Physician Fee Schedule Proposed Rule for 2023
Summary Part I

Medicare and Medicaid Program: 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts

[CMS-1770-P]

On July 7 2022, the Centers for Medicare & Medicaid Services (CMS) placed on public display a proposed rule relating to the Medicare physician fee schedule (PFS) for CY 2023[1] and other revisions to Medicare Part B policies. The proposed rule is scheduled to be published in the July 29, 2022 issue of the *Federal Register*. If finalized, policies in the proposed rule generally would take effect on January 1, 2023. **The 60-day comment period ends at close of business on September 6, 2022.**

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

Part I includes payment policies under the PFS including changes in coding and documentation for evaluation and management (E/M) services; telehealth services; codes and documentation for chronic pain management services; dental and oral health services; and colorectal cancer screening. The proposed rule contains several comment solicitations including strategies for improving global surgery payment; Medicare potentially underutilized services; and coverage and payment for mental health and behavioral health services.

Table of Contents – Part I

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

I. Introduction

The proposed rule would update the PFS payment policies that apply to services furnished in all sites by physicians and other practitioners. In addition to physicians, the PFS is used to pay a variety of practitioners and entities including nurse practitioners, physician assistants, physical therapists, radiation therapy centers, and independent diagnostic testing facilities (IDTFs). The proposed rule includes proposals to rebase and revise the Medicare Economic Index (MEI) cost share weights; revisions of malpractice RVUs, changes in coding and payment for Other E/M visits;[2] coding and payment for chronic pain management services; and changes to policies for skin substitute products. CMS is also proposing policies for expansion of colorectal cancer screening, preventive vaccine administration, and clarification of certain aspects of Medicare policies for dental services.

[2] Other E/M visits includes hospital inpatient, hospital observation, emergency department, nursing facility, home or residence services, and cognitive impairment assessment.

The proposed conversion factor for 2023 is $33.0775, which reflects the expiration of the 3.0 percent increase for services furnished in 2022[3], the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act, and a budget neutrality adjustment of -1.55 percent.

Special-specific payments impact in most years is related to changes to RVUs for specific services, including RVUs for new and revised codes. For 2023, specialty level changes can largely be attributed to the revaluation of the other E/M services, the second-year transition to updated clinical labor pricing, and the updated malpractice premium data. These specialty impacts range from an increase of 5 percent for infectious disease, increase of 3 percent for geriatrics and internal medicine, an increase of 2 percent for diagnostic testing facility, nurse practitioner, physical medicine, psychiatry, and a pulmonary disease to a decrease of 4 percent for interventional radiology, a decrease of 3 percent for radiology, nuclear medicine, and vascular surgery, and a decrease of 2 percent for allergy/immunology, clinical psychologist, clinical social worker, oral/maxillofacial surgery, podiatry, and rheumatology. These payment impacts, however, do not show the impact of a statutory expiration of the 3.00 percent increase for service furnished in 2022. For example, if CMS specifies a -2 percent reduction for a given specialty, the combined effect of RVU changes with the CF reduction from the expiration of the statutory change would be roughly -5 percent.

CMS also seeks comment on and discusses several issues in this proposed rule that could have large redistributive effects by specialty for future payment years. These include adjusting RVUs to match the rebased and revised PE share of the MEI, updating "indirect" PE data inputs, such as office rent, IT costs, and other non-clinical expenses, and revaluation of the 4,000 services paid as global surgical packages under the PFS.

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

[3] The Protecting Medicare and American Farmers from Sequester Cuts Act provided an increase to PFS payments for 2022 of 3.00 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 2023, 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 2019).

CMS also recognizes that 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)

As explained further in section II. M of this proposed summary, CMS is proposing to rebase and revise the Medicare Economic Index (MEI) to reflect more current market conditions faced by 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 CF to produce the appropriate balance in RVUs among the PFS components and payment rates for individual services. The most recent adjustments of this type were made for the 2014 RVUs, when the MEI was last updated.[4] In that update, CMS adjusted several steps in its PE RVU methodology to adjust the pool of direct and indirect PE costs for the revised MEI and recalibrate its relativity adjustment (steps 3, 10, and 18).

In this rule, CMS proposes to delay these adjustments to the PE calculation until the public has an opportunity to comment on the proposed rebased and revised MEI. CMS believes this is necessary given the delay since the last rebasing and revision of the MEI as well as the proposed methodological and data source changes. For similar reasons, CMS is also delaying the implementation of the proposed rebased and revised MEI for use in the PE geographic practice cost index (GPCI), which is discussed in section II.G. of this summary.

CMS solicits comment on when and how to best incorporate the proposed rebased and revised MEI into PFS rate setting, and whether it would be appropriate to consider a

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

transition to full implementation for potential future rulemaking. In the regulatory impact section and alternative policies considered in this summary, CMS details the specialty-specific impacts of implementing the proposed rebased and revised MEI in PFS rate setting through a 4-year transition and through full immediate implementation, that is, with no transition period. It notes that give the significance of those impacts and its potential interaction with other 2023 proposals, it did not consider proposing to fully implement a rebased and revised MEI in PFS rate setting for CY2023.

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 2023: 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 2023, CMS proposes to update the prices of eight 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 extended external ECG patch, medical magnetic tape recorder, which CMS established a proposed price of $245.69 (an increase from $200.15) for the SD339 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 eight supplies and two equipment items from which it received information. It cited several reasons including that the price received from the invoice was not typical based on when StrategyGen researched its pricing, confusion about the unit used

to determine the price, lack of an invoice for the item, or an invoice with the same price as currently in the PE database.

CMS notes that in addition to a request to update the pricing of the International Normalized Ratio (INR) analysis and reporting system w-software (EQ312), it received a request to change the crosswalk for home PR/INR monitoring services to All Physicians or Pathology which would partially offset the reduction that HCPCS code G0249 is facing due to changes in the clinical labor rates. CMS notes it finalized a crosswalk to the General Practice specialty for these services and has not received any new information that All Physicians or Pathology would be a more appropriate crosswalk.[5]

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 2022). 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.

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 has 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 it 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 2023, the clinical labor pricing would be in Year 2 of the transition.

[5] CMS directs readers to the 2021 PFS final rule (85 FR 84477 and 84478) and the 2022 PFS final rule (86 FR 65000) for a more detailed discussion.

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	

(1) 2023 Clinical Labor Pricing Update Proposal

For 2023, CMS received information from one stakeholder regarding the pricing of the Histotechnologist (L037B) clinical labor type. They provided data from the 2019 Wage Survey of Medical Laboratories which provides support for an increase in the per-minute rate from the $0.55 finalized in the 2022 PFS final rule to $0.64. Two related labor categories would also receive an increase: Lab Tech/Histotechnologist (L035A) would increase from $0.55 to $0.60 as it is a blend of the two labor categories, and Angio Technician (L041A) would also increase to $0.60. Table 5 in the proposed rule (excerpt shown below) includes the increases for these three clinical labor types; pricing for all other clinical labor categories remain unchanged from the pricing finalized in the 2022 PFS final rule.

Excerpt of Selected Labor Categories from Table 5: Clinical Labor Pricing						
Labor Code	**Labor Description**	**Source**	**2021 Rate Per Minute**	**Final Rate Per Minute**	**Y2 Phase-In Rate Per Minute**	**Total % Change**
L023A	Physical Therapy Aide	BLS 31-2022	0.23	0.28	0.255	22%
L026A	Medical/Technical Assistant	BLS 31-9092	0.26	0.36	0.310	38%
L032B	EEG Technician	BLS 29-2098	0.32	0.44	0.380	38%
L035A*	Lab Tech/Histotechnologist	L0333A, L037B	0.35	0.60	0.473	70%
L037B*	Histotechnologist	BLS 29-2010	0.37	0.64	0.505	73%
L037D	RN/LPN/MTA	L051A, BLS 29-2061, L026A	0.37	0.54	0.455	46%
L038B	Cardiovascular Technician	BLS 29-2031	0.38	0.60	0.490	58%
L042A	RN/LPN	L051A, BLS 29-2061	0.42	0.63	0.525	50%
L042B	Respiratory Therapist	BLS 29-1126	0.42	0.64	0.530	52%
L043A	Mammography Technologist	BLS 29-2034	0.43	0.63	0.530	47%
L045A	Cytotechnologist	BLS 29-2035	0.45	0.76	0.605	69%
L046A	CT Technologist	BLS 29-2035	0.46	0.76	0.610	65%
L047A	MRI Technologist	BLS 29-2035	0.47	0.76	0.615	62%

Excerpt of Selected Labor Categories from Table 5: Clinical Labor Pricing						
Labor Code	**Labor Description**	**Source**	**2021 Rate Per Minute**	**Final Rate Per Minute**	**Y2 Phase-In Rate Per Minute**	**Total % Change**
L050C	Radiation Therapist	BLS 29-1124	0.50	0.89	0.695	78%
L051A	RN	BLS 29-1141	0.51	0.76	0.635	49%
L051B	RN/Diagnostic Medical Sonographer	L051A, BLS 29-2032	0.51	0.77	0.640	51%
* Updated for 2023						

4. Soliciting Public Comment on Strategies for Updates to Practice Expense Data Collection and Methodology

CMS reviews the updates it has made in recent years to PE inputs. CMS notes that its recent efforts to update the "direct" inputs used in PFS rate setting, supply and equipment pricing and clinical labor rates, is part of its effort to provide more consistent updates that improve standardization and transparency for all PE inputs. It notes, however, that the "indirect" PE data inputs, such as office rent, IT costs, and other non-clinical expenses, remain tied to legacy information that is well over a decade old and is need of a data refresh. 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.

CMS notes that it has explored issues related to indirect PE in previous rulemaking and contracted with the RAND corporation to examine this issue.[6] In general, stakeholders have raised the following concerns about CMS' current approach to indirect PE allocation:

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

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 believes it is necessary to establish a roadmap toward more routine PE updates, especially because potentially improper or outdated allocation of PE across services may affect access to certain services, which could exacerbate disparities in care and outcomes. As part of this effort,

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

CMS has contracted with RAND to develop and assess potential improvements in the current methodology used to allocate indirect practice costs in determining PE RVUs for a service, model alternative methodologies for determining PE RVUs, and identify and assess alternative data sources that CMS could use to regularly update indirect practice cost estimates.[7]

In this proposed rule, CMS states that it is signaling its intent to move to a standardized and routine approach to valuation of indirect PE and welcomes feedback from interested parties on what this might entail. It would propose this new approach to valuation of indirect PE in future rulemaking.

Specifically, it seeks comments on the following topics related to identification of the appropriate instrument, methods, and timing for updating specialty-specific PE data:

- Potential approaches to design, revision, and fielding of a PE survey that foster transparency (i.e., the methods of survey design, the content of the survey instrument, and access to raw results for informing PFS ratesetting); and
- Mechanisms to ensure that data collection and response sampling adequately represent physicians and non-physician practitioners across various practice ownership types, specialties, geographies, and affiliations.

It also seeks comment on any alternatives to the above that would result in more predictable results, increased efficiencies, or reduced burdens. For example:

- Use of statistical clustering or other methods that would facilitate a shift away from specialty-specific inputs to inputs that relate to homogenous groups of specialties without a large change in valuation relative to the current PE allocations.
- Avenues by which indirect PE can be moved for facility to non-facility payments, based on data reflecting site of service cost differences.
- Methods to adjust PE to avoid the unintended effects of undervaluing cognitive services due to low indirect PE.
- A standardized mechanism and publicly available means to track and submit structured data and supporting documentation that informs pricing of supplies or equipment.
- Sound methodological approaches to offset circularity distortions, where variable costs are higher than necessary costs for practices with higher revenue.

It also asks specific questions on the cadence, frequency, and phase-in of adjustments for each major area of prices associated with direct PE inputs (Clinical Labor, Supplies/Equipment).

- Whether CMS should stagger updates year-to-year for each update or establish "milestone" years at regular intervals during which all direct PE inputs would be updated in the same year.
- The optimal method of phasing in the aggregate effect of adjustments, such that the impacts of updates gradually ramp up to a full 100 percent over the course of a few years (for example, 25 percent of the aggregate adjustment in Year 1, then 50 percent of the aggregate adjustment in Year 2, etc.).

[7] Burgette et. al., 2018

- How often CMS should repeat the cycle to ensure that direct PE inputs are based on the most up-to-date information, considering the burden of data collection on both respondents and researchers fielding instruments or maintaining datasets that generate data.

CMS also seeks comment on current and evolving trends in health care business arrangements, use of technology, or similar topics that might affect or factor into indirect PE calculations. It is interested in learning whether any PE data inputs may be obsolete, unnecessary, or misrepresentative of the actual costs involved in operating a medical practice.

5. Soliciting Public Comment on Strategies for Improving Global Surgical Package Valuation

a. Global valuation and data collection, analysis, and findings

CMS is seeking public comment on strategies to improve the accuracy of payment for global surgical packages (or "global packages") under the PFS. There are over 4,000 physicians' services paid as global packages under the PFS. These generally include the surgical procedure and any services typically provided during the pre-and postoperative periods (including the evaluation and management (E/M) services and hospital discharge services). There are three types of global packages:

- The 0-day global package, which includes the procedure and the preoperative and postoperative physicians' services on the day of the procedure
- The 10-day global package, which includes services on the day of, and 10 days after, the procedure. And
- The 90-day global package, which includes services furnished on day prior to the procedure, and on the day of, and 90 days immediately following the procedure.[8]

CMS notes that in the past decade it has engaged with interested parties regarding numerous concerns about the accuracy and validity of the valuation of global packages, with particular attention paid to the E/M visits include in the services. It states that it wants to expand its discussion with the public on the multi-year data collection and analysis project, as well as ongoing changes it has made to payments for other types of patient care that may impact global packages.

CMS reviews its history of global valuation. In 2015, CMS proposed and finalized a policy in the 2015 PFS final rule (79 FR 67586) that it would transition over several years all services with 10-day and 90-day global periods to 0-day global periods. Its proposal and policy were based on concerns about whether E/M visits were actually being performed by the physician receiving the global package payment, among other concerns. CMS believed that its 2015 policy would more accurately value the surgical procedure-day services separately from postop E/M visits and would avoid potentially duplicative or unwarranted payments. The implementation of this policy, however, was halted by the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015

[8] More detail on how global packages are billed can be found in Chapter 12, Section 40, of the Medicare Claims Processing Manual (Pub. 100-04).

that prohibited the Secretary from implementing the transition policy finalized in the 2015 PFS final rule. It also required CMS to collect additional data on how best to value global packages and to reassess every 4 years the continued need for this data collection. In response to these requirements, CMS finalized a claims-based process to collect data from practitioners on both the number and level of postoperative visits furnished as part of the 10-dand 90-day global packages It also contracted with RAND to support the data collection and analysis.

CMS reviews the findings from the three RAND reports that examined and analyzed the claims-based and survey-based data. In particular, CMS found that reported number of E/M visits matched the expected number for only 4 percent of reviewed 10-day global packages and 38 percent of reviewed 90-day global packages.[9] Public commenters raised various concerns about the findings in the report, including questions as to whether the E/M visits data were collected from a true representative sample of practitioners. CMS notes, however, that it not yet received data suggesting that postoperative E/M visits are being performed more frequently than indicated by the data collected and analyzed in the RAND reports. **CMS seeks comment on ideas for other sources of data that would help it assess global package valuation (including the typical number, and level of services), as well as its data collection methodology and the RAND report findings**.

b. Changes to health care delivery and payment for E/M services

CMS is interested in hearing from the public on whether the postoperative health care landscape has changed in ways that impact the relevance of the global packages. **CMS is soliciting comment on whether changes to health care delivery**, including changes in coordination of care and use of medical technology over the past 3 decades, as well as during the recent PHE, have impacted: the number and level of postoperative E/M visits needed to provide effective follow-up care to patients; the timing of when postoperative care is being provided; and who is providing the follow-up care.

CMS also solicits comment on whether global packages, and especially those with 10- and 90-day global periods, continue to serve a purpose when physicians could otherwise bill separately not only for the postoperative E/M visits they furnish, but also for aspects of postoperative care management they furnish for some patients. It also would like to hear generally what, if any, components of preoperative or postoperative care are currently only compensated as part of payment for global packages. It notes that one change that may impact global packages is the expansion of payment for non-face-to-face care management services.

It also welcomes additional comment on perceived misalignment between the E/M visits included in global packages and separately billable E/M services, including thoughts on how this current tension reflects on global payment valuation and the appropriate methodology for determining appropriate values for global packages.

[9] These three RAND reports were made available to the public and are available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection-

c. Strategies to Address Global Package Valuation

CMS continues to believe that that: (1) there is strong evidence suggesting that the current RVUs for global packages are inaccurate; (2) many interested parties agree that the current values for global packages should be reconsidered, whether they believe the values are too low or too high; and (3) it is necessary to take action to improve the valuation of the services currently valued and paid under the PFS as global surgical packages.

CMS is soliciting additional input on the RAND methodology, including advantages and drawbacks of applying the RAND methodology to revaluation. It also requests input on specific alternatives, including: (1) requesting the RUC to make recommendations on new values; or (2) another method proposed by the public.

CMS seeks feedback on possible strategies for a revaluation process for global services. It notes that because there are a large number and volume of services paid as global packages, it states that it must consider the resources needed to revalue even a subset of the global packages as well as its impact across the PFS and healthcare delivery system. CMS states that it is considering various approaches, such as: (1) revaluing all 10- and 90-day global packages at one time (perhaps with staggered implementation dates); (2) revaluing only the 10-day global packages (because these appear to have the lowest rate of postoperative visit performance, per RAND's analysis of claims data); (3) revaluing 10-day global packages and some 90-day global packages (such as those with demonstrated low postoperative visit performance rates as identified in RAND's analysis of these services); or (4) relying on the Potentially Misvalued Code process to identify and revalue misvalued global packages over the course of many years.

CMS also notes that it is taking comments on additional considerations affecting valuation of global services that may not have been thoroughly explored. It notes, for example, that perhaps not enough attention has been paid to the value of preservice work bundled into the global payment. It also solicits comment on any other aspects of the global payment structure (aside from valuation) that commenters believe are noteworthy. It also seeks comment on any concerns about beneficiaries' access to care, continuity of care, cost sharing, or program integrity.

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,

publishes a list of 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

Table 6 (reproduced below) lists the submissions CMS received under the potentially misvalued code initiative. Submissions for specific, PE-related inputs for codes are discussed above as part of the discussion on PE RVUs.

Table 6: Interested Parties' Nominations of CPT Codes as Potentially Misvalued for 2023

CPT Code	CPT Descriptor
Home Visits codes:	
99344	New patient home visit, typically 1 hour
99345	New patient home visit, typically 75 minutes
99349	Established patient home visit, typically 40 minutes
99350	Established patient home visit, typically 1 hour
Cataract Surgery codes:	
65820	Relieve inner eye pressure
66174	Translum dil eye canal
66982	Xcapsl ctrc rmvl cplx wo ecp
66984	Xcapsl ctrc rmvl w/o ecp
66989	Xcpsl ctrc rmvl cplx insj 1+
66991	Xcapsl ctrc rmvl insj 1+
Retinal Procedure codes:	
67015	Release of eye fluid
67036	Removal of inner eye fluid
67039	Laser treatment of retina
67040	Laser treatment of retina
67041	Vit for macular pucker
67042	Vit for macular hole
67043	Vit for membrane dissect
67108	Repair detached retina
67113	Repair retinal detach cplx
Spinal Surgery code:	
20931	Allograft, structural, for spine surgery only (add-on code)

CPT Codes for Home Visits
The nominator raised concerns that the overall RVUs for CPT codes 99344, 99345, 99349, and 99350 did not include the resources associated with: (1) physician's transportation costs to patients' homes; (2) lost income opportunity because of the time commuting to patients' homes; and (3) in-house Social Determinants of Health (SDOH) assessment work associated with assessing a patient's home environment. The nominator suggested that if these resources were taken into account, the payment rate for these codes would increase approximately 222 percent.

CMS notes that historically it does not take into account: (1) travel costs incurred by the physician or other practitioner; (2) potential opportunity costs; or (3) physician or other practitioner's works and time in performing activities outside the scope of the specific services described by the CPT code. Since home-based E/M codes were reviewed by the AMA RUC and are part of the discussion of the valuation of specific codes (section II.F in this summary), CMS does not consider these as potentially misvalued codes.

CPT Codes for Cataract Surgery and Retinal Procedures
CPT codes for cataract surgery (65820, 66174, 66982, 66984, 66989, and 66991) and CPT codes for retinal procedures (67015, 67036, 67039-67043, 67108, and 67113) were nominated as potentially misvalued because there are no established non-facility payment rates. The nominator included a list of practice expenses needed to furnish these services. The nominator suggests these procedures can be properly performed in the non-facility setting.

CMS notes these codes are complex surgical eye procedures that require dedicated spaces and possible clinical staff, including anesthesia services that are not typically associated with the non-facility ophthalmologist office. Because of concerns for patient safety and the intricate nature of these surgeries, CMS thought these procedures would only be performed in a well-equipped and fully staffed medical facility. CMS notes that in the 2022 PFS final rule,[10] it did not establish non-facility value for other cataract surgery CPT codes (66982 through 66986).

CMS seeks comments on whether to establish non-facility values for these codes or to continue to consider these codes only in the facility setting.

CPT Code for Spinal Surgery
Add-on CPT code 20931 (Allograft, structural for spine surgery only) was nominated as a potentially misvalued service. The nominator discussed the two different methods for vertebral fusion and believes that there should be an equivalent total payment for all services involved in vertebral fusion regardless of whether a biochemical synthetic cage device or structural allograft bone is used. The nominator stated that the total payment for spinal surgery using the allograft bone method is undervalued and there is a potential incentive for physicians to use synthetic cage devices because of the higher available payment amount.

CMS notes that CPT code 22853 (synthetic cage device) is a 45-minute add-on code with an IWPUT (intra-service work (RVU) per unit of time) of 0.0944, whereas CPT code 20931 (allograph) is a 20-minute add-on code with an IWPUT of 0.0905. Based on these difference,

[10] 86 FR 65096 - 65097

CMS would expect the allograph method of vertebral fusion would have a lower total sum of work RVUs. CMS notes that the stakeholder's determination that the code is potentially misvalued is based on the billing patterns for the two methods of a procedure. CMS notes that it generally does not examine the summed differences in total RVUs based on the billing patterns for different methods of performing services as evidence of a potential misvalued code. CMS does not believe that this code is potentially misvalued but seeks additional comments supporting this nomination.

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. Category 2 services are not similar to services on the telehealth list, and 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.[11]

In the 2021 PFS final rule (85 FR 84507), CMS created a third category for the Medicare telehealth list, Category 3. This new category describes services that 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 considered the following criteria when assessing whether there was a potential likelihood of a clinical benefit for a service and if the service should be added to the telehealth list on a Category 3 basis:

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

[11] 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.

The Medicare telehealth services list is available on the CMS website at https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html. Information about submitting a request to add services to the Medicare telehealth services list is also available on this website. For 2023, requests must have been received by February 10, 2022.

b. Requests to Add Services to the Medicare Telehealth Services List for 2023

CMS received several requests to permanently add services to the Medicare telehealth services list for 2023 (Table 7 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.

Consistent with the provisions of the Consolidated Appropriations Act, 2022 (CAA, 2022), CMS proposes to continue to allow certain telehealth services (services that are not in Category 1, 2 or 3) that would not otherwise be available via telehealth after the expiration of the PHE to remain on the Medicare Telehealth List for 151 days after the expiration of the PHE (discussed below in section 1.d).

Requests for Permanent Addition to the Medicare Telehealth List for 2023		
Code Family	**CPT codes**	**Basis**
Lactation classes	S9443	N/A
Therapy Services	90901, 97110, 97112, 97116, 97150, 97161-97164, 97530, 97535, 97337, 97542, 97550, 97555, 97663, 98960-98962	1
Telephone E/M	99441-99443	3
Gastrointestinal tract imaging	97110	3
Ambulatory continuous glucose monitoring	95251	N/A
Electronic analysis of implanted neurostimulator pulse generator/transmitter	95976 & 95977	1
	95970, 95983, 95984	3
Adaptive behavior treatment and assessment	997151-97158, 0362T, 0373T	2

Lactation classes (HCPCS code S9443)
HCPCS code S9443 (Lactation services, non-physician provider, per session) is a temporary code established by private payors and for Medicare has a status code of "I", which means it is not valid for Medicare billing purposes and is not separately billable under the PFS. Because this service is not billable under the PFS when furnished in-person, CMS does not believe it would be appropriate to allow the service to be separately billed when furnished as a Medicare telehealth service. CMS is not proposing to add CPT code S9443 to the telehealth list.

Therapy Services
CMS received a request to add the following codes on a Category 1 basis: Therapy Procedures (97110, 97112, 97116, 97150, 97530); Physical Therapy Evaluations (97161-97164); Therapy Personal Care Services (97535, 97537, 97542); and Therapy Tests and Measurements (97750, 97755, 97763). 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 do not meet Category 2 criteria,

because there isn't sufficient evidence to determine whether the service could be furnished remotely.

CMS notes that some of these codes (97110, 97112, 97116, 97150, 97530, 97161-97164, 97535, 97543, 97550, and 97755) have been added to the telehealth list on a temporary basis as Category 3 codes.

CMS believes that the therapy services that are listed on the telehealth list on a temporary basis for the PHE (95150, 97530, and 97542) may continue to be furnished safely via two-way, audio-video communication technology outside of the PHE. CMS proposes that CPT codes 97150, 97530, and 97542 should be added to the telehealth list on a temporary Category 3 basis. CMS believes that keeping these services as Category 3 codes would preserve access to care and they may be safely furnished. CMS notes that if the PHE and the 151 day period following the expiration of the PHE both end in 2023, the pre-PHE rules will take effect, and these services could no longer be furnished by therapists as Medicare telehealth services.

Certain other requested services (97537, 97763, 90981, and 98960-98962) are not currently on the Medicare telehealth list. CMS proposes to add these codes on a Category 3 basis. CMS believes that including these as Category 3 services will provide additional time for the development of evidence for potential permanent addition to the telehealth list.

Telephone E/M Services
CMS received a request to temporarily add Telephone E/M visit codes, CPT codes 99441-99443 on a Category 3 basis.

CMS reviews its prior discussion of audio-only services,[12] and reiterates it belief that the statute requires that telehealth services be analogous to in-person care and are essentially a substitute for a face-to-face encounter. CMS believes these audio-only telephone E/M services are inherently non-face-to-face services and outside the PHE would not be a substitute for a face-to-face encounter (excluding mental health services). CMS proposes not to keep the telephone E/M services on the telehealth list on a Category 3 basis. After the end of the PHE and the 151-day extension period, CMS will assign these CPT codes a bundled status on the PFS.

Gastrointestinal (GI) Tract Imaging and Continuous Glucose Monitoring
CMS received a request to add GI Tract Imaging (CPT code 91110) and Ambulatory Continuous Glucose Monitoring (CGM) (CPT code 95251) on a Category 3 basis.

CMS believes these codes describe services that are inherently non-face-to-face services and therefore do not describe services that are a substitute for an in-person visit. CMS proposes not to add these services to the telehealth list either for the PHE or as a Category 3 service.

Neurostimulator Pulse Generator/Training
CMS received requests to add codes describing the electronic analysis of an implanted neurostimulator pulse generator/transmitter to the Medicare Telehealth Services List: CPT codes

[12] 85 FR 19264-19266, 85 FR 27589-27590, and 86 FR 65055.

95976 and 95977 on a Category 1 basis and CPT codes 95970, 95983, and 95984 on a temporary Category 3 basis.

The request for CPT codes 95976 and 95977 did not provide any supporting evidence. CMS proposes not to add them on a Category 1 basis because they do not describe services that are similar to services currently on the telehealth services list.

CMS did include general brain nerve neurostimulation CPT codes (95970, 95983, and 95984) on the telehealth service list on a temporary basis during the PHE. CMS notes that claims data suggests that these services are being provided via telehealth. CMS proposes to add CPT codes 95970, 95983, and 95984 to the telehealth list on a Category 3 basis.

Emotional/behavior assessment, Psychological, or Neuropsychological Testing and Evaluation Services
CMS received requests to add the following CPT codes on a Category 2 basis: 997151-97158, 0362T, and 0373T. These services are currently on the telehealth list temporarily for the duration of the PHE. CMS believes there is likely to be clinical benefit when these services are furnished via telehealth and proposes to include these services on a Category 3 basis.

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

CMS proposes to add services to the Medicare Telehealth Services List on a Category 3 basis; these services are currently included on the telehealth list on a temporary basis during the PHE. This additional time would allow CMS to evaluate data that may support their permanent addition to the list on a Category 1 or Category 2 basis. Table 8, reproduced below, includes the 53 services CMS proposes as Category 3 telehealth services.

Table 8: Services Proposed for Addition to the Medicare Telehealth Services List on a Category 3 Basis

HCPCS	Short Descriptor
90875	Psychophysiological therapy
90901	Biofeedback train any meth
92012	Eye exam estab pat
92014	Eye exam & tx estab pt 1/>vst
92507	Speech/hearing therapy
92550	Tympanometry & reflex thresh
92552	Pure tone audiometry air
92553	Audiometry air & bone
92555	Speech threshold audiometry
92556	Speech audiometry complete
92557	Comprehensive hearing test
92563	Tone decay hearing test
92567	Tympanometry
92568	Acoustic refl threshold tst
92570	Acoustic immitance testing
92587	Evoked auditory test limited
92588	Evoked auditory tst complete
92601	Cochlear implt f/up exam <7
92625	Tinnitus assessment
92626	Eval aud funcj 1st hour

Table 8: Services Proposed for Addition to the Medicare Telehealth Services List on a Category 3 Basis	
HCPCS	**Short Descriptor**
92627	Eval aud funcj ea addl 15
94005	Home vent mgmt supervision
95970	Alys npgt w/o prgrmg
95983	Alys brn npgt prgrmg 15 min
95984	Alys brn npgt prgrmg addl 15
96105	Assessment of aphasia
96110	Developmental screen w/score
96112	Devel tst phys/qhp 1st hr
96113	Devel tst phys/qhp ea addl
96127	Brief emotional/behav assmt
96170	Hlth bhv ivntj fam wo pt 1st
96171	Hlth bhv ivntj fam w/o pt ea
97129	Ther ivntj 1st 15 min
97130	Ther ivntj ea addl 15 min
97150	Group therapeutic procedures
97151	Bhv id assmt by phys/qhp
97152	Bhv id suprt assmt by 1 tech
97153	Adaptive behavior tx by tech
97154	Grp adapt bhv tx by tech
97155	Adapt behavior tx phys/qhp
97156	Fam adapt bhv tx gdn phy/qhp
97157	Mult fam adapt bhv tx gdn
97158	Grp adapt bhv tx by phy/qhp
97537	Community/work reintegration
97542	Wheelchair mngment training
97530	Therapeutic activities
97763	Orthc/prostc mgmt sbsq enc
98960	Self-mgmt educ & train 1 pt
98961	Self-mgmt educ/train 2-4 pt
98962	Self-mgmt educ/train 5-8 pt
99473	Self-meas bp pt educaj/train
0362T	Bhv id suprt assmt ea 15 min
0373T	Adapt bhv tx ea 15 min

CMS proposes to create three HCPCS codes GXXX1, GXXX2, and GXXX3 to replace existing codes that describe prolonged services associated with certain types of E/M services (discussed in section II.F in this summary). CMS notes these services are similar to services currently on the Medicare telehealth list on a Category 1 basis and proposes to add them to the telehealth list on a Category 1 basis (Table 9, reproduced below).

