community Health Workers (CHWs) that are members of an interdisciplinary team for Medicare beneficiaries. CMS noted that there is no separately enumerated Medicare benefit category that provides direct payment to CHWs and HCPCS coding does not specifically identify services provided by CHWs. In the 2023 PFS proposed rule, CMS solicited comments on how services involving CHWs are furnished in association with the specific statutory benefits. Commenters were supportive of potential separate coding and payment for services involving CHWs and provided testimonials and evidence about the effectiveness of CHWs.

CMS also discussed the AMA's recognition in the CPT E/M Guidelines that SDOH needs can increase complexity of practitioner's medical decision making (MDM) for an E/M visit and increase the risk to the patient, when diagnosis or treatment is significantly limited by SDOH.[21] The CPT E/M Guidelines defined SDOH as, "Economic and social conditions that influence the health of people and communities. Examples may include food or housing insecurity."[22] Effective January 1, 2021, CMS adopted these revised guidelines. CMS discussed the additional resources practitioners expend to obtain information from the patient about SDOH and develop

[21] 2021 CPT Codebook, p. 16.
[22] 2021 CPT Codebook, p. 14.

and implement treatment plans that take these needs into account. CMS believes that social workers, CHWs, and other auxiliary personnel are performing these activities incident to the billing practitioner's supervision.

CMS notes that when it refers to community-based organizations (CBOs), it means public or private not-for-profit entities that provide specific services to the community or targeted populations in the community to address the health and social needs of those populations.[23] These may include community-action agencies, housing agencies, area agencies on aging, centers for independent living, aging and disability resource centers or other non-profits that apply for grants or contract with healthcare entities to perform social services.

b. Community Health Integration (CHI) Services

CMS finalizes its proposal to create two new G codes describing CHI services performed by certified or trained auxiliary personal, which may include a CHW, incident to the professional services and under the general supervision of the billing practitioner.

Commenters were generally supportive of establishing CHI services. CMS disagrees with a comment that the proposal to create new G codes for CHI services is duplicative of existing CPT codes. CMS believes that the new G codes describe and account for integrated services supported by certified or trained auxiliary personnel who will assist the practitioner in connecting the patient with helpful resources. CMS states these services are separate from the work furnished as part of the MDM in an E/M visit; these services consist of activities to address SDOH needs that are significantly limiting the practitioner's ability to diagnose or treat problems addressed in an initiating CHI visit. These services include a person-centered assessment, practitioner, home- and community-based care coordination, health education, building patient self-advocacy skills, health care access/health system navigation, facilitating and providing social and emotional support, and leveraging lived experience when applicable.

CMS finalizes the following proposals, with some modifications for the specific codes and descriptors that incorporate the required elements for CHI services:

i. CHI Services Codes

CMS finalizes the proposed code descriptor for G0019 with a few minor changes. The final code descriptor removes 'E/M" from the code descriptor because CMS finalizes an CHI initiating visit can also be the E/M service that is part of a TCM service and an AWV. CMS also adds a service element for the SDOH risk assessment to describe when a CHW or other auxiliary personnel identifies an additional SDOH that the furnishing practitioner did not identify and when informed, the billing practitioner determines whether the SDOH would impact their ability to diagnose and treat the problem addressed in the initiating visit.

CMS finalizes its proposal for the add-on code, G0020.

[23] 87 FR 46102 and 87 FR 69790

G0019: *CHI 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 SDOH need(s) that are significantly limiting ability to diagnose or treat problems(s) addressed in an initiating visit:*

- Person-centered assessment, performed to better understand the individualized context of the interaction between the SDOH need(s) and the problems(s) addressed in the initiating E/M visit:
    - Conducting a person-centered assessment to understand patient's life story, strengths, needs, goals, preferences and desired outcomes, including understanding cultural and linguistic factors and including unmet SDOH needs (that are not separately billed).
    - Facilitating patient-driven goal-setting and establishing an action plan.
    - Providing tailored support to the patient as needed to accomplish the practitioner's treatment plan.
- Practitioner, Home- and Community-Based Care Coordination
    - Coordinating receipt of needed services from healthcare practitioners; providers and facilities; and from home- and community-based service providers, social service providers, and caregiver (if applicable).
    - Communication with practitioners, home- and community-based service providers, hospitals, and skilled nursing faculties (SNFs) (or other facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.
    - Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges form hospitals, SNFs or other health care facilities.
    - Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) to address the SDOH need(s).
- Health education- Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, and preferences, in the context of the SDOH need(s), and educating the patient on how to best participate in medical decision-making.
- Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services addressing the SDOH need(s), in ways that are more likely to promote personalized and effective diagnosis or treatment.
- Health care access/health system navigation
    - Help the patient access healthcare, including identifying appropriate practitioners or providers for clinical care and helping secure appointments with them,
- Facilitate behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.
- Facilitating and providing social and emotional support to help the patient cope with the problem(s) addressed in the initiating visit, the SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.

- Leveraging lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.

G0022: *CHI services, each additional 30 minutes per calendar month (List separately in addition to G0019)*

ii. CHI Requirements

CMS finalizes the following requirements:

a. CHI initiating visit. CMS finalizes that CHI services can be furnished monthly, as medically necessary, following an initiating E/M visit (other than a low-level E/M visit that can be performed by the billing practitioner who would also be furnishing the CHI services during the subsequent calendar month(s). An E/M visit furnished as part of TCM, or an AWV can also be considered the CHI initiating visit. However, when the AWV is provided by a type of professional who does not have an "incident to" benefit (e.g., health educator and a registered dietitian), the AWV cannot serve as the initiating visit for the CHI. The CHI initiating visit would be separately billed and would be a pre-requisite for billing CHI services.

In response to comments about where these services can be provide and who can bill these services, CMS provides the following clarifications:

- These services can only be furnished and billed by physicians and practitioners who can bill for services performed by auxiliary personnel incident to their professional services.
- The individual billing for the initiating visit must be the same practitioner billing for CHI.
- Billing practitioners must have a statutory benefit and be able to enroll as they would for any other services on the fee schedule and specifically be able to bill an E/M service. There is no statutory benefit category that would allow community-based organizations to bill the PFS directly.

CMS does not consider inpatient/observation visits and ED visits as CHI initiating visits because these practitioners would not be following the patient longitudinally in the community or furnishing the CHI services. CMS believes that services provided by clinical psychologists (CPT codes 90791 and 96156) are better addressed with the PIN service elements. CMS does agree with comments that the AWV and the E/M visit included as part of TCM services could serve as an initiating visit for CHI.

b. Subsequent CHI services. CMS finalizes that a subsequent CHI services can be performed by a CHW or other auxiliary personnel incident to the professional services of the practitioner who bills the CHI initiating visit. CHI visits must be furnished in accordance with the "incident to" regulation at §410.26.

- An initiating E/M visit every month that CHI services are billed is not required.

c. Supervision level. CMS finalizes the designation of CHI services as care management services that may be furnished under the general supervision of the billing practitioner. General

supervision means the service is furnished under the physician's (or other practitioner's) overall direction and control but their presence is not required during the performance of the service.

Most commenters supported the proposal to allow general supervision for CHI services. In response to comments about whether auxiliary personnel providing CHI services can identify additional unmet SDOH, CMS states the scope of practice of auxiliary personnel does not allow them to make a determination that a given SDOH impacts the ability of the billing practitioner to diagnose or treat problems addressed in an initiating visit. CMS notes general supervision requires the CHI services to be furnished under the billing practitioner's direction; the auxiliary personnel must review all unmet SDOH needs they find in order for them to be addressed by the billing practitioners in the CHI services.

In response to comments, CMS clarifies the codes were specifically designed to capture services commonly performed by community health workers, but do not limit the types of other health care professionals, such as registered nurses and social workers), that can perform CHI services incident to the billing practitioner's professional services.

d. "*Problem Addressed"*. This term refers to the definition in the CPT E/M Guidelines that CMS adopted for E/M visits.[24]

- A problem is a disease, condition, illness. Injury, symptom, finding, complaint, or other matter addressed at the encounter, with or without a diagnosis being established at the time of the encounter."
- A problem is addressed or managed when it is evaluated or treated at the encounter by the physician or other qualified health care professional reporting the service. This includes consideration of further testing or treatment that may not be elected by virtue of risk/benefit analysis of patient/parent/guardian/surrogate choice.
    - Notation in patient's medical record that another professional is managing the problem without additional assessment or care coordination does not qualify as addressing or managing the problem.
    - Referral without evaluation does not qualify as being addressed or managed.

e. SDOH. SDOH means economic and social condition(s) that influence the health of people and communities, as indicated in the CPT E/M Guidelines.[25] In addition to the CPT examples of SDOH, CMS finalizes that SDOH's may include but are not limited to food insecurity, transportation insecurity, housing insecurity, and unreliable access to public utilities, when they significantly limit the practitioner's ability to diagnose or treat the problem(s) addressed in the CHI initiating visit. CMS notes that since Medicare payment generally is limited to items and services that are reasonable and necessary for the diagnosis or treatment of illness or injury, CHI services need to address the particular SDOH(s) that are interfering with, or presenting a barrier to, diagnosis or treat the patient's problem(s) addressed in the CHI initiating visit.

f. Certified or trained auxiliary personnel. CMS finalizes that for CHI services, auxiliary personnel must be certified or trained to perform all included service elements, and authorized to

[24] 2023 CPT codebook, p. 6-8.
[25] 2023 CPT codebook, p. 11.

perform them under applicable State laws and regulations. Under §410.26(a)(1), auxiliary personnel must meet any applicable requirements to perform the services performed incident to the billing practitioner's professional services, including licensure, that are imposed by the State in which the services are being furnished. In states where there are no applicable licensure or other laws and regulations related to individuals performing CHI services, auxiliary personnel providing CHI services would need to be trained.

- Training must include the competencies of patient and family communication, interpersonal and relationship building, patient and family capacity-building, service coordination and system navigation, patient advocacy, facilitation, individual and community assessment, professionalism and ethical conduct, and the development of appropriate knowledge base, including local-community based resources. CMS believes these competencies reflect professional consensus regarding appropriate core competencies for CHWs providing this service.[26]

Commenters offered many recommendations ranging from offering a legacy certification option for CHWs to specific time and course content recommendations. CMS notes it is the billing practitioner's responsibility to ensure that all payment rules and applicable State requirements are met including licensure, certification, and/or training. The billing practitioner is not required to provide the licensure, certification, and/or training themselves, but rather they must insure that the Medicare requirements for billing and payment of CHI services are met.

g. Documentation. CMS finalizes that the time spent furnishing CHI must be documented in the patient's medical record in its relationship to the SDOH need(s) and how the activities are intended to address and the clinical problem(s) they are intended to help resolve. Documentation includes the activities performed by the auxiliary personnel, just as all clinical care is documented in the medical record.

- The SDOH(s) need to be recorded in the patient's medical record.
- For data standardization, practitioners are encouraged to record the associated ICD-10 Z code (Z55-Z65) in the medical record and on the claim.

In response to comments requesting clarification about the documentation requirements, CMS refers commenters to the 2020 and 2021 PFS FR.[27] These policies state that any individual who is authorized under Medicare law to furnish and bill for their professional services, whether or not they are acting in a teaching role, may review and verify (sign and date) the medical record for the services they bill, rather than re-document notes in the medical record made by physicians, residents, nurses, and students, or other members of the medical team. CBOs may enter data following CMS' general policy, as long as the biller reviews and verifies the documentation.

h. Billing practitioner's arrangement with auxiliary personnel. CMS finalizes a billing practitioner may arrange to have CHI services provided by auxiliary personnel who are external to, and under contract with the practitioner or their practice. This contract could be with a

[26] https://chwtraining.org/c3-project-chw-skills/.
[27] 2020 PFS final rule (84 FR 62681-62684) and 2021 PFS final rule (85 FR 84594-84596)

community-based organization[28] that employs CHWs, if all of the incident to and other requirements and conditions for payment of CHI services are met.

- CMS stresses that CHI services performed by auxiliary personnel under a contract with a third party requires sufficient clinical integration between the third party and the billing practitioner in order for the services to be fully provided, and the connection between the patient, auxiliary personnel, and the billing practitioner must be maintained.
- CMS expects the auxiliary personnel performing the CHI services to communicate regularly with the billing practitioner, continue to involve the billing practitioner in evaluating the continuing need for CHI services, and ensure proper documentation in the medical record.

i. Frequency of billing. CMS finalizes the following:

- Only one practitioner per beneficiary per calendar month could bill for CHI services.
- A practitioner could separately bill for other care management services during the same month as CHI services if time and effort are not counted more than once and requirements to bill other care management services are met.
- CHI services could not be billed while the patient is under a home health plan of care under Medicare Part B. CMS believes there would be a significant overlap between services furnished under a home health plan of care and CHI services.

In response to commenters requesting CMS reconsider the exclusion of home health patients, CMS reiterates its belief that there is significant overlap between CHI services and services furnished under a home health plan of care.

j. Time and duration of CHI services. CMS finalizes 60 minutes for the base code (G0019) and 30 minutes for the add-on code (G0020). CMS finalizes there is no frequency limitation for the add-on code as long as the time spent is reasonable and necessary.

CMS agrees with commenters that more than 75 minutes a month may need to be spent on providing CHI services, especially during the first month.

k. Where and how CHI services will be provided. CMS believes that most of the elements of CHI would involve direct contact between the auxiliary personnel and the patient and that a substantial portion would be in-person but some services might be performed via two-way audio.

CMS acknowledges comments that CHI services would be available in person, virtually, or a combination. CMS continues to believe that most services would involve direct contact between the auxiliary personnel and the patient and it does not plan to provide a higher payment for services delivered in person.

l. Patient Consent. CMS did not propose to require consent for CHI because it believes these services typically involve direct patient care and largely provided in-person.

[28] CMS defines community-based organizations as public or private not-for-profit entities that provide specific services to the community or target populations in the community to targeted populations in the community to address the health and social needs of those populations (87 FR 46102).

Most commenters stated that patient consent should be obtained prior to initiating services for CHI so the patient can be informed of the services being provided, in addition to potential co-insurance and cost sharing requirements. Commenters recommended CMS allow the patient to provide a verbal consent. A few commenters disagreed with requiring consent but stated if CMS required consent it should consider verbal consent or consent as part of the annual consent treatment. In response to comments, CMS notes that it does not have the statutory authority to waive cost sharing for care management or other services.

After consideration of comments, CMS finalizes that patient consent is required in advance of providing CHI services. Consent may be obtained either in writing or verbally, as long as the consent is documented in the medical record. Consent may be obtained by auxiliary personnel and a new consent must also be obtained if there is a change in the billing practitioner. The consent process must include explaining to the patient that cost sharing applies and that only on practitioner may furnish and bill the services in a given month.

m. Similar services provided by other payers.
In the proposed rule, CMS sought comments about whether States typically cover services similar to CHI under their Medicaid programs and would coverage of the CHI service codes be duplicative.

Some commenters stated that most State Medicaid programs do not directly cover CHI services and that States that do bill for CHW services have insufficient and unsustainable reimbursement rate. Commenters also stated that as compared to Medicaid, the Medicare proposal takes a more holistic approach and address all pertinent SDOH impacting a beneficiary's medical condition.

iii. CHI Services Valuation

For G0019, CMS finalizes its proposal of a work RVU of 1.00 based on a crosswalk to CPT code 99490 (Chronic care management) , including a crosswalk for direct PE inputs. For G0020, CMS finalizes a work RVU of 0.70 based on a crosswalk to CPT code 99439 (Chronic care management, each additional 20 minutes of time), including a crosswalk for direct PE inputs.

Most commenters were supportive of the proposed crosswalks and code valuations. Several commenters suggested that every subsequent 20 minutes of CHI services up to 60 minutes should have a separate HCPCS code and have an equivalent RVU crosswalk to CPT code 99490. In response, CMS believes CHI services would typically take longer than 20 minutes per month and that it continues to believe that 60 minutes promotes the comprehensiveness and integrity of the service. CMS will monitor the utilization of these codes and consider any changes in possible future rulemaking.

In response to comments requesting CHI (and other services addressing health-related social needs) be excluded from budget neutrality, CMS reiterates that the statute requires that increases or decreases in RVUs may not cause the amount of Medicare Part B expenditures for the year to differ by more than $20 million from what expenditures would have in the absence of these changes. There is no statutory exception available for CHI services.

c. Social Determinants of Health (SDOH) – HCPSC Code G0136

i. Proposed Risk Assessment Code

CMS finalizes its proposal for a HCPCS code to identify and value the work involved administering a SDOH risk assessment as part of a comprehensive social history when medically reasonable and necessary.

CMS finalizes HCPCS code *G0136, Administration of a standardized evidence based SDOH Risk Assessment, 5-15 minutes, not more often than every 6 months*.

CMS proposed the following requirements:

- The SDOH risk assessment must be furnished by the practitioner on the same date they furnish an E/M visit. The SDOH assessment would be reasonable and necessary when used to inform the patient's diagnosis and treatment plan established during the visit.
- The assessment includes administration of a standardized, evidence based[29] SDOH risk assessment tool that has been tested and validated through research and includes the domains of food insecurity, housing insecurity, transportation needs, and utility difficulties.[30]
    - Billing practitioners may choose to assess for additional domains.
- SDOH needs identified through the risk assessment must be documented in the medical record and may be documented using ICD-10 Z-codes (Z55-Z65).
- Limit the SDOH assessment service to once every 6 months.

CMS believes appropriate follow-up is necessary to mitigate the effects of the identified SDOH on a person's health. CMS also sought comments on whether it should require as a condition of payment for SDOH risk assessment that the billing practitioner also have the capacity to furnish CHI, PIN, or other care management services, or have partnerships with community-based organizations to address identified SDOH needs.

Responses/Comments. Commenters were overall supportive of CMS' definition of SDOH; several commenters requested that CMS use consistent naming conventions and noted that many other CMS programs use social drivers of health. A few commenters opposed the proposal because it was duplicative of the E/M coding structure which allows reporting a higher code to capture increased intensity services, such as when SDOH considerations are present.

CMS acknowledges there are many definitions and names for similar assessments and it shares the desire to align naming conventions across programs. CMS notes that many definitions have slight differences in their intent or meaning. For this service, CMS used the SDOH as defined by

[29] https://health.gov/healthypeople/tools-action/browse-evidence-based-resources/types-evidenc-based-resources.
[30] Possible evidence-based tools include the CMS Accountable Health Communities tool (https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf.), the Protocol for Responding to & Assessing Patients' Assets, Risks & Experiences (https://www.nachc.org/research-and-data/prepare/.) , and instruments identified for MA Special Needs Population Health Risk Assessment (CMS-10825)

the CPT coding guidelines. CMS continues to believe this code represents work that is not currently accounted for.

CMS does not agree with commenters who stated that this type of information will impose surveillance data gathering that is intrusive to patients. The information collected could be sensitive in nature, and might be perceived as intrusive to some beneficiaries, but the information is already being collected in some medical settings and is important to the health care patients receive. CMS notes it is not proposing new forms of data collection, but seeking to acknowledge this work through payment.

Same day as an E/M visit requirement. CMS received many comments related to the proposed requirement that SDOH risk assessment must be furnished the same day as the E/M visit. Commenters cited operational difficulties in performing the assessment during the visit. Some commenters requested that clinical psychologists be allowed to furnish SDOH risk assessment and that the assessment should be billable with CPT code 90791 and health behavior and assessment intervention (HBAI) codes. Some commenters requested clinical social workers be added to the list of practitioners who can perform risk assessment.

In response, CMS emphasizes that the service is for SDOH risk assessment, not screening. It is intended to be used when a practitioner has reason to believe there are unmet SDOH needs that are interfering with the practitioner's diagnosis and treatment of a condition or illness. CMS believes that there a limited scenarios where a clinician may wish to get an SDOH risk assessment during pre-check-in paperwork. CMS does not believe that all practitioners who can bill Medicare should qualify to perform the SDOH risk assessment, but it does believe that practitioners who can bill E/M or similar behavioral health visits can provide follow-up and assessment in a longitudinal way.

Settings for a SDOH risk assessment. Several commenters requested clarification of the settings in which a SDOH risk assessment can occur, including emergency department, observation unit, during the perioperative period and as part of the E/M visit of TCM. CMS is concerned about paying for an SDOH risk assessment upon every interaction with the health care system, but agrees that it could be beneficial with hospital discharge planning, with the E/M visit of TCM, and in an outpatient setting.

Standardized, evidence-based SDOH risk-assessment tool. Commenters were generally supportive of this requirement and appreciated the operational flexibility of CMS not requiring a specific tool. A few commenters requested CMS specify one specific tool and a few commenters requested CMS only accept tools that meet ONC interoperability standards. Commenters were in favor of requiring the use of a tool which includes the specified domains and the option to add additional domains as relevant. CMS appreciates these comments. Because there is not a national consensus around one specific tools, CMS believes it is appropriate to have practitioners choose the tool that fits their needs.

Follow-up. Commenters were mixed on the potential requirement to furnish follow-up care for SDOH risk assessment. Many agreed it was a reasonable requirement but others discussed that operational limitations of practitioners who do not have the appropriate resources in place for

follow-up. CMS clarifies it is focused on SDOH risk assessment to identify issues that impact the practitioner's ability to diagnose and treat the patient. CMs will reevaluate this decision on an ongoing basis.

Frequency. Many commenters noted operational difficulties if the frequency limitation was per beneficiary because beneficiaries often have many practitioners across different health systems and lack the ability to verify if a patient had received an SDOH risk assessment in the last 6 months. Other commenters noted a new diagnosis may cause a rapid shift in SDOH needs. CMS appreciates these concerns but states it also needs to consider the patient's cost sharing responsibilities each time the service is furnished separately from the AWV. CMS will continue to evaluate this issue.

Final Rule Action: After consideration of comments, CMS finalizes, with modifications, its proposed requirements:

- The SDOH risk assessment is furnished in association with an outpatient E/M visit (other than a level 1 visit by clinical staff), the AWV, with CPT code 90791 (Psychiatric diagnostic evaluation) and the HBAI services (CPT codes 96156, 96158, 96159, 96164, 96165, 96167, and 96168)
    - The SDOH risk assessment may also be furnished with hospital discharge visit and the E/M visit of TCM.
    - The SDOH risk assessment can be billed in outpatient settings.
- The SDOH assessment would be reasonable and necessary when used to inform the patient's diagnosis and treatment plan established during the visit.
- The assessment includes administration of a standardized, evidence based[31] SDOH risk assessment tool that has been tested and validated through research and includes the domains of food insecurity, housing insecurity, transportation needs, and utility difficulties.[32]
    - Billing practitioners may choose to assess for additional domains.
- SDOH needs identified through the risk assessment must be documented in the medical record and may be documented using ICD-10 Z-codes (Z55-Z65).
- Limit the SDOH assessment service to once every 6 months.

CMS does not finalize the requirement that the SDOH risk assessment must be performed on the same date as the associated E/M or behavioral health visit. This is consistent with the policy when HCPCS code G0136 is performed in conjunction with an AWV, as the AWV may be split over two visits (discussed in section III.S.)

CMS also does not finalize a requirement that the practitioner who furnishes the SDOH risk assessment must also have the capacity to furnish CHI, PIN, or other care management services, or have partnerships with CBOs. CMS does expect that the practitioner would refer the patient to

---

[31] https://health.gov/healthypeople/tools-action/browse-evidence-based-resources/types-evidenc-based-resources.

[32] Possible evidence-based tools include the CMS Accountable Health Communities tool (https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf.), the Protocol for Responding to & Assessing Patients' Assets, Risks & Experiences (https://www.nachc.org/research-and-data/prepare/.) , and instruments identified for MA Special Needs Population Health Risk Assessment (CMS-10825)

relevant resources and take into account the results of the assessment in their medical decision making, or diagnosis and treatment plan for the visit.

ii. Valuation for SDOH Risk Assessment (HCPCS Code G0136)

CMS finalizes its proposal to directly crosswalk this service to HCPC code G0444 (Screening for depression, 5-15 minutes) with a work RVU of 0.18, including a crosswalk for the direct PE inputs.

CMS also finalizes its proposal to add this code to the Medicare Telehealth Services List.

In response to comments, CMS agrees that the time spent performing HCPCS code G0136 can count towards the 60 minutes per month spent in the performance of PIN services.

d. Principal Illness Navigation (PIN) Services

In the proposed rule, CMS discussed the findings of navigation experts demonstrating the benefits of navigation services for patients needing treatment for cancer and other high-risk, serious illnesses. In healthcare, navigation refers to providing individualized help to the patient (and caregiver, if applicable) to identify appropriate practitioners and providers for care needs and support, and access necessary care timely, especially when the delaying care can be deadly.

CMS notes it currently makes separate payment for a number of care management and other services that may include aspects of navigation services but these services are focused heavily on clinical aspects of care rather than social aspects. CMS also believes these services are generally performed by auxiliary personnel who may not have lived experience or training in the specific illness being addressed.

For 2024, CMS proposed new coding for navigation services, PIN services. CMS notes that PIN services are similar to CHI services but PIN services focus on patients with a serious, high-risk illness who may not have SDOH needs. PIN also includes services to refer patient to appropriate supportive services, provide information about clinical trials, and includes lived experience or training for the specific condition being addressed. The reader will note many similarities between these sections of the summary.

i. PIN Service Codes

CMS proposed two HCPCS codes, G0023 and G0024. As discussed below, CMS finalizes an additional set of PIN codes, G0140 and G0146, for Principal Illness Navigation – Peer Support (PIN-PS). CMS notes that where it refers to PIN, it means all the associated finalized PIN codes (HCPCS codes G0023, G0024, G0140, and G0146). CMS will specifically indicate if there are items that do not apply to all PIN codes.

CMS finalizes the proposed code descriptor for G0023 with a modification. In response to comments, CMS adds the addition of "and including unmet SDOH needs (that are not separately

billed)" as part of the person-centered assessment in G0023. CMS finalizes the proposed code descriptor for G0023.

G0023: *PIN services performed by certified or trained auxiliary personnel under the direction of a physician or other practitioner; including a patient navigator or certified peer specialist; 60 minutes per calendar month, in the following activities:*

- Person-centered assessment, performed to better understand the individualized context of the serious, high-risk condition.
    - Conducting a person-centered assessment to understand patient's life story, strengths, needs, goals, preferences and desired outcomes, including understanding cultural and linguistic factors and including unmet SDOH needs (that are not separately billed).
    - Facilitating patient-driven goal-setting and establishing an action plan.
    - Providing tailored support to the patient as needed to accomplish the practitioner's treatment plan.
- Identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services.
- Practitioner, Home- and Community-Based Care Coordination
    - Coordinating receipt of needed services from healthcare practitioners; providers and facilities; and from home- and community-based service providers, social service providers, and caregiver (if applicable).
    - Communication with practitioners, home- and community-based service providers, hospitals, and skilled nursing faculties (SNFs) (or other facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.
    - Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges form hospitals, SNFs or other health care facilities.
    - Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) to address the SDOH need(s).
- Health education- Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, and preferences, and SDOH need(s), and educating the patient (and caregiver if applicable) on how to best participate in medical decision-making.
- Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services (as needed), in ways that are more likely to promote personalized and effective diagnosis or treatment.
- Health care access/health system navigation
    - Help the patient access healthcare, including identifying appropriate practitioners or providers for clinical care and helping secure appointments with them.
    - Provide the patient with information/resources to consider participation in clinical trials or clinical research as applicable.

- Facilitate behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.
- Facilitating and providing social and emotional support to help the patient cope with the condition, SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.
- Leveraging knowledge of the serious, high-risk condition and/or lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.

G0024: *PIN services, each additional 30 minutes per calendar month (List separately in addition to G0023)*

In response to comments, CMS finalizes an additional set of PIN codes, G0140 and G0146, for Principal Illness Navigation – Peer Support (PIN-PS).

G0140: *PIN services – 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:*

- Person-centered assessment, performed to better understand the individualized context of the serious, high-risk condition.
    - Conducting a person-centered assessment to understand patient's life story, strengths, needs, goals, preferences and desired outcomes, including understanding cultural and linguistic factors and including unmet SDOH needs (that are not separately billed).
    - Facilitating patient-driven goal-setting and establishing an action plan.
    - Providing tailored support to the patient as needed to accomplish the practitioner's treatment plan.
- Identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services.
- Practitioner, Home- and Community-Based Care Coordination
    - Assist the patient in communicating with practitioners, home- and community-based service providers, hospitals, and skilled nursing faculties (or other facilities) regarding the patient's psychosocial strengths and needs, goals, preferences, and desired outcomes, including cultural and linguistic factors.
    - Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) to address the SDOH need(s).
- Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services (as needed), in ways that are more likely to promote personalized and effective treatment of their condition.
- Developing and proposing strategies to help meet person-centered treatment goals and supporting the patient in using chosen strategies to reach person-centered treatment goals.
- Facilitating and providing social and emotional support to help the patient cope with the condition, SDOH need(s), and adjust daily routines to better meet person-centered diagnosis and treatment goals.

- Leveraging knowledge of the serious, high-risk condition and/or lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.

G0024: *PIN services – Peer Support, each additional 30 minutes per calendar month (List separately in addition to G0140)*

*ii. PIN Requirement*s

CMS notes that where it refers to PIN, it means all the associated finalized PIN codes (HCPCS codes G0023, G0024, G0140, and G0146). CMS indicates if there are items that do not apply to all PIN codes. CMS finalizes the following requirements:

a. Characteristics of a serious high-risk condition/illness/disease. CMS finalizes a high-risk condition/illness/disease has the following characteristics:

- One serious, high-risk condition expected to last at least 3 months and that places the patient at significant risk of hospitalization, nursing home placement, acute exacerbation/decompensation, functional decline, or death;
- The condition requires development, monitoring or revision of a disease-specific care plan and may require frequent adjustment in the medication or treatment regimen, or substantial assistance from a caregiver.

Examples include, but are not limited to, cancer, chronic obstructive pulmonary disease, congestive heart failure, dementia, HIV/AIDS, severe mental illness, and SUD.

CMS received many comments requesting clarification of the characteristics of a serious, high-risk condition. CMS responds that the definition of a serious, high-risk condition is dependent on clinical judgement. The list of conditions CMS provided was illustrative and it will monitor utilization across beneficiaries and specialties to ascertain where and how PIN services are being utilized. CMS disagrees with requests to not limit PIN to conditions expected to last at least 3 months. CMS believes that an expected 3 month period is a reasonable benchmark because it believes PIN services are necessary to treat serious, high-risk conditions that require navigation over several months.

Several commenters requested clarification on whether PIN services could start before a definitive diagnosis; commenters stated that for some types of cancer, a definitive diagnosis requires a surgical intervention. CMS agrees with commenters and notes that its definition of a "high risk condition" does not exclude conditions without a definitive diagnosis. CMS clarifies that a definitive diagnosis is not required before the practitioner makes a clinical determination that the patient has a serious high-risk condition.

b. PIN initiating visit. PIN services could be furnished monthly, as medically necessary, following an initiating E/M visit (referred to as the PIN initiating visit). CMS proposed the PIN initiating visit would be an E/M visit (other than a low-level E/M visit that can be performed by clinical staff) performed by the billing practitioner who will also be furnishing the PIN services

during the subsequent calendar month(s). The billing practitioner would identify the medical necessity of PIN services and establish an appropriate treatment plan.

- CMS believes that certain types of E/M visits, such as inpatient/observation services, ED visits and SNF visits would not typically serve as PIN initiating visits because the practitioner furnishing these E/M settings would not typically be providing PIN services.
- The PIN initiating visit would be separately billed (if all requirements are met).
- The PIN initiating visit would be a pre-requisite to billing for PIN services.

Similar to the CHI initiating visit, commenters recommended that CMS should not restrict the PIN initiating visit to E/M visits. CMS agrees with commenters that clinical psychologists should be able to bill PIN codes, especially for those with behavioral health conditions. CMS also agrees with commenters that the initiating visit for PIN services could be considered the E/M visit done as part of TCM and the AWV. CMS again notes that the AWV could only qualify when it is furnished by a physician or provider that can bill for E/M services. CMS notes that there is no benefit under the PFS for facility settings in accordance with the "incident to" regulation at §410.26. Since PIN services are provided under incident to regulations, inpatient/observation E/M visits and ED visits cannot serve as the initiating visit for PIN.

CMS finalizes its proposal with modifications. The PIN initiating visit can be an E/M visit (other than a low-level E/M visit that can be performed by clinical staff), the E/M visit that is part of TCM, and the AWV when the service is furnished by a practitioner who has identified in the AWV a high-risk condition(s) that would qualify for a PIN service. In addition, CPT code 90791 (Psychiatric diagnostic evaluation) and the HBAI services described by CPT codes 96156, 96158, 96159, 96164, 96165, 96167, and 96168 as initiating visits for PIN services.

c. Subsequent PIN services. Subsequent PIN services can be performed by other auxiliary personnel incident to the professional services of the practitioner who bills the PIN initiating visit. PIN visits must be furnished in accordance with the "incident to" regulation at §410.26.

- An initiating E/M visit every month that PIN services are billed is not required.

d. Supervision level. CMS finalizes PIN services as care management services that may be furnished under the general supervision of the billing practitioner. General supervision means the service is furnished under the physician's (or other practitioner's) overall direction and control but their presence is not required during the performance of the service.

e. "SDOH need". For the PIN code descriptor, "SDOH need(s)" means an SDOH need(s) that is identified by the billing practitioner as significantly limiting the practitioner's ability to diagnose or treat the serious, high-risk condition/illness/disease addressed in the initiating E/M visit.

f. "*Problem Addressed*". This term refers to the definition in the CPT E/M Guidelines that CMS adopted for E/M visits.[33]

- A problem is a disease, condition, illness. Injury, symptom, finding, complaint, or other matter addressed at the encounter, with or without a diagnosis being established at the time of the encounter."

[33] 2023 CPT codebook, p. 6-8.

- A problem is addressed or managed when it is evaluated or treated at the encounter by the physician or other qualified health care professional reporting the service. This includes consideration of further testing or treatment that may not be elected by virtue of risk/benefit analysis of patient/parent/guardian/surrogate choice.
    - Notation in patient's medical record that another professional is managing the problem without additional assessment or care coordination does not qualify as addressing or managing the problem.
    - Referral without evaluation does not qualify as being addressed or managed.

f. SDOH. SDOH means economic and social condition(s) that influence the health of people and communities, as indicated in the CPT E/M Guidelines.[34] In addition to the CPT examples of SDOH, as indicated in the CPT E/M Guidelines,[35] CMS finalizes that SDOH's may include but are not limited to food insecurity, transportation economic and social condition(s) that influence the health of people and communities. In addition to the CPT examples, CMS finalizes that SDOH's may include but are not limited to food insecurity, transportation insecurity, housing insecurity, and unreliable access to public utilities, when they significantly limit the practitioner's ability to diagnose or treat the problem(s) addressed in the PIN initiating visit. CMS notes that since Medicare payment generally is limited to items and services that are reasonable and necessary for the diagnosis or treatment of illness or injury, PIN services need to address the particular SDOH(s) that are interfering with, or presenting a barrier to, diagnosis or treat the patient's problem(s) addressed in the PIN initiating visit.

g. Peer Support. CMS received many comments from the peer support community supporting CMS' proposal to include certified peer support specialists in the code descriptor for PIN services. Commenters provided many recommendations about how to improve the description of peer support services in the code descriptors including removing care coordination descriptors to align these services with peer support competencies. Commenters also discussed the challenges that peer support specialists encounter including misinformation about their roles and the lack of experience that clinicians have working with peer support specialists.

CMS appreciates all the recommendations and is sympathetic to the nuances of the interactions between peer support specialists and clinicians. CMS clarifies that its intention in creating the PIN service elements was to include a navigation role for certified peer support specialists in treating serious, high-risk conditions, including severe mental illness and SUD.

After consideration of comments, CMS finalizes two new codes for PIN-PS (HCPCS code G0140 and G0146.

h. Certified or trained auxiliary personnel. CMS finalizes that PIN services must be certified or trained to perform all included service elements, and authorized to perform them under applicable State laws and regulations. Under §410.26(a)(1) , auxiliary personnel must meet any applicable requirements to perform the services performed incident to the billing practitioner's professional services, including licensure, that are imposed by the State in which the services are

[34] 2023 CPT codebook, p. 11.
[35] 2023 CPT codebook, p. 11.

being furnished. In states where there are no applicable licensure or other laws and regulations related to individuals performing PIN services, auxiliary personnel providing PIN services would need to be trained.

- Where applicable, CMS defers to State requirements for all types of auxiliary personnel.
- For States with no applicable State requirements, training must include the competencies of patient and family communication, interpersonal and relationship building, patient and family capacity-building, service coordination and system navigation, patient advocacy, facilitation, individual and community assessment, professionalism and ethical conduct, and the development of appropriate knowledge base, including special certification or training on the serious, high-risk condition/illness/disease addressed in the initiating visit.
- For PIN-PS, if no applicable State requirement exists, the training must be consistent with the National Model Standard for Peer Support Certification published by SAMHSA.

