hfma
healthcare financial management association

Physician Fee Schedule Final 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 and Coverage Policies; Medicare Shared Savings Program Requirements; Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts; and COVID-19 Interim Final Rules

[CMS-1770-F, CMS-1751-F2, CMS-1744-F2, CMS-5531-IFC]

On November 2, 2022, the Centers for Medicare & Medicaid Services (CMS) placed on public display a final rule relating to the Medicare physician fee schedule (PFS) for CY 2023[1] and other revisions to Medicare Part B policies. The final rule is scheduled to be published in the November 18, 2022 issue of the *Federal Register*. Policies in the final rules will go into effect on January 1, 2023.

HFMA is providing a summary 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 will cover the Medicare Shared Savings Program Requirements. Part III will cover the updates to the Quality Payment Program.

Part I includes payment policies under the PFS including 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.

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

I. Introduction

The final rule updates the PFS payment policies that apply to services furnished in all sites by physicians and other practitioners. In addition to physicians, the PFS is used to pay a variety of practitioners and entities including nurse practitioners, physician assistants, physical therapists, radiation therapy centers, and independent diagnostic testing facilities (IDTFs). The final rule includes policies 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 finalizing 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 final conversion factor for 2023 is $33.0607, which is 4.5 percent lower than 2022. The 2023 conversion factor 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 -1.60 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 7 percent for diagnostic testing facility, increase of 4 percent for infectious disease, increase of 3 percent for internal medicine, and increase of 2 percent for physical medicine, geriatrics, and psychiatry to a decrease of 3 percent for interventional radiology and vascular surgery, and a decrease of 2 percent for sixteen other specialties. 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 discusses several issues for which it sought comment in this final 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 Final Rule for PFS

A. Background

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

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

[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 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.

In this section CMS finalizes additions to its list of expected specialty assignments for low volume services based on comments received. These 64 additions are listed in Table 1 in the final rule.

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

As explained further in section II. M of this final rule summary, CMS finalized its proposal 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).

CMS is delaying these adjustments to the PE calculation given the delay since the last rebasing and revision of the MEI as well as the methodological and data source changes. For similar reasons, CMS is also delaying the implementation of the rebased and revised MEI for use in the PE geographic practice cost index (GPCI), which is discussed in section II.G. of this summary.

[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.

CMS discusses its comments related to the rebased and revised MEI in section II. M. of this final rule and summary.

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 updates the prices of eight supplies and two equipment items in response to the public submission of invoices. The prices for these items were generally calculated following its standard methodology of averaging together the prices on the submitted invoices. This includes, for example, the extended external ECG patch, medical magnetic tape recorder, which CMS establishes a price of $260.35 (an increase from $200.15) for the SD339 supply based on averaging the 21 invoices received including some additional ones received during the comment period.

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 also received additional comments associated with supply and equipment pricing. This included creation of a new supply code to describe an alternative form of a basic injection pack (SA135), updated price of the fluorescein injectable (SH033), updated the price of the 3C patch

system (SD343), among others. See Table 19 in the final rule for details on the updated prices, CPT codes affected, and number of services impacted.

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 in the past and continues to believe that the direct-to-indirect cost percentages to furnish home PT/INR monitoring are not reflective of the Pathology specialty.[5] In response to comments and recognition that its standard PE methodology approach may not work in all cases, CMS will switch the specialty assignment for these services to the All Physician specialty. This is consistent with how it has treated other new services that do not quite fit it PE methodology in recent rulemaking (cites G2082 and G2083 as examples). It believes that this approach will improve stability in payments, preserve access to care for beneficiaries, as it works to identify longer term solutions.

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 2023). 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 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).

[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.

CMS also agreed with commenters that a multi-year transition would help smooth out the changes in payment resulting from the clinical labor pricing update and avoid potentially disruptive changes in payment and promote payment stability. CMS finalized the implementation of the clinical labor update over 4 years to transition from current prices to the final updated prices in 2025. CMS provides an example of how this transition would be implemented in Table 4 of the final rule (reproduced below). For 2023, the clinical labor pricing would be in Year 2 of the transition.

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

(1) 2023 Clinical Labor Pricing Update

For 2023, CMS received information from one stakeholder prior to the proposed rule and received additional information during the comment period. One stakeholder provided data from the 2019 Wage Survey of Medical Laboratories 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. Lab Tech/Histotechnologist (L035A) would also increase from $0.35 to $0.60.

Several commenters disagreed with the proposed pricing for different technologist clinical labor types. The commenters stated that basic certification is required for a radiologic technologist and that there are additional advanced modality certifications, such as for Computed Tomography (CT), Magnetic Resonance (MRI), and Vascular Intervention (VI), which require additional educational programs and training for these advanced modalities/disciplines. Commenters also requested that CMS update the title of Angio Technicians (L041A) clinical labor type to "Vascular Interventional Technologists" as this would better align with the advance certification required to assist physicians with minimally invasive, image-guided vascular procedures. Commenters submitted wage data from the 2022 Radiologic Technologist Wage and Salary Survey and requested that the pricing for these four clinical labor types be updated to reflect the wage data from the submitted survey. Based on this information, CMS updated the clinical labor pricing for the following three labor types: Vascular Interventional Technologist (L041A), Mammography Technologist (LO43A); and the CT Technologist (L046A).

CMS did not finalize an increase in the pricing of the MRI Technologist (L047A) as it is able to use direct BLS wage data for the occupation as it still believes that BLS is the most accurate source of information for wage data.

Table 8 shows the clinical labor prices CMS finalized in Table 8 – excerpt below show the labor categories that were updated for 2023.

Excerpt of Selected Labor Categories from Table 8: Clinical Labor Pricing						
Labor Code	**Labor Description**	**Source**	**2021 Rate Per Minute**	**Final Rate Per Minute**	**Y2 Phase-In Rate Per Minute**	**Total % Change**
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%
L041A*	Vascular Interventional Technologist	ASRT Wage Data	0.41	0.84	0.624	104%
L043A*	Mammography Technologist	ASRT Wage Data	0.43	0.79	0.611	84%
L046A*	CT Technologist	ASRT Wage Data	0.46	0.78	0.622	70%
* Updated for 2023						

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

CMS did not propose any technical corrections to the direct PE input database, but it received public comments regarding the assigned physician specialty for indirect PE allocation for HCPCS codes G2082 and G2083 (includes high direct costs associated with esketamine supplies). One commenter urged CMS to adopt a clear and recurring process to update, on an annual basis, supply costs for codes G2082 and G2083 with the most recently available wholesale acquisition cost (WAC) data and to include the "Psychiatry" specialty type in the allocation of the indirect PE for G2082 and G083.

Specifically, the commenter urged CMS to provide additional insight behind its specialty designation of "All Physicians" for HCPCS codes G2082 and G2083, and argued that CMS deviated from its normal practice of using the specialty mix contained in the claims data for these codes. The commenter stated that, while CMS has cited concerns in applying the actual specialty mix, CMS has not provided sufficient information or data to suggest that the rates produced when the "Psychiatry" specialty is included produces an inaccurate payment. The commenter also stated that in CY 2021, CMS updated the price for the esketamine supply item for these codes using WAC data from the most recent available quarter, but did not again update the price using the latest WAC data in the CY 2022 PFS final rule, or propose to update the price in the CY 2023 PFS proposed rule. The commenter stated that, based on WAC data on submitted invoices for the most recently available quarter, the supply input that describes 56 mg (supply code SH109) for HCPCS code G2082 should be priced at $683.67, and the supply input describing 84 mg of esketamine (supply code SH110) for HCPCS code G2083 should be priced at $1025.50.

In response, CMS states that it continues to believe that it would not be accurate to assign the Psychiatry specialty for HCPCS codes G2082 and G2083 due to its outlier status among specialties, whereby Psychiatry allocates indirect costs at a 15:1 ratio based on direct costs as compared to most other specialties having approximately a 3:1 ratio. It does not believe that Psychiatry would be an accurate specialty designation for HCPCS codes G2082 and G2083

given the high direct costs associated with esketamine. It will continue to use the All Physician specialty as the specialty assignment for these codes. CMS, however, agrees that it should update supply costs of self-administered esketamine to reflect the WAC data from the most recent available quarter. CMS finalizes an increase in the price of the SH109 supply to $683.67 and an increase in the price of the SH110 supply to $1025.50 to reflect the updated market-based prices associated with esketamine.

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

a. Background

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, 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,

[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.

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 the proposed rule, CMS stated its intent to move to a standardized and routine approach to valuation of indirect PE and welcomed feedback from interested parties on what this might entail. It would propose this new approach to valuation of indirect PE in future rulemaking.

Specifically, CMS sought 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 sought 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 asked 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.).
- 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.

[7] Burgette et. al., 2018

CMS also sought 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.

b. Analysis of Comments

i. Data collection, analysis, and findings

Most commenters that responded to this RFI recommended that CMS delay any change to update the indirect PE survey inputs and to specifically wait for AMA data collection efforts prior to implementing changes. The AMA emphasized that the PPIS continues to be the best available source of data necessary for calculating indirect PE and that CMS has relied on this data sources for 50 years in updating the MEI and 30 years updating the RBRVS. They urged CMS to continue to work with the AMA and various specialty societies until an updated set of data becomes available for use. AMA anticipated that refreshed PPIS data would likely be ready by early 2024. Another commenter submitted a jointly-signed letter that did not support the AMA RUC approaches and advocated for a different means of data collection and analysis for updating the PE methodology. The letter recommended among other suggestions that CMS form an expert advisory group, multidisciplinary in composition, and backed with a dedicated research and development team of CMS staff, to support CMS' strategic plans to update PPIS ratesetting.

In response, CMS reiterates that it continues to believe that the current AMA PPIS data does represent the best available source of information at this time. It remains concerned, however, about consistent and transparent data refreshes and possible alternatives to use of a sole source of data. It believes that transparency and repeatability should be key principles for examining future work to update indirect PE inputs. CMS argues that this is particularly important given that the economic and medical landscapes continue to change rapidly. It cites the example of a research question of interest of whether clinical labor is saved, or replaced by use of automation in the context of furnishing practitioner services. It believes that it needs more verifiable, more objective data sets in the future to supplement or augment survey data alone to help answer such questions.

CMS remains concerned about the current timing for AMA's planned update and that it would be unable to refresh data for several years and thus relying on data nearly 20 years old to form indirect PE inputs used to set rates for services on the PFS. This is significantly at tension with the feedback it receives on a regular basis from stakeholders about the PE methodology shortcomings in its ratesetting methodology. It notes its appreciation for the diversity of perspectives on these issues as it believes this will help foster a more robust set of options moving forward. It reiterates that this RFI does not contain any specific proposals but that it will consider these ideas for future rulemaking.

ii. Changes to health care delivery and practice ownership structures, and business relationships among clinicians and health care organizations.

CMS also solicited comments on current and evolving trends in health care business arrangements, use of technology, or other similar topics that might affect or factor into indirect PE calculations. A few commenters responded to CMS prompt to explore ways that indirect PE can be moved from facility to non-facility payments. They suggested that indirect PE inputs should not be part of payment for the facility rate of payment as the facility bears the indirect costs for provision of services at the facility.

In its response, CMS states that the face value of a change that would reduce the indirect PE portions of its current facility fees for physician' services to zero may have merit. It cites two considerable shifts in today's healthcare business models that provide support for such a change: (1) many physicians and NPP's have become employed staff, versus independent practitioner, and (2) variation in the ways that organizations interact and contract for clinical staff and auxiliary personnel, and structure their compensation. CMS states that it would want, however, to better understand whether potentially reducing to zero any indirect PE portion that is part of the facility fee for physician services may or may not have on reducing competition.

iii. Unintended consequences and missing information

CMS also solicited comment on additional information that it may not have considered or discussed about updating and maintaining PE data inputs. A few commenters expressed concern that topics of AI, a related evolution of software and technology used to support provision of services, and ties to health equity are not well-suited for the process of updates to its annual rulemaking cycle. It states that it received a similar response from many interested parties that question how CMS has in the past, and will in the future, address definition of topics and terms that shape its PE inputs.

In its reply, CMS encouraged interested parties to continue to provide feedback and suggestions to CMS that in general, give an evidentiary basis to shape optimal PE data collection and methodological adjustments over time. Submissions should discuss the feasibility and burden associated with implementation of any suggested adjustments, and should highlight opportunities to optimize the cadence, frequency, and phase-in of resulting adjustments.

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

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

i. Background

CMS sought 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. CMS 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 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**

[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).

[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-

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.

ii. Analysis of comments

While some commenters supported the findings and methodology of the RAND reports, other commenters expressed skepticism of the RAND report findings and methodology. They urged CMS to continue to rely on RUC valuations of global packages (including the number of embedded E/M visits included in the RUC surveys). Commenters urged CMS to continue to examine claims data and electronic health records or obtain postoperative E/M information through direct surveys of practitioners.

CMS stated that the comments it received, particularly those critical of RAND reports and methodology, echo to feedback it received several years ago when it shared the RAND reports for public comment. It states it did not receive new data that might either affirm or contradict RAND's overall findings regarding E/M performance. It states that it will continue to evaluate potential sources of data regarding E/M performance as it has done for many years in response to MACRA requirements. It agrees with commenters who suggest that the overall lack of transparency within global packages can make identifying the nature of postoperative care provision difficult and it continues to call into question the accuracy of globals that have been valued through standard valuation processes.

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

i. Background

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 solicited 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 solicited 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 welcomed 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.

ii. Analysis of comments

On whether the postoperative health care landscape has changed, many commenters stated that postoperative care provided by the proceduralists should still be considered a best practice. Other commenters noted for clinical reasons patients may not need to return for in-person postoperative care within the global period, or that scheduling conflicts may make timely return difficult. In addition, patients, for reasons of convenience, may receive some postoperative care from community practitioners rather than returning to the hospital where the surgical procedure was performed. On the overall relevance of global packages, commenters were mixed on whether postoperative care should be paid separately as standalone visits or should continue to be part of the global packages.

Many commenters provided input on the valuation of the E/M visits embedded in global packages as compared to standalone E/M visits. They urged CMS to increase the value of global packages to reflect the increase in standalone E/M visits (both the office/outpatient increases finalized in CY 2020 at 84 FR 62851 through 84 FR 62854, and increases to certain hospital inpatient E/M visits proposed in CY 2023 at 87 FR 45993.)

CMS agrees with commenters that in-person visits with the proceduralist is the standard of care on which global packages were based, but that it will continue to examine whether this specific model of postoperative care is still necessary or relevant for all procedures.

CMS continues to disagree with commenters' interpretation of the MACRA amendments. It notes that section 1848(c)(8) of the Act, as amended by section 523(a) of the MACRA, directs CMS to use the information collected to improve the accuracy of valuation of these services specifically requires that it use the data obtained through data collection to revalue the global packages. CMS states that its data currently suggests that at least some global packages are inaccurately, revalued. CMA also states that it would be inappropriate to apply an across-the board adjustment to the packages that is not supported by data. Additionally, CMS states that it is also working to reconcile public recommendations that it revalue global packages on a holistic or case-by-case basis (discussed in greater detail in section II.B.6.d. of the final rule).

c. Strategies to Address Global Package Valuation

i. Background

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

CMS sought feedback on possible strategies for a revaluation process for global services. It noted that because there are a large number and volume of services paid as global packages, it stated 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 stated 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 noted that it wanted 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 solicited comment on any other aspects of the global payment structure (aside from valuation) that commenters believe are noteworthy. It also sought comment on any concerns about beneficiaries' access to care, continuity of care, cost sharing, or program integrity.

ii. Analysis of comments

Comments received by CMS were mixed on whether global packages were misvalued. Some commenters encouraged CMS to revalue the packages in order to reduce the impacts of improper valuation on the relative value scale. Other commenters stated that they do not believe that global packages were misvalued or, if they are misvalued, they should be revalued on a holistic and case-by-case basis using the RUC process or the Potentially Misvalued Code process.

CMS also received diverse comments on approaches for revaluing the codes, including revaluing all 10- and 90-day packages, revaluing some 10- and 90-day packages, or focusing just on the 10-day packages. Comments also varied in whether revaluation should occur at once or over a number of years to avoid too much disruption to the relative value scale.

CMS notes the spectrum of comments demonstrate lack of public consensus on this issue and the preferred strategy for valuing globals. It stated that it will consider the specific strategies proposed by the commenters and the concerns regarding impact on the relative value scale and the resources that would be required to revalue these codes.

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 10 (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 10: 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

Table 10: Interested Parties' Nominations of CPT Codes as Potentially Misvalued for 2023	
CPT Code	**CPT Descriptor**
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)

CMS finalizes its proposal not to adopt any of the nominated codes as potentially misvalued codes.

CPT Codes for Home Visits.
Commenters were disappointed because CMS did not take into account the nominator's request for consideration for travel costs, opportunity costs, and the time to assess a patient's home environment. CMS states that these costs are not included in the valuation of services under the PFS. CMS also notes that as discussed below in section II.F (E/M Visits) these codes have been evaluated for 2023.

CPT Codes for Cataract Surgery and Retinal Procedures
Many commenters summarized the evolution of the Cataract and Retinal Surgery codes as they progress from being exclusively performed in hospitals, then performed in ASCs, and now beginning to be performed in Office-Based Surgeries (OBS). Commenters were mainly in favor of establishing payment amounts for services in the non-facility setting. Some hospital/ASC-based commenters raised a number of concerns about shifting these services toward OBS including the lack of independent, high-quality, peer-reviewed clinical data supporting the safety or feasibility of retina surgery performed in the office setting. The AMA RUC commented it defers to the specialty societies to determine whether these services could be safely performed in the non-facility setting; the specialty societies recommended CMS not make these services payable as OBS services. CMS appreciates these comments and will continue to gather information about these procedures in the non-facility office setting.

In response to comments requesting CMS revise the work RVUs for CPT code 66176, CMS notes the code was reviewed in 2022 (85 FR 65095) and will not consider this code as potentially misvalued for 2023.

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.[10]

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

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

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

The 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 11, reproduced with modifications below). CMS does not finalize adding any

[10] 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.

of these requests as Category 1 or Category 2 services; it does finalize 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 will 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). **

Table 11: 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	91110	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 finalizes its proposal not 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 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 finalizes its proposal that CPT codes

97150, 97530, and 97542 should be added to the telehealth list on a Category 3 basis. CMS believes that keeping these services as Category 3 codes would preserve access to care and 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 will 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 finalizes its proposal 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.