Table 9: Services Proposed for Permanent Addition to the Medicare Telehealth Services List on a Category 1 Basis	
HCPCS	Short Descriptor
GXXX1	Prolonged inpatient or observation services by physician or other QHP
GXXX2	Prolonged nursing facility services by physician or other QHP
GXXX3	Prolonged home or residence services by physician or other QHP

d. Services Proposed for Removal from the Medicare Telehealth Services List After 151 Days Following the End of the PHE

In the 2022 PFS final rule, CMS noted that when the PHE ended, the associated waivers and interim policies will expire and that payment for Medicare telehealth services will be limited by the requirements of section 1834(m) of the Act. Services that had been added to the Medicare Telehealth Services List on a Category 3 basis will remain on the list through the end of 2023. Under CMS' current policy, all services that were temporarily added on an interim basis and have not been added to the telehealth list on a Category 1, 2, or 3 basis would not remain on the list after the end of the PHE.[13]
CMS proposes to extend the duration of time that services are temporarily included on the telehealth services list during the PHE, but are not included on a Category 1, 2, or 3 basis for a period of 151 days following the end of the PHE (CAA, 2022). Table 10 (reproduced below) lists these services. CMS believes this proposal will simplify the process of when flexibilities will end and minimize possible errors. CMS notes that on the 152nd day after the end of the PHE, payment will no longer be available for these services.

Table 10: Services to be Removed from the Medicare Telehealth Services List After 151 Days Following the End of the PHE

HCPCS	Short Descriptor
77427	Radiation tx management x5
92002	Eye exam new patient
92004	Eye exam new patient
92550	Tympanometry & reflex thresh
92552	Pure tone audiometry air
92553	Audiometry air & bone
92555	Speech threshold audiometry
92556	Speech audiometry complete
92557	Comprehensive hearing test
92563	Tone decay hearing test
92565	Stenger test pure tone
92567	Tympanometry
92568	Acoustic refl threshold tst
92570	Acoustic immitance testing
92587	Evoked auditory test limited
92588	Evoked auditory tst complete
92601	Cochlear implt f/up exam <7
92625	Tinnitus assessment
92626	Eval aud funcj 1st hour
92627	Eval aud funcj ea addl 15
93750	Interrogation vad in person
94002	Vent mgmt inpat init day
94003	Vent mgmt inpat subq day
94004	Vent mgmt nf per day
96125	Cognitive test by hc pro
99218	Initial observation care
99219	Initial observation care
99220	Initial observation care
99221	Initial hospital care
99222	Initial hospital care

[13] 85 FR 84506-84509

Table 10: Services to be Removed from the Medicare Telehealth Services List After 151 Days Following the End of the PHE	
HCPCS	**Short Descriptor**
99223	Initial hospital care
99234	Observ/hosp same date
99235	Observ/hosp same date
99236	Observ/hosp same date
99304	Nursing facility care init
99305	Nursing facility care init
99306	Nursing facility care init
99324	Domicil/r-home visit new pat
99325	Domicil/r-home visit new pat
99326	Domicil/r-home visit new pat
99327	Domicil/r-home visit new pat
99328	Domicil/r-home visit new pat
99341	Home visit new patient
99342	Home visit new patient
99343	Home visit new patient
99344	Home visit new patient
99345	Home visit new patient
99441	Phone e/m phys/qhp 5-10 min
99442	Phone e/m phys/qhp 11-20 min
99443	Phone e/m phys/qhp 21-30 min
99468	Neonate crit care initial
99471	Ped critical care initial
99475	Ped crit care age 2-5 init
99477	Init day hosp neonate care

e. Implementation of Telehealth Provisions of the CAA 2021 and CAA 2022

CMS discusses the provisions of the CAA 2021[14] and CAA 2022[15] that extend certain Medicare telehealth flexibilities adopted during the PHE for 151 days after the end of the PHE.

CMS proposes to implement the telehealth provisions in the CAA, 2022 through program instructions or other subregulatory guidance. These provisions extend 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;[16]
- 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

[14] The CAA 2021 (Pub. L. 116-260) was enacted December 27, 2020.
[15] The CAA 2022 (Pub. L. 117-103) was enacted March 15, 2022.
[16] 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.

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

f. Use of Modifiers for Medicare Telehealth Services Following the End of the PHE for COVID-19

For the duration of the PHE, CMS finalized on an interim basis the use of CPT telehealth modifier, "95" to indicate on a claim line services furnished via telehealth. CMS also finalized on an interim basis that the practitioner should report the place of service (POS) code where the service would have occurred has it not been furnished via telehealth.

For telehealth services furnished on or before the 151st day after the end of the PHE, CMS proposes to:

- Continue to process for payment as telehealth services claims submitted with modifier "95" and
- Continue to allow physicians and practitioners to report the POS code that would have been reported had the service been furnished in-person.

Telehealth services performed with dates of service occurring on or after the 152nd day after the end of the PHE will revert to pre-PHE rules and will no longer require modifier "95" to be appended to the claim. The appropriate POS indicator will need to be included on the claim to properly identify the place the service was furnished. For telehealth services furnished on or after the 152nd day after the end of the PHE, the POS indicators for Medicare telehealth will be:

- POS "02" – Telehealth Provided Other than in Patient's Home and
- POS "10" – Telehealth Provided in Patient's Home

CMS notes that in the 2022 PFS final rule[17] it defined home as: "both in general and for this purpose, a beneficiary's home can include temporary lodging, such as hotels and homeless." CMS also clarified that for circumstances where the patient, for privacy or other personal reasons, chooses to travel a short distance from the exact home location during a telehealth service, the service is still considered to be furnished 'in the home of an individual'.

On the 152nd day after the end of the PHE, POS "02" will be required for all Medicare telehealth claims. POS "10" will be used for Medicare telehealth mental health services, clinical assessments for patients with ESRD that are receiving home dialysis, and Medicare telehealth mental health services that are co-occurring with substance use treatment that are furnished with the patient in their home.

On or after the 152nd day after the PHE has expired, payment for telehealth services using either of the POS codes will be made at the PFS facility payment rate. CMS proposes to align payment for telehealth described as taking place in the beneficiary's home (POS "10") and those services not taking place in the home (POS "02") to be made at the same facility payment amount.

[17] 86 FR 65059

CMS also proposes that beginning January 1, 2023, a physician or other qualified health care practitioner billing for telehealth services furnished using audio-only communications technology shall append CPT modifier "93" to Medicare claims to identify them as having been furnished using audio-only technology. CMS also proposes to require RHCs, FQHCs, and other OTPs to use modifier "93" when billing for eligible mental health services furnished via audio-only telecommunications technology. CMS will continue to require supervising practitioners to append the "FR" modifier on any applicable telehealth claim when they are required to be present through an interactive real-time, audio and video telecommunications link.

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

Expiration of PHE Flexibilities for Direct Supervision Requirements
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 finalized continuation of this policy through the end of the year in which the PHE ends.[18]

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 continues to seek 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.

3. Telehealth Originating Site Facility Fee Update

Section 1834 (m)(2)(B) of the Act established the initial Medicare telehealth originate site facility fee for telehealth services furnished from October 1, 2001 through December 31, 2002 at $20.00. For services furnished on or after January 1 of each subsequent year, the telehealth originating site fee is increased by the percentage increase in the MEI. The proposed MEI increase for 2023 is 3.7 percent; the proposed payment for HCPCS code Q3014 (Telehealth originating site facility fee) is $28.61. The final facility fee update will be revised in the final rule (Table 11).

Regulatory Impact
After the expiration of the flexibilities put in place during the PHE, CMS expects a significant reduction in the volume of Medicare telehealth services overall, and a corresponding reduction in

[18] 85 FR 19245-19245 and 85 FR 84538-84540.

aggregate spending for Medicare telehealth services. CMS also expects that many of the services that had been furnished via telehealth during the PHE will return to in-person settings. CMS does not expect significant growth in telehealth services by aggregate volume.

Given the provisions of the CAA, 2021 and CAA, 2022, CMS anticipates that volume and spending for Medicare telehealth mental health services will increase from pre-pandemic levels. CMS anticipates that this will result in continued utilization of telehealth services during the remainder of the PHE and the immediate subsequent 151 days at levels comparable to observed utilization of these services during the PHE.

E. Valuation of Specific Codes

The proposed work RVUs, work time and other payment information for all the proposed payable codes in 2023 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[19] in the proposed rule provide additional details about the proposed 2023 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. CMS states that to establish RVUs it 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.[20] CMS notes the importance of not only the RUC-recommended work and time values but also the accompanying rationales for setting those values.[21]

[19] Tables 12-17 are incorrectly titles as CY 2022 instead of CY 2023 (a mistake we can relate to).
[20]Approaches include RUC survey data, building block, key reference code crosswalks, magnitude estimation, incremental difference applications, and time ratio calculations.
[21]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-

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

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

Table 12 list the codes and proposed work RVUs, including all codes that CMS received recommendations from the RUC by February 10, 2022.

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);

service time packages. There are pre-service time packages for services typically furnished in the facility setting and pre-service packages for services typically furnished in the nonfacility setting.

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

CMS received invoices for several existing and new supply and equipment items (see Tables 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 2023, CMS identified 11 new and revised codes as services which meet the definition of "imaging services" for purposes of the OPPS cap. This includes CPT code 0493T (Contact near-infrared spectroscopy studies); CPT codes 0640T-0642T (Noncontact near-infrared spectroscopy studies); 0651T (Magnetically controlled capsule endoscopy); 0658T (Electrical impedance spectroscopy); 0689T and 0690T (Quantitative ultrasound tissue characterization); 0694T (3-D volumetric image and reconstruction of breast tissue); 0701T (Molecular fluorescent imaging); and 76XX0 (Ultrasound, nerves).

4. Proposed Valuation for Specific Codes

This section discusses proposal for 41 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. As discussed below, CMS also seeks comments about:**

- Services involving community health workers,
- Potentially underutilized services,
- Intensive outpatient mental health treatment, and
- Payment for behavioral health services.

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	Anterior Abdominal Hernia Repair*	157X1, 49X02-49X15	No	No
2	Removal of Sutures or Staples	15851, 158X1, & 158X2	Yes	Yes
3	Arthrodesis Decompression*	22630, 22632-22634, 63052, & 63053	No	Yes
4	Total Disc Arthroplasty*	22857 & 228XX	NA**	NA
5	Insertion of Spinal Stability Distractive Device	28869 & 22870	NA	Yes
6	Knee Arthroplasty	27446 & 27447	Yes	Yes
7	Endovascular Pulmonary Arterial Revascularization	338X3-338X7	No	NA
8	Percutaneous Arteriovenous Fistula Creation*	368X1 & 368X2	No	NA
9	Energy Based Repair of Nasal Valve Collapse	37X01 & 30468	No	Yes
10	Drug Induced Sleep Endoscopy	42975	No	Yes
11	Endoscopic Bariatric Device Procedures	43235, 43X21, & 43X22	Yes	No
12	Delayed Creation Exit Site from Embedded Catheter	49436	NA	No
13	Percutaneous Nephrolithotomy*	50080 & 50081	No	Yes
14	Laparoscopic Simple Prostatectomy	55821, 55831, 55866 & 558XX	Yes	Yes
15	Lumbar Laminotomy with Decompression*	63020. 63030, & 63035	No	No
16	Somatic Nerve Injections	64415-64117, 64445-64448, 76942, 77002, & 77003	No	Yes
17	Transcutaneous Passive-Implant-Temporal Bone	69714, 69716, 69717, 69719, 69726, 68726, 69XX0-69XX2	No	Yes
18	Contrast X-Ray of Knee Joint	73580	Yes	Yes
19	3D Rendering with Interpretation and Report*	76377	Yes	Yes
20	Neuromuscular Ultrasound	76881, 76882, & 76XX0	No	No
21	Immunization Administration*	90460, 90461, 90472-90474	Yes	No
22	Orthoptic Training	92065 & 920XX	Yes	Yes
23	Dark Adaptation Eye Exam	92284	No	No
24	Anterior Segment Imaging	92287	Yes	Yes
25	External Extended ECG Monitoring*	93241-93248	NA	NA
26	Cardiac Ablation Services	93653-93657	No	NA

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
27	Pulmonary Angiography	93XX0-93XX3, 93563-93568	No	NA
28	Quantitative Pupillometry	959XX	No	Yes
29	Caregiver Behavior Management Training*	96X70 & 96X71	NA	NA
30	Cognitive Behavior Therapy Monitoring	989X6	NA	NA**
31	Annual Alcohol Misuse and Depression Screenings*	G0442 & G0444	NA	NA
32	180-Day Implantable Interstitial Glucose Sensor System*	G0308 & G0309	NA**	NA**
33	Chronic Pain Management and Treatment Bundles*	GYYY1 & GYYY2	NA	NA
34	Behavior Health Services*	NA	NA	NA
35	Behavior Health Integration*	GBH11	NA	NA
36	RFI: Services Involving Community Health Workers*	NA	NA	NA
37	Recognition of the Nurse Portfolio Credentialing Commission*	NA	NA	NA
38	RFI: Potentially Underutilized Services*	NA	NA	NA
39	Family Psychotherapy*	90847 & 90849	NA	NA
40	Intensive Outpatient Mental Health Treatment*	NA	NA	NA
41	Payment for Behavioral Health Services*	NA	NA	NA
*Discussed in HPA summary **Contractor Priced Codes				

(1) Anterior Abdominal Hernia Repair (CPT codes 157X1, 49X01-49X15)

This code family is an example of the application of CMS' 23-Hour Stay Outpatient Surgical Services Policy.[22] The work RVUs for services typically performed in the outpatient setting and require a hospital stay of less than 24 hour may in some cases involve multiple overnight stays while the patient is still considered to be an outpatient for purposes of Medicare payment. Since these services are typically furnished in the outpatient setting, the work RVUs should not include any values associated with inpatient services. CMS does not believe the RUC correctly applied this policy and discusses the valuation methodology in the proposed rule. CMS is also concerned that the RUC recommended 90-day preservice times despite surveying the service as a 00-day service. CMS also disagrees with the RUC-recommended direct PE inputs for all of the codes in this family. CMS continues to believe that the standard clinical labor packages associated with the survey global period is the most appropriate for valuation of clinical labor.

[22] 75 FR 73226

(3) Arthrodesis Decompression (CPT codes 2260, 22632-22634, 63052 and 63053)

This code family is example of codes with decreased survey changes in time without any evidence of increased intensity. CMS believes it would be inappropriate to maintain the current work RVUs given the decrease in intraservice time.

(4) Total Disc Arthroplasty (CPT codes 22857 and 228XX)
The specialty societies indicated that the survey results were erroneous and the codes needed to be resurveyed; the RUC agreed. CMS proposes to maintain the RUC-recommended work RVUs for CPT code 22857 and contractor pricing for CPT code 228XX.

(8) Percutaneous Arteriovenous Fistula Creation (CPT codes 368X1 and 368X2)
CMS proposes to delete HCPCS codes G2170 and G2171 and replace them with CPT codes 368X1 and 368X2. CMS disagrees with the RUC-recommended work RVUs for these codes because these recommendations are high when compared to other codes with similar time values.

CMS seeks additional information on two equipment items and four supply items. CMS requests information explaining why the Wavelinq generator (EQ403) is so much more expensive on its invoice than the Ellipsys generator (EQ404) ($18,580 vs. $3,000). For the supply items, CMS wants to know if supply items SD149 and SD152 are typically used and if so, how often they are used with these codes, and why SF056 and SF057 are direct PE inputs for CPT code 368X2.

(13) Percutaneous Nephrolithotomy (CPT codes 50080 and 50081)
These codes are an example of the changing practice of medicine and how that impacts the valuation of services. The code descriptors were revised to reflect the fact these services are performed less than 50 percent of the time in the inpatient setting but both codes have 90-day global periods which include post-op inpatient hospital E/M services. CMS notes these codes had not been reviewed for nearly 30 years. CMS disagrees with the RUC-recommended work RVUs because the codes do not accurately reflect the surveyed decrease in intra-service time.

(15) Lumbar Laminotomy with Decompression (CPT codes 63020, 63030 and 63035)
This code family is another example of codes with a change from being performed in the inpatient to outpatient setting and incomplete application of the 23-hour policy. CMS notes that in the summary of recommendations submitted by the RUC, the specialty societies asserted that the survey total time would be the same as the current total time if the 23-hour policy was not fully applied to the immediate post-service time and post-operative period, with only a shift of work from facility to office. CMS disagrees and proposes work RVUs less than the values recommended by the RUC.

(19) 3D Rendering with Interpretation and Report (CPT code 76377)
CMS disagrees with the specialty societies position that CPT codes 76376 and 76377 are separate code families. CMS reiterates it believes that CPT code 73637 and 76377 should be viewed as a code family and requests that they be surveyed together.

(21) Immunization Administration (CPT codes 90460, 90461, 90472-90474)
CMS discusses the importance of appropriate payment for immunization administration and its policy objective to ensure maximum access to immunization services. **CMS seeks information** that specifically identifies the resource costs and inputs that should be considered to establish payments for vaccine administration services.

(25) External Extended ECG Monitoring (CPT codes 93241-93248)
CMS believes it has sufficient, reliable information for pricing the new supply item associated with these codes, the "extended external ECG patch, medical magnetic tape recorder" (SD339). Based on consistent invoice data submitted during the past two years, CMS proposes a national price of $245.69.

(29) Caregiver Behavior Management Training (CPT codes 96X70 and 96X71)
The two CPT codes are to be used to report the total duration of face-to-face time spent by the physician or other qualified health professional providing group training to guardians or caregivers of patients. Although the patient does not attend the group trainings, the goals and outcomes of the sessions focus on interventions aimed at improving the patient's daily life. The RUC provided work RVU recommendations to CMS.

CMS has determined that CPT codes 96X70 and 96X71 are not payable under the PFS. Under section 1862(a)(1)(A) of the Act, Medicare payment is generally limited to those items and services that are reasonable and necessary for the diagnosis or treatment of illness or injury or that improve the functioning of a malformed body part. Because the codes for caregiver behavior management training describes services furnished exclusively to caregivers rather than to individual Medicare beneficiaries, CMS does not consider these Medicare eligible services.

CMS seeks comments about the services described by these codes. Specifically:

- The ways in which a patient may benefit when a caregiver learns strategies to modify the patient's behavior.
- How current Medicare policies regarding these caregiver training services may impact a Medicare beneficiary's health?
- How the services described by these codes might be bundled into Medicare covered services as incident to services or as practitioner work that is part of care management codes?

(31) Code Descriptor Changes for Annual Alcohol Misuse and Annual Depression Screenings (HCPCS codes G0442 and G0444)
CMS agrees with the request to revise these code descriptors to state, "up to 15 minutes" instead of the current "15 minutes". CMS proposes to modify the descriptor for HCPCS codes G0442 to "Annual alcohol misuse screening, 5 to 15 minutes" and HCPCS code G0444 to "Annual depression screening, 5 to 15 minutes".

(32) *Insertion, and Removal and Insertion of new 180-Day Implantable Interstitial Glucose Sensor System (HCPCS codes G0308 and G0309)*
For 2021, CMS established national pricing for 3 Category III CPT codes that describe continuous glucose monitoring (CGM) using interstitial glucose sensors. The direct PE inputs for CPT code 0446T include a 90-day supply item SD344 (implantable interstitial glucose sensor) and a 90-day smart transmitter proxy equipment item EQ392 (heart failure patient physiologic monitoring equipment package).

To allow beneficiaries access to a newly approved 180-day CGM system, CMS established two new HCPCS codes to describe the 180-day CGM system, G0308 and G0309. Effective July 1, 2022 these codes are contractor priced.

CMS is seeking information and invoices on the costs of the 180-day interstitial glucose supply and 180-day smart transmitter equipment direct PE inputs for HCPCS codes G0308 and G0309. CMS notes that SD334 is currently priced at $1,500 and EQ392 is currently priced at $1000.

(33) Chronic Pain Management (CPM) and Treatment Bundles (HCPCS codes GYYY1 and GYYY2)
CMS discusses the challenges for adequate treatment of pain, including information from the CDC, HHS and the National Academy of Medicine. The SUPPORT Act[23] outlines national strategies to help address the opioid and substance use disorders (SUD) and policies to improve the treatment of pain and SUD.

CMS acknowledges there are no existing codes that specifically describe the work of the clinician involved in performing the tasks necessary for pain management care. CMS notes that chronic care management (CCM) supports chronic disease management but it believes the complexity and resources required for pain management may not be adequately captured and paid through these codes.

In the 2022 PFS proposed rule, CMS solicited comments about how to value CPM services, including whether CPM should have or standalone code or E/M add-on code, the specific activities involved in CPM, the practitioners providing this care, and the settings the care is provided. CMS received over 1,900 comments; almost all commenters were supportive of developing codes and payment for CPM. After consideration of the comments, CMS proposes to create separate coding and payment for CPM services.

a. Proposal for Monthly CPM Services

CMS proposes to define chronic pain management as "persistent or recurrent pain lasting longer than three months". **CMS seeks comments on the following:**

- Is this an appropriate definition of chronic pain or should it include some other interval or description to define chronic pain?
- How the chronic nature of the person's pain should be documented in the medical record?

[23]Pub. L. 115-271, October 24, 2018

CMS proposes to create two HCPCS G-codes.
HCPCS code GYYY1: CPM and treatment, monthly bundle including diagnosis; assessment and monitoring;

- Including:
    - administration of a validated pain rate scale or tool;
    - the development, implementation, revision and maintenance of a person-centered care that that includes strengths, goals, clinical needs and desired outcomes;
    - overall treatment management;
    - facilitation and coordination of any necessary behavioral health treatment;
    - medication management;
    - pain and health literacy counseling;
    - any necessary chronic pain related crises care; and
    - ongoing communication and care coordination between relevant practitioners furnishing care (e.g., PT and OT, and community based care), as appropriate.
- Required initial face-to-face visit at least 30 minutes provided by a physician or other qualified health professional; first 30 minutes personally provided by physician or other qualified health care professional, per calendar month.
    - When using GYYY1, 30 minutes must be met or exceeded.

HCPCS code GYYY2: Each additional 15 minutes of CPM and treatment by a physician or other qualified health care professional, per calendar month (List separately in addition to code for GYYY1). (When using GYYY2, 15 minutes must be met or exceeded.)

CMS requests comments on the proposed code descriptors:

- Should the "administration of a validated pain assessment rating scale or tool" be included within the proposed code descriptor? Would a repository or list of such tool be helpful?
- How pain and health literacy counseling is or may be effectively used as a service element to help beneficiaries with chronic pain make well-informed decisions about their own care, weigh risks and benefits, make decisions, and take actions that are best for them and their health?
- Is the proposed initial face-to-face visit of at least 30 minutes and additional 15 minutes appropriate or should CMS consider a longer duration for GYYY1 (45 minutes or 1 hour) GYYY2 (20-minute intervals)?
- The service is for beneficiaries already diagnosed with chronic pain and for those being diagnosed with chronic pain during the visit. Is this appropriate?

CMS also welcomes comments on the following related issues:

- How best to conduct the initial visit and subsequent visits (e.g., in-person, telehealth, or the use or a telecommunications system) and any implications for additional or different coding.
    - Based on comments, CMS will consider whether to add the CPM codes to the Medicare Telehealth Services List.

- Are there components of the proposed CPM services that do not necessarily require face-to-face interaction with the billing practitioner and could be provided by auxiliary staff incident to the billing practitioner's services.
    - For any component that could be furnished "incident to" can these be appropriately furnished under the general supervision of the billing physician or non-physician practitioner (e.g., administration of pain rating scale or some elements of care coordination, as allowed for certain care management services)?

CMS proposes to permit billing by another practitioner after HCPCS code GYYY1 has already been billed in the same calendar month by a different practitioner. CMS believes that most CPM services would be billed by primary care practitioners who are focused on long-term management of their patients with chronic pain but acknowledges that some individuals with chronic pain are followed by a pain specialists. CMS anticipates there could be occasional instances where the care of a patient is transferred between a pain specialist or other specialists from a primary care practitioner and vice versa. In these instances, CMS anticipates GYYY1 and potentially GYYY2 could be billed by another practitioner during the same month, for the same beneficiary. CMS proposes to place a limit on the number of times the code could be billed per beneficiary per month, at a maximum of twice per month. **CMS seeks comments** on this proposal to allow billing by another practitioner after the GYYY1 has already been billed and the appropriate frequency of this happening each month.

CMS proposes to require that the beneficiary's verbal consent to receive CPM services at the initiating visit be documented in the beneficiary's medical record. CMS believes that at the initial visit patients should be informed of any cost sharing. **CMS seeks comments** on how best to effectively educate both practitioners and beneficiaries about the benefits of CPM. CMS also seeks comments on whether the initiating visit is the appropriate time to obtain beneficiary consent, should it be given at each visit, and should it be obtained by the practitioners with whom CPM billing practitioners coordinate other services?

CMS proposes that the CPM codes could be billed in the same month as a care management service, such as CCM and Behavior Health Integration (BHI), and in the same month as bundled payments for opioid use disorders (HCPCS codes G2086-G2088). Patient consent would need to be obtained for all these services. CMS believes there might be some potential for duplicative payment, including additional financial burden to the Medicare beneficiary and expects to refine these codes through future rulemaking. **CMS welcomes comments** regarding what, if any, Medicare services it should consider that could not be billed by the same practitioner for the same patient concurrent with any other services.

CMS is also interesting in information about potential coding and payment to address acute pain. Specifically:

- The definition for acute pain.
- Should CMS create a standalone or E/M add-on code and how to value these services?
- Which health care settings and which type of providers should furnish acute pain care?
- The specific activities furnished for acute pain care and what, if any, can be furnished "incident to" the billing practitioner?

b. Valuation of CPM

CMS proposes to develop inputs for HCPCS code GYYY1 using a crosswalk to CPT code 99424 (Principal care management services) and for GYYY2 using a crosswalk to 99245 (each additional 30 minutes). For GYYY1 CMS proposes a work RVU of 1.45 and the direct PE inputs associated with 99424. For GYYY2 CMS proposes a work RVU of 0.50; CMS notes that 99245 has a work RVU of 1.0 but it is for twice the time duration as GYYY2. CMS proposes to use half of the direct PE inputs associated with 99245.

CMS proposes that GYYY1 can only be billed when the full 30 minutes of service time has been met or exceeded. Similarly, CMS proposes that GYYY2 can only be billed when the full 15 minutes of service time is met or exceeded.

CMS proposes that GYYY1 and GYYY2 could not be billed on the same date of services as CPT codes 99202-99215 (Office/outpatient visits new) since these are related services. CMS will allow billing of GYYY1 and GYYY2 on the same day as CCM services, Transitional Care Management Services; or BHI services.

CMS notes that the proposed CPM codes would be limited to beneficiaries in office or other outpatient or domiciliary settings. **CMS seeks comments on other settings where CPM services could be provided**.

(c) Request for Comment

In addition to the above requests for comments, **CMS seeks comments on the following** (some are repeats):

- CMS discusses that a beneficiary receiving CPM services may need referrals or recommendations for services or interventions that are not included as elements of the CPM services, such as PT and OT. CMS is interested in information about care coordination that may occur between relevant practitioners, such as complementary and integrative care, and on the community-based care element included in the code descriptors.
- How documentation of the CPM service elements are best addressed in medical recordkeeping?
- Are there elements of the CPM service code descriptors that should be removed or added?
- What CPM elements could be furnished as “incident to” services and what elements could be furnished under general or direct supervision?
- CMS acknowledges that the CPM codes may involve collaboration with other health care providers or other members of the care team such as a psychologist, dentist, or social workers. Should the proposed CPM code and payment account for these types of team-based care and if so, how should they be included?

(34) *Proposed Revisions to the "Incident to" Physicians' Services Regulation for Behavioral Health Services*

CMS discusses the increasing demand for behavior health services and the projected shortage of behavioral health practitioners. CMS discusses how licensed professional counselors (LPCs) and Licensed Marriage and Family Therapists (LMFTs) could help provide behavior health services.[24] Because there is no separate benefit category under the statute that recognizes the professional services of LPCs and LMFTs, payment cannot be made under the PFS for services made by these professionals. Payment can be made under the PFS indirectly when an LPC or LMFT performs services as auxiliary personnel incent to, the services, and under the direct supervision, of the billing physician or other practitioner.

CMS proposes to amend the direct supervision requirement under the "incident to" regulations (§410.26) to allow behavioral health services to be furnished under the general supervision of a physician or non-physician practitioners (NPP)[25] when these services or supplies are provided by auxiliary personnel incident to the services of a physician or NPP. CMS believes that any risk associated with this proposal would be minimal, since the auxiliary personal would need to meet all the applicable requirements to provide incident to services, including any applicable State license requirements (§410.26(a)(1)).

35. New Coding and Payment for General Behavioral Health Integration (BHI) billed by Clinical Psychologists (CPs) and Clinical Social Workers (CSWs)

CMS again discusses the increasing demand for behavior health services and the projected shortage of behavioral health practitioners. Stakeholders have suggested to CMS that a CP might serve as the primary practitioner that integrates medical care and psychiatric expertise.

