Physician Fee Schedule Proposed 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-P]

On July 13, 2023, the Centers for Medicare & Medicaid Services (CMS) placed on public display a proposed rule relating to the Medicare physician fee schedule (PFS) for CY 2024[1] and other revisions to Medicare Part B policies. The proposed rule is scheduled to be published in the August 7, 2023 issue of the *Federal Register*. If finalized, policies in the proposed rule generally would take effect on January 1, 2024. **The 60-day comment period ends at close of business on September 11, 2023.**

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. The proposed rule contains several comment solicitations including strategies for implementing updates to indirect practice expense; reforming the process for establishing values for E/M visits and other services; and the use of digital therapeutics in clinical practice.

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I. Introduction

The proposed rule would update the PFS payment policies that apply to services furnished in all sites by physicians and other practitioners. In addition to physicians, the PFS is used to pay a variety of practitioners and entities including nurse practitioners, physician assistants, physical therapists, radiation therapy centers, and independent diagnostic testing facilities (IDTFs). The proposed rule includes proposals to not incorporate the 2017-based Medicare Economic Index (MEI) in PFS ratesetting for 2024, implementation of the E/M O/O complexity add-on code, coding and payment for services community health integration services, social determinants of health risk assessment, and principal illness navigation services; and payment for dental services. CMS is also proposing 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 proposed conversion factor (CF) for 2024 is $32.7476, 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 -2.17 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 proposed valuation changes making up the other 10 percent. The proposed 2024 PFS CF is -3.6% lower than the 2023 CF.

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 proposed implementation of the O/O E/M visit complexity add-on code, the Year 3 update to clinical labor pricing, and the proposed 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, and vascular surgery. **These payment impacts, however, do not take into account the impact of the 2.50 and the 1.25 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 Proposed Rule for PFS

A. Background

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

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

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

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 proposed 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 propose a variable maintenance factor, though it continues to investigate ways of capturing such information.

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

In the 2023 PFS final rule, CMS finalized its proposal to rebase and revise the Medicare Economic index (MEI) to reflect more current market conditions faced physicians in furnishing physicians' 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 is not

[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.

proposing 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 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.

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 proposes to update the prices of 16 supplies and two equipment items in response to the public submission of invoices. The proposed prices for these items were generally calculated following its standard methodology of averaging together the prices on the submitted invoices. This includes, for example, the UltraView Universal DAB Detection Kit, which CMS established a proposed price of $12.28 (an increase from $9.70) for the SL488 supply based on averaging the invoices received. See Table 15 in the proposed rule for details on the updated prices, CPT codes affected, and number of services impacted.

CMS does not update the price of another eleven supplies from which it received information. 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 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 proposed average or mean wage data for calculation of clinical labor rates. Based on comments received, CMS used the fringe benefits multiplier of 1.296 for employees in private industry based on a BLS release from June 17, 2021 (USDL-21-1094).

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

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

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

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

For 2024, 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. Thus, the proposed clinical labor pricing for 2024 is based on the prior year clinical labor pricing updated for year 3 of the phase-in transition.

Excerpt of Selected Labor Categories from Table 5: Proposed 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 29-2035	0.45	0.76	0.683	69%
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%

d. 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 proposes to add the correct 20 minutes of intraservice work time for this code for 2024.

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

In 2023, CMS issued an RFI to solicit public comment on strategies to update PE data collection and methodology. CMS noted that it has explored issues related to indirect PE in previous rulemaking and 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:

- 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.

[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.

b. Request for Information

CMS states that considering its ratesetting methodology and prior experiences implementing new data, it is issuing a follow-up solicitation for general information. **CMS seek 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 seeks 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 requests 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?

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 notes the requests 4 rods of Dilapan-S would increase the supply costs of this code by a factor of five.

CMS does not propose to consider this code as potentially misvalued. CMS does not agree that the use of the Dilapan-S supply is typical for this service. CMS does agree 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.

(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 claims 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.

[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.

CMS is 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. **CMS seeks comments on this nomination as a misvalued code.**

(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 disagrees 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 6). CMS proposes to maintain the values that were finalized for 2023 and not to nominate these codes 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 seeks comments on whether or not these codes are 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 believes these two codes appear similar but have differences in their purpose, physician work times, and direct Pes. **CMS does not think CPT code 44205 is misvalued and seeks feedback on this nomination**.

(6). CPT codes 93655 (Intracardiac catheter ablation of a 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 and not the finalized value of 5.50. CMS proposes to maintain the values that were finalized for 2023 and not to nominate these codes as potentially misvalued.

(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 7, in the proposed rule, list the nominator's recommendations for practice expense items for these codes. **CMS seeks comments as to whether or not these codes are potentially misvalued.**

(8) CPT codes 0596T and 0597& (Insertion of temporary valve-pump in female urethra)
These temporary CPT category III codes are all contractor priced. The nominator states 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 seeks comments as to whether these temporary category III codes are potentially misvalued and whether or not they should remain contractor priced.**

(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 does not support this methodology for determining Medicare payment. CMS is not proposing to nominate this code 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 now 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 proposes these 19 codes, listed below in Table 8, as potentially misvalued codes.

Table 8: 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

Table 8: 19 "Always Therapy" Service Codes Nominated for Potential Misvaluation	
HCPCS	**Long Descriptor**
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]

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.

[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.

- 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 Medicare telehealth services list is available on the CMS website at https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html. This list includes proposed additions discussed in this proposed rule. Information about submitting a request to add services to the Medicare telehealth services list is also available on this website. For 2024, requests must have been received by February 10, 2023. CMS notes that information submitted as part of a request is subject to public disclosure, including discussion in the PFS proposed rule.

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.

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

CMS received several requests to permanently add services to the Medicare telehealth services list for 2024 (Table 9 in the proposed rule, reproduced with modifications below). CMS does not propose the permanent addition of any of these requests as Category 1 or Category 2 services; it does propose adding some of these services to the telehealth service list as Category 3 services.

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 does 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. CMS does not consider this service to be a telehealth service under section 1834(m) of the Act and regulations at §410.78. CMS reiterates that services routinely paid separately prior to enactment of section 1834(m) of the Act and do not usually include patient interaction, such as remote interpretation of diagnostic tests, are not considered Medicare telehealth services (83 FR 59483).

[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

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 notes 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 proposes not to include these services permanently on the telehealth list on a Category 1 basis. CMS proposes to continue to include these services on the telehealth list through CY 2024.

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 believes there is not yet sufficient evidence to consider these services for permanent addition under the Category 2 criterion. CMS proposes not to include these services permanently on the telehealth list on a Category 1 basis. CMS proposes to continue to include these services on the telehealth list through CY 2024.

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 reiterates 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 stresses that available evidence needs to address all elements of the service and not focus on any individual service within one specific clinical scenario. CMS proposes not to add these services to the telehealth list on a Category 1 or Category 2 basis.

CMS proposes to keep these therapy services on the telehealth list through CY 2024. CMS also notes that 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 proposes to continue these services on the telehealth service list though 2024.

[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.

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 proposes to add these codes the telehealth list on a temporary basis for 2024.

CMS believes the evidence submitted is evolving and suggest that these services could possibly meet the Category 2 criteria as additional evidence is obtained. CMS notes that the evidence needs to establish clinical benefit when delivered directly by or under the supervision of professionals who are Medicare telehealth practitioners.

CMS Proposal to Add New Codes to the List (HCPCS code GXXX5)
CMS proposes to permanently add HCPCS code GXXX5 (Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment (SDOH) tool, 5-15 minutes) to the telehealth list; this proposal is contingent upon finalizing CMS' proposal for this code (discussed in Section II.E).

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

CMS reviews 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 believes 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 proposes to replace the Category 1-3 status with permanent or provisional status for any service assigned to the telehealth list.

CMS emphasizes 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 that presents studies suggesting a clinical benefit sufficient for the services to remain on the list to allow time for confirmative studies. CMS notes 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 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 proposed changes would not change the timeline for requests related to the Medicare Telehealth List; requests would 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 proposes that if a submitted service is not separately payable under the PFS, it would not conduct any further review of the service. CMS would 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 would determine 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 proposes that if a submitted service does not meet the provisions of section 1834(m) of the Act, it would not conduct any further review of the service. CMS would 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 would determine 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 would 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 proposes 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 proposes that even if a code under review is not a successor code, it would 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 proposes that the step 4 analysis would 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 proposes that any service satisfying Step 4, would be proposed for permanent addition to the telehealth list in the next PFS proposed rule. If Step 4 is not met, CMS would 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 would review 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 proposes that if there is enough evidence to suggest that further study may demonstrate that the service provided via telehealth is a clinical benefit, it would 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 would assign the code a "permanent" status.

Proposed Assignment of "Permanent" or "Provisional" Status to a Service and Changes in Status
CMS proposes to replace the Category 1-3 taxonomy with "permanent" or "provisional" status. CMS would 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 would 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 would 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 would review change in status by using all the proposed 5 steps.

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

For 2024, CMS proposes to redesignate any services on the Medicare Telehealth Services List on a Category 1 or 2 basis and would be on the list for 2024, to the permanent category. Any service currently added on a "temporary Category 2" or Category 3 basis would be assigned to the provisional category. CMS proposes 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.

e. Implementation of Provisions of the CAA, 2023

CMS discusses 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, 2013 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

[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.