Several commenters supported the addition of the additional therapy services on a Category 3 basis but believed that many of these codes should be permanently added on a Category 1 or Category 2 basis. Commenters stated these many of the therapy codes have been provided as telehealth services and have shown the same quality of care as in-person visits. CMS encourages interested parties to use the extended time for telehealth coverage on a Category 3 basis to gather data on the use of these services.

In response to a comment, CMS clarifies that CPT codes for Occupational Therapy (97165-97168) and Speech Therapy (92522 and 92523) were included in the list of Category 3 codes.

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,[11] 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 finalizes its proposal 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.

Many commenters urged CMS to continue to make payment for Telephone E/M visit codes; some commenters stated these should be made permanent telehealth services and others requested that they be added on a Category 3 basis. Commenters provided a variety of reasons for recognizing these codes including access issues and lack of broadband access. A commenter noted that during the PHE, CMS believes telephone E/Ms were serving as a substitute for in-person E/M visits and reimburses them at the same rate as in-person E/M visits.

In response, CMS reiterates that audio-only telephone E/M services are inherently non-face-to-face services. CMS acknowledges that it added the telephone E/M services to the Telehealth List on a temporary basis during the PHE to address the extraordinary public health and safety, and healthcare access issues. However, outside of the PHE, CMS believes its longstanding regulatory

[11] 85 FR 19264-19266, 85 FR 27589-27590, and 86 FR 65055.

interpretation of "telecommunications system" generally precludes the use of audio-only technology, with the exception of certain circumstances related to SUD or a mental health disorder (§410.78(a)(3)).

CMS disagrees with the suggestion to create a third and higher level of virtual check-in service instead of the telephone E/M CPT codes. CMS believes that if a patient requires E/M services that are sufficiently longer than HCPCS code G2252 (11-20 minutes) there are many other E/M visit codes that are already available as Medicare telehealth.

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 finalizes its proposal not to add these services to the telehealth list either for the PHE or as a Category 3 service.

A commenter agreed that CPT code 91110 is inherently a non-face-to-face service as the patient is not present in order for the service to be furnished in its entirety. The commenter stated that the ingestion of the capsule is the only component of this service that requires direct observation by the health care provider and the FDA has approved this direct observation to be done by a telehealth visit. CMS states the face-to-face portion of the service requires the patient to be physically present.

Some commenters agreed that Ambulatory CGM, CPT code 95251, is an inherently non-face-to-face service and does not describe a service that is a substitute for an in-person visit. A few commenters opposed the proposal. CMS continues to believe, and commenters have confirmed, that CPT code 95251 is not a substitute for an in-person visit, as this code describes physician analysis, interpretation, and reporting.

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 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 finalizes its proposal 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. Commenters agreed with CMS that the full scope of service elements described by CPT codes 95976 and 95977 cannot currently be furnished by two-way, audio-video communication technology.

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 finalizes its proposal to add CPT codes 95970, 95983, and 95984 to the telehealth list on a Category 3 basis.

Commenters supported the proposal to add CPT codes 95970, 95983, and 95984 to the Telehealth List on a Category 3 basis; some commenters were disappointed that they were not added on a permanent basis. In response to CMS' comment solicitation regarding safety concerns, a commenter provided detailed information about the safety features including the device automatically reverting to a "safe" program when issues arise. CMS continues to believe that these services are most appropriately Category 3 services. It reiterates that interested parties to use the extended time period of telehealth coverage to support their potential addition to the Telehealth Lost on a Category 1 or Category 2 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 finalizes its proposal to include these services on a Category 3 basis.

Many commenters supported the addition of these services on a Category 3 basis. A few commenters responded to CMS' concerns about patient safety, quality of care and whether the full scope of service elements can be met via a two-way audio video communication technology. A commenter agreed that some patients may not be able to fully be assessed using this technology but believed the benefits of furnishing these services via telehealth outweigh the concerns. One commenter did not support these services remaining on the Telehealth List because of beneficiary safety and quality-of-care issues. CMS responds that adding these codes on a Category 3 basis allows for the collection and evaluation of data that could potentially support permanent inclusion.

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

CMS finalizes its proposal 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 12, reproduced below, includes the 53 services CMS finalizes as Category 3 telehealth services.

Table 12: Services Finalized for Addition to the Medicare Telehealth Services List on a Category 3 Basis Through the End of 2023

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

Table 12: Services Finalized for Addition to the Medicare Telehealth Services List on a Category 3 Basis Through the End of 2023	
HCPCS	**Short Descriptor**
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
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 finalizes its proposal to create three HCPCS codes G0316, G0317, and G0318 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 finalizes its proposal to add them to the telehealth list on a Category 1 basis (Table 13, reproduced below).

Table 13: Services Finalized for Permanent Addition to the Medicare Telehealth Services List on a Category 1 Basis	
HCPCS	Short Descriptor
G0316	Prolonged inpatient or observation services by physician or other QHP
G0317	Prolonged nursing facility services by physician or other QHP
G0318	Prolonged home or residence services by physician or other QHP
G3002	Chronic pain tx monthly
G3003	Addition 15 m pain mang

Many commenters supported these proposals. CMS acknowledges the information provided related to patient safety for audiology services, including information about the Veteran's Administration use of audiology services provided by telehealth. Many comments identified additional services to be considered on a Category 3 basis; CMS considers these comments outside the scope of the proposed rule because they had not been proposed.

For 2023, CMS finalized its proposal two create two HCPCS G-codes (G3002 and G3003) to describe monthly Chronic Pain Management and Treatment Services (discussed in Section E in this summary). In the proposed rule, CMS considered whether to add these services to the Telehealth List. Based on comments received about these services, CMS finalized the addition of these services to the Telehealth List on a Category 1 basis. CMS states that as provided in the code descriptor the initial CPM services visit billed under G3002 must be furnished in-person without the use of telecommunications technology.

One commenter asked if the CPM codes could also be furnished through audio-only technology. CMS states that in the 2022 PFS final rule, it finalized a policy to revise the definition of "telecommunications system" at §410.78(a)(3) to allow the use of audio-only technology for the diagnosis, evaluation, or treatment of mental health conditions under certain circumstances (86 FR 64996, 65056-65060) that allow visits and other services furnished via audio-only technology to be reported as Medicare telehealth services, with the appropriate modifier. CMS acknowledges that certain aspects of CPM may pertain to the diagnosis, evaluation, or treatment of mental health conditions. CMS states it expects physicians to bill with the code that most accurately describes the services furnished, including instances where the service being furnished might be determined by the technology used to deliver the service.

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.[12]

CMS finalizes its proposal 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 14 (reproduced below) lists these services. CMS believes this policy 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 14: 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
94664*	Evaluate pt use of inhaler
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
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

[12] 85 FR 84506-84509

Table 14: Services to be Removed from the Medicare Telehealth Services List After 151 Days Following the End of the PHE	
HCPCS	**Short Descriptor**
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
* Inadvertently omitted from Table 10 in the proposed rule.	

Many commenters supported CMS' proposal; some commenters stated that CMS should eliminate the temporary designation and make permanent all services currently available. CMS continues to believe that services, including those added on a temporary basis during the PHE, should be considered for permanent placement on the Telehealth List through the regular annual process.

CMS notes that services on the Telehealth List on a Category 3 basis will remain on the list for an additional period beyond 151 days after the end of the PHE, which is currently through the end of 2023. CMS acknowledges that the 151-day period after the PHE may end on a date beyond December 31, 2023. CMS clarifies that in this instance, the Category 3 services would remain on Telehealth List through December 31, 2023 or 151 days after the PHE, if later. CMS will consider whether any additional extensions are needed.

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

CMS discusses the provisions of the CAA 2021[13] and CAA 2022[14] that extend certain Medicare telehealth flexibilities adopted during the PHE for 151 days after the end of the PHE.

CMS finalizes its proposal 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;[15]

[13] The CAA 2021 (Pub. L. 116-260) was enacted December 27, 2020.
[14] The CAA 2022 (Pub. L. 117-103) was enacted March 15, 2022.
[15] These services include certain behavioral health, counseling, and educational services that are listed on the

- Allow physical therapists, occupational therapists, speech-language pathologists and audiologists to furnish telehealth services;
- Allow continued payment for telehealth services furnished by FQHCs and RHCs using the methodology established during the PHE

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

CMS received public comment on its proposal to implement section 304(a) of the CAA, 2022 regarding the requirement that an in-person visit with the physician or practitioner must occur within 6 months prior to the initial mental health telehealth service. Many commenters were concerned that a sudden shift in the in-person visit requirements could create beneficiary access issues and put additional strain on the existing health care workforce shortage. CMS also received comments on possible risks to patient safety when patients with certain mental health conditions were treated remotely.

In response, CMS states it did not propose to modify its established policies to implement the in-person visit requirements (except as it pertains to the 151-day extension for the 6-month requirement for an in-person visit for mental health treatment). CMS emphasizes that the availability of furnishing these services via telehealth does not preclude practitioners from seeing patients in-person. CMS also clarifies that it does not believe the required in-person, non-telehealth visit within 6 months prior to the first mental health services furnished via telehealth applies to beneficiaries who began receiving mental health telehealth services during the PHE or during the 151-day period after the end of the PHE. If a beneficiary began receiving mental health telehealth services during the PHE or during the 151-day period after the end of the PHE, they would not be required to have an in-person visit within 6 months; rather, they will be considered established and will instead be required to have at least one in-person visit every 12 months, so long as all the other requirements are met.

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 proposed 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.

Medicare Telehealth Services List available at https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.

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[16] 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 proposed 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.

CMS also proposed 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 proposed 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.

Some commenters expressed concern regarding the proposed approach to the use of modifiers for billing of telehealth services and provided feedback on technical issues associated with the proposals. CMS reiterates that 151 days after the end of the PHE, Medicare telehealth services will once again be subject to the statutory requirements in section 1834(m) of the Act.

Many commenters requested that CMS continue to allow for services that would have been furnished in a non-facility setting outside of the PHE to be billed at the non-facility rate for telehealth services following the end of the PHE. One commenter requested maintaining payment at the non-facility-based rate for telehealth services furnished in office settings through

[16] 86 FR 65059

the end of 2023. The commenter noted that changing payment to the facility rate would result in a nearly 30 percent cut for some services which will harm access to telehealth services. Some commenters, including MedPAC, expressed concern that payment at the facility rate will create the unintended effects of shifting beneficiaries toward higher intensity and a higher volume of virtual care modalities.

CMS acknowledges commenters' concerns about payment stability in the post-PHE period, as care delivery will be potentially transitioning between virtual, hybrid, and in-person models. CMS finalizes that it will continue to allow for payment to be made for Medicare telehealth services at the place of service for telehealth services that ordinarily would have been paid under the PFS if the services were furnished in-person through the later of the end of 2023 or the end of the calendar year in which the PHE ends.

Final Decision: After consideration of public comments, CMS finalizes its proposals, with some modifications:

- Practitioners will continue to bill modifier 95 along with the POS code corresponding to where the service would have been furnished in-person through the later of the end of the year in which the PHE ends or 2023.
    - For services furnished in a facility as an originating site, POS 02 may be used, and the corresponding facility fee can be billed, per pre-PHE policy, beginning the 152nd day after the end of the PHE.
- Effective on and after January 1, 2023, CPT modifier "93" can be appended to claim lines, as appropriate, for services furnished using audio-only communications technology in accordance with the regulation at §410.78(a)(3).
- All providers, including RHCs, FQHCs, and OTPs must append Medicare modifier "FQ" for allowable audio-only services furnished in those settings. All providers, including RHCs, FQHCs, and OTPs must append Medicare modifier "93" when billing for eligible mental health services furnished via audio-only telecommunications technology.
    - Providers have the option to use "FQ" or "93" or both where appropriate since they are identical in meaning.
- Supervising practitioners continue to be required to append the "FR" modifier on any applicable telehealth claim when they provide direct supervision for a service using virtual presence through appropriate telecommunications technology.

CMS reiterates that for Medicare telehealth services, it will continue to maintain payment at the POS had the service been furnished in-person. This will allow payments to continue to be made at the non-facility-based rate for Medicare telehealth services through the later of the end of 2023 or the end of the calendar year in which the PHE ends.

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.[17]

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 notes it did not propose to make the temporary exception to allow immediate availability for direct supervision through virtual presence permanent. In the proposed rule, CMS sought information on whether the flexibility to meet the immediately availability requirement for direct supervision through the use of real-time, audio/video technology should potentially be made permanent, including whether this should be allowed only for a subset of services.

Commenters offered a wide range of perspectives and suggestions for ways that CMS could modify the direct supervision requirements. Many commenters recommended a permanent change to direct supervision; others noted that certain NPPs are authorized in many states under statutory requirements to practice independently under virtual supervision of a physician; and others recommended CMS establish a permanent virtual direct supervision on a specialty-level or service-level. CMS appreciates this information and notes its current policy was adopted to address the circumstances of the PHE.

CMS notes that absent any further action by the Secretary regarding the PHE for COVID-19 the PHE would expire on January 11, 2023. CMS expects to continue to permit direct supervision through virtual presence through at least the end of 2023 and will consider the comments received for potential future rulemaking.

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 final MEI increase for 2023 is 3.8 percent; the final payment for HCPCS code Q3014 (Telehealth originating site facility fee) is $28.64.

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 aggregate spending for Medicare telehealth services. CMS also expects that many of the services

[17] 85 FR 19245-19245 and 85 FR 84538-84540.

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 final rule at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

The following tables in the proposed rule provide additional details about the proposed 2023 valuation of specific codes:

Table 16	Work RVUs for New, Revised, and Potentially Misvalued Codes
Table 17	Direct PE Refinements
Table 18	Direct PE Refinements: Equipment Refinements Conforming to Changes in Clinical Labor
Table 19	Invoices Received for Existing Direct PE Inputs
Table 20	New Invoices
Table 21	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.[18] CMS notes the importance of not only the RUC-recommended work and time values but also the accompanying rationales for setting those values.[19]

[18]Approaches include RUC survey data, building block, key reference code crosswalks, magnitude estimation, incremental difference applications, and time ratio calculations.
[19]Time is parsed into pre-service, intra-service, and post-service components, summing to the total time for each service. To assist in the development of pre-service time recommendations, the RUC created standardized pre-service time packages. There are pre-service time packages for services typically furnished in the facility setting and pre-service packages for services typically furnished in the nonfacility setting.

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.

Commenters continue to raise concerns about CMS' methodology, including its use of time and key references. CMS discussed why it continues to believe its methodology is appropriate.

Table 16 lists the codes and proposed work RVUs, including all codes that CMS received recommendations from the RUC by February 16, 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 18 details CMS' refinements of the RUC's direct PE recommendations at the code specific level. Table 17 details proposed refinements in direct PE due to changes in the equipment time and the conforming changes in clinical labor time.

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

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

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

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

CMS received invoices for several existing and new supply and equipment items (see Tables 19 and 20). 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 19 and 20.

Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap
For 2023, CMS identified proposed 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).

CMS acknowledges that CPT codes 0493T, 0642T, 0651T, 0658T, and 76883 are not within the statutory scope of services to which the OPPS cap applies, as they only describe the processional component and these codes were added in error.

CMS finalizes adding eight CPT codes to the OPPS cap list: 0640T, 0641T, 0689T, 0690T, 0694T, 0700T, and 0701T.

4. Valuation for Specific Codes

This section discusses proposal for 43 code groups (listed in the table below). Highlights of some of CMS' discussions are summarized; the numbering is consistent with the preamble format. The reader is referred to the final rule for more specific details.

Code Group Number and Name		Codes (CPT and HCPCS Codes)	CMS Proposed RVUs Agrees with RUC Recommendations		CMS Finalizes Proposed RVUs	
			Work	PE	Work	PE
1	Anterior Abdominal Hernia Repair*	15778, 49591-49596, 49613-49618, & 49621-49623	No	No	No	Yes
2	Removal of Sutures or Staples	15851, 15853, & 15854	NA	Yes	NA	Yes
3	Arthrodesis Decompression	22630, 22632-22634, 63052, & 63053	No	Yes	No	Yes
4	Total Disc Arthroplasty	22857 & 22860	NA**	NA	NA**	NA
5	Insertion of Spinal Stability Distractive Device	28869 & 22870	NA	Yes	NA	Yes
6	Knee Arthroplasty	27446 & 27447	Yes	Yes	Yes	Yes
7	Endovascular Pulmonary Arterial Revascularization	33900-33904	No	NA	Yes	NA
8	Percutaneous Arteriovenous Fistula Creation*	36836 & 36837	No	NA	Yes	NA
9	Energy Based Repair of Nasal Valve Collapse	30468 & 30469	No	Yes	Yes	Yes
10	Drug Induced Sleep Endoscopy	42975	No	Yes	Yes	Yes
11	Endoscopic Bariatric Device Procedures	43235, 43290, & 43291	Yes	No	Yes	Yes
12	Delayed Creation Exit Site from Embedded Catheter	49436	NA	No	Yes	Yes,
13	Percutaneous Nephrolithotomy	50080 & 50081	No	Yes	No	Yes
14	Laparoscopic Simple Prostatectomy	55821, 55831, 55866 & 55867	Yes	Yes	Yes	Yes
15	Lumbar Laminotomy with Decompression	63020. 63030, & 63035	No	No	Yes	Yes
16	Somatic Nerve Injections	64415-64117, 64445-64448, 76942, 77002, & 77003	No	Yes	No	Yes
17	Transcutaneous Passive-Implant-Temporal Bone	69714, 69716, 69717, 69719, 69726-69730	No	Yes	Yes	Yes
18	Contrast X-Ray of Knee Joint	73580	Yes	Yes	Yes	Yes
19	3D Rendering with Interpretation and Report	76377	Yes	Yes	Yes	Yes
20	Neuromuscular Ultrasound	76881-76883	No	No	No	No
21	Immunization Administration	90460, 90461, 90472-90474	Yes	No	Yes	No
22	Orthoptic Training	92065 & 92066	Yes	Yes	Yes	Yes

Code Group Number and Name		Codes (CPT and HCPCS Codes)	CMS Proposed RVUs Agrees with RUC Recommendations		CMS Finalizes Proposed RVUs	
			Work	PE	Work	PE
23	Dark Adaptation Eye Exam	92284	No	No	Yes	No
24	Anterior Segment Imaging	92287	Yes	Yes	Yes	Yes
25	External Extended ECG Monitoring*	93241-93248	NA	NA	NA	NA
26	Cardiac Ablation Services	93653-93657	No	NA	No	NA
27	Pulmonary Angiography	93563-93568, & 93573-93575	No	NA	No	NA
28	Quantitative Pupillometry	95919	No	Yes	Yes	Yes
29	Caregiver Behavior Management Training*	96202 & 96203	NA	NA		NA
30	Cognitive Behavior Therapy Monitoring	98978	NA	NA**	NA	NA**
31	Annual Alcohol Misuse and Depression Screenings	G0442 & G0444	NA	NA	NA	NA
32	180-Day Implantable Interstitial Glucose Sensor System*	G0308 & G0309	NA**	NA**	NA**	No
33	Chronic Pain Management and Treatment Bundles*	G3002 & G3003	NA	NA	Yes	Yes
34	Behavior Health Services*	NA	NA	NA	NA	NA
35	Behavior Health Integration*	G0323	NA	NA	Yes	NA
36	RFI: Services Involving Community Health Workers*	NA	NA	NA	NA	NA
37	Recognition of the Nurse Portfolio Credentialing Commission*	NA	NA	NA	NA	NA
38	RFI: Potentially Underutilized Services*	NA	NA	NA	NA	NA
39	Family Psychotherapy*	90847 & 90849	NA	NA	NA	NA
40	Intensive Outpatient Mental Health Treatment*	NA	NA	NA	NA	NA
41	Payment for Behavioral Health Services*	NA	NA	NA	NA	NA
42	Interstitial Device Remote Monitoring*	G2066	NA	NA	NA	NA
43	Radiation Oncology Model*	NA	NA	NA	NA	NA

*Discussed in HPA summary
**Contractor Priced Codes

(1) Anterior Abdominal Hernia Repair (CPT codes 15778, 49591-49596, 49613-49618, & 49621-49623)

This code family is an example of the application of CMS' 23-Hour Stay Outpatient Surgical Services Policy.[20] 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.