Commenters had various suggestions about the time required for training. CMS does not finalize a required number of hours of training for auxiliary personnel to provide PIN services.

CMS received many comments about the training and certification requirements for certified peer support specialists. Commenters requested CMS not require any additional training for peer support specialists beyond State certification. A few commenters recommended CMS mandate training alignment with the SAMHSA National Model Standards. CMS incorporates these recommendations in its final policy.

i. Documentation. CMS finalizes that the time spent furnishing PIN must be documented in the patient's medical record in its relationship to the serious, high-risk illness. Documentation would include the activities performed by the auxiliary personnel, just as all clinical care is documented in the medical record.

- If present, the SDOH(s) need to be recorded in the patient's medical record.
- For data standardization, practitioners would be encouraged to record the associated ICD-10 Z code (Z55-Z65) in the medical record and on the claim.

j. Billing practitioner's arrangement with auxiliary personnel. A billing practitioner may arrange to have PHI services provided by auxiliary personnel who are external to, and under contract with the practitioner or their practice. This contract could be with a community-based organization[36] that employs CHWs, if all of the incident to and other requirements and conditions for payment of PIN services are met.

- CMS stresses that PIN services performed by auxiliary personnel under a contract with a third party requires sufficient clinical integration between the third party and the billing practitioner in order for the services to be fully provided, and the connection between the patient, auxiliary personnel and the billing practitioner must be maintained.
- CMS expects the auxiliary personnel performing the PIN services to communicate regularly with the billing practitioner, continue to involve the billing practitioner in

[36] CMS defines community-based organizations as public or private not-for-profit entities that provide specific services to the community or target populations in the community to targeted populations in the community to address the health and social needs of those populations (87 FR 46102).

evaluating the continuing need for PIN services, and ensure proper documentation in the medical record.

k. Frequency of billing.
CMS proposed only one practitioner per beneficiary per calendar month could bill for PIN services. A practitioner could separately bill for other care management services during the same month as PIN services if time and effort are not counted more than once and requirements to bill other care management services are met.

Commenters had various suggestions about requiring a new initiating visit at various time frames. CMS finalizes that a new initiating visit must be conducted once per year.

Many commenters asked for clarification about the billing limitation by one practitioner. Commenters notes that a patient may be receiving PIN for one condition and get diagnosed with another illness or condition that also meets PIN criteria. CMS responds that its intention was to limit PIN services to one per month per beneficiary because of concerns about care fragmentation. CMS acknowledges that patients can have multiple principal illnesses at a time and that some types of navigation, such as peer support and oncology navigation are very condition-specific. CMS is still concerned about the duplication of time and effort if the same practitioner bills two kinds of PIN services for the same beneficiary.

After consideration of comments, CMS finalizes that PIN services can be provided more than once per practitioner per month for any single serious high-risk condition. CMS does not expect a patient to require multiple PIN for a prolonged period of time, except in circumstances in which a patient is receiving PIN services for highly specialized navigation, such as behavioral health or oncology. CMS also clarifies that PIN and PIN-PS should not be billed concurrently for the same serious, high-risk condition. Practitioners may furnish PIN services and care management services as appropriate for managing and treating a patient's illness; the time furnished for PIN services and other care management services cannot be counted more than once.

l. Time and duration of PIN services.
CMS finalizes 60 minutes for the base code (G0023 and G0140) and 30 minutes for the add-on code (G0024 and G0146). CMS finalizes there is no frequency limitation for the add-on code as long as the time spent is reasonable and necessary.

CMS agrees with commenters that the time requirements for navigation will vary across conditions and that the duration will average 3-6 months depending on the condition. In response to comments requesting 20 minute intervals for the base code, CMS states that if a patient requires less than 60 minutes per month for PIN services, then their needs may be best addressed by other types of care management services.

m. Where and how PIN services will be provided. CMS believes that most of the elements of PIN would involve direct contact between the auxiliary personnel and the patient and that a substantial portion would be in-person but some services might be performed via two-way audio.

Commenters discussed how patients in rural areas and immunocompromised patients benefit from not requiring face-to-face contact. Commenters did not directly discuss the current amount of time spent each month furnishing navigation services in person versus the amount of time spent using telecommunications. CMS also did not receive comments discussing the amount of time navigators spend performing activities on behalf of the patient without the patient being present. CMS agrees with commenters that PIN services will likely benefit from the use of two-way audio or audio-visual technology but it cannot make the determination that all PIN services meet the standards of services that are inherently in-person services that are instead furnished using an interactive telecommunications system as described in §410.78(1)(3). CMS does not finalize PIN services on the Medicare Telehealth Services List. CMS will consider this issue for future potential rulemaking.

n. Patient Consent. CMS did not propose to require consent for PIN because it believes these services typically involve direct patient care and largely provided in-person. CMS notes that it does not have the statutory authority to waive cost sharing for care management or other services.

Similar to CHI, most commenters stated that patient consent should be obtained prior to initiating services for PIN so the patient can be informed of the services being provided, in addition to potential co-insurance and cost sharing requirements. Commenters recommended CMS allow the patient to provide a verbal consent. A few commenters disagreed with requiring consent but stated if CMS required consent, it should consider verbal consent or consent as part of the annual consent treatment. In response to comments, CMS notes that it does not have the statutory authority to waive cost sharing for care management or other services.

After consideration of comments, CMS finalizes that patient consent is required in advance of providing PIN services. Consent may be obtained either in writing or verbally, as long as the consent is documented in the medical record. Consent may be obtained by auxiliary personnel and a new consent must also be obtained if there is a change in the billing practitioner. The consent process must include explaining to the patient that cost sharing applies and that only on practitioner may furnish and bill the services in a given month. CMS also finalizes that consent must be obtained annually.

iii. PIN Services Valuation

For G0023, CMS finalizes its proposal of a work RVU of 1.00 based on a crosswalk to CPT code 99490 (Chronic care management), including a crosswalk for direct PE inputs. CMS finalizes the same work RVUs and direct PE inputs for G0140. For G0024, CMS finalizes a work RVU of 0.70 based on a crosswalk to CPT code 99439 (Chronic care management, each additional 20 minutes of time), including a crosswalk for direct PE inputs. CMS finalizes the same work RVUs and direct PE inputs for G0146.

(29) Maternity Services (CPT codes 59400, 59410, 59425, 5926, 59430, 59510, 59515, 59610, 59614, 59618, 59622)
In 2021, CMS finalized ta decision to revalue the bundled maternity codes used to bill for delivery, antepartum, and postpartum maternity services to account for increases in the values of

office/outpatient E/M services. For 2024, CMS proposed to update the work RVUs and work times of maternity services to reflect any relevant E/M updates associated with their global period that were finalized in 2023.

Commenters supported this proposal and identified a technical error for calculating the time increase. CMS appreciates identification of this potential technical error and acknowledges that incorrect work time values were used in the proposed rule. CMS uses correct work times in the final rule and finalizes these new work values for 2024. (Table 13).

F. Evaluation and Management (E/M) Visits

1. Background

E/M visits account for approximately 40 percent of all allowed charges under the PFS; approximately 20 percent is associated with office/outpatient (O/O) E/M visits and approximately 20 percent is associated with Other E/M visits (such as inpatient/observation visits, nursing facility visits, and home/residence visits). E/M visits are furnished by nearly all specialties, but represent a greater share of total allowed charges for physicians and other practitioners who do not routinely furnish procedural interventions or diagnostic tests.

CMS reviews its multi-year effort with the AMA and other interested parties to update coding and payment for the E/M visits. Effective January 1, 2021, the CPT Editorial Panel redefined the O/O E/M visit code family such that the visit level is based on the amount of time spent performing the visit or the level of medical decision-making (MDM). In addition, history and a physical exam are no longer required elements or used to select the O/O E/M level. CMS generally adopted these codes and changes in the documentation guidelines but it did not accept the revisions for the prolonged O/O services. CMS created HCPCS G2212 for reporting prolonged O/O E/M services. CMS also created add-on code G2211 (O/O E/M visit complexity) that could be reported in conjunction with O/O E/M visits to account for resources related to a patient's single, serious, or complex chronic condition(s). The CAA, 2021 imposed a moratorium on Medicare payment for G2211 before January 1, 2024. Although the O/O E/M visit complexity add-on code can be reported, it is currently assigned a bundled payment status indicator.

In 2023, the CPT Editorial Panel revised the remaining E/M visit code families (except critical care services) to match the general framework of the O/O E/M visits. CMS refers to these other E/M visit code families as "Other E/M" visits or CPT codes. "Other E/M" visits include inpatient and observation visits, emergency department visits, nursing facility visits, domiciliary or rest home visits, home visits, and cognitive impairment assessment. Specifically, effective January 1, 2023, the visit level is based on the amount of time spent performing the visit or the level of MDM. In addition, history and a physical exam are no longer determine the E/M level. This revision also consolidated the Other E/M codes by combining inpatient and observation visits into a single code set and also combining home and domiciliary visits into a single code set; this reduced the Other E/M CPT codes from approximately 75 to approximately 50.

2. Office/Outpatient (O/O) E/M Visit Complexity Add-on Implementation

The O/O E/M visit complexity add-on code (G2211) describes intensity and complexity inherent to O/O E/M visits associated with medical care services that serve as the continuing focal point for all needed health care services and/or medical care services that are a part of ongoing care related to a patient's single, serious, or complex condition (85 FR 84569-84571).

a. Proposal for O/O E/M Visit Complexity Add-on HCPCS code G2211

During the CAA, 2021 moratorium, interested parties made recommendations regarding implementation and potential refinement to this service. Recommendations ranged from delaying implantation to speedy implementation. Some commenters also recommended ways to clarify the intended use of the code, which could reduce redistributive impacts. In the 2021 PFS final rule, CMS assumed that specialties relying on O/O E/M visit codes to report the majority of their services would likely report the O/O E/M visit complexity add-on code with every O/O E/M visit they reported (85 FR 84572).

CMS finalizes its proposal to change the status of HCPCS code G2211 to make it separately payable by assigning the "active" status indicator, effective January 1, 2024. CMS also finalizes its proposals for several policy refinements, including refinements of its utilization assumptions.

CMS finalizes its proposal that the G2211 would not be payable when the O/O E/M visit is reported with payment modifier -25 (denotes a separately billable E/M service by the same practitioner furnished on the same day of a procedure or other service. In the 2021 PFS final rule CMS stated it would not expect G221 to be reported when the O/O E/M service is reported with modifier -25 but did not preclude reporting G2211.

In the proposed rule, CMS refined its previous utilization assumptions. CMS discussed prior comments and recent feedback it received indicating that many practitioners delivering care in settings designed to address acute health care needs, without coordination or follow-up, will regularly have encounters with patients that are not part of continuous care. CMS provided examples of encounters provided by a professional whose relationship with the patient is a discrete, routine, or time-limited; such as a mole removal, counseling related to seasonal allergies and treatment for a fracture.

CMS estimated that HCPCS code G2211 will initially be billed with 38 percent of all O/O E/M visits initially. CMS took into account the likelihood that primary care specialties will have a higher utilization of the add-on code than other specialties and surgical specialties will have the lowest utilization since they are less likely to establish longitudinal care relationships. CMS revised its estimate by excluding (1) claims from practitioners participating in CMS capitated models, and (2) claims for established patient visits by certain specialties that are unlikely to have a longitudinal care relationship with a beneficiary. CMS also excluded visits that it considered as consults or for the purpose of obtaining a second clinical opinion.

CMS estimated that when fully adopted, G2211 will be billed with 54 percent of all O/O E/M visits.

Comments/Responses
MedPAC appreciated CMS' focus on ensuring that E/M services are accurately paid and stated that longstanding misvaluations in the fee schedule resulted in overvaluation of non-E/M services and had a detrimental impact on accurate primary care valuation. However, MedPAC did not support payment for the add-on code because there is too much ambiguity regarding the code's use and the assumed resource costs. MedPAC and other commenters were concerned that without further clarification, the code would likely be misused and could potentially duplicate payment for other services, such as the care management services. Similarly, many commenters questioned how the complexity add-on code would reflect additional work and some commenters asserted that the code is duplicative because the selection of a visit level by MDM and/or time allows incorporation of a patient visit requiring unusual resources.

In response, CMS states the inherent complexity code will address longstanding issues with coding and valuation of O/O E/M services that do not fully account for resource costs for primary care and other longitudinal care for complex care for visits associated with longitudinal, non-procedural care. CMS acknowledges that many commenters disagree with its assertions that under recognition in coding and valuation of resources in primary and nonprocedural care are an inherent part of the coding and valuation system. CMS believes that because E/M codes are used very broadly, the complexity of services required to provide this type of care is not fully incorporated in the valuation of the work RVUs when the E/M code by itself is used as the primary way to report professional work. Specifically, because many physicians rely on procedural codes with work RVUs that account for their particular expertise and the intensity associated with furnishing care, CMS believes the expertise of those who predominately rely on E/M services is underrecognized in the E/M coding and valuation structure. CMS does not believe the inherent complexity code is duplicative of care management services because the inherent complexity recognizes the professional work within the visit and care management codes recognize services that happen outside the visit.

CMS acknowledges that other payment mechanisms could be utilized to address these problems, including changes MedPAC has recommended to Congress. However, CMS believes that it has the obligation to value services as accurately as possible and until changes are made to specifically address the under recognition of the complexity inherent to these kinds of visits, the RVUs continue to undervalue primary and longitudinal, non-procedure care.

Other commenters supported the proposal and provided examples of the additional time, intensity, and practice expense inherent to providing longitudinal care. Commenters noted that primary care physicians may provide care management and coordination services for a condition addressed in an O/O E/M visit that does not meet the requirements for care management services. Commenters provided examples of the complexity inherent in providing primary care including evaluating how each condition and treatment, new symptom or challenge, unmet social needs, and recommended preventive services interact and impact an individual's overall health. CMS appreciates support from these commenters.

After consideration of comments, CMS finalizes its proposal to change the status of HCPCS code G2211 to make it separately payable by assigning it an "active" status indicator, effective January 1, 2024. In addition, CMS clarifies when this code can be used:

- The add-on code is intended to characterize the O/O E/M visit based on the kind of care furnished (medical care that serves 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, or complex condition) to better account for the inherent complexity of these visits that would otherwise be unaccounted for.
- The application of the code is not based on the characteristics of a particular patient but is based on the *relationship* between the patient and the practitioner.
    - The "continuing focal point for all needed health care services" describes a relationship between the patient and the practitioner in which the practitioner is the continuing focal point for all health services the patient needs.
    - The add-on code also describes "medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition". "Ongoing care" describes a longitudinal relationship between the practitioner and the patient.

CMS provides examples of relationships between the patient and the practitioner. In the first example, a patient has a primary care practitioner that is the continuing focal point for all health services and is being evaluated by this practitioner for sinus congestion. CMS states that the inherent complexity is not in the clinical condition, sinus congestion, but rather the cognitive load of the continued responsibility of being the focal point for all needed services for this patient. Specifically, G2211 captures the previously unrecognized cognitive effort of utilizing the longitudinal relationship itself in the diagnosis and treatment plan. CMS discusses how the primary care practitioner must decide what treatment plan would lead to the best health outcome while simultaneously building an effective, trusting longitudinal relationship for the patient's primary health needs. In the second example, CMS discusses the "ongoing care" longitudinal relationship between an infectious disease physician who is following the ongoing care of a patient with HIV.

In response to a commenter providing additional examples, CMS stresses that the most important information used to determine whether or not the add-on code could be billed is the relationship between the practitioner and the patient. CMS also reiterates that this code is not restricted to medical professionals based on particular specialties. It should be used by all medical professionals with O/O E/M visits (except those reported with the -25 modifier) for care that serves 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.

In response to comments about the restrictions related to modifier -25, CMS clarifies that modifier -25 is reported when the physician billing the O/O E/M is the same one billing the significant separately identifiable procedure or other service on the same day. CMS states that it intends to monitor the utilization of the code to ensure that a physician is not performing a service on the same day as the O/O E/M visit to avoid the policy that does not allow payment of G2211 when the visit is reported with modifier -25. CMS appreciates suggestions for other ways to implement this restriction but believes they are all associated with increased administrative burden and would unnecessarily delay activation of the complexity add-on code.

In response to comments disagreeing with CMS' utilization estimates for G2211, CMS believes the additional clarifications discussed in this rule will give providers increased confidence to bill the code appropriately. CMS disagrees with comments recommending aligning utilization estimates with the actual first year utilization of care management codes; it believes the documentation requirements specific to these codes may have contributed to the slower utilization than was estimated for the first year. In response to suggestions that CMS make mid-year retrospective adjustments to the conversion factor, CMS states that it makes budget neutrality calculations on a prospective annual basis.

b. Request for Comment About Evaluating E/M Services More Regularly and Comprehensively

CMS discussed suggestions made for different approaches for valuing services that relies on research and data other than the AMA RUC's specialty-specific valuation recommendations. Some commenters have suggested convening expert panels to independently assess pertinent research and recommended resource recalibrations for updating the PFS relative values.

In the proposed rule, CMS sought comments on the following questions:

a. Do the existing E/M HCPCS codes accurately define the full range of E/M services with appropriate gradations for intensity of services?
b. Are the methods used by the RUC and CMS appropriately to accurately value E/M and other HCPCS codes?
c. Are the current Non-E/M HCPCS codes accurately defined?
d. Are the methods used by the RUC and CMS appropriate to accurately value the non-E/M codes?
e. What are the consequences if services described by HCPCS codes are not accurately defined?
f. What are the consequences if services described by HCPCS codes are not accurately valued?
g. Should CMS consider valuation changes to other codes similar to the approach used for behavioral health (discussed in section II.J.)?

Comments/Responses. In the final rule, CMS provides a specific discussion about each question. In general, many commenters supported the current AMA processes for coding and RVU recommendations and many commenters did not support the current processes. Commenters that supported the AMA coding methodology for E/M and non-E/M codes and the RUC process for recommending RVUs raised concerns about CMS' process for developing codes and payment. Similarly, commenters that did not support the AMA processes for coding and RVU recommendations supported CMS' process for developing codes and payment, especially for E/M codes.

MedPAC reiterated their long-standing problems with the methodology used to determine RVUs which they believe has resulted in certain services (e.g., procedures, imaging, and tests) being overvalued relative to other services (e.g., E/M services). MedPAC believes CMS relies heavily on the RUC recommendations even though the RUC members have a financial interest in setting payment rates. MedPAC recommended that CMS augment the RUC with a standing panel of

experts and continue to support CMS' prior proposal to convert all 10- and 90-day global surgical codes to 0-day global codes and allow postoperative E/M visits to be billed separately.

Some commenters supported addressing the significant administrative burden associated with documentation and billing. Commenters stated they have limited time to participate in data collection; some suggested CMS should explore collecting information from EHRs. A commenter stated that documentation should be utilized for clinical purposes and not to satisfy administrative or billing requirements.

CMS appreciates all the perspectives shared by commenters. It believes its implementation of the inherent complexity add-on code reflects several years of engagement with interested parties to address long-standing concerns about the E/M codes.

CMS also requested comments about the AMA RUC:

- Is the AMA RUC the entity best positioned to provide recommendations to CMS on resource inputs for work and PE valuations?
- Would another independent entity better serve CMS and interested parties in providing these recommendations?

Comments/Responses. Many commenters objected to the questions; commenters stated that any individual or entity, including the RUC can provide recommendations to CMS on resource inputs and work and PE. Several commenters discussed the process used by the RUC and many commenters believed the RUC is best suited for valuing physician services. In contrast, several commenters thought CMS should not consider the RUC as the sole source of knowledge and expertise and encouraged CMS to use additional sources including, another independent entity that would include pharmacists and other clinical staff and expert panels. Commenters raise concerns about the lack of public accessibility to RUC data and requested CMS develop an equitable, accessible, and accurate valuation process.

CMS appreciates the varying perspective and comments on how to best determine inputs for services. CMS will consider all these comments and it considers how to improve the accuracy of valuing services and how it might evaluate E/M services for future rulemaking.

3. Split (or Shared) Visits

In the 2022 PFS final rule[37], CMS finalized a policy for E/M visits furnished in a facility setting, to allow payment to a physician for a split (or shared) visit (including prolonged visits), where a physician and NPP provide the service together and the billing physician personally performed a substantive portion of the visit. CMS finalized a phased in approach to the definition of substantive portion of the visit:

- For 2022, the definition of substantive portion could be one of the follow: history, or exam, or MDM, or more than half of the total time.
- For 2023, CMS finalized that the definition of substantive portion would be limited to more than half of total time for the visit.

[37] 86 FR 65150-65159

For FY 2023, based on continued concerns about the implementation of this policy and requests to recognize MDM as the substantive portion of the visit, CMS delayed implementation of its definition of the substantive portion to more than half of the total time of the visit until January 1, 2024. CMS continued to believe that time is the appropriate basis for the definition of substantive portion of the visit but thought the delay will allow for providers to get accustomed to the new coding and payment changes for Other E/M visits. In addition, the delay allowed additional time to evaluate this policy.

In response to ongoing concerns, CMS proposed to delay the implantation of its definition of the "substantive portion" as more than half of the total time through at least December 31, 2024. For 2024, CMS proposed to maintain the current definition of substantive portion that allows for use of either one of the three key components (history, exam, or MDM) or more than half of the total time spent to determine who bills the visit. CMS also acknowledged that the CPT Editorial Panel was considering revisions to aspects of split or share visits. When available, CMS planned review these changes and consider whether a further implementation delay beyond 2024 is needed.

Most commenters supported the proposed additional year delay. Several commenters noted that the AMA CPT Editorial Panel was in the process of strengthening their guidance for reporting split (or shared) visits using MDM, and this information will be included in the 2024 publication. Commenters asked CMS to adopt the new CPT guidance.

CMS notes that the CPT Editorial Panel revised its guidelines for split (or shared) visits for 2024. After reviewing the revisions in the 2024 CPT codebook publication,[38] CMS agrees with commenters that it should align its definition of substantive portion with the CPT E/M guidelines which defines the "substantive portion" of a split (or shared) visit to mean more than half of the total time spent by the physician and NPP performing the split (or shared) visit, or a substantive part of the medical decision making.

For 2024, CMS finalizes a revision to its definition of "substantive portion" of a split (or shared) visit to include the revisions to the CPT guidelines. Specifically, for Medicare billing purposes the "substantive portion" means more than half of the total time spent by the physician and NPP performing the split (or shared) visit, or a substantive part of the MDM except concerning critical care visits which do not use MDM and only use time. For critical care split (or shared) visits, "substantive portion" continues to mean more than half of the total time by the physician and NPP performing the visit. CMS will revise its regulations at §415.140 to reflect these changes.

G. Geographic Practice Cost Indices (GPCI)

1. GPCI Update

As required by statute,[39] CMS is required to develop separate Geographic Practice Cost Indices (GPCIs) to measure relative cost differences among localities compared to the national average

[38] 2024 CPT Codebook, pg. 6
[39] Section 1848(e)(1)(A) of the Act.

for each of the three fee schedule components: work, PE, and MP. At least every 3 years, CMS is required to review and, if necessary, adjust the GPCIs.[40] If more than 1 year has elapsed since the last date of the last previous GPCI adjustment, the adjustment would be half of the adjustment that otherwise would be made. CMS finalized its proposal in 2023 to update the GPCIs and phase in 1/2 of the latest GPCI adjustment in 2023 and will phase-in the remaining ½ of the adjustment for 2024. The last update had been implemented in 2020 and 2021.

CMS notes that Congress extended the 1.0 work GPCI only through December 31, 2023. Thus the 2024 work GPCIs and summarized GAFs do not reflect the 1.0 work floor. See Addenda D and E to this final rule, which are available on the CMS website under supporting documentation of the 2024 PFS final rule.[41]

2. Calculation of GPCIs in California

Section 220(h) of the PAMA added a new section 1848(e)(6) to the Act that modifies the fee schedule areas used for payment purposes in California beginning in 2017. The statute requires that fee schedule areas used for payment in California must be Metropolitan Statistical Areas (MSAs) as defined and that all areas not located in an MSA must be treated as a single rest-of-state fee schedule area. The resulting modifications to California's locality structure increased its number of localities from 9 under the current locality structure to 27 under the MSA-based locality structure, although for payment the actual number of localities under the MSA-based structure is 32.[42] CMS refers readers to the 2017 PFS final rule (81 FR 80267) for a detail discussion of this issue.

In the 2023 PFS final rule, CMS finalized its proposal to identify the Los Angeles-Long Beach-Anaheim MSA, containing Orange County and Los Angeles County, by one unique locality number, 18, and the San Francisco-Oakland- Berkeley MSA containing San Francisco, San Mateo, Alameda, and Contra Costa counties by one unique locality number, 05. CMS was unable to operationalize these changes for 2023 due to timing constraints relating to the actions and coordination with the various systems maintainers required to effectuate changes to claims processing (87 FR 69621). CMS notes that in the 2023 PFS final rule it stated that it would operationalize these finalized changes for 2024. Thus, it will operationalize these locality number changes for 2024 via instruction to the MACs, and locality numbers 06, 07, and 26 will no longer be used for the PFS starting January 1, 2024. These changes, when operationalized, do not have any payment implications under the PFS because these counties are not transition areas and will receive the same GPCI values, for PFS payment purposes, going forward.

3. Comments

Some commenters highlighted the expiration of the work GPCI floor of 1.0 on December 31, 2023, and expressed concern with the CY 2024 work GPCIs that are calculated without the work

[40] Section 1848(e)(1)(C) of the Act
[41] See https://www.cms.gov/files/zip/cy-2024-pfs-final-rule-addenda.zip
[42] The total number of physician localities is 109 payment localities – 34 statewide areas (one locality for the entire state) and 75 localities in the other 16 states (based on changes to California localities).

GPCI floor in place. They asked that CMS consider a two- or three-year phase in of the work GPCI floor expiration and recalculate the CY 2024 work GPCIs based on a transition period if the statutory floor is allowed to expire. In response, CMS states that the 1.0 work GPCI floor is required by statute and set to expire on December 31, 2023. CMS does not have the authority to extend the 1.0 work GPCI floor beyond this date (only Congress), or to establish a permanent policy to establish the 1.0 work GPCI floor.

CMS did not receive any comments about its planned operationalization of the changes to the California localities that it finalized in the CY 2023 PFS final rule beginning for CY 2024. It is proceeding with implementation as planned for CY 2024.

H. Payment for Skin Substitutes

In the 2023 PFS proposed rule, CMS proposed to bundle skin substitutes into its PFS practice expense payments with the graft application procedures. However, it did not finalize this policy. In the 2024 PFS proposed rule, CMS said 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. As part of this process, CMS did not make any proposals for 2024 but solicited public comments[43] on the following issues:

Sources of Price Information: The proposed rule indicated that CMS has used market research and invoices to develop direct practice costs for medical supplies. It further suggests using average sales price (ASP) reported by skin substitute manufacturers or wholesale acquisition cost to develop direct cost pricing.

Billing Approaches: CMS is considering how to account for the products' variability and resource costs and suggests potentially using a grouping approach like is used under the outpatient prospective payment system (OPPS) to link the cost of the skin substitute to a given procedure code. Another suggested method is crosswalking to a similarly resourced service in order to establish RVUs for the service that includes the skin substitute.

In general, public commenters opposed packaging and paying for skin substitutes as supplies indicating that the concept of the "typical" that is used in the practice expense methodology does not apply to skin substitutes as wound sizes can vary greatly from patient to patient. Some commenters expressed their support for separate payment under the ASP+6 percent methodology citing an OIG report (https://oig.hhs.gov/oei/reports/OEI-BL-23- 00010.asp) that highlighted significant cost savings for Part B if ASP data were to be reported by all skin substitute manufacturers.

There were commenters concerned about the potential payment redistributions that could result from bundling skin substitutes into the application procedure. Other commenters suggested alternative policies such as separate payment for high-cost disposable supplies priced at more

[43] CMS also requested comments on these issues during the 2023 PFS proposed rule when CMS proposed to bundle skin substitutes into PFS payments as a practice expense; for a Town Hall meeting that CMS held this past January; and in the 2024 PFS proposed rule.

than $500 or establishing new codes to describe the more complex wound procedures and larger wounds. CMS will consider the suggestions and concerns raised by commenters to help inform future rulemaking.

I. Supervision of Outpatient Therapy Services, KX Modifier Thresholds, Diabetes Self-Management Training (DSMT) Services by Registered Dietitians and Nutrition Professionals, and DSMT Telehealth Services

1. Supervision of Outpatient Therapy Services in Private Practices

a. Remote Therapeutic Monitoring (RTM) for Physical Therapists and Occupational Therapists in Private Practice

Current regulations[44] for RTM for physical therapists and occupational therapists in private practice require all occupational and physical therapy services to be performed by, or under the direct supervision of, the occupational therapist (OT) or physical therapist (PT), respectively. Thus, OTs and PTs in private practice must directly supervise the provision of RTM services furnished by occupational therapy assistants (OTAs) and physical therapist assistants (PTAs). CMS finalizes its proposal (without modification) to establish an RTM-specific general supervision policy to permit OTs and PTs in private practice to provide general supervision only for RTM services furnished by their OTAs and PTAs. CMS retains the OTPP and PTPP direct supervision requirement for PTs or OTs who are not enrolled as suppliers under the program, clarifying that the RTM general supervision regulations at §§410.59(c)(2) and 410.60(c)(2) apply only to the OTAs and PTAs and does not include unenrolled OTs or PTs.

Commenters were supportive of the proposed policy changes.

b. Comment Solicitation on General Supervision for PTs and OTs in Private Practice

In response to feedback from stakeholders, CMS considered revising the current direct supervision policy for PTs and OTs in private practice of their PTAs and OTAs to general supervision for all physical therapy and occupational therapy services furnished in these private practices at this time. It sought comment on whether changing the PTA and OTA supervision policy from direct supervision to general supervision in the private practice setting could raise safety concerns or cause a change in utilization. With respect to safety concerns, CMS asks whether state laws or policies permit a PTA or OTA to practice without a therapist in a therapy office or in a patient's home; feedback was also sought on whether safety concerns could be addressed by limiting the types of services to be furnished under general supervision or requiring a periodic visit by the PT or OT.

Many commenters supported the general supervision standard because it would align with the level of supervision required of all other Medicare therapy settings and nearly all state practice acts for physical and occupational therapy. They believe it would increase access to services, permit therapists and therapy assistants to work different or overlapping schedules, remove

[44] §§410.59(a)(3)(ii) and 410.60(a)(3)(ii)

additional labor costs, and eliminate potential disruptions in care. Commenters did not believe there are safety concerns with a change to general supervision. Some noted that Medicare regulations already limit the types of services that may be performed by PTAs and OTAs for all settings not just private practice; for example, they may not provide evaluation services, make clinical judgments or decisions, or take responsibility for the service. CMS will take the comments into consideration for possible future rulemaking.

2. KX Modifier Thresholds

Under the proposed rule, CMS would have increased the 2023 KX modifier threshold amount by the most recent forecast of the 2017-based MEI, which was estimated to be 4.5 percent, based on the IHS Global, Inc. (IGI) first quarter 2023 forecast with historical data through the fourth quarter of 2022. Using more recent data, CMS calculates a 4.6 percent increase. However, the MEI of 4.6 percent was not enough to formulate a change to the proposed KX modifier threshold amounts for 2024. Thus, for 2024 the per beneficiary threshold amount is $2,330 for physical therapy and speech-language pathology services combined and $2,330 for occupational therapy services.

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

3. Diabetes Self-Management Training (DSMT) Services Furnished by Registered Dietitians (RDs) and Nutrition Professionals

Stakeholders have raised concerns that the wording of §410.72(d) causes confusion for DSMT entities/suppliers and Part B MACs about whether RD or nutrition professionals must personally provide DSMT services. In response, the agency proposed to clarify in regulations the distinction between when a RD or nutritional professional is personally providing medical nutrition therapy (MNT) services in accordance with the MNT regulations and when they are acting as or on behalf of an accredited DSMT entity and billing for DSMT services that may be provided by a group of other professionals working under an accredited DSMT entity.

CMS finalizes its proposal to amend §410.72(d) to clarify that a RD or nutrition professional must personally perform MNT services and that a RD or nutrition professional may bill for, or on behalf of, the entire DSMT entity as the DSMT certified provider regardless of which professional furnishes the actual education services. It clarifies that, except for DSMT services furnished as, or on behalf of, an accredited DSMT entity, RDs and nutrition professionals can be paid for their professional MNT services only when the services have been directly performed by them.

The comments received were positive. Two commenters recommended that paraprofessionals be specifically included as examples of additional professionals for whom the RD may bill in

DSMT. CMS responds that it limited the professionals named in the clarification of the policy to DSMT team members that the National Standards quality standards recognize to provide services independently, without the supervision of the RD, RN, or pharmacist. Thus, CMS reasons that by naming the RD, RN, and pharmacist, the policy would encompass the paraprofessionals or other individuals who are being supervised in accredited ADA or ADCES DSMT entities.

4. DSMT Telehealth Issues

a. Distant Site Practitioners

Section 1834(m)(4)(E) of the Act specifies that RDs and nutrition professionals can serve as distant site practitioners for Medicare telehealth services. CMS had proposed to codify (at §410.78(b)(2)(x)) billing rules for DSMT services furnished as Medicare telehealth services with a technical modification. The proposed regulatory text would have provided that distant site practitioners who can appropriately report DSMT services furnished in person by the DSMT entity, such as RDs and nutrition professionals, physicians, NPs, PAs, and CNSs, may also report DSMT services furnished via telehealth by the DSMT entity, including when the services are performed by others as part of the DSMT entity. In response to comments, CMS agrees to substitute the term "bill for" for the term "report". As finalized, §410.78(b)(2)(x) reads as follows:

> (x) Any distant site practitioner who can appropriately bill for diabetes self-management training services may do so on behalf of others who personally furnish the services as part of the DSMT entity.

The agency notes that DSMT services are on the Medicare Telehealth Services List, and are subject to the requirements and conditions of payment under section 1834(m) of the Act and §410.78, including originating site and geographic location requirements, when they are in effect.

Almost half of the comments received objected to the omission of outpatient hospitals and pharmacies from the definition of the term distant site practitioner. CMS notes that while outpatient hospitals and pharmacies are recognized as certified providers of DSMT services under section 1861(qq) of the Act and can bill for DSMT services they provide in-person (regardless of which professional furnishes the service), the telehealth statute is clear that only physicians and NPPs listed at section 1842(b)(18)(C) of the Act qualify as distant site practitioners.

b. Telehealth Injection Training for Insulin-Dependent Beneficiaries

Current manual instructions for payment of DSMT require one hour of the 10-hour DSMT benefit's initial training and one hour of the 2-hour follow-up annual training to be furnished in-person to allow for effective injection training when applicable for insulin-dependent beneficiaries. CMS finalizes its proposal (without modification) to revise this policy and allow

the one hour of in-person training (for initial and/or follow-up training), when required for insulin-dependent beneficiaries, to be provided via telehealth.

J. Advancing Access to Behavioral Health

1. Implementation of Section 4121(a) of the Consolidated Appropriations Act, 2023

a. Statutory Background

The CAA, 2023 amended multiple provisions of title XVIII of the Act to provide for a new benefit category[45] under part B of Medicare to cover and pay for marriage and family therapist (MFT) services and mental health counselor (MHC) services. Statutory definitions for the terms marriage and family therapist services, marriage and family therapist, mental health counselor services, and mental health counselors are specified under section 1861(lll) of the Act. Amounts paid under part B for these services are 80 percent of the lesser of the actual charge for the services or 75 percent of the amount determined for payment of a psychologist under Medicare.[46] MFT and MHC services are excluded from consolidated billing requirements under the skilled nursing facility (SNF) PPS.[47] MFTs, MHCs, and other practitioners described in 1842(b)(18)(C) of the Act may not bill the beneficiary for any services for which Medicare makes payment, other than for deductible and coinsurance amounts.

b. Finalized Regulatory Definitions and Changes

To implement the new part B benefit and its related statutory requirements, CMS finalizes several changes to its regulations as follows.

Marriage and Family Therapist; Mental Health Counselor. CMS finalizes its proposal to define an MFT at §410.53 as an individual who:

- Possesses a master's or doctor's degree which qualifies for licensure or certification as an MFT pursuant to state law of the state in which the services are performed;
- After obtaining such degree, has performed at least 2 years or 3,000 hours of clinical supervised experience in marriage and family therapy in an appropriate setting; and
- Is licensed or certified as an MFT by the state in which the services are performed.

CMS finalizes its proposal to define an MHC at §410.54 as an individual who:

- Possesses a master's or a doctor's degree which qualifies for licensure or certification as an MHC, clinical professional counselor, or professional counselor under the state law of the state in which the services are performed;
- After obtaining such a degree, has performed at least 2 years or 3,000 hours of clinical supervised experience in MH counseling in an appropriate setting; and

[45] Section 1861(s)(2)(II) of the Act provides for a new benefit category under part B.
[46] See section 1833(a)(1)(FF) of the Act for payment under part B for MFT services and MHC services. Payment for services of a psychologist is under section 1833(a)(1)(L).
[47] See section 1888(e)(2)(A)(ii) of the Act, as well as the FY 2024 SNF PPS proposed rule (88 FR 21316).