CMS proposes to create a new G code, CBH11, describing General BHI performed by CPs or CSWs to account for monthly care integration where the mental health services furnished by a CP or CSW are serving as the focal point of care integration.

HCPCS code GBH11: Care management services for behavioral health conditions, at least 20 minutes of CP or CSW time, per calendar month with the following required elements:

- Initial assessment or follow-up monitoring including the use of applicable validated rating scales;
- Behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes;
- Facilitating and coordinating treatment such as psychotherapy, coordination with and/or referral to physicians and practitioners who are authorized by Medicare to prescribe medications and furnish E/M services, counseling and/or psychiatric consultation; and
- Continuity of care with a designated member of the care team.

[24] According to the American Counseling Association there are more than 140,000 LPCs. BLS data indicates there were approximately 54,800 LMFTs as of May 2021.

[25] Non-Physician Practitioners (NPPs) include certified nurse midwifes (CNMs), certified nurse specialist (CNSs), nurse practitioner s(NPs) and Physician Assistant (PA)s.

CMS proposes to value proposed GBHI1 based on a direct crosswalk to the work values and direct PE inputs for CPT code 998484 (BHI). The proposed work value for GBH11 is 0.61.

Based on the authorizations under the CP and CSW statutory benefit categories, CPs are authorized to furnish and bill for services that are provided by clinical staff incident to their professional services when the "incident to" requirements are met. CSWs are only able to bill Medicare for services they furnish directly and personally. CMS proposes to add GBH11 to the list of designated care management services and allow general supervision.

In the 2017 PFS final rule, CMS finalized requiring an initiating visit for the BHI codes for new patients or beneficiaries not seen within a year of commencement of BHI services. CMS notes the existing eligible initiating visit codes are not, in their entirety, within the scope of the CP's practice. CMS proposes to allow a psychiatric diagnostic evaluation (CPT 90791) to serve as the initiating visit for GBH11. **CMS seeks comments** on whether it should consider additional codes to qualify as the initiating visit.

CMS proposes that GNH11 could be billed during the same month as CCM and TCM services, provided that all requirements to report each service are met and time and effort are not counted more than once. The patient consent requirements would apply to each service independently.

36. Request for Information: Medicare Part B Payment for Services Involving Community Health Workers (CHWs)

The American Public Health Association (APHA) defines a community health worker as a "frontline public health worker who is a trusted member of and/or has an unusually close understanding of the community served. This trusting relationship enables the worker to serve as a liaison/link/intermediary between health/social services and the community to facilitate access to services and improve the quality and cultural competence of service delivery." CHW are classified as a workforce category by the Department of Labor. The CHW Core Consensus Project (C3) lists the following ten roles of CHWs[26]: cultural mediation; culturally appropriate health education and information; care coordination, case management, and system navigation; coaching and social support; advocating for individuals; building individual and community capacity; providing direct service; implementing individual and community assessments; conducting outreach; and participating in evaluation and research.

CMS is interested in learning more about the role of CHWs in providing health care. Specifically:

- Whether and how CHWs, as auxiliary personnel of physicians and hospitals, may provide reasonable and necessary services to Medicare beneficiaries under the appropriate supervision of health care professionals for medical care, including behavioral health care.
- How services involving CGWs are accounted for under CCM codes, other care management of BHI services.

[26] St John, JA, Mayfield-Johnson, SL & Hernandez-Gordon, WD, (2021). Introduction: Why CHWs? In *Promoting the Health of the Community* (pp. 3-10). Springer, Cham.

- Would the employment and supervision arrangements usually adopted with in the industry would meet the requirements that allow for billing by supervising professionals or providers, including RHCs and FQHCs?
- How payments between health care provider organizations, and community-based organizations, local governments, and social service organizations, account for the costs of services provided by CHWs, and how these organizations ensure that the funding is sufficient to cover the costs of CHW services?
- Whether and to what extent CHW services are provided in association with preventive services, including those covered by Medicare?
- To understand how CHWs might be recognized as auxiliary personnel in Medicare, CMS is interested in learning how States may have determined whether and under what circumstances CHWs have the necessary qualifications to perform services that would improve the health of Medicare beneficiaries being treated by supervising professionals or providers.

37. Proposed Recognition of the Nurse Portfolio Credentialing Commission (NPCC)

CMS proposes to add the NPCC organization to the list of recognized national certifying bodies in manual instructions for nurse practitioners (NPs) at section 200 and clinical nurse specialists (CNNs) at section 210 of the Medicare Benefit Policy Manual, pub. 100-02.

38. Request for Information: Medicare Potentially Underutilized Services
CMS seeks comments on ways to identify specific services and possible barriers to improve access to high value, potentially underutilized services by Medicare beneficiaries. CMS notes that in some cases, limited use of these services occurs disproportionately in underserved communities.

Specifically, CMS seeks comments on the following:

- How to best define and identify high value, potentially underutilized health services.
- What existing services within current Medicare benefits may represent high value, potentially underutilized services, such as: preventive services;[27] diabetes management training; cancer screenings; and care management services.
- Specific obstacles to access these services and how specific potential policy, payment or procedural changes could reduce potential obstacles and facilitate better access to high value health services. CMS is soliciting new and innovative ideas that may help broaden perspectives about potential solutions.
    - Examples of some ideas may be educational or marketing strategies; aligning Medicare and other payer coding, payment and documentation requirements; State recommendations on how to best raise awareness of underutilized services, especially among the dual-eligible population; data sharing; and how CMS should issue regulations and policies related to "high value" services.
- How CMS might promote high value care and high equity.

[27] Other examples of preventive services are available at https://www.cms.gov/Medicare/Preventive/PreventiveGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html.

CMS notes that comments received may be used to identify potential opportunities for improvement and refinement to Medicare FFS and MA programs.

39. Changes in Procedure Status for Family Psychotherapy
Family psychotherapy services (CPT codes 90847 and 90849) are payable under Medicare but are assigned a restricted status indicator in the PFS payment files. CMS is proposing to update its payment files to remove the restricted ("R") procedure status indicator for CPT codes 90847 and 90849 and assign these codes an active ("A") procedure status indicator.

CMS notes there is a national coverage determination (NCD) addressing family psychotherapy services[28] and the change to the "A" status indicator does not alter the applicable coverage determinations for these codes.

40. Comment Solicitation on Intensive Outpatient Mental Health Treatment, Including Substance Use Disorder (SUD) Treatment, Furnished by Intensive Outpatient Programs (IOP)
CMS acknowledges that some people do not require a level of care for mental health needs that meets the stands for partial hospitalization programs (PHP). PHPs closely resemble a highly structured, short-term hospital inpatient program and is at a level more intense than outpatient day treatment or psychosocial rehabilitation.[29]

CMS is interested in whether or not the current coding and payment under the PFS adequately account for intensive outpatient services. CMS discusses the role of IOP programs for SUDs.
Specifically, CMS seeks comments on the following:

- Whether there is a gap in coding under the PFS or other payment systems that may be limiting access to needed levels of care for treatment of mental health or SUDs?
- Would potential gaps be best addressed by new codes, revisions of billing rules, or better valuation to reflect the relative resource costs for furnishing intensive outpatient mental health services?
- Detailed information about IOP services, including range or services offered, practitioner types, settings of care, and other information that would ensure that Medicare beneficiaries have access to this care.

41. Comment Solicitation on Payment for Behavioral Health Services under the PFS
CMS discusses how the PFS ratesetting methodology and application of budget neutrality may impact certain services more significantly than others based on factors such as how frequency codes are revalued and the ratio of physician work to PE. CMS notes that primary therapy and counseling services for treatment of behavioral health conditions, including SUD, are among the services most affected by its methodology.

CMS solicits comments on how it can best ensure beneficiary access to behavioral health services, including any potential adjustments to the PFS ratesetting methodology.

[28] Medicare NCD Manual, Pub, 100-03, section 70.1, "Consultations with a Beneficiary's Family and Associates".
[29] Medicare Benefit Policy Manual, Chapter 6, section 70.3

F. Evaluation and Management (E/M) Visits

1. Background

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 office/outpatient (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.

For 2023, the CPT Editorial Panel has 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 with be 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 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.

The RUC resurveyed the Other E/M visits and associated prolonged service codes. Table 12 in the proposed rule lists the proposed work RVUs and Table 13 lists the proposed direct PE inputs. **CMS notes that the final policies for the Other E/M visits will have a significant impact on relative resource valuation under the PFS**. In total, E/M visits account for approximately 40 percent of all allowed charges; the Other E/M visits account for approximately 20 percent of all allowed charges.

2. Overview of Policy Proposals for Other E/M Visits

CMS proposes to adopt the new CPT codes and descriptors for Other E/M visits except for prolonged services. Consistent with prolonged O/O E/M visits, CMS proposes a HCPCS G code for each family of services which prolonged services, inpatient/observation services, nursing facility visits, and home or residence visits).

CMS also proposes to generally adopt the revised CPT E/M Guidelines for Other E/M visits.[30] CMS proposes to adopt the general CPT framework, including selection of time or MDM to be

[30] CPT E/M Guidelines are available at www.ama-assn.org/cpt-evaluation-management.

used to determine the E/M visit level and not use history and the physical exam to select the visit level. CMS proposes to use the list of qualifying activities by the physician or NPP associated with the Other E/M visits to count toward the time spent when time is used to select the visit level. CMS proposes to adopt the CPT E/M Guidelines for determining level of MDM.

CMS is not adopting the general CPT rule[31] where a billable unit of time associated with a visit level is considered to have been attained when the midpoint is passed; CMS would not consider a service with a time descriptor of 30 minutes to have been met if only 15 minutes has been spent providing the service. Consistent with its policy for O/O E/M visits, when time is used to select the visit level, CMS proposes to require the full time within the CPT code descriptor to be met to select a visit level based on time.

CMS is maintaining its longstanding payment policy that physicians and NPPs are not classified as having the same specialty and subspecialties.[32] CMS continues to consider whether it could better align payment taxonomy with clinical practice and consider NPPs as working in the same specialty or recognized subspecialty as the physicians they work with.

CMS discusses the valuation of the Other E/M CPT codes and raises concerns with the RUC recommended direct work RVU being based on comparison to O/O E/M codes. CMS believes this direct comparison to the O/O codes may not be appropriate or accurate given the differences between visits in the office setting as compared to other settings. CMS states that the challenge of coordinating care and gathering information in the office setting may add additional time and complexity to visits. In addition, CMS notes that the values it established for the revised O/O E/M codes were finalized in conjunction with a policy that would have provided separate payment for the add-on code G2211 (inherent complexity to E/M visits). Consequently, CMS is concerned that many of the RUC-recommended values do not fully account for the complexity of office visits, especially since separate payment for G2211 is not available.

3. Hospital Inpatient or Observation Care (CPT Codes 99218-99236)

a. Coding Changes and Visit Selection

Effective January 1, 2023 the CPT Editorial Panel deleted seven observation care codes and revised nine codes to create a single set of codes for inpatient and observation care (inpatient and observation discharge codes are discussed below in section 4).

CPT codes 99218-99220 and 99224-99226 were deleted. The six hospital inpatient care codes were revised to be reported for hospital inpatient or observation care services and codes revised to allow code selection based on either MDM or time. The code family name was changed from "Hospital Inpatient Care" to "Hospital and Observation Care" and includes three initial hospital or observation care codes (CPT codes 99221-99223) and three subsequent care codes (CPT codes 99231-99233).

[31] Introduction to 2022 CPT Codebook, p. xviii
[32] Medicare Claims Processing Manual Chapter 26, Section 10.8

The CPT Editorial Panel also revised the three codes (CPT codes 99234-99236) under "Observation of Inpatient Care Services (including Admission and Discharge)", also referred to as the "same-day discharge' codes, to allow code selection based on either MDM or time.

CMS proposes to adopt the revised CPT codes 99221-99223 and 99231-99236. CMS proposes that when selecting a code based on time, the number of minutes specified in the code descriptor must be "met or exceeded".

CMS notes that the descriptors for these codes specify that the time counted toward the code is "per day". CMS proposes to adopt the 2023 CPT Codebook instruction that "per day" (also referred to as "date of encounter") means the "calendar date". CMS also proposes to adopt the CPT instructions that when using MDM or time for code selection, a continuous service that spans the transition of 2 calendar dates is a single service and is reported only on one date, the date the encounter begins. For a service that is continuous before and through midnight, all the time is applied to the reported date of service which is the calendar date the encounter began. (CMS notes this proposal is not in conflict with its proposed retention of the "8 to 24 hour rule" which is discussed below.)

In addition, CMS proposes to retain its policy that only one visit – either initial visit, subsequent visit, or admission and discharge visit - can be billed by the billing practitioner per calendar day. The practitioner would select the code that reflects all of the services provided during the date of service.

b. Proposed "8 to 24 Hour Rule"

The "8 to 24 hour rule" was designed to avoid unintended incentives to keep a patient in the hospital past midnight during a stay lasting less than 24 hours.[33] CMS proposes to retain the following policies for a beneficiary receiving hospital inpatient or observation services:

- If a beneficiary receives less that 8 hours of services, the practitioner may not bill for hospital inpatient and observation discharge day management services (99238 and 99239). CMS proposes that the practitioner would bill only inpatient or observation care (99221, 99222 or 99223).
- If a beneficiary receives services for a minimum of 8 hours but less than 24 hours, CMS proposes that the practitioner would bill CPT codes 99234, 99235, or 99236. CMS notes these codes include both admission and discharge as part of a single service and are valued to include the time spent admitting, caring for, and discharging the patient.
- If a beneficiary is admitted for care and is discharged after more than 24 hours, CMS proposes that the practitioner would bill an initial inpatient or observation care code (99221-99223) for the date of admission, and a hospital discharge day management service (99238 or 99239) on the date of discharge.

CMS believes it is necessary to retain these policies because hospital admissions can occur 24 hours a day and relying solely on the calendar date of an admission or observation stay to

[33] Medicare Claims Processing Manual Chapter 12, Sections 30.6.8.B and 30.6.9.1.C

determine a billing day can be misleading. CMS provides examples of correct billing in the proposed rule.

c. Proposed Definition of Initial and Subsequent Hospital Inpatient or Observation Visit

Because the 2023 CPT Codebook definitions for an initial and subsequent visit include references to subspecialties, CMS proposes slightly amended definitions to account for the fact that CMS does not recognize subspecialties. Specifically, CMS proposes:

- An initial service would be defined as one that occurs when the patient has not received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the same specialty who belongs to the same group practice during the stay.
- A subsequent service would be defined as one that occurs when the patient has received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the same specialty who belongs to the same group practice during the stay.

CMS proposes the same definitions for initial and subsequent nursing facility visits.

CMS also proposes that for both initial and subsequent visits, when advanced practice nurses and physician assistants are working with physicians, they are always classified in a different specialty than the physician (discussed below in section 2).

d. Transitions Between Settings of Care and Multiple Same-Day Visits for Hospital Patients Furnished by a Single Practitioner

CMS proposes to retain the following policies:[34]

- For the purposes of reporting an initial hospital or observation care service, a transition from observation status to inpatient status does not constitute a new stay. Consistent with the 2023 CPT Codebook instructions, if a practitioner places a beneficiary in observation status on one date of service (and bills 99221-99223) and then determines later in the stay the beneficiary should be admitted to the hospital this would not be considered a second initial visit for the hospital inpatient stay. The practitioner would bill the work done on the inpatient admission day as a subsequent visit (99231-99233).
- If a patient is seen in a physician office on one day and receives care at a hospital for inpatient or observation care, both visits are payable to the physician, even if less than 24 hours has elapsed between the visit and the hospital inpatient or observation care.
- When a patient is admitted to outpatient observation or as a hospital inpatient via another site (i.e., hospital, emergency department (ED), physician's office) all services provided by the physician in conjunction with the admission are considered part of the initial hospital inpatient or observation care when performed on the same date as the admission.

[34] Medical Claims Processing Manual, Chapter 12

- A physician may bill only for an initial hospital or observation care service if the physician sees the patient in the ED and decides to either place the patient in observation status or admit the patient as a hospital inpatient.
- If the inpatient care is being billed by the hospital as inpatient hospital care, the hospital care codes apply. If the inpatient care is being billed by the hospital as nursing facility care, the nursing facility codes apply.

CMS provides examples of correct billing in the proposed rule.

e. Impact of Changes to Codes on Billing and Claims Processing Policies

CMS proposes that starting in 2023, hospital inpatient and observation care will be billed by using the same CPT codes, 99221-99223, 99231-99233, and 99238 and 99239. **CMS seeks feedback on potential challenges to billing or claims processing policie**s including possible impact on billing for patients during a global period; documentation requirements, modifiers associated with hospital inpatient or observation care claims; and any other issues needing additional guidance.

f. Prolonged Services

For 2023, the CPT Editorial Panel created CPT code 993X0 for prolonged inpatient or observation E/M service(s) time. The 2023 CPT Codebook states, "CPT code 993X0 is to be used to report prolonged total time (that is, combined time with and without direct patient contact) provided by the physician or other qualified health care professional on the date of an inpatient service (99223,99233,99236,99255, 99306, 99310). Prolonged total time is time that is 15 minutes beyond the time required to report the highest-level primary service."

CMS believes the billing instructions for CPT code 993X0 will lead to administrative complexity and limit its ability to evaluate claims data. CMS proposes not to adopt CPT code 993X0 and proposes a single G code, GXXX1, that describes a prolonged service and applies to CPT codes 99223, 99233, and 99236. GXXX1 is for each additional 15 minutes and should not be reported for any time unit less than 15 minutes.

CMS proposes that the GXXX1 code can only be applied to the highest level hospital inpatient or observation care visit codes and can only be used when selecting E/M visit level based on time. CMS proposes that a prolonged code is only applicable after both the total time described in the base E/M code descriptor is complete and the full 15-minutes described by the prolonged G code is also obtained.

CMS proposes that GXXX1 can begin 15 minutes after the total times (as established by the Physician Time File) for CPT codes 99223, 99233, and 99236 have been met. For administrative simplicity, CMS proposes to round the time when the prolonged service begins to the nearest 5 minutes. CPT code 99223, which has a RUC-proposed total time of 74 minutes, would be treated as though it has 75 total minutes; CPT code 99233 which has a RUC-proposed time of 52 minutes, would be treated as though it has 50 minutes; and CPT code 99236, which has a RUC proposed time of 97 minutes would be treated as though it has 95 total minutes. The entire 15-miunute increment must be completed to bill GXXX1. CMS provides examples of correct billing

in the proposed rule. (CMS summarizes prolonged services in Table 18, reproduced below in section 11.)

CMS proposes that GXXX1 would apply to both face-to-face and non-face-to-face time spent on the patient's care within the survey timeframe. For CPT codes 99223 and 99233, this would be time spend on the date of encounter. For CPT code 99236, this would be time spent within 3 days of the encounter. CMS proposes that CPT codes 99358 and 99359 for prolonged E/M services cannot be billed and the time will be reported under GXXX1.

g. Valuation of Services

CMS proposes to accept the RUC recommendations for work RVUs for these codes; there are no PE inputs for these codes.

Valuation of Hospital Inpatient or Observation Care Services		
CPT Code	**Work RVUs**	**Total Time**
99221	1.63	40 minutes
99222	2.60	55 minutes
99223	3.50	74 minutes
99231	1.00	25 minutes
99232	1.59	36 minutes
99233	2.40	52 minutes
99234	2.00	50 minutes
99235	3.24	76 minutes
99236	4.30	97 minutes

4. Hospital or Observation Discharge Day Management (CPT codes 99217, 99238, and 99239)

Effective January 1, 2023 the CPT Editorial Panel deleted the observation discharge code (99271) and revised the two hospital discharge day management codes (99238 and 99239) to be used for discharge of hospital inpatient or observation patients. CMS proposes to adopt the revised CPT codes 99238 (discharge day management 30 minutes or less) and 99239 (more than 30 minutes).

CMS proposes to retain its current hospital inpatient discharge policy and expand it to include observation care.[35] Specifically, CMS proposes that CPT codes 99238 and 99239 are billed by the practitioner who is personally responsible for discharge service (or the death pronouncement). Services furnished by other practitioners would be reported as subsequent hospital inpatient or observation care. CMS also proposes that the same physician may not bill a hospital discharge code on the same day as the subsequent visit code.

[35] Medicare Claims Processing Manual, Chapter 12

b. Prolonged Services

CMS proposes that a practitioner would not be able to bill prolonged services for hospital discharge; CPT codes 993X0, 99358, 99359 and the proposed GXXX1 code would not be payable with the discharge management codes 99238 or 99239.

CMS notes that the descriptor for the CPT code states the code is for "30 minutes or more" of discharge day management services and the RUC survey timeframe was within 3 calendar days of the encounter. CMS believes that all face-to-face and non-face-to-face activities performed by the practitioner during the date of encounter and within 3 calendar days from the date of encounter should be counted toward CPT code 99239, as applicable. CMS does not believe it is appropriate to allow any prolonged codes to be billed with 99239 as the base code.

c. Valuation

CMS proposes to accept the RUC recommendations for CPT codes 99238 (work RVUs 1.50, total time 38 minutes) and 99239 (work RVUs 2.15, total time 64 minutes). CMS also proposes the RUC-recommended direct PE inputs for these codes (Table 13).

5. Emergency Department Visits (CPT Codes 99281-99285)

a. Coding

Effective January 1, 2023, the CPT Editorial Panel revised the five ED visit codes to allow level of service based on MDM. The descriptor for CPT code 99281 was revised to not require the presence of a physician or other qualified health care provider. In addition, the MDM level for CPT code 99282 was revised from low to straightforward and the MDM level for CPT code 99283 was revised from moderate to low.

b. Sites of Service and Multiple Same-Day E/M Visits for ED Patients

CMS proposes that if a physician advises their patient to go to a hospital ED for inpatient care or observation and the patient is asked by the ED physician to come to the hospital to evaluate the patient, the physicians should bill as follows:

- If the patient is admitted to the hospital or placed in observation status by the patient's personal physician, then this physician should bill only the appropriate level of the initial hospital inpatient or observation care (99221-99223), because all of the services provided by that physician in conjunction with the admission are considered part of the initial hospital inpatient or observation care when performed on the same date as the admission. The ED physician should bill the appropriate ED code.
- If the ED patient, based on the advice of the patient's physician who also saw the patient in the ED, sends the patient home, the ED physician should bill the appropriate ED code. The patient's physician should also bill the appropriate ED code. If the patient's physician only advises by telephone, the physician cannot bill the ED code.

Similarly, CMS proposes that if the ED physician requests that another physician evaluates a patient, the other physician should bill an ED visit code. If the patient is admitted by the other physician, then that physician should bill the initial hospital inpatient or observation code and not an ED visit.

CMS notes that the 2023 CPT Codebook allows billing of both critical care and ED services on the same day under certain circumstances. In the 2022 PFS final rule, CMS finalized that critical care and ED visits may be billed on the same day if performed by the same physician, or by physicians in the same group and specialty, if there is documentation that the E/M service was provided prior to the critical care service at a time the patient did not require critical care. In addition, the documentation needs to indicate the two services are separate and distinct without duplicative elements. Practitioners must use modifier -25 when reporting critical care services.

c. Valuation

CMS proposes the RUC-recommended work for four of the five codes in the ED (Table 12). CMS proposes a work RVU of 0.25 for CPT code 99281, a work RVU of 0.93 for CPT code 99282, a work RVU of 1.60 for CPT code 99283 and a work RVU of 4.00 for CPT code 99285.

CMS disagrees with the RUC-recommended work RVU of 2.60 for CPT code 99284 and proposes to maintain the current work RVU of 2.74. CMS notes that given there was no change in the surveyed work time or level of MDM for this service, it believes that the work RVU of 2.74 finalized in 2021 is the most accurate valuation of this code.

There are no direct PE inputs for the ED visit codes.

d. Prolonged Services

CMS proposes the proposed prolonged services would not be reported with ED visit codes. CMS notes ED visit codes are not reported based on the amount of time spent with the patient.

6. Nursing Facility Visits (CPT Codes 99304-99318)

a. Coding Overview

Effective January 1, 2023, the CPT Editorial Panel deleted CPT code 99318, annual nursing facility assessment. The descriptors for the three initial nursing facility care E/M codes (99304-99306) and the four subsequent nursing facility care E/M codes (99307-99310) were revised to indicate that the appropriate level of code could be based on either time or MDM. CMS proposes that when total time is used to select the appropriate code, both face-to-face and non-face-to-face time personally spent by the physician or other qualified health care professional are summed to select the appropriate code to bill. CMS proposes to adopt the 2023 CPT Codebook guidance for reporting initial nursing facility care, including that transitions between skilled nursing facility level of care and nursing facility level of care do not constitute a new stay.

CMS proposes to retain the following billing policies:

- The required initial comprehensive assessment should be billed as an initial NF care visit (99304-99306). CMS proposes that a practitioner may bill the most appropriate initial nursing facility or subsequent nursing facility care code, if the practitioner furnishes services that meet the code descriptor requirements, even if the service is furnished prior to the required initial comprehensive assessment.
- A physician will not be paid for an ED visit or an office visit and a comprehensive nursing facility assessment on the same calendar day. CMS states the services furnished on the same date and provided in sites other than the nursing facility are bundled into the initial nursing facility care code when performed on the same date as the nursing facility admission by the same physician.

CMS proposes the same definition for "initial" and "subsequent" for nursing facility care as it proposed for inpatient and observations services (discussed above).

b. Valuation
CMS proposes to adopt the RUC-recommended work RVUs and the RUC-recommended direct PE input for theses codes (Tables 12 and 13).

CMS discusses several issues it considered when evaluating the recommended work RVUs. For CPT code 99306, CMS considered maintaining the current work RVU of 3.06 instead of the RUC-recommended value of 3.50. CMS does not understand why the work RVU for this code has increased although the code descriptor has not changed since the last valuation. CMS also does not understand how CPT code 99205 (O/O E/M code) is a valid comparison. For CPT code 99308, CMS also considered maintaining the current work RVU of 1.16 instead of the RUC-recommended value of 1.30. CMS solicits comments regarding these RUC recommendations.

CMS also seeks comments regarding the discrepancies in times between several of the CPT code descriptors and the time described to select the visit level.

c. Prolonged Services

CMS proposes that GXXX2 would be reported for prolonged nursing facility services by a physician or NPP. The code would be used when the total time (in the time file) is exceeded by 15 or more minutes; each additional 15 minutes would be billed. GXXX2 would not be reported for any time unit less than 15 minutes. GXXX2 would be billed for each additional 15 minute increment of time beyond the total time for CPT codes 99306 (95 minutes) and 99310 (85 minutes).

CMS proposes that the practitioner would include any prolonged service time spend within the survey timeframe, which includes the day before the visit, the day of the visit, and up to and including 3 days after the visit (Table 18 below in section 11). CMS proposes to change the payment status for CPT codes 99358 and 99359 to "I" (Not valid for Medicare purposes. Medicare uses another code for reporting of, and payment for, these services).

7. Nursing Facility Discharge Management (CPT Codes 99315 and 99316)

The nursing facility discharge day management codes are used to report the total duration of time spent by a physician or other qualified health care professional for the final nursing facility discharge of a patient. These services require a face-to-face encounter which may be performed on a calendar day prior to the actual discharge date. CMS proposes that CPT codes 99315 and 99316 can be reported for a patient who has expired only if the physician or qualified NPP personally performed the death pronouncement.

CMS proposes the RUC-recommended work RVU of 1.50 for CPT code 99315 and 2.50 for CPT code 99316. CMS also proposes the RUC-recommended direct PE inputs for these codes (Table 13). CMS proposes that prolonged services would not be reported with nursing facility discharge management codes.

8. Annual Nursing Facility Assessment (CPT Code 99318)

CPT code 99318 (Annual nursing facility assessment) was recommended for deletion for 2023. Because CPT codes 99308-99310 could be used to report the required annual visit, CMS proposes to accept CPT's deletion of 99318. The RUC recommended that 10 percent of the utilization of CPT code 99318 would go to 99308, 85 percent of the utilization would go to 99309, and 5 percent of the utilization would go to 99310.

CMS is concerned that without this code, CMS would not have a way to track how often the required annual visit is performed. **CMS requests comments on whether there is a need to keep CPT code 99318 for Medicare purposes**.

9. Home or Residence Services (CPT Codes 99341, 99342, 99344, 99345, 99347-99350)

For 2023, the home and domiciliary E/M code family will be revised to include services provided in assisted living facilities, group homes, custodial care facilities, residential substance abuse treatment facilities and the patient's home. The domiciliary and rest home CPT codes were combined with the home visit CPT codes to create a single family of CPT codes. CPT also revised the descriptors to allow reporting that is based on time or MDM.

CMS proposes the RUC-recommended work RVUs for all eight codes in the family (Table 12). The RUC survey time includes pre-service time 3 days before the date of encounter, intraservice time on the date of encounter, and 7 days of post-service time. CMS proposes the RUC-recommended direct PE inputs for CPT codes 99345 and 99347-99350 (Table 13). CMS is concerned that CPT codes 99341, 99342, and 99342 have duplicative supplies and proposes to remove these supplies from the RUC-recommended direct PE inputs.

CMS proposes that prolonged home or residence services would be reported with GXXX3. The code would be used when the total time (in the time file) is exceeded by 15 or more minutes; each additional 15 minutes would be billed. GXXX3 would not be reported for any time unit less than 15 minutes. GXXX3 would be billed for each additional 15 minute increment of time beyond the total time for CPT codes 99345 (126 minutes) and 99350 (97 minutes).

CMS proposes that the practitioner would include any prolonged service time spend within the survey timeframe, which includes the day before the visit, the day of the visit, and up to and including 7 days after the visit (see summary Table 18 in section 11). CMS proposes to change the payment status for CPT codes 99358 and 99359 to "I" (Not valid for Medicare purposes. Medicare uses another code for reporting of, and payment for, these services).

10. Cognitive Assessment and Care Planning (CPT Code 99483)

The 2023 descriptor time for CPT code 99843 will be increased from 50 to 60 minutes typical time. CMS does not accept the RUC-recommended work RVU of 3.5 and proposes a slight increase from the current 3.80 to 3.84 to account for the increase in physician time. CMS proposes the RUC-recommended PE inputs (Table 13). CMS proposes that prolonged services would not be reported with CPT code 99483.

11. Prolonged Services Valuation

Prolonged Services with Direct Patient Contact (CPT Codes 99354-99357). The CPT Editorial Panel is deleting CPT codes 99354-99357. CMS proposes to accept this deletion and as previously discussed, proposes GXXX1-GXXX2 to report these services.