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 proposes 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.

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

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 proposes 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 proposes 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.

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 proposes 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 seeks 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.

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 proposes continuing 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 proposal aligns with the timeframe of extended provisions of the CAA, 2023.

CMS believes this additional time will allow collection of additional information for development of a permanent policy for direct supervision. **CMS seeks 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 is 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 is also interested in potential integrity concerns, such as overutilization or fraud and abuse.

CMS discuss 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. **CMS seeks comments on this potential approach**, as well as other options that would protect patient access and safety, maintain quality of care, and program integrity concerns.

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 proposes 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 will continue exercising enforcement discretion to this policy through 2024.

CMS seeks 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.

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, CMS clarifies 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.

Data collection requirements. At the end of the PHE, CMS reinstated the 16-day monitoring requirement over a 30-day period. For 2024, CMS clarifies the data collection requirements. As specified in the code descriptions, CPT codes 99876-98978, 98980, and 98981 require no fewer than 16 days of data in a 30-day period.

CMS reiterates that remotely monitored monthly services should only be reported once during a 30-day period when reasonable and necessary. CMS clarifies that for either RPM or RTM, only

one practitioner can bill CPT codes 9956 and 99454, or CPT codes 98976, 98977, 98980, and 98981, 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 reiterates 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 reiterates 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 clarifies 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).

CMS requests comments on the clarifications and general feedback that may be useful for development of remote monitoring services payment policies.

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 proposes 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 10). The proposed MEI increase for 2024 is 4.5 percent; the proposed payment for HCPCS code Q3014 (Telehealth originating site facility fee) is $29.92. The final facility fee update will be revised in the final rule.

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

CMS reviews 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. CMS is now reconsidering this guidance.

Through 2024, CMS proposes 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 seeks 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 seeks 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 seeks comm**ents 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]

CMS is also considering 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 notes 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 seeks 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.

[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

E. Valuation of Specific Codes

The proposed work RVUs, work time and other payment information for all the proposed payable codes in 2024 are available on the CMS website under downloads for the PFS proposed rule at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

The following tables in the proposed rule provide additional details about the proposed 2024 valuation of specific codes:

Table 12	Work RVUs for New, Revised, and Potentially Misvalued Codes
Table 13	Direct PE Refinements
Table 14	Direct PE Refinements: Equipment Refinements Conforming to Changes in Clinical Labor
Table 15	Invoices Received for Existing Direct PE Inputs
Table 16	New Invoices
Table 17	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.[15] CMS notes the importance of not only the RUC-recommended work and time values but also the accompanying rationales for setting those values.[16]

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

[15]Approaches include RUC survey data, building block, key reference code crosswalks, magnitude estimation, incremental difference applications, and time ratio calculations.
[16]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 12 list the codes and proposed work RVUs, including all codes that CMS received recommendations from the RUC by February 10, 2023.

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 15 and 16). 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 15 and 16.

For 2024, CMS proposes nine new and revised codes as services which meet the definition of "imaging services" for purposes of the OPPS cap[17]. This includes CPT code 76883 (Ultrasound, nerve(s), per extremity); 7X001-7X003 (Intraoperative epicardial cardiac ultrasound for congenital heart disease); and 9X000, 9X002-9X005 (Venography for congenital heart defect(s)).

CMS notes that in the 2023 PFS proposed rule it proposed to add CPT code 76883 (Ultrasound, nerves) to the list of codes to which the OPPS cap applies. CMS did not finalize this proposal because the code could not be split into professional and technical components. Based on feedback from billing practitioners, CPT code 76883 now has a PC/TC split and CMS proposes to add it to the OPPS cap list for 2024.

4. Valuation for Specific Codes

This section discusses proposal for 28 code groups (listed in the table below). Highlights of some of CMS' discussions are summarized; the numbering is consistent with the preamble format. The reader is referred to the proposed rule for more specific details. **CMS seeks comments on the work values, direct PE inputs, or both, for all these code groups.**

Code Group Number and Name		Codes (CPT and HCPCS Codes)	CMS Proposed Work RVUs Agrees with RUC Recommendations	CMS Proposed Direct PE RVUs Agrees with RUC Recommendations
1	Dorsal Sacroiliac Joint Arthrodesis	2X000	Yes	Yes
2	Vertebral Body Tethering	2X002-2X004	Yes	Yes
3	Total Disc Arthroplasty	22587 & 22860	No	Yes

[17] 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 Work RVUs Agrees with RUC Recommendations	CMS Proposed Direct PE RVUs Agrees with RUC Recommendations
4	Phrenic Nerve Stimulation System	3X008-3X015, & 9X046-9X047	Yes	No
5	Posterior Nasal Nerve Ablation	30117, 30118, 3X016, & 3X017	No	No
6	Cystourethroscopy with Urethral Therapeutic Drug Delivery*	5X000	Yes	Yes
7	Transcervical RF Ablation of Uterine Fibroids	5X005	Yes	No
8	Suprachoroidal Injection	6X000	Yes	Yes
9	Skull Mounted Cranial Neurostimulator	619X1-619X3	Yes	Yes
10	Spinal Neurostimulator Services	63685 & 63688	No	Yes
		64XX2-64XX3	NA**	NA**
11	Neurostimulator Service-Bladder Dysfunction*	64590 & 64595	Yes	No
12	Ocular Surface Amniotic Membrane Placement/Reconstruction	65778-65780	Yes	Yes
13	Fractional Flow Reserve with CT*	7X005	Yes	No
14	Ultrasound Guidance for Vascular Access	76937	Yes	Yes
15	Neuromuscular Ultrasound	76881-76883	NA	No
16	Intraoperative Ultrasound Services*	76998, 7X000-7X003	No	NA
17	Percutaneous Coronary Interventions	9X070	Yes	Yes
18	Auditory Osseointegrated Device Services*	926X1 & 926X2	Yes	Yes
19	Venography Services	9X000-9X005	Yes	NA
20	General Behavioral Health Integration Care Management*	99484 & G0323	No	Yes
21	Advance Care Management	99497 & 99498	Yes	Yes
22	Pelvic Exam*	9X036	NA	Yes
23	Hyperthermic Intraperitoneal Chemotherapy	9X034 & 9X035	NA**	NA**
24	Hyperbaric Oxygen Under Pressure*	G0277	NA	No
25	Remote Interrogation Device Evaluations-Cardiovascular*	G2006, 93297 & 93298	NA	Yes
26	Caregiver Training Services*	96202, 96203, 9X015-9X017	Yes	Yes
27	Health-Related Social Needs:*		NA	NA
	Community Health Integration Services	GXXX1 & GXXX2		
	SDOH Risk Assessment	GXXX5		

Code Group Number and Name		Codes (CPT and HCPCS Codes)	CMS Proposed Work RVUs Agrees with RUC Recommendations	CMS Proposed Direct PE RVUs Agrees with RUC Recommendations
	Principal Illness Navigation Services	GXXX3 & GXXX4		
28	Maternity Services*	59400, 59410, 59425, 59426, 59430, 59510, 59610, 59614, 59618 & 59622	NA	NA
*Discussed in HFMA summary **Contractor Priced Codes				

(6) Cystourethroscopy with Urethral Therapeutic Drug Delivery (CPT code 5X000)
Since this is an endoscopic procedure, CMS proposes CPT code 52000 (Cystourethroscopy (separate procedure) as the endoscopic base code for CPT code 5X000. CPT code 5X000 is not an add-on code and has a 0-day global period.

(11) Neurostimulator Services-Bladder Dysfunction (CPT codes 64590 and 64595)
CMS disagrees with the RUC-recommended direct PE inputs for CPT code 64590 in the non-facility setting and requests clarification. CMS believes the RUC inadvertently proposed 56 minutes of equipment time for EQ114 (electrosurgical generator), instead of 48 minutes. CMS believes 48 minutes is appropriate and that time matches the clinical labor time. CMS also believes that the time for EQ209 (programmer, neurostimulator) should be 84 minutes.

(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 (7X005) 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.

CMS reiterates its prior concerns that the software algorithm in the analysis fee for CPT code 7X005 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 proposes to maintain the previous valuation crosswalk to the TC of CPT code 93457 for CPT code 7X005. CMS proposes the RUC-recommended work RVU of 0.75 for the professional component of the code.

(16) Intraoperative Ultrasound Services (CPT codes 76998 & 7X000-7X003)
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.

(18) Auditory Osseointegrated Device Services (CPT codes 926X1 & 926X2)
CMS proposes to add these CPT codes to the list of audiology services that can be billed with the AB modifier which indicates that the service is personally provided by audiologists without a physician/NPP referral for non-acute hearing conditions.[18]

(19) General Behavioral Health Integration Care Plan Management (CPT code 99848 & HCPCS code G0323)
As part of proposed policies for advancing access to behavioral health (discussed below in section J.), CMS proposes to refine the work RVUs of CPT code 99484 by increasing the work RVU to 0.93 from the RUC recommended work RVU 0.61 and increase the work time to 21 minutes. This proposal matches the results of the surveyed work time. For CPT code 99484, CMS proposes the RUC recommended direct PE inputs. CMS proposes to crosswork the values for 99484 to HCPCS code G0323.