- Is licensed or certified as an MH counselor, clinical professional counselor, or professional counselor by the state in which the services are furnished.

The regulatory definitions for MFTs and MHCs differ from those under section 1861(lll) of the Act by allowing for an individual to perform 3,000 hours of post master's degree clinical supervised experience, instead of the required 2 years specified in statute. The agency notes that some states may require a number of hours of such experience for MFT or MHC licensure which differs from the statutory requirement, and that the regulatory requirements for clinical social workers at §410.73(a)(3)(ii) require 2 years or 3,000 hours of supervised experience.

CMS finalizes its proposals to allow addiction counselors to be considered MHCs and be eligible to enroll in and bill Medicare for MHC services if they meet the criteria under the definition of MHC and to include substance use disorder (SUD) services as mental health services for purposes of such services included in MFT, MHC, clinical social worker (CSW), and clinical psychologist (CP) services.

Pursuant to public comments (discussed below) CMS also clarifies in the final rule that to the extent that addiction counselors and alcohol and drug counselors who furnish services for the diagnosis and treatment of mental illnesses meet all of the statutory and regulatory requirements for education, clinical supervised experience, and state licensure for MHCs, such counselors can enroll in Medicare as MHCs. Also, the agency clarifies that individuals who meet such requirements for education and clinical supervised experience for MHCs, and are licensed to furnish mental health counseling in their state, are eligible to enroll in Medicare as MHCs regardless of the title or terminology used by the state for such licensure to furnish mental health counseling.

Marriage and Family Therapist Services; Mental Health Counselor Services. CMS finalizes its proposal, consistent with statute, to define MFT services at §410.53(b)(1) as "services furnished by a marriage and family therapist for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the marriage and family therapist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are furnished."

CMS also finalizes its proposal to define MHC services at §410.54(b)(1) as "services furnished by a mental health counselor (as defined in paragraph (a) of this section) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the mental health counselor is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are furnished."

Consistent with the statutory definitions for the services, both MFT and MHC services will need to be of a type that would be covered if they were furnished by a physician or as incident to a physician's professional service.

Benefit and Payment. Consistent with statute, CMS will add these services to the list of Medicare included medical and other health services at §410.10, and add MFTs and MHCs to the list of individuals who may be paid under Medicare at §410.150. In addition, CMS will add MFTs and

MHCs to the list of practitioners that may order diagnostic tests (to the extent they are authorized to do so under state law) since the list currently includes clinical social workers (CSWs) and clinical psychologists (CPs) who also furnish services for the diagnosis and treatment of mental illness. The agency also is adding MFTs and MHCs to the list of practitioners eligible to furnish Medicare telehealth services, as discussed in section II.D. of the rule.

Consistent with statute, CMS is codifying at §414.53 the payment amounts authorized for MFT and MHC services. It is also codifying payment amounts for CSW services authorized under section 1833(a)(1)(F) of the Act. Specifically, payment amounts for CSW, MFT, and MHC services will be 80 percent of the lesser of the actual charge for the services or 75 percent of the amount determined for clinical psychologist services under the PFS.

Pursuant to public comment, as discussed below, CMS is finalizing an amendment to §405.400 to include MFTs and MHCs as practitioners who may opt out of Medicare.

c. Coding Updates

CMS finalizes its proposal to revise the code descriptor for HCPCS code G0323 in order to allow MFTs and MHCs, as well as CPs and CSWs, to be able to bill for monthly general behavioral health integration services for which the services furnished by the respective practitioner serve as the focal point of care integration. The updated code descriptor is "Care management services for behavioral health conditions, at least 20 minutes of clinical psychologist, clinical social worker, mental health counselor, or marriage and family therapist time, per calendar month. (These services include the following required elements: Initial assessment or follow-up monitoring, including the use of applicable validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; facilitating and coordinating treatment such as psychotherapy, coordination with and/or referral to physicians and practitioners who are authorized by Medicare to prescribe medications and furnish E/M services, counseling and/or psychiatric consultation; and continuity of care with a designated member of the care team.)"

d. Medicare Enrollment of MFTs and MHCs

In order to submit claims under Medicare for MFT services and MHC services, practitioners will need to enroll in Medicare. To do so, they would complete, sign, and submit to their assigned MAC the appropriate Form CMS-855 for Medicare to determine if the practitioner satisfies all requirements of the definition of MFT or MHC, as applicable, in order to enroll and obtain Medicare billing privileges. CMS finalizes its proposal that MFTs and MHCs be subject to limited-risk screening under §424.518. Those that meet such requirements will use the Form CMS-855I application to enroll in Medicare. MFT and MHC services furnished before January 1, 2024 will not be payable.[48]

[48] CAA, 2023 provided for the new benefit under part B starting with services furnished on or after January 1, 2024.

e. Selected Comments/Responses

A few commenters noted that although most licensed and practicing MFTs and MHCs would meet the requirement for at least 2 years or 3,000 hours of clinical supervised experience, there are some who would not, particularly those who may have obtained their experience in a community mental health setting. Other concerns were raised about this requirement, including regarding the ambiguity of interpretation across states that have different requirements and the difficulty for practitioners who have been practicing for an extended period to produce the required documentation of experience. CMS clarifies that per statute the required amount of clinical supervised experience would need to have occurred after obtaining the applicable master's or doctor's degree which qualifies for licensure or certification pursuant to state law. This allows experience earned after licensure to count towards the required thresholds of experience. The agency defers to state law and licensure requirements regarding specifics as to how much of the total of 2 years or 3,000 hours of clinical supervised experience must be direct client contact.

Several commenters noted the variation in terminology used across states. Some commenters suggested that to address such variation CMS clarify that practitioners who meet the applicable requirements but are licensed by their state under a different title can also satisfy the definition of MFT or MHC, as applicable. The agency clarifies that any individual (regardless of title per state licensure) who satisfies the criteria specified under the statutory and regulatory definition of an MHC or MFT are eligible to enroll under Medicare part B as a MHC or MFT, respectively.

Several commenters brought to the agency's attention that regulations at §419.22 were not amended to add the services of MFTs and MHCs to the list of Medicare part B services that are not paid for under the hospital outpatient prospective payment system (OPPS) except when packaged as part of a bundled payment. Such an amendment would clarify that MHC and MFT services are excluded from the payment under the OPPS. CMS responds it inadvertently did not address whether MHC and MFT services are excluded from the OPPS. Since MHC and MFT services are professional services of nonphysician practitioners for which payment is made under the PFS at 75 percent of the payment amount for services of a psychologist, and the list (under §419.22) of services excluded from the OPPS includes services of qualified psychologists, the agency believes per statute it must amend §419.22 to similarly clarify MHC and MFT services are excluded from the OPPS. CMS has addressed these amendments in the CY 2024 OPPS final rule.

Other commenters brought to the agency's attention that the proposed rule did not address the section of the regulation text relating to opting out of Medicare. CMS responds this was inadvertent. Therefore, it amends §405.400, which defines the term practitioner for purposes of opting out of Medicare, to include MFTs and MHCs, which the agency finalizes in the rule.

Several commenters requested that §410.27, which permits certain hospital services to be furnished incident to a physician or nonphysician practitioner's service, be updated to include MFTs and MHCs within the definition of nonphysician practitioner. CMS responds that the omission of amending this section was inadvertent and that the amendment to §410.27 is

addressed in the CY 2024 OPPS final rule to revise the definition of nonphysician practitioner to include MFTs and MHCs.

2. Implementation of Section 4123 of the CAA, 2023

a. Statutory Background

The CAA, 2023 added a new paragraph (12) to section 1848(b) of the Act, which requires the Secretary to establish new HCPCS codes under the PFS for psychotherapy for crisis services furnished in a site of service (other than an office setting) at which the non-facility rate for crisis services applies under the PFS. Per statute, the payment amount for these services must be 150 percent of the PFS amount for non-facility sites of service determined for services identified as HCPCS codes 90839 and 90840.[49]

In addition, the CAA, 2023 requires the Secretary to use existing communication mechanisms to provide education and outreach to providers of services, physicians, and practitioners on the ability of auxiliary personnel, including peer support specialists, to participate in furnishing psychotherapy for crisis services billed under the PFS, behavioral health integration services, and other services that may be furnished to a Medicare beneficiary experiencing a mental or behavioral crisis.

b. Finalized Proposal

CMS finalizes its proposal to create the following 2 new G-codes describing these psychotherapy for crisis services:

- G0017: Psychotherapy for crisis furnished in an applicable site of service (any place of service at which the non-facility rate for psychotherapy for crisis services applies, other than the office setting); first 60 minutes; and
- G0018: Psychotherapy for crisis furnished in an applicable site of service (any place of service at which the non-facility rate for psychotherapy for crisis services applies, other than the office setting); each additional 30 minutes.

The new G-codes will be able to be billed when the services are furnished in any non-facility place of service other than the physician's office setting. When applying the term "non-facility place of service," an individual's home will be broadly interpreted to include temporary lodging.

Consistent with statute, CMS will calculate the work, PE, and MP RVUs for the new G-codes by multiplying the respective RVUs for each of CPT codes 90839 and 90840 by 1.5 (i.e., the fee schedule amount for the two new G-codes will be 150 percent of the current PFS non-facility RVUs for CPT codes 90839 and 90840). Expenditures for the new HCPCS codes will be excluded from PFS budget neutrality adjustments.[50]

[49] HCPCS codes 90839 and 90840 are Psychotherapy for crisis (first 60 minutes) and Psychotherapy for crisis (each additional 30 minutes), respectively.
[50] Section 1848(c)(2)(B)(iv) of the Act excludes 1848(b)(12) from the PFS budget neutrality adjustments.

c. Selected Comments/Responses

Several commenters requested CMS consider creating additional codes, such as for Crisis Psychotherapy with engagement services or for the existing code billed under Medicaid for crisis intervention service per 15 minutes. Others recommended creating a pathway for peer support specialists to be reimbursed when they work with clinicians on mobile crisis teams. Others suggested alternative payment approaches. CMS responds that it was limited by the statutory provisions in implementing section 4123 of the CAA, 2023. However, it agrees with commenters regarding the importance of access to crisis services and may consider this feedback for future rulemaking.

3. Implementation of Section 4124 of the CAA, 2023

CMS refers readers to section VIII of the CY 2024 OPPS final rule for its implementation of section 4124 of the CAA, 2023, which establishes coverage and payment under Medicare for intensive outpatient services for individuals with MH needs when furnished by HOPDs, community mental health centers, RHCs, and FQHCs.

4. Health Behavior Assessment and Intervention (HBAI) Services

HBAI CPT codes are intended to be used for psychological assessment and treatment of psychological, behavioral, emotional, cognitive, and interpersonal factors complicating the medical condition and treatment that is the primary diagnosis of the individual. CPs may currently bill Medicare for HBAI services. MFTs, MHCs, and CSWs are, similar to CPs, educated and trained to address the named psychological and other factors associated with physical health conditions.

CMS, therefore, finalizes its proposal to allow HBAI services described in CPT codes 96156, 96158, 96159, 96164, 96165, 96167, and 96168, and any successor codes, to be billed by CSWs, MFTs, and MHCs, in addition to CPs. All commenters supported the proposal.

5. Adjustments to Payment for Timed Behavioral Health Services

a. Background

CMS describes nationwide cross-setting behavioral health clinician workforce shortages resulting in unprecedented delays for individuals seeking medically necessary services. The agency is continuing to evaluate its processes used for developing relative values under the PFS for behavioral health services to ensure that the values it uses accurately reflect the resources involved in furnishing the services. It describes reasons why work RVUs assigned to these services may be initially undervalued relative to other services and may not accurately reflect the current relative resource costs. For example, in the case of behavioral health services, resources are more focused on conversational interactions rather than physical interactions, which makes the valuation based almost entirely on the practitioner's work. Also, unlike codes for physical services (such as surgery) where more experience providing the service leads to better efficiency

in providing the service, time-based codes describing time with a patient remain static in terms of efficiency.

b. Finalized Proposals

CMS finalizes its proposal to improve the accuracy of the valuation for timed psychotherapy services by applying an add-on code that is determined based on the add-on for valuation for inherent complexity for office/outpatient E/M services discussed in section II.F. of the rule. Specifically, it will apply beginning for 2024 an adjustment to the work RVUs for the psychotherapy codes payable under the PFS that is based on the difference in total work RVUs for office/outpatient E/M visit codes billed with the inherent complexity add-on code compared to the total work RVUs for visits that are not billed with the add-on code.

Therefore, CMS finalizes an increase of 19.1 percent to the work RVUs for standalone psychotherapy codes, as proposed. [51] In addition, in response to public comments received (discussed below), the agency is finalizing the 19.1 percent increase to work RVUs for psychotherapy codes that are billed as an add-on to an E/M visit (CPT codes 90833, 90836, and 90838). Also, the agency finalizes the application of the increase to the work RVUs of the codes describing HBAI services (CPT codes 96156, 96158, 96159, 96164, 96165, 96167, and 96168), since these codes are also timed services and generally provided person-to-person without clinical staff support (similar to the psychotherapy codes noted). CMS will implement these increases over a 4-year transition period.

c. Selected Comments/Responses

Several commenters requested that the proposed increase be applied to psychotherapy codes that are billed as an add-on to an E/M visit. They reasoned that the work involved in furnishing the add-on codes is similar to that of furnishing the stand-alone codes and that not similarly applying the increase to the add-on codes would have the unintended consequence of devaluing the work of psychiatrists and discouraging their participation in Medicare. Similar requests were made with respect to HBAI services. CMS agreed with the reasoning stated for codes billed as an add-on to an E/M visit and for HBAI services codes, believing that the work involved in furnishing those codes is similar to the work involved in furnishing the psychotherapy stand-alone codes. Therefore, the agency finalizes the increase for all of the psychotherapy codes and the HBAI services. Some commenters also requested the increase be applied to the work RVUs of codes describing psychological and neuropsychological testing services, but the agency notes those

[51] CMS finalized, as proposed, the increase for the following specific codes (Note these are in addition to the psychotherapy add-on codes and HBAI codes mentioned above, added pursuant to public comment): CPT code 90832 (Psychotherapy, 30 minutes with patient); CPT code 90834 (Psychotherapy, 45 minutes with patient); CPT code 90837 (Psychotherapy, 60 minutes with patient); 90839 (Psychotherapy for crisis; first 60 minutes); CPT code 90840 (Psychotherapy for crisis; each additional 30 minutes (List separately in addition to code for primary service)); CPT code 90845 (Psychoanalysis); 90846 (Family psychotherapy (without the patient present), 50 minutes); CPT code 90847 (Family psychotherapy (conjoint psychotherapy) (with patient present), 50 minutes); CPT code 90849 (Multiple-family group psychotherapy); CPT code 90853 (Group psychotherapy (other than of a multiple-family group) and newly finalized HCPCS codes GPFC1 and GPFC2 (Psychotherapy for crisis furnished in an applicable site of service (any place of service at which the non-facility rate for psychotherapy for crisis services applies, other than the office setting)).

services are not necessarily timed services provided without clinical staff assistance and therefore believes those services are different from psychotherapy and HBAI services.

In response to comments encouraging the agency to work toward a long-term solution to code valuation, CMS states it is interested in working with the broader community, including the AMA RUC going forward.

6. Updates to the Payment Rate for the PFS Substance Use Disorder (SUD) bundle (HCPCS codes G2086-G2088)

CMS finalizes its proposal to update the valuation for HCPCS codes G2086[52] and G2087[53] (office-based treatment for an SUD for at least 70 minutes in the first month and at least 60 minutes in subsequent months, respectively) by increasing the current payment rate to reflect 2 individual psychotherapy sessions per month based on a crosswalk to the work RVU assigned to CPT code 90834 (reflecting a 45-minunte psychotherapy session instead of the 30-minute session reflected in CPT 90832, which is currently used). The difference in RVU assignment between the current and newly finalized CPT codes is a difference of 0.54 work RVUs. Since the bundled payments described by HCPCS codes G2086 and G2087 include 2 psychotherapy session per month, CMS will add 1.08 RVUs to the work value assigned to those codes, resulting in a work RVU of 8.14 for HCPCS code G2086 and 7.97 for HCPCS code G2087. CMS notes that the finalized increase described above to the work RVUs for CPT code 90834 will carry through here and further increase the RVUs for HCPCS code G2086 and G2087 to 8.36 and 8.19, respectively.

7. Comment Solicitation on Expanding Access to Behavioral Health Services

In the CY 2024 PFS proposed rule the agency sought ways to expand access to behavioral health services, including specifically on (i) access to behavioral health integration (BHI) services, (ii) whether it should consider new coding to allow interprofessional consultation to be billed by practitioners who are authorized by statute for the diagnosis and treatment of mental illness, (iii) intensive outpatient (IOP) services furnished in settings other than those addressed in the CY 2024 OPPS proposed rule, (iv) how to increase psychiatrist participation in Medicare, and (v) whether there is a need for separate coding and payment for interventions initiated or furnished in the emergency department or other crisis setting for patients at risk of suicide, such as safety planning interventions and/or telephonic post-discharge follow-up contacts after an emergency department visit or crisis encounter.

CMS summarized comments received. Such summary included several comments that encouraged the agency to enable wider implementation under Medicare of the Safety Planning

[52] The G2086 descriptor is office-based treatment for a substance use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month.

[53] The G2087 descriptor is office-based treatment for a substance use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month.

Intervention (SPI) and the Post Discharge Telephonic Follow-up Contacts Intervention (FCI), including by improving payment mechanisms and providing suitable billing codes for the interventions. Suggestions also included creating coding to enable IOP services to be delivered in freestanding community-based SUD treatment facilities.

8. Request for Information on Digital Therapeutics

In recent years, the Food and Drug Administration (FDA) has reviewed and cleared several mobile medical applications ("apps") that have been shown to demonstrate a reasonable assurance of safety and effectiveness for treating a variety of health conditions, including sleep disorders, substance use disorders, depression and anxiety. These mobile medical apps require a prescription or referral from a clinician and are used for specific medical purposes rather than general wellness and education.

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. For both RPM and RTM codes, the device used must meet the FDA definition of a device as described in section 201(h) of the Federal Food, Drug and Cosmetic Act.

As it continues to gather information on how remote monitoring services are used in clinical practice, CMS requested information in the proposed rule on a variety of specific questions: distribution and delivery models; practitioners and auxiliary staff involved in furnishing services; collection of data; defining an episode of care; how to code these products and services; scientific and clinical evidence to support reasonable and necessary determinations; Medicare benefit category; improving access to services for underserved populations; and protecting privacy and confidentiality.

Public commenters indicated that CMS has existing authority to pay for digital therapeutics as durable medical equipment (DME) or incident to a physician service. These commenters suggested that CMS should continue to use its authority to code and pay for digital therapeutics that are cleared by the FDA consistent with other prescription medical devices including new codes that are on September 2023 CPT Editorial Panel meeting to allow for reporting of digital CBT.

CMS responded that it routinely, although not exclusively, relies on the CPT coding process as a critical part of how services might be paid under the PFS and looks forward to receiving forthcoming codes and potential recommendations for the valuation of such codes through its standard processes. In response to the comments regarding DME, CMS indicates the product would have to meet the following conditions: (1) Can withstand repeated use; (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years; (3) Is primarily and customarily used to serve a medical purpose; (4) Generally is not useful to

an individual in the absence of an illness or injury; and (5) Is appropriate for use in the home. All five of these conditions must be met in order for equipment to be classified as DME.

K. Medicare Parts A and B Payment for Dental Services

1. Background

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

The proposed rule reviewed CMS' collaboration with the Agency for Healthcare Research and Quality (AHRQ) and cites a number of studies that found treatment of cancer using chemotherapeutic agents may lead to more clinically severe infections and often involves immunosuppression in patients. Dental services to identify and treat oral complications/comorbidities prior to and, sometimes, throughout chemotherapy treatment have been associated with improved outcomes for the patient receiving medical services in the treatment of cancer according to these studies (see proposed rule for specific cites).

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. The deadline for submissions for potential consideration for 2024 rulemaking was February 10, 2023. CMS received eight submissions by the deadline and one submission after the deadline that presented nominations for covered services. The one received after the deadline has already been addressed by CMS' payment policy.

2. Proposed Additions of Dental Services Inextricably Linked to Other Covered Services

CMS proposed that Medicare may cover dental services that are inextricably linked to other covered medical services in the following situations:

- Chemotherapy when used in the treatment of cancer;
- CAR T-Cell therapy, when used in the treatment of cancer; and
- Administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer.

In these circumstances, CMS proposed to pay for:

- Dental or oral examinations performed as part of a comprehensive workup in either the inpatient or outpatient setting.

- Medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to or contemporaneously with any of the above services.
- Services that are ancillary to these dental services, such as x-rays, administration of anesthesia, and use of the operating room.

The above services could be paid under either Part A or B in inpatient or outpatient settings.

Dental Services Linked to Chemotherapy Services. In the 2023 PFS final rule (87 FR 69681), CMS finalized a policy for 2024 that Medicare payment may be made for diagnostic and treatment services to eliminate an oral or dental infection, prior to or contemporaneously with Medicare-covered treatments for head and neck cancer. Public commenters recommended that CMS expand this policy to treatment of all types of cancer not just those involving the head and neck. CMS responded that it would continue to review and evaluate this public comment.

The proposed rule indicated that the treatment of a broad range of malignancies often requires the use of chemotherapeutic agents that in turn suppress the body's production of white blood cells, thereby impairing the body's ability to resist serious (potentially life-threatening) infections. The route of entry of the offending pathogens can be the mouth. If dental or oral infections are left undetected or untreated in these patients, serious complications may occur, negatively impacting the clinical success of the medical services and outcomes for the patients.

CMS believes the evidence supports that the clinical outcomes of the chemotherapy treatment could be compromised absent the provision of the inextricably-linked dental services. Dental services in this situation mitigate the likelihood of occurrence and severity of complications caused by the primary medical services, including infection. Consequently, dental services are integral and inextricably linked to these medical services, and the statutory dental exclusion would not apply.

The proposed rule requested comment on whether radiation therapy in the treatment of cancer more broadly (not in conjunction with chemotherapy, and not in relation to head and neck cancer treatment) are medical services that may be inextricably linked to dental services. CMS does not believe that radiation therapy alone necessarily leads to the same level of treatment-induced immunosuppression as chemotherapy because radiation specifically targets malignant cells and has more targeted and localized effects on the body. However, CMS requested comment on this issue.

CMS proposed to add dental services linked to chemotherapy services to the regulation at §411.15(i)(3)(i)(A) as an example of where Medicare may pay dental services. The proposal clarified that it is not meant to be limited to cases where chemotherapy in the treatment of cancer is provided without the use of other therapies.

Dental Services Linked to CAR T-Cell Therapy. Requestors asked CMS to add dental services linked to CAR T-cell therapy to the list of clinical scenarios indicating that CAR T-cell therapy causes a patient to be immunosuppressed. After consideration of clinical practice guidelines, recommendations provided by the public, and its analyses of the studies and research available regarding the connection between dental services and the clinical success of CAR T-cell therapy,

CMS was persuaded that dental services to diagnose and treat infection prior to CAR T-cell therapy are inextricably linked to the clinical success of CAR T-cell therapy.

CMS believes that proceeding without a dental or oral exam and necessary diagnosis and treatment of any presenting infection of the mouth prior to CAR T-cell therapy when used in the treatment of cancer could lead to systemic infection or sepsis, as well as other complications for the patient. Consequently, CMS proposed to add this clinical scenario to those under which payment can be made for certain dental services in the regulation at §411.15(i)(3)(i)(A).

The proposed rule requested comment on whether to add other types of lymphodepleting medical services used for cancer treatment, in addition to those used in conjunction with CAR T-cell therapy for cancer treatment. CMS believes there may be other immunotherapies that may have a similar lymphodepletion component but had no specific information regarding such therapies.

Dental Services Linked to High-Dose Bone-Modifying Agents (Antiresorptive Therapy). Medication-related osteonecrosis of the jaw (MRONJ) is a serious complication of the administration of bone-modifying agents (such as bisphosphonates and denosumab, and other biosimilar agents) used when managing certain cancers. After consideration of clinical practice guidelines, recommendations provided by the public, and its analyses of the studies and research available regarding the connection between dental services and the clinical success of the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer, CMS proposed to add this clinical scenario to those under which payment can be made for certain dental services in regulation at §411.15(i)(3)(i)(A).

CMS believes there is an inextricable link between dental services and the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer. The standard of care is such that the covered medical services would or could be significantly and materially compromised absent the provision of the inextricably-linked dental services. The dental services are a clinical prerequisite to proceeding with the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer.

Clarifications to Existing Policies. The proposed rule clarified that CMS did not explicitly include both "prior to" and "contemporaneously with" the associated medical service even though its intention was to include these words in all instances of where Medicare will pay for dental services. In addition, with respect to head and neck cancers, CMS clarifies that Medicare Part A and B payments may be made for covered dental services whether the cancer is primary or metastatic, regardless of site of origin, and regardless of initial modality of treatment.

Comments/Responses: Public comments supported CMS' proposals to add the three different clinical scenarios to the list of those where Medicare could cover medically necessary dental services that are inextricably linked to and substantially related to the clinical success of other covered medical services. There were public comments that indicated that the standard of care in many cancer centers includes a comprehensive oral exam prior to starting therapy. Other comments indicated that the National Cancer Institute recommends that cancer patients receiving high-dose chemotherapy, stem cell transplants, or radiation therapy should have an oral care plan in place before treatment begins to mitigate the risk of oral complications.

Several commenters requested that Medicare provide payment for dental and oral examinations performed as part of a comprehensive workup for Medicare beneficiaries with cancer prior to the administration of single modality radiation therapy, outside of usage in the treatment of head and neck cancer. While commenters acknowledged that radiation therapy is targeted and does not have a systemic effect, radiation may directly damage the immune system, the skeletal system, or bone marrow. Immune system damage is of particular concern for treatment of leukemia, lymphoma, or multiple myeloma prior to a patient undergoing a stem cell transplant.

CMS responded that it does not believe that the evidence submitted by commenters is sufficient to demonstrate an inextricable linkage between dental services and the success of single modality radiation therapy during the treatment of certain cancers (other than head and neck cancer). However, 42 CFR §411.15(i)(3)(i) states that dental or oral examinations are covered "to eliminate an oral or dental infection prior to, or contemporaneously with, the organ transplant." The response indicates that its existing regulation would allow Medicare coverage for a comprehensive workup and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, an organ transplant, including hematopoietic stem cell transplant.

A few commenters provided feedback and requested that CMS evaluate whether dental services may be inextricably linked to the clinical success of other immunotherapies that may have a similar lymphodepleting component as CAR T-cell therapies. As CMS did not receive clinical evidence in support of this recommendation, it is not adding this clinical scenario to the list of those where Medicare will cover dental services that are inextricably linked to and substantially related to the clinical success of other covered medical services

With respect to antiresorptive therapy, CMS was asked to clarify "high-dose." CMS responded that the term "high-dose" bisphosphonate therapy refers to the usage of bisphosphonate therapy when used in the treatment of cancer. It is not specifying a dosage level.

Several public comments asked CMS to add additional clinical scenarios to the list of those where Medicare could cover medically necessary dental services that are inextricably linked to and substantially related to the clinical success of other covered medical services. CMS' responded that the MACs retain the flexibility to determine on a claim-by-claim basis whether it may cover an oral exam and medically necessary dental services in other circumstances not specifically addressed within the finalized amendments to 42 CFR §411.15(i)(3)(i).

In addition to adding the above clinical scenarios to the regulations as exceptions to the prohibition on Medicare payment for dental services, CMS clarified its policy on payment for dental services inextricably linked to the clinical success of treatment of head and neck cancers. CMS proposed to modify 42 CFR §411.15(i)(3)(i) to make explicit that Medicare will cover:

(1) Dental or oral examination in either the inpatient or outpatient setting prior to the initiation of, or during, Medicare-covered treatments for head and neck cancer; and
(2) Medically necessary diagnostic and treatment services to eliminate an oral or dental infection in either the inpatient or outpatient setting prior to the initiation of, or during, Medicare covered treatments for head and neck cancer.

Many of the public comments concerned the definition of "head and neck" cancers. CMS responded that head and neck cancer generally refers to a group of cancers that originate in or metastasize to areas of the head and neck, which could include the mucosal surfaces of the oral cavity, pharynx and larynx.

Several commenters indicated that it is important that patients undergoing single modality radiation therapy for any head and neck cancer receive a thorough initial dental evaluation, including dental x-rays, with special attention to any teeth that may require timely procedures, such as root canals and extractions, prior to radiation therapy. CMS agreed that the evidence the commenters provided support allowing Medicare payment for dental services associated with single modality radiation therapy associated with treating head and neck cancers.

Many commenters requested that Medicare payment be permitted after direct treatment is completed for patients undergoing treatment for head and neck cancer. CMS was persuaded by evidence provided by commenters that treatment for head and neck cancer uniquely causes additional significant and acute dental and/or oral complications for the patient, including increased risk of infection even after the direct treatment for head and neck cancer has ended. Therefore, Medicare Parts A and B payment may be made for dental or oral examinations to monitor for oral and dental complications resulting from the treatment for head and neck cancers. CMS would not, however, pay for a dental implant or crown as these services may not be considered immediately necessary to address oral complications caused by the treatment for head and neck cancer.

Final Action: CMS is finalizing all of its policies as proposed. In addition, CMS will permit Part A and B payment for dental or oral examination to address dental or oral complications after radiation, chemotherapy, and/or surgery when used in the treatment of head and neck cancer. CMS intends to issue educational and outreach materials to inform billing and payment for any policies finalized in the final rule.

3. Dental Services Integral to Covered Cardiac Interventions

In the 2023 PFS final rule, CMS finalized a policy to permit payment for dental services inextricably linked to Medicare-covered cardiac valve replacement or valvuloplasty procedures. An interested party has encouraged CMS to consider extending Medicare payment to include dental services to eliminate infection prior to all cardiovascular procedures.

Available evidence does not permit conclusions regarding the effect of pre-treatment dental care for preventing downstream infections related to any cardiac devices, according to CMS. CMS states further that professional society guidelines endorse the provision of patient education on routine oral hygiene practices but have not recommended other pre-treatment dental care prior to insertion of cardiac devices. Nonetheless, CMS requested comment to identify additional cardiac interventions where the risk of infection posed to beneficiaries is similar to that associated with cardiac valve replacement or valvuloplasty.

Commenters requested that CMS permit payment for dental screenings and, when clinically justified, medically necessary dental treatment that a patient may need in order to undergo, or to

avoid complicating or compromising, certain covered cardiac procedures. CMS responded that commenters did not offer clinical evidence to support that dentally sourced infections can cause serious complications of specific cardiovascular interventions already addressed by the regulations. CMS is not making any changes to its proposed policy in response to these commenters.

4. Dental Services Integral to Covered Services for Sickle Cell Disease (SCD) and Hemophilia

Interested parties urged CMS to provide payment for dental services in connection with medical services for individuals living with SCD and hemophilia. CMS requested comment on whether certain dental services are inextricably linked to other covered services used in the treatment of SCD, such as hydroxyurea therapy.

With respect to hemophilia, interested parties noted that periodic dental care reduces the risks of dental complications during tooth extractions or oral surgeries requiring clotting factor replacement therapy. CMS notes that there is a great deal of evidence suggesting that dental health is generally an important component of overall health. However, it requested comment on whether certain dental services are inextricably linked to certain other covered services for hemophilia, as supported by clinical evidence. It also requested comment on whether dental services such as prophylaxis are a standard of care in the management of hemophilia.

CMS did receive information from commenters in response to its request for comments but indicated that it did not support finding that dental services are inextricably linked to a covered medical service for SCD or hemophilia or that the standard of SCD or hemophilia care would be compromised or require dental services to be performed for treatment with these diseases.

5. Dental Services Integral to Other Medicare-Covered Services

CMS urges interested parties to consider the circumstances under which dental services are inextricably linked to specific covered services (not diagnoses) used to treat patients with auto-immune conditions or other chronic conditions. Interested parties who believe dental services are inextricably linked to covered services should use the public submission process to provide information on these clinical scenarios, supported by clinical evidence or other documentation.

The deadline for requesting additional covered dental services for 2025 rulemaking is February 10, 2024. Requests should be provided to: MedicarePhysicianFeeSchedule@cms.hhs.gov. Interested parties should include the words “dental recommendations for CY 2025 review” in the subject line to facilitate processing.

Commenters urged CMS to consider the importance of access to oral health care for people with chronic autoimmune conditions and other chronic disease conditions, such as diabetes, chronic kidney disease and end stage renal disease; procedures such as joint replacement; services such as inpatient substance use disorder treatment; and long-term use of immunosuppressants for the treatment of colitis, Crohn’s, lupus, multiple sclerosis, rheumatoid arthritis, and Sjögren’s disease. CMS responded that the information generally provided by commenters did not

establish an inextricable link between dental services and a covered medical service to necessitate expanding the regulations to include additional medical scenarios.

6. Request for Information on Implementation Issues

CMS discussed the following implementation issues:

Coordination of Benefits: CMS recognizes that many Medicare beneficiaries have separate or supplemental dental coverage. As a result, CMS requested comment on the coordination of multiple dental benefits that Medicare beneficiaries may have, if and how other plans currently cover and pay for dental services, and what type of guidance CMS should provide about the dental payment policies it has established and their relationship to other separate or supplemental dental coverages. CMS received a variety of public comments on this topic,

In response to these comments, CMS indicates it has created Change Request (CR) 13190, Educational Instructions for the Implementation of the Medicare Payment Provisions for Dental Services as Finalized in the Calendar Year (CY) 2023 Physician Fee Schedule (PFS) Final Rule, available at: https://www.cms.gov/files/document/r12047bp.pdf. CMS further encourages MACs to utilize information provided in the CR to develop their own educational and billing materials.

In addition, CMS is continuing to address issues raised by commenters about the dental claim form 837D (https://www.cms.gov/medicare/coverage/dental) including efforts to accommodate the dental claim form within Medicare claims processing systems effective for 2024. Among the issues CMS plans to address in future educational outreach materials is use of a HCPCS, CPT, or Current Dental Treatment (CDT) code modifier that may allow dentists to attest to a particular dental service being inextricably linked and/or a second HCPCS, CPT, CDT modifier to attest that a particular dental service is not inextricably linked.

Denials: Dental professionals may submit a claim to Medicare to receive a denial in order to bill Medicaid or another third-party payer. CMS requested comment on the practices of other payers related to submission of claims in order to generate a denial and how these practices impact claim submission and claim adjudication with third party payers, including state Medicaid programs. CMS received a number of questions and comments on this topic.

In response CMS stated dentists may continue submitting claims using the 837P and 837I claims types with existing HCPCS modifiers when third-party payers need a Medicare claim denial. CMS is continuing to explore options for addressing the need to submit a dental claim to Medicare for the purpose of obtaining a denial so that another carrier or third-party payer may issue primary payment via the 837D dental claims format.

Coordination Among Professionals: The rule notes that documentation of coordination among medical and dental professionals will be needed to support the inextricable link between the dental services and medical services being furnished. Public commenters requested information on how to document that coordination.

CMS is continuing to investigate operational mechanisms to demonstrate that there is an exchange of information between the Medicare enrolled medical and dental professional, such as the usage of the CPT or CDT modifiers or codes, including the KX HCPCS modifier, the CDT code D9311 650 (consultations with a medical health care professional), CPT code for interprofessional consultation (such as CPT 99452), or other modifiers/codes.

Payment in Settings Other than Inpatient and Outpatient: CMS requested information regarding the potential impact of these payment policies in settings other than inpatient and outpatient facilities, such as federally qualified health centers (FQHCs), rural health clinics (RHCs), etc.

Many commenters requested that CMS provide Medicare payment for covered dental procedures in FQHCs. CMS responded that it intends to make necessary modifications to operational procedures to reflect the expansion of this PFS payment policy, including potential updates to billable code lists and other relevant policies in the FQHC setting.

Payment for Dental Services: Medicare covered dental services are currently contractor priced. CMS requested comment on specific information could help inform appropriate payment.

Public commenters both supported and opposed continued contractor pricing of dental services. Those opposed to contractor pricing suggested that CMS use the same processes it uses to price physician services under the PFS. CMS continues to believe that MACs are appropriately situated to contractor price dental services as they have done before these policy changes, until CMS has additional data that could enable national pricing.

Coding and Modifiers: CMS has revised the HCPCS and PFS payment and coding files to include payment indicators for CDT codes, such as bilateralism, multiple procedures, and other indicators that are included in the PFS RVU files. CMS requested comment on whether payment indicators as outlined in the PFS RVU files appropriately align with existing dental billing and coding conventions, or whether edits are necessary.