Commenters disagreed with the application of the 23-hour policy to this code family. Commenters did not believe the 23-hour policy should be applied to codes that the RUC has considered as overnight with a visit on the same day. Commenters did not support CMS' "systemic and formulaic" reduction in work RVUs by using the Reserve Building Block (RBB) methodology; some commenters provided other CPT codes that could be used in the RBB calculation for purposes of comparison. CMS reiterates why it is important to apply the 23-hour stay outpatient surgical services policy. For CPT code 49623, CMS agrees with commenters that there are other more appropriate codes to use as comparison (e.g., CPT 11008) and instead of the proposed work RVU of 2.61, CMS finalizes a work RVU of 3.75 for CPT 49623.

CMS finalizes the work RVUs for this code family as proposed except for CPT code 49623. CMS also finalizes all PE inputs as proposed.

(8) Percutaneous Arteriovenous Fistula Creation (CPT codes 36836 and 36837)
CMS proposes to delete HCPCS codes G2170 and G2171 and replace them with CPT codes 36836 and 36837. 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 requested 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 wanted 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 36837.

Several commenters provided additional information for the four direct PE supply items. The majority of commenters stated that all four of the supply items are typical and should be included as direct PE inputs as recommended by the RUC. Commenters stated that the specialty societies submitted invoice pricing for supplies and equipment to the RUC, and that they do not have any

[20] 75 FR 73226

influence on the prices vendors set for their products. After reviewing this information, CMS finalizes the direct PE supply items SD149, SD152, SF056, and SF057 for CPT codes 36836 and 36837 as recommended by the RUC. CMS is also finalizing the direct PE equipment items (EQ403 and EQ404) as recommended by the RUC.

A few commenters requested that CMS separately identify and pay for high-cost disposable supplies priced at more than $500 using appropriate HCPCS codes, instead of including these high-cost supplies as direct PE inputs. CMS acknowledges it has previously received similar requests from interested parties, including the RUC to implement separately billable Level II HCPCS codes to allow practitioners to be paid the cost of high cost disposable supplies per patient encounter. CMS continues to believe this option presents a series of potential problem related to its ability to price high cost disposable supply items (75 FR 73251).

(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 finalizes its proposal for a national price of $245.69.

Several commenters supported the proposed national price of $245.69 for SD339 supply, but they noted that this result does not adequately reflect the cost of delivering these services by IDTFs. CMS discusses information that KPMG, in conjunction with AdvaMed, performed to develop cost analysis for these services provided by IDTFs. This cost analysis summed to $300.68 for the total cost of providing these services, including capital expenditures and research and developmental costs. A separate commenter submitted a related cost analysis that summed to $283.89. Commenters requested that these services be updated with the costs from the AdvaMed/KPMG analysis as the proposed pricing does not adequately account for all the costs associated with manufacturing and delivery of the associated monitoring services.

CMS appreciates this information but has several concerns with this analysis. CMS notes that delivery, software and processing costs are typically considered to be indirect PE and would not be included in the invoice pricing of the SD339 supply. In addition, costs associated with research and development are not costs included when determining the price of a service under CMS' PE methodology. In addition, CMS uses the "bottom up" methodology to calculate PE RVU and the AdvaMed/KPMG cost analyses is a "top down" analysis which CMS has not used since 2007. CMS states this information could be a useful tool in determining accurate market-based pricing but cannot be directly utilized to determine the most accurate price for SD339.

CMS finalizes national pricing for CPT codes 93241, 93243, 93245 and 93247 and an updated price of $260.35 for the SD339 supply.

(29) Caregiver Behavior Management Training (CPT codes 96202 and 96203)
These 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 96202 and 9603 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 sought comments about the services described by these codes.

Most commenters recommended that CMS pay for these services and use the RUC-recommended values for payment. Commenters notes there is extensive empirical support for caregiver behavior management training and that these services are a component of the standard of care for treatment of behavioral health issues. Commenters stated that although the patient is not present, these codes have many specific, direct benefits for the patient. Commenters also explained how the lack of access to the standard treatments could have a disproportionately negative effect on beneficiaries.

CMS appreciates these comments and intends to address these codes more thoroughly during the 2024 rulemaking process.

(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 sought 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 noted that SD334 is currently priced at $1,500 and EQ392 is currently priced at $1000.

Commenters supported CMS coding proposal. Commenters also requested CMS revalue CPT code 0446T and 04468T to include direct PE costs for the new sensor transmitter since the

current 90-day sensor and transmitter is obsolete; a commenter submitted invoices and pricing information.

In response to comments, CMS finalizes the deletion of G0308 and G0389, effective January 1, 2023. The invoices CMS received from a list showing a supply increase for SD334 from $1,500 to $3,000. The invoices also list the equipment (EQ392) as having an increase in equipment minutes, but not a change in the cost of the transmitter. The physician work remains the same. CMS finalizes a supply input SD334 valued at $3,000 for CPT 0446T and 0448T; CPR 0446 equipment EQ392 will have equipment minutes equal to 51,8140.

(33) Chronic Pain Management (CPM) and Treatment Bundles (HCPCS codes G3002 and G3003, formerly GYYY1 and GYYY2, respectively)
CMS discusses the challenges for adequate treatment of pain, including information from the CDC, HHS and the National Academy of Medicine. The SUPPORT Act[21] 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 a 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 proposed to create separate coding and payment for CPM services.

a. Monthly CPM Services

CMS proposed to define chronic pain management as "persistent or recurrent pain lasting longer than three months". CMS requested comments about this definition and how the chronic nature of the person's pain should be documented in the medical record.

CMS proposed to create two HCPCS G-codes:

HCPCS code G3002 (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;

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

    - 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 G3002, 30 minutes must be met or exceeded.

HCPCS code G3003 (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 30002). (When using G3002, 15 minutes must be met or exceeded.)

CMS requested comments on the proposed code descriptors. CMS also requested comments on what should be required face-to-face services and what services could be provided by auxiliary staff incident to the supervising physician.

CMS also proposed to permit billing by another practitioner after HCPCS code G3002 had 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 G3002 and potentially G3003 could be billed by another practitioner during the same month, for the same beneficiary. CMS proposed 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 proposed 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 proposed 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 also sought information about potential coding and payment to address acute pain.

b. Valuation of CPM

CMS proposed to develop inputs for HCPCS code G3002 using a crosswalk to CPT code 99424 (Principal care management services) and for G3003 using a crosswalk to 99245 (each additional

30 minutes). For G3002, CMS proposed a work RVU of 1.45 and the direct PE inputs associated with 99424. For F3003, CMS proposed a work RVU of 0.50; CMS noted that 99245 has a work RVU of 1.0 but it is for twice the time duration as G3003. CMS proposed to use half of the direct PE inputs associated with 99245.

CMS proposed that G3002 can only be billed when the full 30 minutes of service time has been met or exceeded. Similarly, CMS proposed that G3003 can only be billed when the full 15 minutes of service time is met or exceeded. CMS proposed that G3002 and G3003 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 proposed allowing the billing of G3002 and G3003 on the same day as CCM services, Transitional Care Management Services; or BHI services. CMS also noted that the proposed CPM codes would be limited to beneficiaries in office or other outpatient or domiciliary settings.

(c) Request for Comment

In addition to the above requests for comments, CMS requested comments on a variety of issues many related to referrals or recommendations for services or interventions that are not included as elements of the CPM services, such as PT and OT. CMS was also 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.

(d) Summary of Comments/Responses

CMS received over 150 unique comments from national health care organization, organizations that educate and advocate for people with pain; State-base health care organization; medical societies; health care providers; device manufacturers; and people living with pain and their caregivers. CMS appreciates all these comments and used this information to develop this policy.

Most commenters agreed with CMS' definition for chronic pain; several suggested related to specification of 3 months duration, including one month, 90 days, and the addition of "expected to last longer". A few commenters suggested CMS broaden the definition to ensure specific causes of pain; another commenter was supportive of the proposed language which was inclusive of all types of pain treatment. CMS responds that for operational ease and consistency with the various sources it reviewed, it is finalizing the proposed definition.

In response to the duration and frequency of the CPM codes, most commenters agreed that 30 minutes for G3002 was reasonable and 15-minute intervals for G3003 was adequate. Several comments were concerned the time was not adequate and that the codes should allow for at least an hour for the first visit and 45 minutes for subsequent visits. Another commenter recommended that four visits per month should be allowed for G3002. Based on these comments, CMS finalizes flexibility to bill the G3003 for each additional 15 minutes of care, an unlimited number of times, as medically necessary, per month, after G3002 has been billed. CMS will monitor the use of these codes to better understand how they are used.

CMS agreed with commenters who noted that each person with chronic pain may not need to receive the monthly bundle every month and that a person-centered approach requires variability in how often services are appropriate. CMS finalizes the CPM services for G3002 may not be rendered more than once per month by each individual practitioner billing the code for each beneficiary but could be rendered less than twelve times per year, depending on the specific needs of the person.

In response to comments, CMS revises the code descriptor for G3002 to include complementary and integrative approaches as part of pain management. CMS also revises the descriptor to clarify it does not expect the clinician to develop, implement, revise, and maintain the person-centered care plan each time the CPM codes are billed. CMS acknowledges the many comments it received about the importance of pain and health literacy counseling and includes this in the code descriptor. Many commenters requested that medication management be removed from the code descriptor. CMS disagrees and discusses the literature supporting medication management as an essential element of pain care. CMS also agrees with commenters that certain elements of the CPM bundle, such as care planning, do not likely require face-to-face care.

CMS discusses the many comments it received on the proposal to include administration of a validated pain assessment rating scale or tool, including recommending the use of specific tools. Some commenters raised concerns about using these tools because of the bias that is included in these tools and the need to have separate assessment tools for each population and disease. CMS responds that no prescribed set nor single pain assessment measure will be required because no particular tool or tool set can assess the complex nature of pain across all individuals. CMS discusses the work it is doing with the NIH to create and disseminate an accessible, curated and dynamic set of Pain Assessment resources.

In response to comments about "incident to" billing and its limitations for the creation of collaborative teams, CMS states it may consider further development of CPM codes to recognize components that could be furnished by auxiliary personnel[22] incident to the services of the billing practitioner, and components that could be primarily performed by clinical staff, in the future. CMS also acknowledges that their other practitioners who can potentially support broader chronic pain management. CMS finalizes that G3002 and G3003 are codes for use by physicians and other qualified health professionals. It will consider if there is a benefit to modifying these codes and/or creating new codes in future rulemaking.

Several commenters were concerned about low payment and recommended that the new codes be valued on par with current office and outpatient E/M codes. Many commenters urged CMS to allow the same day E/M billing. In response, CMS states it is not its intent to either underpay, or create incentives for clinicians to use other codes that would constrain the use of new codes. In

[22] Auxiliary personnel is defined at §410.26(a)(1) as any individual who is acting under the supervision of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner), has not been excluded from the Medicare, Medicaid, and all other Federally funded health care programs by the OIG or had their Medicare enrollment revoked, and meets any applicable requirements to provide incident to services, including licensure, imposed by the State in which the services are being furnished.

the absence of any experience, CMS believes the codes are appropriately valued. Based on comments, CMS believes there could be beneficiaries seeing a clinician for the first time, or a subsequent visit, who could also need to be seen by the clinician for the CPM on the same or subsequent day. CMS revises its proposal and will allow both E/M and CPM to be billed on the same day when all the requirements for each service are met and without time or effort being counted more than once. CMS also notes that CPM services (except for the initial visit) have been added to the Medicare Telehealth Services list.

To further assist clinicians and interested parties in understanding how CMS anticipates the CPM services might be used, the final rule includes four scenarios to illustrate how the codes might be used in practice.

- Scenario 1 describes a clinician seeing a new patient who is seeking to establish care for pain management.
- Scenario 2 describes a clinician seeing an established patient who has a stable care plan and is on maintenance medications for management of chronic pain.
- Scenario 3 describes a clinician providing care to a patient with multiple chronic conditions, including pain.
- Scenario 4 describes a clinician transferring care of a patient to another individual clinician in the course of the month for treatment of the patient's chronic pain

(e) Final Decision

In response to public comments, CMS finalizes the descriptor of G3002 with two modifications (shown in italics) and finalizes the descriptor of G3003 as proposed:

HCPCS code G3002: CPM and treatment, monthly bundle including diagnosis; assessment and monitoring;

- Including:
    - administration of a validated pain rate scale or tool; *and/or*
    - 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, *complementary and integrative approaches*, 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 G3002, 30 minutes must be met or exceeded.)

HCPCS code G3003 (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 30002). (When using G3002, 15 minutes must be met or exceeded.)

CMS finalizes its proposed policies for HCPCS codes G3002 and G3003, with modifications:

- CMS defines chronic pain as persistent or recurrent pain lasting longer than 3 months, as proposed;
- CMS requires that the first time G3002 is billed, the physician or qualified health practitioner (QHP) must see the beneficiary in-person. Both individuals must be in a clinical setting such as a primary care practitioner's office or other applicable setting, as proposed;
- A physician or other QHP may bill G3003, for each additional 15 minutes of care, an unlimited number of times, as medically necessary, per month after G3002 has been billed, as revised;
- A work RVU of 1.45 for G3002 and a work RVU of 0.5 of G3003, as proposed;
- That any of the CPM in-person components included in G3002 and G3003 may be furnished via telehealth, as clinically appropriate, in order to increase access to care for beneficiaries, as revised;
- That G3002 and G3003 may be furnished and billed by physicians and other QHPs, as proposed; and
- That both E/M and CPM may be billed on the same day if all requirements to report each service are met, and time spent providing CPM services does not represent time spent for providing any other reported service, as proposed.

In response to comments expressing lack of clarity about certain proposed policies, CMS clarifies the following:

- The beneficiary, at the first visit, need not have an established history or diagnosis of chronic pain, or be diagnosed with a condition that causes or involves chronic pain. It is the clinician's responsibility to establish, confirm, or reject a chronic pain and/or pain-related diagnosis when the beneficiary first presents for care and the clinician first reports G3002.
- Clinicians will be required to furnish all appropriate elements of the code bundle, but CMS does not expect all elements of the code bundle will be appropriate for every patient.
- CMS is not requiring in the code descriptor that a clinician refer a beneficiary to other services; that determination should be made between the clinician and the beneficiary.
- CPM services will be available for billing/reporting in conjunction with remote patient monitoring, remote physiologic monitoring, or remote therapeutic monitoring if all requirements to report each service are met, and the time spent providing CPM services does not represent time spent for any other furnished and billed service.

34. 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.[23] 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 finalizes its proposal 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)[24] 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)).

CMS notes it received a high volume of comments on these proposals. Many commenters supported CMS' proposed revisions to the "incident to" regulations for behavioral health services because the proposal will help expand access, especially in rural and underserved areas and also allow beneficiaries choice to select the type of behavioral health provider that best suits their needs. Several commenters discussed that LPCs and LMTFs possess enough knowledge and training on mental health and addiction to not require any level of supervision; many commenters noted, however, this would require a statutory change.

In response to comments about which services are considered "behavioral health services", CMS states it believes individual practitioners are in the best position to determine what services are behavioral health services. CMS states it generally understands a behavioral health service to be any service furnished for the diagnosis, evaluation, or treatment of a mental health disorder, including substance use disorders (SUD). CMS note in the 210 PFS final rule (74 FR 61787), it referenced the outpatient mental health treatment limitation (which was phased out as of 2104) applied to ICD diagnosis range 290-319; these are the types of behavioral health services that would be eligible to be furnished under this policy. CMS also indicates services could include, but are not limited to psychotherapy, Screening, Brief Intervention and Referral to Treatment (SBIRT) services, psychiatric diagnostic evaluations, and other services furnished primarily for the treatment or diagnosis of mental health or SUD disorders.