(22) Pelvic Exam (CPT code 9X036)
This code is an example of the creation of a new code that captures the additional direct PE of the associated expenses when performed with a E/M code for the visit.

(24) Hyperbaric Oxygen Under Pressure (HCPCS code G0277)
This code is an example of a code with a change in the dominant specialty providing this service. This service is now primarily performed by family medicine and the service is now typically performed by a single clinical staff (RN/Respiratory Therapist) instead of two staff (RN/LPN/MA and an RN/Respiratory Therapist). This change reflects changes in individuals qualified to be certified hyperbaric technologist. CMS agrees with the PE Subcommittee's recommendation to update the clinical staff type but does not agree with their times for clinical labor.

(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

[18] Additional codes not needing a referral are available at https://www.cms.gov/audiology-services.

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 proposes to delete HCPCS code G2066 and propose the RUC-recommended direct PE inputs for CPT codes 93297 and 93298. No recommendations were made for changes in the work RVUs.

(26) Payment for Caregiving Training Services (CPT codes 96202, 96203, 9X015-9X017)

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

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 proposes 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.

CMS seeks comments on its definition of 'caregiver' for purposes of CTS and if there are additional elements of a caregiver that should be incorporated into this proposed definition.

[19] 87 FR 69521-69523
[20] https://www.cms.goc/outreach-and-education/outreach/partnerships.

Patients Who Benefit from Care Involving Caregivers
CMS believe 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. CMS provides 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 discusses the need to avoid potentially duplicative payments for CTS to a patient receiving similar services under another Medicare benefit category or Federal program. CMS does not expect CTS will overlap with any other coverage for patients who are dually eligible. **CMS seeks comments on the following:**

- Whether States typically cover services similar to CTS under their Medicaid programs and whether such coverage would be duplicative of the CTS service codes.
- Whether payment for CTS is currently available through other Federal programs.

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.

CMS seeks comments on whether CTS would be reasonable and necessary when furnished to caregivers in more than one single session or to the same caregivers by the same practitioner for the same patient more than once per year.

Proposals
For 2024, CMS proposes the following for CTS services:

- Active payment status for CPT codes 96202 and 96203 (caregiver behavior management/modification training services) and CPT code 9X015-9X017 (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 seeks comments on how the clinician and caregiver interactions would typically occur, including when the practitioner is dealing with multiple caregivers. CMS is also interested in how often these services would be billed considering the established treatment plan involving caregivers for the typical patient.

Proposed Valuation
For 2024, CMS proposes the following for CTS services:

(ii) 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 proposes the 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 notes that the RUC recommendation suggested that the RUC intends to review these services again soon.

(ii) Caregiver training in strategies and techniques to facilitate the patient's functional performance (CPT codes 9X015-9X017)
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 proposes the RUC-recommended work RVUs for these CPT codes: 1.00 for 9X015, 0.54 for 9X016, and 0.23 per identified patient service for 9X017. The recommendation for 9X017 is based on a median group size of five caregivers. CMS also proposes 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 proposes 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.

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

a. Background

CMS discusses 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 that 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 is also considering how to better recognize through coding and payment policies, Community Health Workers (CHWs) that are members of an interdisciplinary team for Medicare beneficiaries. CMS notes that currently, 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 discusses the AMA 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 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 discusses the additional resources practitioners are expending to obtain information from the patient about SDOH and develop 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.

b. Community Health Integration (CHI) Services

CMS proposes 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. CMS proposes the following specific codes and descriptors that incorporate the required elements for CHI services:

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

i. Proposed CHI Services

GXXX1: *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 E/M 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.
    - 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.

GXXX2: *CHI services, each additional 30 minutes per calendar month (List separately in addition to GXXX1)*

ii. Proposed Requirements

CMS proposes the following requirements:

CHI initiating visit. CHI services could be furnished monthly, as medically necessary, following an initiating E/M visit (referred to as the CHI initiating visit) during which the practitioner identifies the presence of SDOH need(s) that significantly limit the practitioner's ability to diagnose or treat the problems addressed in the visit.

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

Subsequent CHI services. Subsequent CHI services would 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.

Supervision level. CHI services would be designated 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.
"*Problem Addressed*". This term refers to the definition in the CPT E/M Guidelines that CMS adopted for E/M visits.[23]

- 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.

[23] 2023 CPT codebook, p. 6-8.

- 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.

SDOH. SDOH means economic and social condition(s) that influence the health of people and communities, as indicated in the CPT E/M Guidelines.[24] In addition to the CPT examples of SDOH, CMS proposes 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.

Certified or trained auxiliary personnel. CHI 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 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 proposes these competencies because they reflect professional consensus regarding appropriate core competencies for CHWs providing this service.[25]

Documentation. 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 would include 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 would be encouraged to record the associated ICD-10 Z code (Z55-Z65) in the medical record and on the claim.

Billing practitioner's arrangement with auxiliary personnel. 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 community-based

[24] 2023 CPT codebook, p. 11.
[25] https://chwtraining.org/c3-project-chw-skills/.

organization[26] 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.

Frequency of billing.

- 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.

CMS seeks comments on the following related issues:

CHI initiating visit.

- **Should other services, such as an annual wellness visit (AWV) that may or may not include the optional SDOH risk assessment (discussed below in this section) be considered a CHI initiating visit**? Because an AWV can be furnished by other types of health professionals, it is not necessarily furnished incident to the professional services of a physician or other practitioner. In these situations, the CHI services would not necessarily be furnished consistent with the proposed "incident to" requirements for payment. CMS also notes that an E/M visit can be billed in addition to the AWV when medical problems are addressed during an AWV encounter.

Time and duration of CHI services.

- **What is the typical amount of time practitioners spend per month** furnishing CHI services to address SDOH needs that pose barriers to diagnosis and treatment of problems(s) addressed in an E/M visit?
- **What is the typical duration, in terms of the number of months**, practitioners furnish CHI?

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.

[26] 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).

CMS wants confirmation of where and how these services would be typically provided (e.g., in-person, audio-video, two-way audio.)

Patient Consent. CMS is not proposing to require consent for CHI because it believes these services typically involve direct patient care and largely provided in-person. However, **if commenters indicate that CHI services would not involve direct contact with the patient, or could extend for periods of time**, CMS will consider requiring patient consent to receive CHI services in the final rule. Consent requirements would include informing the patient about applicable cost sharing, the right to discontinue services, and where applicable, the limitation that payment is made for the service to only one practitioner per month.

- CMS notes that it does not have the statutory authority to waive cost sharing for care management or other services.

Similar services provided by other payers.

- **Whether States typically cover services similar to CHI** under their Medicaid programs and would coverage of the CHI service codes be duplicative.

Service elements in the proposed CHI service codes.

- **Are there other service elements that should be included** in the proposed CHI service codes?

iii. Proposed CHI Services Valuation

For GXXX1, CMS proposes 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 GXXX2, CMS proposes 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.

c. Social Determinants of Health (SDOH) - Proposal to establish a stand-alone G code

i. Proposed Risk Assessment Code

CMS proposes 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 in relation to an E/M visit.

CMS proposes HCPCS code *GXXX5, Administration of a standardized evidence based SDOH Risk Assessment, 5-15 minutes, not more often than every 6 months*.

CMS proposes 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[27] 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.[28]
    - 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 SDOK on a person's health. **CMS seeks 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.**

ii. Proposed Valuation

CMS proposes a direct crosswalk 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 proposes to add this code to the Medicare Telehealth Services List. **CMS seeks comments on where and how these services would be typically provided.**

d. Principal Illness Navigation (PIN) Services

CMS discusses 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 proposes new coding for navigation services, PIN services. CMS is proposing for PIN services a parallel set of services to the proposed CHI services, but focused on patients with a serious, high-risk illness who may not have SDOH needs; and adding services to refer patient

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[27] https://health.gov/healthypeople/tools-action/browse-evidence-based-resources/types-evidenc-based-resources.
[28] 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)

to appropriate supportive services, provide information about clinical trials, and inclusion of lived experience or training in the specific condition being addressed. The reader will note many similarities between these sections of the summary.

i. Proposed PIN Services

GXXX3: *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.
    - 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 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.

GXXX4: *PIN services, each additional 30 minutes per calendar month (List separately in addition to GXXX3)*

*ii. Proposed Requirement*s

CMS proposes the following requirements:

Characteristics of a serious high-risk condition/illness/disease. 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.

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).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.

Subsequent PIN services. Subsequent PIN services would 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.

Supervision level. PIN services would be designated 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.

"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.

"*Problem Addressed*". This term refers to the definition in the CPT E/M Guidelines that CMS adopted for E/M visits.[29]

- 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.

SDOH. SDOH means economic and social condition(s) that influence the health of people and communities, as indicated in the CPT E/M Guidelines.[30] In addition to the CPT examples of SDOH, CMS proposes 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, as indicated in the CPT E/M Guidelines.[31] In addition to the CPT examples of SDOH, CMS proposes 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.

Certified or trained auxiliary personnel. 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 being furnished. In

[29] 2023 CPT codebook, p. 6-8.
[30] 2023 CPT codebook, p. 11.
[31] 2023 CPT codebook, p. 11.

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.

- 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.

Documentation. 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.

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

Frequency of billing.

- 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.

CMS seeks comments on the following related issues:

PIN initiating visit.