Prolonged Services on a Different Date than the E/M (CPT Codes 99358-99359). The RUC resurvey and provided recommendations for these codes. CMS proposes to assign an inactive status for these codes.

Prolonged Services Clinical Staff Services (CPT Codes 99415 and 99416). These codes describe prolonged clinical staff services provided in addition to an office E/M visits. CMS proposes the RUC-recommended direct PE inputs (Table 13).

HCPCS Codes GXXX1-GXXX3. CMS proposes that these three codes be valued identically across settings, based on the RUC recommended work RVUs of 0.61 for CPT code 99417. CMS also proposes direct PE inputs for these three codes that are identical to the RUC-recommended PE inputs for CPT code 99417 (Table 13). CMS will continue to use HCPCS code G2212 (prolonged O/O E/M) instead of CPT code 99417.

Table 18, reproduced below, summarizes these proposals. proposed rules for reporting Other E/M prolonged services by physicians or NPPs.

Table 18: Summary of Proposed Time Threshold to Report Other E/M Prolonged Services

Primary E/M Service	Prolonged Code*	Time Threshold to Report Prolonged	Count physician/NPP time spent within this time period (surveyed timeframe)
Initial IP/Obs. Visit (99223)	GXXX1	105 minutes	Date of visit
Subsequent IP/Obs. Visit (99233)	GXXX1	80 minutes	Date of visit
IP/Obs. Same-Day Admission/Discharge (99236)	GXXX1	125 minutes	Date of visit to 3 days after

Table 18: Summary of Proposed Time Threshold to Report Other E/M Prolonged Services			
Primary E/M Service	**Prolonged Code***	**Time Threshold to Report Prolonged**	**Count physician/NPP time spent within this time period (surveyed timeframe)**
IP/Obs. Discharge Day Management (99238-9)	n/a	n/a	n/a
Emergency Department Visits	n/a	n/a	n/a
Initial NF Visit (99306)	GXXX2	95 minutes	1 day before visit + date of visit +3 days after
Subsequent NF Visit (99310)	GXXX2	85 minutes	1 day before visit + date of visit +3 days after
NF Discharge Day Management	n/a	n/a	n/a
Home/Residence Visit New Pt (99345)	GXXX3	141 minutes	3 days before visit + date of visit + 7 days after
Home/Residence Visit Estab. Pt (99350)	GXXX3	112 minutes	3 days before visit + date of visit + 7 days after
Cognitive Assessment and Care Planning	n/a	n/a	n/a
Consults	n/a	n/a	n/a
* Time must be used to select visit level. Prolonged service time could be reported when furnished on any date within the primary visit's surveyed timeframe and would include time with or without direct patient contact by the physician or NPP. Consistent with CPT's approach, we would not assign a frequency limitation.			

12. Consultations (CPT Codes 99241-99255)

CMS stopped paying for the consultation codes in 2010. CMS did not review the RUC recommendations for these codes.

13. Payment for Multiple Same-Day Visits

Chapter 12 of the Medicare Claims Processing Manual includes many longstanding policies regarding when more than one Other E/M visit can be billed by the same practitioner for the same patient on the same date of service. CMS proposes continuing these policies.

14. Split (or Shared) Services

In the 2022 PFS final rule[36], 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. After consideration of comments, CMS finalized a phased in approach to the definition of substantive portion of the visit. For 2022, CMS finalized 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.

CMS continues to hear concerns about the implementation of this policy and receives requests to recognize MDM as the substantive portion of the visit. After consideration, CMS proposes to delay implementation of its definition of the substantive portion as more than half of the total

[36] 86 FR 65150-65159

time of the visit until January 1, 2024. CMS continues to believe that time is the appropriate basis for the definition of substantive portion of the visit but 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 allows additional time to evaluate this policy.

CMS proposes to amend the regulations text at §414.140 to revise the definition of substantive portion and note the current definition of substantive portion applies for visits other than critical care visits in 2022 and 2023. For visits other than critical care visits furnished in 2022 and 2023, substantive portion means one of the three key components (history, exam or MDM) or more than half of the total time spent by the physician and NPP performing the split (or shared) visit.

Technical Correction to the Conditions for Payment: Split (or Shared) Visits. CMS discovered an inadvertent typographical error in the instructions used to codify the new regulations at §414.140. CMS proposes to amend part 415 subpart D by removing the regulations at §414.140 and relocating that section to subpart C.

Technical Correction for Split (or Shared) Critical Care Services. In the 2022 PFS final rule, starting at 86 FR 65159, CMS finalized a number of billing policies for critical care CPT codes 99291 and 99292. At 86 FR 565162, CMS stated in error, "the billing practitioner would first report CPT code 99291 and, if 75 or more cumulative total minutes were spent providing critical care, the billing practitioner could report one or more units of CPT code 99292". CMS intended to state that CPT code 99292 could be billed after 104, not 75, or more cumulative total minutes were spent providing critical care. CMS correctly stated elsewhere in the 2022 PFS final rule the 104 minutes cumulative total time. CMS' policy is that CPT code 99291 is reportable for the first 30-74 minutes of critical care services and CPT code 99292 is reportable for additional 30-minute time increments furnished to the same patient (74 + 30 = 104 minutes).

CMS clarifies that its policy is the same for critical care whether the patient is receiving care from one physician, multiple practitioners in the same group and specialty who are providing concurrent care, or physicians and NPPS who are billing critical care as a split (or shared) visit.

G. Geographic Practice Cost Indices (GPCI)

1. GPCI Update

As required by statute,[37] 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.[38] If more than 1 year has elapsed since the last date of the last previous GPCI adjustment, the adjustment would be half of the adjustment that otherwise would be made. Since the previous GPCI update was implemented in 2020 and 2021, CMS proposes to phase in 1/2 of the latest GPCI adjustment in 2023 and the remaining ½ of the adjustment for 2024.

[37] Section 1848(e)(1)(A) of the Act.
[38] Section 1848(e)(1)(C) of the Act

For 2023, CMS proposes updated GPCI values. In addition to the GPCI values, CMS provides summarized geographic adjustment factors (GAFs). GAFs are a weighed composite of each PFS locality's proposed work, PE, and MP expense GPCIs using the national GPCI cost share weights. These are not used to determine payment for a particular service but are useful for comparing overall costs and payments across fee schedule areas.

Each of the three GPCIs relies on its own data source(s) and methodology for calculating its value as described below.

- The work GPCIs are designed to reflect the relative costs of physician labor by Medicare PFS locality. As required by statute, the work GPCI reflects one quarter of the relative wage differences for each locality compared to the national average. CMS calculates the work GPCIs using wage data for seven professional specialty occupation categories,[39] adjusted to reflect one-quarter of the relative cost differences for each locality compared to the national average, as a proxy for physicians' wages. By statute, there is a 1.0 floor for the work GPCI and a 1.5 work GPCI floor for services furnished in Alaska.[40] CMS proposes to use updated BLS Occupational Employment Statistics (OES) data (2017 through 2020) as a replacement for the 2014 through 2017 data to compute the proposed work GPCIs.

- The PE GPCIs are designed to measure the relative cost difference in the mix of goods and services comprising practice expenses (not including malpractice expenses) among the PFS localities as compared to the national average of these costs. The PE GPCIs are comprised of four component indices (employee wages; purchased services; office rent; and equipment, supplies and other miscellaneous expenses). CMS does not vary the medical equipment, supplies, and other miscellaneous index among physician localities (based on the rationale of a national market) assigning a value of 1.0 to each PFS locality. CMS proposes to use updated BLS OES data (2017 through 2020) to calculate the employee wage component and purchased service index of the PE GPCI. In calculating the proposed 2023 GPCI update for the office rent index component, CMS proposes to use the 2015 through 2019 American Community Survey (ACS) 5-year estimates (which proceeded any COVID-19 impacts).[41]

- The MP GPCIs measure the relative cost differences among PFS localities for the purchase of professional liability insurance (PLI). The MP GPCIs are calculated based on insurer rate filings of premium data for $1 million to $3 million mature claims-made policies (policies for claims made rather than services furnished during the policy term).

[39] CMS does not use physician wages in calculating the work GPCIs as this potentially introduces some circularity since Medicare payments contribute to overall physician wages.
[40] Section 1848(e)(1)(G) and Section 1848e(1)(E). The 1.0 floor for the work GPCI was most recently extended by section 101 of the Consolidated Appropriations Act of 2021 through 2023.
[41] CMS notes that it will examine 2020 data when it becomes available but will not consider using these data for the 2021 final GPCIS as the public would not have had an opportunity to comment.

CMS notes that the proposed 2023 MP GPCI update reflects premium data presumed in effect no later than December 31, 2020.

CMS proposes to continue using the current 2006-based MEI cost share weights for determining the proposed PE GPCI values. CMS notes that it is proposing to rebase and revise the MEI cost share weights for 2023 (section II. M of summary) but that it is proposing to maintain the use of the current 2006-based MEI cost share weights for the 2023 GPCIs. The proposed GPCI cost share weights for 2023 are displayed in Table 19 in the proposed rule (reproduced below).

Table 19: Proposed Cost Share Weights for 2023 GPCI Update			
Expense Category	**Current Cost Share Weight**	**Proposed 2023 Cost Share Weight**	**Rebased and Revised Cost Share Weights as Proposed in Section II.M**
Work	50.866%	50.866%	47.261%
Practice Expense	44.839%	44.839%	51.341%
- Employee Compensation	16.553%	16.553%	24.716%
- Office Rent	10.223%	10.223%	5.893%%
- Purchased Services	8.095%	8.095%	13.914%
- Equipment, Supplies, Other	9.968%	9.968%	6.819%
Malpractice Insurance	4.295%	4.295%	1.398%
Total	100.000%	100.000%	**100.000%**

CMS invites comment on the delay in implementation of the MEI cost share weights for the 2023 GPCIs and PFS ratesetting and how best to proceed with implementation of the rebased and revised MEI cost share weights in the future. CMS also solicits comments on specifically whether it should incorporate the rebased and revised MEI cost share weights into the 2024 GPCIs. If completed in 2024, CMS would not be required by statute to phase-in the adjustment over 2 years, but if it applied them in 2025 the adjustment would occur over 2 years.

With respect to the PE GPCI floor for frontier states, there are no changes in the states identified as Frontier States for 2023.[42] The qualifying states are: Montana, Wyoming, North Dakota, South Dakota, and Nevada. In accordance with statute, CMS would apply a 1.0 PE GPCI floor for these states in 2023.

In calculating GPCIs for the U.S. territories, CMS currently uses two distinct methodologies—one for Puerto Rico and the Virgin Islands, and a second approach for the Pacific Islands (Guam, American Samoa, and Northern Marianas Islands). As finalized in the 2017 PFS final rule, CMS assigns the national average of 1.0 to each GPCI index for both Puerto Rico and the Virgin Islands. For the Pacific Island territories (Guam, American Samoa, and Northern Marianas Islands), CMS assigns the Hawaii GPCI values for each of the three GPCIs.

[42] In general, a frontier state is one in which at least 50 percent of the counties are "frontier counties," which are those that have a population per square mile of less than 6.

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.[43] CMS refers readers to the 2017 PFS final rule (81 FR 80267) for a detail discussion of this issue.

Those fee schedule areas that were in the rest-of-state locality (as of 2013) and locality 3 (Marin, Napa, and Solano counties) are part of a transition area as defined by statute (section 1848(e)(6)(D) of the Act). As such, GPCI values used for payment in a transition area are to be phased in over 6 years, from 2017 through 2021, using a weighted sum of the GPCIs calculated under the new MSA-based locality structure and the GPCIs calculated under the current PFS locality structure. These areas fully transitioned to MSA-based locality structure in 2022.

Section 1848(e)(6)(C) of the Act also establishes a hold harmless for transition areas beginning with 2017 whereby the applicable GPCI values for a year under the new MSA-based locality structure may not be less than what they would have been for the year under the current locality structure. There are a total of 58 counties in California, 50 of which are in transition areas and thus subject to the hold harmless provision. The hold harmless requirement is not time-limited and in still in effect. For purpose of calculating budget neutrality, CMS uses an approach consistent with its implementation of the GPCI floor provisions.

CMS proposes a technical refinement that would change the number of distinct fee schedule areas for payment purposes in California from 32 to 29. **It seeks comment on the proposed technical refinements to consolidate unique fee schedule areas and their locality numbers in California where the unique localities are not operationally necessary.** For example, CMS is proposing to identify the Los Angeles-Long Beach-Anaheim MSA, containing Orange County and Los Angeles County, by one unique number, 18, as opposed to two, thus retiring locality number 26, as it is no longer needed. The changes, if finalized, would not have any payment implications under the PFS.

3. Refinements to the GPCI Methodology

In the process of calculating GPCIs for the purposes of this proposed rule, CMS identified four technical refinements to the methodology that it states yield improvement over the current method.

[43] 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 proposed changes to California localities).

- Proposes the addition of two new occupation groups (and their corresponding occupation codes), Management Occupations and Business and Financial Operation Occupations, to the preexisting seven occupation groups for 2023 (Table 20 in the proposed rule).
- Proposes to add four occupation codes to the Computer, Mathematical, Life and Physical Science group, and three occupation codes to the Social Science, Community and Social Service, and Legal group (Table 21 in the proposed rule).
- Proposes to modify the list of occupation codes used within the first PE GPCI component, Employee Wages, to more closely conform to the clinical labor categories used in PFS ratesetting. Adds six occupation codes listed as sources for clinical labor rates used to establish PE RVUs.
- Proposes a technical refinement to the method used to calculate each locality's GAF. Instead of using the 2006-based MEI cost share weights, CMS plans to calculate the weights based on Medicare utilization data from 2020.

CMS discusses in much detail in the proposed rule alternatives considered relative to the use of the American Community Survey (ACS) data for office rent index. Commenters have commented in the past that CMS should collect commercial rent data and use it to either as the basis for measuring geographic differences in physician office rents, or if this is not possible use it to validate the residential rents as a proxy for physician office rents. It developed five criteria to analyze the potential data sources: (1) applicability to planned use; (2) standardization of the measure; (3) potential bias; (4) geographic scope, distribution, and granularity of the data; and (5) availability, continuity, and price of the data. It identified eight data sources for analysis as potential alternatives to the ACS, but all failed to meet one or more of the five key criteria that would allow it to better reflect geographic cost variation for the office rent component of the PE GPCI that is currently measured using the ACS.

After analysis of alternatives to the ACS data, CMS concludes that there is still no acceptable national data source available for physician office or other comparable commercial rents. Thus, it proposes to continue to use county-level residential rent data from the ACS as a proxy for the relative cost differences in commercial office rents for the proposed 2023 update.

4. Proposed GPCI Update Summary

The proposed 2023 updated GPCIs for the first and second year of the 2-year transition, along with the GAFs, are displayed in Addenda D and E to the proposed rule. This is available on the CMS website at https://www.cms.gov/files/zip/cy-2023-pfs-proposed-rule-gpci-public-use-files.zip.

H. Determination of Malpractice Relative Value Units (MP RVUs)

1. Overview

Section 1848(c) of the Act requires that each service paid under the PFS be comprised of three components: work, PE, and MP expense. By way of background, the resource-based formula to determine the MP for a given service is comprised of three major components: (1) specialty-level

risk factors derived from data on MP premiums incurred by practitioners, (2) service-level risk factors —or the mix of practitioners providing the service—compared to all other specialties, and (3) intensity/complexity based on either the higher of the work RVU or clinical labor portion of the direct PE RVU for the service.[44] In 2015, CMS implemented the third comprehensive five-year review and update of MP RVUs, which updated each specialty's risk factor based upon updated insurance premium data. In 2016, CMS finalized a policy to conduct annual MP RVU updates to reflect changes in the mix of practitioners providing services (using Medicare claims data) and to adjust MP RVUs for intensity and complexity (using the work RVU or clinical labor RVU). CMS also finalized a policy to modify the specialty mix assignment methodology by using an average of the 3 most recent years instead of the most recent year of data.

In 2020, CMS implemented the fourth review and update of the MP RVUs (84 FR 40504 through 40510). For the 2020 update of MP RVUs CMS finalized a policy to align the update of MP premium data with the update to the MP GPCIs to increase efficiency. Effective beginning in CY 2020, CMS' policy is to review, and if necessary, update the MP RVUs at least every 3 years, similar to its review and update of the GPCIs.

2. Methodology for the Proposed Revision of Resource-based Malpractice RVU

a. General Discussion

CMS calculated the MP RVUs that it is proposing using updated malpractice premium data obtained from state insurance filings. The methodology CMS proposes to use for the 2023 review and update largely parallels the approach CMS used in the 2020 update. CMS is incorporating several methodological refinements as described below. CMS uses four data sources in its calculation of MP RVUs: malpractice premium data in effect as of December 31, 2020; 2020 Medicare payment and utilization data; higher of the 2022 proposed work RVUs or the clinical labor portion of the direct PE RVUs; and 2022 MP GPCIs.

Malpractice premium data were obtained from the insurers with the largest market share in each state and was collected from all 50 states and the District of Columbia. Malpractice premiums were collected for coverage limits of $1 million/$3 million, mature, claims-made policies. Premium data were included for all physicians and nonphysician practitioner (NPP) specialties, and all risk classifications that were available in the rate filings.

b. Proposed Methodological Refinements

CMS proposes two methodological refinements: (1) Improving its current imputation strategy to develop a more comprehensive data set, and (2) Creation of a risk index for the calculation of MP RVUs.

[44] The specialty risk factors are intended to capture differences in the risk of professional liability and the cost of malpractice claims faced by different specialties. The specialty weight and work value for a given service allows for differences in the risk of professional liability and cost of malpractice claims to be allocated to a particular service.

CMS is proposing to further refine its strategy for imputing risk factor values for specialties that have incomplete data during the data collection process by using rates mapped from the more commonly reported specialty within risk class as opposed to excluding underrepresented filing data. CMS provides the following example. For example, Hospice and Palliative Care is typically assigned the same risk class as Internal medicine. Rather than excluding hospice and palliative care because there is insufficient data, CMS would use Internal Medicine rates in filings that did not explicitly report Hospice and Palliative Care. By doing so, CMS believe that it will retain more data utilizing this small improvement.

It is also proposing to utilize a true MP risk index as opposed to derived risk factors when calculating MP RVUs. CMS notes that historically it has used a risk factor (ratio of a specialty's national average premium to a single reference specialty). This denominator has typically been based on the national average premium for the Allergy/Immunology specialty, which has had the lowest average premium for 2017 and 2020. The proposed risk index would be calculated as a ratio of the specialty's national average premium to the volume-weighted national average premium across all specialties. CMS believes this change will increase consistency with the calculation of MP RVUs, so that changes in the MP risk index reflect changes in payment, as opposed to changes relative only to the specialty with the lowest national average premium. This change should not impact the pricing of services in the PFS.

c. Steps for calculating Malpractice RVUs

CMS calculation of the proposed MP RVUs follows the same conceptual specialty-weighted approach used in the 2015 update, along with the proposed methodological improvements. The specialty-weighted approach for the MP RVUs for a given service is based on a weighted average of the risk factors of all specialties furnishing the service. CMS describes the five steps used for calculating the MP RVUs.

Step 1: Compute a preliminary national average premium for each specialty

CMS maps insurance rate area malpractice premiums for each specialty to the county level. The specialty premium for each county is then multiplied by its share of the total U.S. population (from the U.S. Census Bureau's 2015-2019 American Community Survey (ACS) 5-year estimates). This calculation is then divided by the average MP GPCIs across all counties for each specialty to yield a normalized national average premium for each specialty.

Step 2: Determine which premium service risk groups to use within each specialty

CMS determined that there was sufficient data for surgery and non-surgery premiums, as well as sufficient differences in rates between classes for 17 specialties (there were 15 such specialties in the 2020. The 2023 update uses the same structure of specialty/service risk group as the previous update except that Unknown Physician Specialty (99) is now divided into surgery and non-surgery groups. Table 26 shows the specialties subdivided into service risk groups.

Table 26: Proposed Specialties Subdivided into Service Risk Groups	
Service Risk Groups	**Specialties**
Surgery/No Surgery	Otolaryngology (04), Cardiology (06), Dermatology (07), Gastroenterology (10), Neurology (13), Ophthalmology (18), Cardiac Electrophysiology (21), Urology (34), Geriatric Medicine (38), Nephrology (39), Endocrinology (46), Podiatry (48), Emergency Medicine (93) Unknown Physician Specialty (99)
Surgery/No Surgery/OB	General Practice (01), Family Practice (08), OB/GYN (16)

Step 3: Calculate a risk factor for each specialty

As noted above, the relative differences in national average premiums between specialties are expressed in its methodology as a specialty-level risk index. These risk index values are calculated by dividing the national average premium for each specialty by the volume weighted national average premium across all specialties. For specialties with sufficient surgical and non-surgical premium data, CMS calculated both a surgical and non-surgical risk index value. It completed the same steps for other specialties with service risk subgroups.

Table 27 in the proposed rule shows the risk index values for all specialties by specialty type and service risk group.

Step 4: Calculate malpractice RVUs for each CPT/HCPCS code.

In this step, CMS calculates malpractice RVUs for each CPT/HCPCS code. Using 2020 utilization data, CMS identifies the percentage of services furnished by each specialty for each code. This percentage is then multiplied by each respective specialty's risk index factor (as calculated in step 3). The products for all specialties from these calculations are added together to derive the weighted malpractice costs across all specialties furnishing that service. This service specific risk factor is then multiplied by the greater of the work RVU or clinical labor portion of the direct PE RVU for that service.

Based on the methodology refinements discussed above, CMS now has specialty-specific data for many more specialties. CMS notes, however, that the new data produce premiums and risk index values that are significantly lower for some specialties that the ones it applied in the absence of sufficient specialty-specific data. Given its potential negative impact, CMS is proposing to phase in the reduction in MP RVUs over the 3 years that precedes the next update, by 1/3 of the change in MP RVUs for those specialties in each year that have a 30 percent or more threshold reduction in risk index values as a result of the update.

CMS continues to use service level overrides to determine the specialty for low volume procedures for both PE and MP calculations, as finalized in the 2018 PFS final rule (82 FR 53000-53006).

The proposed list of codes and expected specialties is available on its website. It also includes the list of specialties that would be subject to the phase-in under this proposed policy.[45]

Step 5: Rescale for budget neutrality

The final step applies a budget neutrality adjustment. This scaling is necessary to maintain the work RVUs for individual services from year to year while also maintaining the overall relationship among work, PE, and MP RVUs. In this adjustment, CMS includes all specialties in its calculation.

The proposed resource based MP RVUs are shown in Addendum B, which is available on the CMS website at https://www.cms.gov/files/zip/cy-2023-pfs-proposed-rule-mp-risk-index-premium-amounts-specialty.zip.

Estimates of the impact on payment can be found in the Regulatory Impact Section. Overall, the impact of these changes was minimal at the specialty level, though changes could be larger for certain services. Radiology is expected to obtain a 2 percent decrease in Medicare payments based on the MP RVU changes, and several specialties (audiologist, clinical psychologist, clinical social worker, nuclear medicine, and physical/occupational therapy) are expected to see a 1 percent decrease. Several specialties are expected to see small increase in MP RVUs of 1 percent (critical care, emergency medicine, infectious disease, internal medicine, neurosurgery, and pulmonary disease).

I. Non-Face-to-Face Services/Remote Therapeutic Monitoring (RTM) Services

The RTM codes is a family of five codes that includes three PE-only codes and two codes that include professional work. In the 2022 PFS final rule[46], CMS finalized payment for the three PE-only RTM codes: CPT code 98975 (RTM, initial set-up and patient education); CPT code 99876 (RTM, device supply & transmission for respiratory system) and CPT code 99877 (RTM, device & transmission for musculoskeletal system). CMS also finalized payment for the two CPT codes for RTM treatment management codes (98980 and 98981) based on the RUC-recommended values for work and direct PE inputs.

CMS was concerned that the treatment management codes included clinical labor and considered these codes as "incident to" services which cannot be billed independently by physical therapists and other practitioners who are not physicians or NPPs. "Incident to" serves are an integral part of the physician's professional service and only physicians and certain other practitioners are authorized to furnish and bill incident to services.[47] In addition, RTM codes required direct supervision by the billing practitioner. Commenters stated that direct supervision was

[45] See https://www.cms.gov/files/zip/cy-2023-pfs-proposed-rule-anticipated-specialty-assignment-low-volume-services.zip

[46] 86 FR 65114-65117

[47] The CMS Benefit Policy Manual, Chapter 15 (sections 60.1A and 60.1B) defines "incident to" services as services that are an integral, although incidental, part of the physician's professional service; commonly rendered without charge or included in the physician's bill; of a type that are commonly furnished in physician's offices or clinics; and furnished by the physician or by auxiliary personnel under the physician's direct supervision.

burdensome and suggested CMS designate these codes as care management services which only require general supervision or develop HCPCS G codes that would allow services to be furnished under general supervision.

For 2023, CMS proposes four HCPCS G codes with a pair for RTM treatment management services provided by physician or NPP and another pair for RTM assessment services (Table 20, reproduced below with modifications). CMS did not develop a generic RTM device code and requests comments about RTM devices that are used to deliver services that meet the "reasonable and necessary" standard for Medicare coverage. **Specifically, CMS seeks information about the following issues**:

- The types of data collected using RTM devices;
- How the data collected solve specific health conditions and what those health conditions are;
- The costs associated with RTM devices that are available to collect RTM data;
- How long the typical episode of care by condition might last; and
- The potential number of beneficiaries for whom an RTM device might be used by the health condition type.

Summary of Proposed HCPCS G Codes for Remote Therapeutic Monitoring Services		
HCPCS Code	**Code Descriptor**	**Proposed Work RVU**
GRTM1	RTM treatment management services, physician or NPP professional time over a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar; first 20 minutes - Report once each 30 days, regardless of the number of parameters remotely monitored - CPT codes 98975 and 98976 or 98977 must be billed prior to reporting GRTM1 and GRTM2 - At least 16 days of data must be reported - Do not report for services less than 20 minutes - Do not report in conjunction with 93264, 992457, 99458, 98980, 98981, GRTM3, GRTM4 - Do not report in the same calendar month as 99473, 99474	0.62
GRTM2	RTM treatment management services, physician or NPP professional time over a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar; each additional 20 minutes (List separately in addition to primary code) - Use GRTM2 in conjunction with GRTM1 - CPT codes 98975 and 98976 or 98977 must be billed prior to reporting GRTM1 and GRTM2 - Do not report for services less than 20 minutes - Do not report in conjunction with 93264, 992457, 99458, 98980, 98981, GRTM3, GRTM4	0.61
GRTM3	RTM treatment assessment services, first 20 minutes furnished personally/directly by a nonphysician qualified health care professional over a calendar month requiring at least one interactive communication with the patient/caregiver during the month - Report once each 30 days, regardless of the number of parameters remotely monitored - CPT codes 98975 and 98976 or 98977 must be billed prior to reporting GRTM1 and GRTM2	0.62

Summary of Proposed HCPCS G Codes for Remote Therapeutic Monitoring Services		
HCPCS Code	**Code Descriptor**	**Proposed Work RVU**
	- At least 16 days of data must be reported - Do not report for services less than 20 minutes - Do not report in conjunction with 93264, 992457, 99458, 98980, 98981, GRTM3, GRTM4 - Do not report in the same calendar month as 99473, 99474	
GRTM4	RTM treatment assessment services, each additional 20 minutes furnished personally/directly by a nonphysician qualified health care professional over a calendar month requiring at least one interactive communication with the patient/caregiver during the month (List separately in addition to primary code) - Use GRTM4 in conjunction with GRTM5 - CPT codes 98975 and 98976 or 98977 must be billed prior to reporting GRTM3 and GRTM4 - Do not report for services less than 20 minutes - Do not report in conjunction with 93264, 992457, 99458, 98980, 98981, GRTM1, GRTM2	0.61

RTM Treatment Management Services (GRTM1 and GRTM2)
CMS proposes that these codes include clinical labor activities that can be furnished by auxiliary personnel under general supervision. CMS proposes the work RVUs and direct PE inputs associated with CPT codes 98980 and 98981 and proposes CPT codes 98980 and 98981 would be non-payable by Medicare.

RTM Treatment Assessment Services (GRTM3 and GRTM4)
For the two proposed RTM assessment services codes (GRTM3 and GRTM4), CMS does not include "incident to" activities in the PE because these codes do not include clinical labor inputs in the direct PE. CMS notes this would facilitate RTM services furnished by qualified nonphysician healthcare professionals who cannot bill under Part B for services furnished incident to their professional services. CMS proposes the work RVUs currently finalized for CPT codes 98980 and 98981 and proposes CPT codes 98980 and 98981 would be non-payable by Medicare.

CMS notes that all the RTM codes, including GRTM3 and GRTM4, would be designated as "sometimes therapy" codes which allows billing outside a therapy plan of care by physicians and certain NPPs. However, when GRTM3 and GRTM4 are furnished by PTs, OTs, or SLPs, the services would always need to be furnished under a therapy plan of care.[48]

Review of new RTM device code: Cognitive Behavior Therapy Monitoring (CPT code 989X6)
For 2023, the CPT Editorial Panel replaced two Category III codes (0702T and 0703T) for RTM of a standardized online digital cognitive behavioral therapy program with Category I code 989X6. CPT code 989X6 is defined as *Remote therapeutic monitoring (e.g., therapy adherence, therapy response); device(s); supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor cognitive behavior therapy, each 30 days*.

[48] RTM services that relate to devices specific to therapy services should always be furnished under a therapy plan of care regardless of who provides them (Medicare Benefit Policy Manual, Chapter 15, Section 230).

CPT code 989X6 is a PE-only device code. CMS proposes to accept the RUC recommendation that this code should be contractor priced to learn more about the devices used to furnish this service.

CMS also notes that for 2023, the CPT Editorial Panel also revised the descriptors for RTM codes 98975-98977 to include "cognitive behavioral therapy" as another example of the type of service described by the coding. The RUC considered this to be an editorial revision and the codes did not need to be revalued.