Many commenters stated that multiple procedure reductions and payment indicators should be removed from the PFS payment files because they do not align with existing dental billing and coding conventions. Given feedback from interested parties, CMS has recently removed multi-procedure payment reductions payment indicators for dental services described by CDT codes in the July 2023 release of the PFS RVU files. However, CMS will continue to study this issue to determine applicable payment policies under the PFS that should apply to dental services.

Specialty Codes: Dentists who practice general or specialized dentistry currently self-designate their specialty under two specialty codes, specialty 19 (oral surgery—dentists only) or specialty 85 (maxillofacial surgery). CMS requested comment on whether additional specialty codes should be considered for use in Medicare, and if so, what other specific specialties that should be included.

Some commenters supported CMS creating new dental specialty codes for use by dentists enrolling in the Medicare program to promote the correct coding and processing of Medicare claims for dental services. CMS has created new dental specialty codes to advance accurate

coding and claims processing (see guidance issued on August 31, 2023 via Change Request 13323, New Dental Specialty Codes for Medicare available at: https://www.cms.gov/files/document/r12231cp.pdf.)

III. Other Provisions of the Final Rule

A. Drugs and Biological Products Paid Under Medicare Part B

1. Provisions from the Inflation Reduction Act Relating to Drugs and Biologicals Payable Under Medicare Part B (§§410.152, 414.902, 414.904, 489.30)

The final rule codifies provisions of the IRA relating to payment limits under Part B for biosimilars and relating to beneficiary out-of-pocket costs for certain Part B drugs.

a. Payment for Drugs under Medicare Part B During an Initial Period

Under certain circumstances, the payment limit of a drug is based on its wholesale acquisition cost (WAC). CMS finalizes its proposal (without modification) to codify the payment limits under section 1847A(c)(4)(B) of the Act (as added by section 11402 of the IRA) for new biosimilars furnished on or after July 1, 2024 during the initial period when ASP data is not sufficiently available. In this case, the payment limit for the biosimilar is the lesser of—

1. An amount not to exceed 103 percent of the WAC of the biosimilar or the Medicare Part B drug payment methodology in effect on November 1, 2003 (i.e., generally 95 percent of the average wholesale price), or
2. 106 percent of the lesser of the WAC or ASP of the reference biological, or in the case of a selected drug under the Drug Price Negotiation Program during a price applicability period, 106 percent of the maximum fair price of the reference biological.

CMS also codifies in its regulations the statutory change to section 1847A(c)(4) of the Act made by section 6 of the Sustaining Excellence in Medicaid Act of 2019 (Pub. L. 116-39) that specified, effective January 1, 2019, a payment limit not to exceed 103 percent of the WAC or based on the Part B drug payment methodology in effect on November 1, 2003 (i.e., generally 95 percent of the average wholesale price) during an initial period when ASP data is not sufficiently available.

Comments/Responses. A commenter believes that CMS has the discretion to eliminate the 3-percent add-on for new drugs paid based on WAC and recommends that the agency do so to reduce excess payments and increase affordability for beneficiaries and taxpayers. CMS may consider doing so in future rulemaking, and it notes that MACs are not required to pay 103 percent of WAC because the operative language "not to exceed 103 percent of the WAC" sets a ceiling but not a floor for the payment amount.

b. Temporary Increase in Medicare Part B Payment for Certain Biosimilar Biological Products

Section 11403 of the IRA established a temporary payment limit increase for qualifying biosimilar biological products furnished during the applicable 5-year period. These are

biosimilars with an ASP (as described in section 1847A(b)(8)(A)(i) of the Act) that is less than the ASP of the reference biological for a calendar quarter during the applicable 5-year period. Payment for these biosimilars is made at ASP plus 8 percent of the reference biological's ASP (rather than 6 percent) during the applicable 5-year period. CMS finalizes its proposal (without modification) to codify the definitions of the terms "applicable 5-year period" and "qualifying biosimilar biological product" as follows:

Applicable five-year period means:

1. For a qualifying biosimilar biological product for which payment has been made under section 1847A(b)(8) as of September 30, 2022, the 5-year period beginning on October 1, 2022; and
2. For a qualifying biosimilar biological product for which payment is first made under section 1847A(b)(8) during a calendar quarter during the period beginning October 1, 2022 and ending December 31, 2027, the 5-year period beginning on the first day of such calendar quarter during which such payment is first made.

Qualifying biosimilar biological product means a biosimilar biological product (as described in section 1847A(b)(1)(C)) with an average sales price (as described in section 1847A(b)(8)(A)(i)) that is less than the average sales price of the reference biological for a calendar quarter during the applicable 5-year period.

c. Inflation-adjusted Beneficiary Coinsurance and Medicare Payment for Medicare Part B Rebatable Drugs

Manufacturers must pay a rebate to the Medicare program for their Part B drugs whose ASP increases by more than the rate of inflation for a period; the drugs are referred to as rebatable drugs. CMS finalizes its proposal (with minor technical changes to correct typographical errors) to codify in §489.30 the coinsurance amount for Part B rebatable drugs as required by section 1847A(i)(5) of the Act. The coinsurance amount is equal to 20 percent of the inflation-adjusted payment amount for such quarter, which CMS refers to as the inflation-adjusted coinsurance amount. The inflation-adjusted coinsurance amount is applied as a percent, determined by CMS, to the payment amount that would otherwise apply for the calendar quarter involved; this also applies to selected drugs under the Drug Price Negotiation Program.

CMS also codifies in regulations that the amount the program will pay for a rebatable drug during a calendar quarter involved will, subject to the deductible, be equal to the difference between the allowed payment amount determined under section 1847A of the Act and 20 percent of the inflation-adjusted amount; this will be applied as a percent to the payment amount for the calendar quarter involved.
Comments/Responses. Clarification was sought on whether a reduction or waiver of an inflation rebate due to a drug shortage would affect the reduced beneficiary coinsurance for that drug. Another commenter argued that Medicare Advantage units should not be included when calculating the drug inflation rebates. CMS does not respond to these comments but notes the issues were raised in the context of the initial Part B inflation rebate guidance. Comments received in response to that guidance will be considered for future rulemaking.

d. Limitations on Monthly Coinsurance and Adjustments to Supplier Payment Under Medicare Part B for Insulin Furnished Through Durable Medical Equipment

Section 11407 of the IRA made three changes to the way in which beneficiaries pay for insulin when furnished through covered DME:

1. The Part B deductible for the insulin is waived.
2. Beginning July 1, 2023, the beneficiary's coinsurance for a month's supply of insulin may not exceed $35.
3. CMS must increase the payment amount above 80 percent if the coinsurance amount for insulin is less than 20 percent of that payment amount. This is designed to pay for the full difference between the payment amount and coinsurance, and to ensure the supplier is not responsible for the reduction in beneficiary coinsurance.

CMS implemented these provisions by applying the $35 coinsurance limit to the duration of the calendar month in which the date of service occurs and by setting the $35 coinsurance limit for each calendar month. Similarly, a coinsurance limit of $105 would apply for a 3-month's supply for that 3-month period. CMS codifies these elements (currently in program instruction) for 2024 and future years in its regulations.

Comment/Response. A commenter sought clarification on whether compounded insulin is exempt from the Part B insulin monthly coinsurance limitation. CMS responds that compounded insulin is subject to the monthly coinsurance limitation if furnished through covered DME. The limitation applies to insulin that is transferred from vials into a cartridge for insertion into an insulin pump if that pump is a covered item of DME. By contrast, insulin administered through a prosthetic device would not be subject to the $35 monthly coinsurance limitation.

e. Indexing the Part B Deductible to Inflation

The Part B deductible is increased for inflation by the annual percentage increase in the Part B actuarial rate for enrollees aged 65 and over, which is rounded to the nearest dollar. CMS finalizes revisions to §489.30(b)(1) to update the regulatory text for the Part B deductible to take into account changes made by the IRA described above.

2. Request for Information (RFI): Drugs and Biologicals which are Not Usually Self-Administered by the Patient, and Complex Drug Administration Coding

Medicare may pay for services and supplies, including drugs and biologicals that are not usually self-administered by the patient, which are furnished as "incident to" a physician's professional service. The MACs publish a description of the process they use to determine whether a drug is usually self-administered as well as a list of the drugs that are subject to the self-administered exclusion on their website (self-administered drug (SAD) lists). The lists are not identical across all MACs. Stakeholders have asked for clarification of the SAD list guidance.

Relatedly, some stakeholders have complained that payment for complex non-chemotherapeutic drug administration has become increasingly inadequate because existing coding and Medicare billing guidelines do not accurately reflect the resources used to furnish these infusion services.

CMS asked for comments on both these issues, including potential changes in defined terms (e.g., administered, self-administered, and usually) and the process for determining which drugs are not usually self-administered for the SAD list. For complex non-chemotherapeutic drug administration infusion services, input is sought on relevant resources that could be used in determining appropriate coding and payment and whether policy guidelines should be revised for how these services are furnished and billed.

Comments/Responses. Several issues were addressed, including appeals, FDA labeling, and accommodating patients who are under caregivers' care and/or patients who cannot self-administer drugs. CMS will consider the input for future rulemaking. Other comments focused on appropriate reimbursement for non-chemotherapeutic complex drug administration coding; clarification was sought on the conditions under which infusion drugs may be considered complex and may be appropriately reported using the chemotherapy administration CPT codes 96401-96549. CMS indicates that the manual[54] outlines the categories under which payment is made for both types of injections and infusions and the considerations for determining which drugs may be considered chemotherapy under Medicare. MACs may also provide additional guidance. The agency also acknowledges that the clinical work and expense for some complex drug infusion services are not adequately accounted for as currently reimbursed, but it notes that payment for the chemotherapy administration CPT code series (96401-96549) accounts for clinical staff and supply costs as part of physician practice expenses for the administration service. CMS is interested in further discussions to more accurately account for the costs involved in complex drug administration services.

3. 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[55] 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);

[54] 100-4 Chapter 12, section 30.5 of Internet Only Manual (IOM)
[55] https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifierfaqs.pdf.

- 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.

It finalized the manner in which the refund would be calculated as well as a policy permitting CMS to increase the applicable percentage to 35 percent 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. However, some proposals relating to the invoicing and collection of discarded drug refunds were not finalized due to the enactment of the IRA and the agency's efforts to align the operations of the refunds with the inflation rebate programs.

In the proposed rule, CMS proposed (i) a date for the initial report to manufacturers, (ii) a date for subsequent reports, (iii) a method of calculating refunds for discarded amounts in lagged claims data, (iv) a method of calculating refunds when there are multiple manufacturers for a refundable drug, (v) the increased applicable percentages for certain drugs with unique circumstances, and (vi) 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 proposed modifications to the JW and JZ modifier policy for drugs payable under Part B from single-dose containers that are furnished by a supplier who is not administering the drug.

b. Provision of Information to Manufacturers

Initial Refund Report. CMS finalizes its proposals (with modification) to provide an initial refund report to manufacturers no later than December 31, 2024, which will include all calendar quarters of information for 2023. This report is separate and distinct from the preliminary report the agency intends to issue by December 31, 2023, which will include estimated discarded amounts based on available claims data for the first two quarters of 2023.

Subsequent Annual Reports. For reports for quarters in 2024 and subsequent years, CMS will seek to align delivery of the refund reports with the delivery of Part B and Part D inflation rebate reports to the extent practicable. Specifically, it will send annual refund reports for discarded drug refunds for the 4 quarters of a calendar year at or around the time it sends the Part B inflation rebate report for the first quarter of the following year. For example, the annual report for 2024 would be sent no later than September 30, 2025.

Annual reports issued after the initial refund report will include data, including lagged claims data, for eight quarters—four from the previous calendar year (referred to as new refund quarters) and four from 2 calendar years prior (referred to as updated refund quarters). These reports will include the following information for updated refund quarters to address lagged claims data:

- The updated total number of units of the billing and payment code of such drug, if any, that were discarded during such updated refund quarter, as determined using a

mechanism such as the JW modifier (or any such successor modifier that includes such data as determined appropriate by the Secretary).
- The updated refund amount for which the manufacturer is liable with respect to such updated quarter that was not previously accounted for in the prior year's report.

CMS defines the terms "new refund quarter" and "updated refund quarter" at §414.902 and would revise §414.940(a)(3) to reflect the inclusion of lagged data in reports subsequent to the initial refund report.

Comments/Responses. Support was expressed for the alignment of discard drug refund reports with inflation rebate reports. Some commenters suggesting limiting lagged data to one quarter; they argued that manufacturers are not responsible for delays in claims submissions and thus should not be liable for refunds on lagged claims. They also believe such a proposal would reduce administrative burden. CMS disagrees; it believes using the existing claims submission, review and finalization process will provide the most accurate determination of discarded amounts and refunds for each quarter.

c. Manufacturer Provision of Refund

In the 2023 rulemaking cycle, CMS proposed to require manufacturers to provide refunds annually by December 31 based on the report provided to them October 1. In the case of a dispute, payment of the refund would have been due no later than 30 days after the resolution of the dispute. These policies were not finalized.

Taking into account the proposals for the initial refund report and subsequent reports described above, CMS finalizes its proposal (without modification) to require that the refund amounts specified in the initial refund report be paid no later than February 28, 2025, except in circumstances where a report is under dispute.

As noted above, the second annual refund report will be issued to manufacturers no later than September 30, 2025, and once annually thereafter no later than September 30 for each year involved. Thus, manufacturers will be required to pay refunds specified in each report no later than December 31 of the year in which the report is sent, except in circumstances where a report is under dispute. In the case of a dispute, payment of the refund will be due no later than 30 days after the resolution of the dispute.

CMS disagrees with a commenter who asserted the policy proposal violates due process principles of fair notice. The agency notes that its policies affect refunds that will be paid in the future after the promulgation of the rule and that there are no retroactive effects on payments that have already been made.

d. Refund Amount

(1) Calculation of Refund Amounts for Updated Quarters

Because CMS will include information on lagged claims data in all reports (other than the initial refund report), it will calculate the refund with updated data in the same manner as was finalized in the 2023 PFS final rule (87 FR 69727) and subtract the refund amount already paid for such refundable drug for such quarter to determine the updated quarter refund amount.

Specifically, CMS will calculate the refund for an updated refund quarter as the estimated amount by which:

- The product of:
  - The Medicare payment limit, and
  - The number of billing units that were discarded
- Exceeds the difference of:
  - An amount equal to the applicable percentage (10 percent unless increased as explained below) of the estimated total allowed charges for such a drug (less the amount paid for packaged drugs) during the quarter, and
  - The refund amount previously paid for such refundable drug for the given quarter.

If the resulting refund calculation for an updated quarter is a negative number, it is netted out of any refund owed for other updated quarters or new quarters.

(2) Calculation of Refund for a Drug when there are Multiple Manufacturers

Because a refundable drug could have more than one manufacturer (e.g., repackagers or relabelers or for authorized generics), a method for apportioning billing units of a rebatable drug for the manufacturers involved must be established. CMS finalizes its proposal (without modification) to identify these refundable drugs using the ASP sales data reported for the calendar quarter for which a refund amount is calculated, and to apportion financial responsibility for the refund amount among each manufacturer by dividing:

- The sum of the individual manufacturer's billing units sold during the refund quarter for all the manufacturer's NDCs assigned to the billing and payment code, by
- The sum of all manufacturers' billing units sold during the refund quarter for all NDCs of the refundable drug assigned to the billing and payment code.

It will apportion the discarded drug refund when there is more than one manufacturer for a refundable drug, using the proportion of billing unit sales, expressed as a percentage, attributed to each NDC (at the NDC-11 level) assigned to the billing and payment code for such refund quarter. The number of billing unit sales for each NDC will be the reported number of NDCs sold (as submitted in the ASP report to CMS each quarter) multiplied by the billing units per package for such NDC.

CMS will calculate the refund amount attributed to the NDCs for which each manufacturer is liable as the estimated amount by which:

- The product of:
    - The Medicare payment limit;
    - The total number of units of the billing and payment code for such drug that were discarded during such quarter; and
    - The percentage of billing unit sales of the applicable code attributed to the NDC
- Exceeds an amount equal to:
    - The applicable percentage of the estimated total allowed charges for such a drug (less the amount paid for packaged drugs) during the quarter, and
    - The percentage of billing unit sales of the applicable code attributed to the NDC.

Table 21 in the final rule provides an example.

CMS will apply this methodology starting with calendar quarters in 2023 included in the initial refund report (which would be sent no later than December 31, 2024) for new refund quarters and updated refund quarters for 2024 and subsequent years. CMS clarifies that the sales quarter of the ASP data used for this calculation will align with the dates of service for a new refund quarter or updated refund quarter.

Comments/Responses. Some commenters observed that the calculation could result in a manufacturer owing a discarded drug refund even if the amounts discarded from the manufacturer's refundable drugs did not exceed the applicable percentage. They assert that a manufacturer's liability should only be determined based on the manufacturer's product. They also believe the discarded drug refund should be calculated at the NDC-11 level if a refund is due for a refundable drug when there are multiple manufacturers of such drug, and that CMS should develop a process under which claims without NDC-11 level information are rejected for purposes of the refund,

CMS is not swayed by comments that its methodology for calculating the refund would result in one manufacturer owing any significant amount of refund that would have been owed by the other manufacturer. It believes that discarded amounts will be the same in nearly all instances in which a product is used from the same size containers (with same labeled amount of drug) regardless of who is manufacturing the product. However, the agency will monitor report information for refundable drugs with multiple manufacturers.

(3) Increased Applicable Percentage for Drugs with Unique Circumstances

Section 1847A(h)(3) of the Act authorizes CMS to increase the applicable percentage as appropriate, through notice and comment rulemaking, in the case of a refundable single-dose container or single-use package drug that has unique circumstances involving similar loss of product as those requiring filtration. As noted above, it adopted an increased applicable percentage of 35 percent for drugs reconstituted with a hydrogel and with variable dosing based on patient-specific characteristics.

Stakeholders have provided feedback to CMS on the criteria to use in determining when it is appropriate to increase the applicable percentage. Based on this input, CMS proposed a hybrid approach of the use of two categorical unique circumstances (i.e., low volume dose drugs and

orphan drugs) as well as an application process. Commenters were generally supportive, and CMS finalizes its proposals without modification.

CMS finalizes the establishment of two categorical unique circumstances (with associated increased applicable percentages), and it finalizes an application process for manufacturers to request that CMS consider whether an increased applicable percentage is appropriate for a particular drug in light of its unique circumstances. If CMS determines in response to such a request that an increased applicable percentage is appropriate, it will be proposed in future notice-and-comment rulemaking.

Drugs with a Low Volume Dose

The first categorical unique circumstance is for drugs with a "low volume dose." CMS defines this term as follows:

> Low volume dose means, with respect to the determination of whether an increased applicable percentage is warranted, an FDA-labeled dose of a drug for which the volume removed from the vial or container containing the labeled dose does not exceed 0.4 mL.

This definition of low volume dose applies even if the drug is further diluted after removal from the vial and before administration. In order for a drug to meet these unique circumstances, all labeled doses of the drug must be low volume doses. Additionally, the definition of low volume dose only applies for the determination of whether a higher applicable percentage is warranted for a drug.

The amount of the increase to the applicable percentage for drugs with a low volume dose is bifurcated as follows:

- Refundable drugs with labeled doses that are contained within 0.1 mL or less when removed from the vial or container will have an increased applicable percentage of 90 percent; and
- Refundable drugs with labeled doses that are contained within 0.11 – 0.4 mL when removed from the vial or container will have an increased applicable percentage of 45 percent.

A couple of commenters suggested an increased applicable percentage of 100 percent for drug low volume doses with 0.1 mL or less. CMS disagrees with this suggestion because it would essentially be an exemption of the drug from liability for any discarded drug refund.

Clarification was also sought on how CMS determines whether a particular drug is a low volume dose because clinicians administering drugs may not know the precise amount contained in a vial. CMS responds that it will publish a list of drugs it has identified as having low volume doses and will have an increased applicable percentage no later than December 31, 2023, which will be updated no later than December 31 of each subsequent year. Similarly, for orphan drugs, CMS intends to communicate a list of drugs that would have met conditions for having unique circumstances of rarely utilized orphan drugs for 2022 no later than December 31, 2023.This list would be provided as informational only and may not necessarily reflect the same list of drugs that have unique circumstances of rarely utilized orphan drugs when the data is analyzed for the initial refund report.

Orphan Drugs

The second categorical unique circumstance is for orphan drugs administered to a low volume of unique beneficiaries. To qualify as an orphan drug under this category, all FDA-labeled indications for the drug must be orphan indications. CMS refers to these drugs as rarely utilized orphan drugs, for which it finalizes an increased applicable percentage of 26 percent.

A low volume of unique beneficiaries is defined as fewer than 100 unique Medicare fee-for-service beneficiaries per calendar year. However, in response to a comment, CMS modifies its proposal in the final rule for this 100-unique Medicare fee-for-service beneficiaries per calendar year threshold. The threshold will be met with respect to an orphan drug if either of the two following conditions are satisfied:

- The number of unique beneficiaries to whom the drug is furnished is less than 100 during the calendar year in which the refund quarter occurs; or
- The average number of unique beneficiaries per year for the calendar year in which the refund quarter occurs and the 2 previous calendar years (3-year average) is less than 100. In the case that a drug for which at least 2 but less than 3 years of data available, CMS will calculate the average to determine whether the 100-beneficiary threshold is met.

Comments/Responses. Some commenters questioned the amount of the increased applicable percentage and the use of 100 as the limit on number of Medicare fee-for-service beneficiaries per calendar year for the low volume of unique beneficiaries; further details were sought on how CMS arrived at this threshold. Some suggested higher thresholds, such as 500 or 1,000 unique beneficiaries while others sought a higher increased applicable percentage. CMS responds that the 100-beneficiary threshold was derived from an analysis of quarterly discarded drug data from 2021 and 2022, which showed a higher probability that the percentage of discarded amounts for rarely utilized orphan drugs may not have a normal statistical distribution from quarter to quarter. The same variability was not observed for orphan drugs administered to more than 100 unique beneficiaries per year. CMS disagrees with suggestions for a higher threshold.

As finalized, a rarely utilized orphan drug is a drug that meets these unique circumstances and for which the increased applicable percentage will apply for as long as the drug meets these conditions, even after the orphan-drug exclusivity period ends.

CMS will identify drugs that have unique circumstances of low volume doses and rarely utilized orphan drugs in reports sent to manufacturers and apply the increased applicable percentages based on these categorical unique circumstances proposals. Manufacturers may dispute the applicable percentage increase that was applied to the refund calculation by submitting an error report. The categorical unique circumstances of certain drugs will apply beginning with the initial refund report, which will be sent no later than December 31, 2024.

Application Process for Increased Applicable Percentages

CMS finalizes its proposal (with some modifications to the proposed deadlines described below) to establish a process by which a manufacturer may request an increased applicable percentage for an individual drug with unique circumstances. This could include a drug that satisfies the criteria for one of the categorical unique circumstances described above. The manufacturer must submit a written request for an increased applicable percentage for its drug, the FDA-approved

labeling, and a justification for both the increased applicable percentage for the drug based on unique circumstances and the amount of the requested increase.

CMS will evaluate requests based on the documentation submitted, such as a minimum vial fill volume study or dose preparation study. One commenter expressed strong support for the use of these types of studies.

CMS had proposed that applications would have to be submitted by February 1 of the year before the calendar year in which the increased applicable percentage would apply. A commenter noted that the February 1 deadline for supporting documentation would create a significant lag for consideration and approval of an increased applicable percentage request if a drug is approved on or after the deadline. CMS agrees there may be circumstances where a manufacturer with a product that is close to FDA approval should be able to request an increased applicable percentage. In the final rule, applications for increased applicable percentage prior to FDA approval may be submitted if the product's application for FDA approval has been accepted by the FDA for review and documentation of FDA acceptance can be provided to CMS at the time of application for increased applicable percentage prior to the application deadline. Further, FDA approval must be granted by August 1, and notice of the approval must be sent to CMS by September 1. Thus, CMS establishes the following three deadlines for drug products in these circumstances:

- February 1 for all required documentation other than the FDA-approved label, including documentation of FDA acceptance of the product's application for review;
- August 1 for FDA approval; and
- September 1 for applicants to notify CMS of the product's FDA approval and submit the approved label.

Analysis of the applications as well as determinations of whether the drug warrants an increased applicable percentage (and, if so, by how much) will be provided in the PFS proposed rule following the application period. CMS will also include summaries of applications for which no increase is proposed.

At this time, CMS does not consider the following to be unique circumstances warranting an increased applicable percentage: weight-based doses, BSA-based doses, varying surface area of a wound, loading doses, escalation or titration doses, tapering doses, and dose adjustments for toxicity. Some commenters objected to the exclusion of these types of unique circumstances, and they note the difficulty of reconciling highly varied patient characteristics into a limited set of vial or container sizes, as well as those for drugs with loading doses. CMS acknowledges the challenges, but it notes that because the drug loss in not unavoidable in these cases, they are not similar to products that require filtration during preparation.
In response to another comment, CMS clarifies that once an increased applicable percentage is finalized through rulemaking, it continues to apply until modified by subsequent rulemaking.

e. Clarification for the Definition of Refundable Drug

CMS aims to create a consistent coding and payment approach for skin substitutes. It proposed that billing and payment codes that describe skin substitutes not be counted for purposes of identifying refundable drugs for calendar quarters during 2023 and 2024. The agency finalizes that JW units of skin substitutes will not be used for the discarded drug refund calculations, and it will not issue reports to manufacturers with respect to skin substitutes. The agency plans to revisit discarded drug refund obligations for skin substitutes in future rulemaking.

Comments/Responses. Many supported the exclusion for 2023 and 2024 for various reasons, including, because payment for skin substitutes is inconsistent across settings. This is because claims edits for appropriate JW and JZ modifier use were not in place for the first three quarters of calendar year 2023 to ensure accurate accounting of discarded amounts. Other commenters asserted that the agency is precluded from including these products because they fall outside the definition of a refundable drug; the agency does not respond specifically to this comment.

In response to another comment, CMS clarifies that, under section 1847A(c)(6)(C)(ii) of the Act, single source drugs or biologicals that were within the same billing and payment code as of October 1, 2003, will be treated as multiple source drugs for the purposes of the discarded drug refund.

f. Clarification for the Determination of Discarded Amounts and Refund Amounts

CMS clarifies that the JW modifier requirement does not apply to units billed to Medicare Advantage (MA) plans and that the refund amount calculations under section 1847A(h)(3) will not include units billed to MA plans. The rationale for this policy is that the agency cannot ensure data for refundable drugs billed to plans is consistently collected in accordance with the same reporting requirements as under Medicare FFS. Further, CMS clarifies that MA plans may adopt the JW and JZ modifier requirements under Medicare FFS, but those units will not be included in the calculation of the refund amount.

g. Use of the JW Modifier and JZ Modifier Policy

On October 1, 2023, CMS will begin editing for correct use of both the JW and JZ modifiers for billing and payment codes for drugs from single-dose containers. Because currently there is no claims modifier to designate that a drug was dispensed, but not administered, by the billing supplier, the policy finalized last year exempting self-administered drugs from the JW/JZ modifier policy may result in claims rejections absent a modification. CMS continues to find it unreasonable to collect discarded drug data from beneficiaries; thus, it proposed requiring that drugs separately payable under Part B from single-dose containers that are furnished by a supplier who is not administering the drug be billed with the JZ modifier. It finalizes the proposal without modification.

Comments/Responses. Both support for and opposition to the proposal were expressed. Some encouraged CMS to abandon the JZ modifier and instead work with providers and suppliers on

improved compliance with the JW modifier. Others suggested a new modifier for these drugs to separate them from the calculation of the discarded drug refund. CMS does not believe expanded education efforts would result in consistent correct reporting of the data necessary for this statutory provision. The agency does not believe adding another code would result in less administrative burden on suppliers. Further, CMS does not believe the JW and JZ modifier requirements impose any new burdens on providers beyond the requirement of measuring and reporting discarded amounts by use of the JW modifier that predates the enactment of the discarded drug refund policy. CMS notes that on October 16, 2023, it updated the JW and JZ Modifier FAQ[56] to provide additional clarity and resolve concerns about processing claims for single-dose drugs that are self-administered by a patient or caregiver in the patient's home before the 2024 billing requirement updates take effect. Finally, CMS reiterates that even if a drug is excluded from the definition of refundable single-dose container or single-use package drug and not subject to refunds (e.g., multiple source drugs), claims for such drugs furnished from a single-dose container must still use the JW and JZ modifiers in accordance

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. Implementation of the Consolidated Appropriations Act (CAA), 2023

Section 4113 of the Consolidated Appropriations Act, 2023. Effective January 1, 2022, RHCs and FQHCs can be paid for mental health visits furnished via real-time, telecommunication technology in the same way they currently do when these services are furnished in-person. Medicare's policy requires an in-person mental health service no more than 6 months prior to the telecommunications service and at least every 12 months while the beneficiary is receiving mental health treatment services. The in-person visit requirement can be waived if the physician or practitioner and patient agree that the risks and burdens outweigh the benefits as documented in the patient's medical record (86 FR 65210 and 65211).

Section 304 of the Consolidated Appropriations Act, 2022 (CAA, 2022) delayed the in-person requirements for Medicare mental health services furnished through telehealth under the PFS and in RHCs and FQHCs until 151 days after the end of the COVID-19 PHE. Section 4113(d) of the CAA, 2023 further delayed these requirements until January 1, 2025. CMS proposed conforming changes to the regulation to implement this statutory provision.

[56] https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf

Public commenters generally supported the extension of telehealth flexibilities for RHCs and FQHCs and the delay of the in-person requirements for mental health services, as required under section 4113 of CAA, 2023. Some public commenters requested that CMS extend these telehealth flexibilities beyond December 31, 2024. CMS responded it is beyond the agency's authority to extend the telehealth provisions past December 31, 2024

There were comments asking CMS to revise the definition of a face to face encounter (e.g., beyond just mental health visits) that is eligible for the FQHC PPS or the RHC AIR payment by allowing it to be furnished via interactive telecommunications technology. CMS responded that this comment was out-of-scope to any of the proposed rule policies.

One commenter requested allowing telehealth visits to be billed under the codes describing the service being provided rather than HCPCS code G2025. CMS responded that if it were to implement such a change through its claims processing systems, payment would be unchanged. The only change would be how RHCs and FQHCs bill for services. Such changes could be effectuated through sub-regulatory guidance. (It is unclear if CMS intends to pursue such sub-regulatory changes).

With regard to mental health services and the requirement to have an in-person visit at least six months prior to initiating a telehealth visit and at least every 12 months thereafter, a public commenter raised concerns that these requirements would inhibit patients seeking access to mental health care. CMS responded that if the patient and practitioner consider that, on balance, the risks of an in-person visit outweigh the benefits, and the practitioner documents the basis for that decision in the patient's medical record, the in-person visit requirement is not applicable for that 12-month period.

CMS finalized the conforming changes to the regulations as proposed.

Direct Supervision via Use of Two-way Audio/Video Communications Technology. Services and supplies furnished incident to physician's services are generally required to be furnished under direct physician supervision. Direct supervision means the physician must be immediately available to provide assistance and direction throughout the time the incident to service or supply is being furnished to a beneficiary. During the COVID-19 PHE, CMS modified the requirements for direct supervision to include the use of a virtual supervisory presence through the use of interactive audio and video telecommunications technology.

CMS believes that extending this definition of direct supervision for RHCs and FQHCs through December 31, 2024, would align 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 proposed to continue to define "immediately available" as including real-time audio and visual interactive telecommunications through December 31, 2024.

Public commenters universally supported CMS' proposal. CMS' response indicates that it would consider extending the option to provide virtual direct supervision in future rulemaking.

Licensed Marriage and Family Therapists (MFTs) or Mental Health Counselors (MHCs). RHC and FQHC services may be provided by physicians, physician assistants (PAs), nurse practitioners (NPs), certified nurse-midwives (CNMs), qualified clinical psychologists (CPs) and clinical social workers (CSWs). Services and supplies furnished incident to professional services of these practitioners may also be covered as RHC and FQHC services.

Effective January 1, 2024, CAA, 2023 establishes coverage of MFT and MHC services under the PFS. CAA, 2023 extended the scope of RHC and FQHC services to include those provided by MFTs and MHCs. CMS proposed conforming changes to its regulations to include MFTs and MHCs as eligible practitioners that may provide RHC and FQHC services.

Further, CMS proposed to clarify that when MFTs and MHCs provide the services described by HCPCS code G0323 for behavioral health integration services (BHI) in an RHC or FQHC, the RHC or FQHC can bill HCPCS code G0511. Previously, these codes were limited to BHI services provided by CPs and CSWs.

Public commenters supported CMS' proposals. In response to comments, CMS clarifies that mental health practitioners who meet all of the applicable statutory qualifications for the mental health counselor benefit category but are licensed by their state under a different title, are eligible to enroll in Medicare under the Part B "Mental Health Counselor" statutory benefit category. CMS further confirmed that MFTs and MHCs will not be subjected to a productivity standard as is required for physicians, NPs, PAs, and CNMs (but not CPs or CSWs) in the RHC setting.

CMS is finalizing all of its policies as proposed indicating that MFTs and MHCs should follow the same policies and supervision requirements as a PA, NP, CNM, CP, and CSW. In addition, CMS is finalizing as proposed a provision to allow addiction counselors that are licensed or certified as MHCs, clinical professional counselors, or professional counselors by the state in which the services are furnished to enroll in Medicare as MHCs.

Intensive Outpatient Program (IOP) Services. Effective January 1, 2024, CAA, 2023 establishes coverage and payment for IOP services. In the 2024 PFS proposed rule, CMS indicates that FQHCs and RHCs are eligible to furnish IOP services and be paid at the same rate as a hospital. IOP services include occupational therapy, family counseling, beneficiary education, diagnostic services and individual and group therapy. More details on CMS' implementation of this benefit are included in the 2024 OPPS rule.

3. Supervision Requirements for Behavioral Health Services Furnished at RHCs and FQHCs

Under the PFS, CMS requires general supervision for behavioral health services furnished by auxiliary personnel. These services remain subject to the direct supervision requirements in RHCs and FQHCs. Consistent with the PFS supervision requirement, CMS proposed that behavioral health services furnished by auxiliary personnel at RHCs and FQHCs may also be furnished under general supervision. Public comments support this proposal that CMS is finalizing without change.

4. General Care Management Services in RHCs and FQHCs

Remote Physiologic Monitoring (RPM) and Remote Therapeutic Monitoring (RTM). 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 they should be paid separate and apart from the AIR or FQHC PPS payment that is for a face-to-face visit.

The proposed rule discussed RPM and RTM—services that are not currently paid as stand-alone billable visits in RHCs and FQHCs. RHCs and FQHCs have inquired about receiving a separate payment for RTM and RPM services. They have stated that CMS should expand HCPCS code G0511 to include RPM treatment management services or establish G-codes for RPM set-up and patient education on use of equipment (CPT code 99453) and monthly data transmission (CPT code 99554) to allow payment to RHCs and FQHCs.

CMS proposed to include the CPT codes that comprise RPM and RTM in the general care management HCPCS code G0511 when these services are furnished by RHCs and FQHCs. The requirements for RPM and RTM services are similar to the non-face-to-face requirements for the general care management services furnished in RHCs and FQHCs. Allowing a separate payment for RPM and RTM services in RHCs and FQHCs is intended to reflect the additional resources necessary for the unique components of these services.

Public commenters universally supported CMS' proposal to allow payment for RPM and RTM services in FQHCs and RHCs. However, some commenters do not believe G0511 reflects the costs of providing these services. CMS responded that it is revising the weighted average of the services that comprise HCPCS code G0511 to incorporate RPM and RTM. The weighted average is $72.98 or within the range of the $43.04 to $133.18 paid under the PFS for these services.

CMS is finalizing its policies as proposed.

Community Health Integration Services (CHI) and Principal Illness Navigation (PIN) Services. RHCs and FQHCs sometimes help newly diagnosed cancer patients and other patients with similarly serious, high-risk illnesses navigate their care, such as helping them understand and implement the plan of care, and locate and reach the right practitioners and providers to access recommended treatments and diagnostic services, considering the personal circumstances of each patient.

CMS proposed to create two codes for CHI services that may be billed by RHCs and FQHCs when furnished by certified or trained auxiliary personnel, which may include a community health worker when furnished incident to the professional services under the general supervision of a physician or non-physician practitioner. The first code (GXXX1) would be for the first 60 minutes of service while the second code (GXXX2) would be for each additional 30 minutes.

PIN services describe those of a patient navigator or certified peer specialist involved in the patient's health care navigation as part of the treatment plan for a serious, high-risk disease

expected to last at least 3 months, that places the patient at significant risk of hospitalization or nursing home placement, acute exacerbation/decompensation, functional decline, or death. CMS proposed to create two codes for PIN services that may be billed by RHCs and FQHCs when furnished by certified or trained auxiliary personnel incident to the professional services under the general supervision of a physician or non-physician practitioner. The first code (GXXX3) would be for the first 60 minutes of service while the second code (GXXX4) would be for each additional 30 minutes.