- **Should other services, such as an annual wellness visit (AWV) that may or may not include the optional SDOH risk assessment be considered a PIN initiating visit**?

[32] 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).

Because an AWV can be furnished by other types of health professionals, it is not necessarily furnished incident to the professional services of a physician or other practitioner. In these situations, the PIN services would not necessarily be furnished consistent with the proposed "incident to" requirements for payment. CMS also notes that an E/M visit can be billed in addition to the AWV when medical problems are addressed during an AWV encounter.

Time and duration of PIN services.

- **What is the typical amount of time practitioners spent per month** furnishing PIN services and whether a frequency limit is necessary for the add-on code?
- **What is the typical duration, in terms of the number of months**, practitioners furnish PIN services?

Training requirements for auxiliary personnel.

- **What should be the required number of hours for training, what should be in the training content and who should provide the training?**

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. **CMS wants confirmation of where and how these services would be typically provided (e.g., in-person, audio-video, two-way audio.)**

Patient Consent. CMS is not proposing to require consent for PIN because it believes these services typically involve direct patient care and largely provided in-person. However, **if commenters indicate that PIN services would not involve direct contact with the patient, or could extend for periods of time**, CMS will consider requiring patient consent to receive PIN services in the final rule. Consent requirements would include informing the patient about applicable cost sharing, the right to discontinue services, and where applicable, the limitation that payment is made for the service to only one practitioner per month.

- CMS notes that it does not have the statutory authority to waive cost sharing for care management or other services.

Similar services provided by other payers.

- **Whether States typically cover services similar to PIN** under their Medicaid programs and would coverage of the PIN service codes be duplicative.

Service elements in the proposed PIN service codes.

- **Are there other service elements that should be included** in the proposed PIN service codes?

iii. Proposed PIN Services Valuation

For GXXX3, CMS proposes 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 GXXX4, CMS

proposes 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.

(28) Maternity Services (CPT codes 59400, 59410, 59425, 5926, 59430, 59510, 59515, 59610, 59614, 59618, 59622)
In 2021, CMS finalized 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 proposes 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 (Table 11).

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 will 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 have made recommendations regarding implementation and potential refinement to this service. Recommendations have 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 proposes to change the status of HCPCS code G2211 to make it separately payable by assigning the "active" status indicator, effective January 1, 2024. After considering feedback and comments, CMS proposes several policy refinements, including refinements of its utilization assumptions.

CMS proposes 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.

CMS has also refined its previous utilization assumptions. CMS agrees with prior comments and recent feedback 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 provides 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 now estimates 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 estimates that when fully adopted, G2211 will be billed with 54 percent of all O/O E/M visits.

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

CMS discusses 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.

As CMS considers how to potentially reform establishing values for E/M and other services, it is interested in receiving 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.)?

CMS is interested in ways to improve processes and methodologies and request specific recommendations on ways to improve data collection, including how to obtain data, and to make better evidence-based and more accurate payments for E/M and other services. CMS is also interested in ways to make more timely improvements to its methodologies to reflect changes in the Medicare population, treatment guidelines and new technologies that represent standards of care.

CMS also seeks 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?

3. Split (or Shared) Visits

In the 2022 PFS final rule[33], 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:

[33] 86 FR 65150-65159

- 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.

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 proposes 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 proposes 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 believes the proposed delay allows interested parties to have another opportunity to comment on this policy. **Specifically, CMS seeks comments on**:

- How facilities are currently implementing its split (or shared) policy in their workflows and how facilitates are currently accounting for services of billing practitioners that are performed split (or shared).
- How to better account for the services of the billing practitioner in team-based clinical scenarios.

CMS also acknowledges that the CPT Editorial Panel is considering revisions to aspects of split or share visits. When available, CMS will review these changes and consider whether a further implementation delay beyond 2024 is needed. CMS will address any changes through future rulemaking.

CMS proposes to amend 42 CFR 415.140 to revise the definition of "substantive" by replacing "the year 2022 and 2023" with "the years 2022 through 2024".

G. Geographic Practice Cost Indices (GPCI)

1. GPCI Update

As required by statute,[34] CMS is required to develop separate Geographic Practice Cost Indices (GPCIs) to measure relative cost differences among localities compared to the national average 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.[35] If more than 1 year has elapsed since the

[34] Section 1848(e)(1)(A) of the Act.
[35] Section 1848(e)(1)(C) of the Act

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 proposed rule, which are available on the CMS website under supporting documentation of the 2024 PFS proposed rule.[36]

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.[37] 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.

H. Payment for Skin Substitutes

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

[36] See https://www.cms.gov/files/zip/cy-2024-pfs-proposed-rule-addenda.zip

[37] 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).

skin substitutes as supplies under the PFS ratesetting methodology. As part of this process, CMS is not making any proposals for 2024 but **solicits public comments** on the following issues:

Sources of Price Information: The proposed rule indicates that CMS has used market research and invoices to develop direct practice costs for medical supplies. It further suggests using average sales price 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 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.

CMS indicates that public comment on the methods discussed above may help reflect the resource costs involved with skin substitute products as furnished with different skin application procedures. It is worth noting that this will be the third time CMS has 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 this proposed rule.

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[38] 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 by occupational therapy assistants (OTAs) and physical therapist assistants (PTAs). CMS proposes 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. However, CMS proposes to retain the OTPP and PTPP direct supervision requirement for PTs or OTs who are not enrolled as suppliers under the program, clarifying that the proposed RTM general supervision regulation at §§410.59(c)(2) and 410.60(c)(2) applies only to the OTA and PTA and does not include unenrolled OTs or PTs. **Comment is sought on this proposal.**

[38] §§410.59(a)(3)(ii) and 410.60(a)(3)(ii)

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

In response to feedback from stakeholders, CMS is considering whether to revise 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. **Comment is sought** 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. On 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 is 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.

2. KX Modifier Thresholds

For 2024, CMS proposes to increase the 2023 KX modifier threshold amount by the most recent forecast of the 2017-based MEI, which is estimated to be 4.5 percent, based on the HIS Global, Inc. (IGI) first quarter 2023 forecast with historical data through the fourth quarter of 2022. This results in a per beneficiary proposed threshold amount of $2,330 for physical therapy and speech-language pathology services combined and $2,330 for occupational therapy services for 2024; CMS would use more recent data for the final rule if available.

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

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 proposes 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.

Specifically, CMS proposes 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 would further clarify 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.

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 is proposing to codify billing rules for DSMT services furnished as Medicare telehealth services at §410.78(b)(2)(x) to allow 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, to 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. 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.

b. Telehealth Injection Training for Insulin-Dependent Beneficiaries

Current manual instructions for payment of DSMT require 1 hour of the 10-hour DSMT benefit's initial training and 1 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 proposes to revise this policy and allow the 1 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[39] 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 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.[40] MFT and MHC services are excluded from consolidated billing requirements under the skilled nursing facility (SNF) PPS.[41] 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.

[39] Section 1861(s)(2)(II) of the Act provides for a new benefit category under part B.
[40] 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).
[41] See section 1888(e)(2)(A)(ii) of the Act, as well as the FY 2024 SNF PPS proposed rule (88 FR 21316).

b. Regulatory Definitions and Changes

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

Marriage and Family Therapist; Mental Health Counselor. CMS proposes 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 proposes to define an MHC at §410.54 as an individual who:

- Possesses a master's 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
- 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 is interested in public comments** regarding states that have a supervised clinical requirement for MFT or MHC licensure that is less than the statutorily required 2 years.

CMS proposes 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. The agency **seeks information** on other practitioners who may satisfy the applicable requirements. CMS also proposes to include substance use disorder (SUD) services as mental health services for purposes of such services included in MFT, MHC, CSW, and CP services.

Marriage and Family Therapist Services; Mental Health Counselor Services. Consistent with statute, CMS proposes 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."

Consistent with statute, CMS proposes 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 would 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 would 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 proposes to add MFTs and MHCs to the list of practitioners that may order diagnostic tests (to the extent they are authorized 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 proposes to also add 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 proposes at §414.53 to codify the payment amounts authorized for MFT and MHC services, as well as to take the opportunity to codify payment amounts for CSW services authorized under section 1833(a)(1)(F) of the Act. Specifically, payment amounts for CSW, MFT, and MHC services would 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.

c. Coding Updates

CMS proposes 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. **CMS welcomes comments** on any other HCPCS codes that may require updating to allow MFTs and MHCs to bill for services described in the code descriptor.

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. CMS proposes MFTs and MHCs be subject to limited-risk screening under §424.518. Those that meet such requirements would use the Form CMS-855I application to enroll in Medicare. MFT and MHC services furnished before January 1, 2024 will not be payable.[42]

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

2. Implementation of Section 4123 of the CAA, 2023

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.[43]

CMS, therefore, proposes to create the following 2 new G-codes describing these psychotherapy for crisis services:

- GPFC1: 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
- 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); each additional 30 minutes.

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

Consistent with statute, CMS proposes to 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. Expenditures for the new HCPCS codes would be excluded from PFS budget neutrality adjustments.[44]

3. Implementation of Section 4124 of the CAA, 2023

CMS refers readers to section VIII of the CY 2024 OPPS proposed rule for its proposed 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

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

physical health conditions. CMS, therefore, proposes 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.