J. Payment for Wound Care Management Products (Skin Substitutes)

1. Background

Stakeholders have expressed concerns that CMS' policies for "wound care management products" (currently known as "skin substitutes") are inconsistent as follows:

- Coding: Some products have Q codes while others have A codes—ostensibly Q codes are biological products while A codes are for synthetics, although even this distinction has not been consistent.
- Payment: In the physician office setting, some of these products are priced using average sales price (ASP)+6 percent while others are contractor priced.
- Packaged/Separate Payment: Under the outpatient prospective payment system (OPPS), CMS packages payment into the application procedure but pays separately for the products in physician offices.

CMS is proposing to revise its payment policies for wound care management products with the following objectives:

1. Ensuring a consistent payment approach across the physician office and hospital outpatient department settings;
2. Ensuring that all products are assigned an appropriate HCPCS code;
3. Using a uniform benefit category across products within the physician office setting regardless of whether the product is synthetic or biological; and
4. Maintaining clarity for interested parties.

2. Proposals

Changing the Terminology. CMS proposes to use the term "wound care management products" in place of "skin substitutes." The proposed rule indicates that these products do not actually function like human skin that is grafted onto a wound. Instead, these products are applied to wounds to aid healing through various mechanisms of action to regenerate lost tissue.

"Wound care products" does not include bandages or standard dressings that are assigned to either the high-cost or low-cost wound care product groups under the OPPS. Bandages and standard dressings are not reported with either CPT codes 15271 through 15278 or HCPCS codes C5271 through C5278 that are for application of a wound care management product.

The proposed rule indicates that the terms "care management" or "management" are not intended include E/M or care management codes (99424-99427, 99437, 99439, 99487, 99489, 99490-99491), or G-codes that describe care management services. The proposed terms would describe a category of items or products, not a type of service.

Revising Payment. CMS acknowledges that it has inconsistent payment policies for different types of wound care management products in the physician office setting (contractor pricing or ASP+6 percent). These inconsistencies arose over time as CMS treated wound care management products as biologicals when it initially established ASP pricing in 2005. Synthetic wound care products are a more recent innovation in wound care management products. CMS has not been treating synthetic wound care products as biologicals, resulting in the pricing inconsistency that has caused CMS to reexamine its policies.[49]

CMS acknowledges the overlap in purpose between synthetic and biological wound care products. As a result, CMS proposes to establish a consistent pricing policy for all wound care management products used in physician office setting by categorizing them as "incident to supplies" under section 1861(s)(2)(A) of the Act effective January 1, 2024. Under the proposal, CMS would no longer pay separately for skin substitute products under the ASP+6 percent payment methodology in the physician office setting. Treating these products as incident to supplies would mean that the resource costs for these products would be included in establishing PE relative value units for the associated physicians' service with which they would be furnished.

CMS would not implement the policy until January 1, 2024 to allow for changes in coding proposed elsewhere in the rule. Under the coding policy proposal, CMS would continue to pay using ASP+6 percent for wound care management Q codes for all of 2023. However, CMS proposes to retire all wound care management Q codes by January 1, 2024 while providing 12 months from January 1, 2023 for interested stakeholders to apply for A codes for wound care management products. For all wound care management products meeting the criteria for a HCPCS Level II code, CMS proposes contractor pricing these codes effective January 1, 2024.[50]

K. Audiologists Furnishing Certain Diagnostic Tests Without a Physician Order

Under section 1861(ll)(3) of the Act, audiologists may provide and be paid under Medicare Part B for hearing and balance assessment services as the audiologist is legally authorized to perform under state law, as would otherwise be covered if the services were furnished by a physician. Section 1862(a)(7) of the Act excludes payment for hearing aids and related examinations whether performed by an audiologist or any other practitioner.

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[49] While this statement is accurate, CMS' policies have been inconsistent in recent years with respect to biologic wound management products, e.g., older products are priced as drugs and biologicals while newer products are contractor-priced.

[50] HPA is seeking clarification from CMS as the proposed rule appears internally inconsistent. Earlier, CMS says that payment for wound care management products would be bundled into the physician fee schedule payment for the application procedure. Later, it says that these products will be contractor priced beginning January 1, 2024 once HCPCS "A" codes are established for all wound care management products.

Longstanding Medicare policy requires that all diagnostic tests, including audiology tests, be ordered by a physician or non-physician practitioner (NPP)[51] who is treating the beneficiary and will use the results to manage the beneficiary's care. NPPs (but not physicians) must accept Medicare payment on an assignment-related-basis and may only collect 20 percent coinsurance from the beneficiary. Since 2008, CMS has allowed audiologists to enroll in Medicare and bill directly for diagnostic tests directly, but audiologists are not required to accept assignment and may charge beneficiaries 15 percent over the Medicare physician fee schedule amount.

Over the past several years, CMS has been asked to eliminate the physician/NPP order requirement for hearing and balance assessment services furnished by audiologists. According to the requestors, Medicare would realize savings over 10 years of approximately $108 million, which includes a savings of $36 million in beneficiary copayments from beneficiaries not being required to have a visit with a physician or NPP that orders audiology services. These requestors indicate eliminating the order requirement would be consistent with the policies of other payers such as Medicare Advantage plans, Medicaid, plans under the Federal Health Benefit Program, and the Veterans Administration.

CMS remains concerned that audiologists are not recognized under Medicare Part B to treat or manage the patient. Absent the order requirement, the audiologist will have no obligation to refer the patient to a physician or NPP and the audiology test results may not be used in managing the beneficiary's medical condition and the services will not be medically necessary. Furthermore, CMS remains concerned about patient safety if Medicare beneficiaries seek hearing and balance services directly from audiologists as the beneficiary may have an acute condition or symptom that needs to be diagnosed and treated by a physician or NPP. There are a wide variety of possible causes of disequilibrium that could be potentially life threatening (for example, stroke, heart attack, arrythmias) that speak to the importance of a physician or NPP being involved in the initial patient assessment.

For these reasons, CMS believes that patients with disequilibrium would be best served by seeing a physician or NPP before being referred to an audiologist. CMS also believes that without the order requirement, direct access to audiologists might incent overutilization of audiology services that are not subject to assignment and could lead to higher beneficiary costs both through additional coinsurance and balance billing.

Nevertheless, CMS believes it would be appropriate to provide a limited exception to the order requirement for diagnostic hearing testing services furnished by audiologists to broaden patient access to these services. CMS proposes to remove the order requirement for non-acute hearing conditions other than balance assessments for patients with disequilibrium. Table 29 of the proposed rule provides a list of services that CMS proposes an audiologist may furnish without the order of the treating physician or NPP. Vestibular tests that are typically used in balance assessments are excluded from Table 29.

[51] For this purpose, NPP means physician assistant, nurse practitioner, clinical nurse specialist, certified nurse midwife, qualified psychologist and clinical social worker.

CMS proposes to create HCPCS code GAUDX for audiology services performed without a physician/NPP order. This code may only be used for non-acute hearing assessment unrelated to disequilibrium that are not for the purpose of prescribing, fitting, or changing hearing aids. CMS proposes to limit use of this code to once every 12 months per beneficiary. The proposed 12-month limitation was selected because 6 months did not seem long enough for a new, non-acute hearing condition to arise, and if an acute hearing condition were to manifest, it would necessitate an evaluation with a physician/NPP. Additionally, beneficiaries may always elect to see their physician/NPP for any hearing conditions ─ acute or non-acute ─ or for conditions with disequilibrium symptoms.

This code would include and be used to bill for any number of audiology services furnished in an encounter with the beneficiary. No more than one unit of code GAUDX could be billed in a 12-month period.

CMS proposes to value HCPCS code GAUDX using the combined values of CPT codes 92557 (Comprehensive Hearing Test) and 92567 (Tympanometry), which CMS believes would represent a typical service provided by audiologists. CMS utilization data indicates that HCPCS code 92557 represents 72 percent of all billings for audiologists. Including all physicians, NPPs and audiologists, HCPCS code 92557 is billed with code 92567 over 60 percent of the time, and code 92567 is billed with code 92557 over 83 percent of the time in the same clinical encounter.

CMS proposes:

- Total work RVUs of 0.8 for GAUDX (the sum of a 0.60 work RVU for CPT code 92557 and 0.20 work RVU for CPT code 92567);
- Practice expense inputs of:
    - Supplies: two SD046 (Ear tip, tympanometry probe), two SJ053 (Swab pad, alcohol), one SM0251 (Specula tips, otoscope), one (SK059) sheet of recording paper, and two SD047 (Ear tip insert with sound tube);
    - Equipment: EQ054 (Audiometric soundproof booth (exam and control room)) for 20 minutes, EQ053 (Audiometer, clinical, diagnostic) for 20 minutes, and EQ244 (Tympanometer with printer) for 4 minutes.

L. Payment for Dental Services

1. Background on Medicare Payment for Dental Services

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 (referred to collectively in the proposed rule as "dental services"). That section of the statute also includes an exception to allow payment to be made under Medicare Part A for inpatient hospital services in connection with the provision of dental services if the individuals, because of their underlying medical condition and clinical status or because of the severity of the dental procedure, require hospitalization in connection with the provision of such services. 42 CFR § 411.15(i) codifies this provision of statute.

CMS will make payment under both Medicare Part A and Part B when a dentist furnishes dental services that are an integral part of the covered primary procedure or service furnished by another physician treating the primary medical illness. The Medicare Benefit Policy Manual (IOM Pub 100-02, Chapter 15, section 150) and the Medicare National Coverage Determinations Manual Chapter 1, Part 4 (IOM Pub 100-03, Chapter 1, Part 4, section 260.6) list examples of when Medicare can make payment for dental services.[52] CMS has received requests to broaden the list of dental services that Medicare will cover when they are directly related to the clinical success of an otherwise covered medical service under Medicare Parts A and B.

2. Request for Comment on Inpatient Dental Services

As indicated above, section 1862(a)(12) of the Act provides an exception to the dental services exclusion when hospitalization is required because of (1) a patient's underlying medical condition and clinical status or (2) the severity of the dental procedure. CMS requests public comments on professional services, including, but not limited to dental services that may occur during and prior to the patient's hospitalization or procedure requiring hospitalization under this exception. CMS may consider finalizing, based on its review of public comments, additional exceptions to the dental services exclusion.

3. Clarifying the Inpatient Dental Services Exception

CMS indicates that some dental services that would ordinarily be excluded by statute from payment are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services. In these circumstances, CMS proposes to interpret section 1862(a)(12) of the Act to permit Medicare payment under Parts A and B for dental services regardless of whether the services are furnished in an inpatient or outpatient setting. CMS indicates that the examples of covered dental services furnished in connection with other medical services in the Medicare Benefit Policy Manual (the MBP Manual) and the Medicare Coverage Determinations Manual (the NCD Manual) reflect this interpretation.

The NCD Manual states that, when performing a dental or oral examination prior to renal transplant surgery, a dentist is not recognized as a physician under section 1861(r) of the Act. However, this statement is inconsistent with section 1861(r) of the Act that recognizes dentists as physicians and with other manual provisions. As such, CMS proposes to amend 42 CFR § 411.15(i) to clarify that Medicare Part B coverage and payment can be made for a dental or oral examination prior to renal transplant surgery when performed by a dentist as defined in section 1861(r)(2) of the Act.

[52] The examples include the wiring of teeth when done in connection with a reduction of a jaw fracture, the extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease, an oral or dental examination on an inpatient basis performed as part of a comprehensive workup prior to renal transplant surgery, the reconstruction of a ridge when it is performed as a result of and at the same time as the surgical removal of a tumor (other than for dental purposes), and a dental splint when performed in conjunction with treatment that is determined to be a covered medical condition (the last example can be found in section 100 of the Medicare Benefit Policy Manual, Chapter 15).

The MBP Manual states that if an otherwise noncovered procedure or service is performed by a dentist as incident to and as an integral part of a covered procedure or service, the total service is covered. In all of the circumstances listed in the MBP and the NCD Manuals, CMS indicates that the dental services could be covered and paid, because they are inextricably linked to, and substantially related and integral to the clinical success of a covered medical service regardless of where the service is provided. As such, dental services in these circumstances would not be excluded from coverage under section 1862(a)(12) of the Act.

CMS proposes to modify the regulations text at 42 CFR § 411.15(i) to include each of these scenarios listed in the manuals as covered dental services and codify the following longstanding policies:

- Payment can be made for dental services provided in conjunction with medical services that are inextricably linked to, and substantially related and integral to the clinical success of, covered medical services, such as X-rays, administration of anesthesia, and use of the operating room; and
- Payment can be made for services and supplies furnished incident to other dental services for which Medicare payment can be made, for example, services furnished incident to the dentist's professional services by a dental technician or registered nurse under the dentist's direct supervision.

The proposed rule lists other examples of covered procedures and requests comment on:

- Whether its descriptions of dental services that were longstanding in the manual are clinically accurate and appropriate; and
- The propriety of performing any of the examples in inpatient or outpatient settings.

The proposed rule notes that CMS is not making any changes to its policy that dental services are not covered, regardless of complexity or difficulty, when the primary procedure is excluded from Medicare coverage.

4. Proposed Update to Current Payment Policies for Dental Services

CMS indicates that there may be additional circumstances that are clinically similar to the examples listed above where the dental services are inextricably linked to, and substantially related and integral to the clinical success of, the other covered medical service(s). CMS proposes to revise § 411.15(i)(3) to allow for coverage of dental services (and ancillary services such as x-rays, administration of anesthesia, and use of an operating room) when the patient has:

- An organ transplant;
- Cardiac valve replacement; or
- Valvuloplasty procedures.

In these circumstances, Medicare would cover dental services if the patient has an oral infection and success of the procedure could be compromised if the infection is not properly diagnosed and treated. Under the proposal, Medicare Parts A and B would make payment for these dental services, as applicable, regardless of whether the services are furnished in an inpatient or outpatient setting. Only dental services necessary for success of the covered procedure would be

covered. Additional dental services, such as a dental implant or crown that are not immediately necessary to eradicate the infection prior to surgery would not be covered.

Payable services would include:

- The dental or oral examination as part of a comprehensive workup prior to the procedure; and
- Necessary dental treatments and diagnostics to eliminate the infection.

CMS proposes to contractor-price the dental services until it has data to establish prospective payment rates. The proposed rule explicitly requests public comment on the expected utilization of these dental services.

5. Other Clinical Scenarios

CMS provides the following examples of additional clinical scenarios that may warrant coverage of dental services prior to:

- Treatments for head and neck cancers, such as radiation therapy with or without chemotherapy;
- The initiation of immunosuppressant therapy; and
- Joint replacement surgery (such as total hip and knee arthroplasty surgery).

The proposed rule indicates that the evidence is mixed regarding the need for a dental exam and necessary treatment prior to total joint replacement surgery. Therefore, CMS is interested in public comment providing systematic clinical evidence as to whether there is an inextricable link between dental service(s) and joint replacement surgery such that the dental services are substantially related and integral to the clinical success of the surgical procedures. If public comment provides compelling clinical evidence, CMS may allow Medicare coverage of dental services provided in conjunction with joint replacement surgery in the final rule.

CMS requests comment on other clinical scenarios where dental services are a critical clinical precondition to proceeding with the primary medical procedure and/or treatment, and therefore may be inextricably linked to, and substantially related and integral to the clinical success of the covered procedure. Based on public comments, CMS may consider including these additional clinical scenarios as examples of covered dental services in 42 CFR § 411.15(i)(3) in the final rule.

Under prior and proposed policies, Medicare will only pay for dental services that would occur either prior to, or contemporaneously with, the covered medical service. CMS requests comment whether there are clinical circumstances under which Medicare payment could be made for dental services furnished after the covered medical procedure or treatment.

6. Establishing a Process for Considering Additional Clinical Scenarios

CMS proposes to establish a process where the agency can consider additional clinical scenarios where Medicare would cover dental services that are inextricably linked to, and substantially

related and integral to the clinical success of, certain covered medical services. Under this process, CMS invites interested parties to provide relevant medical literature, clinical guidelines or generally accepted standards of care, and other supporting documentation to support CMS' review and consideration of the clinical scenario involving dental services. Information would be required annually by February 10 to allow CMS to consider the additional scenarios in its annual physician fee schedule rulemaking for the following calendar year. Information would be submitted to MedicarePhysicianFeeSchedule@cms.hhs.gov.

7. Dental Services Integral to Covered Medical Services and Improved Outcomes

There may be clinical scenarios where dental services are integral to improved patient outcomes but not inextricably linked to, or substantially related and integral to the clinical success of, the otherwise covered medical service. For example, medical care or treatment of a diabetic patient could be improved if certain dental services are furnished.

8. Request for Comment on Other Potentially Impacted Policies

CMS seeks comment on the following issues:

- Whether CMS' policies make clear that time spent by physicians or non-physician practitioners coordinating care with dentists may be counted towards the time requirements for applicable care management codes; and
- Coordination of dental benefits when Medicare beneficiaries have separate or supplemental dental coverage, such as through a Medigap plan or other plan offering.

9. Potential Future Payment Models for Dental and Oral Health Care Services

Under section 1115A(d)(1) of the Act, CMS may waive requirements of Medicare and certain Medicaid statute and regulations to develop models that improve care and/or reduce costs. In 2014, CMS made Health Care Innovation Awards (HCIA). Several participants used their HCIA Round 2 funds to test models of clinical care that included payment for dental and oral care services. CMS seeks comment on additional ways to integrate the payment for dental and oral health care services using its waiver authority including models focused on equity, care coordination, total cost of care, and specific disease conditions.

M. Revising MEI

1. Background

The MEI is a fixed-weight input price index, with an adjustment for the change in economy-wide, private nonfarm business multifactor productivity. This index is comprised of two broad categories: (1) physicians' own time; and (2) physicians' PE. Rebasing the MEI refers to moving the base year for the structure of costs, while revising relates to other types of changes, such as changing data sources, cost categories, or price proxies.

The current 2006-based MEI relies on data collected from the AMA for self-employed physicians from the Physician Practice Information Survey (PPIS). The AMA has not fielded

another survey since that 2006 data collection effort and so the MEI has continued to be based on 2006-based costs. It notes that the MEI cost weights have historically been used to update the GPCI cost share weights to weigh the four components of the practice expense GPCI (employee compensation, the office rent, purchased services, and medical equipment, supplies, and other miscellaneous items. It is also used to recalibrate the relativity adjustment to ensure that the total pool of aggregate PE RVUs remains relative to the pool of work and MP RVUs (as discussed in section II. B of this summary). The most recent recalibration was done for the 2014 RVUs, when the MEI was last updated.

CMS believes that the MEI cost weights need to be updated to reflect more current market conditions, but that it is proposing to delay the implementation of the proposed rebased and revised MEI cost weights for both PFS ratesetting and the proposed 2023 GPCIs. It believes that this will allows stakeholders the opportunity to review and comment on the proposed rebased and revised MEI cost share weights before CMS uses these weights for purposes of proportioning the work, PE, and MP RVU pools in PFS ratesetting and updating the GPCIs.

In this proposed rule, CMS is proposing to rebase and revise the MEI based on a methodology that uses publicly available data sources for input costs that represent all types of physician practice ownership; that is, not limited to only self-employed physicians. The following sections discuss CMS' proposals regarding derivation of the cost categories and associated cost share weights, selection of the price proxies in the MEI, and the results of the proposed 2017-based MEI as compared to the current 2006-based MEI are discussed.

2. Developing the Cost Weights for Use in the MEI

CMS proposes to use annual expense data collected from the U.S. Census Bureau's Services Annual Survey (SAS, https://www.census.gov/programs-surveys/sas.html) to develop the 2017-based MEI cost weights. It also considered and analyzed other potential sources of expense data for physician offices including the Bureau of Economic Analysis (BEA) Benchmark Input-Output data, the Internal Revenue Services (IRS) Statistics of Income data for sole proprietors, and Medical Group Management Association (MGMA) cost and revenue data. It concluded that the SAS data was the most technically appropriate data source available based on various factors including public availability, level of detail of expense categories, and sample representativeness of the universe. The SAS data are publicly available data that provide annual receipts estimates for the service industries. Collected data include sources of revenue and expenses by type for selected industries and selected industry-specific items. Specifically, CMS proposes to use the 2017 SAS data from Table 5, Estimated Selected Expenses for Employer Firms for NAICS 6211 (Office of Physicians).

CMS chose 2017 SAS data because the survey data collection in 2018 and 2019 were scaled back and therefore, data by expense category was limited. The 2020 SAS data were more comprehensive, but CMS was concerned that the presence of the PHE for COVID-19 raised questions regarding the representativeness and stability of the data given impacts on the utilization of physicians' services and associated expenses. Therefore, CMS proposes to use the 2017 SAS data for the proposed 2017-based MEI because it is the most recently available and complete data.

CMS also proposes to supplement the 2017 SAS expense data by using several data sources for further disaggregation of compensation costs and all other residual costs, including: the 2017 Bureau of Labor Statistics (BLS) Occupational Employment and Wage Statistics (OEWS), the 2012 BEA Benchmark Input-Output data(I/O), the 2006 AMA PPIS, and the 2020 AMA Physician Practice Benchmark Survey.

Table 30 (reproduced below) lists the set of mutually exclusive and exhaustive cost categories and weights for the proposed 2017- based MEI compared to the 2006-based MEI. Physician compensation is a lower share, practice expense is higher, and malpractice is lower in the proposed 2017-based MEI compared with the current 2006-based MEI. More technical details about the development of the cost weights for each cost category is provided in the proposed rule.

Table 30: Proposed 2017-based MEI and 2006-based MEI Cost Categories and Weights

Cost Category	Proposed 2017-based	Current 2006-based
MEI Total	**100.000%**	**100.000%**
Physician Compensation	**47.261%**	**50.866%**
Wages and Salaries	39.226%	43.641%
Benefits	8.034%	7.225%
Practice Expense	**52.739%**	**49.134%**
Non-physician Compensation	**24.716%**	**16.553%**
Non-physician Wages	**20.514%**	**11.885%**
Non-health, Non-physician Wages	12.306%	7.249%
Professional and Related	1.381%	0.800%
Management	2.171%	1.529%
Clerical	7.947%	4.720%
Services	0.807%	0.200%
Health related, Non-physician Wages	8.208%	4.636%
Non-physician Benefits	**4.202%**	**4.668%**
Other Practice Expense	**28.024%**	**32.582%**
Utilities	0.366%	1.266%
All Other Products	2.055%	2.478%
Telephone	0.471%	1.501%
Postage	-	0.898%
All Other Professional Services	**13.914%**	**8.095%**
Professional, Scientific, & Tech. Services	6.350%	2.592%
Administrative & Waste Services	2.341%	3.052%
All Other Services	5.223%	2.451%
Capital	**7.748%**	**10.310%**
Fixed Capital	5.527%	8.957%
Moveable Capital (including medical)	2.221%	1.353%
Professional Liability Insurance	**1.398%**	**4.295%**
Medical Equipment	-	1.978%
Medical Supplies	2.071%	1.760%

3. Selection of Price Proxies for Use in the MEI

CMS uses price proxies to ensure that the MEI accurately measures changes over time in prices paid by physician practices, changes in employee wage rates and employer costs, and other inputs used to derive the weights. Most of the proxy measures CMS considered are based on BLS data and are grouped into three categories:

- Producer Price Indices (PPIs): PPIs measure the average change over time in the selling prices received by domestic producers for their output. The prices included in the PPI are from the first commercial transaction for many products and some services (https://www.bls.gov/ppi/).

- Consumer Price Indices (CPIs): CPIs measure the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services (https://www.bls.gov/cpi/).

- Employment Cost Indices (ECIs): ECIs measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour.

CMS evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance and concluded that the proposed PPIs, CPIs, and ECIs selected meet these criteria. Table 37 (reproduced below) provides a detailed explanation of the price proxies that CMS proposes to use for the proposed 2017-based MEI. Almost all of the proxies that it is proposing to use for the proposed 2017-based MEI are the same as those used in the 2006-based MEI. For "all other products," CMS is proposing to use the PPI-Final Demand-Finished Goods less foods and energy (BLS series code WPUFD413) as the price proxy for this category. The 2006-based MEI used several PPI and CPI series to proxy the price growth for the products reflected in this category.

Table 37: Proposed 2017-Based MEI Cost Categories, Weights, and Price Proxies

Cost Category	2017	2017 Price Proxy
MEI Total	**100.000%**	
Physician Compensation	**47.261%**	
Wages and Salaries	39.227%	ECI - Wages and salaries for Private industry workers in Professional and related
Benefits	8.034%	ECI - Total Benefits for Private industry workers in Professional and related
Practice Expense, including PLI	**52.739%**	
Non-physician compensation	**24.716%**	
Non-physician wages	**20.514%**	
Non-health, non-physician wages	12.306%	
Professional and Related wages	1.381%	ECI - Wages and salaries for Private industry workers in Professional and related
Management wages	2.171%	ECI - Wages and Salaries for Private Industry workers in Management, Business, and Financial

Table 37: Proposed 2017-Based MEI Cost Categories, Weights, and Price Proxies		
Cost Category	2017	2017 Price Proxy
Clerical wages	7.947%	ECI - Wages and Salaries for Private Industry workers in Office and Administrative Support
Services wages	0.807%	ECI - Wages and Salaries for Private Industry workers in Service Occupations
Health related, non-physician wages	8.208%	ECI - Wages and salaries for All Civilian workers in Hospitals
Non-physician benefits	**4.202%**	Composite - ECI - Total Benefits for the 5 non-physician wage categories
Other Practice Expense	**28.023%**	
Utilities	0.366%	CPI - Fuels and utilities
All Other Products	2.055%	PPI - Final demand - Finished goods less foods and energy
Telephone	0.471%	CPI - Telephone Services
All Other Professional Services	**13.914%**	
Professional, Scientific, and Technical Services	6.350%	ECI - Total compensation for Private industry workers in Professional, scientific, and technical services
Administrative support & waste	2.341%	ECI - Total compensation for Private industry workers in Office and administrative support
All Other Services	5.223%	ECI - Total compensation for Private industry workers in Service occupations
Capital	**7.748%**	
Fixed Capital	5.527%	PPI - Industry - Lessors of nonresidential buildings
Moveable Capital	2.221%	PPI - Commodity - Machinery and equipment
Professional Liability Insurance	**1.398%**	**CMS - Professional Liability Insurance Index, physicians**
Medical supplies	2.071%	Composite: PPI - Commodity - Medical and surgical appliances and supplies (50%), PPI - Commodity - Surgical and medical instruments (50%)

4. Productivity Adjustment to the MEI

The MEI has been adjusted for changes in productivity since its inception. CMS proposes to continue to use the current method of applying a productivity adjustment to the full MEI increase factor in the proposed 2017-based MEI. It believes this adjustment is appropriate because it explicitly reflects the productivity gains associated with all inputs (both labor and non-labor). The 10-year moving average percent change in economy-wide total factor productivity will be based on the latest available data as measured and published by BLS.

5. Results of Proposed Rebasing and Revising of the MEI

The results of the proposed update to the MEI cost weights for physician compensation, practice expense, and PLI comparing the 2006-based cost distribution to the proposed 2017-based cost distribution is shown in Table 38 in the proposed rule (recreated below). The 2017 proposed weights are significantly different than the 2006-based current weights. The practice expense

share, for example, increased by 6.5 percentage points from 44.8% to 51.3%.

Table 38: Percent Distribution of Major Physician Expense Components: 2006 and 2017		
	Weight	
RVU Component	**Current**	**Proposed**
	2006	2017
Physician Work	50.9%	47.3%
Practice Expense	44.8%	51.3%
Malpractice or PLI	4.3%	1.4%
Total	100.0%	100.0%

CMS also shows the average calendar year percent change for 2006 to 2023 for both the 2006-based MEI and proposed 2017-based MEI (Table 39 in the proposed rule). The comparison shows that the proposed 2017-based MEI annual percent changes differ from the 2006-based MEI annual percent changes by 0.1 to 0.2 percentage point for any given year. For example, the percent change of the proposed 2017-based MEI for 2023 is an increase of 3.8 percent, one-tenth higher than the 2006-based MEI.

III. Other Provisions of the Proposed Rule

A. Refunds of Discarded Drugs from Single-Dose Vials

1. Background

For Medicare Part B drugs administered from single-use vials, CMS will pay up to the labeled amount on the vial including any unused and discarded amount. CMS instructs using JW modifier on a Medicare bill to identify the amount of a drug that is discarded and eligible for payment. Use of the JW modifier has been mandatory since January 1, 2017.

Effective January 1, 2023, section 1847A of the Act requires Part B drug manufacturers to refund discarded drug amounts exceeding 10 percent of total charges for the drug in a given calendar quarter. Radiopharmaceutical or imaging agents, certain drugs requiring filtration, and certain new drugs are excluded from this policy.

2. Discarded Amounts

CMS proposes to use the JW modifier to determine the refund amount due for a discarded drug. Under the OPPS and ASC payment systems, the JW modifier is only required for separately paid drugs. As such, CMS proposes to only subject separately payable drugs under the OPPS and ASC payment systems to this policy. CMS proposes to exclude packaged drugs under the OPPS and ASC payment systems from this policy.

The proposed rule indicates that the JW modifier is often omitted on claims. One reason for this may be lack of a strong incentive to bill accurately if payment is up to the full amount of the labeled dose of the vial irrespective of the amount of the drug administered and discarded.

To address this issue, CMS proposes to establish new modifier JZ. Modifier JZ will be used to attest that the physician did not discard any drugs being billed from a single-use vial. Under CMS' proposed policy, the provider would bill Medicare for the amount of drug administered on one line of the claim and the amount discarded with the JW on another line of the claim. Units administered and units discarded will total to the labeled dose on the vial. Alternatively, the provider may administer the full amount of the drug included in the single-use vial and bill one line with the JZ modifier attesting the entire vial was administered and no amount is being billed for discarded drugs.

CMS does not believe the proposed JZ modifier requirement will increase burden as the provider already needs to determine whether or not there are any discarded units from a single-use vial or package, record discarded amounts in the patient medical record, and specify administered and discarded amounts on the Medicare claim form.

3. Refundable Single-dose Container or Single-use Package Drug

CMS proposes that "refundable single-dose container or single-use package drug" would apply to any drugs paid under Medicare Part B, not just those that are paid using the ASP payment methodology. The proposed policy would apply to any drug being supplied in a "single-dose" container or "single-use" package based on FDA-approved labeling or product information. This definition also includes drugs described in FDA-approved labeling as a "kit" that is intended for a single dose or single-use.