Public commenters supported these proposals. Commenters recommended that CMS consider a standalone HCPCS code for CHI and PIN services in RHCs and FQHCs because of the potential for increased claim denials for duplicate billing when numerous care management services are included in HCPCS code G0511. CMS responded that an RHC or FQHC may bill HCPCS code G0511 multiple times in a calendar month as long as all requirements are met and there is not double counting. CMS believes that G0511 will provide adequate payment and support access to these services.

CMS is finalizing its policies as proposed.

Social Determinants of Health (SDOH) Risk Assessment. CMS is allowing the SDOH risk assessment to be an optional element of Annual Wellness Visit (AWV) paid under the PFS. Public commenters asked how the SDOH risk assessment would be paid in FQHCs and RHCs. CMS responded that FQHCs and RHCs are currently eligible to furnish the AWV and as such, they will also be eligible to furnish a SDOH risk assessment as an additional element of the AWV. When the SDOH risk assessment is furnished as an optional element of the AWV, only one visit is paid, that is, it will be paid under the AIR or the lesser of charges or the PPS rate with the AWV adjustment.

Revision to Payment for HCPCS Code G0511. Payment for HCPCS code G0511 is an average of the PFS payments for the billable general care management services included in the code. If CMS were to revise the payment for HCPCS code G0511 to include the additional proposed services (e.g., RPM, RTM, CHI and PIN), the payment would decline from $77.94 to $64.13.

CMS proposed to revalue HCPCS code G0511 using a weighted average of utilization in the physician office setting of its composite codes. As CMS proposed to use 2021 utilization for this purpose, there would be no utilization for some of G0511's composite codes that were not yet in effect at that time (Chronic Pain Management, general BHI, CHI and PHI). Once more data is available, CMS would revisit the payment for G0511 to include these services. Under CMS' proposal, the payment would decline from $77.94 to $72.98.

Most commenters supported CMS' proposal. Some commenters said this payment would be insufficient as RHCs and FQHCs can only bill G0511 once per month. However, CMS responded that RHCs and FQHCs may bill HCPCS code G0511 multiple times in a calendar month, as long as all of the requirements are met and resource costs are not counted more than once. CMS is finalizing its policy as proposed.

Beneficiary Consent for Chronic Care Management (CCM) Services. CMS has required beneficiary consent for CCM services by the practitioner billing for the service or by auxiliary staff under the direct supervision of the billing practitioner. During the COVID-19 PHE, CMS provided flexibility on meeting these requirements.

CMS proposed to clarify that FQHCs and RHCs must obtain informed consent prior to the start of CCM services. Consent does not have to be obtained at the required initiating visit prior to beginning CCM that must be performed by the RHC or FQHC practitioner, but it can be obtained at that time. If consent is separately obtained, it may be obtained under general supervision, and can be verbal as long as it is documented in the medical record and includes notification to the beneficiary of the required information. There need not be an employment relationship between the person obtaining consent and the RHC or FQHC practitioner. The clinical staff obtaining the verbal or written consent can be under contract with the RHC or FQHC.

CMS reiterates that the importance of obtaining advance beneficiary consent to receive CCM services is to ensure the beneficiary is informed, educated about CCM services, and aware of applicable cost sharing. It also helps reduce the potential for duplicate billing of the services.

For the proposed rule, CMS requested comment on the standard practice used by practitioners to obtain beneficiary consent for CCM services. Public commenters supported obtaining consent for care management under general supervision that allows CCM vendors with trained enrollment staff to obtain proper consent from patients. Several commenters believe an efficient Medicare system requires CCM services to leverage the potential of EHR systems, patient portals, texting/SMS services, chatbot technologies, interactive mobile medical apps, and direct patient calls to obtain consent. The commenters encouraged CMS to permanently allow providers to obtain beneficiary consent under general supervision.

CMS reiterated that consent does not have to be obtained at the required initiating visit before beginning CCM that must be performed by the RHC or FQHC practitioner, but it can be obtained at that time. Since the RHC or FQHC practitioner discusses CCM with the beneficiary during the initiating visit, if consent is separately obtained, it may be obtained under general supervision, and can be verbal as long as it is documented in the medical record and includes notification of the required information. Further, clinical staff obtaining the verbal or written consent can be under contract with the RHC or FQHC.

Virtual Communication Services. During the COVID-19 PHE, CMS allowed RHCs and FQHCs to furnish virtual communication services under HCPCS code G0071. CMS allowed consent to be obtained when the service was furnished and before being billed. Consent could be obtained by staff under general supervision of an RHC or FQHC practitioner. CMS adopted the same policy for virtual communication services as CCM—that is, consent from the beneficiary to receive virtual communication services can be documented by auxiliary staff under general supervision, as well as by the billing practitioner.

The policy on obtaining consent for virtual communication services via general supervision ended with the end of the COVID-19 PHE. However, CMS believes the same philosophy applies

to consent for virtual communications as it does for CCM. In an effort to continue promoting access to timely, quality care for Medicare beneficiaries and to align with the PFS, CMS proposed to clarify that the consent from the beneficiary to receive virtual communication services can be documented by auxiliary staff under general supervision, as well as by the billing practitioner. Public commenters supported this proposal that CMS is finalizing without modification.

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

Under the current CfCs, RHC and FQHC services may be provided by physicians, PAs, NPs, CNMs, CPs and CSWs. Effective January 1, 2024, CAA, 2023 establishes coverage of MFT and MHC services. CAA, 2023 extended the scope of RHC and FQHC services to include those provided by MFTs and MHCs. CMS proposed to change the CfCs to add MFTs and MHCs (and also CPs, CSWs and CNMs who were added by statute as RHC and FQHC practitioners but not previously included in the CFCs). In addition, MFTs and MHCs are added to the list of practitioners that may be an owner, employee or furnish services under contract to the clinic or center.

The current CfCs specify two organizations that must certify primary care NPs to be eligible RHC and FQHC practitioners. One of these organizations has changed its name. The proposed rule indicated that that there are national organizations other than ones specified in the regulations that also certify primary care NPs. Rather than specify a national approving body, CMS proposed to change the definition of NP for the CfCs to include a recognized national certifying body that has established standards for nurse practitioners and possession of a master's degree in nursing or a Doctor of Nursing Practice doctoral degree. CMS proposed to add the education requirement to the definition because the American Nurses Association has stated that for someone to become an NP, one must be a registered nurse or have a Bachelor of Science in nursing, complete an NP-focused master's or doctoral nursing program, and pass the National NP Certification Board Exam.

The NP scope of practice allows NPs to provide care to patients based on the acuity of the patient's needs, rather than the setting in which the services are administered. This implies that an acute care NP can offer their services to patients within their scope of practice in RHCs and FQHCs, and other settings. NPs increasingly provide services to Medicare beneficiaries; however, the scope of benefits between primary care and acute care may be different. The FQHC and RHC CfCs require an NP to have a certification in primary care. CMS requested comments on whether it should retain the requirement that an NP certification be in primary care.

Public commenters supported all of the above proposals that CMS is finalizing with the modification that it is removing the restriction that an NP have a certification in primary care to be an eligible practitioner in an FQHC or RHC.

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

Under regulations implementing the Protecting Access to Medicare Act, 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 was January 1, 2019 through June 30, 2019. While the second data reporting period was originally January 1, 2020 through March 31, 2020, a series of subsequent statutory amendments—the latest being the CAA, 2023—delayed the next reporting period until January 1, 2024 through March 31, 2024 without changing the date of the second data collection period. These statutory amendments also limited the reduction in payment to 0 percent from 2021 to 2023 and 15 percent for each year 2024 through 2026.

CMS proposed to conform its regulations at 42 CFR part 414, subpart G, to the latest statutory amendments. Public commenters supported CMS' proposals but raised concerns about the long delay between the data collection period from 2019 and the data reporting period in 2024. Commenters noted that private payer rate data from 2019 would be several years old and not reflect tests that came on the market after the data collection period. CMS acknowledged this concern but indicated it is a function of statutory provisions and not any policy within CMS' authority.

There were other comments regarding outreach and education activities for data reporting purposes if there are any future changes to the timeline for data reporting, since significant time and resources are required for entities to properly collect and report data. CMS responded that it regularly updates its website and has leveraged different media platforms to disseminate various educational materials and other resources to prepare applicable laboratories for data reporting and inform them of changes to reporting requirements. The final rule points readers towards a video that CMS created as one outreach tool to inform applicable laboratories of their requirement to report private payer rates: https://youtu.be/c3eiPYeRA_U.

Commenters also raised concerns about the phase-in of payment reductions to CLFS payment amounts that would be required to resume in 2024. CMS responded that the phase-in of payment reductions to the CLFS is statutory and unable to be changed by the agency.

There were also comments supporting legislation that would give CMS new authority to collect private market data through statistically valid sampling from all laboratory segments for the widely available test services. CMS responded that any legislative changes would require Congressional action and could not be adopted by CMS without a change in law.

CMS is finalizing all of its policies as proposed without modification.

E. Pulmonary Rehabilitation, Cardiac Rehabilitation, and Intensive Cardiac Rehabilitation Expansion of Supervising Practitioners

Section 1861(eee) of the Act provides conditions of coverage under Medicare part B for items and services furnished under cardiac rehabilitation (CR) programs and intensive cardiac rehabilitation (ICR) programs and section 1861(fff) of the Act provides for conditions of coverage under Medicare part B for items and services furnished under pulmonary rehabilitation (PR) programs. Initially, the statute required these items and services be furnished under the supervision of a physician. Section 51008 of the BBA of 2018 amended these sections to authorize, beginning January 1, 2024, physician assistants (PAs), nurse practitioners (NPs), and clinical nurse specialists (CNSs) to also be included as practitioners who may supervise PR, CR, and ICR programs.

CMS finalizes, as proposed, the following revisions to §§410.47 and 410.49 in order to carry out the amendments made by section 51008 of the BBA of 2018:

- Adding the new term "nonphysician practitioner" (NPP), which would be defined as a PA, NP, and CNS.
- Changing the term "supervising physician" to "supervising practitioner," which would mean a physician or NPP.
- Changing the definition for the programs to specify they are physician or NPP-supervised.
- Specifying that a physician or NPP must be immediately available and accessible when services are being furnished under the programs.
- Specifying that the sections include supervising practitioner standards (not just supervising physician standards).

Many commenters supported the changes to expand the types of practitioners who may supervise the PR, CR, and ICR programs because they believed the changes would expand access to the programs and the additional practitioners included as NPPs are highly trained to serve in supervisory roles. Some commenters did not support the revisions that would expand supervision roles under the programs to include the additional practitioners because they do not believe the skillsets of the NPPs and of physicians are interchangeable. The importance was raised of ensuring physician involvement in diagnosis and treatment decisions. However, CMS states it is required to follow the statutory changes that were made by the BBA of 2018.

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

1. Background

Section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act[57] created a new Part B benefit

[57] P.L. 115-271, enacted October 24, 2018.

category for OUD treatment services furnished by Opioid Treatment Programs (OTPs) beginning January 1, 2020. In the 2020 and 2021 PFS final rules, CMS implemented the following:

- Medicare coverage and provider enrollment requirements;
- A methodology for determining bundled payments for episodes of care;
- Codes for payments for weekly episodes of care that include methadone, oral buprenorphine, implantable buprenorphine, injectable buprenorphine or naltrexone, and non-drug episodes of care; and
- Add-on codes for intake and periodic assessments, take-home dosages for methadone and oral buprenorphine, additional counseling, and take-home supplies of nasal naloxone and injectable naloxone.

In the 2022 PFS final rule, CMS established a new add-on code and payment for a higher dose of nasal naloxone, as well as allowed OTPs to furnish individual and group therapy and substance use counseling using audio-only telephone calls after the conclusion of the PHE in cases where audio/video communication is not available to the beneficiary, provided other requirements are met.

In the 2023 PFS final rule, with respect to methadone, CMS adjusted the methodology for pricing the drug component of the weekly bundle and the add-on code for take-home supplies. Other changes included basing the payment rate for individual therapy in the non-drug component of the bundled payment on the rate for longer therapy sessions, to better account for the greater severity of needs for patients with an OUD who are receiving treatment in the OTP setting. The agency also clarified that services furnished via OTP mobile units will be treated as if the services were furnished in the physical location of the OTP for purposes of payments to OTPs under the Medicare OTP bundled payment codes and/or add-on codes.

2. Additional Flexibilities for Periodic Assessments via Audio-only Telecommunications

CMS has implemented several flexibilities for OTPs regarding the use of telecommunications, both during the PHE and outside of the PHE. Most recently, the 2023 PFS final rule extended telecommunications flexibilities for the initiation of treatment with buprenorphine outside of the PHE—specifically, to allow for the following:

- 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, if authorized by the Substance Abuse and Mental Health Services Administration (SAMHSA) and Drug Enforcement Administration (DEA);
- Use of audio-only communications technology to initiate treatment with buprenorphine in cases where audio-video technology is not available to the beneficiary, provided all other applicable requirements are met; and
- Through the end of 2023, periodic assessments to be furnished audio-only when video is not available, if authorized by SAMHSA and DEA at the time of service and in a manner consistent with all applicable requirements.

CMS proposed to extend the audio-only flexibilities for periodic assessments furnished by OTPs through the end of 2024—in cases where a beneficiary does not have access to two-way audio-

video communications technology and all other applicable requirements are met. This aligns with similar statutory changes extending telehealth flexibilities through the end of 2024 for certain other services and providers.[58] CMS said extending this flexibility would promote continued beneficiary access to audio-only periodic assessments, citing numbers on increased telemedicine offerings by SUD facilities and that telephone-based (that is, audio-only) support services provided by SUD programs have been found to be one of the most common modes of telehealth for treatment of OUD.

The agency also cited evidence that Medicare beneficiaries who are racial/ethnic minorities, dual-enrollees, or living in rural areas, or who experience low broadband access, low-income, and/or not speaking English as their primary language, are more likely to be offered and use audio-only telemedicine services than audio-video services. Thus, minimizing disruptions to care for beneficiaries currently receiving audio-only periodic assessments may further promote health equity and minimize disparities, while providing CMS time to further consider whether the flexibility should continue past 2024 for patients who are receiving treatment via buprenorphine, methadone, and/or naltrexone at OTPs.

Comments/Responses: Commenters were supportive of extending the audio-only flexibilities for periodic assessments furnished by OTPs through the end of CY 2024 and reiterated that audio-only telehealth encounters are more prominent among individuals who are older, Black, Hispanic, American Indian/Alaskan Native, Spanish-speaking, living in areas with low broadband access, low-income, and with public insurance. Others shared data that audio-only visits produce many of the same benefits as video-based visits. A few commenters noted additional safeguards should accompany the greater regulatory flexibility, with periodic in-person visits required, for example.

CMS agreed with commenters and said it will continue to defer to SAMHSA and DEA clinical guidance and other applicable requirements to ensure safety and quality of care. CMS said it will continue to analyze clinical evidence and monitor claims and utilization data, and may address any concerns through future rulemaking.

Many commenters requested that CMS make the extension for audio-only periodic assessments permanent. CMS restated that it will continue evaluating the issue and may consider additional changes in future rulemaking.

Final Action: CMS finalizes its proposal so that, through the end of CY 2024, the definition of "Opioid use disorder treatment service" at §410.67(b) includes cases where a beneficiary does not have access to two-way audio-video communications technology, permitting Medicare payment for periodic assessments using audio-only telephone calls if all other applicable requirements are met.

---

[58] See section 4113 of Division FF, Title IV, Subtitle A of the Consolidated Appropriations Act of 2023 (CAA, 2023) (P.L. 117-328, December 29, 2022). For example, it extended the flexibilities available during the PHE that allow for certain Medicare telehealth services defined in section 1834(m)(4)(F)(i) of the Act to be furnished via an audio-only telecommunications system through December 31, 2024.

3. Intensive Outpatient Program (IOP) Services Provided by OTPs

In July 2022, CMS sought comment in the 2023 PFS regarding intensive outpatient program (IOP) services in OTP settings. In December 2022, the CAA, 2023 was enacted, which included a provision establishing Medicare coverage for intensive outpatient services effective for items and services furnished on or after January 1, 2024. CMS refers readers to the 2024 OPPS final rule for the full policy discussion and additional details regarding the proposal to establish Medicare payment for IOP services provided by OTPs.

G. Medicare Shared Savings Program

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

H. Medicare Part B Payment for Preventive Vaccine Administration Services (§§§410/10,410.57,410.152)

CMS reviews the history for the payment rates for Part B vaccines (i.e., influenza, pneumococcal, hepatitis B virus (HBV)[59], 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 describe the services to administer an influenza, pneumococcal, and HBV vaccine, respectively. In the 2023 PFS final rule, CMS finalized it would maintain a payment rate of $40 for the administration of COVID-19 vaccines through the end of the calendar year in which the March 27, 2020 Emergency Use Authorization declaration for drugs and biological products ends.[60] Effective January 1 of the year following the EUA declaration ends, the administration payment for COVID-19 vaccine would align with the payment rate for the other Part B vaccines. The current payment rates for the CPT codes that describe administration of COVID-19 vaccines is available on the CMS COVID-19 Vaccines website.[61] 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.

The payment rates for these services, with the annual update applied for 2024, are available in Tables 46A and 46B included in the final rule and reproduced at the end of this section.

In response to comments requesting clarification about the transition date for the vaccine payment amount for COVID-19 vaccines, CMS discusses the differences between an EUA declaration under section 564 of the Food, Drug & Cosmetic (FD&C) Act and an HHS PHE

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

declaration under section 319 of the PHS Act. Although the HHS PHE declaration for COVID-19 expired on May 11, 2023, the EUA issued for drugs and biological products with respect to COVID-19 continues to remain in effect.[62]

CMS refers commenters with questions about how CMS determined the COVID-19 vaccine administration rate to the 2022 PFS final rule (87 FR 65184-65186) which contains an extensive discussion on its rationale for initially setting the $40 COVID-19 vaccine administration rate, and for eventually aligning that rate with the rate for the administration of the other Part B preventive vaccines at $30 per vaccine. As discussed above, this transition is set to occur on January 1 of the year following the year in which the Secretary ends the March 27, 2020, EUA declaration.

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

a. Background

In the 2022 PFS final rule, CMS finalized add-on payment (HCPCS code M0201) for in-home COVID-19 vaccine administration, under specific circumstances. In the 2023 PFS final rule, CMS finalized it would continue this additional payment ($35.50); this payment is adjusted for the percentage increase in the MEI and the GAF to reflect geographic cost differences.

The following requirements apply when billing for HCPCS code M0201:[63,64]

- The patient has difficulty leaving the home to get the vaccine; difficulty leaving the home could mean any of the following:
    - They have a condition, due to an illness or injury, that restricts their ability to leave home without a supportive device or help from a paid or unpaid caregiver
    - They have a condition that makes them more susceptible to contracting a pandemic disease like COVID-19; or
    - They are generally unable to leave the home, and if they do leave home, it requires a considerable and taxing effort.
- The patient is hard-to-reach because they have a disability or face clinical, socioeconomic, or geographical barriers to getting a COVID-19 vaccine in settings other than their home. These patients face challenges that significantly reduce their ability to get vaccinated outside the home, such as challenges with transportation, communication, or caregiving.
- The sole purpose of the visit is to administer the COVID-19 vaccine. Medicare will not pay the additional amount if the provider or supplier furnished another Medicare covered service in the same home on the same date.
- A home can be a private residence, temporary lodging (e.g., a hotel or motel, campground, hostel, or homeless shelter); an apartment in an apartment complex or a unit

[62] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/faqw-what-happens-euas-when-public-health-emergency-ends.
[63] https://www.cms.gov/medicare/covid-19/medicare-covid-19-vaccine-shot-payment
[64] https://www.cms.gov/files/document/vaccine-home.pdf.

in an assisted living facility[65] or group home; a patient's home that is made provider-based to a hospital during the PHE for COVID-19; or communal spaces of a multi-unit living arrangement or communal living arrangement.

- A home cannot be an institution which meets the requirements of sections 1861(e)(1), 1819(a)(1), or 1919(a)(1) of the Act (relating to hospitals, skilled nursing facilities, and most Medicaid nursing facilities).

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

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

b. Policies for 2024 and Subsequent Years

As discussed in the proposed rule, analysis of data for in-home COVID-19 vaccinations among Medicare fee-for-service beneficiaries from June 2021 to June 2022 showed the payment code M0201 (COVID-19 vaccine home administration) was used at a disproportionately high rate by underserved populations, including individuals who are dual eligible and individuals 85 years of age and older. Based on this information, CMS proposed 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,[66] it proposed to extend 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.

Since expanding this policy could mean that multiple vaccine are administered during the same visit to the home, CMS proposed to limit the additional payment to one payment per home visit, even if multiple vaccines are administered during the same home visit. CMS planned to monitor utilization of the M0201 billing code for the in-home additional payment for inappropriate use or abuse of the code. CMS noted that every vaccine dose that is furnished during a home visit will still receive its own unique vaccine administration payment. Additionally, CMS noted it currently limits payment of M0201 for up to a maximum of 5 vaccine administration services per home unit or communal space within a single living location, but only when fewer than 10 patients receive a COVID-19 vaccine dose on the same day at the same group living location.

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

Commenters were overwhelmingly supportive of these proposals because they would greatly improve access to vaccines for vulnerable, hard to reach and medically underserved populations. In response to commenters recommending expansion of Part B vaccine coverage, CMS notes that in accordance with the statute, Part B payment can only be made for the preventive vaccines specified at section 1861(s)(10) of the Act.

Final Rule Action. CMS finalizes these policies as proposed. Providers and suppliers can continue to bill Medicare Part B for the additional payment for the in-home administration of COVID-19 vaccines, and beginning January 1, 2024, they will also be able to bill Medicare Part B for the in-home additional administration of pneumococcal, influenza and hepatitis B vaccines. All in-home additional payments for the administration of Part B vaccines will be geographically adjusted based on the PFS GAF, and annually updated by the 2024 MEI percentage increase. The MEI percentage increase for the 2024 final rule is 4.6 percent and the 2024 in-home additional payment for Part B preventive vaccine administration is $38.55 ($36.85x1.04). CMS amends the Part B payment for preventive vaccine administration regulations at §410.152(h) to reflect the finalized policies.

TABLE 47: CY 2024 Part B Payments for Preventive Vaccine Administration if the EUA Declaration for Drugs and Biologicals with Respect to COVID-19 Continues into CY 2024

Category of Part B Product Administration	Part B Payment Amount (Unadjusted)	Annual Update[6]	Geographic Adjustment
Influenza, Pneumococcal, Hepatitis B Vaccines[1,4]	$32.57	MEI	GAF
COVID-19 Vaccine[2,4]	$43.43	MEI	GAF
In-Home Additional Payment for Part B Vaccine Administration (M0201)	$38.55	MEI	GAF
COVID-19 Monoclonal Antibodies (for Treatment or Post-Exposure Prophylaxis) [3,4,5]			
Infusion: Health Care Setting	TBD	N/A	GAF
Infusion: Home	TBD	N/A	GAF
Intravenous Injection: Health Care Setting	TBD	N/A	GAF
Intravenous Injection: Home	TBD	N/A	GAF
Injection: Health Care Setting	TBD	N/A	GAF
Injection: Home	TBD	N/A	GAF
COVID-19 Monoclonal Antibodies (for Pre-Exposure Prophylaxis)[3,4,5]			
Injection: Health Care Setting	TBD	N/A	GAF
Injection: Home	TBD	N/A	GAF

1 HCPCS Codes G0008, G0009, G0010.

2 *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price/vaccine- pricing.*

3 *https://www.cms.gov/monoclonal*. As of the issuance of the CY2024 PFS final rule, there are no COVID-19 monoclonal antibodies approved or authorized for use against the dominant strains of COVID-19 in the United States.

4 Beneficiary coinsurance and deductible are not applicable.

5 To be determined (TBD). As of the issuance of the CY 2024 PFS final rule, there are no COVID-19 monoclonal antibodies approved or authorized for use against the dominant strains of COVID-19 in the United States.

6 The 2024 MEI percentage increase is 4.6 percent based on the most recent historical data through the 2nd quarter of 2023.

TABLE 48: Part B Payments for Preventive Vaccine Administration Beginning January 1, 2024, if the EUA Declaration for Drugs and Biologicals with Respect to COVID 19 is Terminated on or Before December 31, 2023			
Category of Part B Product Administration	**Part B Payment Amount (Unadjusted)**	**Annual Update[7]**	**Geographic Adjustment**
Influenza, Pneumococcal, Hepatitis B[1,4]	$32.57	MEI	GAF
COVID-19[2,4]	$32.57	MEI	GAF
In-Home Additional Payment for Part B Vaccine Administration (M0201)	$38.55	MEI	GAF
COVID-19 Monoclonal Antibodies (for Treatment or Post-Exposure Prophylaxis)[3,5]	Medicare payment under the applicable payment system		
COVID-19 Monoclonal Antibodies (for Pre-Exposure Prophylaxis)[4,5]	TBD [5,6]	N/A	GAF

[1] HCPCS Codes G0008, G0009, G0010.

[2] *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price/vaccine- pricing.*

[3] Payment is in accordance with the applicable payment system of the setting in which the product is administered. Beneficiary coinsurance and deductible are applicable.

[4] Beneficiary coinsurance and deductible are not applicable.

[5] As of the issuance of the CY2024 PFS final rule, there are no COVID-19 monoclonal antibodies approved or authorized for use against the dominant strains of COVID-19 in the United States.

[6] Please see section III.H.4 of this final rule.

[7] The 2024 MEI percentage increase is 4.6 percent based on the most recent historical data through the 2nd quarter of 2023.

2. Regulatory Updates and Conforming Changes

In the 2023 PFS final rule, CMS established a policy to continue coverage and payment for monoclonal antibodies used for pre-exposure prophylaxis (PrEP) of COVID-19 under the Part B preventive vaccine benefit if they meet applicable coverage requirements. CMS proposed to revise §§410.40(l) and 410.57(c) to reflect these finalized policies. CMS notes that the in-home additional payment proposals are not applicable to the administration of monoclonal antibodies for PrEP of COVID-19.

CMS notes that at the time of the publication of this final rule, there are no COVID-19 monoclonal antibodies approved or authorized for use against the dominant strains of COVID-19 in the US. Therefore, it is not finalizing any payment regulations regarding monoclonal antibodies for PrEP of COVID-19 at this time. If and when a new monoclonal antibody for PrEP of COVID-19 becomes authorized for use, CMS will establish specific coding and payment rates for the administration of that product through technical directions to the MAC and publish the information on the CMS website.

CMS also finalizes its proposed corrections at §410.152(h) to reorganize some elements of the regulation text for the in-home additional payment and include the effective date for the MEI policy for vaccine administration.

I. Medicare Diabetes Prevention Program (MDPP)

CMS' Medicare Diabetes Prevention Program Expanded Model (MDPP) was established in 2017 as an in-person "additional preventive service" under Medicare. MDPP is the expansion of CMMI's DPP model test that ran from 2012 to 2016. MDPP is an evidence-based behavioral intervention that aims to prevent or delay the onset of type 2 diabetes for eligible Medicare beneficiaries diagnosed with prediabetes, requires no Medicare cost sharing, and is available once per lifetime to eligible beneficiaries.

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

MDPP is a non-pharmacological behavioral intervention consisting of at least 22 intensive sessions using a CDC-approved National Diabetes Prevention Program (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 proposed the following changes to MDPP regulations, summarized in greater detail below:

- Revise and add definitions to provide greater flexibility, including for virtual sessions;
- Increase the maximum number of payable sessions during the MDPP core services period;
- Extend by 4 years certain flexibilities that were originally implemented due to the PHE; and
- Streamline the MDPP payment structure by adding service-based attendance payments, while still retaining the diabetes risk reduction performance payments for 5 percent and 9 percent weight loss.

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

CMS proposed the following changes to various MDPP definitions:

- Delete the following definitions:
    - Core maintenance session interval
    - Ongoing maintenance sessions
- Add definitions for the following:
    - Combination delivery—that is, distance and in-person learning
    - Distance learning—that is, with a live coach
    - Extended flexibilities and extended flexibilities period (through December 31, 2027)
    - Full-Plus CDC DPRP recognition

    - Online delivery—that is, a session without a live coach, where participants experience content on their own time—which is not included in current or proposed MDPP flexibilities
    - Virtual session—that is, an MDPP session not furnished in person but in a manner consistent with the DPRP standards for distance learning sessions
- Revise definitions for the following:
    - Make-up session
    - MDPP services period
    - MDPP session

These changes would permit and promote virtual MDPP, which was permitted beginning with the PHE and, as proposed, would continue until December 31, 2027—the extended flexibilities period. The first of these two virtual flexibilities permits alternatives to the in-person requirement for weight measurement. That is, an MDPP supplier may obtain weight measurements for MDPP beneficiaries for the baseline weight and any weight loss-based performance achievement goals either (1) via digital technology, such as scales that transmit weights securely via wireless or cellular transmission, or (2) via self-reported weight measurements from the at-home digital scale of the MDPP beneficiary.[67] The other flexibility through December 31, 2027 that CMS proposed was to eliminate the limit on the number of virtual MDPP sessions; during the extended flexibilities period, all MDPP services may be provided virtually or in person (consistent with the CDC standards for distance learning).

These flexibilities would only be available to MDPP suppliers that have and maintain CDC DPRP in-person recognition. CMS is maintaining the policy that virtual-only suppliers are not permitted to provide MDPP services because MDPP beneficiaries may elect to return to in-person services and MDPP suppliers need to be able to accommodate their request. CMS reviews the history of MDPP, how it was established as an in-person service in the original DPP test, and that certification as an expanded model was based on in-person delivery. CMS says that extending the flexibilities permitted during the PHE through December 31, 2027, will make MDPP more equitable and accessible for beneficiaries by providing both suppliers and beneficiaries more flexibility in how MDPP services are delivered, including in-person, distance learning, or a combination of in-person and distance learning—for example, for beneficiaries who reside in rural communities and who may have transportation and other barriers to attending in-person classes.[68]

---

[67] Although this current regulatory language on additional requirements related to the self-reported weight measurements (§410.79(e)(3)(iii)) is somewhat confusing, CMS did not propose amending it. In the preamble, the agency clarifies that either (1) the self-reported weight must be obtained during live, synchronous online video technology with the MDPP coach observing the weighing and the weight, or (2) the beneficiary may submit to the MDPP supplier a date-stamped photo or video recording of the beneficiary's weight, with the beneficiary visible in their home, that clearly documents the weight of the MDPP beneficiary as it appears on the digital scale on the date associated with the billable MDPP session.

[68] CMS notes that MDPP supplier locations have traditionally clustered proximate to large metropolitan areas, leaving significant gaps throughout rural communities. It believes MDPP's in-person requirements have contributed to significant underutilization, not only for those who reside in rural communities, but also populations that experience excessive diabetes related disparities, including populations of color, low-income beneficiaries, those living in Tribal and rural communities, and the disabled.

To better track and evaluate the use of distance learning through claims, CMS proposed the creation of a new HCPCS G-code specific to "distance learning" that will more accurately do the following:

- Track sites from which distance learning occurs and the number of MDPP sessions delivered by distance learning;
- Monitor the expanded model for fraud, waste, or abuse; and
- Evaluate the impact of distance learning and in-person delivery modalities of MDPP relative to cost-savings and diabetes risk reduction among participants.[69]

The definitional changes also conform to the proposed payment approach described below, with FFS payment for beneficiary attendance, replacing the current, confusing arrangement based on the "core maintenance session interval."[70] The "core services period" remains unchanged, consisting of at least 16 core sessions offered at least one week apart during months 1 through 6 of the MDPP services period, and two 3-month core maintenance session intervals offered during months 7 through 12 of the MDPP services period. Although beneficiaries could attend 16 or more weekly sessions in months 1-6, and 6 or more monthly sessions in months 7-12, MDPP suppliers were only paid five times for beneficiary attendance—that is, after a beneficiary attends the 1st, 4th and 9th sessions in months 1-6, and after attending the second core maintenance session in months 7-9 and in months 10-12.

After 5 years of testing, CMS determined the attendance-based performance payments were not working. For example, 5 attendance-based performance payments currently occur over the 12-month MDPP service period, with a potential 4- to 5-month lag between the third and fourth payments. CMS' monitoring data shows that attendance sharply drops after the first quarter, likely after the 9th weekly session has been attended and because the current payment structure does not incentivize beneficiary retention.

As a result, CMS proposed FFS payments for beneficiary attendance, allowing for up to 22 attendance-based payments versus the 5 currently in place. Thus, beneficiaries could attend a maximum of 22 sessions during the core services period, including up to 16 sessions in months 1-6 and up to 6 sessions in months 7-12.

Comments/Responses: Overall, commenters were very supportive of the proposed changes.

Several encouraged CMS to consider adopting the same definitions for MDPP as CDC uses for the National DPP, including distance learning, online delivery, and combination modalities to better align the two programs. CMS said that while that is generally desirable, there are times when the programs diverge, given that CMS is the payer of the MDPP set of services and CDC

[69] Prior to the PHE, CMS permitted the use of a limited number of virtual make-up sessions, the claims for which must include a virtual modifier (VM). Since the PHE flexibilities, as proposed to continue through December 31, 2027, eliminate the maximum number of virtual make-up sessions and considering the inconsistent use of the modifier, CMS says that the HCPCS code is proposed as a replacement to the VM; however, CMS is not proposing to remove the VM, in case it is needed in future rulemaking.

[70] "Core maintenance session interval" is defined as one of the two consecutive 3-month time periods during months 7 through 12 of the MDPP services period, during which an MDPP supplier offers an MDPP beneficiary at least one core maintenance session per month.

sets quality standards for organizations that deliver the National DPP. The agencies worked closely for their respective updates for 2024, and CMS may make conforming changes in the future.

Commenters were overwhelmingly supportive of the proposed changes to streamline the MDPP payment structure, including the creation of a new G-code for in-person delivery (G9886), distance learning (G9887), and maintenance of 5 percent weight loss from baseline in months 7 to 12 (G9888). They were also unanimously supportive of extending for 4 years the PHE flexibilities, which increased access to MDPP for both coaches and participants by removing barriers related to transportation and time.

Multiple commenters expressed disappointment that CMS is not allowing virtual-only providers to enroll in Medicare as MDPP suppliers, even though it is permitted in the CDC's National DPP, severely limiting supplier participation. CMS responds that the agency's certification of MDPP as an expanded model was based on in-person delivery only and that MDPP suppliers need to accommodate beneficiary requests for in-person services. Distance learning delivery of MDPP may not be appropriate for every beneficiary—for example, beneficiaries may not have the required technological competency and access. Given this, CMS reminds suppliers that they are required to maintain capacity to deliver MDPP Set of services in-person.

Final Action: CMS is finalizing its proposal with no changes.

2. Changes to Medicare Payment for MDPP Services (§414.84)

Since MDPP launched in April 2018, only a third of the 300 MDPP suppliers have submitted claims due to the complex payment structure. Related challenges include irregular flow of operating funds, a lack of incentive to retain participants after the 9th core session due to the potential 4- to 5-month payment lag, and claims denials due to the complicated payment structure.

CMS proposed to update the payment structure from a performance-based attendance and weight loss structure to a hybrid structure that pays for attendance on a FFS basis and diabetes risk reduction (weight loss) on a performance basis. In the current payment structure, suppliers must submit a claim after a participant completes the first, fourth, and ninth sessions during the first 6 months, then following months 7-9 and 10-12 in the core maintenance sessions phase. Instead, CMS proposed an Attendance Payment, which is a FFS payment when the MDPP beneficiary attends an MDPP core or core maintenance session. Suppliers would receive an Attendance Payment after submitting a claim for each MDPP session, starting with the first core session, using a new HCPCS G-code, *Behavioral counseling for diabetes prevention, in-person, group, 60 minutes, or Behavioral counseling for diabetes prevention, distance learning, 60 minutes*, for dates of service on or after January 1, 2024.

CMS notes that this proposed payment structure is similar to that for Intensive Behavioral Counseling for Obesity (IBTO) and Diabetes Self-Management Training (DSMT). MDPP suppliers would receive regular payments for services for up to a year during a 12-month MDPP service period for up to 22 sessions, either in person or distance learning, or a combination of

both. In months 1 to 6, payments would be allowed for one in-person or distance learning session every week up to a maximum of 16 sessions. During months 7 to 12, payments would be allowed for one in-person or distance learning session every month up to a maximum 6 sessions.

CMS also proposed that the MDPP supplier's performance payment would be based solely on MDPP beneficiaries achieving weight loss goals (5 percent and 9 percent, as under current regulation) and would drop the performance goal based on attendance.

Table 49 of the final rule, duplicated below, shows the finalized MDPP payments for 2024 and the associated G-codes. CMS notes this is simpler than the current claims submission process, which requires that suppliers submit 11 to 15 G-codes for different attendance-based sessions at irregular intervals, as shown in Table 50 of the proposed rule (not duplicated here). Both tables show a total maximum payment in 2024 of $768.