5. Adjustments to Payment for Timed Behavioral Health Services

CMS describes nationwide cross-setting behavioral health clinician workforce shortages resulting in unprecedented delays to 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.

CMS proposes 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 proposed rule. Specifically, it would 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 proposed inherent complexity add-on code compared to the total work RVUs for visits that are not billed with the add-on code. This would result in an approximate increase of 19.1 percent for work RVUs for these services, which CMS proposes to implement over a 4-year transition period.[45] CMS believes that, if finalized, this proposal combined with the proposal for the add-on for E/M visits, if finalized, would mitigate any negative impact in valuation for psychotherapy services that may result from redistributive impacts if only the inherent complexity add-on for E/M visits were to be finalized. **CMS welcomes comments** on this proposal, specifically how the PFS valuation processes for these services and similar services can be improved.

[45] CMS proposes the increase for the following specific codes (note that psychotherapy codes that are performed with an E/M visit will be eligible to be billed with HCPCS code G2211 and would already be eligible for an adjustment under section II.E. of the proposed rule and would not be included for this separate adjustment): 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 proposed 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).

In the CY 2018 PFS final rule (82 FR 52999) CMS identified outlier codes for which it applied a minimum nonfacility indirect PE RVU, which was implemented over a 4-year (2018-2021) transition period. **CMS requests comment** on whether this minimum value adjustment to the indirect PE sufficiently accounted for resources involved or whether further adjustments should be considered, and whether further changes should be phased-in over a 4-year transition.

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

In the CY 2023 PFS final rule (87 FR 69772 through 69774), CMS finalized a change to the payment rate for the non-drug component of the bundled payment for episodes of care under the Opioid Treatment Program benefit, which based such rate on a crosswalk to CPT code 90834 (reflecting a 45-minute, instead of 30-minute, psychotherapy session). CMS is proposing to similarly update the valuation for HCPCS codes G2086[46] and G2087[47] (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 proposed 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 proposes to 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 if its proposed increase through the add-on described above to RVUs for CPT code 90834 is finalized that increase would carry through to this proposal 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

CMS welcomes feedback on 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.

[46] 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.

[47] 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.

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 addressing 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 requests information** on a variety of specific questions on: 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.

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 reviews 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 that have already been addressed by CMS' payment policy.

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.

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

CMS is proposing 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 proposes to pay for:

- Dental or oral examination 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 for 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 indicates 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 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 seeks 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 seeks comment on this issue.

CMS is proposing 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 clarifies 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 is 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 is proposing 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 **requests 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. Commenters specifically stated that CAR T-cell therapies constituted lymphodepleting therapies. CMS believes there may be other immunotherapies that may have a similar lymphodepletion component but received 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 proposes 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 clarifies 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.

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. Further, 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 seeks 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. CMS encourages interested parties to submit recommendations and relevant clinical evidence for establishing this connection.

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 **seeks 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 **seeks comment on whether certain dental services are inextricably linked to certain other covered services for hemophilia**, as supported by clinical evidence. It also seeks comment on whether dental services such as prophylaxis are a standard of care in the management of hemophilia.

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 as provided for in this proposed rule and the 2023 PFS final rule.

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 seeks 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.
- Denials: Dental professionals may submit a claim to Medicare to receive a denial in order to bill Medicaid or another third-party payer. CMS seeks 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.
- 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.
- Payment in Settings Other than Inpatient and Outpatient: CMS is seeking 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.
- Payment for Dental Services: Medicare covered dental services are currently contractor priced. CMS seeks comment on specific information could help inform appropriate payment.
- Coding and Modifiers: CMS has revised the HCPCS and PFS payment and coding files to include payment indicators for Current Dental Terminology (CDT) codes, such as bilateralism, multiple procedures, and other indicators that are included in the PFS RVU

files. CMS seeks 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.

- 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 seeks comment on whether additional specialty codes should be considered for use in Medicare, and if so, what other specific specialties that should be included.

III. Other Provisions of the Proposed 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 proposed rule would codify certain 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 proposes 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 would be 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 proposes to codify 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.

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 proposes 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 proposes to codify in §489.30 the coinsurance amount for Part B rebatable drugs as required by section 1847A(i)(5) of the Act. That 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 would also apply to selected drugs under the Drug Price Negotiation Program.

CMS also proposes to codify 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 would be applied as a percent to the payment amount for the calendar quarter involved.

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 proposes to codify these elements (currently in program instruction) for 2024 and future years in its regulations.

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 seeks comment 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.

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[48] addressing the correct use of these modifiers.

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

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

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.

CMS now proposes a date for the initial report to manufacturers, a date for subsequent reports, a method of calculating refunds for discarded amounts in lagged claims data, a method of calculating refunds when there are multiple manufacturers for a refundable drug, the increased applicable percentages for certain drugs with unique circumstances, and a future application process by which manufacturers may apply for an increased applicable percentage for a drug, which would precede proposals to increase applicable percentages in rulemaking. It also proposes 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 proposes to provide an initial refund report to manufacturers no later than December 31, 2024, which would include all calendar quarters of information for 2023. This report would be separate and distinct from the preliminary report the agency intends to issue by December 31, 2023, that 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 intends 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 proposes to 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 would include data, including lagged claims data, for eight quarters—four from the previous calendar year (referred to as new refund

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

quarters) and four from 2 calendar years prior (referred to as updated refund quarters). These reports would 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 would define 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.

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 proposes 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 would 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 would 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 would be due no later than 30 days after the resolution of the dispute.

d. Refund Amount

(1) Calculation of Refund Amounts for Updated Quarters

Because CMS proposes to include information on lagged claims data in all reports (other than the initial refund report), it also proposes to 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 would 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 would be 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 proposes 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 proposes to 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 would 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 would calculate the refund amount attributed to the NDCs for which each manufacturer would be 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 18 in the proposed rule provides an example.

CMS proposes to 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.

(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 proposes a hybrid approach. First, it proposes two categorical unique circumstances (with associated proposed increased applicable percentages) and, second, it proposes an application process for manufacturers to request that CMS consider whether an increased applicable percentage would be appropriate for a particular drug in light of its unique circumstances. If CMS determined in response to such a request that an increased applicable percentage is appropriate, it would then be proposed in future notice-and-comment rulemaking.

Drugs with a Low Volume Dose
The first categorical unique circumstance would be for drugs with a "low volume dose." CMS would define 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 would apply 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 would have to be low volume doses. Additionally, the definition of low volume dose would only be applied 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 would be bifurcated as follows:

- Refundable drugs with labeled doses that are contained within 0.1 mL or less when removed from the vial or container would 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 would have an increased applicable percentage of 45 percent.

Orphan Drugs

The second categorical unique circumstance would be 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 proposes an increased applicable percentage of 26 percent.

CMS proposes that a low volume of unique beneficiaries would be fewer than 100 unique Medicare fee-for-service beneficiaries per calendar year. The number of beneficiaries receiving a rarely utilized orphan drug in the calendar year would correspond with the refund quarter. For example, for refund quarters in 2023, CMS would use the number of beneficiaries receiving the drug in the 2023 calendar year to determine if the unique circumstances and increased applicable percentage would apply.

Under the proposal, a rarely utilized orphan drug would be a drug that meets these unique circumstances and for which the increased applicable percentage would apply for as long as the drug meets these conditions, even after the orphan-drug exclusivity ends.

CMS would identify drugs that have unique circumstances of low volume doses and rarely utilized orphan drugs in reports sent to manufacturers and apply the proposed increased applicable percentages based on these categorical unique circumstances proposals. Manufacturers could dispute the applicable percentage increase that was applied to the refund calculation by submitting an error report.

The proposals for the categorical unique circumstances of certain drugs would apply beginning with the initial refund report proposed to be sent no later than December 31, 2024. **Comment is sought on the proposals**, including on the proposed volume (mL) tiers for drugs with low volume doses and the associated increased applicable percentages and on the increased applicable percentage of 26 percent for rarely utilized orphan drugs.

Proposed Application Process for Individual Drugs
An application process would be established for manufacturers to request an increased applicable percentage for an individual drug with unique circumstances, which could include a drug that satisfies the criteria for one of the categorical unique circumstances described above. A manufacturer would have to 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 would evaluate requests based on the documentation submitted, such as a minimum vial fill volume study or dose preparation study.

Applications would have to be submitted by February 1 of the year before the year the increased applicable percentage would apply. Analysis of the applications as well as determinations of whether the drug warrants an increased applicable percentage (and, if so, by how much) would be provided in the PFS proposed rule following the application period. CMS would 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. **Comment is sought** on the proposal, including on the factors CMS should use in considering these applications, the factors it should use to assess appropriate increases to applicable percentages, and the types of additional or alternative documentation to help analyze justifications for increased applicable circumstances.

e. Clarification for the Definition of Refundable Drug

CMS aims to create a consistent coding and payment approach for skin substitutes, and **it seeks comments on this issue**. It proposes 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 plans to revisit discarded drug refund obligations for skin substitutes in future rulemaking.

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.

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 proposes to require 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.

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 is proposing conforming changes to the regulation to implement this statutory provision.

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 is proposing to continue to define "immediately available" as including real-time audio and visual interactive telecommunications through December 31, 2024.