In response to request for clarification about the definition of auxiliary personnel, CMS reiterates the regulatory definition at §410.26. CMS notes the definition of general supervision requires the services to be furnished under the physician's (or other practitioner's) overall direction and control. In addition, in order for payment to be made under Medicare Part B for services and supplies incident to the services of the physician (or other practitioner), the service must be an integral, though incidental, part of the service provided in the course of diagnosis or treatment of

[23] 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.
[24] Non-Physician Practitioners (NPPs) include certified nurse midwifes (CNMs), certified nurse specialist (CNSs), nurse practitioner s(NPs) and Physician Assistant (PA)s.

an injury or illness (§410.26(b)). To meet this requirement, CMS expects a course of treatment established by the physician or practitioner in which they are actively participating and managing.

Several commenters recommended allowing behavioral health services to be furnished under general supervision in the RHC and FQHC. CMS responds it may consider changes in the future but notes that the types of practitioners' services that can be considered RHC and FQHC services are specified in section 1861(aa)(1) and (3) of the Act, respectively, and do not include the services of LPCs and LMFTs.

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 that a CP might serve as the primary practitioner that integrates medical care and psychiatric expertise.

CMS finalizes its proposal to create a new G code, G0323, 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. Many commenters supported this proposal.

HCPCS code G0323: 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.

CMS finalizes its proposal to value G0323 based on a direct crosswalk to the work values and direct PE inputs for CPT code 998484 (BHI). The final work value for G0323 is 0.61. Many commenters supported this value and a few discussed reasons for a higher value. CMS notes it may consider changes in how this code is valued for future rulemaking.

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 finalizes its proposal to add G0323 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 finalizes its proposal to allow a psychiatric diagnostic evaluation (CPT 90791) to serve as the initiating visit for G0323. CMS does not agree with commenters requesting CPT code 96156 and other E/M visit codes, could also serve as an allowable initiating visit for the BHI code. CMS believes that CPT 90791 is the best option that aligns with the services that CPs and SCWs are authorized to furnish under State law and scope of practice.

CMS finalizes its proposal that G0323 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. In response to comments, CMS states G0323 could be billed for the same patient in the same month as RPM or RTM services as long as all applicable requirements for the individual codes are met.

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[25]: 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 received several comments in response to its RFI for information about t the role of CHWs in providing health care. CMS appreciates this information and may consider these comments in future rulemaking.

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

CMS finalizes its proposal 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 200 of the Medicare Benefit Policy Manual, pub. 100-02 for NPs and, 210 for CNSs.

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

[25] 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.

communities. CMS appreciates the numerous comments it received and plans to consider these suggestions for possible future rulemaking and program refinement.

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 finalizes its proposal 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. Several commenters supported this proposal. In response to a comment, CMS may consider changes to the procedure status for CPT 90846 in the future,

CMS notes there is a national coverage determination (NCD) addressing family psychotherapy services[26] 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.[27]

CMS received several comments about intensive outpatient mental health treatment and may consider these comments in future rulemaking.

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 received several comments about payment for behavioral health services and may consider these comments in future rulemaking.

42. Payment for Interstitial Device Remote Monitoring (G2066)
CMS did not make any proposals to change the payment rate for G2066. In response to the many comments regarding payment and concerns about price transparency and payment stability for certain contractor priced services, CMS believes it is important for interested parties to continue to engage with their local MAC to address these concerns. CMS notes that ideally, these interactions would support dialogue and the exchange of information through the sharing of applicable and requested information.

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

43. Radiation Oncology Model
On August 29, 2022, CMS finalized delaying the current start date of the Radiation Oncology Model (ROM) to be a date to be determined in future rulemaking. CMS notes that it is reviewing its current coding and payment policies for the radiation therapy services, including whether we should adopt the revised CPT coding established in 2015 to allow for coding and payment consistency. Any changes would be addressed in future rulemaking.

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.

CMS notes that the final policies for the Other E/M visits has 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. Table 16 in the final rule lists the work RVUs.

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

CMS finalizes its proposal 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 finalizes 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 finalizes its proposal to generally adopt the revised CPT E/M Guidelines for Other E/M visits.[28] CMS finalizes adopting the general CPT framework, including selection of time or MDM to be used to determine the E/M visit level and not use history and the physical exam to select the visit level. CMS finalizes using the CPT 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 finalizes adopting the CPT E/M Guidelines for determining level of MDM.

CMS does not adopt the general CPT rule[29] where a billable unit of time associated with a visit level is considered to have been attained when the midpoint is passed. CMS will 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 finalizes requiring 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.[30] 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.

In response to commenters recommending that CMS follow the CPT rule for determining time based on the midpoint of the time for a specific E/M code, CMS reiterates that it has not interpreted the CPT reporting instructions this way and states it would be helpful if CPT would explicitly clarify in the E/M Guidelines that the midpoint rule for reporting of times services does not apply. Consistent with its policy for O/O E/M visits, when time is used to select the visit level, CMS require the full time within the CPT code descriptor to be met to select a visit level based on time.

[28] CPT E/M Guidelines are available at www.ama-assn.org/cpt-evaluation-management.
[29] Introduction to 2022 CPT Codebook, p. xviii
[30] Medicare Claims Processing Manual Chapter 26, Section 10.8

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 day 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 report hospital inpatient or observation care services and the codes were 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).

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 finalizes its proposal to adopt the revised CPT codes 99221-99223 and 99231-99236. CMS finalizes 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 finalizes its proposal to adopt the 2023 CPT Codebook instruction that "per day" (also referred to as "date of encounter") means the "calendar date". CMS also finalizes adopting 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 policy is not in conflict with its proposed retention of the "8 to 24 hour rule" which is discussed below.)

In addition, CMS finalizes its proposal 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.

Many commenters supported the proposals to adopt the CPT's consolidation of these codes. In response to a concern that the code consolidation will discourage physicians from performing a comprehensive history and physical exam, CMS notes a medically appropriate history and/or examination is required but will no longer be used to select a visit level. In addition, CMS reminds practitioners working in hospitals that documentation needs to meet requirements for all payment systems and the Conditions of Participation (CoPs). A few commenters requested a delay in the implementation of the consolidated codes to allow system updates and provider education. CMS responds that the CPT changes become effective January 1, 2023 and retaining

the current codes would require CMS to create G-codes to replace the deleted or altered CPT codes and delay revaluation of the codes.

One commenter suggested that the consolidation of the code families indicates that CMS should discontinue the application of the "23-hour rule".[31] CMS plans to review whether, and if so, how policies relating to hospital inpatient and observation services interact and will address these issues in future rulemaking.

b. "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.[32] CMS proposed 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 proposed 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 proposed that the practitioner would bill CPT codes 99234, 99235, or 99236. CMS noted 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 proposed 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 provided examples of correct billing in the proposed rule.

CMS acknowledges that when it summarized this policy in the proposed rule, it inadvertently removed references to discharge "on the same calendar date" or "on a different calendar date" and corrects the proposed policy to incorporate these references and retracts the examples in the proposed rule. CMS intended to retain the billing policy for Hospital Inpatient codes in the Medicare Claims Processing Manual (Chapter 12, section 30.6.9.1C) and to retain the "8 to 24" hour policy for observation care as stated in the Medicare Claims Processing Manual (Chapter 12, section 30.6.8.B).

CMS notes that the policy for observation care refers to CPT codes that will no longer be valid effective January 1, 2023. CMS clarifies that it intended to propose that while relevant policies in the Medicare Claims Processing Manual would still apply, hospital inpatient and observation coding should be billed as follows:

- When a patient receives hospital inpatient or observation care for less that 8 hours of services, only the Initial Hospital Inpatient or Observation care (99221-99223) are reported by the practitioner for the date of admission. Hospital or Observation Day Management (99238 and 99239) are not reported.

[31] The "23-hour rule" is discussed in the 2011 PFS final rule at 75 FR 73226.
[32] Medicare Claims Processing Manual Chapter 12, Sections 30.6.8.B and 30.6.9.1.C

- When a patient is admitted for hospital inpatient or observation care and then is discharged on a different calendar date, the practitioner reports Initial Hospital Inpatient or Observation Care (99221-99223) and a Hospital Inpatient or Observation Discharge Day Management (99238 and 99239).
- When a patient receives hospital inpatient or observation care for a minimum of 8 hours and is discharged on the same calendar date (thus the stay is less than 24 hours), the practitioner reports the appropriate CPT code (99234-99236). CPT codes 99238-99239 cannot also be reported for this scenario.

Despite the inadvertent misstatement of its policy, 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 determine a billing day can be misleading.

Commenters raised questions about how the "8 to 24-hour rule" interacts with the "23-hour rule" and the "2-midnight rule".[33] CMS acknowledges that it has multiple time-based policies, applicable under different payment systems, which relate to services delivered to hospital inpatients and outpatient and it will review how these policies interact.

CMS notes that the difference between its current "8 to 24-hour rule" and the 2023 CPT reporting instructions, appears to be related to how to handle stays lasting less than 8 hours and the definition of "encounter" in the CPT instructions for same-day admission and discharge codes when there is an admission encounter and discharge encounter on the same day (2023 CPT Codebook, p.17). CMS acknowledges that there may be circumstances in which patients in the hospital for short stays require significant practitioner time and, in these circumstances, the practitioner may be able to bill the prolonged HCVPCS code G0316 (discussed below). CMS recommends that the AMA review this issue.

After consideration of comments, CMS finalizes its proposal to retain the "8 to 24-hour rule" as clarified above. This final policy is summarized in Table 22, reproduced below.

Table 22: Summary of Final Policy for the "8 to 24-Hour" Rule		
Hospital Length of Stay	Discharged On	Code(s) to Bill
< 8 hours	Same calendar date as admission or start of observation	Initial hospital or observation services only*
8 or more hours	Same calendar date as admission or start of observation	Same-day admission/discharge*
< 8 hours	Different calendar date than admission or start of observation	Initial hospital or observation services only*
8 hours or more	Different calendar date than admission or start of observation	Initial hospital or observation services* AND discharge day management
*Plus, prolonged inpatient/observation services, if applicable		

[33] The "23-hour rule" is discussed in the 2011 PFS final rule at 75 FR 73226 and the "2-midnight rule" is discussed in the 2016 OPPS final rule at 80 FR 70305.

c. 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 finalizes its proposal to slightly amend these definitions to account for the fact that CMS does not recognize subspecialties. Specifically, CMS finalizes:

- 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 finalizes its proposal to use the same definitions for initial and subsequent nursing facility visits.

CMS also finalizes its proposal 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.

In response to commenters requesting that CMS adopt the CPT definition which includes subspecialties, CMS states it is continuing to consider whether it could better align its payment taxonomy with clinical practice which would include whether to recognize subspecialties. CMS retains its current taxonomy which does not include the recognition of subspecialties as described in the Medicare Claims Processing Manual (chapter 26, section 10.8, *et seq*). This current taxonomy recognizes NPPs as being in their own specialty.

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

CMS finalizes its proposal 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.
- If a patient is seen in an office setting on one date and receives care at a hospital (for inpatient or observation care) on the next date from the same practitioner, both visits are payable to that practitioner, even if less than 24 hours has elapsed between the visits.
- 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 practitioner 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. Prolonged time can be counted toward reporting of prolonged inpatient/observation services.

[34] Medical Claims Processing Manual, Chapter 12

- A practitioner may bill only for an initial hospital or observation care service if the practitioner 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.

Several commenters did not support retaining the current policy about the billing of multiple visits in different settings by the same practitioner for the same patient on the same date. Commenters noted the CMS policy does not align with CPT guidance for multiple same-day visits. CMS acknowledges that its policies may differ from CPT reporting instructions and notes the AMA indicated in its comment letter that it may refer the issue of multiple same-day billing to CPT for additional review.

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

CMS finalizes its proposal 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.

In response to CMS' request for feedback on potential challenges to billing or claims processing policies, CMS received requests for clarification of the following:

- Changes (if any) to place of services (POS) for observation care claims;
- Changes (if any) to billing in circumstances where practitioners previously would have billed O/O E/M codes; and
- Changes (if any) to the use of the AI modifier to identify the attending practitioner on claims.

CMS appreciates this feedback and will consider these requests for future policies.

Absent further clarifications or additional rulemaking, billing practitioners should continue to submit claims as they would prior to the coding consolidation of the inpatient and observation services, including the POS that is placed on a claim for a patient receiving observation care. For further assistance, CMS directs questions regarding hospital billing or payment to their MACS.

f. Prolonged Services

For 2023, the CPT Editorial Panel deleted CPT codes 99356 and 99357 for prolonged inpatient or observation E/M service(s) time and created CPT code 99418. The 2023 CPT Codebook states, "CPT code 99418 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." (2023 CPT Codebook, p. 29.)

CMS believes the billing instructions for CPT code 99418 will lead to administrative complexity and limit its ability to evaluate claims data. CMS finalizes its proposal not to adopt CPT code

99418 and finalizes a single G code, G0316, that describes a prolonged service (with or without direct patient contact) that applies to CPT codes 99223, 99233, and 99236. G0316 is for each additional 15 minutes and should not be reported for any time unit less than 15 minutes.

CMS finalizes its proposal that G0316 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 finalizes 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 finalizes that G0316 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. CMS notes the RUC-recommended times for when prolonged service can be used do not include post-service time. CMS believes the total time established in the Physician Time File[35] should be used as the base time. For administrative simplicity, CMS finalizes its proposal to use the information in the Physician Time File and 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 G0316. CMS provides examples of correct billing in the final rule.

CMS finalizes that G0316 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 finalizes that CPT codes 99358 and 99359 for prolonged E/M services cannot be billed and this time will be reported under G0316.

Additional information about prolonged services is discussed below in section 11, including a summary table and response to comments.

g. Valuation of Services

CMS finalizes its proposal 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**	**Intraservice Time**	**Total Time**
99221	1.63	40 minutes	40 minutes
99222	2.60	55 minutes	55 minutes
99223	3.50	74 minutes	74 minutes

[35] The time file is included in the public files provided in the finalized PFS which are posted at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulatilon-Notices.

Valuation of Hospital Inpatient or Observation Care Services			
CPT Code	**Work RVUs**	**Intraservice Time**	**Total Time**
99231	1.00	25 minutes	25 minutes
99232	1.59	36 minutes	36 minutes
99233	2.40	52 minutes	52 minutes
99234	2.00	45 minutes	50 minutes
99235	3.24	68 minutes	76 minutes
99236	4.30	85 minutes	97 minutes

Several commenters, although not challenging the RUC recommendations, were concerned that these E/M valuations may be low. Other commenters opposed the proposed values. CMS continues to disagree with comments that facility-based codes are always inherently more intense than E/M services provided in other settings.

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 proposed adopting the revised CPT codes 99238 (discharge day management 30 minutes or less) and 99239 (more than 30 minutes).

CMS proposed retaining its current hospital inpatient discharge policy and expand it to include observation care.[36] Specifically, CMS proposed that CPT codes 99238 and 99239 should be 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 proposed that the same physician may not bill a hospital discharge code on the same day as the subsequent visit code.

Several commenters requested clarification on the proposed policy that the discharge day management code can only be billed by the practitioner "personally responsible for" the discharge service. Commenters suggested this policy is difficult to interpret for team approaches to care delivery.

After consideration of comments, CMS finalizes adopting the revised descriptors for CPT codes 99238 and 99239 and other additional policies as proposed with the following clarifications:

- Only one claim for CPT code 99238 or 99239 may be submitted per patient, per hospital stay. The claim is submitted by the attending practitioner who is responsible for the discharge service. In the case of the death of the patient, these codes are billed by the practitioner who personally performs the death pronouncement.
- The same practitioner may not bill both a hospital discharge CPT code and a subsequent visit CPT codes (99231-99233) for the same patient on the same day.

[36] Medicare Claims Processing Manual, Chapter 12

b. Prolonged Services

CMS finalizes its proposal that a practitioner is not able to bill prolonged services for hospital discharge; CPT codes 99418, 99358, 99359 and the G0316 code are not payable with the discharge management codes 99238 or 99239.

CMS notes that the descriptor for the CPT code 99329 states the code is for "more than 30 minutes" 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 finalizes its proposal 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 finalizes the RUC-recommended direct PE inputs for these codes (Table 17).

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. CMS finalizes its proposal to adopt these revisions.

Several commenters raised concerns relating to the changes in the MDM guidelines because time was needed for training and education; other commenters believe the MDM guidelines do not properly reflect the level of MDM visits appropriately for the ED visits and are requesting CPT to change these guidelines for 2024. Other commenters were supportive of the revisions and supported CMS' decision to implement these changes. In response, CMS states that it is aware that an ED specialty society will propose CPT changes to the MDM guidelines that would impact ED visit level selection beginning in 2024, if passed by CPT. CMS will consider additional changes if they are made by CPT, but it believes it should adopt the changes that have been made for 2023, since they already reflect an initial round of input from ED physicians in the AMA Workgroup and a consensus that was reached at CPT.

In response to a comment requesting clarification of CPT code 99281, CMS states that for 2023, this code is revised to describe an ED visit for the E/M of a patient that may not require the presence of a physician of other QHP. This revision is consistent with the level 1 O/O visits. An example provided by CMS in the ED setting might be a patient presenting for suture removal for a laceration repair that was performed by another provider in a different location when the

wound is healing well. CMS notes it will be monitoring claims data to assess billing patterns for this and other E/M visits under the new framework.

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

CMS finalizes its proposal that if a physician advises their patient to go to a hospital ED for inpatient care or observation and the physician 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 finalizes 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.

Comments related to the ED to nursing facility section are discussed below in section 6 (Nursing Facility Visits).

c. Valuation

CMS finalizes its proposal to accept the RUC-recommended work for four of the five codes in the ED . CMS finalizes 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 finalizes its proposal 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.

CMS only received comments about the work RVUs for the level 4 ED visit – some commenters supported the RUC recommended value and other commenters supported CMS' proposal. Commenters supporting the RUC recommended value stated that the work RVU for the ED codes should be equivalent to the O/O visit codes, based on the level of MDM and raised concerns that CPT code 99284 would have notably higher intensity due to it shorter work time and create a rank order anomaly within the family of ED codes. CMS disagrees with these comments and believes that the small difference in intensity between CPT codes 99284 and 99285 (about 3 percent higher for 99284) is counterbalanced by the much longer work time of CPT code 99285. CMS does not believe the work RVU of CPT code 99284 should be deliberately lowered to manipulate the intensity into a lower value than CPT code 99285.

d. Prolonged Services

CMS finalizes its proposal that 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 finalizes its proposal 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 finalizes adopting 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 is concerned, however, about inconsistencies and errors, where the time described in certain CPT code descriptors does not correctly relate to the time that would be used to select the visit level (e.g., CPT codes 99306 and 99310 have the same times in the descriptors but one is an initial visit and one is a subsequent visit).