TABLE 49: Changes to MDPP Payment Structure to Include Attendance-Based Service Payments and Diabetes Risk Reduction Performance Payments

HCPCS Code	Payment Description*	2024
G9886*	Behavioral counseling for diabetes prevention, in-person, group, 60 minutes	$25
G9887*	Behavioral counseling for diabetes prevention, distance learning, 60 minutes	$25
G9880	5 percent WL Achieved from baseline weight	$145
G9881	9 percent WL Achieved from baseline weight	$25
G9888**	Maintenance 5 percent WL from baseline in months 7-12	$8
G9890	Bridge Payment	$25
Subtotal Maximum Attendance-Based Payment		**$550**
Total Maximum Payment		**$768**

Notes: "WL" is weight loss. In short, 42 CFR 414.84(c) defines a "bridge payment" as a payment to a supplier for a session with an MDPP beneficiary who previously received MDPP services from a different MDPP supplier.
* Medicare pays up to 22 sessions billed with codes G9886 and G9887, combined, in a 12-month period:
Months 1-6: 1 in-person or distance learning session every week (max 16 sessions)
Months 7-12: 1 in-person or distance learning session every month (max 6 sessions)
** Suppliers must submit claim for 5 percent weight loss (G9880) prior to submitting claims for the maintenance 5 percent WL from baseline in months 7-12 (G9888).

Commenters were generally positive regarding these proposed changes, although some did make recommendations, including for increased payment rates and increasing the number of sessions (from 22) that CMS would pay for. CMS said such changes could jeopardize the certification of MDPP as an expanded model. CMS finalizes the rule as proposed.

3. Changes to MDPP Provider Requirements (§424.205)

As previously mentioned, the CDC's DPRP implements the quality assurance function of the National DPP, including for MDPP. Although existing MDPP regulations mention previous, interim categories, DPRP now has four categories of recognition: pending, preliminary, full, and full-plus. Organizations may participate in MDPP with preliminary, full, or full-plus CDC recognition, and advance by demonstrating their ability to effectively deliver the behavioral

change program (preliminary) and achieve the outcomes shown to prevent or delay type 2 diabetes (full and full-plus). The rule describes CDC's detailed standards at each level.

CMS proposed to eliminate from the MDPP regulation the outdated "interim preliminary recognition" standard and to require that, at the time of enrollment, organizations have preliminary, full, or full-plus CDC DPRP recognition. Commenters were unanimous in their support of this proposal, and CMS finalizes it without modification.

J. Appropriate Use Criteria for Advanced Diagnostic Imaging

1. Background

Section 218(b) of the PAMA amended Title XVIII of the Act to add section 1834(q) directing CMS to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. AUC are a set of individual criteria that present information in a manner that links a specific clinical condition or presentation, one or more services, and an assessment of the appropriateness of the service(s). Evidence-based AUC for imaging can assist clinicians in selecting the imaging study that is most likely to improve health outcomes for patients based on their individual context. AUC must be integrated into the clinical workflow.

There are four major components of the AUC program, each with its own implementation date: (1) establishment of AUC by November 15, 2015 (1834(q)(2)); (2) mechanisms for consultation with AUC by April 1, 2016 (1834(q)(3)); (3) AUC consultation by ordering professionals and reporting on AUC consultation by furnishing professionals by January 1, 2017 (1834(q)(4)); and (4) annual identification of outlier ordering professionals for services furnished after January 1, 2017 (1834(q)(5)). CMS did not identify mechanisms for consultation by April 1, 2016 and did not publish the list of qualified clinical decision support mechanisms (CDSMs) by January 1, 2017; therefore, ordering professionals were not required to consult CDSMs and furnishing professionals were not able to report information on the consultation by January 1, 2017.

CMS reviews the history for its development and implementation of policies for the four major components of the AUC program. In the 2016 PFS final rule, CMS primarily addressed the first major component under section 1834(q)(2) – the process for establishment of AUC, along with relevant aspects of the definitions under section 1834(q)(1). CMS defined the term provider-led entities (PLE) to include national professional medical societies, health systems, hospitals, clinical practices and collaborations of such entities such as the National Comprehensive Cancer Network. Qualified PLEs may also collaborate with third parties. In June 2016, CMS identified 11 qualified PLEs.[71]

In the 2017 PFS final rule, CMS primarily addressed the second major component of the AUC program - the identification of qualified CDSMs that could be used by ordering professionals for consultation with applicable AUC under section 1834(q)(3) of the Act. CMS defined CDSM as an interactive, electronic tool for use by clinicians that communicates AUC information to the

[71] The list of qualified PLEs can be accessed at https://www.cms.gov/Medicare/Quality-Initiative-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html.

user and assists them in making the most appropriate treatment decision for a patient's specific condition. In June 2017, CMS identified six qualified CDSMs and nine CDSMs with preliminary qualifications.[72]

In the 2018 PFS final rule, CMS addressed the third major component of the AUC program under section 1834(q)(4) of the Act, Consultation with Applicable Appropriate Use Criteria. CMS established a January 1, 2020 effective date for the ACU consultation and reporting requirements. A voluntary period was also established during which ordering professionals could begin reporting limited information on Medicare claims from July 2018 through December 2019. On January 1, 2020, CMS began an educational and operations testing period during which claims continued to be paid whether or not they correctly include AUC consultation information.

The fourth major component of the AUC program is in section 1834(q)(5) of the Act, Identification of Outlier Ordering Professionals. This section facilitates a prior authorization requirement for outlier professionals beginning January 1, 2020, as specified under section 1834(q)(6) of the Act. In the 2017 PFS final rule, CMS finalized the first list of priority clinical areas[73] which served as part of the basis for identifying outlier ordering professionals. CMS has not proposed or codified the methods for identifying outlier ordering professionals and has not subjected any ordering professional to prior authorization.

2. AUC Program Paused for Reevaluation

CMS finalizes its proposal to pause implementation of the AUC program for reevaluation and to rescind the current AUC regulations at §414.94. CMS believes the removal of these regulations is consistent with its decision to pause efforts to implement the AUC program.

CMS discusses that this pause is necessary because it has exhausted all reasonable options for fulling operationalizing the AUC program consistent with the statutory provisions requiring real-time claims-based reporting to collect information on AUC consultation for advanced diagnostic imaging services to ultimately inform outlier identification and prior authorization. CMS expects this program reevaluation to be difficult and does not propose a time frame for recommencing implementation.

CMS acknowledges the existing Medicare claims processing system does not have the capacity to fully automate the process for distinguishing between advanced diagnostic imaging claims that are or are not subject to the AUC program requirement to report AUC consultation information as prescribed by section 1834(q)(4)(B) of the Act. CMS discusses the practical complexity of the AUC when an advanced diagnostic imaging service is furnished in two settings and only one of the settings is an applicable setting, a not uncommon scenario. CMS also discusses risks from the implementation of the AUC program related to data integrity and accuracy, beneficiary access,

[72] The list of qualified CDSMs can be accessed at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/CDSM.html.

[73] The first list of priority clinical areas includes coronary artery disease (suspected or diagnosed, suspected pulmonary embolism, headache (traumatic and non-traumatic), hip pain, low back pain, shoulder pain (includes suspected rotator cuff injury), cancer of the lung (primary or metastatic, suspected or diagnosed), and cervical or neck pain.

and potential beneficial financial liability for advanced diagnostic imaging services. CMS concludes it has not identified any practical way to move the AUC program forward beyond the educational and operations testing period.

CMS notes that clinical decision support tools can still be beneficial is assisting with clinical decision making and encourages continued use of these tools. CMS also discusses how many of the AUC program goals have been met by the QPP and other comprehensive accountable care initiatives such as the MSSP.

Many commenters supported the proposal to pause efforts to implement the AUC program for reevaluation and to rescind and reserve the current AUC program regulations at §414.94. Stakeholders representing ordering professionals believed the AUC program imposed undue burden and administrative costs on providers. Manu commenters agreed with CMS' concerns about unintended costs to beneficiaries for improperly denied claims, as well as potential delays in accessing needed imaging studies. Many commenters hoped that CMS would permanently forgo the AUC program. Some commenters provided mixed comments and a few believed that the PAMA statute must be changed to successfully implement an AUC program.

Some commenters were opposed to the proposal and cited the benefits of using AUC for promoting cost containment. A few commenters expressed concern about the resources, including money and training, they have spent to implement the AUC program. Two commenters suggested CMS is not interpreting the statute correctly and that CMS has the authority to incorporate the AUC program into other quality and value-based programs. CMS disagrees with these suggestions; it cannot simply ignore or reinterpret the PAMA statute and it cannot incorporate AUC into other programs without additional amendments to the statute. CMS also notes that a change in statute would be required to transfer responsibility for reporting and auditing on CDSM/Guideline usage to CDSMs. CMS will continue efforts to identify a workable implementation approach and will propose to adopt any approach through rulemaking, including implementing any amendments Congress might make to the AUC statutory provisions.

CMS appreciates recommendations that it contract for additional technical assistance. CMS reiterates that negative impacts are not just occasional incidences of ordering professionals consulting AUC when it is not required. Using only services billed on the professional claims type, CMS estimated over 30 million advanced diagnostic services to be subject to the AUC and this number only increases with the addition of relevant institutional claims. Because it cannot fully automate the claims processing system to accurately identify claims that are and are not subject to the real-time claims-based reporting requirements, millions of claims are at risk of improper processing, including unwarranted denials.

Regulatory Impact. CMS acknowledges by pausing implementation of the AUC program, the Medicare program may not realize the estimated savings, and clinicians will not experience the estimated costs. Table 129 (reproduced below) includes the AUC program-related activities and their corresponding impact estimates. CMS notes that these previously estimated costs and savings are no longer accurate and will not be realized because the program cannot be implemented as written in statute. Because the statute cannot be implemented the savings are negligible.

Table 129: AUC Program Related Activities with Impact Estimates From 2022 PFS	
AUC Program Related Activity	**2002 PFS Rule Impact Estimates**
Impact of required AUC consultations by ordering professionals	$51,039,109
Impact to Medicare beneficiaries	$54,789,518
Impact on transmitting order for advanced diagnostic imaging	$94,495,192
AUC automated solution	$1,851,356,888
Medicare program impacts associated with advanced diagnostic imaging services	$700,000,000

K. Medicare and Medicaid Provider and Supplier Enrollment

1. Medicare Provider Enrollment

a. Background

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers into the Medicare program. The enrollment process helps confirm that providers and suppliers seeking to bill Medicare for items and services furnished to Medicare beneficiaries meet all federal and state requirements. CMS describes it as a "gatekeeper" that prevents unqualified and potentially fraudulent individuals and entities from entering and inappropriately billing Medicare. To clarify or strengthen certain components of the enrollment process, CMS proposed several changes to its existing Medicare provider enrollment regulations.

b. Medicare Provider Enrollment Provisions

Revocations. CMS may revoke a Medicare provider's or supplier's enrollment for any of the reasons specified within §424.535(a), including failure to adhere to Medicare enrollment requirements or felony conviction within the previous 10 years. Reasons for revocation have been added over the years. After revocation, a provider or supplier is generally barred from reenrolling in Medicare for 1 to 10 years. This "reenrollment bar" is determined based on the severity of the basis of the revocation. The maximum reenrollment bar is typically restricted to egregious acts of misconduct.

CMS proposed the following modifications regarding revocations.

Non-Compliance Revocation Grounds. The proposed rule would broaden the regulatory enrollment requirements that could subject a provider or supplier to revocation to those "described in this title 42," rather than just those "described in this subpart P." This would then encompass, for example, opioid treatment programs. CMS finalized the provision as proposed.

Misdemeanor Convictions. Under current regulations, CMS may not revoke a provider's or supplier's enrollment due to a misdemeanor. CMS provides two problematic examples of misdemeanors. The first was a physician who wrote and filled prescriptions in fictitious patients' names to obtain Schedule II controlled substances for personal use. The physician pled guilty to

a reduced misdemeanor charge for attempting to obtain controlled substances by fraud. The second was an owner of a provider charged with felony assault with a dangerous weapon; however, the court reduced the charge to a misdemeanor as part of a guilty plea and sentenced the defendant to 2 years of probation.

Under the proposal, CMS may revoke a provider's or supplier's enrollment if they, or any owner, managing employee or organization, officer, or director thereof, have been convicted (as that term is defined in 42 CFR §1001.2) of a misdemeanor under federal or state law within the past 10 years that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries, including:

- Fraud or other criminal misconduct involving the provider's or supplier's participation in a federal or state health care program or the delivery of services or items.
- Assault, battery, neglect, or abuse of a patient (including sexual offenses).
- Any other misdemeanor that places the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.

Comments/Responses: Numerous commenters opposed CMS' proposed misdemeanor revocation authority, citing concerns that the purview was too broad (potentially covering misdemeanors involving comparatively modest conduct) or could apply to physicians with misdemeanor convictions for violating state laws restricting gender-affirming care or reproductive rights.

Final Action: After reviewing the comments, CMS is not finalizing this proposal but will continue to monitor cases of misdemeanor convictions involving significant misconduct and may pursue future rulemaking. Many misdemeanors—especially those involving assault, battery, neglect, or abuse of a patient (including sexual offenses)—remain of concern.

False Claims Act Civil Judgments. The False Claims Act (FCA, 31 USC §§3729-3733) is the federal government's principal civil—that is, not criminal—remedy for addressing false or fraudulent claims for federal funds. Section 3729(a)(1) of the FCA lists specific actions that can result in an FCA judgment against a defendant—for example, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval.

A party liable under the FCA must pay a civil penalty of between $5,000 and $10,000 for each false claim (revised for inflation) and triple the amount of the government's damages. CMS says the FCA has proven effective in helping to stem Medicare fraud, but an FCA civil judgment against a provider or supplier does not impact their Medicare enrollment. Even if, for example, a provider is found to have knowingly submitted fraudulent claims and is liable for $100,000 in FCA damages, CMS has no ability to revoke the provider's enrollment on this basis, which is a concern since the actions identified in section 3729(a)(1) of the FCA involve serious misbehavior.

CMS proposed that it could revoke the enrollment of a provider or supplier if the provider or supplier, or any owner, managing employee or organization, officer, or director thereof, has had

a civil judgment under the FCA imposed against them within the previous 10 years.[74] Recognizing that the specific facts and circumstances of each case will differ, CMS proposed that the regulatory language would list the following factors that the agency would consider in its decision:

- The number of provider or supplier actions that the judgment incorporates (for example, the number of false claims submitted).
- The types of provider or supplier actions involved.
- The monetary amount of the judgment.
- When the judgment occurred.
- Whether the provider or supplier has any history of final adverse actions (as defined in §424.502).
- Any other information that CMS deems relevant to its determination.

Comments/Responses: Although one commenter expressed support for the proposal, several were opposed, concerned it would (1) harm good-faith providers who inadvertently submitted false claims and (2) pressure providers to settle their case to maintain Medicare enrollment, even if the provider believes no wrongdoing was committed. CMS responds that it will have discretion under this provision and will only take action after a careful assessment of the factors outlined and the circumstances of the case. The agency does not believe the new authority will compel providers to settle FCA cases and is unaware of situations where providers have pled guilty to a misdemeanor charge instead of contesting a felony charge out of concern of having their Medicare enrollment revoked.

Final Action: CMS is finalizing its proposal with no changes.

Violation of Provider and Supplier Standards. Beyond general enrollment requirements in 42 CFR part 424, subpart P, other regulations list detailed Medicare enrollment standards for independent diagnostic testing facilities (IDTFs), DMEPOS suppliers, opioid treatment programs (OTPs), home infusion therapy (HIT) suppliers, and Medicare diabetes prevention programs (MDPPs). CMS proposed that it could revoke the enrollment of an IDTF, DMEPOS supplier, OTP, HIT supplier, or MDPP based on a violation of any of those other standards or conditions.

Several commenters stated that CMS should only apply §424.535(a)(23) when the provider has a pattern of non-compliance and refuses to remedy the matter when requested to do so. CMS disagrees, stating that it should not be compelled to wait for the commission of additional violations, and finalizes its proposal with no changes.

Existing Treasury Department Debt. Under §424.535(a)(17), CMS may revoke enrollment if the provider or supplier has an existing debt that CMS appropriately refers to the United States Department of Treasury. In determining whether a revocation is appropriate, CMS considers six factors outlined in the regulation—for example, the reason for the provider's failure to pay the debt. The provision is intended to spur providers to repay their financial obligations to Medicare; not doing so raises doubts as to whether they can be a reliable partner of the Medicare program.

[74] CMS notes that "civil judgment" would not include FCA *settlement agreements*, but a *judgment* against the provider or supplier.

CMS has received inquiries as to whether this provision applies to debts that are no longer being collected or are being appealed.

CMS proposed to exclude from the purview of §424.535(a)(17) those cases where (1) the provider's or supplier's Medicare debt has been discharged by a bankruptcy court; or (2) the administrative appeals process concerning the debt has not been exhausted or the timeline for filing such an appeal, at the appropriate appeal level, has not expired. In CMS' view, the debts in these two situations have not been finally and fully adjudicated and thus basic fairness to the provider or supplier justifies the revision.

In §424.535(a)(17)(i), CMS proposed to change the term "existing debt" to "failure to repay a debt" in order to allow the agency to potentially use its revocation authority even if collection action has ceased and the debt was ultimately terminated as a result. CMS' central concern is more with the provider's or supplier's inaction in fulfilling its financial obligations to Medicare rather than with the particular status or result of CMS' collection efforts, including if it was "written off." CMS emphasizes that it would still apply the aforementioned six factors in all potential revocation cases, including "reason(s) for the failure to fully repay the debt (to the extent this can be determined)," so as to ensure fairness to the provider or supplier.

While several commenters expressed concern about the proposed terminology change to "failure to repay a debt" in §424.535(a)(17), CMS reiterated that its core concern was not about the intent of the provider but the repayment failure itself. CMS finalizes its proposal with no changes.

Reasons for Denial. Some of the previously described proposals for revoking Medicare provider enrollment for current providers are also proposed to apply as reasons for denial of new providers:

- Based on enrollment requirements "described in this title 42," rather than just those "described in this subpart P."
- If convicted of a misdemeanor under federal or state law within the past 10 years that CMS deems detrimental to the best interests of Medicare and its beneficiaries.
- If a civil judgment under the FCA has been imposed within the previous 10 years, with the same previously described factors that CMS would also consider in its decision.
- Based on a violation of any of the additional standards or conditions that apply to an IDTF, DMEPOS supplier, OTP, HIT supplier, or MDPP.

As with the previously described proposals regarding revocations, CMS is finalizing its proposal without modification to deny new providers based on FCA judgments, supplier standard/condition violations, and violations of enrollment provisions in title 42. However, it is not finalizing the proposal concerning denials for misdemeanor convictions.

Effective Date of Revocation. Although a revocation generally becomes effective 30 days after CMS or the contractor mails notice of its determination to the provider or supplier, under existing regulations, there are four exceptions. CMS proposed revisions to §424.535(g) to make clearer the following four retroactive revocation situations that exist in current regulations:

- For revocations based on a federal exclusion or debarment, the date of the exclusion or debarment.
- For revocations based on a felony conviction, the date of the felony conviction.
- For revocations based on a state license suspension or revocation, the date of the license suspension or revocation.
- For revocations based on a CMS determination that the provider's or supplier's practice location is non-operational, the date on which the provider's or supplier's practice location was no longer operational (per CMS' or the CMS contractor's determination).

CMS also proposed to add the following new situations where a retroactive date would be warranted:[75]

- For revocations regarding misdemeanor convictions, the date of the misdemeanor conviction.
- For revocations based on a state license surrender in lieu of further disciplinary action, the date of the license surrender.
- For revocations based on termination from a federal health care program other than Medicare (for example, Medicaid), the date of the termination.
- For revocations based on termination of a provider agreement under 42 CFR part 489, for the type of provider involved, the later of the following: (1) the date of the provider agreement termination; or (2) as applicable, the date that CMS establishes under 42 CFR 489.55, which permits payments beyond the provider agreement termination date in certain instances and for a certain period.
- Revocations based on proposed §424.535(a)(23)—that is, based on the additional standards or conditions that apply to an IDTF, DMEPOS supplier, OTP, HIT supplier, or MDPP:
    - If the standard or condition violation involved the suspension, revocation, or termination (or surrender in lieu of further disciplinary action) of the provider's or supplier's federal or state license, certification, accreditation, or MDPP recognition, the revocation effective date would be the date of the license, certification, accreditation, or MDPP recognition suspension, revocation, termination, or surrender.
    - If the standard or condition violation involved a non-operational practice location, the revocation effective date would be the date the non-operational status began.
    - If the standard violation involved a felony conviction of an individual or entity described in §424.67(b)(6)(i), the revocation effective date would be the date of the felony conviction.

CMS cites two comments—one in favor of the proposal and one that offered an amendment, which CMS declined to incorporate. CMS finalizes its proposal, except for the language referencing misdemeanor convictions, since that underlying policy was not finalized.

[75] CMS proposed an additional technical modification—that the revocation would essentially be the later of the date listed or the provider's enrollment date. This is because, technically, a provider's enrollment cannot be revoked until they have been enrolled.

Timeframes for Reversing a Revocation. If a revocation was due to adverse activity (sanction, exclusion, felony) by one of the parties listed in §424.535(e)—for example, owner, managing employee, authorized or delegated official, supervising physician—the revocation can be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that party within 30 days of the revocation notification. CMS has been concerned about this 30-day period—that a provider or supplier should be afforded so much time to terminate this business relationship, since each day the revoked provider or supplier remains affiliated with the party in question, the more Medicare dollars that could be paid.

CMS proposed to reduce this 30-day period to 15 days. The agency noted an even shorter period—for example, 5 days—might be administratively and financially difficult to immediately terminate the business relationship in question, especially an owner's interest in the provider or supplier. However, the reduction from 30 days to 15 days evidences CMS' concern about making Medicare payments to providers and suppliers that have relationships with parties presenting program integrity risks. The agency also noted that this change would have no impact on a revoked provider's ability to appeal a revocation under existing regulations (42 CFR part 498) but would only affect the provider's utilization of §424.535(e) to reverse the revocation.

Comments/Responses: Several commenters opposed the proposed reduction from 30 days to 15 days, stating this is insufficient time to terminate the affiliation and submit proof. Revocation letters can take 5 or more days to reach the provider, leaving no more than 10 days to comply with the requirements of §424.535(g). Some suggested that if the proposal is finalized, the provider should have 15 days from the documented date of receipt of the revocation letter to end the affiliation and provide proof, and that CMS should send all revocation notices through certified mail.

CMS reiterated that it is imperative that providers always take quick measures to resume compliance with enrollment requirements and that CMS' overriding concern must be the protection of the Trust Funds, even if this means providers have less time to comply with the requirements of §424.535(g). The agency also disagreed with the idea that the 15-day timeframe should begin with the provider's receipt of the notice, since that could provide additional days of payment involving thousands of dollars.

Final Action: CMS finalizes its proposal without modification.

Stay of Enrollment. Existing §424.540(a) lists reasons for CMS to deactivate a provider's Medicare billing privileges. A deactivation differs from a revocation in that it (1) merely involves the stoppage, rather than the termination, of the provider's or supplier's billing privileges; and (2) does not entail any reenrollment bar under §424.535(c) and thus providers can reactivate their billing privileges by following the procedures in §424.540(b) rather than waiting for the expiration of the 1- to 10-year bar period for a revoked provider. CMS says it sometimes imposes a deactivation instead of a revocation when a more modest sanction is warranted, which can still impose a potential burden on a provider. In fact, CMS says it may be too punitive in certain cases—that a middle ground between a deactivation and non-action is warranted, to take appropriate, fair and reasonable measures that are commensurate with the degree of the provider's action, inaction or noncompliance.

CMS proposed in new §424.541 a new enrollment status labeled a "stay of enrollment" that would be a preliminary, interim status—prior to any subsequent deactivation or revocation. It would represent a "pause" in enrollment, during which the provider or supplier would still remain enrolled in Medicare and CMS would neither formally nor informally treat the stay as a sanction or adverse action for purposes of Medicare enrollment. CMS would also notify the affected provider or supplier in writing of the stay.

CMS proposed two prerequisites for a stay's implementation. First, the provider or supplier must be non-compliant with at least one enrollment requirement in Title 42. Mere suspicion of or information alleging non-adherence is insufficient; actual non-compliance is required. Second, CMS ascertains that the provider or supplier can remedy the non-compliance via the submission of a Form CMS-855, Form CMS-20134, or Form CMS-588 change of information or revalidation application. This change request could involve, for example, reporting a new street number (CMS illustrates with a provider's address changing from 10 Smith Street to 15 Smith Street) that the provider previously failed to disclose to CMS.

When a "stay period" is imposed, the provider or supplier would not receive payment for services or items furnished during this period, because they were non-compliant with enrollment requirements. Thus, even after the stay concludes, they would not receive payment for services or items furnished during this period. Claims submitted by the provider with dates of service within the stay period would be denied.

A stay period would not last more than 60 days. This makes it different from a denial of payment that occurs with a deactivation under §424.540, which has no finite timeframe. In addition, MACs can generally process Form CMS-855 change requests more rapidly than a reactivation application, thus enabling a provider or supplier subject to a stay to begin receiving payments sooner than if deactivated.

CMS states that the issue of burden is the core consideration behind this proposal. It does not wish to have to proceed to a deactivation (much less a revocation) in all cases of non-compliance—especially if the non-adherence can be fairly quickly corrected via the provider's submission of updated enrollment data. Nevertheless, CMS also believes the affected provider or supplier should have an opportunity to raise a concern about a stay by submitting a rebuttal, which is delineated in detail in the new §424.541(b)—generally to mirror that for deactivations and payment suspensions (§424.546 and §405.374, respectively). For example, the provider or supplier will have 15 calendar days from the date of the stay's written notice to submit a rebuttal, unless CMS extends the timeframe, at its discretion.

CMS emphasizes that its authority to impose a stay would be discretionary. For example, it could elect to proceed directly to a deactivation or revocation without applying a stay as a first step. Its decision regarding which action is most appropriate would depend upon the facts and circumstances of the case.

Existing regulations (§424.555(b)) state that payment may not be made for Medicare services and items furnished to a Medicare beneficiary by a deactivated, denied, or revoked provider or

supplier, and that the beneficiary has no financial liability for such services and items. To this list of categories, CMS proposed to add providers and suppliers currently under a stay of enrollment.

Comments/Responses: While several commenters supported the concept of a stay of enrollment in lieu of the other harsher options, many opposed the prohibition against payment for services furnished during the stay. Once the provider has resumed compliance and the stay has been lifted, payment should be made retroactively for services provided during the stay. According to the comments, it would be unfair to deny payment for inconsequential cases of non-compliance that CMS did not deem significant enough to warrant a deactivation or revocation. If no retroactive payment is permitted, then stays are not much different than deactivations.

CMS agrees with these commenters. Upon further consideration, the agency does not believe allowing retroactive payments in stay situations would be inherently contrary to its obligation to safeguard the Trust Funds, if the requirements outlined in this final rule are met.

Final Action: CMS finalizes the creation of a stay period. Claims submitted during the stay period will be rejected (rather than "denied," as stated in the proposed rule). This change will make it easier for the provider to later resubmit the claims. CMS adds in the final rule that these claims are eligible for payment (and may be resubmitted by the provider within applicable timeframes specified in title 42) if (1) CMS or its contractor determines that the provider or supplier has resumed compliance with all Medicare enrollment requirements in Title 42, and (2) the stay ends on or before the 60th day of the stay period.

Reporting Changes in Practice Location. Under current regulations, the following provider and supplier types must report a change in practice location within 30 days of the change: (1) DMEPOS suppliers; (2) IDTFs; and (3) physicians, nonphysician practitioners, and physician and nonphysician practitioner organizations.[76] All other provider and supplier types must report practice location changes within 90 days of the change (§424.516(e)(2)).

CMS notes instances of practice locations moving without the agency being notified. CMS says this is problematic for two reasons. First, Medicare payments are often based on the provider's specific geographic location. CMS could be making incorrect payments to the provider for an extended period (for instance, 90 days), which would be inconsistent with CMS' obligation to protect the Trust Funds. Second, CMS would be unable to promptly determine whether the new site is compliant with Medicare provider enrollment requirements (for example, via a site visit). The provider might be furnishing services from an invalid location, hence resulting in improper payments.

CMS proposed that all provider and supplier types would be required to report practice location changes within 30 days of the change. Across the various regulations,[77] CMS also proposed to

[76] §§424.57(c)(2), 410.33(g)(2), and 424.516(d)(1)(iii), respectively.
[77] §§410.33(g)(2), 424.516(d)(1)(iii), and 424.516(e)(1). CMS says a similar revision for DMEPOS (§424.57(c)(2)) is unnecessary because *all* changes to enrollment data—including practice location additions, deletion and changes—must already be reported within 30 days.

clarify that a change of practice location includes adding a new location or deleting an existing one.

After reviewing comments, CMS finalizes the proposal without modification.

"Pattern or Practice." Three pre-existing Medicare enrollment revocation reasons are based on the provider or supplier engaging in a "pattern or practice" of conduct:

- The provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements (§424.535(a)(8)(ii)).
- The physician or eligible professional has a pattern or practice of prescribing Part B or D drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or fails to meet Medicare requirements (§424.535(a)(14)).
- The physician or eligible professional has a pattern or practice of ordering, certifying, referring, or prescribing Medicare Part A or B services, items, or drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or otherwise fails to meet Medicare requirements (§424.535(a)(21)).

CMS has received questions from interested parties over the years as to what constitutes a pattern or practice under these provisions. The agency says it has always made these determinations on a case-by-case basis and did not propose changing this general procedure, due to the flexibility it provides. To clarify, CMS proposed to establish a definition of "pattern or practice" in §424.502 to mean the following (along with some technical conforming amendments):

- For purposes of §424.535(a)(8)(ii), at least three submitted non-compliant claims.
- For purposes of §424.535(a)(14), at least three prescriptions of Part B or Part D drugs that are abusive, represent a threat to the health and safety of Medicare beneficiaries, or otherwise fail to meet Medicare requirements.
- For purposes of §424.535(a)(21), at least three orders, certifications, referrals, or prescriptions of Medicare Part A or B services, items, or drugs that are abusive, represent a threat to the health and safety of Medicare beneficiaries, or otherwise fail to meet Medicare requirements.

CMS notes that this does not mean three non-compliant claims, orders, etc., would always trigger a revocation. To the contrary, it would often take more than three (and, on occasion, considerably more) to warrant revocation action. The agency says that in only the rarest of circumstances would it revoke based on three claims, referrals, etc.—typically due to egregious non-compliance by the provider or supplier. It specifically chose three as the threshold to account for these isolated instances.

Comments/Responses: Some commenters opposed the definition, noting that the threshold of three non-compliant claims (1) is too low, (2) cannot adequately establish a pattern or practice of intentional or harmful behavior, and (3) could be arbitrarily applied by CMS. One commenter stated that the term "pattern or practice" is typically understood to require more than three instances and means activity done in a systematic way, and that CMS' proposed definition is inconsistent with this standard meaning.

Final Action: After reviewing the comments received, CMS is not finalizing the proposed definition of "pattern or practice" or the corresponding technical revisions, but may reconsider this issue for future rulemaking.

Indirect Ownership Interest. Providers and suppliers are required to report on their enrollment application all of their 5 percent or greater indirect owners. Indirect ownership interest is defined in §420.201 as "any ownership interest in an entity that has an ownership interest in the disclosing entity. The term includes an ownership interest in any entity that has an indirect ownership interest in the disclosing entity."

CMS proposed to leverage the definition in §420.201 and add a modified version in §424.502, as follows:

- Any ownership interest in an entity that has an ownership interest in the enrolling or enrolled provider or supplier. For example, Provider A is owned by Entity B. Entity B is owned by Entity C. Entity C would have an indirect ownership interest in (and be an indirect owner of) Provider A.
- Any ownership interest in an indirect owner of the enrolling or enrolled provider or supplier. Using the previous example, if Entity D had an ownership interest in Entity C, Entity D would have an indirect ownership interest in Provider A.
- The amount of indirect ownership interest is determined by multiplying the percentages of ownership in each entity. For example, if A owns 10 percent of the stock in a corporation that owns 80 percent of the provider or supplier, A's interest equates to an 8 percent indirect ownership interest in the provider or supplier and must be reported on the enrollment application. If B owns 80 percent of the stock of a corporation that owns 5 percent of the stock of the provider or supplier, B's interest equates to a 4 percent indirect ownership interest and need not be reported.[78]

CMS received a single comment, in support, and finalizes the proposed definition of "indirect ownership" without modification.

PTs and OTs in Private Practice and Speech-Language Pathologists. Physical therapists in private practice (PTPPs), occupational therapists in private practice (OTPPs), and speech-language pathologists (SLPs) are permitted by statute to receive payment for furnishing Medicare services, even though they do not fall within the regulatory definition of "supplier" in §400.202. While the services they provide are payable under Medicare (thus allowing these individuals to enroll in the program), PTPPs, OTPPs and SLPs are not formally recognized in either the Act or the CFR as types of "suppliers." Nevertheless, CMS has applied the provisions of subpart P of part 424 to PTPPs, OTPPs and SLPs via current guidance and afforded them the same appeal rights as all other enrolling or enrolled individuals and entities.

To codify these practices in regulation, CMS proposed several regulatory provisions:

- Define "supplier" in §424.502 as "for purposes of this subpart, all of the following: (1) the individuals and entities that qualify as suppliers under §400.202; (2) physical

[78] This mirrors an example in §420.202(a).

therapists in private practice; (3) occupational therapists in private practice; and (4) speech-language pathologists."

- Include the same definition of "supplier" within new §405.800(d), because subpart H of part 405 addresses various types of provider enrollment appeals under Medicare Part B.
- Pertaining to provider enrollment appeals, revise one part of the definition of "supplier" in §498.2—"(6) Physical therapist in independent practice"—to state, "(6) For purposes of this part, physical therapist in private practice, occupational therapist in private practice, or speech-language pathologist."

CMS received a single comment, in support, and finalizes the proposal without modification.

Authorized Officials. Current regulations require an authorized official or delegated official to sign the Medicare enrollment application (for example, Form CMS-855A) if the provider or supplier is a corporation, partnership, group, limited liability company, or other organization.

The terms authorized official and delegated official are defined in §424.502. Specifically, an authorized official is "an appointed official (for example, chief executive officer, chief financial officer, general partner, chairman of the board, or direct owner) to whom the organization has granted the legal authority to enroll it in the Medicare program, to make changes or updates to the organization's status in the Medicare program, and to commit the organization to fully abide by the statutes, regulations, and program instructions of the Medicare program." Regarding that definition, interested parties have inquired whether "organization" means (1) the entity listed in Section 2 of the Form CMS-855 as identified by its legal business name (LBN) and tax identification number (TIN); or (2) the provider or supplier type that is enrolling.

To illustrate, CMS provides this example. Suppose Entity A (with its unique LBN and TIN) submits three separate Form CMS-855A initial enrollment applications to enroll an HHA, a hospice, and a skilled nursing facility (SNF), all of which have Entity A's LBN and TIN. The question is whether "organization" refers to Entity A or to the three separate ones—that is, the HHA, hospice and the SNF.

CMS proposed, within and limited to this definition of "authorized official," to define "organization" as the enrolling entity as identified by its LBN and TIN—not the provider or supplier type(s) that the entity is enrolling as. Thus, in the example, an authorized official serves on behalf of the enrolling entity (Entity A) and could sign CMS provider enrollment applications concerning the HHA, hospice and the SNF. The HHA, hospice and the SNF are not legal entities.

CMS received no comments and finalizes the proposal without modification.

2. Medicaid and CHIP Provider Enrollment

a. Background

Federal law requires each state to enroll providers if they wish to furnish, order, prescribe, refer or certify eligibility for Medicaid or CHIP items or services in that state. States may also establish their own additional provider enrollment requirements. Similar to Medicare, the

purpose of Medicaid and CHIP provider enrollment processes is to ensure that providers (1) meet all Medicaid or CHIP requirements (and any other state-specific or federal requirements); (2) are qualified to furnish, etc., Medicaid and CHIP services, items, and drugs; and (3) are eligible to receive payment, where applicable.

Different states may have different provider enrollment processes in operating their programs but must all comply with federal Medicaid and CHIP provider enrollment requirements, including those in part 455, subparts B and E. CMS provides two examples. First, under subpart B, providers must disclose information regarding ownership and control of the provider entity, certain business transactions, and criminal convictions related to federal health care programs. Second, states must deny or terminate a provider's Medicaid or CHIP enrollment for reasons listed in §455.416. Of particular importance from that list is that the state must deny or terminate the provider's enrollment if the provider is terminated under the Medicare program, or the Medicaid program or CHIP of any other state. On the other hand, a state may forgo termination for some of the other reasons in §455.416 if the state (1) determines that such an action would not be in the Medicaid program's best interests, and (2) documents this decision in writing.