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 proposes conforming changes to its regulations to include MFTs and MHCs as eligible practitioners that may provide RHC and FQHC services.

Further, CMS proposes to clarify that when MFTs and MHCs provide the services described in 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.

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 is proposing that behavioral health services furnished by auxiliary personnel at RHCs and FQHCs may also be furnished under general supervision.

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 discusses 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 is proposing 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.

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 is proposing 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 (CHW) 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 is proposing 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.

Proposed 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 is proposing to revalue HCPCS code G0511 using a weighted average of utilization in the physician office setting of its composite codes. As CMS proposes 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.

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 is proposing 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 for 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 of the required information. There need not be an employment relationship between the person obtaining the 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 is aware of applicable cost sharing. It also helps reduce the potential for duplicate billing of the services.

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 is proposing to adopt 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.

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 proposes 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 and the proposed rule indicates 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 proposes 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 (DNP) doctoral degree. CMS is proposing 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. CMS is interested in **comments on whether it should retain the requirement that a certification be in primary care**.

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

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

The second data collection period 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 for 2023 and 15 percent for each year 2024 through 2026.

CMS proposes to conform its regulations at 42 CFR part 414, subpart G, to the latest statutory amendments.

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 proposes 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).

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[49] created a new Part B benefit 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 allowing 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, that better account for the greater severity of needs for patients with an OUD and 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 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);

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

- 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 proposes 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.[50] CMS says 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 cites 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.

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. On December 29, 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 proposed rule, in which section VIII.B contains the policy discussion and additional details regarding 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.

[50] 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.

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)[51], 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.[52] 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.[53] 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 annual update for all vaccine administration services will be made available in the 2024 PFS final rule.

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:[54,55]

- 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

[51] 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).
[52] https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines
[53] https://www.cms.gov/medicare/medicare-part-b-drug/average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.
[54] https://www.cms.gov/medicare/covid-19/medicare-covid-19-vaccine-shot-payment
[55] https://www.cms.gov/files/document/vaccine-home.pdf.

    - 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 in an assisted living facility[56] 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. Proposals for CY 2024 and Subsequent Years

Analysis of data for in-home COVID-19 vaccinations among Medicare fee-for-service beneficiaries from June 2021 to June 2022 shows 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 proposes to maintain the additional payment for the administration of a COVID-19 vaccine in the home. CMS notes that since the statutory authority to regulate Part B is identical for all four preventive vaccines,[57] it proposes 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

[56] 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.
[57] Section 1861(s)(10) of the Act

these additional vaccines need to meet the current payment requirements. If this proposal is finalized, CMS will broaden the conditions for payment to reflect preventive vaccines for the other diseases.

Since expanding this policy could mean that multiple vaccine are administered during the same visit to the home, CMS proposes to limit the additional payment to one payment per home visit, even if multiple vaccines are administered during the same home visit. CMS plans to monitor utilization of the M0201 billing code for the in-home additional payment for inappropriate use or abuse of the code. CMS notes that every vaccine dose that is furnished during a home visit will still receive its own unique vaccine administration payment.

CMS notes 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. **CMS seeks comments on the applicability of this policy** to the proposed policy to expand this additional payment to all Part B preventive vaccines.

CMS proposes to amend the Part B payment for preventive vaccine administration regulations at §410.152(h) to reflect the following:

> Effective January 1, 2024, the payment policy allowing additional payment for the administration of a COVID-19 vaccine in the home would be extended to include the other three preventive vaccines included in the Part B preventive vaccine benefit, and the payment amount for all four vaccines will be identical. The additional payment would be annually updated using the percentage increase in the MEI and adjusted to reflect the geographic cost variations using the PFS GAF.

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 proposes 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 is also proposing 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 proposes 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. Proposed Changes to MDPP Conditions of Coverage (§410.79)

CMS proposes numerous 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 and 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.[58] The other flexibility through December 31, 2027 that CMS proposes is 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.[59]

To better track and evaluate the use of distance learning through claims, CMS proposes 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

[58] Although the current regulatory language on additional requirements related to the self-reported weight measurements is somewhat confusing, CMS does 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.

[59] 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.

- Evaluate the impact of distance learning and in-person delivery modalities of MDPP relative to cost-savings and diabetes risk reduction among participants.[60]

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."[61] 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. Under the current payment structure, 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 are 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 has determined the current attendance-based performance payments are 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 is proposing 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.

2. Proposed 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 proposes to update the payment structure from a performance-based attendance and weight loss structure to a hybrid structure that pays for attendance on a FSS 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

[60] 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.

[61] "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.

months, then following months 7-9 and 10-12 in the core maintenance sessions phase. Instead, CMS proposes an Attendance Payment, which is an 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 proposes 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 41 of the proposed rule, duplicated below, shows the proposed 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 42 of the proposed rule (not duplicated here). Both tables show a total maximum payment in 2024 of $768.

TABLE 41: Proposed Changes to MDPP Payment Structure to Include Attendance-Based Service Payments and Diabetes Risk Reduction Performance Payments

HCPCS Code	Payment Description*	2024
GXXX0	Behavioral counseling for diabetes prevention, in-person, group, 60 minutes	$25
GXXX1	Behavioral counseling for diabetes prevention, distance learning, 60 minutes	$25
G9880	5 percent WL Achieved from baseline weight	$145
GXXX2**	Maintenance 5 percent WL from baseline in months 7-12	$8
G9881	9 percent WL Achieved from baseline weight	$25
G9890	Bridge Payment	$25
Subtotal Maximum Attendance-Based Payment		**$550**
Total Maximum Payment		**$768**

Notes: "WL" is weight loss. In the proposed rule, the only appearance of "Bridge Payment" is in tables 41 and 42; 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 GXXX1 and GXXX0, 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.

3. Proposed 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 proposes 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.

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.[62]

[62] The list of qualified PLEs can be accessed at https://www.cms.gov/Medicare/Quality-Initiative-Patient-

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 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.[63]

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[64] 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. Proposal to Pause Program for Reevaluation

CMS proposes 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 proposal to pause efforts to implement the AUC program.

CMS discusses that this proposal 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

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Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html.

[63] 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.

[64] 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.

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, 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.

Regulatory Impact. CMS acknowledges by pausing implementation of the AUC program, the Medicare program may not realize the estimated savings, and clinicals will not experience the estimated costs. Table 115 (reproduced below) includes the AUC program-related activities and their corresponding impact estimates.

Table 115: 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. Proposed 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 proposes 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.

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.

CMS solicits comments on this proposal—specifically, whether there are any potential unintended consequences of the proposal that the agency is not considering, and any guardrails it should consider so as not to create unintended consequences for persons with misdemeanor convictions.

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 proposes 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.[65] Recognizing that the specific facts and circumstances of each case will differ, CMS proposes 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.

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 proposes 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.

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. CMS has received inquiries as to whether this provision applies to debts that are no longer being collected or are being appealed.

[65] CMS notes that "civil judgment" would not include FCA *settlement agreements*, but a *judgment* against the provider or supplier.

CMS proposes 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 proposes 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.

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.

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 proposes 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 proposes to add the following new situations where a retroactive date would be warranted:[66]

- 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.

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 proposes to reduce this 30-day period to 15 days. The agency notes it is not proposing, for instance, a 5-day period because it 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

[66] CMS proposes 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.

presenting program integrity risks. The agency also notes that this change would have no impact on a revoked provider's or supplier's ability to appeal a revocation under existing regulations (42 CFR part 498) but would only affect the provider's or supplier's utilization of §424.535(e) to reverse the revocation. **CMS is soliciting comments** on whether 15 days is an appropriate timeframe.

Stay of Enrollment. Existing §424.540(a) lists reasons for CMS to deactivate a provider's or supplier'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 the provider or supplier can reactivate its 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 or supplier. 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 or supplier. 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 or supplier's action, inaction, or noncompliance.

CMS proposes 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 proposes 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 the provider or supplier was non-compliant with enrollment requirements. Thus, even after the stay concludes, the provider or supplier would not receive payment for services or items furnished during this period. Claims submitted by the provider or supplier 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 or supplier'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 the proposed rule 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 would 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; it would not be required to stay the provider's or supplier's enrollment. 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 proposes to add providers and suppliers currently under a stay of enrollment.

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.[67] 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 or supplier's specific geographic location. CMS could be making incorrect payments to the provider or supplier 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 or supplier might be furnishing services from an invalid location, hence resulting in improper payments.

CMS proposes that all provider and supplier types would be required to report practice location changes within 30 days of the change. Across the various regulations,[68] CMS also proposes to clarify that a change of practice location includes adding a new location or deleting an existing one.

[67] §§424.57(c)(2), 410.33(g)(2), and 424.516(d)(1)(iii), respectively.
[68] §§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.

"Pattern or Practice." Three 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 does not propose changing this general procedure, due to the flexibility it provides. However, in order to "furnish elucidation to the provider community" and institute minimum regulatory parameters, CMS proposes 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.

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 proposes 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.[69]

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 proposes 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 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."

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

[69] This mirrors an example in §420.202(a).

by the statutes, regulations, and program instructions of the Medicare program." Regarding that definition, interested parties have questions 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 proposes, 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 welcomes comments on the proposed clarification**.

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 proposes 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.[70]
- 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 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.