CMS finalizes its proposal to retain the following billing policies reflected in the Medicare Claims Processing Manual (Chapter 12, section 30.6.13):

- The required initial comprehensive assessment should be billed as an initial NF care visit (99304-99306). CMS finalizes 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 finalizes the same definition for "initial" and "subsequent" for nursing facility care as it proposed for inpatient and observations services.

- An initial service is one that occurs when the patient has not received any professional services from the physician or other qualified healthcare professional (QHP) or another physician or other QHP of the exact same specialty who belongs to the same group during the stay.
- A subsequent service is one that occurs when the patient has received any professional service from the physician or other QHP or another physician or other QHP of the exact same specialty who belongs to the same group during the stay.

In response to a comment requesting clarification about payment for the hospital discharge manage code (CPT 99238 or 99239), CMS states that consistent with the other policies regarding billing by the same practitioner providing multiple E/M services to the same patient on the same day it will allow for payment of the hospital discharge day management code and a separate nursing facility admission code when they are billed by the same practitioner with the same date of service (Medicare Claims Processing Manual, Chapter 12, section 30.6.9.2.D).

One commenter asked that CMS allow billing of an ED E/M visit on the same day as a NF admission/comprehensive assessment, whether by the same or another practitioner. CMS responds that the main goal of the finalized policies in this area is to maintain current policy while CMS considers what policies for multiple, same-day E/M visits should be revised. For 2023, CMS continues its policy that payment for a NF initial visit can be made to a practitioner other than the practitioner who furnished the ED visit on the same day. If the NF initial visit and ED visit are furnished by the same practitioner for the same day, and time is used to select NF visit level, the time spent for the ED visit can be counted toward prolonged NF services (G0317; see Table 24).

b. Valuation

CMS finalizes its proposal to adopt the RUC-recommended work RVUs and the RUC-recommended direct PE input for theses codes (Tables 16 and 17).

In the proposed rule, CMS discussed 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 did not understand why the work RVU for this code has increased although the code descriptor has not changed since the last valuation. CMS also did 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 sought comments regarding these RUC recommendations.

CMS also sought comments regarding the discrepancies in times between several of the CPT code descriptors and the time described to select the visit level. In their public comment, the AMA explained that the wording of the code descriptors for CPT codes 99306 and 99310 was intentional, such that descriptor times and MDM are the same and that these codes only differ in their inclusion of the times "initial" versus "subsequent". CMS appreciates this clarification but notes that CPT does not appear to consistently apply this approach within or across E/M visit families. CMS recommends that CPT revise the descriptor for 99306, revise the descriptor for CPT code 99308 to 20 minutes, and clarify the methodology being used to establish CPT code descriptor times within and across E/M visit families.

MedPAC agreed with CMS' concerns and did not support CMS' proposal to accept the RUC recommendations for this code family. MedPAC suggested the RUC address these concerns by revising the RVUs or that CMS develop its own RVUs for these services. CMS considered proposing new coding or different work values to address concerns, but after reviewing all the options it concluded it would be least disruptive to adopt the revised code set and values as proposed. CMS intends to monitor this code set and will propose any necessary changes through future rulemaking.

c. Prolonged Services

CMS finalizes its proposal that G0317 is reported for prolonged nursing facility services by a physician or NPP. The code is used when the total time (in the time file) is exceeded by 15 or more minutes; each additional 15 minutes would be billed. G0317 is not reported for any time unit less than 15 minutes. G0317 is billed for each additional 15 minute increment of time beyond the total time for CPT codes 99306 (95 minutes) and 99310 (85 minutes).

CMS finalizes its proposal that the practitioner includes 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 24 below in section 11). CMS finalizes changing 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).

Comments related to the prolonged services are discussed below in section 11 (Prolonged Services).

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

Coding. The nursing facility discharge day management codes (99315 and 99316) 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 finalizes its proposal 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.

Payment. CMS finalizes its proposal to accept the RUC-recommended work RVU of 1.50 for CPT code 99315 and 2.50 for CPT code 99316. CMS also finalizes the RUC-recommended direct PE inputs for these codes (Table 17).
Prolonged Services. CMS finalizes its proposal that prolonged services cannot be reported with nursing facility discharge management codes.

8. Annual Nursing Facility Assessment (CPT Code 99318)

Coding. 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 finalizes its proposal to accept CPT's deletion of 99318.

CMS was concerned that without this code, CMS would not have a way to track how often the required annual visit is performed. All commenters supported the CPT Editorial Panel decision to delete CPT code 99318 and stated that the service is sufficiently reported with other codes.

Payment. 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 finalizes its proposal to accept the RUC-recommended utilization estimates.

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

Coding. 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 finalizes its proposal to adopt the CPT codes as revised for reporting these services.

Payment. CMS finalizes its proposal to adopt the RUC-recommended work RVUs for all eight codes in the family (Table 16). 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 also finalizes the RUC-recommended direct PE inputs for CPT codes 99345 and 99347-99350 (Table 17). CMS is concerned that CPT codes 99341, 99342, and 99342 have duplicative supplies and finalizes its proposal to remove these supplies from the RUC-recommended direct PE inputs.

A few commenters stated the RVUs for these codes were too low and failed to adequately account for travel, addressing social determinants of health, and other comprehensive care. CMS acknowledges these concerns and notes that travel costs are not included in the valuation of E/M codes and the RUC survey for these codes did not include information on physician travel or mileage. In addition, the CPT E/M guidelines specifically indicate that time spent on travel is not considered in the calculation of time (2023 CPT Codebook, p.26).

Prolonged Services. CMS finalizes its proposal that prolonged home or residence services would be reported with G0318. 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. G0318 is not reported for any time unit less than 15 minutes. G0318 is billed for each additional 15 minute increment of time beyond the total time for CPT codes 99345 (126 minutes) and 99350 (97 minutes).

CMS finalizes its proposal 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 24 in section 11). CMS finalizes its proposal 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).

One commenter suggested that CMS allow G2211 (Visit complexity inherent to E/M service) to be reported with the home or residence visit codes. CMS notes that Section 113 of the Consolidated Appropriations Act, 2021 delayed Medicare payment for G2211 until at least January 1, 2024.

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

Coding. The 2023 descriptor time for CPT code 99843 will be increased from 50 to 60 minutes typical time.

Payment. CMS does not accept the RUC-recommended work RVU of 3.5 because it continues to believe that this service is appropriately valued more highly that the analogous O/O E/M visit code 99205. CMS finalizes its proposal to increase the current work RVUs of 3.80 to 3.84 to account for the increase in physician time. CMS finalizes the RUC-recommended PE inputs (Table 17).

Prolonged Services. CMS proposed that prolonged services could not be reported with CPT code 99483.

A commenter did not agree with this proposal and stated that prolonged service has always be allowed with CPT code 99483 and that if prolonged service could not be reported, the practitioner may have incentives to use time and report 99205. CMS agrees and believes this would be consistent with its approach to other prolonged E/M services.

After consideration of the public comment, CMS is not finalizing its proposal that prolonged services could not be reported with 99483. Instead, CMS finalizes that CPT code 99483 can be billed with HCPCS code G2212 (prolonged O/O E/M services) when 15 or more minutes beyond the total time is spent by the physician or NPP (see Table 24). Time spent by the physician or NPP on any date within the surveyed timeframe for CPT code 9983 (within 3 days prior or 7 days after the date of the in-person visit) may be counted toward reporting prolonged services. CMS is also revising the long descriptor for G2212 to include reference to CPT code 99483.

11. Prolonged Services

CMS finalizes its proposal to create Medicare-specific coding for prolonged Other E/M services. CMS finalizes three G codes (G0316, G0317, G0318) for reporting of prolonged Other E/M services. Table 24, reproduced below, summarizes the required time thresholds and time period for these codes.[37]

Table 24: Required 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)	G0316	105 minutes	Date of visit
Subsequent IP/Obs. Visit (99233)	G0316	80 minutes	Date of visit
IP/Obs. Same-Day Admission/Discharge (99236)	G0316	125 minutes	Date of visit to 3 days after
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)	G0317	95 minutes	1 day before visit + date of visit +3 days after
Subsequent NF Visit (99310)	G0317	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)	G0318	140 minutes	3 days before visit + date of visit + 7 days after
Home/Residence Visit Estab. Pt (99350)	G0318	110 minutes	3 days before visit + date of visit + 7 days after
Cognitive Assessment and Care Planning (99483)	G2212	100 minutes	3 days before visit + date of visit + 7 days after
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 includes time with or without direct patient contact by the physician or NPP. Consistent with CPT's approach, we do not assign a frequency limitation.

Many commenters did not support the proposal to use Medicare-specific coding for prolonged Other E/M services for several reasons including the concern for potential confusion and administration burden due to the different approaches between Medicare and CPT, and the potential for variation among payers. Some comments suggested that CMS should not use surveyed time frames. Some commenters supported the proposal and agreed with CMS that Medicare-specific coding will avoid duplicative payment and corrects the lack of transparency in CPT reporting times in comparison to survey times and work valuation.

The AMA strongly disagreed with the CMS proposal and stated it is imperative that physicians have one set of clear codes and guidelines to report prolonged services. The AMA's preference is for CMS to rely on CPT codes and guidelines, and if this isn't possible, will reconvene the AMA Workgroup on E/M to discuss possible revisions to the CPT codes and guidelines. The AMA

[37] Table 18 in the proposed rule provides similar information.

also urged CMS to work with the CPT/RUC Workgroup to align these services and for CMS to give input earlier into the CPT process instead of waiting for the rulemaking cycle.

In their comments, the AMA outlined ways in which they have worked to align the revised CPT coding with CMS' historical approach to prolonged services and avoid creating a global period for E/M visits. The AMA recognized CMS' concerns and agreed that potential overlap should be eliminated and requested that if the CPT Editorial Board consider revisions to these codes that CMS be an active participant in the public and open CPT process.

CMS appreciates the concerns raised by commenters and agrees that the ideal approach would be a CPT code set for prolonged services. Medicare-specific coding is created only when there is a significant program integrity concern or programmatic need, such as needing a code for a specific Medicare statutory benefit category. CMS notes that 2023 will be the first year in the PFS history that almost any E/M visit can be selected using time, whether that time was spent on the same day or another day. In addition, almost all the E/M visit codes have been revised to incorporate new times, new survey data, new parameters for selecting the visit level, and revised MDM levels. CMS believes that all of these changes resulted in reevaluating its policies for prolonged services.

CMS appreciates the opportunity to attend the AMA meetings, but it is obligated under the Administrative Procedure Act and section 1871 of the Act to use notice and comment rulemaking procedures to establish regulations. In addition, CMS engages in extensive internal deliberative process to develop proposed and final polices. CMS notes that it has raised concerns with the AMA's approach to prolonged services in several rulemaking cycles.[38] CMS believes that prolonged service codes function like add-on codes for "extra-long" E/M visits and that these codes should account for time spent beyond the total service time. CMS states this is in contrast to the AMA policy to view prolonged services as accounting for time spent beyond the intra-service time, which is only part of the visit. CMS notes that the total time used by the RUC are not limited to intra-service time and also include pre- and post-service time. CMS believes that adopting the CPT codes for prolonged services would result in duplicative counting and using reporting times that do not align with work times used for valuation.

12. Prolonged Service Valuation

Prolonged Services with Direct Patient Contact (CPT Codes 99354-99357). The CPT Editorial Panel is deleting CPT codes 99354-99357. CMS finalizes its proposal to accept this deletion and as previously discussed, finalizes Medicare-specific codes.

Prolonged Services on a Different Date than the E/M (CPT Codes 99358-99359). CMS finalizes its proposal 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 finalizes its proposal to accept the RUC-recommended direct PE inputs (Table 17).

[38] 81FR 80228-80230, 84 FR 62847-62851, and 85 FR 84572-84575

HCPCS Codes G0316, G0317 and G0318). CMS finalizes its proposal 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 finalizes direct PE inputs for these three codes that are identical to the RUC-recommended PE inputs for CPT code 99417 (Table 17). CMS will continue to use HCPCS code G2212 (prolonged O/O E/M) instead of CPT code 99417.

The AMA disagreed with CMS' approach because this methodology would result in decreased valuation for prolonged services as compared to their historical valuation. Given the myriad of changes in the E/M visit coding and payment, CMS does not believe it is possible to estimate how prolonged service reporting and payment may change in 2023 compared to historical level and how this might impact the amount of time spent with patients. CMS notes that the Medicare-specific coding has comparable or higher work per unit of time (Table 23). CMS will monitor the claims data and potentially consider future rulemaking if it observes underreporting of prolonged services.

13. Consultations (CPT Codes 99241-99255)

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

14. 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 finalizes its proposal to continue these policies.

15. Split (or Shared) Services

In the 2022 PFS final rule[39], 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 the total time for the visit.

CMS continues to hear concerns about the implementation of this policy and received requests to recognize MDM as the substantive portion of the visit. After consideration, CMS finalizes its proposal to delay implementation of its definition of the substantive portion as more than half of the total 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 this delay will allow for

[39] 86 FR 65150-65159

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 finalizes its proposal 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.

Commenters were general supportive of the delay and reiterated comments consistent with the public comments received and addressed in the 2022 final rule (86 FR 65152-65156). Comments reiterated concerns related to burden, disruption of team-based care, and time being dependent on the expertise of practitioner, and suggested allowing MDM to serve as the substantive portion of the visit. The AMA indicated it intends to refer the definition of split (or shared) services back to CPT for further review. CMS acknowledges the concerns raised and will continue to consider these issues and will also take any revised CPT definitions or guidance into consideration for possible future rulemaking.

16. 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 finalizes its proposal to amend part 415 subpart D by removing the regulations at §414.140 and relocating that section to subpart C.

17. 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.

CMS notes that although this was a technical correction, it received many comments requesting modification of the billing policy and adoption of CPT's policy for reporting CPT code 99292 when 75 minutes had elapsed. Some commenters suggested this policy undervalues CPT code

99291 which is 30-74 minutes because the CMS policy extends the time covered by CPT code 99291 from 30-103 minutes.

In response, CMS disagrees that the technical correction reflects a policy change citing the language discussed above at 86 FR 65162. CMS will take commenters' concerns regarding alignment with CPT instructions and the valuation of CPT code 99291 under consideration.

G. Geographic Practice Cost Indices (GPCI)

1. GPCI Update

As required by statute,[40] 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.[41] 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. The previous GPCI update was implemented in 2020 and 2021

CMS finalizes its proposal to phase in 1/2 of the latest GPCI adjustment in 2023 and the remaining ½ of the adjustment for 2024. In addition to the GPCI values, CMS provides summarized geographic adjustment factors (GAFs). GAFs are a weighed composite of each PFS locality's 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,[42] 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.[43] For the 2023 GPCI update, CMS used updated BLS Occupational Employment Statistics (OES) data (2017 through 2020) as a replacement for the 2014 through 2017 data to compute the work GPCIs.

[40] Section 1848(e)(1)(A) of the Act.
[41] Section 1848(e)(1)(C) of the Act
[42] 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.
[43] 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.

- 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 used updated BLS OES data (2017 through 2020) to calculate the employee wage component and purchased service index of the PE GPCI. In calculating the 2023 GPCI update for the office rent index component, CMS used the 2015 through 2019 American Community Survey (ACS) 5-year estimates (which proceeded any COVID-19 impacts).

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

CMS finalizes its proposal to continue using the current 2006-based MEI cost share weights for determining the PE GPCI values. The final 2023 GPCI cost share weights are displayed in Table 25. The finalized rebased and revised cost share weights discussed in section II. M of the final rule and summary are also displayed in Table 25 for awareness regarding potential future rulemaking and GPCI updates.

Table 25: Final GPCI Cost Share Weights for 2023

Expense Category	Current Cost Share Weight	Final 2023 Cost Share Weight	Rebased and Revised Cost Share Weights as Finalized in Section II.M
Work	50.866%	50.866%	47.522%
Practice Expense	44.839%	44.839%	51.129%
- Employee Compensation	16.553%	16.553%	25.451%
- Office Rent	10.223%	10.223%	5.684%%
- Purchased Services	8.095%	8.095%	13.419%
- Equipment, Supplies, Other	9.968%	9.968%	6.575%
Malpractice Insurance	4.295%	4.295%	1.349%
Total	100.000%	100.000%	**100.000%**

With respect to the PE GPCI floor for frontier states, there are no changes in the states identified as Frontier States for 2023.[44] The qualifying states are: Montana, Wyoming, North Dakota,

[44] 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.

South Dakota, and Nevada. In accordance with statute, CMS will 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.

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.[45] 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 finalizes a technical refinement that effectively changes the number of distinct fee schedule areas for payment purposes in California from 32 to 29. For example, CMS will 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, have no payment implications under the PFS. CMS notes that that is unable to operationalize these changes for 2023 due to timing constraints relating to various

[45] The total number of physician localities is 109 payment localities – 34 statewide areas (one locality for the entire state) and 75 localities in the other 16 states (based on changes to California localities).

system changes required to effectuate changes to claims processing. Therefore, there will be no changes to the existing locality numbers 05, 06, 08, 18, or 26. It intends to operationalize these finalized changes for 2024.

3. Refinements to the GPCI Methodology

In the process of calculating GPCIs, CMS finalizes four technical refinements to the methodology that it states yield improvement over the current method.

- Adds 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 26 in the final rule).
- Adds 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 27 in the final rule).
- Modifies 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.
- Adopts a technical refinement to the method used to calculate each locality's GAF. Instead of using the 2006-based MEI cost share weights, CMS will calculate the weights based on Medicare utilization data from 2020.

CMS discusses in much detail in the final 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 will 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 2023 GPCI update.