Provider Terminations since the Cures Act. The 21st Century Cures Act (P.L. 114-255; December 13, 2016) addressed a variety of nationwide health care issues. Some of these statutory provisions specific to Medicaid and CHIP provider terminations include the following:

- States must report the termination of a provider under Medicaid or CHIP to the Secretary within 30 days after the effective date of the termination.
- Specific information must be included in the termination notification that the state sends to CMS but is limited to terminations for reasons specified in §455.101 as in effect on November 1, 2015—that is, terminations "for cause" (including terminations for reasons relating to fraud, integrity, or quality)—and use the effective date of the termination as the later of (1) the effective date specified in the notice of termination, or (2) the date on which applicable appeal rights have been exhausted or the timeline for appeal has expired.
- Within 30 days of receiving notification of a Medicaid or CHIP provider termination, the Secretary will review it and, if appropriate, include such termination in any database or similar system developed under section 6401(b)(2) of the Affordable Care Act.
- Except for emergency items or services (but not including items or services furnished in a hospital emergency department), no federal financial participation (FFP) funds—that is, federal Medicaid or CHIP matching funds—may be paid for items and services furnished by a provider terminated under Medicaid or CHIP beginning 60 days after the date the termination is included in the termination database.

Besides the statute and regulations, CMS also has extensive sub-regulatory guidance in its Medicaid Provider Enrollment Compendium (MEPC), which reflects the Cures Act provisions. Based on that guidance and its processes, when a state reports a "for cause" termination, CMS determines if (1) the state submitted the required termination data in accordance with section 1902(kk)(8) of the Act, and (2) the termination is, indeed, "for cause." If CMS concludes that the reported termination is "for cause," the information is uploaded into a CMS-managed database per the statute. This database contains information on Medicaid and CHIP terminations

and Medicare revocations, the latter of which is updated at least monthly, and enables a state to review Medicaid and CHIP terminations in other states, as well as Medicare revocations. With this information, under §455.416(c), a state can deny enrollment or take its own termination action against a provider also enrolled in its state.

Termination Lengths. There are two termination database-related matters that have generated uncertainty during the agency's implementation of the §455.416(c) termination requirement: (1) the length of time for which a termination remains active in the termination database, and (2) the interaction of different termination periods imposed by the states and/or the Medicare program.

Under §424.535(c), if a Medicare provider or supplier is revoked from Medicare, they are barred from participating in the Medicare program from the effective date of the revocation until the end of the reenrollment bar, which is generally 1 to 10 years. This 1- to 10-year period typically constitutes (1) the time period for which the provider or supplier is revoked from Medicare, and (2) the amount of time that the Medicare revocation will remain in the termination database.

Many states have similar reenrollment bars (also known as termination periods) for terminated Medicaid and CHIP providers. Yet these termination periods often differ among states, even for the same conduct. While CMS recognizes the traditional deference given to states regarding the establishment of reenrollment bars, the interplay between varying termination period lengths has caused confusion among states, providers, and other interested parties.

b. Proposed Medicaid and CHIP Provider Enrollment Provisions: Termination Lengths

CMS proposed to specify in regulation the length of time for which "for cause" provider terminations will remain in the database and, by extension, the period for which other states must deny or terminate the provider under §455.416(c), with the following specific changes:

- A clause would be added to the end of §455.416(c)—"and is currently included in the termination database under § 455.417"—to clarify that the denial and termination requirement in §455.416(c) is predicated on the provider's inclusion in the termination database.
- A provider would remain in the termination database for the lesser of:
    - The length of the termination period imposed by the initially terminating state Medicaid program or CHIP, or the reenrollment bar imposed by Medicare; or
    - 10 years (for those Medicaid or CHIP terminations greater than 10 years).
- All other state Medicaid programs or CHIPs in which the provider is enrolled or seeking to enroll would be required to terminate or deny the provider's enrollment for at least the same length of time as the termination database period.
- A state would not be prohibited from imposing a termination period of greater than 10 years (or longer than another state's termination period), whether by the initially terminating state or by a state acting in response to another state's termination.[79]
- If the initially terminating state agency or Medicare reinstates the provider prior to the end of the termination period originally imposed by the initially terminating state or

[79] However, CMS notes the termination period cannot be *shorter* than the period in which the provider is to be included in the termination database.

Medicare, CMS would remove the provider from the termination database after the reinstatement has been reported to CMS. However, nothing prohibits CMS from immediately re-including the provider in the database if a separate basis for doing so exists.

CMS provides two hypothetical examples:

Example 1.

- State A, the initially terminating state, terminates a provider for 5 years.
- The provider would remain in the termination database for 5 years.
- State B's termination of the provider must be at least 5 years (the termination database period).
- If State B imposed an 8-year termination period, the provider would still only remain in the termination database for 5 years.

Example 2.

- State A, the initially terminating state, terminates a provider for 15 years.
- The provider would remain in the termination database for 10 years (the maximum period).
- State A may enforce its 15-year termination period regardless of the shorter termination database period.
- State B's termination period must be at least 10 years.

Several commenters supported the termination database proposals, which CMS finalizes without modification.

L. Expand Diabetes Screening and Diabetes Definitions

For 2024, as explained in greater detail below, CMS proposed to:

- Expand coverage of diabetes screening tests to include the Hemoglobin A1C (HbA1c) test;
- Expand and simplify the frequency limitations for diabetes screening; and
- Simplify the regulatory definition of "diabetes" for—
    - Diabetes screening (§410.18(a)),
    - Medical Nutrition Therapy (MNT) (§410.130), and
    - Diabetes Outpatient Self-Management Training Services (DSMT) (§410.140).

CMS finalizes these policies as proposed.

Current Part B regulations allow for coverage of two specific diabetes screening tests—the fasting plasma glucose (FPG) test and the post glucose tolerance test (GTT). Regarding diabetes screening tests, the statute for Medicare Part B gives the Secretary flexibility to select "other tests, and modifications to tests, as the Secretary determines appropriate, in consultation with appropriate organizations" (section 1861(yy)(1)(B)). Regulations further specify that such coverage must occur through a national coverage determination (§410.18(c)(2)). To date, no diabetes screening tests have been approved in this way.

CMS proposed to exercise its statutory authority in section 1861(yy)(1) to add the HbA1c test to the types of diabetes screening tests covered under §410.18(c), in consultation with recommendations by appropriate organizations. CMS compares the HbA1c test to the FPG and GTT tests and describes how the United States Preventive Services Task Force (USPSTF) and specialty societies have identified the HbA1c test as clinically appropriate for diabetes screening.

Although the statute allows up to two diabetes screening tests within a 12-month period (beginning with the date of the most recent test), current regulations are more prescriptive:

- Two screening tests "per calendar year" if the patient was previously diagnosed with pre-diabetes, and
- One screening test "per year" for patients who were previously tested who were not diagnosed with pre-diabetes, or who were never tested before.

CMS proposed to simplify these frequency limitations by aligning to the statutory limitation of not more often than twice within the 12-month period following the date of the individual's most recent diabetes screening test.[80]

In current regulations, the definition of "diabetes" is identical for diabetes screening, MNT and DSMT, and includes specified levels from clinical tests. CMS proposed to simplify each by removing the codified clinical test requirements from the definition because it has been overtaken by evolving clinical standards. For example, since 2020, the American Diabetes Association (ADA) has expanded its definition to include the HbA1c test and a random plasma glucose test for a patient appearing to have hyperglycemia or hyperglycemic crisis. The agency says it is unnecessary to codify clinically specific test criteria into the regulatory definition, which reduces flexibility to adapt to evolving clinical standards without potentially producing programmatic benefit. The proposed revised definition of diabetes would be shortened to describe diabetes as diabetes mellitus, a condition of abnormal glucose metabolism.[81]

Comments/Responses: Commenters expressed broad support to add the HbA1c test to the types of diabetes screening tests covered under §410.18(c), stating that it will reduce patient burden for those with diabetes (a disease disproportionally impacting minority and disadvantaged populations) and allow measurement of different aspects of the disease compared to the other tests. Covering HbA1c tests for diabetes screening will align Medicare coverage policies with USPSTF and ADA recommendations and should increase patient referrals to MDPP.

Many commenters recommended that CMS eliminate Part B cost sharing for the HbA1c test when provided as a screening test. CMS is "happy to clarify" that Part B coinsurance and deductibles will not apply to the HbA1c test when furnished as a covered diabetes screening test, since no Part B cost sharing applied to covered preventive services recommended with a grade of

[80] Since the distinction for screening purposes between diabetes and pre-diabetes would no longer be relevant, CMS also proposed deleting the definition of "pre-diabetes" at §410.18(a).

[81] CMS notes that even without clinical test criteria codified in the regulatory definitions of diabetes and pre-diabetes, a Medicare claim that includes a diagnosis of diabetes or pre-diabetes would still need to include appropriate coding, substantiation in the medical record, and compliance with claims processing instructions from CMS and Medicare Administrative Contractors (MACs).

A or B by the USPSTF.[82] However, the HbA1c test will continue to require Part B cost sharing when furnished for diabetes management.

Numerous public comments expressed approval of simplifying the definition of diabetes for screening, MNT and DSMT, as well as for expanding and simplifying frequency limitations for diabetes screening to not more than twice within the 12-month period following the date of the individual's most recent diabetes screening test. One commenter disagreed with the frequency limitations, stating they should be determined by the furnishing clinician, with no limitations imposed by CMS; the agency disagreed—for the protection of beneficiaries and the Trust Funds from overutilization and fraud, waste and abuse—and said it did not have the statutory authority to do so anyway.

Final Action: CMS finalizes the regulatory changes as proposed.

M. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan (§423.160(a)(5))

Enacted in 2018, the SUPPORT Act required electronic prescribing for controlled substances (EPCS) covered under Part D by January 1, 2021, but allowed for exceptions in certain circumstances. CMS finalized related regulations in the PFS final rules for 2021, 2022 and 2023, establishing a threshold that at least 70 percent of a prescriber's Schedule II, III, IV and V controlled substances prescribed under Part D had to be prescribed electronically, with some exceptions. However, the rules delayed compliance actions or had compliance actions consist of sending notices to non-compliant prescribers. The 2023 PFS rule extended the previous non-compliance action of sending notices to non-compliant prescribers through December 31, 2024, among other changes.

1. Updates to NCPDP Standards

CMS' intent for the EPCS Program is that prescribers use the same version of the NCPDP SCRIPT standard for their electronic prescribing of Schedule II-V controlled substances under Part D as for other electronic prescribing for Part D eligible individuals. Although the agency finalized the NCPDP SCRIPT standard version 2017071 as the standard in the CY 2021 PFS final rule, CMS clarifies that the existing regulatory text for the CMS EPCS Program (§423.160(a)(5)) automatically adopts the electronic prescribing standards at §423.160(b) as they are updated. Thus, for example, any proposals from the 2024 Medicare Advantage and Part D Policy and Technical Changes final rule to standards at §423.160(b) will apply to the CMS EPCS program, as well.

Commenters appreciated the clarification, but one pointed to confusing language in the 2024 PFS proposed rule's preamble. To provide additional clarity, CMS points to existing language at §423.160(a)(5) that cross-references the Part D standards in §423.160(b); this requires the CMS

[82] In August 2021, the USPSTF expanded recommended screening, with a grade of B, for prediabetes and type 2 diabetes in adults aged 35 to 70 years who have overweight or obesity, and that clinicians should offer or refer patients with prediabetes to effective preventive interventions, including FPG, GTT and HbA1c tests.

EPCS Program to use the same version(s) of standards finalized through rulemaking for Medicare Part D e-prescribing.

2. Standards for the Same Legal Entity

The 2022 PFS final rule added the same entity exception—that is, for prescriptions issued where the prescriber and dispensing pharmacy are the same entity—removing these transactions from the calculation for the 70 percent compliance threshold. Since then, however, CMS has found the following:

1. The Prescription Drug Event (PDE) data used for CMS EPCS compliance does not have a field that consistently and accurately identifies prescribers and dispensing pharmacies that are part of the same entity, making it impossible to exclude these prescriptions.
2. It *would* be possible to include prescriptions where the prescriber and dispensing pharmacy are the same entity without triggering the concerns that originally prompted the same entity exception, if CMS removes the regulatory requirement to use only the NCPDP SCRIPT standard listed in §423.160(b) and points to a different Part D provision related to same entity prescribing standards that permits use of HL7 messages (§423.160(a)(3)(iii)).

CMS proposed to:

- Expand the available standards under the CMS EPCS Program for prescribers that are within the same legal entity as the dispensing pharmacy by cross-referencing Part D standards at §423.160(a)(3)(iii); and
- Remove the same entity exception at §423.160(a)(5)(i) from the CMS EPCS Program.

As a result, prescriptions prescribed and dispensed within the same legal entity would be included in CMS EPCS Program compliance calculations as part of the 70 percent compliance threshold; these prescribers would not be exempt from the requirement to prescribe electronically at least 70 percent of their Part D Schedule II-V controlled substances. CMS says these changes would advance e-prescribing standardization and address potential concerns about burdening prescribers within the same legal entity, including workflow and data errors.

Several commenters supported the proposal to remove the same entity exception and use HL7 messages or the NCPDP SCRIPT standard. One did not, because some prescribers, especially those in rural communities, may use proprietary codes rather than HL7 messages or the NCPDP SCRIPT standard (although such a situation is available for exemption at §423.160(a)(3)(iii)). CMS responds that it intends to align CMS EPCS Program requirements with the Medicare Part D electronic prescribing standards as much as possible. CMS finalizes its proposals without modification.

3. Definition of Prescriptions for Compliance Calculation

The 2022 PFS final rule defined the compliance threshold requirement for the CMS EPCS Program—prescribers are required to prescribe at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs electronically, except in cases where an exception or waiver applies. The compliance threshold for each prescriber is calculated by

examining PDE data at the end of the measurement year and dividing the number of Part D controlled substances that were e-prescribed by the total number of Part D controlled substance prescriptions (excluding from both the numerator and denominator any prescriptions issued while a prescriber falls within an exception or is subject to a waiver).

The 2022 PFS final rule did not define how prescriptions with multiple fills would affect the compliance threshold calculation. Refills are not separately transmitted prescriptions; they are documented as part of the original prescription transmittal, which includes any refills issued against the original prescription (by the pharmacy). However, *renewals* of prescriptions (such as those for maintenance medications) require prescribers to generate a new prescription along with a new set of refills.

CMS proposed count *renewals* as an additional prescription in the CMS EPCS Program compliance threshold calculation, but will not count *refills* as an additional prescription unless the refill is the first occurrence of the unique prescription in the measurement year. CMS says if it were to include every fill in the compliance threshold calculation, approximately 23,000 prescribers would no longer qualify for the small prescriber exception.

CMS finalizes its proposal without modification.

4. Updates to Exceptions for Recognized Emergencies and Extraordinary Circumstances

The 2022 PFS final rule included two exceptions related to exceptional circumstances that may prevent prescribers from being able to conduct EPCS:

- Prescribers in a geographic area of an emergency or disaster declared by a federal, state, or local government entity.
- Prescribers who request and receive from CMS a waiver for extraordinary circumstances—that is, a situation outside of the control of a prescriber that prevents them from electronically prescribing a controlled substance to a Part D beneficiary, but who are *not* in an emergency or disaster area.

CMS proposed to modify the following:

- The recognized-emergency exception and extraordinary-circumstances waiver;
- The rules for when these exceptions apply by enabling prescribers to apply for waivers in times of an emergency and disaster and by limiting the emergencies or disasters that would trigger the recognized-emergency exception; and
- The duration of both exceptions.

CMS finalizes its proposal without modification.

Circumstances as Recognized Emergencies and as Extraordinary Circumstances: The current exception for recognized emergencies applies to all prescribers with an address (in PECOS or the National Plan and Provider Enumeration System (NPPES)) in the geographic area of a declared emergency or disaster. Because CMS may not identify every local or state emergency, some prescribers may not be able to receive the recognized-emergency exception; the extraordinary-circumstances waiver is not available as a second option because they *were* in an area with an

emergency, which is disqualifying for that waiver. Moreover, CMS says it may not be appropriate to automatically apply the recognized-emergency exception to all prescribers in an affected geographic area, since not every emergency will impact the ability of prescribers to conduct EPCS.

CMS reviews the Quality Payment Program's Merit-based Incentive Payment System (MIPS) automatic policy for extreme and uncontrollable circumstances and the extraordinary circumstances exceptions (ECE) for quality reporting and value-based purchasing programs for hospitals and other facilities. The agency believes it would be beneficial for the CMS EPCS Program to have a similar policy where providers apply for an exception versus having an automatic exception for all prescribers in an affected region. CMS says this would streamline communications across its programs and ensure it can, where appropriate, except all prescribers for an appropriate circumstance beyond their control, including disasters or emergencies.

For the CMS EPCS Program, the agency proposed to modify the definition of "extraordinary circumstance" to mean a situation outside of the control of a prescriber that prevents the prescriber from electronically prescribing a Schedule II-V controlled substance that is a Part D drug. This updated definition would drop the restriction "other than an emergency or disaster," so that prescribers could request a waiver regardless of whether the recognized-emergency exception is triggered.

The agency also proposed to modify the recognized-emergency exception so that CMS must identify on a case-by-case basis which emergencies or disasters trigger this exception—with its intent to generally align its determination with the MIPS automatic extreme and uncontrollable circumstances policy. CMS says it would inform prescribers of which emergencies or disasters qualify for the exception using normal communication channels such as listservs and the CMS EPCS Program website.

Duration of Recognized-Emergency Exceptions: CMS proposed that when the CMS EPCS Program recognized-emergency exception is triggered, it would apply for the entire measurement year, not just for the duration of the emergency.

Duration and Timing of Extraordinary Circumstances Waiver Exception: Current regulations include an attestation process for prescribers to request a waiver. CMS proposed that:

- The waiver would apply for the entire measurement year;
- If those exceptional circumstances extend beyond December 31, a new waiver application would be required for the next measurement year; and
- A prescriber would have 60 days from the date of the notice of non-compliance to request a waiver.

CMS finalizes its proposals without modification.

5. Actions for Non-Compliance

In the 2022 PFS final rule, CMS limited compliance actions with respect to 2023 to a non-compliance notice sent to prescribers who are violating the CMS EPCS Program requirement. In the 2023 PFS final rule (87 FR 70013), CMS extended this approach through 2024. The notices say prescribers are violating the CMS EPCS Program requirements and provide information about how they can come into compliance, the benefits of EPCS, and a link to the CMS EPCS Program dashboard where the prescriber may request a waiver and provide information as to why they are not conducting EPCS.

CMS proposed to continue the practice of issuing a prescriber notice of non-compliance as a non-compliance action for subsequent measurement years. CMS believes that continuing to send non-compliance notices would support increased EPCS adherence, encourage increased EPCS adoption rates, and be more effective than imposing more restrictive non-compliance actions or penalties that may increase burden on prescribers.

The agency notes it did not receive a large number of comments in response to its solicitation in the 2023 PFS proposed rule regarding ideas for possible non-compliance actions that would be operationally feasible and support the ongoing fight against drug abuse and diversion without adding administrative burden to prescribers or hindering beneficiary access to needed medications. CMS says it did not propose new non-compliance actions but will continue to evaluate compliance and prescriber performance under the CMS EPCS Program and consider whether to propose changes in future years.

Comments/Responses: Many commenters supported the proposal to send non-compliance notices to prescribers who do not meet the CMS EPCS Program requirements in subsequent years without imposing additional penalties, believing this would promote increased EPCS adoption, especially for those who require additional time to update their technological abilities. Added provider penalties for non-compliance beyond the notice and education could be counterproductive.

A few commenters did not support the proposal, expressing concerns that additional penalty mechanisms are needed (with some suggestions offered) to increase prescriber adoption and compliance with EPCS. CMS said it considered multiple additional actions but continues to believe providing non-compliant prescribers with notices—along with using CMS EPCS Program non-compliance information in its processes for identifying fraud, waste and abuse—is sufficient incentive to encourage EPCS adoption.

Final Action: CMS finalizes its proposal without modification.

N. Changes to the Regulations Associated with the Ambulance Fee Schedule and the Medicare Ground Ambulance Data Collection System (GADCS)

1. Background on Ambulance Services

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. 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, discussed below.

2. Ambulance Extender Provisions

CMS reviews some longstanding increases to the AFS that it considers self-implementing statutory requirements, requiring no substantive exercise of discretion by the Secretary:

- A 3 percent increase for covered ground ambulance transports originating in a rural area or a rural census tract of a metropolitan statistical area,
- A 2 percent increase for covered ground ambulance transports that do *not* originate in a rural area or in a rural census tract of a metropolitan statistical area, and
- A 22.6 percent Super Rural Bonus, applying to transports originating in a rural area comprising the lowest 25th percentile of all rural populations by population density.

The CAA, 2023 extended these provisions through December 31, 2024, and CMS proposed conforming amendments to these regulations, which it is finalizing without modification.

3. Revisions to the Medicare Ground Ambulance Data Collection Instrument

The BBA of 2018 required ground ambulance organizations to submit cost and other information and required the Secretary to develop a data collection system (which may include use of a cost survey) to collect cost, revenue, utilization, and other information determined appropriate by the Secretary. The Secretary was required to specify the data collection system by December 31, 2019, and to identify the ground ambulance providers and suppliers that would be required to submit information to it or receive, beginning January 1, 2022, a 10 percent payment reduction to AFS payments for the applicable period. The statute defines "applicable period" for a ground ambulance provider or supplier as a year specified by the Secretary not more than 2 years after the end of the period for which the Secretary has made a determination that the ground ambulance provider or supplier has failed to sufficiently submit information under the data collection system.

The 2020 PFS final rule codified regulations governing data reporting by ground ambulance organizations and establishing a data collection system that collects detailed information on ground ambulance provider and supplier characteristics, including service areas, service volume, costs, and revenue through a data collection instrument, commonly referred to as the Medicare

Ground Ambulance Data Collection Instrument, via a web-based system. Since then, PFS rules have made other changes, including clarifications to the Medicare Ground Ambulance Data Collection Instrument to reduce burden on respondents, improve data quality, or both.[83]

CMS proposed the following changes to the Medicare Ground Ambulance Data Collection Instrument based on ad hoc questions and feedback, as well as its own data analysis, while also continuing to update the GADCS FAQ document and User Guide.

Partial-Year Responses: Some ground ambulance organizations selected to participate in the GADCS may only have been in operation for part of the 12-month data collection period but are still required to collect and report data. Because there is currently no field for these organizations to report that they were in operation for less than 12 months, CMS would not know that is why the costs, revenue, and utilization reported by these partial-year organizations are comparatively smaller and may bias some statistics from analyses of GADCS data downward. Thus, CMS proposed to revise one of the questions to permit an organization to flag that it is billing Medicare for ground ambulance services "but for only part of the organization's continuous, 12-month data collection period." Selecting this response would prompt the organization to enter the date they started and/or stopped operations in the data collection period.

Two commenters supported these changes, and CMS finalizes them without modification.

Programming Logic for Hospitals and Other Medicare Providers of Services: The current GADCS printable instrument has a question and related programming notes that has caused many hospital-based organizations to answer in a way that was not intended, according to CMS, and results in confusion for hospital-based organizations. CMS proposed changing the programming note after Section 2, Question 9 in the GADCS printable instrument so that provider-based ground ambulance organizations will have a more straightforward selection between paid and volunteer staff, without confusing, inapplicable references to staff with fire, police and other public safety responsibilities.

Two commenters supported these changes, and CMS finalizes them without modification.

Typos and Technical Corrections: CMS lists 4 wording changes/corrections it proposed to make. Two commenters supported these changes, and CMS finalizes them without modification.

O. Hospice: Changes to the Hospice Conditions of Participation (CoPs)

The CAA, 2023[84] established that the hospice interdisciplinary group (IDG) is required to include at least one social worker (SW), marriage and family therapist (MFT), or mental health

[83] The 54-page printable version of the "Medicare Ground Ambulance Data Collection Instrument" from November 7, 2022, is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/Downloads/Medicare-Ground-Ambulance-Data-Collection-System-Instrument.pdf.

[84] Section 4121(b) of the CAA specifically adds these services to covered hospice care services under section 1861(dd)(2)(B)(i)(III) of the Act.

counselor (MHC). Hospices have the flexibility to determine which disciplines(s) are appropriate to serve on the IDG.

CMS proposed to modify the requirements at §418.56(a)(1)(iii) for the hospice CoPs to require that the IDG must include a SW, MHC, or MFTs depending on the preferences and needs of the patient. CMS also proposed to modify the hospice personnel qualifications at §418.114(c) to include qualifications for an MFT and an MHC.

In response to comments, CMS clarifies that there are no regulatory requirements for the supervision of MFT and MHC other that what is referenced in the CoP: Interdisciplinary group, care planning, and coordination of services at §418.56(a)(1). The role of the IDG is to meet the physical, medical, psychosocial, emotional, and spiritual needs of the hospice patients and families facing terminal illness and bereavement.

Several commenters expressed concern that CMS was misinterpreting the statute and congressional intent by proposing that the patient preferences and needs of the patient should determine the IDG membership. The commenters pointed out that the provision in the CAA 2023 was meant to be optional, allowing the hospice to determine which practitioner will sit on the IDG. CMS believes it is important for the hospice IDG to consider the patients' needs to ensure the IDG member, whether it is a SW, MFT or MHC, has the appropriate knowledge to share and recommend care options related to the services a patient is receiving or need. CMS agrees that the hospice has the choice to select either a SW, MFT or MHC. CMS is not finalizing the requirement that the SW, MFT, or MHC be a member of the IDG "based on the needs and preferences of the patient".

Multiple commenters expressed concern over the staffing shortages and lack of mental health professional in certain areas of the country, including rural areas. CMS acknowledges that hospices in rural areas experience challenges in recruiting and retaining staff and that there is a shortage of behavioral health providers. CMS notes that hospices have the option to directly employ MFTs and MHCs full time, part time or per diem, which provides additional flexibilities. In response to concerns about the enforcement of these provisions, CMS states it will follow the standard survey and enforcement process.

CMS appreciates a commenters suggestion that the MFT and MHC should be cited at §418.114(a) instead of the proposed §418.114(c). CMS agrees that it would be appropriate for the MFT and MHC personnel requirements to be located at a different regulation citation. However, CMS believes it is more appropriate to redesignate the proposed personnel requirements at §418.114(b)(9) and (10) with the personnel qualifications for certain disciplines in order to reflect the State licensure requirements that the MFT and MHC have at §§410.53 and 410.54.

CMS acknowledges concerns that publishing these proposed and finalized requirements in a hospice rule may have been more apparent to the hospice industry but due to the hospice wage index publication dates and the CAA implementation requirements CMS determined that the 2024 PFS rulemaking was the best vehicle for these requirements. All the hospice CoP information and requirements related to MHCs and MFTs are published in this final rule and CMS does not plan to republish this information in a separate hospice rule. CMS will provide

additional information regarding the implementation of these provisions in interpretative guidance that will be published after the publication of this final rule.

Final Rule Action: CMS finalizes its proposals with modifications:

- CMS finalizes the requirements at §418.56(a)(1)(iii) for the hospice CoPs to require that the IDG must include a SW, MHC, or MFTs.
- CMS finalizes the hospice personnel qualifications at §418.114(b)(9) and (10) and reference requirements at §§410.53 and 410.54, respectively to include qualifications for an MFT and an MHC.

P. RFI - Clinical Laboratory Improvement Act (CLIA) Updates

Histopathology. CMS indicates that regulations related to histopathology have not been updated since 1992. Slide staining and tissue processing have not been subject to CLIA regulations. Also, the CLIA regulations do not cover the precise timeframe for which the review of gross tissue examination must be completed.

The regulation requested comments on whether, and how, CMS should provide oversight of histopathology preparation and processing of tissue samples for slide staining as well as qualifications of staff and supervisory staff doing this work. CMS also requested public comment on an acceptable timeframe between the review of the macroscopic gross tissue examination, and the review and confirmation of these tissue findings by a pathologist prior to the microscopic review of slides to protect the integrity of the macroscopic tissue.

Cytology Testing at Remote Locations. During the COVID-19 PHE, CMS provided enforcement discretion to allow pathologists to examine histopathology and cytology slides remotely under specific conditions. The pathology community has expressed their desire to make this enforcement discretion a permanent provision after the end of the PHE for COVID-19.

CMS requested public comment on the definition of remote location, conditions under which a pathologist would examine histopathology or cytology slides/images remotely without obtaining a separate CLIA certification, conditions when a primary location would cease permitting testing at a remote location, how the remote location would be included on a final payment report, and how the survey would be done at the remote location.

Clinical Cytogenetics. A cytogenetics test may be conducted at one facility, or involve a testing workflow model in which one facility performs the analytical bench testing activities (for example, sample processing), and another facility conducts the non-bench testing activities (for example, review of images, analysis, interpretation or reporting of the results). Any facility performing clinical cytogenetics testing activities (bench or non-bench) must be CLIA certified and meet high complexity testing requirements.

Under the enforcement discretion during the pandemic, CMS allowed clinical cytogenetics personnel the opportunity to examine clinical cytogenetics digital images (that is, non-bench testing activities) at a remote testing location without obtaining a separate CLIA certificate for

the remote site under certain conditions. Some interested parties have requested CMS make this enforcement discretion permanent.

CMS requested public comment on the circumstances that it would allow remote locations or testing facilities to examine clinical cytogenetics images without obtaining a separate CLIA certification; circumstances where the examination of clinical cytogenetics images be unacceptable for the remote location scenario; clinical cytogenetics testing processes the primary laboratory should have in place to ensure the remote site complies with the CLIA requirements; and "conditions" or "criteria" necessary for the remote location to ensure quality testing for the examination of clinical cytogenetics images.

There were 52 public comments in response to CMS' proposed rule request. CMS did not summarize the comments but indicates that it will consider the comments to evaluate possible changes to the CLIA regulations.

Q. Changes to the Basic Health Program Regulations

The Basic Health Program (BHP) was established in the Affordable Care Act (ACA, P.L. 111-148, as amended) as an option for states to provide BHP coverage to lawfully present individuals under age 65 with household income between 133 and 200 percent of the federal poverty level (FPL) who are not eligible for Medicaid, CHIP, or other minimum essential coverage.[85] Currently, only New York and Minnesota have implemented a BHP.

Federal funding for BHP is based on 95 percent of the value of the premium tax credits (PTC) and cost sharing reduction (CSR) subsidies that BHP enrollees would have received had they instead enrolled in Qualified Health Plans (QHPs) through an Exchange. These funds are paid to trusts established by the states and dedicated to the BHP, which the states then administer to BHP standard health plans. The ACA requires that federal funding for the BHP only be used to reduce the premiums and cost sharing of, or to provide additional benefits for, eligible individuals enrolled in standard health plans within the state.

1. Allowing States to Suspend a BHP

Under current regulations, states operate a BHP under a certified Blueprint approved by CMS and continue operating the BHP as long as the approved certified Blueprint is in place. A state may terminate its BHP, which requires the BHP trust fund balance to be refunded to the federal government (42 CFR §600.140). In the proposed rule, CMS said a state had inquired about whether it could "suspend" its program so that it could shift BHP enrollees to other comparable coverage while maintaining its BHP trust fund, which it could use if the state were to resume the BHP.

Although CMS does not name the state that made this request, New York submitted an application in May 2023 for a State Innovation Waiver under authority in section 1332 of the

[85] In addition, states may use BHP to cover lawfully present non-citizens who are ineligible for Medicaid or CHIP due to immigration status whose household income is between zero and 200 percent.

ACA. The purpose would be to extend its BHP coverage to higher income individuals, up to 250 percent FPL for 2024 to 2028. Because eligibility above 200 percent FPL is not permitted under BHP policies in section 1331 of the ACA, "New York is requesting a suspension of its Basic Health Program for the duration of the waiver and the maintenance of New York's current Basic Health Program trust fund to be used for the currently allowable purposes."[86] As of September 29, 2023, New York requested that the federal government pause its consideration of its pending 1332 waiver application; no reason was given for the requested pause.[87]

CMS sees the value in allowing a state currently operating a BHP to experiment with other ways of providing coverage that increases the number of people covered while not increasing federal costs. Thus, CMS proposed giving states the option of temporarily "suspending" a BHP program, while retaining accrued funds in the BHP trust fund for a limited period of time. If the state decides to resume operating its BHP, the suspension will allow the state to leverage accrued funds and avoid the processes of terminating the program and refunding trust funds, and then later having to submit a new BHP application for approval.

Specifically, CMS proposed amending §600.140 to add an option at paragraph (b) for a state to suspend its BHP, via an application submitted to HHS at least 9 months before the proposed effective date of the suspension or extension. However, for states seeking to suspend a BHP in the first plan year that begins following publication of the final rule adopting this proposal, such states would have to submit an application within 30 days of the publication of such a final rule and HHS would approve or deny the application as expeditiously as possible. A suspension application would need to be approved prior to the effective date of suspension, except in the case of a state seeking to suspend a BHP in the first plan year that begins following publication of the final rule adopting this proposal.

Specifically, CMS proposed that the suspension application must address the following substantive requirements:

- Benefits provided under the new coverage option must be at least equal to the BHP benefits in the certified Blueprint in effect on the effective day of suspension.
- During the period of suspension, the cost sharing under the new coverage option should not exceed BHP amounts—that is, the actuarial value of the new coverage option must meet or exceed the actuarial value of the BHP standard health plans in effect immediately prior to the suspension period.[88]
- During the period of suspension, the premiums under the new coverage option should not exceed BHP amounts—that is, premiums charged to individuals under the new coverage

[86] New York Department of Health Acting Commissioner James V. McDonald to Treasury Secretary Janet Yellen and HHS Secretary Xavier Becerra, May 12, 2023, https://info.nystateofhealth.ny.gov/sites/default/files/NY%201332%20Waiver%20Application_5.12.2023.pdf.
[87] CMS, "Section 1332: State Innovation Waivers," https://www.cms.gov/marketplace/states/section-1332-state-innovation-waivers, visited November 6, 2023.
[88] CMS notes that this may result in cost sharing for individual benefits differing between the BHP and the new coverage program, which is permissible provided the actuarial value of the new coverage options meets or exceeds the actuarial value of the BHP standard health plans. If multiple health plans are offered under the new coverage option and/or multiple standard health plans, CMS proposed that the median actuarial value of plans offered under the new coverage option must meet or exceed the median actuarial value of the BHP standard health plans.

option must be comparable to BHP standard health plan premiums in effect immediately prior to the suspension period, beyond reasonable increases due to inflation as measured by the Consumer Price Index (CPI).
- Eligibility criteria for coverage during the suspension is not more restrictive than the BHP criteria.

CMS says the suspension period should be long enough to allow the state to evaluate the alternative coverage but should not be indefinite. Therefore, CMS proposed an initial suspension of up to 5 years, after which a state could request an extension of up to 5 additional years. Additional extension periods would not be allowed. Five years was chosen to align with the duration of initial waivers and demonstration projects approved under section 1332 of the ACA and section 1115 of the Social Security Act.

As proposed, when the suspension period, including any extension period, ends, the state would need to either transition the BHP-eligible population back to the BHP or terminate the BHP. A state would be required to submit a transition plan to HHS at least 9 months before the end of the suspension period, explaining how it will either reinstate its BHP or terminate the BHP, and to notify the public of this change. As proposed, a state also could elect to end a BHP suspension before the end of any suspension period by following the same process.

CMS also proposed to require the following from states regarding the BHP suspension:
- Notices to affected individuals and plans;
- Submission of data regarding BHP enrollment, payment reconciliation, and trust fund balance (with any interest accrued during the suspension to be remitted to HHS annually in the form and manner set by HHS); and
- Annual BHP reports (with specified content) during the suspension period.

The Secretary could withdraw approval of the suspension if the state does not meet these requirements, ends implementation of the alternative coverage program for any reason, or fails to continue to meet the coverage and cost sharing requirements of the alternative coverage program. The Secretary could also withdraw approval if there is significant evidence of harm, financial malfeasance, fraud, waste, or abuse.

As proposed, the Secretary could withdraw approval only after providing the state with:
- Notice of the findings upon which the Secretary is basing the withdrawal,
- A reasonable period for the State to address the finding, and
- An opportunity for a hearing before issuing a final finding.

The proposal said that the Secretary shall make every reasonable effort to resolve proposed findings without withdrawing approval of the suspension plan and, in the event of a decision to withdraw approval, will accept a request from the state for reconsideration. The effective date of an HHS determination withdrawing approval would not be earlier than 120 days following issuance of a final finding. Within 30 days following a final finding, the state would be required submit a transition plan to HHS.

The proposal specified that during the transition period from the BHP to other coverage, the state may not use funds from the BHP trust fund toward the unwinding of the BHP program and transition to the new coverage program, per section 1331(d)(2) of the ACA and current regulations at §600.705(c). States cannot use federal BHP funding to cover premiums and cost sharing (or additional benefits) for individuals that would otherwise be eligible for BHP funding.