The proposed rule indicates that CMS may need to revise or establish billing and payment codes for drugs that meet the definition of refundable single-dose container or single-use package that do not have a unique billing and payment code. Additionally, there may be drugs for which there are national drug codes (NDC) with both single-dose and multiple-dose containers under the same FDA approval. These NDCs may be assigned to the same billing and payment code. CMS proposes that for a drug to meet the definition of "refundable single-dose container or single-use package drug," all NDCs assigned to the drug's billing and payment code must be single-dose containers or single-use packages, as described in each product's labeling.

4. Exclusions

Consistent with section 1847A(h)(8)(B)(i) and (ii) of the Act, CMS proposes to exclude 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.

Drugs that require in-line filters only as part of the drug administration process would not meet this exclusion. If multiple drugs are included in a single billing and payment code and any one of them requires filtration then all NDCs of such drugs or biologicals would be excluded from this policy even if other products under the relevant approval and assigned to that billing and payment code do not require such filtration.

For new drugs that have been paid by Medicare Part B for less than 18 months, CMS proposes to begin the 18-month period using the first day of the calendar quarter following the date of first sale reported to CMS with ASP data. Under this proposal, CMS would exclude the drug from the refund policy for six calendar quarters beginning with the 1st day of the calendar quarter that follows date of the first sale reported to CMS.

CMS proposes that exclusion would apply only once for a new drug (e.g., to the first NDC of the drug assigned to the billing and payment code and paid under Medicare Part B). If additional NDCs are assigned to the same billing and payment code under the same FDA approved application (such as a new vial size or ready-to-use syringe), these subsequent NDCs would not start a new 18-month exception period. CMS believes this proposed approach is needed to prevent a drug from periodic or continual exemption from reports and refunds due to new NDCs that are marketed under the same FDA-approval.

5. Information to Manufacturers

Section 1847A(h)(1) of the Act requires the Secretary to provide each manufacturer of a refundable single-dose container or single-use package drug with a report for each calendar quarter beginning on or after January 1, 2023, that includes:

- The total number of units of the billing and payment code of such drug, if any, that were discarded during such quarter; and
- The refund amount due.

CMS proposes to use the definition of manufacturer at section 1847A(c)(6)(A) of the Act and 42 CFR § 414.802 that includes any entity that is engaged in the following (this term does not include a wholesale distributor of drugs or a retail pharmacy licensed under state law):

1. Production, preparation, propagation, compounding, conversion or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis.
2. The packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

CMS proposes to identify the manufacturer responsible for the provision of refunds by the labeler code of the refundable single-dose container or single-use package drug. If such product does not have an NDC, CMS proposes to use manufacturer information included on the ASP data submission for the product.

The proposed rule explains that there is a time lag between the date a drug is administered and the date a claim is submitted. CMS proposes to provide an annual report to manufacturers with information for each calendar quarter with a minimum time lag of 3 months after calendar quarter's end. The annual reports would be sent October 1 of each year and would reflect claims received through June 30.

For 2023, CMS would provide its first annual report no later than October 1, 2023 that only reflects one quarter of information (January 1, 2023 through March 31, 2023) with claims received through June 30, 2023. For 2024, CMS' October 1 report would reflect four quarters of data (the last 3 quarters of 2023 and the first quarter of 2024) including all claims received through June 30, 2024.

Subsequent reports after 2024 would include data for eight quarters—the last three quarters of the prior calendar year and the first quarter of the current year plus any lagged claims from the prior four quarters not included in prior year reports. CMS believes this methodology would result in its report to the manufacturers reflecting more than 99 percent of claims.

6. Manufacturer Refund Timing

CMS proposes 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 is due no later than 30 days after the resolution of the dispute.

7. Refund Amount

Section 1847A(h)(3) of the Act provides the refund amount equals the difference between:

- The product of the Medicare payment limit and the number of billing units that were discarded; and
- 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.

CMS provides an example illustrating how the refund amount would be determined:

- Payment Limit = $100.
- Discarded Product Billed Using the JW modifier = 2,000 units.
- Discarded Product Amount = $100 X 2,000 = $200,000.
- Total Product Billed = 15,000 units.
- Total Product Amount = $100 X 15,000 units = $1,500,000.
- 10% of Total Product Amount = $150,000.
- Refund Amount = $200,000 - $150,000 = $50,000.

The proposed rule indicates that the statute authorizes the refund amount to be estimated and it likely will not be exact because of lagged claims data, appeals, or reversals in the case of an audit. While CMS estimates it will have more than 99 percent of claims for a calendar quarter

using the process outlined above, it is possible that inclusion of additional lagged claims in subsequent reports may change a refund amount (either an increase or decrease) in which case the manufacturer may owe more to CMS or be owed money by CMS.

8. Increasing the Applicable Percent for Drugs with Unique Circumstances

Section 1847A(h)(3) of the Act specifies that the applicable percentage is 10, but authorizes CMS to increase this 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. At this time, CMS is not proposing an increase of the applicable percentage for any drugs with unique circumstances.

CMS does acknowledge that there are very rare situations where the amount of drug identified on the package or labeling far exceeds the amount administered to a patient, thus leading to a substantial percentage of drug that is discarded. In the example CMS provides, the unique circumstances of the product make it impossible to extract the labeled amount from the vial—for example, the product adheres to the side of the container—and the discarded amount can routinely exceed 25 percent (or more if the patient does not require a maximum dose). CMS is considering whether to adopt a higher applicable percentage for a drug in this circumstance and requests comments on whether there are other drugs where CMS should raise the applicable percentage.

9. Dispute Resolution

A dispute resolution process is not expressly required by section 1847A(h) of the Act. However, CMS proposes that each manufacturer have an opportunity to dispute the refund amount by submitting an error report that includes identifying information plus an explanation of the nature of the error, how the error affects the refund calculation, how the manufacturer established that an error occurred, the proposed correction to the error, and why CMS should make the correction.

CMS proposes to provide a 30-day period following the issuance of its report for the manufacturer to request a change to the refund amount. CMS proposes a 30-day period for it to evaluate whether a correction is required. If a correction is required, CMS would issue a new report with updated discarded amounts and/or refund. Alternatively, CMS could find that no error was made and the original refund amount would be owed. CMS requests comment on developing an appeal mechanism in future rulemaking.

10. Enforcement – Audits and Civil Monetary Penalties

Audits. Section 1847A(h)(6)(A)(i) of the Act requires that CMS perform periodic audits on each manufacturer of a refundable single-dose container or single-use package drug. CMS proposes that it will periodically audit manufacturers of refundable single-dose container or single-use package drugs consistent with this requirement. CMS requests public comments on what such audits should entail.

Section 1847A(h)(6)(A)(ii) of the Act requires CMS to conduct periodic audits of claims for drugs that are from refundable single-dose container or single-use package drugs. CMS proposes that its Medicare review contractors periodically review Part B drug claims to ensure the JW modifier, JZ modifier (if adopted), and discarded drug amounts are billed appropriately consistent with normal claims audit policies and protocols.

Civil Money Penalty. Section 1847A(h)(6)(B) authorizes civil money penalties on a manufacturer of a refundable single-dose container or single-use package drug who fails to comply with the refund provision for discarded drugs in the statute. The civil money penalty would be an amount equal to the sum of:

- The amount that the manufacturer would have paid under such paragraph with respect to such drug for such quarter; and
- 25 percent of such amount.

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.

For the past several years, CMS has also paid RHCs and FQHCs outside of the RHC AIR and the FQHC PPS for care management services that comprise non-face-to-face time. These services include Chronic Care Management (CCM), Behavioral Health Integration (BHI), psychiatric Collaborative Care Management (CoCM) and Principal Care Management (PCM).

2. Chronic Pain Management (CPM) and General Behavioral Health Integration (GBHI)

The proposed rule indicates that two new codes are being created for a specified set of pain management and treatment services. The first code (GYYY1) is for the first 30 minutes of face-to-face time provided by a physician or other qualified health care professional, per calendar month. The second code (GYYY2) is for each additional 15 minutes of face-to-face time. Another code is being created for GBHI services (GBHI1) for care management of behavioral health conditions that includes at least 20 minutes of clinical psychologist or clinical social worker time, per calendar month.

CMS indicates that the RHC AIR and the FQHC PPS amounts do not include the non-face-to-face time required to coordinate care in these services. CMS proposes to allow for separate payment of these services to reflect the additional time and resources necessary for the unique components of care coordination services. For CPM, CMS proposes to pay the initial code but

not the add-on code because RHCs and FQHCs do not pay their practitioners based on additional minutes spent by practitioners, as is the case for practitioners under the PFS.

CMS proposes that CPM and GBHI would be billed by RHCs and FQHCs using HCPCS code G0511 that is used to bill for all care management services. The payment rate would be based 2.29 total non-facility RVUs ($75.25 based on CMS' proposed rates for 2023). This compares to physician fee schedule payments of $78.72 for GYYY1 and $41.35 for GBHI1.

CMS does not explain why the proposed rate paid to an RHC or an FQHC for GBHI services would be so much higher in an FQHC or RHC compared to payment under the physician fee schedule, although it does note that G0511 is an average of the total non-facility RVUs for six care management and general behavior health codes (CPT codes 99484, 99487, 99490, 99491, 99424 and 99425). In future rulemaking, CMS may consider other approaches for calculating the rate of HCPCS code G0511 as the number of care management services it includes is growing each year.

3. Conforming Technical Changes to 42 CFR 405.2463

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. CMS proposes to apply the 151-day extension of non-in-person visits to all RHC and FQHC mental health visits and is making conforming changes to the regulations to reflect this policy. [53]

The Coronavirus Relief and Economic Security Act (CARES) waived provisions of the Act during the COVID-19 PHE to allow FQHCs and RHCs to be distant site providers for services delivered via an interactive telecommunications system. CAA, 2022 extended these temporary telehealth provisions for 151 days beyond the end of the COVID-19 PHE. CMS intends to implement these provisions through program instruction or other sub-regulatory means as authorized by CAA, 2022.

[53] Section 304 only modified provisions of the Act applicable to hospice patients served by RHCs and FQHCs. However, CMS will apply the provisions to all mental health visits provided by RHCs and FQHCs consistent with what it believes is the overall intent of section 304.

4. Provider-Based RHC Payment-Limit Per-Visit

Beginning April 1, 2021, section 1833(f)(2) raises the national RHC AIR limit from $100 in 2021 to $190 in 2028. In subsequent years, the national limit on the RHC AIR will be increased by MEI. These limits apply to freestanding RHCs.

An RHC may also be provider-based to a hospital that has fewer than 50 beds. A provider-based RHC was not subject to a national limit on the AIR prior to April 1, 2021. Beginning April 1, 2021, a provider-based RHC is subject to a limit on its AIR that is the higher of the national limit or its per visit costs in a base year increased by the MEI. To be a provider-based RHC, the RHC must have been enrolled in Medicare and be provider-based to a hospital as of December 31, 2020 or have submitted an enrollment application by that date.

The base year for a provider-based RHC may be different depending on whether or not the RHC had a per visit limit in 2020. If the RHC had a per visit limit in 2020, its 2021 AIR limit will be the higher of its 2020 AIR limit increased by the MEI or the national per visit limit. If the RHC did not have a per visit limit in 2020, its 2021 AIR limit will be the higher of its reasonable cost per visit or the national limit. Subsequent limits for both categories of provider-based RHCs will equal the greater of the previous year's limit increased by the MEI or the national limit.

In the proposed rule, CMS clarifies how the base year per visit limit will be determined for provider-based RHCs. For provider-based RHCs that had an AIR established for services furnished in 2020, CMS proposes that MACs use the cost report ending in 2020 that reports costs for 12 consecutive months to establish the base year AIR. If the RHC does not have a 12 consecutive month cost report ending in 2020, the MACs should use the next most-recent final settled cost report that reports costs for 12 consecutive months (for example, a cost reporting period October 1, 2020 through September 30, 2021 would be acceptable).

For provider-based RHCs that did not have an AIR established for services furnished in 2020, CMS proposes that MACs use the cost report ending in 2021 that reports costs for 12 consecutive months. If the RHC does not have a 12-consecutive month cost report ending in 2021, the MACs should use the next most-recent final settled cost report that reports cost for 12 consecutive months.

Once an RHC is provider-based to a hospital with 50 beds, the hospital must continue to have less than 50 beds (except during the COVID-19 PHE when CMS waived the 50-bed requirement) to retain provider-based status. If an RHC is provider-based to a hospital with more than 50 beds at any time, the provider-based RHC would be subject to the national RHC payment limit and will not be able to regain a provider-based payment limit.

C. Clinical Laboratory Fee Schedule (CLFS): Revised Data Reporting Period and Phase-in of Payment Reductions, and Proposals for Specimen Collection Fees and Travel Allowance for Clinical Diagnostic Laboratory Tests

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

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

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

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

2. Laboratory Specimen Collection Fee

In general, section 1833(h)(3) of the Act requires the Secretary to provide for and establish a nominal fee for specimen collection for laboratory testing and a fee to cover transportation and personnel expenses for trained personnel to collect specimens from homebound patients and "non-hospital inpatients."[54] Many provisions related to the specimen collection fee and travel allowance have only been in manual provisions. CMS proposes to codify longstanding policies at 42 CFR § 414.523(a)(1) while also proposing certain changes to modify or clarify those policies.

Longstanding CMS policy paid $3 as the specimen collection fee. This fee was raised to $5 by PAMA effective April 1, 2014 only when the specimen collection is from SNF patients or a laboratory on behalf of a home health agency. Otherwise, the specimen collection fee remained $3. During the COVID-19 PHE, the proposed rule indicates that "the nominal specimen collection fee for COVID-19 testing for homebound and non-hospital inpatients generally is $23.46 and for individuals in a SNF and individuals whose samples are collected by laboratory

[54] It is unclear what CMS means by "non-hospital inpatient." CMS uses this terminology because section 1834(h) of the Act refers to the travel allowance that is paid in addition to the specimen collection fee when the specimen is drawn from a "homebound [patient] or an inpatient in an inpatient facility (other than a hospital)." Section 1834A (b)(5) indicates that the specimen collection fee is increased by $2 when "collected from an individual in a skilled nursing facility or by a laboratory on behalf of a home health agency." Given the section 1834A of the Act language, it seems likely that "non-hospital inpatient" is intended to mean a patient in a skilled nursing facility irrespective of whether the stay is covered by Medicare. However, as noted in the next footnote, CMS appears to make distinction between "non-hospital inpatient" and a SNF patient.

on behalf of an HHA is $25.46.[55] In addition, the travel allowance will be paid when the sample is collected from homebound patients and non-hospital inpatients. In prior rulemaking, CMS requested public comments on its specimen collection and travel fee allowances policies.

The Medicare Claims Processing Manual (chapter 16, § 60.1.1) describes specimen collection fees for physicians. Specifically, the manual states that Medicare allows a specimen collection fee for physicians only when (1) it is the accepted and prevailing practice among physicians in the locality to make separate charges for drawing or collecting a specimen and (2) it is the customary practice of the physician performing such services to bill separate charges for drawing or collecting the specimen. CMS believes these provisions originated before adoption of the physician fee schedule on January 1, 1992 and are now obsolete. CMS proposes to eliminate these provisions from the manual and not include them among its regulatory changes.

CMS' policy would result in no specimen collection fee being paid to any physician office including those that have their own laboratories. While CMS believe it should not pay the specimen collection fee to a physician office laboratory as patients are neither homebound or non-hospital inpatients and no travel would be required to collect the sample, CMS is requesting comment on whether it should continue to pay the specimen collection fee when physician office laboratories are collecting specimens for their own patients.

The Medicare Claims Processing Manual (chapter 16, § 60.1.3) describes specimen drawing for dialysis patients. CMS believes the manual provisions that allow the specimen collection fee from ESRD patients have now become obsolete as these costs are now included in the ESRD PPS that was adopted January 1, 2011. CMS is proposing to eliminate the manual provision that allows payment for collecting a specimen from ESRD patients.

In codifying its manual provisions, CMS proposes to:

- Maintain the collection fee of $3 for all specimens collected in a single patient encounter when collected from patients other than a patient in a SNF or by a laboratory on behalf of an HHA.
- Maintain the collection fee of $5 for a specimen collected in a single patient encounter by a laboratory technician from an individual in either a SNF or by a laboratory on behalf of an HHA to a homebound patient.
- The $5 fee for specimen collection may only be paid for an individual in a SNF or on behalf of an HHA when no qualified personnel are available at the facility to collect a specimen.
- The specimen collection fee would only be paid for blood collected through venipuncture and urine through catheterization. The specimen collection fee would not be payable for any other specimen types, for example, a throat culture or a routine capillary puncture for clotting or bleeding time.
- For the specimen collection fee to be paid, it must be drawn by a "trained technician" (as opposed to "technician" as the terminology currently used in the Medicare Claims Processing Manual, chapter 16, § 60.2). CMS indicates that a "trained technician" is

[55] It is not clear what the difference is between a "non-hospital inpatient and a patient in skilled nursing facility" that will result in a $2 difference in the specimen collection fee and payment of the travel allowance.

qualified to collect samples and also perform tests to analyze body fluids, tissue, and other substances.

3. Laboratory Specimen Collection Travel Allowance

Section 1833(h)(3)(B) of the Act requires the Secretary to provide a fee for transportation and personnel expenses for trained personnel to collect laboratory samples from an individual who is homebound or a non-hospital inpatient. CMS' travel allowance fees are longstanding and only included in sub-regulatory guidance (Medicare Claims Processing Manual, chapter 16, § 60.2). The manual specifies two codes that can be used for billing the travel allowance:

- P9603: For trips greater than 20 miles. Mileage rate is used. The per mile allowance is computed using the Federal mileage rate (as determined by the Internal Revenue Service (IRS)) plus an additional 45 cents a mile to cover the technician's time and travel costs.
- P9604: For trips less than 20 miles. Flat rate is used. CMS will pay a minimum of $10.40 based on the assumption that a trip is an average of 15 minutes and up to 10 miles one way and uses the Federal mileage rate (as determined by the IRS) and a laboratory technician's time of $17.66 an hour, including overhead.

The rates paid above are to be prorated when specimens are collected from more than one Medicare beneficiary and non-Medicare beneficiaries. The manual indicates that the proration is based on the number of patients seen on a single trip. However, change request (CR) 12593 indicates that the travel allowance is prorated based on the number of specimens collected from each patient. The travel allowance is only payable when the specimen collection by a trained technician (not a physician or nursing home personnel) is reasonable and necessary.

Stakeholders have complained that CMS' policies for the travel allowance are unclear and inconsistent as well as administratively burdensome due to the requirements to track mileage. Some of these comments suggested creating a single per-encounter flat-rate payment for travel with a rural add-on for laboratories serving Medicare beneficiaries residing in remote areas. These commenters also indicated that CMS should automatically reprocess claims and provide claims adjustments in instances where the MAC incorrectly used a prior year's travel allowance rates to process current year claims. Similar concerns were expressed by OIG in a 2021 report.[56]

In response, CMS began allowing laboratories to maintain electronic documentation to support mileage claimed in the 2022 PFS rule. It also instructed the MACs to identify and adjust any paid claims that incorrectly used the previous year's rate. For 2023, CMS proposes to codify in the CR the following longstanding provisions of the manual:

- The additional allowance can be made only where a specimen collection fee is also payable, i.e., no travel allowance is made where the technician merely performs a messenger service to pick up a specimen drawn by a physician or nursing home personnel.
- Medicare Part B covers a specimen collection fee and travel allowance for a laboratory

[56] CMS Needs To Issue Regulations Related to Phlebotomy Travel Allowances A-06-20-04000 08-25-2021 (hhs.gov)

technician to draw a specimen only from a nursing home or homebound patient.

CMS also proposes to codify the following provision of the manual with one minor change:

- Only one travel allowance payment may be made for specimen collection for a Medicare beneficiary based on the beneficiary's location, and only when a Medicare beneficiary requires the collection of a specimen necessary for performance of the test. Rather than prorating the travel allowance among Medicare and non-Medicare beneficiaries as currently provided for in the manual, CMS proposes to only account for travel costs to draw specimens from Medicare beneficiaries.
- The flat rate methodology would continue to be used for trips of 20 miles or less but would be limited to only those trips with one location where a specimen (or specimens) is (are) collected.
- The per mile methodology would continue to be used for trips where the trained technician travels more than 20 eligible miles to and from one location for specimen collection from one or more beneficiaries or when the trained technician travels to more than one location for specimen collection from more than one Medicare beneficiary.

CMS proposes to adopt the following policies related to the per mile methodology. These provisions are largely the same as current policy found in sub-regulatory guidance. The modifications include that CMS would update the hourly rate for the laboratory technician and the travel allowance fee is divided by the number of Medicare beneficiaries from whom a specimen was obtained rather than the number of specimens that were collected:

- Eligible miles would begin at the laboratory and end at the laboratory where the trained technician returns the specimen(s) for testing. Eligible miles would not include miles traveled for any purpose unrelated to specimen collection, such as collecting specimens from non-Medicare beneficiaries or for personal reasons.
- The travel allowance would equal the product of the sum of the standard mileage rate and trained technician mileage rate and the number of eligible miles traveled.
- The travel allowance fee is divided among the number of beneficiaries for whom a specimen collection fee is paid.
- The transportation component of the travel allowance mileage rate would equal the IRS standard mileage rate (currently $0.585).
- The laboratory technician component of the travel allowance would be based on the Bureau of Labor Statistics (BLS) wage rate for phlebotomist ($17.97 per hour for 2021) divided by 40 ($0.45 per mile) assuming average speed of 40 miles per hour.
- The travel allowance rates would updated annually through sub-regulatory guidance.

CMS proposes to incorporate the current manual provisions related to the flat rate methodology into the CFR with a clarification that the travel allowance fee is divided by the number of Medicare beneficiaries from whom a specimen was obtained rather than the number of specimens that were collected as CMS had specified in CR 12593.

Under current policy, MACs have the flexibility to make a travel allowance payment where tests are needed on an emergency basis. CMS' proposal would eliminate this flexibility although it explicitly seeks comment on this provision of its proposal.

D. Expansion of Coverage for Colorectal Cancer Screening and Reducing Barriers

1. Reduction of Minimum Age Limitation to 45

Citing updated colorectal cancer (CRC) screening guidance from the CDC and a supporting revised recommendation from the United States Preventive Services Task Force (USPSTF) issued in May 2021, CMS proposes to expand Medicare coverage of certain colorectal cancer screening tests by reducing the minimum age payment limitation to 45 years. The tests in the May 2021 USPSTF revised recommendation include stool-based tests of gFOBT, iFOBT and sDNA, and direct visualization test of flexible sigmoidoscopy. CMS proposes the same age reduced age limitation for barium enema tests, blood-based biomarker tests, and screening colonoscopy.[57] CMS does not propose to modify existing conditions of coverage or payment for maximum age limitations and frequency limitations. The agency consulted a number of organizations with relevant expertise in developing its proposal; **it invites comment on the proposal**.

2. Complete Colorectal Cancer Screening

Responding to concerns about health equity, low follow-up colonoscopy rates, and patient access barriers, the agency also proposes to expand the regulatory definition of CRC screening tests to include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based CRC screening test returns a positive result. Historically, CMS has treated colonoscopy after a positive non-invasive stool-based CRC screening test as diagnostic colonoscopy. However, government bodies and professional societies have reconsidered their understanding of a complete CRC screening and now consider CRC screening incomplete for individuals with a positive result on a stool-based test until a follow-on screening colonoscopy is also completed.

Under the proposal, beginning January 1, 2023, CMS would establish a new Medicare covered CRC screening test (which it refers to as a complete colorectal cancer screening) that includes a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based colorectal cancer screening test returns a positive result. It would waive the frequency limitations that would otherwise apply for CRC tests for the follow-on screening colonoscopy test when furnished as part of its proposed new complete colorectal cancer screening benefit. This means beneficiary cost sharing for the initial screening stool-based test and the follow-on screening colonoscopy test would not apply; Medicare payment for both tests would be 100 percent. CMS cites the May 2021 revised USPSTF recommendation as well as support from a number of organizations with relevant expertise for this proposal.

[57] The Medicare statute (section 1834(d)(3)) does not impose a minimum age requirement for screening colonoscopy.

The issue of when the follow-on screening colonoscopy involves the removal of tissue or other matter or other procedure furnished in connection with, as a result of, and in the same clinical encounter as the screening test would not change from the current policy that was finalized in the 2022 PFS final rule. Beneficiary coinsurance under these circumstances will be reduced over time from 15 percent for services furnished during 2023 through 2026, to 10 percent for services furnished during 2027 through 2029, and to zero percent beginning in 2030 and thereafter.

3. Authority; Regulatory Impact

CMS cites relevant statutory and regulatory authority for its proposals, including sections 1861(pp)(1)(D) and 1834(n) of the Act, regulations at §410.37, and NCD 210.3. It emphasizes that the proposals are limited to CRC screening tests and do not address the coverage or payment status of other screening services or tests recommended by the USPSTF or covered by Medicare.

CMS estimates the impact of its proposals from additional utilization to be approximately $10 million in additional spending.

E. Removal of Selected National Coverage Determinations

In the 2021 PFS final rule[58], CMS established rulemaking as an appropriate vehicle for receiving public comment on removing outdated NCDs. CMS did not establish an exclusive list of criteria that it would use to identify and evaluate NCDs for removal. CMS will consider proposing the removal of an NCD if:

- It believes that allowing local contractor discretion to make a coverage decision better services the needs of the Medicare program and its beneficiaries.
- The technology is generally acknowledged to be obsolete and is no longer marketed.
- In the case of a noncoverage NCD based on the experimental status of an item or service, the item or service in the NCD is no longer considered experimental.
- The NCD has superseded by subsequent Medicare policy. The national policy does not meet the definition of an "NCD" as defined in sections 1862(l)[59] or 1869(f)[60] of the Act.
- The benefit category determination is no longer consistent with a category in the Act.

In addition, CMS also considers the general age of an NCD, changes in medical practice/standard of care, the pace of medical technology since the last determination, and the availability and quality of clinical evidence and information to support removal of an NCD.

CMS believes that proactively removing obsolete or unnecessary NCDs removes barriers to innovation and reduces burden for interested parties and CMS. Eliminating an NCD for items and services previously nationally covered means that item or service will no longer be automatically covered by Medicare; the coverage determination will be made by MACs. If the NCD barred

[58] 85 FR 84472

[59] Section 1862(l) of the Act describes the national and local coverage determination process.

[60] Section 1869(f)(1) of the Act defines national coverage determination as ''a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII, but does not include a determination of what code, if any, is assigned to a particular item or service covered under this title or a determination with respect to the amount of payment made for a particular item or service so covered.''

coverage, MACs would be able to cover the item or service if the MAC determines such action is appropriate under the statute.

CMS proposes to remove the NCD for Ambulatory electroencephalographic (EEG).[61] External interested parties recommended removal of this NCD. CMS' rationale for proposing the removal of this NCD is summarized below.

NCD 160.22 Ambulatory EEG Monitoring (June 12, 1984)

- Circumstances/criterion: Local contractor discretion to make a coverage decision better serves the needs of the program.
- Rationale: External stakeholders suggested that portions of this NCD are outdated language that is inconsistent with, and contrary to current standards of care. The NCD makes mention of a 24-hour duration of monitoring, however, recent coding structures permit monitoring in increments including 36-60 hours, 60-84 hours and >84 hours. Removing the outdated NCD will allow MACs to update guidance for this established diagnostic test.

CMS solicits comments on its proposal to remove this NCD. CMS request commenters include a rational to support their comments to help CMS take one of the following actions: remove the NCD as proposed; retain the current NCD; or reconsider revising the NCD. CMS also requests that comments suggesting a revision include new evidence to support a change in national coverage.

Regulatory Impact

CMS estimates there will be de minimis change to 2023 payment, compared to 2021 because this is a long-established service for which MACs already have local coverage determinations (LCDs) and guidance articles. Claims data for 2021 shows that for the 20 CPT/HCPCS codes associated with this NCD, CMS paid 167,242 FFS claims for approximately 78,267 beneficiaries totaling payments of approximately $49 million.

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

Section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act[62] 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;

[61] The NCD is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items?CMS014961.
[62] P.L. 115-271, enacted October 24, 2018.

- 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.

Current payment rates for OUD treatment services provided by OTPs can be found on the CMS OTP website[63] under Billing and Payment.

Methadone Pricing. In the 2020 PFS final rule, CMS finalized that the payment for the drug component of episodes of care would be updated annually using the most recent data available. For oral medications, if average sales price (ASP) data are available, the payment amount is 100 percent of ASP, based on ASP data calculated consistent with 42 CFR part 414, subpart J and voluntarily submitted by drug manufacturers.[64] Using this method, the payment amount for methadone furnished by OTPs during an episode of care in 2021 was set at $37.38, which was 100 percent of ASP.

In September 2021, CMS found that the volume-weighted ASP for oral methadone, based on manufacturer-reported ASP data, had decreased by just over 50 percent compared to the 2021 rate, from $37.38 to $17.64. This reduction was due to the inclusion of newly reported ASP data for methadone tablets, whereas previously the manufacturer-reported ASP data reflected only sales of the methadone oral concentrate. Although ASP is volume-weighted, there are a number of data limitations:

- ASP reporting is not required for oral methadone.
- Only a small subset of methadone manufacturers voluntarily submits ASP data.
- CMS does not have data showing whether OTPs utilize oral methadone concentrate or tablets more often, or if the two formulations are utilized equally.[65]

Due to these concerns, as well as reports regarding the effects of the PHE on individuals with substance use disorders (SUDs), CMS believed it was in the public's best interest not to implement a significant decrease in the 2022 payment rate for methadone furnished by OTPs as part of OUD treatment services without first having an opportunity to review the issue and seek

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[63] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Opioid-Treatment-Program

[64] If ASP data are not available, the payment amount for methadone will be based on the TRICARE rate.

[65] Among comments cited by CMS was one representing a large number of OTPs across the country stating that OTPs rarely dispense methadone tablets and instead administer the oral concentrate formulation. This commenter stated that methadone oral concentrate is more expensive to acquire and administer than the tablet form, but that it has been shown to lead to better clinical outcomes for their patients, which is why it is their doctors' formulation of choice.

input from the OTP community. In November 2021, CMS issued an interim final rule with comment period (IFC) (86 FR 66031), establishing a limited exception to the methodology for determining the payment amount for the drug component of an episode of care. This froze the payment amount for methadone furnished during an episode of care in 2022 at the $37.38 payment amount that was determined for 2021, allowing time for CMS to study the issue further and, if appropriate, to develop an alternative payment methodology for methadone that could be proposed through notice-and-comment rulemaking for 2023.