[70] However, CMS notes the termination period cannot be *shorter* than the period in which the provider is to be included in the termination database.

- 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.

L. Expand Diabetes Screening and Diabetes Definitions

For 2024, as explained in greater detail below, CMS proposes 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).

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 proposes 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 tests), 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 proposes 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.[71]

In current regulations, the definition of "diabetes" is identical for diabetes screening, MNT and DSMT, and includes specified levels from clinical tests. CMS proposes to simplify each by removing the codified clinical test requirements from the definition because it has been

[71] Since the distinction for screening purposes between diabetes and pre-diabetes would no longer be relevant, CMS also proposes deleting the definition of "pre-diabetes" at §410.18(a).

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.[72]

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

In the preamble of this rule, CMS clarifies that its 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 says 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 proposed rule to standards at §423.160(b) that are finalized will apply to CMS EPCS program, as well.

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:

[72] CMS notes that note 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).

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 proposes 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.

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 proposes 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.

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.

In this rule, CMS proposes 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.

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 proposes 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 proposes 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 proposes 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 proposes 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.

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 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 proposes 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 is not proposing new non-compliance actions at this time, but will continue to evaluate compliance and prescriber performance under the CMS EPCS Program and consider whether to propose changes in future years. CMS **seeks public comment** on the proposal to continue the action of sending notice to prescribers who are identified as non-compliant.

N. Proposed 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 proposes conforming amendments to these regulations.

3. Proposed 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.[73]

CMS proposes 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 proposes 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.

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 proposes changing the programing 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.

Typos and Technical Corrections: CMS lists 4 wording changes/corrections it proposes to make.

O. Hospice: Changes to the Hospice Conditions of Participation (CoPs)

The CAA, 2023[74] established that the hospice interdisciplinary group is required to include at least one social worker (SW), marriage and family therapist (MFT), or mental health counselor (MHC).

CMS proposes to modify the requirements at (§418.56 for the hospice CoPs to allow social workers, MHC, or MFTs to serve as members of the interdisciplinary group. CMS also proposes to modify the hospice personnel qualifications at §418.114(c) to include qualifications for an MFT and an MHC.

[73] 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.

[74] 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.

CMS discusses the similarities and differences between SWs, MFTs, and MHCs. CMS emphasizes that it is important for the hospice to assess and determine which care and services best align with the preferences and needs of the patient.

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 requests **public comment** on whether, and how, CLIA 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 asks for **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 requests **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 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 requests **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.

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.[75] 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). CMS says a state has 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 recently submitted an application for a State Innovation Waiver under authority in section 1332 of the 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."[76]

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 proposes to give a state the option of temporarily "suspending" its BHP program, while retaining accrued funds in the BHP trust fund for a limited period of time. If the

[75] 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.
[76] 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.

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 proposes 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, states would have to submit an application within 30 days of the publication of such a final rule; 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 proposes 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.[77]
- 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 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 reviews a number of alternatives it considered for the foregoing proposed policies and seeks comment.

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 proposes 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.

[77] 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 proposes 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.

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 proposes 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 says 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 specifies 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.

CMS solicits comment on these proposals—specifically, how far in advance of suspension a state must submit a suspension application, how far in advance of suspension CMS must approve or deny the suspension request, and the duration of time a state may suspend their BHP without terminating the program.

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 proposes 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 significant change(s) that alter program operations, the BHP benefit package, enrollment, disenrollment and verification policies described in its certified BHP Blueprint. CMS proposes 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 proposes 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.

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 proposes 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.

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 proposes 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 is proposed at §600.145(f)(2) to include appeals of health services matters as a core operation of a BHP.

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.

In this proposed rule, CMS is proposing 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. For example, CMS proposes to replace current references to "2015 Edition health IT certification criteria" with "ONC health IT certification criteria." CMS also proposes cross-references to ONC regulations to 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 proposal would 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 determine when it will propose requiring participants to complete measures that require the use of certified health IT. This additional flexibility would 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.

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 proposes to exercise its authority in section 1861(hhh)(2)(I) to add other elements to the AWV by adding 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 (GXXX5) 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 proposes to exercise its authority in section 1861(hhh)(2)(I) of the Act to add elements to the AWV by adding 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.[78] 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

[78] See section II.E. for additional information on the separate proposal to establish a standalone G code (GXXX5) for SDOH Risk Assessment furnished in conjunction with an E/M visit, its pricing, and additional conditions of payment.

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.

CMS invites **public comment** on this proposal and, for consideration in future rulemaking, whether the AWV may be more effectively furnished if elements were allowed to be completed over multiple visits and days, or prior to the AWV visit.

IV. Updates to the Quality Payment Summary – Part III

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 proposed 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 proposed valuation changes making up the other 10 percent.

The proposed CF for 2024 is $32.7476, 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 -2.17 percent. The 2024 proposed anesthesia conversion factor is $20.4370, 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 102 and 103 from the proposed rule, reproduced below.

Table 102: Calculation of the Proposed 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	-2.17 percent (0.9783)	
2024 1.25 Percent Increase Provided by the CAA, 2023	1.25 percent (1.0125)	
2024 Conversion Factor		**$32.7476**

Table 103: Calculation of the Proposed 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	-2.17 percent (0.9783)	
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		**$20.4370**

Table 104 (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, revaluation of the other E/M services and/or 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 proposals 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 104. 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 104 for a given specialty, the combined effect of RVU changes with the net CF reduction from the CAA would be roughly -3.25 percent.[79]

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 proposed implementation of the separate payment for the O/O E/M visit complexity add-on code, the Year 3 updated to clinical labor pricing, and/or the proposed 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, and vascular surgery. The specialties with increases largely benefit from the proposed 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, proposed revaluation of individual procedures based on reviews by the AMA RUC and CMS.

Column F of Table 104 (reproduced below) shows the estimated 2024 combined impact on total allowed charges by specialty of all the proposed RVU and other changes. CMS also provides an additional impact table (table 105 in the proposed rule) that includes a facility/non-facility breakout of payment changes.

Table 104: 2024 Proposed Rule Estimated Impact on Total Allowed Charges by Specialty

(A)	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F)* Combined Impact
Allergy/Immunology	$216	0%	-1%	0%	-1%
Anesthesiology	$1,647	-2%	-1%	0%	-2%
Audiologist	$69	-1%	-1%	0%	-2%
Cardiac Surgery	$174	-1%	-1%	0%	-2%
Cardiology	$5,989	0%	0%	0%	0%
Chiropractic	$644	-1%	-1%	0%	-2%
Clinical Psychologist	$711	1%	0%	0%	2%

[79] CMS displays the combined impact percentage in Table 104 to the nearest whole number so adjusting these numbers for the net decrease of 1.25 percent could be off as much as +/- 0.5 percentage points.

Table 104: 2024 Proposed Rule Estimated Impact on Total Allowed Charges by Specialty					
(A)	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F)* Combined Impact
Clinical Social Worker	$795	2%	0%	0%	2%
Colon and Rectal Surgery	$147	-1%	-1%	0%	-2%
Critical Care	$331	-1%	0%	0%	-1%
Dermatology	$3,713	0%	0%	0%	-1%
Diagnostic Testing Facility	$828	0%	-2%	0%	-2%
Emergency Medicine	$2,460	-2%	-1%	0%	-2%
Endocrinology	$507	1%	1%	0%	3%
Family Practice	$5,504	2%	2%	0%	3%
Gastroenterology	$1,474	0%	0%	0%	0%
General Practice	$361	1%	1%	0%	2%
General Surgery	$1,614	-1%	-1%	0%	-1%
Geriatrics	$180	0%	1%	0%	1%
Hand Surgery	$251	-1%	0%	0%	-1%
Hematology/Oncology	$1,591	1%	0%	0%	2%
Independent Laboratory	$546	-1%	-1%	0%	-1%
Infectious Disease	$573	-1%	0%	0%	-1%
Internal Medicine	$9,618	0%	1%	0%	1%
Interventional Pain Mgmt	$849	0%	0%	0%	0%
Interventional Radiology	$457	-1%	-3%	0%	-4%
Multispecialty Clinic/Other Phys	$146	0%	0%	0%	0%
Nephrology	$1,803	-1%	0%	0%	-1%
Neurology	$1,323	0%	0%	0%	1%
Neurosurgery	$694	-1%	0%	0%	-1%
Nuclear Medicine	$51	-1%	-2%	0%	-3%
Nurse Anes / Anes Asst	$1,081	-2%	0%	0%	-2%
Nurse Practitioner	$6,260	1%	1%	0%	2%
Obstetrics/Gynecology	$558	0%	1%	0%	1%
Ophthalmology	$4,647	0%	0%	0%	-1%
Optometry	$1,292	-1%	-1%	0%	-2%
Oral/Maxillofacial Surgery	$62	-1%	-1%	0%	-2%
Orthopedic Surgery	$3,358	-1%	0%	0%	-1%
Other	$55	0%	-1%	0%	0%
Otolaryngology	$1,112	0%	0%	0%	0%
Pathology	$1,136	-1%	-1%	0%	-2%
Pediatrics	$55	0%	1%	0%	1%
Physical Medicine	$1,087	0%	0%	0%	-1%
Physical/Occupational Therapy	$5,257	-1%	-2%	0%	-2%

Table 104: 2024 Proposed Rule Estimated Impact on Total Allowed Charges by Specialty					
(A)	**(B) Allowed Charges (mil)**	**(C) Impact of Work RVU Changes**	**(D) Impact of PE RVU Changes**	**(E) Impact of MP RVU Changes**	**(F)* Combined Impact**
Physician Assistant	$3,366	1%	1%	0%	2%
Plastic Surgery	$300	-1%	-1%	0%	-1%
Podiatry	$1,890	0%	0%	0%	0%
Portable X-Ray Supplier	$75	0%	0%	0%	-1%
Psychiatry	$897	1%	1%	0%	2%
Pulmonary Disease	$1,290	0%	0%	0%	0%
Radiation Oncology and Radiation Therapy Centers	$1,552	0%	-2%	0%	-2%
Radiology	$4,517	-1%	-2%	0%	-3%
Rheumatology	$509	1%	1%	0%	2%
Thoracic Surgery	$292	-1%	-1%	0%	-2%
Urology	$1,623	0%	0%	0%	1%
Vascular Surgery	$1,009	0%	-3%	0%	-3%
Total	$88,549	0%	0%	0%	0%
* **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 104:

- 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 proposed changes in the work RVUs, including the impact of changes due to potentially misvalued codes.