Comments/Responses: CMS received four public comments, all of which supported allowing states to suspend their BHP, but with some specific suggested changes—for example, for states to notify physicians who provide care to BHP enrollees. CMS said it will be adding that requirement but anticipates informally asking states how they will notify providers, including physicians, of the change.

One commenter requested that CMS require the Secretary to approve an application to suspend the BHP as submitted by the state. CMS notes that HHS would approve or deny such application as expeditiously as possible. The state may not implement a suspension or extension of suspension without prior approval by the Secretary, unless the state is proposing to suspend its BHP in 2024. The last provision is a minor change from the proposed regulation. CMS is finalizing that, for states proposing to suspend their BHP in 2024, the suspension application be submitted within 30 days of the effective date of this final rule.

One commenter suggested states be allowed to suspend their BHP beyond 10 years, subject to CMS approval. However, CMS believes allowing a suspension of 5 years plus a one-time extension of an additional 5 years is sufficient.

Final Action: CMS finalizes its proposal with minor changes.

2. Submission and Review of BHP Blueprints

While current §600.125(a) says a state seeking to make significant changes to its BHP must submit a revised Blueprint to the Secretary for review and certification, it does not specify any timeframes for submission and review. It also includes only a limited number of changes that require submission of a revised Blueprint—specifically, CMS notes that the current regulation does not require the submission of a revised Blueprint in response to changes in federal law or regulations.

CMS believes additional parameters are necessary to ensure effective and efficient operation of the BHPs and its review of a revised Blueprint, consistent with section 1331(a)(1) of the ACA. Thus, the agency proposed changes to §600.125 to establish timeframes and procedures for the submission and review of BHP Blueprints, similar to the Medicaid and CHIP State plan amendment (SPA) submission and review processes. These proposed timeframes only apply to the submission and review of *revised* Blueprints, not for the submission and review of an *initial* Blueprint. Also similar to Medicaid and CHIP SPAs, BHP Blueprints should permit approval of a retroactive effective date, according to CMS.

Current requirements are that states must submit a revised Blueprint whenever they seek to make any significant change that alters program operations, the BHP benefit package, enrollment,

disenrollment and verification policies described in its certified BHP Blueprint. CMS proposed to broaden those circumstances to include significant changes that alter any core program operations under §600.145(f), or whenever necessary to reflect changes in federal law, regulations, policy interpretations, or court decisions that affect provisions in their certified Blueprint.

CMS also proposed the following changes:

- The effective date of a revised Blueprint may be as early as, but not earlier than, the first day of the quarter in which an approvable revision is submitted to HHS, mirroring standards for Medicaid SPAs at §430.20(b).
- A revised Blueprint will be deemed approved unless HHS, within 90 days after receipt of the revised Blueprint, sends the state written notice of disapproval or written notice of additional information HHS needs in order to make a final determination.
- If HHS requests additional information, the 90-day review period will be stopped and will resume the day after HHS receives all of the requested additional information from the state.
- HHS may send written requests for additional information as many times as needed to obtain all information necessary to certify the revised Blueprint (which is similar to CHIP but differs from Medicaid, which has a 90-day review period that can be stopped once by a request for additional information, followed by a second 90-day review period when the state responds).
- HHS may disapprove a Blueprint amendment if the Secretary determines that the Blueprint revision is not consistent with section 1331 of the ACA or the regulations set forth in this part at any time during the review process, including when the 90-day review clock is stopped due to a request for additional information.
- Some existing parameters for initial Blueprint submissions would be extended to Blueprint revisions.
    - A state may withdraw the proposed revised Blueprint during HHS review if the state has not yet implemented the proposed changes and provides written notice to HHS.
    - HHS will accept a state's request for reconsideration of a decision not to certify a revised Blueprint and provide an impartial review against standards for certification if requested.

One public commenter supported these changes, and CMS finalizes them as proposed.

3. BHP Notices

HHS Office for Civil Rights regulations at 45 CFR §92.101—which apply to Medicaid, CHIP and BHP—require states to take reasonable steps to provide meaningful access for individuals with limited English proficiency (LEP) and to ensure effective communication with individuals with disabilities. CMS believes it is important for these obligations to also be described clearly in the BHP regulations and proposed to add paragraph (f) to §600.330 to require that BHP eligibility notices be written in plain language and be provided in a manner which ensures that

eligible individuals with LEP are provided with meaningful language access and individuals with disabilities are provided with effective communication.

One public commenter supported these changes, and CMS finalizes them as proposed.

4. BHP Appeals

Under current §600.335(b), individuals must be given the opportunity to appeal BHP eligibility determinations through the appeals rules of either the state's Medicaid program or the Exchange, as indicated in the state's Blueprint. Current BHP and Exchange regulations do not provide for appeals of health services matters, although CMS believes all BHP enrollees should be afforded the opportunity to appeal not only eligibility determinations but also decisions about health services matters. Exchange rules do not include an opportunity to appeal a health services matter, as such appeals are typically handled by state departments of insurance, as opposed to the Exchange itself.

CMS proposed to remove the option for states to conduct their BHP appeals process according to Exchange rules. States would be required to provide individuals an opportunity to appeal a delay, denial, reduction, suspension or termination of health services, in whole or in part, including a determination about the type or level of service, after individuals exhaust appeals or grievances through the BHP standard health plans. A conforming amendment was proposed at §600.145(f)(2) to include appeals of health services matters as a core operation of a BHP.

Comments/Responses: One commenter supported the proposed changes for appeals of health care services. One requested clarification on whether an appellant must exhaust utilization review and external appeals before filing a health service appeal through the proposed BHP appeal process. CMS says that, as noted in the preamble, individuals must first exhaust appeals or grievances through the BHP standard health plans before appealing to the state; to provide further clarity, CMS is adding this requirement to the regulation text. A commenter requested that states be permitted flexibility to establish the health service appeals process in a manner that takes individual states' needs into account, such as being able to choose the department that will oversee the appeals. CMS agrees and revises the finalized regulation text to permit states to request an appeals process for BHP eligibility determinations and health services matters that differ from the state's Medicaid program.

Final Action: CMS finalizes its proposal with modifications specifying that, subject to HHS approval, a state may request to follow an appeals process for BHP eligibility determinations and health service matters that differs from the state's Medicaid program, in which case specific new requirements to ensure adequate state oversight apply (45 CFR §600.335(c)).

R. Updates to the Definitions of Certified Electronic Health Record Technology

1. Background

The American Recovery and Reinvestment Act of 2009 (P.L. 111-5, enacted February 17, 2009) (ARRA) authorized incentive payments to eligible professionals, eligible hospitals and critical

access hospitals (CAHs), and Medicare Advantage (MA) organizations to promote the adoption and meaningful use of certified electronic health record (EHR) technology (CEHRT). In 2010, the Office of the National Coordinator for Health Information Technology (ONC) launched the Health IT Certification Program (ONC Health IT Certification Program) to provide for the certification of health information technology (IT), including EHRs. The ONC Health IT Certification Program supports the use of certified health IT under CMS programs, including the Medicare Promoting Interoperability Program (previously known as the Medicare and Medicaid EHR Incentive Programs), the Shared Savings Program, and the Quality Payment Program (QPP), which includes the MIPS Promoting Interoperability performance category and the Advanced Alternative Payment Models (Advanced APMs). Regulatory definitions of CEHRT in these programs continued to evolve. More recently, to satisfy the definitions of CEHRT, technology must be certified in accordance with the updated 2015 Edition certification criteria (2015 Edition Cures Update), as finalized in the "ONC 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program" (Cures Act) final rule (85 FR 25642).

In the ONC "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing" proposed rule (88 FR 23746 through 23917) (ONC HTI-1 proposed rule), which appeared in the *Federal Register* on April 18, 2023, ONC proposed to discontinue the year themed "editions," which ONC first adopted in 2012, to distinguish between sets of health IT certification criteria finalized in different rules. ONC noted public comments stating that the continued use and reference to the 2015 Edition inaccurately implies an age and outdatedness to the certification criteria ONC has adopted. Given these concerns, ONC stated that it believes there should be a single set of certification criteria, which will be updated in an incremental fashion in closer alignment to standards development cycles and regular health IT development timelines. To implement this simplified approach, ONC has proposed to rename all criteria within the ONC Health IT Certification Program simply as "ONC Certification Criteria for Health IT," proposing associated changes to the regulations at 45 CFR part 170 (88 FR 23759). CMS says this is similar to its own approach, focusing on implementing incremental changes to individuals measures in its programs, which it expects to continue.

2. Updates to Definition of CEHRT in Medicare Promoting Interoperability Program and QPP

Given the updates made to the 2015 Edition certification criteria described in the 2021 PFS final rule (85 FR 84815 through 84828), CMS had finalized that health care providers participating in the Medicare Promoting Interoperability Program and eligible clinicians participating in QPP must use certified health IT that:

- Satisfies the definitions of CEHRT at §495.4 and §414.1305, respectively, and
- Is certified under the ONC Health IT Certification Program, in accordance with the 2015 Edition Cures Update certification criteria, which included—
    - Technology to meet the 2015 Edition Base EHR definition at 45 CFR §170.102,
    - Technology certified to the criteria necessary to be a meaningful EHR user under the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category, and
    - Technology certified to the criteria necessary to report on applicable objectives and measures.

CMS finalizes revisions to the CEHRT definitions in the Medicare Promoting Interoperability Program (§495.4) and QPP (§414.1305, on which the Shared Savings Program's definition of CEHRT at §425.20 also relies) to support the proposed transition from the historical state of year themed "editions" to the "edition-less state" in the ONC HTI-1 proposed rule. In addition, CMS finalizes cross-references to ONC regulations that will automatically incorporate updates by ONC. These changes will ensure the CEHRT definitions do not need to be updated in CMS regulations to reflect modified terminology.

CMS notes, however, that this does not mean that any update to a certification criterion by ONC would immediately be required for use in CEHRT in the Medicare Promoting Interoperability Program, QPP, and Shared Savings Program. In determining requirements for any potential new or revised measures, CMS will consider factors such as implementation time and provider readiness to decide when it will propose requiring participants to complete measures that require the use of certified health IT. This additional flexibility will allow eligible hospitals, CAHs, and MIPS-eligible clinicians to adopt, implement and use ONC's updated certification criteria for health IT, including EHRs, as it becomes available from their chosen vendor, without the need to wait for CMS to first update the regulations at §495.4 and §414.1305 through separate rulemaking.

Comments/Responses: Many commenters supported the proposal to streamline CEHRT definitions and the proposed cross-references to ONC's regulations and terminology, which should help avoid confusion and administrative burden. Other commenters requested clarification on the timelines when various certification criteria would apply. CMS notes that ONC sets timelines through their rulemaking and declines to finalize separate effective dates in the CEHRT definition within the Medicare Promoting Interoperability Program or the Quality Payment Program. However, CMS will continue to determine when new or revised versions of measures that require the use of certified health IT would be required for participation under the Medicare Promoting Interoperability Program and the Quality Payment Program.

Final Action: CMS finalizes its proposal.

S. A Social Determinants of Health Risk Assessment in the Annual Wellness Visit

Medicare coverage for the Annual Wellness Visit (AWV) under Part B is primarily described in statute at section 1861(hhh) of the Act and in regulation at 42 CFR §410.15. CMS proposed to exercise its authority in section 1861(hhh)(2)(I) to another element to the AWV—a new Social Determinants of Health (SDOH) Risk Assessment as an optional, additional element with an additional payment. CMS says the proposed new SDOH Risk Assessment would enhance patient-centered care and support effective administration of an AWV, which has no deductible or Part B coinsurance requirement (§§410.160(b)(12) and 410.152(l)(13), respectively). This proposal builds on one described earlier (section II.E.) to establish a stand-alone G code (G0136) for SDOH Risk Assessment furnished in conjunction with an Evaluation and Management (E/M) visit.

1. Background

CMS reviews details of the AWV—for example, that it is the establishment (or update) of the patient's medical and family history, application of a health risk assessment, and the establishment (or update) of a personalized prevention plan. The AWV also includes an optional Advance Care Planning (ACP) service. The AWV is covered for eligible beneficiaries who are no longer within 12 months of the effective date of their first Medicare Part B coverage period and who have not received either an Initial Preventive Physical Examination (IPPE) or AWV within the past 12 months.

The agency also reviews the definition of SDOH, broad groups of SDOH (for example, economic stability), and HHS efforts to support addressing SDOH to advance health equity. Between 2017 and 2022, CMS tested the Accountable Health Communities (AHC) Model, which included the development and application of the AHC Health-Related Social Needs (HRSN) Screening Tool to help providers to identify patients' SDOH related needs, including housing instability, food insecurity, family and community support, and mental health.

CMS has heard from many health care professionals and beneficiary groups that there are barriers to completing the AWV, including language and communication, differences in cultural perspectives, and expectations regarding engagement with the healthcare system. The 2018 *Health Affairs* article "Practices Caring for the Underserved Are Less Likely to Adopt Medicare's Annual Wellness Visit" points out, "One of our most striking results was that while underserved patients were less likely to receive an annual wellness visit regardless of where they sought care, practices in rural areas and those caring for underserved and sicker populations were less likely to provide such visits to any of their patients—which suggests these practices may face resource constraints or have priorities that compete with adoption of the visit." The 2022 *Journal of the American Geriatrics Society* article "Medicare's annual wellness visit: 10 years of opportunities gained and lost" recommends that "Medicare AWVs should include screening and counseling for social determinants of health as a means of mitigating the growing disparities in health and longevity for underserved older adults."

2. Statutory and Regulatory Authority

Section 1861(hhh)(2) of the Act describes a number of elements included in the AWV, while section 1861(hhh)(2)(I) of the Act authorizes the addition of any other element determined appropriate by the Secretary. In the preamble, CMS reviews the long list of services, not duplicated here, in a beneficiary's first AWV (§410.15(a)). It also recounts adding Advance Care Planning (ACP) as an optional element (at beneficiary discretion) as a voluntary, separately payable element of the AWV, with separate CPT codes and no beneficiary cost sharing.

3. Proposal (§410.15)

CMS proposed to exercise its authority in section 1861(hhh)(2)(I) of the Act to add a new SDOH Risk Assessment as an optional, additional element of the AWV. The new SDOH Risk Assessment would be separately payable with no beneficiary cost sharing when furnished as part of the same visit with the same date of service as the AWV. CMS says this would inform the

care the patient is receiving during the visit, including taking a medical and social history, applying health assessments and prevention services education and planning. It also encourages partnerships with community-based organizations such as Area Agencies on Aging to help address identified social needs.

Specifically, the SDOH Risk Assessment service would include the administration of a standardized, evidence-based SDOH risk assessment tool, furnished in a manner so that all communication with the patient is appropriate for the patient's educational, developmental and health literacy level, and be culturally and linguistically appropriate. CMS believes this proposal would directly reduce barriers, expand access, promote health equity and improve care for populations that have historically been underserved by recognizing the importance that SDOH be considered and assessed, where appropriate, as an additional, optional element in the AWV service.

Recognizing that SDOH risk assessments are an emerging and evolving tool, CMS does not restrict the proposal to a specific list of approved assessments. However, in selecting an evidence-based tool, CMS encourages clinicians to explore the many widely adopted and validated tools available, including the CMS Accountable Health Communities tool, the Protocol for Responding to & Assessing Patients' Assets, Risks & Experiences (PRAPARE) tool, and instruments identified for Medicare Advantage Special Needs Population Health Risk Assessment. The agency also encourages clinicians, where feasible, to select screening instruments that maximize opportunities to collect and analyze standardized, quantifiable and actionable data.

Comments/Responses: Overall, commenters expressed broad support and approval of the proposal. Reactions were mixed about whether the SDOH Risk Assessment should be optional for the patient and clinician, but CMS reiterated its belief that it should not be a mandatory element of the AWV at this time.

A few commenters requested clarification regarding the type of clinician eligible to furnish the SDOH Risk Assessment as an additional element of the AWV. CMS responds that it would be clinicians within the definition of health professional at 42 CFR §410.15(a)—a physician who is a doctor of medicine or osteopathy; a physician assistant, nurse practitioner, or clinical nurse specialist; or a medical professional (including a registered nurse, a licensed clinical social worker, a health educator, a registered dietitian, or nutrition professional, or other licensed practitioner) or a team of such medical professionals, working under the direct supervision (as defined in §410.32(b)(3)(ii)) of a physician.

Numerous commenters requested clarification on whether elements of the AWV, including the health risk assessment and the SDOH Risk Assessment, could be initiated by the patient prior to the date of the AWV—and if so, whether it would fit within the requirement of the PFS proposed rule that it be furnished on the same date of service and as part of the same visit as the AWV. CMS clarifies that in some cases, for various reasons, elements of the AWV may be initiated and furnished over a period of multiple days, with the claim reporting the date of services on which the entirety of the AWV is completed. While the medical record documentation may reflect that the service began on one day and was completed another day, the date of service will show a

single date. This is consistent with regulations regarding the health risk assessment of the AWV, which may be administered prior to or as part of the AWV encounter.[89]

Final Action: CMS finalizes its proposal.

IV. QPP

This section is summarized in Part III of the HFMA summary of the PFS.

V. Regulatory Impact Analysis

A. RVU Impacts

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, CMS makes adjustments to preserve budget neutrality.

CMS states that its estimates of changes in Medicare allowed charges for PFS services compare payment rates for 2023 with payment rates for 2024 using 2022 Medicare utilization for all years. The payment impacts reflect averages for each specialty based on Medicare utilization. The payment impact for an individual physician would be different from the average, based on the mix of services the physician provides. As usual, CMS asserts that the average change in total revenues would be less than the impact displayed here because physicians furnish services to both Medicare and non-Medicare patients and specialties may receive substantial Medicare revenues for services that are not paid under the PFS. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical laboratory services that are not paid under the PFS.

Prior to 2015, the annual update to the PFS conversation factor (CF) was previously calculated based on a statutory formula (the Sustainable Growth Rate methodology that was largely overridden each year by Congressional action). MACRA established the update factor for calendar years 2015 and beyond and amended section 1848(d) of the Act. This provision requires an update of 0.0 percent for 2024, before applying any other adjustments. The 2024 PFS CF calculation takes into account one-time increases in PFS amounts from the CAA, 2023. CMS first removes the 2.5 percent one-time increase applied to the 2023 PFS CF from the 2024 calculation before applying the one-time 1.25 percent increase in PFS payment amount for services in 2024. The calculation for 2024 also takes into account a significant RVU budget neutrality adjustment. CMS notes that about 90 percent of the budget neutrality adjustment is attributable to the O/O E/M visit complexity add-on code with all other valuation changes making up the other 10 percent.

[89] See also MLN article # SE17023, https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/se17023.pdf.

The CF for 2024 is $32.7442, which reflects the expiration of the 2.5 percent increase for services furnished in 2023, the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act, the 1.25 percent increase provided by the CAA, 2023, and a budget neutrality (BN) adjustment of -2.18 percent. The 2024 anesthesia conversion factor is $20.4349, 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 116 and 117 from the final rule, reproduced below.

Table 116: Calculation of the 2024 PFS Conversion Factor		
2023 Conversion Factor		**$33.8872**
Conversion Factor without CAA, 2023 (2.5 Percent Increase for CY 2023)		$33.0607
2024 RVU Budget Neutrality Adjustment*	-2.18 percent (0.9782)	
2024 1.25 Percent Increase Provided by the CAA, 2023	1.25 percent (1.0125)	
2024 Conversion Factor*		**$32.7442**
Note: CMS published a different budget neutrality factor of -2.20 percent and a 2024 CF of $32.7375 in Table 16. It confirmed that this was erroneous and the preamble text is correct.		

Table 117: Calculation of the 2024 Anesthesia Conversion Factor		
2023 National Average Anesthesia Conversion Factor		**$21.1249**
Conversion Factor without CAA, 2023 (2.5 Percent Increase for CY 2023)		$20.6097
2024 RVU Budget Neutrality Adjustment	-2.18 percent (0.9782)	
2024 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	0.11 percent (1.0011)	
2024 1.25 Percent Increase Provided by the CAA, 2023	1.25 percent (1.0125)	
2024 Conversion Factor		**$20.4349**

Table 118 (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 includes changes to RVUs for specific services and the third-year transition to updated clinical labor pricing. It also includes changes in spending which result from finalized policies within budget neutrality, such as the updated policy associated with the complexity add-on code G2211. 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 2.50 and the 1.25 percent payment supplements for 2023 and 2024, respectively are statutory changes that take 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 118. As explained previously, there is a net decrease of 1.25 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 118 for a given specialty, the combined effect of RVU changes with the net CF reduction from the CAA would be roughly -3.25 percent.[90]

[90] CMS displays the combined impact percentage in Table 118 to the nearest whole number so adjusting these

2024 PFS Impact Discussion

The most widespread specialty impacts of RVU changes in most years is related to changes to RVUs for specific services, including RVUs for new and revised codes. For 2024, specialty level changes can largely be attributed to the implementation of the separate payment for the O/O E/M visit complexity add-on code, the Year 3 update to clinical labor pricing, and the adjustment to certain behavioral health services. These specialty impacts range from an increase of 3 percent for endocrinology and family practice, increase of 2 percent for clinical psychologist, clinical social worker, general practice, hematology/oncology, nurse practitioner, physician assistant, psychiatry, and rheumatology, and a decrease of 4 percent for interventional radiology, and a decrease of 3 percent for nuclear medicine, radiology, physical/occupational therapy and vascular surgery. The specialties with increases largely benefit from the implementation of the separate payment for the O/O E/M complexity add-on codes and those specialties with decreases are negatively affected by the redistributive effects of increases in work RVUs for other codes and/or rely primarily on supply/equipment items for their practice expense costs. Other factors that could impact changes include, for example, revaluation of individual procedures based on reviews by the AMA RUC and CMS.

Column F of Table 118 (reproduced below) shows the estimated 2024 combined impact on total allowed charges by specialty of all the RVU and other changes. CMS also provides an additional impact table (table 119 in the final rule) that includes a facility/non-facility breakout of payment changes.

Table 118: 2024 PFS 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	$217	0%	-1%	0%	-1%
Anesthesiology	$1,650	-2%	-1%	0%	-2%
Audiologist	$69	-1%	-1%	0%	-2%
Cardiac Surgery	$175	-1%	-1%	0%	-2%
Cardiology	$6,015	0%	0%	0%	0%
Chiropractic	$649	-1%	-1%	0%	-2%
Clinical Psychologist	$717	1%	0%	0%	2%
Clinical Social Worker	$801	2%	0%	0%	2%
Colon and Rectal Surgery	$147	-1%	-1%	0%	-2%
Critical Care	$333	-1%	0%	0%	-2%
Dermatology	$3,717	0%	0%	0%	-1%
Diagnostic Testing Facility	$833	0%	-1%	0%	-2%
Emergency Medicine	$2,473	-2%	-1%	0%	-2%
Endocrinology	$509	1%	1%	0%	3%
Family Practice	$5,538	2%	2%	0%	3%

numbers for the net decrease of 1.25 percent could be off as much as +/- 0.5 percentage points.

Table 118: 2024 PFS 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
Gastroenterology	$1,476	0%	0%	0%	0%
General Practice	$368	1%	1%	0%	2%
General Surgery	$1,625	-1%	-1%	0%	-1%
Geriatrics	$184	0%	1%	0%	1%
Hand Surgery	$252	-1%	0%	0%	-1%
Hematology/Oncology	$1,595	1%	0%	0%	2%
Independent Laboratory	$551	-1%	-1%	0%	-1%
Infectious Disease	$576	-1%	0%	0%	-1%
Internal Medicine	$9,683	0%	1%	0%	1%
Interventional Pain Mgmt	$853	0%	0%	0%	0%
Interventional Radiology	$458	-1%	-3%	0%	-4%
Multispecialty Clinic/Other Phys	$147	0%	0%	0%	0%
Nephrology	$1,813	-1%	0%	0%	-1%
Neurology	$1,330	0%	0%	0%	1%
Neurosurgery	$699	-1%	0%	0%	-1%
Nuclear Medicine	$51	-1%	-2%	0%	-3%
Nurse Anes / Anes Asst	$1,081	-2%	0%	0%	-2%
Nurse Practitioner	$6,297	1%	1%	0%	2%
Obstetrics/Gynecology	$560	0%	1%	0%	1%
Ophthalmology	$4,647	0%	0%	0%	-1%
Optometry	$1,299	-1%	-1%	0%	-2%
Oral/Maxillofacial Surgery	$63	-1%	-1%	0%	-2%
Orthopedic Surgery	$3,369	-1%	0%	0%	-1%
Other	$56	0%	0%	0%	0%
Otolaryngology	$1,115	0%	0%	0%	0%
Pathology	$1,142	-1%	-1%	0%	-2%
Pediatrics	$56	0%	0%	0%	1%
Physical Medicine	$1,093	0%	0%	0%	-1%
Physical/Occupational Therapy	$5,281	-1%	-2%	0%	-3%
Physician Assistant	$3,377	1%	1%	0%	2%
Plastic Surgery	$303	-1%	-1%	0%	-1%
Podiatry	$1,910	0%	0%	0%	0%
Portable X-Ray Supplier	$76	0%	0%	0%	-1%
Psychiatry	$907	1%	1%	0%	2%
Pulmonary Disease	$1,295	0%	0%	0%	0%
Radiation Oncology and Radiation Therapy Centers	$1,556	0%	-2%	0%	-2%

Table 118: 2024 PFS 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
Radiology	$4,536	-1%	-2%	0%	-3%
Rheumatology	$510	1%	1%	0%	2%
Thoracic Surgery	$293	-1%	-1%	0%	-2%
Urology	$1,630	0%	0%	0%	1%
Vascular Surgery	$1,011	-1%	-3%	0%	-3%
Total	$88,967	0%	0%	0%	0%
* **HFMA note** – The combined impact numbers CMS displays in Column F **do not** take into account the 2.50 and the 1.25 percent payment supplements for 2023 and 2024, respectively, as these are statutory changes that take place outside of budget neutrality requirements. Thus, there is a net decrease of 1.25 percent to the PFS CF from these statutory changes 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 net CF reduction from the CAA, 2023 would be roughly -3.25 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 118:

- 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 2022 utilization and 2023 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 2024 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 2024 impact on total allowed charges of the changes in the PE RVUs.

- Column E (Impact of MP RVU Changes): This column shows the estimated 2024 impact on total allowed charges of the changes in the MP RVUs.

- Column F (Combined Impact): This column shows the estimated 2024 combined impact on total allowed charges of all the changes in the previous columns.

Health Equity

CMS expanded it PFS impact analysis to considered what a health equity framework might accurately provide insight into the relationship between PFS policies and health equity. CMS

notes that in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27621 through 27266), it included a table that details providers in terms of the beneficiaries they serve, as well as differences in estimated average payments per case and changes in estimated average payments per case relative to other providers. It uses this approach as a guide for examining these issues in the PFS.

CMS used several proxies to identify disadvantaged or underserved patient population, including elements from claims data and Medicare enrollment data. This included race/ethnicity, dual eligibility for Medicaid and Medicare, Medicare low income subsidy (LIS) enrollment, a joint indicator for dual or LIS enrollment, presence of an ICD-10-CM Z code indicating a "social determinant of health" (SDOH), presence of a behavioral health diagnosis code, receiving ESRD Medicare coverage, qualifying for Medicare due to disability, living in a rural area, and living in an area with an area deprivation index (ADI) greater than or equal to 85. In the final rule, CMS details how it derived and constructed these measures.

Table 121 in the final rule displays the share of utilization for each of these health equity measures. It lists the share of enrollees with each characteristic, by beneficiaries, and by provider specialty. CMS notes that the information displayed does not form the basis or rationale for the policies in the final rule.

CMS sought comment on how it might structure such PFS impact analysis, how this framework would allow it to develop policies to enhance health equity, alternative measures of health equity it might consider, and additional categories or potential data sources that should be considered.

CMS received a few comments on its health equity framework. One commenter suggested an alternative index of vulnerability in place of the ADI, citing concerns about the accuracy of the ADI. CMS notes that it may consider an alternative vulnerability index in future rulemaking. Another commenter requested clarification about the Medicare Bayesian Improved Surname Geocoding (MBISG), specifically how it addresses mixed-race couples and individuals who are not appropriately placed in any racial category. CMS notes that the purpose of the MBISG method is to augment CMS administrative measures of race and ethnicity to assign individuals more accurately into racial and ethnic categories for purposes of displaying utilization data across specialty. It acknowledges that while no imputation method is 100 percent accurate, it believes it is an improvement over administrative data.

B. Impacts of Other Policies

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, advancing access to behavioral health, proposals on drug and biological products paid under Medicare Part B, clinical laboratory fee schedule, modifications to the MSSP, Medicare Part B payment for preventive vaccine administrative services, effects of proposals related to the Medicare Diabetes Prevention Program Expanded model, the Medicare and Medicaid provider and supplier enrollment changes, hospice conditions of participation changes, 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 (686,650) will be assigned a MIPS score because others will be ineligible for or excluded from MIPS. Table 131, reproduced below, provides the details of clinicians' MIPS eligibility status for 2026 MIPS payment year (2024 MIPS performance year).[91] CMS notes it is difficult to predict whether clinicians will elect to opt-in to participate in MIPS.

TABLE 131: Description of MIPS Eligibility Status for CY 2024 Performance Period/2026 MIPS Payment Year Using the 2024 PFS Final Rule Assumptions**			
		CY 2024 PFS Final Rule estimates	
Eligibility Status	**Predicted Participation Status in MIPS Among Clinicians***	**Number of Clinicians**	**PFS allowed charges ($ in mil)*****
Required eligibility (always subject to a MIPS payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria)	Reported to MIPS*	104,757	$26,305
	Did not Report to MIPS	41,899	$10,634
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low- volume threshold in all 3 criteria)	Had a group submission	533,440	$11,776
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	6,554	$318
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**686,650***	**$49,034**
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	Opt-in Eligible; Do not opt-in	178,216	$4,958
	Group Eligible; Did not Report	405,940	$8,539

[91] CMS refers to the final rule assumptions in the table header and the 2023 performance period/2025 MIPS payment year, which is inconsistent with the final rule regulatory text. The header is modified to be consistent with the final rule text.

TABLE 131: Description of MIPS Eligibility Status for CY 2024 Performance Period/2026 MIPS Payment Year Using the 2024 PFS Final Rule Assumptions**			
		CY 2024 PFS Final Rule estimates	
Eligibility Status	**Predicted Participation Status in MIPS Among Clinicians***	**Number of Clinicians**	**PFS allowed charges ($ in mil)*****
eligibility or 2) opt-in eligibility criteria)			
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	129,806	$714
Excluded for other reasons (Non-eligible clinician type, newly-enrolled)	Not applicable	60,471	$450
Qualified Participant (QP)***	Not applicable	359,816	$15,817
Total Number of Clinicians Not MIPS Eligible		1,134,249	$30,479
Total Number of Clinicians (MIPS and Not MIPS Eligible)		1,820,899	$79,513

* Participation excludes facility-based clinicians who do not have scores in the 2021 MIPS submission data.

** Allowed charges estimated in 2021 dollars. Low-volume threshold is calculated using allowed charges. MIPS payment adjustments are applied to the paid amount.

*** Our QP estimate differs from that reported in section VI.E.22.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 2026 payment year, it would redistribute about $491 million in payment adjustments on a budget neutral basis. CMS estimates that payment adjustments range from -9 percent to a maximum of positive payment adjustment of 2.985 percent. The overall proportion of clinicians receiving a positive or neutral payment adjustment is expected to be 78.40 percent and 21.60 percent of clinicians are expected to receive a negative adjustment. The percent of clinicians expected to receive a negative adjustment is much smaller in the final rule as CMS did not finalize the performance threshold of 82 which would have resulted in more than twice as many MIPS eligible clinicians receiving a negative payment adjustment (estimated at 46.67 percent in the proposed rule). Beginning with the CY 2025 MIPS payment year, the additional MIPS payment adjustment for exceptional performance is no longer available.

The table below combines elements of Tables 132 and 136 displayed in the final rule and shows the impact of payments by practice size, including proportion of eligible clinicians with a negative payment adjustment and the maximum positive payment adjustment. CMS notes that the percentage of clinicians receiving a positive or neutral adjustment varies little between the baseline and final rule policies models with slight variation for medium and large practices.

Tables 132 and 136 – Estimated Proportion of Eligible Clinicians with a Positive or Neutral and a Negative Payment Adjustment and Median Positive and Negative Payment Adjustment Estimates by Practice Size					
Practice Size	**Number of MIPS eligible clinicians**	**Percent Eligible Clinicians with Positive or Neutral Payment Adjustment**	**Percent Eligible Clinicians with Negative Payment Adjustment**	**Median Positive Payment Adjustment**	**Median Negative Payment Adjustment**
Baseline Policy Model					
1) Solo	18,867	53.72%	46.28%	2.08%	-9.00%
2) Small 2-15	71,908	76.35%	23.65%	1.83%	-5.17%
3) Medium 16-99	150,382	76.11%	23.89%	1.69%	-1.32%
4) Large 99+	445,493	80.55%	19.45%	1.73%	-0.95%
Overall	686,650	78.40%	21.60%	1.73%	-1.24%
Final Rule Policies					
1) Solo	18,867	53.72%	46.3%	2.08%	-9.00%
2) Small 2-15	71,908	76.36%	23.6%	1.83%	-5.18%
3) Medium 16-99	150,382	76.09%	23.9%	1.69%	-1.34%
4) Large 99+	445,493	80.51%	19.5%	1.73%	-0.95%
Overall	686,650	78.37%	21.6%	1.74%	-1.24%

CMS notes that after performance year 2022, which correlates with payment year 2024, there is no further statutory authority for a 5 percent APM Incentive Payment for eligible clinicians who become QPs for a year. In performance year 2024, which correlates with payment year 2026, the statute does not provide for any type of incentive for eligible clinicians who become QPs. Beginning in performance year 2026, as required by statute, there shall 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, the scoring model results presented in the final rule assume that 2021 Quality Payment Program data submissions and performance are representative of modeled performance. Likewise, CMS states that it is difficult to predict whether clinicians will elect to opt-in to participate into the MIPS program. In addition, to the extent that there are year-to-year changes in the data submission, volume, and mix of services provided by MIPS eligible clinicians, the actual impact on total Medicare revenues will be different from those shown in Table 132. Given these limitations and others, there continues to be considerable uncertainty around CMS' estimates.

D. Alternatives Considered

The rule contains a range of potential policies, and CMS provides a discussion of alternatives considered for some of these policies. We highlight the alternative considered related to the O/O E/M visit complexity add-on separate payment.

1. Alternatives Considered Related to the O/O E/M Visit Complexity Add-on Separate Payment

CMS considered alternatives to its policy to make separate payment for the O/O E/M visit complexity add-on code, including maintaining the utilization assumption finalized in 2021 and delaying the implementation of this policy until 2025.

If CMS had maintained its higher 2021 utilization assumptions, the estimated impact on the change to the PFS CF would have been -3.2 percent compared with the -2.0 percent for 2024. CMS states that maintaining the 2021 policy utilization assumption would not reflect its limitation on billing of the O/O E/M visit complexity add-on code for services billed with modifier 25 which is used to indicate that the service is billed on the same day as a minor procedure or another E/M visit. Specifically, CMS now estimates that the G2211 code will be billed with 38 percent of all O/O E/M visits initially and it anticipates that primary care specialties will have a higher utilization of the add- on code than other specialties as they are more likely to have longitudinal care relationships with patients.

CMS also considered not making separate payment for the O/O E/M visit complexity add-on code for 2024, by continuing to consider the utilization data and seeking comment on not making separate payment until 2025 instead of 2024. It acknowledges that by doing so it would reduce the change to the CF and the redistributive impacts among specialties, but argues that it would not capture the work associated with visits that are part of ongoing, comprehensive primary care and/or care management for patient with a single, serious, or complex chronic condition would remain present.

E. Impact on Beneficiaries

CMS believes that a number of changes in this final rule will increase participation in a more sustainable way for ACOs serving medical complex, high-cost beneficiaries. CMS estimates that its policy to cap an ACO's regional service area risk score growth, use a uniform approach to calculating risk scores, mitigate the negative impact on regional adjustments on benchmarks, and revise the definition of an assignable beneficiary is expected to increase participation in the Shared Savings Program over the 2024-2033 period by roughly 10 to 20 percent. By doing so, CMS believes that increased participation in the MSSP will extend ACO care coordination and quality improvement to segments of the beneficiary population most likely to benefit from care management.

It also believes that several changes to the quality payment program are expected to have a positive effect on beneficiaries. For example, CMS states that the MVP and subgroup policies 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 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. CMS estimates that the cost of reviewing this rule is $123.06 per hour, including overhead and fringe benefits. In addition, CMS assumes that it would take about 8 hours for the staff to review half of this final rule. For each facility that reviews the rule, the estimated cost is $984.48 (8.0 hours x $123.06) and the total cost of reviewing this regulation is about $21.7 million ($984.48 x 22,019 reviewers on this year's proposed rule).