In this proposed rule, for 2023 and subsequent years, CMS is proposing to revise the methodology for pricing the drug component of the methadone weekly bundle and the add-on code for take-home supplies of methadone. Specifically, the payment amount for the drug component of HCPCS codes G2067 and G2078 for 2023 and subsequent years would be based on the payment amount for methadone in 2021, updated annually to account for inflation using the PPI for Pharmaceuticals for Human Use (Prescription).

Because CMS froze the payment amount for methadone at the 2021 amount for 2022, CMS is proposing for 2023 that the methadone payment amount would be based on the projected increase for the 2-year period from 2021 to 2023. Based on the 2022 Q1 forecast from IHS Global Inc. (IGI), the proposed 2023 methadone payment amount would be $39.29, which is the 2022 payment amount of $37.38 increased by a projected 5.1 percent growth in the applicable PPI from 2021 to 2023 ($37.38 * 1.051 = $39.29).

CMS also proposes to do the following:

- If more recent data become subsequently available (for example, a more recent estimate of the PPI), such data would be used in the final rule for the final 2023 methadone payment amount.[66]
- For subsequent years, continue to update this rate annually using the PPI for Pharmaceuticals for Human Use (Prescription).
- Continue to monitor methadone pricing in order to determine whether additional changes are necessary through future rulemaking to account for any significant changes in the acquisition costs for methadone or if new or more reliable data on methadone pricing become available.

CMS asks for public comment on other potential data sources that could be used to estimate an OTP's cost for acquiring methadone.

Proposed Changes to the Rate for Individual Therapy in the Bundled Rate. The 2020 PFS final rule finalized a payment rate for the non-drug component of the bundled payment for episodes of care based on a crosswalk to CPT code 90832, for 30 minutes of psychotherapy. Since then, CMS received feedback that the current rate for individual therapy provided may not accurately reflect the resource costs involved with furnishing this service in the OTP setting and that for the first several months of treatment patients typically receive weekly 50-minute individual therapy

[66] The proposal would also eliminate use of the TRICARE rate as an alternative pricing methodology for methadone. Using the TRICARE payment amount for methadone for 2023 would result in a decrease of $13.34 compared to the rate that applied in 2021 and 2022.

sessions. CMS also reviewed 2 years of utilization data and now believes that the severity of needs of the patient population diagnosed with OUD receiving services in the OTP setting is generally greater than that of patients receiving 30-minute psychotherapy services.

Thus, CMS is proposing to base the payment rate for the non-drug component of the bundled payment for an episode of care for individual therapy on a crosswalk to CPT code 90834 (*Psychotherapy, 45 minutes with patient*, with a 2019 rate of $91.18), instead of 90832 (*Psychotherapy, 30 minutes with patient*, with a 2019 rate of $68.47). CMS would then apply the MEI updates for 2021, 2022, and 2023 to these adjusted payment rates to determine the 2023 payment amounts.

Mobile Components Operated by OTPs. In 2021, the Drug Enforcement Administration (DEA) authorized OTPs to add a "mobile component" to their existing registration, eliminating a requirement for mobile medication units of OTPs to have a separate registration. SAMHSA issued related guidance to OTP Directors, State Opioid Treatment Authorities (SOTAs), and State Directors, clarifying the range of services that can be provided by mobile units.

In light of the new SAMHSA guidance and to expand access to medications for treatment of OUD for Medicare beneficiaries, CMS clarifies that services furnished via OTP mobile units will be considered for purposes of determining payments to OTPs under the Medicare OTP bundled payment codes and/or add-on codes, to the extent that the services are medically reasonable and necessary and are furnished in accordance with SAMHSA and DEA guidance. CMS proposes applying locality adjustments for services furnished via mobile units as if the service were furnished at the OTP.

Flexibilities for OTPs to Use Telecommunications for Initiation of Treatment with Buprenorphine. Numerous statutory and regulatory steps have been taken to increase telehealth flexibilities for mental health conditions, including SUDs.[67] CMS previously finalized several flexibilities for OTPs regarding the use of telecommunications, both during and outside of the PHE for COVID-19. For example, even after the conclusion of the PHE for COVID-19, OTPs are permitted to furnish substance use counseling and individual and group therapy via audio-only telephone calls when the beneficiary cannot access or does not consent to the use of audio and video.

SAMHSA regulations required a complete physical evaluation before a patient begins treatment at an OTP. However, during the PHE, DEA and SAMHSA have allowed OTPs to initiate treatment with buprenorphine—but not methadone—via audio/video and audio-only communication without first conducting an in-person evaluation. This exemption will continue only for the duration of the PHE for COVID-19 unless regulations are issued making this flexibility permanent.

[67] For example, section 2001(a) of the SUPPORT Act and section 123 of the Consolidated Appropriations Act, 2021, as well as CMS' revision of the regulatory definition of an "interactive telecommunications system" to permit the use of audio-only communications technology for mental health telehealth services under certain conditions when provided to beneficiaries located in their home.

CMS is proposing to allow the OTP intake add-on code to be furnished via two-way audio/video communications technology when billed for the initiation of treatment with buprenorphine, to the extent authorized by DEA and SAMHSA. CMS is also proposing to permit the use of audio-only communication technology to initiate treatment with buprenorphine in cases where audio/video technology is not available to the beneficiary. CMS interprets the requirement that audio/video technology is "not available to the beneficiary" to include circumstances in which the beneficiary is not capable of or has not consented to the use of devices that permit a two-way, audio/video interaction.

CMS seeks comment on whether to allow periodic assessments to continue to be furnished using audio-only communication technology following the end of the PHE for COVID-19 for patients who are receiving treatment via buprenorphine, and if this flexibility should also continue to apply to patients receiving methadone or naltrexone.

G. **Medicare Shared Savings Program**

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

H. **Medicare Part B Payment for Preventive Vaccine Administration Services**

1. Background

CMS reviews the history for the payment rates for Part B vaccines (i.e., influenza, pneumococcal, hepatitis B virus (HBV), and COVID-19 vaccines) and their administration. Vaccine administration services under 1861(s)(10) of the Act are not technically valued or paid under the PFS, but payment rates have been historically based on an evaluation of the resource costs involved in furnishing the service, which is similar to the methodology that is used to establish PFS payment rates. Prior to 2022, for the administration of influenza, pneumococcal, and HBV vaccines, CMS generally established rates by crosswalking the specific vaccine administration HCPCS codes (G0008-G0010) to CPT code 96372 (Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular) which resulted in a reduction over time of the valuation of the vaccine administration codes.

For 2022, CMS decoupled payment for vaccine administration services from the PFS crosswalk and finalized a uniform payment rate of $30 for the administration of an influenza, pneumococcal or HBV vaccine. For COVID-19 vaccines, CMS established administration rates for COVID-19 vaccines furnished on or after March 15, 2021 of $40 per dose. In the 2022 PFS, CMS finalized a payment rate of $40 for the administration of COVID-19 vaccines until January 1 of the year that begins after the termination of the PHE when the payment rate for administration of the COVID-19 vaccines will be the same as the payment rate for administration of the other Part B preventive vaccines.

In the 2022 PFS final rule, CMS inadvertently neglected to address a geographic adjustment policy for the vaccine administration payment rates and noted only that payments would be geographically adjusted. CMS' posted 2022 payment rates for preventive vaccine administration,

including COVID-19, are locality-specific payment rates based on application of the PFS GPCIs to the finalized payment rates.

2. Refinements to the Payment Amount for Preventive Vaccine Administration

For 2023 and subsequent years, CMS proposes to annually update the payment amount for the administration of Part B preventive vaccines based upon the increase in the MEI. CMS also proposes to adjust this payment amount for the geographic locality based upon the fee schedule area where the preventive vaccine is administered using the geographic adjustment factor (GAF). Effective January 1, 2023, these adjustments would apply to vaccine administration HCPCS codes G0008-G0010. Under this proposal, effective January 1, 2023 CMS would also update the $40 payment amount for COVID-19 vaccine administration as long as the Emergency Use Authorization (EUA) declaration is still in place (see discussion below in section 3 for use of the EUA for drugs and biological products).

The MEI is defined in section 1842(i)(3) of the Act and is used to update payment amounts in several health care settings, including the originating site facility fee for Medicare telehealth services (discussed in Section II.M). CMS considered other potential update factors, including the BLS Consumer Price Index for All Urban Consumers (CPI-U) but concluded that a healthcare-specific update factor would be more appropriate. The current forecast of the increase in the MEI for 2023 is 3.8 percent based on the proposed MEI; the 2023 MEI increase factor for the final rule will be based on historical data through the 2nd quarter of 2022.

The GAF is calculated using the three component GPCIs (work, PE, and malpractice) and is calculated for each PFS fee schedule area as the weighted composite of all three GPCIs for each fee schedule area using the national GPCI cost share weights (discussed in section II.G). Specific proposed GAF values for each fee schedule area are posted in Addendum D to this proposed rule. CMS believes application of the single GAF to geographically adjust the payment rates would be a more appropriate, streamlined approach and facilitates updating the preventive vaccine administration rates independent of the PFS components.

CMS proposes to amend its regulations at §410.152 to codify the payment amount established for administration of preventive vaccines in the 2022 PFS final rule and the proposed payment adjustments for 2023 and subsequent years.

3. Payment for COVID-19 Vaccine Administration in the Home

a. Background

Effective June 8, 2021, CMS announced a new add-on payment (HCPCS code M0201) with a national rate of $35.50. The following requirements apply when billing for HCPCS code M0201:[68,69]

- The patient has difficulty leaving the home to get the vaccine; difficulty leaving the home could mean any of the following:

[68] https://www.cms.gov/medicare/covid-19/medicare-covid-19-vaccine-shot-payment

[69] https://www.cms.gov/files/document/vaccine-home.pdf.

    - They have a condition, due to an illness or injury, that restricts their ability to leave home without a supportive device or help from a paid or unpaid caregiver
    - They have a condition that makes them more susceptible to contracting a pandemic disease like COVID-19; or
    - They are generally unable to leave the home, and if they do leave home, it requires a considerable and taxing effort.
- The patient is hard-to-reach because they have a disability or face clinical, socioeconomic, or geographical barriers to getting a COVID-19 vaccine in settings other than their home. These patients face challenges that significantly reduce their ability to get vaccinated outside the home, such as challenges with transportation, communication, or caregiving.
- The sole purpose of the visit is to administer the COVID-19 vaccine. Medicare will not pay the additional amount if the provider or supplier furnished another Medicare covered service in the same home on the same date.
- A home can be a private residence, temporary lodging (e.g., a hotel or motel, campground, hostel, or homeless shelter); an apartment in an apartment complex or a unit in an assisted living facility[70] 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 does 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 of approximately $40 (i.e., without the additional in-home add-on payment amount).

b. Proposals for CY 2023

CMS proposes to continue the additional payment of $35.50 when a COVID-19 vaccine is administered in a beneficiary's home under the circumstances described above. CMS also proposes to adjust this payment amount for geographic cost differences; for 2023, CMS would adjust this payment amount based upon the fee schedule area GAF where the COVID-vaccine is administered. In addition, for 2023, CMS would update the $35.50 by the 2023 MEI as it proposed to do for the other preventive vaccine administration services.

[70] 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.

CMS welcomes comments and suggestion related to program integrity and beneficiary protections associated with payments for administering preventive vaccines in the home, including the COVID-19 vaccine and other preventive vaccines under Medicare Part B.

3. Clarification on Policies for COVID-19 Vaccine and Monoclonal Antibodies Products

a. Background

CMS discusses the distinctions between a PHE declared under section 319 of the Public Health Service (PHS) Act and an EUA under section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act. Under section 310 of the PHS Act, the Secretary can declare a PHE if they determine that: (1) a disease or disorder presents a PHE or (2) a PHE, including significant outbreaks of infectious diseases or bioterrorist attack, otherwise exist. A PHE declaration authorizes the Secretary to take a variety of discretionary actions to respond to the PHE under the statues HHS administers. If the criteria under section 564 of the FD&C Act are met, the Secretary may make a declaration that circumstances exist justifying an EUA of unapproved drugs, devices or biological products, or of approved drugs, devices, or biological products for an unapproved use.

Declarations under section 319 of the PHS Act generally last for 90 days but may be extended by the Secretary.[71] In contrast, an EUA continues until specifically terminated.[72] An EUA declaration may remain in effect beyond the duration of the section 319 PHE declaration. When an EUA declaration is to be terminated, notice is published in the *Federal Register* to provide a reasonable period of advance notice that the EUA declaration is being terminated and to permit time, if necessary, to transition away from EUA products.

Currently, three COVID-19 vaccines are authorized or approved for use in the US to prevent COIVD-19. CMS notes that there are some individuals who receive the FDA approved Pfizer and Moderna vaccines under an EUA. The monoclonal antibody products for treatment or post-exposure prevention of COVID-19 are available through EUAs.

When monoclonal antibody products were authorized during the PHE for COVID-19, CMS decided to cover and pay for them under the COVID-19 vaccine benefit in section 1861(s)(10) of the Act meaning, among other policy considerations, that beneficiaries did not have any cost-sharing for either the product or its administration. It also allowed almost all Medicare enrolled providers and suppliers, as permitted by state law and consistent with the terms of the EUA, to furnish and bill for administering these products across settings of care. Payment for the administration of COVID-19 monoclonal antibody products under the Part B preventive vaccine benefit depends on route of administration, and whether the product is furnished in a healthcare setting or in the beneficiary's home. Payment ranges from $150.50 to $750.00.[73]

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[71] https://www.phe.gov/emergency/news/healthactions/phe/PAges/default.aspx

[72] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/faqs-what-happens-euas-when-public-health-emergency-ends.

[73] Details are discussed in the COVID-19 Monoclonal Toolkit available at https://www.cms.gov/monoclonal.

b. Clarification of Medicare Part B Policies

CMS notes that in policy statements for COVID-19 vaccines and monoclonal antibodies it has used phrases referencing the end of the PHE. Because of the timing distinctions between a PHE declared under section 319 of the PHS Act and an EUA declaration under section 564 of the FD&C Act, CMS believes it needs to clarify that an EUA for a drug or biological product may remain in effect beyond the duration of the section 319 of the PHS Act. CMS discusses these clarifications in the proposed rule and summarizes these clarifications in Tables 71 and 72 (reproduced below). Table 71 displays the 2023 Part B payment for preventive vaccine administration if the EUA declaration persists into calendar year 2023 and Table 72 displays the Part B payment for preventive vaccine administration beginning January 1, 2023 if the EUA declaration ends on or before December 31, 2022.

Table 71: CY 2023 Part B Payment for Preventive Administration if EUA Declaration Persists into CY 2023

Category of Part B Product Administration	Part B Payment Amount (Unadjusted)	Annual Adjustment?	Geographic Adjustment?
Influenza, Pneumococcal, Hepatitis B Vaccines[1,4]	$30	MEI	GAF
COVID-19 Vaccine[2,4]	$40	MEI	GAF
COVID-19 Monoclonal Antibodies (for Treatment or Post-Exposure Prophylaxis)[3]			
Infusion: Health Care Setting	$450.00	N/A	GAF
Infusion: Home	$750.00	N/A	GAF
Intravenous Injection: Health Care Setting	$350.50	N/A	GAF
Intravenous Injection: Home	$550.50	N/A	GAF
Injection: Health Care Setting	$150.50	N/A	GAF
Injection: Home	$250.50	N/A	GAF
COVID-19 Monoclonal Antibodies (for Pre-Exposure Prophylaxis)[3,4,5]			
Injection: Health Care Setting	$150.50	N/A	GAF
Injection: Home	$250.50	N/A	GAF

[1] HCPCS Codes G0008, G0009, G0010.
[2] https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.
[3] https://www.cms.gov/monoclonal.
[4] Beneficiary coinsurance and deductible are not applicable.
[5] As of the issuance of the CY2023 PFS NPRM, this product is only available under EUA as injection.

Table 72: Part B Payment for Preventive Vaccine Administration Beginning January 1, 2023 if EUA Declaration Ends on or Before December 31, 2022			
Category of Part B Product Administration	**Part B Payment Amount (Unadjusted)**	**Annual Adjustment?**	**Geographic Adjustment?**
Influenza, Pneumococcal, Hepatitis B[1,4]	$30	MEI	GAF
COVID-19[2,4]	$30	MEI	GAF
COVID-19 Monoclonal Antibodies (for Treatment or Post-Exposure Prophylaxis)[3]	Medicare payment under the applicable payment system		
COVID-19 Monoclonal Antibodies (for Pre-Exposure Prophylaxis)[4,5]	$150.50/$250.50	N/A	GAF

[1] HCPCS Codes G0008, G0009, G0010.
[2] https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.
[3] Payment is in accordance with the applicable payment system of the setting in which the product is administered and beneficiary coinsurance and deductible are applicable.
[4] Beneficiary coinsurance and deductible are not applicable.
[5] There are no monoclonal antibody products for pre-exposure prophylaxis of COVID-19 that have marketing authorization at this time.

4. Regulatory Updates and Conforming Changes

In the November 6, 2020 interim final rule with comment (IFC)[74], "Additional Policy and Regulatory Revisions in Response to COVID-19 PHE", CMS published several changes to the regulations governing Part B preventive vaccines and their administration to include COVID-19 vaccine and its administration. Since section 3717 of the CARES Act added the COVID-19 vaccine and its administration to section 1861(s)(10)(A) of the Act in the same subparagraph as the flu and pneumococcal vaccines and their administration, CMS made changes in several regulations regarding the influenza, pneumococcal, and HBV vaccinations. CMS intends to finalize regulatory changes adopted in the November 6, 2020 IFC.

I. Medical Necessity and Documentation Requirements for Nonemergency, Scheduled, Repetitive Ambulance Services

CMS proposes revised language at §410.40(e)(2)(ii) to clarify the documentation and medical necessity requirements for nonemergency, scheduled, repetitive ambulance services. The revised paragraph would emphasize that the documentation of medical necessity for these services requires medical record entries describing relevant aspects of the beneficiary's condition (e.g., inability to ambulate) as well as a completed Physician Certification Statement. The revised paragraph would read as follows:

> (ii) In all cases, the provider or supplier must keep appropriate documentation on file and, upon request, present it to CMS. The ambulance service must meet all program coverage criteria including vehicle and staffing requirements. While a signed physician certification statement (PCS), does not alone demonstrate that transportation by ground ambulance was medically necessary, the PCS and additional documentation from the

[74] 85 FR 71147

beneficiary's medical record may be used to support a claim that transportation by ground ambulance is medically necessary. The PCS and additional documentation must provide detailed explanations, that are consistent with the beneficiary's current medical condition, that explains the beneficiary's need for transport by an ambulance, as described at §410.41(a), that includes observation or other services rendered by qualified ambulance personnel, as described in §410.41(b).

CMS bases its proposal on the agency's experience gained with documentation challenges identified during testing by the CMS Innovation Center of the Repetitive, Scheduled, Non-Emergent Ambulance Transport (RSNAT) Prior Authorization model.[75] CMS notes that the proposed language revision aligns with MedPAC's prior recommendation for CMS to more precisely define medical necessity requirements for nonemergency transports to dialysis facilities. CMS further notes that the HHS OIG has investigated and concluded that the nonemergency transport benefit is highly vulnerable to abuse.

J. Medicare Provider and Supplier Enrollment and Conditions of DMEPOS Payment

1. 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 services and items 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.

2. Proposed Medicare Enrollment Provisions

a. Expansion of Authority to Deny or Revoke Based on OIG Exclusion and Associated Definitions

CMS proposes to expand the categories of parties listed within its denial and revocation provisions (§§424.530(a)(2) and 424.535(a)(2)), to include: (1) managing organizations; and (2) officers and directors of the provider or supplier if the provider or supplier is a corporation. This provision now includes the "provider or supplier, or any owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel."

CMS defines "managing organization", "officer," and "director" in §424.502.

Director means a director of a corporation, regardless of whether the provider or supplier

[75] More information about the RNSAT model is available for download at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Prior-Authorization-Initiatives/Prior-Authorization-of-Repetitive-Scheduled-Non-Emergent-Ambulance-Transport-#top.

is a non-profit entity. This includes any member of the corporation's governing body irrespective of the precise title of either the board or the member.

Managing organization means an entity that exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operations of the provider or supplier, either under contract or through some other arrangement.

Officer means an officer of a corporation, regardless of whether the provider or supplier is a non-profit entity.

CMS notes that it has received questions over the years from non-profit corporations regarding the need to disclose information on the application about volunteer or ceremonial board members. It requires such persons to be reported.

CMS also proposes to add a new paragraph to §§424.530(a)(2) and 424.535(a)(2) to clarify that the persons and entities listed in those two regulatory provisions include, but are not limited to, W-2 employees and contracted parties of the provider or supplier.

b. Expansion of Authority to Deny or Revoke Based on a Felony Conviction

Under §§424.530(a)(3) and 424.535(a)(3), respectively, CMS may deny or revoke enrollment if the provider or supplier, or any owner or managing employee of the provider or supplier was, within the preceding 10 years, convicted of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries. CMS proposes to expand these two regulatory provisions to include managing organizations, officers, and directors. It would also add new paragraphs at §§424.530(a)(3)(iii) and 424.535(a)(3)(iv) clarifying that these two provisions also apply to contracted parties.

c. Reversal of Revocation or Denial

Sections 424.535(e) and 424.530(c) relate to reversal of revocation or denial and CMS proposes to add managing organizations, officers, and directors to these provisions to maintain consistency with the changes to §§ 424.530(a) and 424.535(a).

d. Medicare Revocation Based on Other Program Termination

Sections 424.535(a)(12)(i) states, in part, that CMS can revoke enrollment if the provider or supplier is terminated, revoked, or otherwise barred from participation in a State Medicaid program or any Federal health care program. However, under § 424.535(a)(12)(ii) revocation cannot occur unless and until the provider or supplier has exhausted all applicable appeal rights. CMS notes that this latter language has cause some confusion about revocation and the timing when the provider or supplies does not appeal the program termination at all. CMS believes that it does not need to wait until the expiration of every subsequent appellate period that would have applied had the provider or supplier appealed to begin revocation. To clarify this via rulemaking,

CMS proposes to add the language "or the timeframe for filing an appeal has expired without the provider or supplier filing an appeal" to the end of § 424.535(a)(12)(ii).

e. Categorical Risk Designation – Ownership Changes and Adverse Actions

Section 424.518 outlines levels of screening by which CMS and its MACs review initial applications, revalidation applications, and applications to add a practice location. These screening categories and requirements are based on a CMS assessment of the level of risk of fraud, waste, and abuse posed by a particular type of provider or supplier. In general, the higher the level of risk that a certain provider or supplier type poses, the greater the level of scrutiny with which CMS will screen and review providers or suppliers within that category.

There are three levels of screening specified in §424.518: high, moderate, and limited.

The MAC performs the following screening functions (irrespective of screening level) upon receipt of an initial enrollment application, a revalidation application, or an application to add a new location:

- Verifies that a provider or supplier meets all applicable Federal regulations and State requirements for their provider or supplier type.
- Conducts State license verifications.
- Conducts database checks on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet the enrollment criteria for their provider or supplier type.

Providers and suppliers at the moderate and high categorical risk levels must also undergo a site visit. For those at the high screening level, the MAC performs two additional functions for individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplies: (1) the MAC requires the submission of a set of fingerprints for a national background check; and (2) it conducts a fingerprint-based criminal history record check of the Federal Bureau of Investigation's Integrated Automated Fingerprint Identification System.

There currently are only four provider or supplier types that fall within the high categorical risk level under §424.518(c)(1): newly/initially enrolling home health agencies (HHAs); newly/initially enrolling DMEPOS suppliers; newly/initially enrolling Medicare Diabetes Prevention Program (MDPP) suppliers; and newly/initially enrolling opioid treatment programs (OTPs).

CMS is concerned, however, that §424.518 lacks clarity on two issues. First, §424.518 does not address change of ownership applications or the reporting of a new owner when a formal change of ownership is not involved such as disclosing a new 10 percent owner. The lack of clear applicability of §424.518 effectively means that a high-risk level provider or supplier can have a new owner without the latter having to undergo the important scrutiny that fingerpaint-based criminal background checks furnish. The second issue involves the risk-level elevation criteria in §424.518(c)(3). There are numerous health care entities that have multiple enrollments under their organizational umbrella. CMS wants to clarify that screening levels for additional

enrollments would be raised to high if, for example, an adverse action was imposed on one of the provider's or supplier's other enrollments.

To address these issues, CMS proposes the following changes to §424.518. CMS first proposes to add to this paragraph change of ownership applications under §489.18 as a transaction in addition to other transactions required by a Medicare contractor screening all initial applications and revalidating applications. Second, CMS proposes to clarify in §424.518(c)(1) that the provider and supplier types included– once enrolled – are subject to high-risk screening if they are submitting a §489.18 change of ownership application or an application to report a new owner (as described in the previous paragraph). Third, the introductory language in §424.518(c)(3) states that CMS adjusts the screening level from limited or moderate to high if any of the previously cited adverse actions against the provider or supplier occur. These adverse actions include, for example, has been excluded from Medicare by the OIG, terminated or is otherwise precluded from billing Medicaid, or had had billing privileges revoked by a Medicare contractor within the previous 10 years. To clarify the extent of such adjustments, CMS proposes to add a new paragraph (c)(4). CMS states that any adjustment under paragraph (c)(3) would also apply to all other enrolled and prospective providers and suppliers that have the same legal business name (LBN) and tax identification (TIN) number as the provider or supplier for which the risk level under (c)(3) was originally raised.

f. Categorical Risk Designation – Skilled Nursing Facilities (SNFs)

SNFs are currently in the limited-risk screening category under §424.518. CMS in recent years has become increasingly concerned about certain problems within the SNF community, particularly potential and actual criminal behavior. CMS cites several government reports involving patient abuse and recent legal cases that have highlighted issue regarding fraud or improper billing among nursing homeowners or operators. It stresses that financial malfeasance and beneficiary abuse are unacceptable, and it believes that more closely scrutinizing the owners of nursing homes through its existing criminal background checks under §424.518 can help detect potential criminal or abusive behavior at the nursing home before it begins.

CMS proposes to revise §424.518 to move initially enrolling SNFs into the high-level of categorical screening; revalidating SNFs would be subject to moderate risk-level screening. CMS believes that requiring all SNF owners with 5 percent or greater ownership to submit fingerprints for a criminal background check would help it detect parties potentially posing a risk of fraud, waste, or abuse and, with this, the threat of patient abuse.

CMS notes its authority under §§424.530(a)(3) and 424.535(a)(3) to deny or revoke enrollment based on a felony conviction within the previous 10 years; this includes a felony conviction against an owner of the provider or supplier. It emphasizes that its authority under §§424.530(a)(3) and 424.535(a)(3) is discretionary, meaning that CMS is not required to exercise it in every case.

g. DMEPOS Payment Denial Based on Violation of Supplier Standard

CMS notes that DMEPOS suppliers have long presented to the Medicare program an elevated risk of fraud, waste, and abuse. In recognition of this potential threat, CMS has established particularly stringent requirements that DMEPOS suppliers must meet in order to enroll and maintain enrollment in Medicare. These include, but not limited to the highest possible level of screening for initially enrolling DMEPOS suppliers, including site visits and submission of fingerprints by each of the DMEPOS supplier's 5 percent or greater owners. CMS has also established conditions of payment that DMEPOS suppliers must meet to review payment and a number of enrollment standards with which DMEPOS suppliers must comply at all times.

CMS cites one such enrollment standard, codified in §424.57(c)(1)(ii)(A), that if the State requires licensure to furnish certain items or services, the DMEPOS supplier must be licensed to provide the item or service. CMS states that it has encountered situations where an unlicensed DMEPOS supplier furnishes items for an extended period creating a potential vulnerability.

CMS proposes to add a new condition of payment in paragraph (b)(6) in §424.57. This would state that in order to receive payment for a furnished DMEPOS item, the supplier must have been in compliance with all conditions of payment in 424.57(b) as well as state licensure and regulatory requirements at the time the item or service was provided.

h. Estimated Impact

CMS estimates that expansion of revocation reasons (i.e., adding provider's or supplier's managing organization, corporate officer, or corporate director) would result in a small increase in the number of revocations that CMS imposes (10 per year). It estimates that the average provider/supplier affected by these revocations has $50,000 Medicare payments each year resulting in a combined projected transfer of $500,000. The expansion of fingerprint requirements would increase the number of providers and suppliers requiring fingerprints by 29,726 at a combined annual burden of about $7 million. The new DMEPOS condition of payment is anticipated to increase DME payment denials. Over a 12-month period, CMS estimates 73,200 claim denials and $15.6 million in unpaid claims constituting an annual transfer to the federal government.

K. State Options for Implementing Medicaid Provider Enrollment Affiliation Provision

On September 10, 2019, CMS published a final rule with comment period regarding "Program Integrity Enhancements to the Provider Enrollment Process" (84 FR 47794), implementing section 1866(j)(5) of the Act. Under that statutory provision, Medicare, Medicaid, and Children's Health Insurance Program (CHIP) providers and suppliers must disclose—in a form and manner and at such time as determined by the Secretary—any current or previous direct or indirect affiliation with a provider or supplier that:

- has uncollected debt;
- has been or is subject to a payment suspension under a Federal health care program;
- has been or is excluded by the OIG from Medicare, Medicaid, and CHIP; or
- has had its Medicare, Medicaid, or CHIP billing privileges denied or revoked.

The Secretary may deny enrollment based on such an affiliation if the Secretary determines that the affiliation poses an undue risk of fraud, waste, or abuse.

These statutory requirements were implemented in §§424.502 and 424.519 for Medicare and §§455.101 and 455.107 for Medicaid and CHIP. Under the Medicare regulation, providers and suppliers must submit affiliation disclosures upon a CMS request. For Medicaid and CHIP, each state, in consultation with CMS, must select one of two options—which becomes irrevocable—for providers that are not enrolled in Medicare but are initially enrolling in Medicaid or CHIP or revalidating their Medicaid or CHIP enrollment information:

- Option 1. They must disclose their affiliations.
- Option 2. A "phased in" approach under which they must disclose their affiliations only upon request from the state—when, in consultation with CMS, the state has determined the provider may have at least one affiliation that meets criteria specified in the regulation.