4. GPCI Update Summary

The 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 final rule. This is available on the CMS website at https://www.cms.gov/files/zip/cy-2023-pfs-final-rule-gpci-public-use-files.zip

5. Analysis of Comments

CMS received a variety of comments on these issues. Some commenters stated that CMS' proposed methodologic changes to the work GPCI occupation groups and codes create unnecessary complexity and limited transparency. It urged CMS to apply a smaller number of professions to the work GPCI, as they thought that doing so would result in a more reliable and accurate proxy for physician work, and provide more information about the correlation between physician work and the proxy professions, which would allow the public to verify its accuracy. Another commenter stated that they agree with the use of more recent wage data, but encouraged CMS to consider the potential effects of the COVID-19 pandemic on the GPCIs given that the timeframe of the BLS OEWS data is pre-pandemic and wages have increased drastically since the start of the pandemic. Others commented that they cannot accurately validate CMS' GPCI calculations because there is little transparency and access to the data and methods used.

In its reply, CMS notes that the work GPCI captures the relative cost of physician and non-physician practitioner labor across Medicare payment localities, not absolute costs. It does not claim that the proxy professions themselves, or the absolute wages of the proxy professionals are correlated to physician wages, but rather, that the geographic variation in proxy professional wages is similar to the geographic variation in physician wages. In response to transparency concerns, CMS refers readers to the step-by-step instructions provided in the final report, "Final Report for the CY 2023 Update of GPCIs and MP RVUs for the Medicare PFS," on its website located under the supporting documents section for the CY 2023 PFS final rule at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.

CMS finalizes the CY 2023 GPCI update, and the methodological refinements, as proposed.

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.[46] 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

[46] 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.

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 Revision of Resource-based Malpractice RVU

a. General Discussion

CMS calculated the MP RVUs using updated malpractice premium data obtained from state insurance filings. The methodology CMS uses 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 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. Methodological Refinements

CMS finalizes 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.

CMS refines 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 as an example that 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 believes that it will retain more data utilizing this small improvement.

CMS will also 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 risk index will 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 MP RVUs follows the same conceptual specialty-weighted approach used in the 2015 update, along with the 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 32 in the final rule shows the specialties subdivided into service risk groups.

Table 32: 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 33 in the final 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 finalizing its proposal 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 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 policy.[47]

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.

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

The 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-final-rule-addenda.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. Only four specialties are expected to be impacted by the changes (a 1 percent decrease): audiologist, clinical psychologist, clinical social worker, and physical/occupational therapy.

d. Analysis of Comments

The majority of commenters were in support of CMS' proposed methodological improvements to its imputation strategy and expanded data collection efforts to create a risk index rather than risk factors. One commenter suggested that CMS make changes to the specialty data source for a few specialties that they believe are incorrectly mapped for purposes of data imputation. Several commenters alerted CMS to a technical ratesetting error for technical component (TC)-only services. They noted that the values for MP RVUs for the professional component appeared too low relative to the TC services. Commenters stated that they believe that this error was caused by the change to a risk index and an error within ratesetting to map TC-only services to a 1.00 risk value. Commenters requested that CMS correct the error or delay implementation of the MP RVU update.

CMS acknowledged the support for its methodological improvements to the imputation strategy and expanded data collection. It agreed with some of the commenter's mapping suggestions for some specialties that require imputation of premium data. Specifically, CMS is finalizing a change for the following specialties for purposes of partial imputation as reflected in Table 8.C.: 72-Pain Management (ALL) to 11-Internal Medicine (ALL), 98-Gynecologist/oncologist (ALL) to 91Surgical oncology (ALL), C0-Sleep medicine (ALL) to 13-Neurology (NO SURG), and C7-Advanced heart failure and transplant cardiology (ALL) to 06-Cardiology (NO SURG).

CMS agrees with commenters that a technical error in its ratesetting system that mapped all TC-only services to a 1.00 risk value resulted in the TC and 26 MP RVU distribution error. It notes in the 2020 update of the MP RVUs (84 FR 62606 through 62615), it finalized that it would assign a risk factor of 1.00, which was the lowest physician specialty risk factor (allergy/immunology), to TC-only services due to a lack of sufficient professional liability premium data. It notes that its expanded data collection resulted in sufficient premium data such it could directly assign a risk value for TC-only services without the need for mapping. However, due to a technical error, CMS continued to assign a 1.0 risk factor for all TC-only services which resulted in an incorrect calculation of the proposed MP RVUs for TC-only services. CMS is finalizing a correction to the ratesetting error for the 2023 update of the MP RVUs. The correction will again map TC-only services to allergy/immunology for this update, which is a risk index value of 0.430. CMS believes that using this risk value will correct the identified error, while also maintaining as much stability as possible for TC-only services so that there is not a major shift in value from current MP RVUs for the TC and 26 components.[48] CMS states that it will continue to re-evaluate the MP RVU methodology for TC-only services for future updates.

[48]This implies that this was not CMS' original intent and that it had planned to use its expanded premium data to

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[49], 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.[50] In addition, RTM codes required direct supervision by the billing practitioner. Commenters stated that direct supervision was 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 proposed 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 34, reproduced below with modifications). CMS did not develop a generic RTM device code and requested comments about RTM devices that are used to deliver services that meet the "reasonable and necessary" standard for Medicare coverage. Specifically, CMS sought 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.

directly assign a risk-value for TC-only services without the need for mapping to the allergy/immunology risk index value of 0.430.

[49] 86 FR 65114-65117

[50] 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.

Table 34: 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 - 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
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 proposed these codes included clinical labor activities that can be furnished by auxiliary personnel under general supervision. CMS proposed the work RVUs and direct PE inputs associated with CPT codes 98980 and 98981 and proposed 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 did not include "incident to" activities in the PE because these codes do not include clinical labor inputs in the direct PE. CMS noted 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 proposed the work RVUs currently finalized for CPT codes 98980 and 98981 and proposed CPT codes 98980 and 98981 would be non-payable by Medicare.

CMS noted 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 were furnished by PTs, OTs, or SLPs, the services would always need to be furnished under a therapy plan of care.[51]

Commenters were supportive of CMS' efforts to enhance access to RTM and RPM services but continued to raise many concerns about the proposal for RTM. In response to these concerns, CMS reiterates its discussion in the 2022 PFS final rule which was the basis for its proposed G-codes. CMS believes that based on the feedback it received for RTM codes it had two options: option one was the creation of new G-codes and option two was for modification of its supervision policy for services furnished incident to a practitioner's professional service to require a general level of supervision, rather than the direct supervision for the existing RTM codes.

Many commenters raised general concerns about all the RTM codes including the burden associated with providing direct supervision for auxiliary staff, the difficulty of recordkeeping and care coordination, and uncertainty about whether a device would be covered. Some commenters were concerned about "claw back" payment for services if an individual beneficiary received concurrent RTM services from two different clinicians engaged in separate episodes of care that involved RTM services for the same beneficiary during the same month. In response, CMS reiterates that even when multiple medical devices are provided to a patient, the services associated with all the medical devices can be billed by only one practitioner, only once per patient, per 30-day period, and only when at least 16 days of data have been collected; and that the services must be reasonable and necessary (85 FR 84545). CMS notes that some of these issues might be addressed in possible changes to CPT coding for both RPM and RTM services and it will consider these changes as they impact CMS policies. CMS appreciated these generalized concerns, including the burden associated with coding and billing for RTM services, and will consider these for possible future rulemaking.

Commenters responded to CMS' request for feedback on the possible development of a generic RTM device code. Commenters were generally supported of a generic RTM device code which would include payment for any FDA approved device for purpose of monitoring various conditions that do not meet the current scope of existing RTM codes. In response, CMS notes it

[51] 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).

in unclear whether a generic device code would be administrable as a permanent policy for several reasons including payment development since there is wide variability in the costs of these devices. In addition, a generic device would require covering many more clinical conditions than the current policy where payment for the RTM codes are limited to musculoskeletal, respiratory, or medication adherence/response to support an episode of therapy.

Commenters also stated that certain types of software are incorrectly categorized as indirect PE allocations within the PFS. One commenter noted that CMS does include specific software costs as supplies within direct PE for other codes and suggested this be the basis for RPM valuations. Many commenters recommended that CMS separately consider Software as a Medical Device (SaMD), use of artificial intelligence (AI)/machine learning algorithms (ML) and related topics as part of a standalone RFI which could provide information about updates to RTM and also other specific codes. In response, CMS refers readers to previous discussion of this topic in the 2019 PFS final rule (83 FR 59577). CMS believes that computer software and associated licensing fees to be indirect costs. CMS also refers readers to available explanations for medical devices, including explanations of SaMD[52] and CPT Appendix S: AT taxonomy for medical services & procedures.[53]

In response to requests that CMS provide specific examples of devices that might be used for RTM services, CMS states that it is not issuing specific examples because this could generate further confusion and imply approval or endorsement of a specific device. CMS would be supportive of the clinical community providing examples in clinical practice guidelines, especially those developed with a patient-centered focus and emphasis on health equity consideration.

Final Decision: After consideration of comments, CMS is NOT finalizing the proposed creation of 4 new G-codes. **For 2023, CMS is maintaining its current policies for the RTM treatment management CPT codes 98980 and 98981 and beginning January 1, 2023 any RTM service may be furnished under general supervision.** Current RTM codes are 98975, 98976, 98977, 98980 and 98981.

a. Review of new RTM device code: Cognitive Behavior Therapy Monitoring (CPT code 98976)

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 98976. CPT code 98976 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*.

CPT code 98976 is a PE-only device code. CMS finalizes its proposal to accept the RUC recommendation that this code should be contractor priced to learn more about the devices used to furnish this service.

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52 https://www.fda.gov/medical-devices/digital-health-center-excellence/software-medical-device-samd.

53 https://www.ama-assn.org/practice-management/cpt/cpt-appendix-s-ai-taxonomy-medical-services-procedures.

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.

b. Therapy KX Modifier Threshold Amounts

The KX modifier thresholds, formerly referred to as therapy caps, were established through section 50202 of the BBA of 2018. For 2023, CMS is increasing the KX modifier threshold amount of $2,150 by the 2023 MEI of 3.8 percent and rounding to the nearest $10 resulting in a 2023 KX threshold amount of $2,230 for PT and SLP services combined and $2,230 for OT services.

For 2023, the targeted medical review (MR) threshold is $3,000 for PT and SLP services combined and $3,000 for OT services. Under the targeted review process, some, but not all claims exceeding the MR threshold amount are reviewed.[54]

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

1. Background

Stakeholders have expressed concerns that CMS' policies for "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 ASP+6 percent while others are contractor priced.
- Packaged/Separate Payment: Under the OPPS, CMS packages payment into the application procedure but pays separately for the products in physician offices.

CMS proposed to revise its payment policies for skin substitutes with the following objectives:

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

[54] Information on the targeted medical review process is available at https://www.cms.gov/ResearchStatistics-Data-and-Systems/MonitoringPrograms/Medicare-FFSCompliancePrograms/Medical-Review/TherapyCap.html.

One comment suggested a 6th objective—aim to provide broad access to these products regardless of wound size, wound type, or anatomic location. CMS will consider this additional objective in future rulemaking.

2. Proposals

Changing the Terminology. CMS proposed 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 indicated that the terms "care management" or "management" are not intended to 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.

While a few commenters agreed with the proposal or at least supported some of the alternative terminology CMS suggested, most commenters opposed the proposal. Objections were in the following categories;

Inconsistency with CPT. Many commenters indicated that the terminology "wound care management product would be inconsistent with how CPT describes these products for using the skin substitute application codes (CPT codes 15271-15278). CPT guidelines for reporting skin substitutes application codes are clear and they do not include the application of non-graft wound dressings (for example, powder, ointment, foam, liquid) or injected skin substitutes. If skin substitutes are "wound care management products," it may create doubt or confusion as to whether the skin substitute application codes remain billable.

CMS Misunderstanding of Skin Substitute Products. The commenters stated that the proposed terminology incorrectly suggests that the skin substitute products are not technically a substitute for skin, but rather, a wound covering that is used to promote healing. The application of skin substitutes serves a specific purpose of temporary or permanent coverage of open skin wounds. The skin substitute is allowing for the construction of natural dermis which goes above and beyond a "wound covering" according to these commenters.

"Wound Care Management Product" will Create More Confusion. A few commenters stated that changing the terminology to wound care management products would conflate skin substitute products with other products like wound care dressings or bandages. The terminology does not sufficiently distinguish skin substitutes from wound care dressings or

bandages that are also used to treat wounds but without a mechanism of action that stimulates the host to regenerate lost tissue.

Misalignment with FDA. There were comments indicating that the FDA regulates some skin substitutes as Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P). These products are for reconstruction, repair, or replacement or skin. The term "wound care management product" would be inconsistent with how FDA describes skin substitutes.

Final Decision: While CMS continues to believe that the term skin substitutes is an overly broad misnomer, it says that additional dialogue will be beneficial before finalizing new terminology. CMS is not finalizing changes to the terminology at this time. It intends to hold a Town Hall in early 2023, prior to CY 2024 rulemaking, to have additional discussions about this issue.

Revising Payment. CMS acknowledges that it has inconsistent payment policies for different types of skin substitutes in the physician office setting (contractor pricing or ASP+6 percent). These inconsistencies arose over time as CMS treated skin substitutes as biologicals when it initially established ASP pricing in 2005. Synthetic skin substitutes are a more recent innovation. CMS has not been treating synthetic skin substitutes as biologicals, resulting in the pricing inconsistency that has caused CMS to reexamine its policies.[55]

CMS acknowledges the overlap in purpose between synthetic and biological skin substitutes. As a result, CMS proposed to establish a consistent pricing policy for all skin substitutes used in the 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 time for changes in coding described in section III. N. Under the coding policy proposal, CMS would continue to pay using ASP+6 percent for skin substitute Q codes for all of 2023. However, CMS proposed to retire all skin substitute Q codes by January 1, 2024 while providing 12 months from January 1, 2023 for interested stakeholders to apply for A codes. For all skin substitutes meeting the criteria for a HCPCS Level II code, CMS proposed contractor pricing these codes effective January 1, 2024 until such time as CMS could bundle payment for skin substitutes into the PFS payment (expected to be 1 to 5 years).

Comments/Responses: Commenters indicated that there was insufficient information available on CMS' proposal to provide meaningful comment. For this reason, commenters

[55] 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.

urged CMS to delay the implementation of its bundling proposal until sufficient information is provided on how skin substitutes would be paid under the PFS.

Many commenters were concerned about that bundling payment for skin substitutes would lead to lower compensation stifling innovation and reducing or eliminating incentives to treat patients with larger wounds. Some commenters were concerned that bundling payments for skin substitutes would increase payment for the application procedures at the expense of all other physician fee schedule services because of the budget neutrality adjustment.

A number of comments indicated that skin substitutes are unlike other medical supplies that are bundled into PFS payments—skin substitutes are incorporated into the wound bed to aid healing and have certain regulatory requirements unique to skin substitutes. Due to these issues, commenters emphasized that skin substitutes are vastly different from other supplies such as wound dressings/bandages, which fall within the incident to supply category. The implication of this comment is that skin substitutes should remain separately payable.

Some commenters argued that categorizing skin substitute products as incident to supplies in the physician office setting would be inconsistent with the applicable payment framework for biologicals provided in a physician in sections 1842 and 1847A in the Act. Under these sections of the Act, manufacturers of biological products report ASP to CMS and CMS makes payment at ASP+6 percent.[56]

Final Decision: In order to provide interested parties more opportunity to comment on the specific details of changes in coding and payment, CMS is not finalizing its proposal to bundle payment for skin substitutes into its PFS payments. CMS plans to conduct a Town Hall in early 2023 to discuss payment under PFS for skin substitutes.

K. Provision to Allow Audiologists to Furnish Certain Diagnostic Tests Without a Physician Order

1. Background

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.

[56] CMS treats skin substitutes as biologicals for payment purposes even though it has not definitely indicated that skin substitutes are biologicals. Effective January 1, 2022, ASP is reported by manufacturers for all products that are paid as a Part B drug or biological irrespective of whether the product is definitively characterized that way. By treating skin substitutes as incident to supplies instead of Part B biologicals, CMS' proposal would no longer have required ASP reporting for skin substitutes.

Longstanding Medicare policy requires that all diagnostic tests, including audiology tests, be ordered by a physician or non-physician practitioner (NPP)[57] 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 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; 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.

2. Proposed Policies

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 proposed to remove the order requirement for non-acute hearing conditions other than balance assessments for patients with disequilibrium. Table 35 of the final rule provides a list of services that CMS proposed an audiologist may furnish without the order of the treating physician or NPP. Vestibular function tests that are typically used in balance assessments are excluded from Table 35.

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

CMS proposed to create HCPCS code GAUDX for audiology services performed by an audiologist without a physician/NPP order. This code could 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 proposed 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 proposed 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 proposed:

- 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.

3. Comments/Responses

While several commenters supported the proposal to provide a limited list of codes that could be provided without the treating physician/NPP order, they objected to the use of HCPCS code GAUDX. They believe GAUDX would be impractical and administratively burdensome, and it might limit beneficiary access to care. The proposed valuation of GAUDX was found to be problematic, and its use to encompass 36 different codes would result in overpayment for some services and underpayment for others. Some recommended the use of existing CPT codes with a modifier, which would be paid at CPT code-specific PFS rates. Some commenters suggested reducing the scope of services/codes that would be bundled under the GAUDX code, which would also allow them to more specifically bill for the services furnished and be paid at rates valued at the established value for those services.

CMS agrees that use of a modifier would be preferable than its proposal to use HCPCS code GAUDX, but it notes that a given modifier would only have one descriptor and uniform rules/restrictions.

Other commenters opposed the proposal because they fear removing physicians, who have more education and training than audiologists, from the care team would have negative consequences for patient care. Those in favor of the proposal disagreed with the safety concerns discussed in the proposed rule. CMS responds that those safety concerns were related to the absence of physician or NPP involvement in patient care for hearing and balance issues.

Some commenters asked for more context on the nonacute terminology and how it applies to nonacute hearing assessments that are unrelated to disequilibrium. CMS indicates that for purposes of this audiologist direct access policy, acute hearing loss involves a sudden onset in one or both ears ─ and is a perceived change in hearing by a beneficiary that is not consistent with the progressive loss of hearing over many years that is typical with the aging process. Nonacute hearing loss is a more gradual hearing loss that one may experience with advancing age, known as presbycusis.[58]

4. Final Decision

Audiologists may furnish the services included on a list of 36 services (as listed in Table 36 (which have been corrected to identify CPT codes, 92651, 92652, and 92653)) without a physician order. The services may be covered and paid when furnished without the order of the treating physician or NPP for nonacute hearing assessment unrelated to disequilibrium, or hearing aids, or examinations for the purpose of prescribing, fitting, or changing hearing aids (in alignment with statutory and regulatory restrictions). The services may be furnished once every 12 months.