- Column D (Impact of PE RVU Changes): This column shows the estimated 2024 impact on total allowed charges of the proposed changes in the PE RVUs.

- Column E (Impact of MP RVU Changes): This column shows the estimated 2024 impact on total allowed charges of the proposed 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

In this proposed rule, CMS expands it PFS impact analysis to considered what 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 proposed rule, CMS details how it derived and constructed these measures.

Table 107 in the proposed 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 proposed policies.

CMS seeks comment on the following issues:

- How it might structure a PFS impact analysis to examine how changes in the PFS would impact beneficiaries of particular groups?
- How such a framework would allow it to consider developing policies that enhance health equity under its existing authority?
- Alternative measures of health equity in its impact analysis, in particular, with regard to the ADI as a proxy for disparities related to geographic variation.
- Additional categories that should be considered in its health equity analysis along with potential data sources.

B. Impacts of Other Proposals

The expected impacts of some of the proposed changes in this rule (other than those associated with changes in RVUs or the update factor) are discussed in previous sections of this summary. This includes the effect of changes related to payment for dental services linked to specific

covered medical services, 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 47 percent of the nearly 1.7 million clinicians billing to Part B (820,047) will be assigned a MIPS score because others will be ineligible for or excluded from MIPS. Table 117, reproduced below, provides the details of clinicians' MIPS eligibility status for 2026 MIPS payment year (2024 MIPS performance year).[80] CMS notes it is difficult to predict whether clinicians will elect to opt-in to participate in MIPS.

TABLE 117: Description of MIPS Eligibility Status for CY 2024 Performance Period/2026 MIPS Payment Year Using the 2024 PFS Proposed Rule Assumptions**

		CY 2024 PFS Proposed 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*	122,183	$34,134
	Did not Report in 2021 but Reported in 2019	9,906	$2,963
	Did not Report in 2021 and did not Report 2019 (or did not have data in 2019)*	14,289	$4,261
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low- volume threshold in all 3 criteria)	Had a group submission	664,562	$17,533
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	9,107	$473
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**820,047***	**$59,363**
Not MIPS Eligible			

[80] 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 proposed rule regulatory text. The header is modified to be consistent with the proposed rule text.

TABLE 117: Description of MIPS Eligibility Status for CY 2024 Performance Period/2026 MIPS Payment Year Using the 2024 PFS Proposed Rule Assumptions**			
		CY 2024 PFS Proposed Rule estimates	
Eligibility Status	**Predicted Participation Status in MIPS Among Clinicians***	**Number of Clinicians**	**PFS allowed charges ($ in mil)*** **
Potentially MIPS eligible (not subject to payment adjustment for non-participation; could be eligible for one of two reasons: 1) meet group eligibility or 2) opt-in eligibility criteria)	Opt-in Eligible; Do not opt-in	185,342	$6,211
	Group Eligible; Did not Report	294,729	$6,701
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	122,231	$834
Excluded for other reasons (Non-eligible clinician type, newly- enrolled)	Not applicable	75,836	$4,442
Qualified Participant (QP)***	Not applicable	242,422	$13,502
Total Number of Clinicians Not MIPS Eligible		921,560	$31,690
Total Number of Clinicians (MIPS and Not MIPS Eligible)		1,741,607	$91,053
* 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 VII.E.23.b) of this proposed rule because we 2021 data and a different simulation methodology			

In the aggregate, CMS estimates that for the 2026 payment year, it would redistribute about $890 million in payment adjustments on a budget neutral basis. CMS estimates that the maximum positive payment adjustment is about 8.82 percent.[81] The overall proportion of clinicians receiving a positive or neutral payment adjustment is expected to be 45.69 percent and 54.31 percent of clinicians are expected to receive a negative adjustment. CMS notes that its proposed policies is expected to increase the number of clinicians receiving a negative adjustment. Beginning with the CY 2025 MIPS payment year, the additional MIPS payment adjustment for exceptional performance was no longer available.

The table below combines elements of Tables 118 and 119 displayed in the proposed rule and shows the impact of payments by practice size, including proportion of eligible clinicians with a

[81] CMS states in the preamble text that in the baseline model it anticipates redistributing $7.4 million and in the proposed policies model it anticipates redistributing $8.9 million as a result of budget neutrality. In another section of the preamble, CMS estimates that $741 million would be redistributed based on the budget neutrality requirement for the baseline model. We believe CMS made an error in this section and that the amount redistributed on a budget neutral manner in the proposed policies model is likely $890 million and not $8.9 million, which is more consistent with prior year estimates.

negative payment adjustment and the maximum positive payment adjustment. CMS notes that the increase in the number of clinicians receiving a negative score will contribute to the increase in the size of the budgetary dollars available. The increase in the size of the budget neutral pool results in an increase in the size of its positive payment adjustment increases.

Tables 118 and 119 – Estimated Proportion of Eligible Clinicians with a Positive or Neutral and a Negative Payment Adjustment and Average and Maximum Positive Adjustments, CY 2024 Performance Period/2026 MIPS Payment year 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**	**Average Positive Adjustment**	**Maximum Positive Payment Adjustment**
Baseline Policy Model					
1) Solo	7,059	46.94%	53.05%	2.49%	4.60%
2) 2-15	50,559	53.76%	46.23%	2.40%	4.60%
3) 16-99	104,742	54.55%	45.44%	2.01%	4.60%
4) 100+	353,970	68.68%	31.31%	1.92%	4.60%
Overall	516,330	63.24%	36.75%	1.99%	4.60%
CY 2024 PFS Proposed Rule Proposed Policies Model					
1) Solo	5,322	35.39%	64.60%	4.62%	8.82%
2) 2-15#	37,503	39.81%	60.18%	4.10%	8.82%
3) 16-99#	72,935	37.44%	62.55%	3.38%	8.82%
4) 100+#	258,849	50.15%	49.84%	3.21%	8.82%
Overall	374,609	45.68%	54.31%	3.35%	8.82%

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, CMS describes several limitations to the analysis underlying the tables. It notes that because many score are clustered near the performance threshold of 75 points and the proposed threshold of 82 points, minor variations in clinicians final scores relative to its estimations could

have significant impacts on the proportion of clinicians receiving a positive or negative payment adjustment. The scoring model results presented in the proposed rule assume that 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. Given these limitations and others, there continues to be considerable uncertainty around CMS' estimates.

D. Alternatives Considered

The proposed rule contains a range of potential policies, and CMS provides a discussion of alternatives considered for some of these policies. 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 proposed policy to make separate payment for the O/O E/M visit complexity add-on code, including proposing to maintain 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 proposed for 2024. CMS states that maintaining the 2021 policy utilization assumption would not reflect its proposed 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 that it continues to believe in the importance of making separate payment for this add-on code as it will improve payment accuracy. It also believes that utilization of high-value preventive services and promotion of healthy behaviors leveraged by these longitudinal patient relationships could result in positive patient outcomes and health equity impacts.

E. Impact on Beneficiaries

CMS believes that a number of changes in this proposed rule will increase participation in a more sustainable way for ACOs serving medical complex, high-cost beneficiaries. CMS estimates that its proposals 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, It

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 proposals, if finalized, will lead to meaningful feedback to beneficiaries on the type and scope of care provided. Beneficiaries could also use the publicly reported information on clinical performance in subgroups to inform their decisions on selection of clinicians and multispecialty groups. It also believes that several of the proposed new quality measures include patient-reported outcome-based measures, which may be used to help patients make more informed decisions about treatment options.

F. Estimating Regulatory Costs

Because regulations impose administrative costs on private entities, CMS estimates the cost associated with regulatory review, such as the time needed to read and interpret the proposed rule. CMS assumes that the total number of unique reviewers for this year's rule will be comparable to the number of unique commenters on last year's proposed rule. CMS also assumes that each reviewer reads approximately 50 percent of the rule. 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 proposed rule. For each facility that reviews the rule, the estimated cost is $984.48 (8.0 hours x $123.06) and the total cost of reviewing this regulation is about $23.0 million ($984.48 x 23,341 reviewers on last year's proposed rule).