The first option requires disclosures with every initial and revalidation application (assuming the provider is not Medicare-enrolled), while the second requires disclosures with the applications only upon the state's request, with a more targeted approach mirroring the approach for Medicare.

A number of states are seeking greater discretion in their operationalization of this policy, believing that requiring the state to continue implementing its selected option without change could hinder its operations and/or its program integrity efforts if that option is proving impracticable or inefficient. Thus, CMS is proposing to permit states that elected Option 2 to change their selection, in consultation with CMS, to Option 1, but not vice versa. This is because Option 1 more thoroughly implements the statutory provision, furnishing greater program integrity protections by requiring all enrolling or revalidating providers to disclose affiliations. CMS cited relevant material from its 2019 rule: "Section 1866(j)(5) of the Act requires every provider and supplier (regardless of the relative risk they may pose) to disclose affiliations upon initial enrollment and revalidation. All States that choose the second option will therefore eventually be required to collect affiliation disclosures from their providers upon the submission of each initial and revalidation application" (84 FR 47816). Consistent with the phased-in approach adopted in the prior rule and in the interest of protecting the Medicaid program and CHIP from fraud, waste, and abuse, CMS believes it is appropriate to allow states the flexibility to move from the second, more limited implementation option to the first, more robust option. Conversely, CMS does not believe states that chose the full-implementation option should be permitted to scale back their approach by changing their selection to the more limited "upon request" option.

L. Electronic Prescribing Controlled Substances under Part D or MA-PD Plans

1. Background

Section 2003 of the SUPPORT Act mandates that, beginning January 1, 2021, the prescribing of a Schedule II, III, IV, or V controlled substance under Medicare Part D be done electronically, with certain exceptions specified in the SUPPORT Act as well as any additional exceptions as

specified by HHS. CMS finalized this provision with an effective date of January 1, 2021 and a compliance date of January 1, 2023.

The agency also finalized a number of exceptions, including exceptions for (1) prescribers who issue 100 or fewer controlled substance prescriptions for Part D drugs per calendar year and (2) prescribers located in emergency or disaster areas.

2. Evaluation of Compliance

In evaluating compliance with requirements or exceptions, the agency proposes to use prescription drug event (PDE) data from the year for which the evaluation is being conducted (i.e., 2023 prescriber practices will be evaluated based on 2023 PDE data). Using this example, the evaluation would not begin until late 2024 and would be based on PDE data used in the Part D Reconciliation for 2023. **It invites comments on the proposal.**

3. Proposed Changes to Exceptions

CMS proposes changes to the two exceptions noted above.

a. Cases Where Prescribers Issue Only a Small Number of Part D Prescriptions

CMS finalized its proposals to exempt prescribers who prescribe 100 or fewer Part D controlled substance prescriptions per year. The exception is available to individual prescribers, regardless of the size of the group practice to which they belong. As finalized, availability of the exception for the year involved is determined by examining PDE claims as of December 31 of the prior year.

CMS proposes to change the year from which PDE data is used to evaluate eligibility for the exception from the preceding year to the current year (i.e., 2023 EPCS compliance with the exception would be assessed using 2023 PDE data). Further, compliance status would be evaluated based on PDE data with a "Date of Service" within the evaluated calendar year using PDE data; this data must be submitted by Part D sponsors mid-way through the following year.

If the proposal is finalized, neither CMS nor the individual prescriber would be able to determine whether the prescriber qualifies for the exception until after the evaluation year unless the prescriber tracks the number of Medicare Part D controlled substance prescriptions issued during the evaluation year. C**omment is sought on the proposal.** CMS acknowledges there is a danger that some prescribers may avoid prescribing controlled substances to Medicare beneficiaries, especially as they near the 100 controlled substance prescription threshold towards the end of the calendar year. **It seeks comment on this possibility.**

CMS also notes that prescribers expect CMS to use 2022 PDE claims data to evaluate compliance with the requirements for the exception in 2023. **It seeks comment on an alternative proposal where, for 2023 only, compliance evaluation would be based on claims for Part D controlled substances prescriptions in 2022 or 2023.**

If finalized, the proposal would be effective for 2023 and subsequent years. CMS notes that the only noncompliance action it would take in 2023 respect to violations of the exception requirements is the issuance of a noncompliance letter; the agency believes that the risk to prescribers of this proposed policy change would be minimal.

b. Cases of Recognized Emergencies

CMS finalized an exception for prescribers who issue prescriptions in areas that are affected by a recognized emergency, such as a natural disaster, a pandemic, or a similar situation where there is an environmental hazard. To qualify for this exception, the circumstance must arise from an emergency or disaster declared by a federal, state, or local government entity for the geographic area associated with the prescriber's address in the National Council for Prescription Drug Programs (NCPDP) database. CMS notes that this exception is applicable only if the dispensing date of the medication occurs during the time period that the declared disaster is occurring.

CMS has discovered that the NCPDP Pharmacy Database contains pharmacy addresses but not prescriber addresses. Therefore, CMS now proposes to use the PECOS address instead of the of the NCPDP Pharmacy Database for those prescribers who have an address in PECOS. For prescribers who do not have a PECOS address, it proposes to use the prescriber address in the National Plan and Provider Enumeration System (NPPES) database. **Comment is sought on the proposal, including potential alternative databases.**

4. Penalties

As finalized in the 2022 PFS final rule, CMS will only issue noncompliance letters in 2023 for prescribers who violate EPCS requirements. The letters notify prescribers that they are violating an EPCS requirement; provide information on how to come into compliance with the requirement; describe the benefits of EPCS; include an information solicitation as to why they are not conducting EPCS; and provide a link to the CMS portal to request a waiver.

CMS proposes to extend its policy of only sending noncompliance letters to noncompliant prescribers for the EPCS program implementation year (i.e., 2023) for another year. Thus, the only noncompliance action the agency would take with respect to EPCS violations in 2023 and 2024 would be the issuance of a noncompliance letter.

CMS again seeks comment on other appropriate types of compliance actions after 2024. The preamble includes a list of specific examples of compliance actions, including requirements for corrective action plans; posting the identity of noncompliant prescribers on the CMS website; publicly reporting the EPCS compliance status of prescribers on the Care Compare website; referring noncompliant prescribers to the DEA; providing lists of noncompliant providers to states; and referral to CMS of noncompliant prescribers for investigation for potential violations of the waste, fraud and abuse laws.

Comment is also specifically sought on the following matters:

- Whether any penalties described above are appropriate as compliance actions without being overly burdensome;
- Whether interested parties believe these penalties will be effective at increasing prescriber compliance;
- Whether penalties should be phased in over time and, if so, after what date CMS should first impose them;
- The utility of posting compliance information to the CMS website or more specifically to the Care Compare website;
- Whether there are any other penalties which CMS should consider to enforce EPCS compliance; and
- How CMS can best enforce EPCS compliance by prescribers who are not billing under Medicare but who prescribe controlled substances to Medicare Part D beneficiaries.

5. Regulatory Impact

CMS does not anticipate that the proposals would have any incremental impact on the cost or time associated with prescriber compliance with the EPCS requirement or the cost to interested parties.

M. Medicare Ground Ambulance Data Collection System

Medicare makes payment for ambulance services based on the ambulance fee schedule. Section 1834(l) of the Act required CMS to develop a data collection system on ambulance costs, revenues and other information by December 31, 2019. The law also required CMS to identify the ground ambulance providers and suppliers by that date that would be required to submit information under the data collection system. If a ground ambulance provider or supplier does not submit information, it could be subject to a 10 percent penalty on its Medicare payments. MedPAC is required to submit a report to Congress based on the information ambulance providers and suppliers provide. CMS designed the survey so that MedPAC's report to Congress can calculate average cost per ground ambulance transport.

As a result of the pandemic, there have been scheduling delays in fielding the survey. Nevertheless, the survey is now in place and CMS has had some learning experiences that have resulted in process changes and improvements to the survey instrument. The proposed rule lists these changes. A draft of the updated instrument that includes all of the 2023 proposed changes to review and provide comments on is posted on the CMS website at: Medicare Ground Ambulance Data Collection Instrument (cms.gov).

Ambulance providers and supplies can apply to be exempt from the 10 percent penalty in the case of a significant hardship, such as a natural disaster, bankruptcy, or other similar situation. In addition, the ambulance provider or supplier may request an informal review of a decision by CMS to apply the 10 percent penalty. CMS outlined the content and procedures that an ambulance provider or supplier must follow to make either of these requests in prior rulemaking (also restated in the 2023 PFS proposed rule).

In the 2020 PFS final rule (84 FR 62897), CMS instructed sending hardship exemption and informal review requests to the Ambulance Open Door Forum (ODF) mailbox (AMBULANCEODF@cms.hhs.gov). In the proposed rule, CMS indicates that it is developing a web-based form via the Medicare Ground Ambulance Data Collection System that will replace sending exemption and informal review requests to Ambulance ODF mailbox. CMS expects to launch the web-based portal in late 2022 and expects it to be more efficient than the current system.

N. Revising HCPCS Level II Coding for Wound Care Management Products

CMS describes the process for creating and revising HCPCS codes and also the FDA approval processes for wound care management products. Some wound care management products are regulated by the FDA as "Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps) under section 361 of the Public Health Service Act. These products must be registered with the FDA but premarket review and approval are not needed. Other wound care management products are regulated by the FDA as devices and may require an approval before they can be marketed.

As of May 2022, there are approximately 150 unique HCPCS Level II codes that describe wound care management products.[76] Prior to 2021, all of these products, including those regulated by the FDA as devices, were assigned a Q code as they were generally considered to be biological products. In the office setting, these products were paid like drugs and biologicals—generally using ASP+6 percent. As part of the HCPCS code application process, CMS required proof of how the product was regulated by the FDA to verify that the product was medical and legally on the market.

Beginning in 2020, CMS required each HCPCS code application for an HCT/P wound care management product to include a letter from the FDA's Tissue Reference Group (TRG) indicating that the product appears to meet the criteria for regulation under the HCT/P FDA regulatory pathway. The proposed rule indicates this information is necessary for CMS to determine for coding purposes how the product should be classified (e.g., as a single source biological, drug or other product).

Effective January 1, 2022, CMS created A codes for 10 FDA approved wound care management products. CMS directed that these products would be contractor-priced by the MACs rather than as drugs and biologicals.

Proposals: CMS is proposing to:

- Assign A codes to all wound care management products that are not drugs or biological products. This proposal would be for all wound care management product products

[76] CMS creates six-digit alphanumeric codes that begin with a letter. For purposes of this discussion, the relevant categories of codes are those beginning with a "Q" (Q codes) or an "A" (A codes). Q codes are used to identify products separately payable as drugs and biologicals under Medicare Part B. A codes are used to identify transportation services and medical and surgical supplies.

previously assigned Q codes and new wound care management products requesting a new HCPCS code.
- Evaluate code application for all wound care management products that are not drugs or biological products on a biannual rather than a quarterly basis consistent with other HCPCS code applications for products that CMS treats as "incident to" medical supplies.
- Allow manufacturers of existing wound care management products with a Q code until January 1, 2024 to apply for an A code before the existing HCPCS code is retired.
- Require all product applicants (including wound care management products with an existing Q code seeking an A code) to furnish a letter from the TRG indicating how the product is or appears to be regulated by the FDA.

Table 74 of the proposed rule lists all wound care management products that currently have Q codes that would be retired on January 1, 2024 where the manufacturer of the product would need to reapply for A code. Manufacturers of these products would have 12 months from January 1, 2023 to apply for an A code including furnishing information from the TRG on how these products are regulated by the FDA in order for CMS to establish an A code that identifies their product.

Table 75 of the proposed rule lists wound care management products that currently have Q codes that would be retired on January 1, 2024 where the manufacturer has already furnished TRG information on how these products are regulated by the FDA. Manufacturers of these products will be granted an A code effective January 1, 2024 without having to reapply for a HCPCS code.

IV. Updates to the Quality Payment Program

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

V. Regulatory Impact Analysis

A. RVU Impacts

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, CMS makes adjustments to preserve budget neutrality.

CMS states that its estimates of changes in Medicare allowed charges for PFS services compare payment rates for 2022 with proposed payment rates for 2023 using 2021 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 2023, before applying any other adjustments. In addition, the expiration of the 3.00 percent increase to PFS payments for 2022 from the Protecting Medicare and American Farmers from Sequester Cuts Act will result in the 2023 CF being calculated as though the 3.00 percent increase for the 2022 CF had never been applied. The CF calculation for 2023 also takes into account an RVU budget neutrality adjustment.

The proposed CF for 2023 is $33.0775, which reflects the expiration of the 3.0 percent increase for services furnished in 2022, the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act, and a budget neutrality (BN) adjustment of -1.55 percent. The 2023 proposed anesthesia conversion factor is $20.7191, 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 136 and 137 from the proposed rule, reproduced below.

Table 136: Calculation of the Proposed 2023 PFS Conversion Factor

2022 Conversion Factor		**$34.6062**
Conversion Factor without 2022 Protecting Medicare and American Farmers from Sequester Cuts Act		$33.5983
Statutory Update Factor	0.00 percent (1.0000)	
2023 RVU Budget Neutrality Adjustment	-1.55 percent (0.9845)	
2023 Conversion Factor		**$33.0775**

Table 137: Calculation of the Proposed 2023 Anesthesia Conversion Factor

2022 National Average Anesthesia Conversion Factor		**$21.5623**
Conversion Factor without 2022 Protecting Medicare and American Farmers from Sequester Cuts Act		$20.9343
Statutory Update Factor	0.00 percent (1.000)	
2023 RVU Budget Neutrality Adjustment	-1.55 percent (0.9845)	
2023 Practice Expense and Malpractice Adjustment	0.53 percent (1.0053)	
2023 Conversion Factor		**$20.7191**

Table 138 (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 second-year transition to updated clinical labor pricing. The table, however, **does not** show the impact of the expiration of the 3.00 percent increase to PFS payments for 2022 from the Protecting Medicare and American Farmers from Sequester Cuts Act. Thus, the combined effect of RVU changes and the conversion

factor is much larger than what CMS displays in Table 138. If, for example, CMS specifies a -2 percent reduction in Table 138 for a given specialty, the combined effect of RVU changes with the CF reduction from the CAA would be roughly -5 percent.

2023 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 2023, specialty level changes can largely be attributed to the revaluation of the other E/M services, the second-year transition to updated clinical labor pricing, and the updated malpractice premium data. These specialty impacts range from an increase of 5 percent for infectious disease, increase of 3 percent for geriatrics and internal medicine, and increase of 2 percent for diagnostic testing facility, nurse practitioner, physical medicine, psychiatry, and a pulmonary disease to a decrease of 4 percent for interventional radiology, a decrease of 3 percent for radiology, nuclear medicine, and vascular surgery, and a decrease of 2 percent for clinical psychologist, clinical social worker, oral/maxillofacial surgery, podiatry, and rheumatology. Other factors that could impact changes include proposed revaluation of individual procedures based on reviews by the AMA RUC and CMS and the continued implementation of previously finalized code-level reductions that are being phase-in over several years.

Column F of Table 138 (reproduced below) shows the estimated 2023 combined impact on total allowed charges by specialty of all the proposed RVU and other changes. For this year, CMS provides an additional impact table (table 139 in the proposed rule) that includes a facility/non-facility breakout of payment changes.

Table 138: 2023 Proposed Rule Estimated Impact on Total Allowed Charges by Specialty

(A) Specialty	(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
Audiologist	$70	0%	1%	-1%	0%
Cardiac Surgery	$197	-1%	-1%	0%	-1%
Cardiology	$6,298	0%	-1%	0%	-1%
Chiropractic	$669	-1%	1%	0%	0%
Clinical Psychologist	$784	-1%	0%	-1%	-2%
Clinical Social Worker	$853	-1%	0%	-1%	-2%
Colon and Rectal Surgery	$155	-1%	-1%	0%	-1%
Critical Care	$351	1%	0%	1%	1%
Dermatology	$3,751	-1%	0%	0%	0%
Diagnostic Testing Facility	$811	0%	3%	0%	2%
Emergency Medicine	$2,530	0%	0%	1%	1%
Endocrinology	$532	0%	0%	0%	0%
Family Practice	$5,777	0%	0%	0%	0%
Gastroenterology	$1,589	0%	0%	1%	0%

General Practice	$371	0%	0%	0%	0%
General Surgery	$1,758	-1%	-1%	0%	-1%
Geriatrics	$175	2%	0%	0%	3%
Hand Surgery	$255	-1%	0%	0%	0%
Hematology/Oncology	$1,707	0%	-1%	0%	-1%
Independent Laboratory	$594	0%	-1%	0%	-1%
Infectious Disease	$586	4%	0%	1%	5%
Internal Medicine	$9,804	2%	0%	1%	3%
Interventional Pain Mgmt	$924	-1%	-1%	0%	-1%
Interventional Radiology	$465	-1%	-3%	0%	-4%
Multispecialty Clinic/Other Phys	$150	0%	-1%	0%	0%
Nephrology	$2,021	1%	0%	0%	1%
Neurology	$1,397	0%	0%	0%	-1%
Neurosurgery	$727	-1%	0%	1%	0%
Nuclear Medicine	$53	-1%	-1%	-1%	-3%
Nurse Anes / Anes Asst	$1,116	-1%	0%	0%	-1%
Nurse Practitioner	$5,802	1%	0%	0%	2%
Obstetrics/Gynecology	$592	-1%	0%	0%	-1%
Ophthalmology	$4,835	-1%	0%	0%	0%
Optometry	$1,306	-1%	0%	0%	-1%
Oral/Maxillofacial Surgery	$72	-1%	-1%	0%	-2%
Orthopedic Surgery	$3,461	-1%	0%	0%	0%
Other	$58	0%	-1%	0%	-2%
Otolaryngology	$1,134	-1%	0%	0%	-1%
Pathology	$1,163	-1%	0%	0%	-1%
Pediatrics	$57	0%	0%	0%	0%
Physical Medicine	$1,090	2%	0%	0%	2%
Physical/Occupational Therapy	$4,978	-1%	1%	-1%	-1%
Physician Assistant	$3,165	0%	0%	0%	0%
Plastic Surgery	$320	-1%	0%	0%	0%
Podiatry	$1,991	-1%	-1%	0%	-2%
Portable X-Ray Supplier	$77	0%	2%	0%	1%
Psychiatry	$978	1%	0%	0%	2%
Pulmonary Disease	$1,395	1%	0%	1%	2%
Radiation Oncology and Radiation Therapy Centers	$1,609	-1%	0%	0%	-1%
Radiology	$4,712	-1%	-1%	-2%	-3%
Rheumatology	$546	-1%	-1%	0%	-2%
Thoracic Surgery	$315	-1%	-1%	0%	-1%
Urology	$1,752	-1%	-1%	0%	-1%
Vascular Surgery	$1,098	0%	-3%	0%	-3%
Total	$90,953	0%	0%	0%	0%

** Column F may not equal the sum of columns C, D, and E due to rounding.
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 138:

- 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 2021 utilization and 2022 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 2023 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 2023 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 2023 impact on total allowed charges of the proposed changes in the MP RVUs.

- Column F (Combined Impact): This column shows the estimated 2023 combined impact on total allowed charges of all the changes in the previous columns.

B. Impacts of Other Proposals

The expected impacts of some of the proposed changes in this rule (other than those associated with changes in RVUs or the update factor) are discussed in previous sections of this summary. This includes the effect of changes related to the clinical laboratory fee schedule, expansion of coverage for colorectal cancer screening, modifications related to Medicare coverage for opioid use disorder treatment services, modifications to the MSSP, Medicare Part B payment for preventive vaccine administrative services, Medicare provider and supplier enrollment changes, proposals related to skin substitute products, effects of proposals for Medicare Part A and B payment for dental services, among others.

C. Changes Due to the Quality Payment Program

CMS estimates that approximately 54 percent of the nearly 1.6 million clinicians billing to Part B (865,116) will be assigned a MIPS score because others will be ineligible for or excluded from MIPS. Table 144, reproduced below, provides the details of clinicians' MIPS eligibility status for 2025 MIPS payment year (2023 MIPS performance year). CMS notes it is difficult to predict whether clinicians will elect to opt-in to participate in MIPS.

TABLE 144: Description of MIPS Eligibility Status for CY 2023 Performance Period/2025 MIPS Payment Year Using the 2023 PFS Proposed Rule Assumptions**			
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)	Participate in MIPS	179,322	$45,466
	Do not participate in MIPS	18,928	$4,686
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low- volume threshold in all 3 criteria and submit as a group)	Submit data as a group	646,749	$17,166
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 and submit data)	Elect to opt-in and submit data	10,933	$574
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**865,116***	**$67,899**
Not MIPS Eligible			
Potentially MIPS eligible (not subject to payment adjustment for non-participation; could be eligible for one of two reasons: 1) meet group eligibility or 2) opt-in eligibility criteria)	Do not opt-in; or Do not submit as a group	424,752	$10,063
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	107,995	$694
Excluded for other reasons (Non-eligible clinician type, newly- enrolled, QP)	Not applicable	207,477	$9,880
Total Number of Clinicians Not MIPS Eligible		740,224	20,637
Total Number of Clinicians (MIPS and Not MIPS Eligible)		1,596,340	88,536

*Estimated MIPS Eligible Population
** This table does not include clinicians impacted by the automatic extreme and uncontrollable policy (approximately 6,000 clinicians and $527 million in PFS allowed charges).
*** Allowed charges estimated using 2019 dollars. Low-volume threshold is calculated using allowed charges. MIPS payment adjustments are applied to the paid amount.

In the aggregate, CMS estimates that for the 2025 payment year, it would redistribute about $1 billion in payment adjustments on a budget neutral basis. CMS estimates that the maximum positive payment adjustment is about 6.9 percent. The overall proportion of clinicians receiving a positive or neutral payment adjustment is 62 percent and 32.5 percent of clinicians are expected to receive a negative adjustment. Beginning with the CY 2025 MIPS payment year, the additional MIPS payment adjustment for exceptional performance will no longer be available.

Table 145, reproduced below, shows the impact of payments by practice size, and based on whether clinicians are engaged --- those who have submitted data from at least on MIPS performance category. CMS notes that because many clinicians scores are close to the

performance threshold, many of these clinician's payment adjustments are fairly small and many negative adjustments are much lower in magnitude than the statutory maximum negative adjustment of 9 percent. Differences in payment adjustments by practice size were small.

Table 145: Estimated 2023 Performance Period/2025 MIPS Payment Year Impact on Total Estimated Allowed Charges by Participation Status and Practice Size**				
Practice Size*	**Number of MIPS eligible clinicians**	**Percent MIPS Eligible Clinicians with Positive or Neutral Payment Adjustment**	**Percent MIPS Eligible Clinicians with Negative Payment Adjustment**	**Combined Impact of Negative and Positive Adjustments as Percent of Paid Amount*** **
Proposed policy model among non-engaged clinicians				
1) Solo	8,758	.000%	100.000%	-8.994%
2) 2-15	7,856	.000%	100.000%	-8.994%
3) 16-99	2,552	.000%	100.000%	-8.980%
4) 100+	1,644	.000%	100.000%	-8.723%
Overall	20,810	.000**%**	100.000**%**	-8.988**%**
Proposed policies model among engaged clinicians ****				
1) Solo	21,955	48.750%	51.250%	-1.387%
2) 2-15#	106,918	53.487%	46.513%	-0.986%
3) 16-99#	215,386	56.052%	43.948%	-0.894%
4) 100+#	492,765	66.560%	33.440%	-0.432%
Overall	837,024	61.719**%**	38.281**%**	-.791**%**

*Practice size is the total number of TIN/NPIs in a TIN.

** 2019 data used to estimate 2023 performance period/2025 payment year payment adjustments. Payments estimated using 2019 dollars trended to 2025.

*** Percentage represents the total adjustments after taking all the positive adjustments and subtracting the negative adjustments for all MIPS eligible clinicians in the same respective practice size.

****Includes facility-based clinicians whose cost and quality data are submitted through hospital programs.

CMS mixed up the numbers in column 4 and column 5 of table 145—corrected in this version.

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 2023, which correlates with payment year 2025, the statute does not provide for any type of incentive for eligible clinicians who become QPs.

Limitations of CMS Analysis

Importantly, CMS describes several limitations to the analysis underlying the tables. It notes that because many score are clustered near the performance threshold of 75 points, minor variations in clinicians final scores relative to is estimations could have significant impacts on the proportion of clinicians receiving a positive or negative payment adjustment. Due to the PHE,

CMS states that it is aware that there may be changes in health care delivery and billing patterns that will impact results for the 2023 performance year/2025 payment year that it was not able to model with its historic data sources. The scoring model results presented in the proposed rule assume that 2019 Quality Payment Program data submissions and performance are representative of 2023. CMS also anticipates that clinicians may submit more performance categories to meet the higher performance threshold to avoid a negative payment adjustment. Likewise, CMS states that it is difficult to predict whether clinicians will elect to opt-in to participate into the MIPS program. CMS states that given these limitations and others, there is considerable uncertainty around its 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 two of particular significance.

1. Alternatives Considered for Adjusting RVUs to Match PE Share of the Medicare Economic Index (MEI)

CMS considered, but did not propose, using the proposed rebased and revised MEI cost share weights for 2023, as discussed in section II. M of this summary. If CMS had updated the MEI cost shares, it would hold the work RVUs constant and adjust the PE RVUs, MP RVUs, and CF to produce the appropriate balance in RVUs among the PFS components and payment rates. That is, the total RVUs on the PFS would be proportioned to approximately 47 percent work RVUs, 51 percent PE RVUs, and 1.5 percent MP RVUs (this would represent a significant shift from the current weights of 51 percent for Work RVUs, 45 percent PE RVUs, and 4 percent MP RVUs). This shift would result in significant specialty specific impacts and a reduction in the PFS CF.

Table 148 in the proposed rule (extract reproduced here) illustrates specialty-specific impacts for the proposed rule if CMS were to use the proposed rebased and revised MEI cost share weights to adjust the RVUs to match the PE share of the MEI.

Extract From Table 148: 2023 PFS Estimated Impact on Total Allowed Charges by Specialty using Rebased and Revised MEI Cost Share Weights as Proposed for 2023

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact No MEI Changes (same as shown in Table 139)	(E) Combined Impact Year 1 MEI Transition	(F) Combined Impact Full MEI Changes
Estimated Conversion Factor			**$34.027**	**$33.642**	**$31.834**
TOTAL	*TOTAL*	$91,046	0%	0%	0%
	Non-Facility	$61,291	-1%	-1%	2%
	Facility	$29,755	2%	1%	-4%

ALLERGY/IMMUNOLOGY	*TOTAL*	$232	-1%	0%	5%
CARDIAC SURGERY	*TOTAL*	$197	-1%	-3%	-9%
CARDIOLOGY	*TOTAL*	$6,310	-1%	-1%	-1%
DIAGNOSTIC TESTING FACILITY	*TOTAL*	$822	3%	5%	16%
EMERGENCY MEDICINE	*TOTAL*	$2,531	1%	-1%	-7%
GENERAL SURGERY	*TOTAL*	$1,760	-1%	-2%	-5%
INDEPENDENT LABORATORY	*TOTAL*	$594	0%	1%	10%
INTERNAL MEDICINE	*TOTAL*	$9,813	3%	3%	1%
NEUROSURGERY	*TOTAL*	$727	0%	-2%	-8%
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	*TOTAL*	$1,608	0%	1%	6%
RADIOLOGY	*TOTAL*	$4,712	-3%	-3%	-2%
THORACIC SURGERY	*TOTAL*	$314	-1%	-2%	-8%

The majority of specialties would experience shifts of 1 percent or greater if CMS used the proposed rebased and revised MEI cost share weights, as opposed to the current weights. Specialties with higher PE costs, such as radiation oncology and radiation therapy centers (+6%) or diagnostic testing facilities (+16%), would realize a positive shift. Those specialties with relatively higher physician cost, such as cardiac surgery (-9%) or neurosurgery (-8%), would experience negative shifts. Notably, the PFS CF would also be adjusted downward due to the shift in the MEI weights related to physician work. If the rebased and revised ME weights were fully implemented for 2023, the PFS CF would have decreased by 6.5% to $31.834.

CMS notes that these shifts are amplified if MEI was fully implemented in one year and thus when implemented, CMS would likely phase-in these changes as shown in Column E in the table above. It also notes that these shifts are also counter to other 2023 proposals that is, changes to E/M services, chronic pain management, and behavioral health services. For these reasons and as discussed in Section II. M of this summary, CMS has proposed to delay the adjustments to allow public comment and finalization of the proposed rebased and revised MEI, and to maintain the use of the current MEI cost share weights.

2. Alternatives Considered for the PE GPCI

CMS notes that it has historically updated the GPCI cost share weights to make them consistent with the most recent update to the MEI. Instead, CMS is proposing to maintain the use of the current 2006-based MEI cost share weights for the 2023 proposed GPCIs.

As an alternative to using the current 2006-based cost share weights, CMS considered using the proposed rebased and revised MEI cost share weights for 2023 for purposes of weighting the four components of the 2023 PE GPCI. Specifically, within the four components of the PE GPCI, CMS considered proposing to update the employee compensation component from 16.553 percent to 24.716 percent, the office rent component from 10.223 percent to 5.893 percent, the purchased services component from 8.095 percent to 13.914 percent, and the medical equipment, supplies, and other miscellaneous expense component from 9.968 percent to 6.819 percent

(Table 149 in the proposed rule).

CMS notes that the use of the proposed rebased and revised MEI cost share weights only impacts the PE GPCI. It found that its proposal to maintain the use of the current 2006-based MEI cost share weights has little to no effect on over 70 percent of the localities' PE GPCIs. It is seeking comment on its proposal to maintain the use of the current 2006-based MEI cost share weights and postpone the implementation of the proposed rebased and revised MEI cost share weights for consideration through potential future rulemaking. CMS provides alternative addenda that incorporated the rebased and revised MEI cost share weights.[77]

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. These proposed policies are designed to reverse recent trends where growth has plateaued, higher spending populations are underrepresented in the programs, and access to ACOs appears to be inequitable. 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. 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 $115.22 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 $921.76 (8.0 hours x $115.22) and the total cost of reviewing this regulation is about $32.7 million ($931.35 x 35,430 reviewers on last year's proposed rule).

[77] See CY 2023 PFS proposed rule at https://www.cms.gov/medicaremedicare-fee-service-paymentphysicianfeeschedpfs-federal-regulation-notices/cms-1770-p