To bill for audiology services furnished without the order of a physician or NPP, audiologists must use the individual CPT codes to identify the services they furnish without the order of a physician or NPP, within the list of 36 allowed services, and append a new modifier (modifier AB). If an audiologist furnishes one or more services on the list of available codes without the order of a physician or NPP on a single date of service, the AB modifier must be appended to each of the CPT codes billed for that date of service, and all of the services will be considered payable. However, if a service is billed with the AB modifier on one date of service and the beneficiary returns at a later date for another service (without an order) and that service is within the 12-month period after the prior service is furnished (either for the same or a different service on the list in Table 36), then the subsequent service(s) would not be payable under the PFS. The long descriptor for Modifier AB is as follows: *Audiology service furnished personally by an audiologist without a physician/npp order for non-acute hearing assessment unrelated to disequilibrium, or hearing aids, or examinations for the purpose of prescribing, fitting, or changing hearing aids; service may be performed once every 12 months, per beneficiary*.

[58] The National Institute on Deafness and Other Communication Disorders defines presbycusis as follows: "Age-related hearing loss (presbycusis) is the loss of hearing that gradually occurs in most of us as we grow older. Age-related hearing loss most often occurs in both ears, affecting them equally."

L. Medicare Parts A and B 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.[59] 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 requested public comments on professional services, including dental services, that may occur during and prior to the patient's hospitalization or procedure requiring hospitalization under this exception.

Many comments supported CMS' proposed interpretation to allow Medicare payment for inpatient hospital services in connection with the provision of dental services if the individual, because of their underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services. Some commenters asked for more clarity on the type of dental services, medical conditions and clinical statuses that would be paid for under this interpretation, such as hospitalizations for mental health or substance use disorders.

[59] 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).

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 proposed 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.

CMS finalizes this proposal effective for 2023. Many commenters supported the proposal and encouraged the agency to apply it in all appropriate clinical circumstances. Others indicated outpatient dental services could be furnished through mobile clinics, teledentistry and in congregate care settings. Other commenters suggested the interpretation was too narrow. Additional guidance on the policy will be provided.

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 proposed 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.

While the regulation text in the final rule does not include this amendment, CMS nonetheless indicates in response to comment that the current language in the NCD manual is based on an unnecessarily narrow reading of section 1861(r) of the Act, and is not consistent with other manual provisions. The statutory definition of physician under section 1861(r) of the Act is clear in its inclusion of a doctor of dental surgery or of dental medicine.

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 clarifies that payment for dental can only occur when dental and medical services are integrated and when the dental services are inextricably linked to certain covered medical services. If there is no exchange of information, or integration, between the medical professional (physician or other non-physician practitioner) in regard to the primary medical service and the dentist in regard to the dental services, then there would not be an inextricable link between the dental and covered medical service within the meaning of §411.15(i)(3). CMS believes the integration between medical and dental professionals can occur when professionals coordinate

care. To bill and be paid under Part B, both the medical professional and the dentist would have to be enrolled in Medicare, and the state scope of practice must support the professional performing the dental service.

Effective for 2023, CMS finalizes its proposal to modify the regulations text at §411.15(i)(3) to clarify that the following scenarios are covered dental services and to codify the following longstanding policies:

(i) Dental services that are inextricably linked to, and substantially related and integral to the clinical success of, a certain covered medical service are not excluded; payment may be made under Medicare Parts A and B for services furnished in the inpatient or outpatient setting. Such services include, but are not limited to:

(A) Dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered organ transplant, cardiac valve replacement, or valvuloplasty procedures; and, medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, the organ transplant, cardiac valve replacement, or valvuloplasty procedure.

(B) The reconstruction of a dental ridge performed as a result of and at the same time as the surgical removal of a tumor.

(C) The stabilization or immobilization of teeth in connection with the reduction of a jaw fracture, and dental splints only when used in conjunction with covered treatment of a covered medical condition such as dislocated jaw joints.

(D) The extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease.

(ii) Ancillary services and supplies furnished incident to covered dental services are not excluded, and Medicare payment may be made under Part A or Part B, as applicable, whether the service is performed in the inpatient or outpatient setting, including, but not limited to the administration of anesthesia, diagnostic x-rays, use of operating room, and other related procedures.

Commenters generally supported this clarification; CMS accepts the suggestion to substitute the term “stabilization of teeth” for “wiring of the teeth” to align with current medical terminology. It notes that services performed by auxiliary personnel incident to physician or practitioner professional services (including dentists) must generally be performed under the direct supervision of the physician or practitioner.

CMS did not propose 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. It also noted that the proposed policies would not prevent a MAC from making a determination that payment can be made for dental services in other circumstances not specifically addressed in the proposed rule and the proposed amendments to §411.15(i).

4. 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). As indicated in the regulation text copied above, CMS finalizes its proposal to revise §411.15(i)(3) to allow

for coverage of dental services (and ancillary services such as x-rays, administration of anesthesia, diagnostic x-rays, and use of an operating room) when the patient has:

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

In these circumstances, Medicare will 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. Payment will be made 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 are covered. Additional dental services, such as a dental implant or crown that are not immediately necessary to eradicate the infection prior to surgery will not be covered. Some commenters asked for clarification regarding the definition of organ transplant and requested that it also include hematopoietic stem cell and other transplants, such as bone marrow transplants or CAR-T cell therapies. CMS agrees and clarifies in the final rule that payment may be made under Parts A and B for dental or oral services prior to organ transplants, which will include bone marrow transplant or hematopoietic stem cell transplant. However, it notes that Medicare payment policies for organ procurement organizations or other payment policies may be applied differently for the purposes of paying for bone marrow and stem cell transplantations.

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.

Many commenters supported the proposed update, which they believe would help promote health equity and access to medically necessary services for vulnerable beneficiaries. The preamble includes examples of dental services to eradicate infection such as extractions, restorations, periodontal therapy, or endodontic therapy. Some commenters asked CMS to also provide payment under Medicare Parts A and B for medically necessary diagnostic and treatment services after an organ transplant dental services both before and after the transplantation procedure itself influences the outcome of the transplant. CMS does not do so at this time but will review the evidence and engage with interested parties to issue additional guidance or future rulemaking as necessary.

CMS finalizes its proposal to contractor-price the dental services until it has data to establish prospective payment rates. Commenters sought additional guidance to help in processing claims for dental services that are inextricably linked to the Medicare-covered medical service, such as what types of specific dental treatments would be billable if provided under the finalized policy prior to, or contemporaneously with, Medicare-covered organ transplant, heart valve replacement, and valvuloplasty procedures. CMS responds that guidance will be given to the MACs to assist them in determining the inextricable link between dental and medical services to make determinations on a claim-by-claim basis whether patient and clinical circumstances do or do not fall within the examples of services listed under §411.15(i), or within the preclusion or

exception specified in section 1862(a)(12) of the Act and §411.15(i). The agency may also use claim modifiers or apply prior authorization policies. In the interim, CMS indicates that dentists who furnish dental services that are eligible for payment under Parts A and B should continue to submit claims using current processes, and they may consult with their MACs for specific claims submission questions.

5. Other Clinical Scenarios

In the proposed rule, CMS provided 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 indicated that the evidence is mixed regarding the need for a dental exam and necessary treatment prior to total joint replacement surgery. Therefore, CMS was 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 provided compelling clinical evidence, CMS indicted it may allow Medicare coverage of dental services provided in conjunction with joint replacement surgery in the final rule.

Many commenters supported the coverage of dental services for these purposes, but few provided clinical evidence to support the link between dental services and the clinical success of these specific medical services. CMS believes it lacks sufficient clinical evidence at this time to fully evaluate whether certain dental services are inextricably linked to, and substantially related to the clinical success of, these medical services. However, it found the clinical evidence supplied by commenters linking dental care and the clinical outcomes of cancer treatments for head and neck cancers persuasive. Thus, CMS believes that this information it received is sufficient to support the basic assertion that removing infections in the oral cavity (in addition to potentially removing teeth) is necessary to prepare patients for treatment and is inextricably linked to, and substantially related and integral to the clinical success of radiation treatment (with or without chemotherapy) for cancers of the head and neck.

Thus, effective for 2024, CMS finalizes a policy that Medicare Parts A and B payment may be made for dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting (as well as medically necessary diagnostic and treatment services to eliminate an oral or dental infection), before or contemporaneously with Medicare-covered treatments for head and neck cancer. It acknowledges that a number of aspects of this policy must still be addressed, including clear guidelines and definitions (such as what conditions head and neck cancer includes), and the qualifying covered medical services for these treatments beyond radiation. CMS notes several times that MACs may determine that payment can be made for dental services in other circumstances not specifically addressed in this final rule.

Commenters recommended payment for dental care for patients taking immunosuppressants for a number of auto-immune conditions as well as for patients on immune checkpoint inhibitors, patients on immunosuppressants as part of a cancer treatment, or who have experienced immunosuppression as a result of cancer treatments, and patients taking immunosuppressants following a transplant surgery. Some sought clarification on how immunocompromised could be defined and which types of therapies could meet the definition. CMS concludes that it needs more time to consider these issues.

CMS is not finalizing, at this time, that payment may be made under Medicare Parts A and B for dental services prior to the initiation of immunosuppressant therapy, joint replacement procedures or other surgical procedures.

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 requested comment on whether there are clinical circumstances under which Medicare payment could be made for dental services furnished after the covered medical procedure or treatment.

Commenters provided several scenarios for follow-up or ongoing dental care after treatment, including for patients treated for head and neck cancer, because patients continue to be at risk for dental caries, osteonecrosis, and other conditions even after treatment is concluded. Others noted that there is a period after treatment when patients remain immunosuppressed, and recommended that follow-up care be provided until the immunosuppression ends and when all dental infections are resolved. Other scenarios include teeth which may become impacted or brittle after radiation treatment and require eventual extraction after the conclusion of the radiation therapy. Other commenters noted that it is not always possible to perform restorative surgeries at the same time as the cancer treatment and requested that payment for restorative dental services performed on a later date.

6. Establishing a Process for Considering Additional Clinical Scenarios

Effective for 2023, CMS finalizes its proposal to establish a process where the agency will 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 will invite 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.

Commenters supported this process and encouraged the agency to thoroughly consider the clinical evidence to determining whether there is an inextricable link between certain dental services and medical services. CMS believes the medical evidence should support that the provision of certain dental services leads to improved healing, improved quality of surgery, and

the reduced likelihood of readmission and/or surgical revisions, because an infection has interfered with the integration of the implant and interfered with the implant to the skeletal structure. Additionally, the evidence should include at least one of the following:

- Relevant peer-reviewed medical literature and research/studies regarding the medical scenarios requiring medically necessary dental care;
- Evidence of clinical guidelines or generally accepted standards of care for the suggested clinical scenario;
- Other ancillary services that may be integral to the covered medical services; and/or
- Other supporting documentation to justify the inclusion of the proposed medical clinical scenario requiring dental services.

M. Revising the Medicare Economic Index (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 is 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. It notes that the MEI cost weights have also 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.

CMS believes that the MEI cost weights need to be updated to reflect more current market conditions. It delayed the implementation of the rebased and revised MEI cost weights for both PFS ratesetting and the 2023 GPCIs. It wanted to provide 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 final rule, CMS finalizes its proposal 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. Specifically, it finalized the proposed 2017-based MEI cost share weights as proposed for all cost categories in the MEI except for the compensation cost category weights where CMS revised the methodology based on public comments received. Specifically, CMS is: (1) revising the methodology for estimating the 2017 expenses for physician net income; (2) correcting the

allocation of registered nurse (RN) compensation costs from physician compensation to clinical, nonphysician compensation; and (3) adjusting the shares for allocating SAS compensation costs between physician and non-physicians by factoring in differences in average weekly hours by occupation.

The following sections discuss derivation of the cost categories and associated cost share weights as revised based on public comments, selection of the price proxies in the MEI, and comparison of the proposed 2017-based MEI and the final 2017-based MEI to the current 2006-based MEI. A detailed summary of public comments is provided at the end of this section.

2. Developing the Cost Weights for Use in the MEI

CMS will 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 will 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 will use the 2017 SAS data for the 2017-based MEI because it is the most recently available and complete data.

CMS also will 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. To estimate the net income expenses for physician compensation by type of ownership CMS will use the Internal Revenue Service (IRS) Statistics of Income (SOI) data for Offices of Physicians.

Table 45 (reproduced below) lists the set of mutually exclusive and exhaustive cost categories and weights for the final 2017-based MEI, proposed 2017- based MEI, and the 2006-based MEI. While the methodology for all other practices expenses did not change from the proposed method, their cost share weights are slightly lower due to the increases in total expenses that

reflect the revised method for estimating physician net income. More technical details about the development of the cost weights for each cost category is provided in the final rule.

Table 45: Final 2017-based MEI, Proposed 2017-based MEI and 2006-based MEI Cost Categories and Weights			
Cost Category	**Final 2017-based**	**Proposed 2017-based**	**Current 2006-based**
MEI Total	**100.000%**	**100.000%**	**100.000%**
Physician Compensation	**47.522%**	**47.261%**	**50.866%**
Wages and Salaries	39.443%	39.226%	43.641%
Benefits	8.079%	8.034%	7.225%
Practice Expense	**52.478%**	**52.739%**	**49.134%**
Non-physician Compensation	**25.451%**	**24.716%**	**16.553%**
Non-physician Wages	**21.124%**	**20.514%**	**11.885%**
Non-health, Non-physician Wages	10.858%	12.306%	7.249%
Professional and Related	1.312%	1.381%	0.800%
Management	2.101%	2.171%	1.529%
Clerical	6.750%	7.947%	4.720%
Services	0.695%	0.807%	0.200%
Health related, Non-physician Wages	10.266%	8.208%	4.636%
Non-physician Benefits	**4.327%**	**4.202%**	**4.668%**
Other Practice Expense	**27.027%**	**28.024%**	**32.582%**
Utilities	0.353%	0.366%	1.266%
All Other Products	1.981%	2.055%	2.478%
Telephone	0.455%	0.471%	1.501%
Postage	-	-	0.898%
All Other Professional Services	**13.419%**	**13.914%**	**8.095%**
Professional, Scientific, & Tech. Services	6.124%	6.350%	2.592%
Administrative & Waste Services	2.258%	2.341%	3.052%
All Other Services	5.037%	5.223%	2.451%
Capital	**7.473%**	**7.748%**	**10.310%**
Fixed Capital	5.331%	5.527%	8.957%
Moveable Capital (including medical)	2.142%	2.221%	1.353%
Professional Liability Insurance	**1.349%**	**1.398%**	**4.295%**
Medical Equipment	-	-	1.978%
Medical Supplies	1.997%	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 will use 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 PPIs, CPIs, and ECIs selected meet these criteria.
CMS finalizes all price proxies as proposed. Table 47 (reproduced below) provides a detailed explanation of the price proxies that CMS will use for the 2017-based MEI. Almost all of the proxies that CMS uses for the 2017-based MEI are the same as those used in the 2006-based MEI. For "all other products," CMS uses 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.

Cost Category	2017 Price Proxy
MEI Total	
Physician Compensation	
Wages and Salaries	ECI - Wages and salaries for Private industry workers in Professional and related
Benefits	ECI - Total Benefits for Private industry workers in Professional and related
Practice Expense, including PLI	
Non-physician compensation	
Non-physician wages	
Non-health, non-physician wages	
Professional and Related wages	ECI - Wages and salaries for Private industry workers in Professional and related
Management wages	ECI - Wages and Salaries for Private Industry workers in Management, Business, and Financial
Clerical wages	ECI - Wages and Salaries for Private Industry workers in Office and Administrative Support
Services wages	ECI - Wages and Salaries for Private Industry workers in Service Occupations
Health related, non-physician wages	ECI - Wages and salaries for All Civilian workers in Hospitals
Non-physician benefits	Composite - ECI - Total Benefits for the 5 non- physician wage categories
Other Practice Expense	
Utilities	CPI - Fuels and utilities
All Other Products	PPI - Final demand - Finished goods less foods and energy
Telephone	CPI - Telephone Services
All Other Professional Services	

Cost Category	2017 Price Proxy
Professional, Scientific, and Technical Services	ECI - Total compensation for Private industry workers in Professional, scientific, and technical services
Administrative support & waste	ECI - Total compensation for Private industry workers in Office and administrative support
All Other Services	ECI - Total compensation for Private industry workers in Service occupations
Capital	
Fixed Capital	PPI - Industry - Lessors of nonresidential buildings
Moveable Capital	PPI - Commodity - Machinery and equipment
Professional Liability Insurance	**CMS - Professional Liability Insurance Index, physicians**
Medical supplies	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 finalizes its proposal to continue to use the current method of applying a productivity adjustment to the full MEI increase factor in the 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 Rebasing and Revising of the MEI

Table 49 in the final rule illustrates the results of the update to the MEI cost weights for physician compensation, practice expense, and PLI from the 2006-based cost distribution, the proposed 2017-based cost distribution, and the final 2017-based cost distribution (recreated below). The final 2017-based weights are significantly different than the 2006-based current weights. The practice expense share, for example, increased by 6.4 percentage points from 44.8% to 51.2%.

Table 49: Percent Distribution of Major Physician Expense Components: 2006-based MEI, proposed 2017-based MEI, and final 2017-based MEI			
	Weights		
RVU Component	**Final 2017-based**	**Proposed 2017-based**	**Current 2006-based**
	2017	2017	2006
Physician Work	47.5%	47.3%	50.9%
Practice Expense	51.2%	51.3%	44.8%
Malpractice or PLI	1.3%	1.4%	4.3%
Total	100.0%	100.0%	100.0%

CMS also shows the average calendar year percent change for 2006 to 2023 for the 2006-based MEI, final 2017-based MEI, and proposed 2017-based MEI (Table 50 in the final rule). The comparison shows that the final 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 final 2017-based MEI for 2023 is an increase of 3.8 percent, the same as the 2006-based MEI.

6. Analysis of Comments

a. Overall Comments

Commenters agreed, including MedPAC, that the data currently used for the MEI is outdated and endorsed the principle of having a methodology that allows for regular and frequent updates to the MEI in the future to help ensure that payment rates reflect the current underlying realities of work, practice expenses, and malpractice insurance. The majority of the commenters, however, urged CMS to delay any change in the MEI until the AMA's practice cost data collection work is completed in order to compare the weights based on the AMA and SAS data. They believed it is important to retain consistency with the MEI measurement that has been based on data collected from the AMA Physician Practice Information (PPI) Survey that has been used by CMS since 1975. MedPAC stated in the long-term CMS should strive to identify or develop a single data source that has more comprehensive information about physician's input costs, such as physician compensation and compensation for other workers.

CMS agrees that it is important to rebase and revise the MEI to a more recent period and that it looks forward to reviewing future data when that information is available to compare to the results of its methodology. It agrees that the methodology is complex as it relies on several disparate data sources but believes the methodology relies on the best available data for this purpose. CMS highlights that the methodology for the 2017-based MEI relies on data that are updated on a regular basis, publicly available, and reflective of the changing practice patterns of the overall industry. It appreciates MedPAC's comments that CMS identify or develop a single data source that has more comprehensive information about physicians' input costs but it is currently not aware of any such data source.

After consideration of comments, CMS finalizes the proposed 2017-based MEI cost share weights as proposed for all cost categories in the MEI except for the compensation cost category weights which it is revising based on public comments received.

b. Technical Comments

CMS received many technical comments on its methodology for rebasing and revising the MEI. These were primarily focused on addressing these subject areas: (1) revising the methodology for estimating the 2017 expenses for physician net income; (2) correcting the allocation of registered nurse (RN) compensation costs from physician compensation to clinical, nonphysician compensation; and (3) adjusting the shares for allocating SAS compensation costs between physician and non-physicians by factoring in differences in average weekly hours by occupation.

CMS also received comments, which it disagreed, regarding excluding expenses for separately billed supplies and drugs and that the decrease in the weight for PLI costs is unrealistic.

Revising the methodology for estimating 207 expenses for physician net income

Many commenters expressed concern with the proposed method for splitting the aggregate payroll and benefits expenses from the SAS data between physician and non-physician compensation. Commenters stated that both the Census Bureau's SAS and BLS OEWS datasets only include costs for employed physicians within NAICS 6211 and excludes 36 percent of physicians who are employed in other health care settings, such as hospitals. Commenters also stated that the proposed methodology for estimating compensation for practice owners (that is, net income) to be unreasonable. Specifically, commenters stated that CMS' estimated share of net income represents just 10 percent of total compensation for all physicians and qualified healthcare professionals (QHPs), which they claim is an unreasonable estimate since nearly half of physician in the United States are owners.

CMS conducted further research and determined an alternative method to estimate net income would be an improvement over its proposed approach. This approach will use the 2017 IRS statistics of Income (SOI) data for Offices of Physicians, by type of ownership. This data source provides the level of revenue/receipts and net income separately for corporations, partnerships, and sole proprietors; the share of net income as a percentage of revenue is 49.6 percent for sole proprietors, 19.5 percent for partnerships, and 6.9 percent for corporations. CMS describes the steps involved in this calculation in the final rule. Using this revised method, it is able to estimate the net income for physician compensation for sole proprietors and partnerships in order to estimate net income that is not directly captured by the SAS survey question. Using this approach, this results in an increase in the cost weight for net income from the proposed 4.8 percent of total expenses to 8.2 percent of total expenses.

Correcting the allocation of registered nurse (RN) compensation costs from physician compensation to clinical, nonphysician compensation

Commenters raised the concern that the estimated share of employee compensation attributed to physicians and QHPs of 63.2 percent is incorrect because it incorrectly classified registered nurses (RNs) in the estimated share of physician expenses rather than classified to non-physician compensation. CMS agrees that registered nurses (RNs) were inadvertently classified in the estimated share of physician expenses and should be classified in non-physician compensation. The revised distribution results in a smaller share of SAS reported compensation costs allocated to physician compensation and an increase to the share of clinical, non-physician compensation.

Adjusting the shares for allocating SAS compensation costs between physician and non-physicians by factoring in differences in average weekly hours by occupation

MedPAC suggested that the occupational splits derived from the OEWS data as proposed do not account for differences in the number of hours worked by different occupational categories. CMS agrees and develops a revised method for estimating the occupational mix shared to account for variation in the number of hours worked by occupation that relies upon data captured

by the Census Bureau's Current Population Survey (CPS). Table 42 in the final rule shows the occupation mix revised weights after reclassifying RNs and average weekly hours. These revisions increase the weights for physician compensation and decreases the weight for clinical, non-physician compensation, and non-health related compensation compared to the proposed 2017-based MEI.

Excluding expenses for separately billed supplies and drugs

Several commenters stated the use of growth in Medicare Part B drug spending to age expenses forward in not entirely appropriate and the use of an index is inclusive of all drugs, such as the CPI or PPI to account for inflation would be better. CMS disagrees with commenters' concerns with the proposed approach for estimating the portion of separately billable supply and drug expenses. It believes that the question on the AMA PPIS survey for drugs and medical supplies align similarly with the types of expenses collected on the SAS survey questionnaire. Moreover, it believes that its proposed method is consistent with how these costs were excluded in the 2006-based MEI. It also notes that the estimated price growth in Part B drugs and the estimated growth in the PPI for prescription drugs are relatively similar and that it believes its proposed approach (to use the estimated price growth in Part B) is the better one.

Decrease in the weight for PLI costs is unrealistic

Many commenters stated that the decrease in the weight for PLI costs was unrealistic and that the 4.5 percent PLI weight is more appropriate than the proposed 1.4 percent weight. CMS disagrees and states that the drop in the PLI weight is the result of using both a more recent year of physician cost data as well as also using a sample of physicians that is inclusive of various ownership types. It verified that this trend is consistent with other data sources. For example, CMS used the IRS Statistics of Income data for Sole Proprietors that indicated that trends of PLI costs between 2006 and 2017 for self-employed, sole proprietors would by itself result in a drop of about 2 percentage points.

III. Other Provisions of the Final 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 the JW modifier on a Medicare claim 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(h) of the Act requires Part B drug manufacturers to refund discarded drug amounts exceeding 10 percent of total Medicare allowed 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 proposed 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. Only separately payable drugs under the OPPS and ASC payment systems will be subject to this policy.

One issue that concerned CMS is 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 proposed 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 use of the 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 administered amounts in the patient medical record, and specify administered and discarded amounts on the Medicare claim form.

Comments/Responses: Public commenters both supported and opposed CMS' proposal. In response to those that opposed CMS' policy, CMS stated it is implementing a requirement of statute. CMS also repeated a number of times in response to various comments that a very high percentage of discarded volume wastage is occurring with a small number of drugs. Specific issues included the following:

Policy will Increase not Reduce Drug Wastage. Some commenters felt that the policy would increase, not reduce drug wastage. CMS provided an example of the opposite—Kyprolis® (carfilzomib) introduced a 10 mg vial in June 2018 in addition to its 60 and 30 mg vials, and its discard percentages were 14.27 percent in 2017, 12.68 percent in 2018, and 5.95 percent in 2019, suggesting the new vial size led to a decrease in the discard percentage below 10 percent.

Policy will Increase Drug Costs. Other commenters stated the policy would increase costs and drug prices. CMS plans to track associated prices of such drugs and assess discretionary aspects of the policy over time and will undertake additional rulemaking, if warranted. In addition, section 1847A(h)(9) of the Act requires OIG to consult with CMS and FDA on the impact of this provision on the licensure, market entry, market retention, or marketing of biosimilar biological products. OIG is required to report to several Congressional committees by November 15, 2024,

Clinical Reasons for Wastage. There were a variety of comments that raised clinical or other reasons for why there would be drug wastage such as administering a lower dosage than initially anticipated. CMS responded that it believes the 10 percent threshold allows for a certain amount of drug to be discarded for various factors, including clinical reasons, without being subject to a refund. The response further noted that there are many drugs provided in single-dose containers with historical discarded amounts below 10 percent, including many chemotherapy drugs, which have specific instructions for reduced dosages in cases of toxicity experienced from the chemotherapy.

Definition of "Unused and Discarded". Commenters described a variety of scenarios for how the drug is administered that could result in various ways to measure and bill for discarded amounts. CMS responded that the amount that is unused and discarded will be the labeled amount on the single-dose container (or containers if more than one is required) minus the dose administered. Even if certain amounts are extracted from the vial or are required to be in the vial to administer the prescribed dose, CMS does not consider them to be used if they are not intended for therapeutic effect as part of the administered dose.

Overfill. Overfill is drug product in a single use vial above the labeled dose on the vial. In the proposed rule, CMS indicated that unused overfill is not considered wastage and should not be billed as discarded product. CMS reiterates this point in response to a comment.

Inclusion of Refunds in Average Manufacturer Price (AMP) and Medicaid Best Price. In response to comments, CMS clarifies that any refunds under this provision are not considered a price concession for determining AMP or Medicaid Best Price. CMS considers discarded product to be "otherwise unsalable returned goods" under section 1927(k)(1)(B)(i)(III) of the Act that are excluded from AMP determinations.

Use of the JZ Modifier. Many commenters opposed requiring the JZ modifier when there is no drug discarded as being administratively burdensome and unnecessary as the lack of a modifier serves the same purpose. CMS disagrees and presented a study from the National Academy of Sciences that found that the level of compliance with use of the JW modifier is poor and inconsistent.[60] CMS stated that a provider is already required to determine whether the administered amount from single-dose packages for entry into the patient's medical record and discarded amounts on the claim. Since the assessment is already required, the only additional action needed by the provider is to add JZ on the claim form when there are no discarded amounts.

Operational Concerns. In response to concerns that provider systems may not be able to process the JZ modifier, CMS is providing a 6-month delay in the requirement to use the JZ modifier allowing providers sufficient time to incorporate necessary updates to their claims systems.

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[60] National Academies of Sciences, Engineering, and Medicine. 2021. Medications in single-dose vials: Implications of discarded drugs. Washington, DC: The National Academies Press. https://doi.org/10.17226/25911. National Academies of Sciences, Engineering, and Medicine. 2021. Medications in Single-Dose Vials: Implications of Discarded Drugs. Washington, DC: The National Academies Press. https://doi.org/10.17226/25911

CMS will make the JZ modifier effective January 1, 2023 but not required until July 1, 2023. For dates of service beginning July 1, 2023 or after, providers will be required to use the JZ modifier on claims for single-dose containers when there are no discarded amounts, but CMS will not perform claims processing edits on its use. Beginning October 1, 2023, CMS will have claims edits for correct use of both the JW and JZ modifiers.

Modifiers Required on All Drugs or Only Refundable Drugs. In response to comments, CMS is clarifying that the requirement is to code either the JW or JZ modifier on claims for drugs from all single-dose containers payable under Medicare Part B, regardless of whether the drug meets the definition of refundable single-dose container or single-use package drug. This policy will include drugs that are statutorily excluded from being a refundable drug.

Modifiers are required on all Part B drug claims to determine whether the drug is subject to a refund. Absent the information on all claims, CMS will be unable to determine whether a given drug's manufacturer will owe a refund on discarded amounts over 10 percent of the single use's vial's labeled dosage amount.

The requirement to use the JW modifier has been in place since 2017 and the JZ modifiers will be effective January 1, 2023. Although CMS will only calculate manufacturer refunds with JW modifier data from single source drugs and biologicals, discarded drug data for drugs that do not meet the definition of refundable single-dose container or single-use package drug will provide with useful information about drug discards in the Medicare program generally.

Absence of the JW and JZ Modifiers: Claims for drugs subject to this provision that do not report the JW or JZ modifier on or after July 1, 2023, may be subject to provider audits. Claims that do not report the modifiers as appropriate on or after October 1, 2023, will be returned as they are not processable. To be processed, the claims must be resubmitted with the required modifier information to know the shares of product administered or discarded.

Use the Actual Vial Administered or the Smallest Vial Available: One commenter referenced MLN Matters Article SE1316 issued August 1, 2013 instructing that discarded drug amounts reported with the JW modifier "must correspond with the smallest dose (vial) available for purchase from the manufacturer(s) that could provide the appropriate dose for the patient, while minimizing any wastage."

CMS indicated that this guidance is out of date and has been replaced by MLN Matters article MM9603, which was issued on June 9, 2016, and effective January 1, 2017. This article instructed providers to use the JW modifier line to bill for discarded amounts from the single use vial or other single use package of the drug or biological administered to the patient.

Final Decision: CMS is finalizing its proposal with the modification that reporting of the JZ modifier for all such drugs with no discarded drug amounts will be required no later than July 1, 2023 and claims edits for both the JW and JZ modifier will begin October 1, 2023.

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

CMS proposed a definition of "refundable single-dose container or single-use package drug" that 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 proposed 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.

CMS did not present any comments on in this section. All comments on this section are subsumed by those presented in the next section.

4. Exclusions

Consistent with section 1847A(h)(8)(B)(i) and (ii) of the Act, CMS proposed 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 prior to dilution 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 proposed to begin the 18-month period using the first day of the calendar quarter following the date of the 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 proposed 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.

Comments/Responses: Several commenters requested CMS add additional exclusions from this provision for various drugs or drug categories (orphan drugs, drugs manufactured by small biotech companies, biosimilars, ophthalmic drugs, low volume vials, etc.). CMS responded to all of these requests by stating the statute defines refundable single-dose container or single-use package drug broadly, and makes limited exceptions to the definition. Specific comments were in the following areas:

Vaccines. In response to comments, CMS stated that many vaccines are available in both single-dose containers (usually prefilled syringes) and multiple-dose containers, and would not meet the definition of "refundable single-dose container or single-use package drug." In addition, CMS will not require the JW and JZ modifiers for pneumococcal, influenza, Hepatitis B and COVID vaccines covered by Medicare under section 1861(s)(10) of the Act.

New Drugs. New drugs are subject to an 18-month exemption period from being a refundable drug after they come on the market. Commenters asked that CMS measure the 18 months from the effective date of the statute, not the date the drug first comes on the market if that date precedes the effective date of the provision. CMS responded that the effective date of the exclusion in the statute is the date of statutory enactment, not the effective date of the provision.

Application in the Outpatient Department. Several commenters stated that the statute makes no reference to the OPPS or ASC sections of statute and is inappropriately applied to drugs paid under these systems. CMS responded that section 1847A(h)(8)(A) of the Act applies to single-dose container or single use packages "for which payment is made under this part" meaning Medicare Part B that would include drugs paid under the OPPS and ASC other than packaged drugs that are explicitly excluded from being refundable drugs by section 1847A(h)(1)(C) of the Act.

ESRD Drugs. Some commenters asked that CMS clarify that the policy does not apply to drugs packaged into the Medicare ESRD PPS. Drugs that are packaged under the Medicare ESRD PPS are not subject to the JW modifier policy or the discarded drug refund policy.

Skin Substitutes. One commenter requested clarification on whether "cellular and/or tissue-based products for skin wounds" are subject to the provision. CMS does not explicitly answer this question but states that the policy applies to "products that are paid as drugs and biologicals." Skin substitutes are paid as drugs and biologicals. If they meet the other requirements to be subject to the policy (single-dose container based on the FDA-approved labeling, is not otherwise excluded, subject to billing using the JW and JZ modifier), data for the product will be used to calculate refund obligations.

Making ASP Public for All Codes. Several commenters requested that CMS make ASP and JW modifier data available for all codes subject to the policy where the public ASP file does not include the drug. Another commenter requested CMS provide a list of drugs that are statutorily excluded from being a refundable drug. CMS responded that since the refunds are determined after claims are submitted and processed, the specific billing and payment codes that will be subject to refund obligations will not be known at the time the annual ASP Drug Pricing File is published. CMS will consider developing lists of drugs that fit a statutory exclusion as part of the operational process of implementing this provision.

Self-Administered Drugs Covered under Part B. Beneficiaries will self-administer certain drugs covered under Part B (durable medical equipment drugs). Commenters asked that these drugs not be considered refundable as the entity furnishing the drug will not know the amount of drug discarded. CMS responded that the JW and JZ modifiers are not required for refundable single-dose container or single-use package drugs that are self-administered by a patient or caregiver in the patient's home. If the JW and JZ modifiers are not applicable, the drug is not a refundable drug.

Specific Excluded Drugs. In response to comments, CMS confirmed that the drugs Susvimo™ and Onpattro® meet the criteria for the filtration exclusion.

Billing for Units of Drugs that are Refundable. In response to comments, CMS clarified that the providers may still bill for the amount discarded using the JW modifier for refundable drugs. The refund applies to the drug manufacturer. It does not affect how providers and practitioners are paid for drugs administered or discarded.

Final Decision: CMS is finalizing the definition of "refundable single-dose container or single-use package drug" as proposed. It is also finalizing its proposals on drugs that are statutorily excluded from being refundable and specifying that Susvimo™ and Onpattro® meet the criteria for being excluded.

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 proposed 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 proposed 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 proposed 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 proposed 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.

Comments/Responses: Most public comments requested engagement with CMS and more sufficient detail in reporting to permit drug manufacturers to be able to do budget and financial planning for processing rebate amounts and validating the rebate amounts that will be owed. There were public comments asking for claims level data in order to be able to do such validation. There were also comments asking that CMS provide information on the JW modifier to manufacturers of drugs that are within the 18-month exclusion window for being subject to a rebate.

CMS agrees that manufacturers have an interest in additional advance notice of their refund obligations and should have time to engage with CMS and address potential disagreements related to discard amounts and refund calculations before obligations are due. In response to the comments asking for claims level information, CMS refers the commenters to aggregate HCPCS code claims data are available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Part-B-National-Summary-Data-File/Overview. In addition, aggregate discarded drug data for all separately payable Part B drugs from single use vials or other single use packages is available at: https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-discarded-drug-units. CMS will provide data to manufacturers of drugs within the 18-month exemption period on billings for the JW modifier.

Final Decision: CMS is not sending the first report to manufacturers no later than October 1, 2023, and subsequent reports no later than October 1 of each year following. Instead, CMS will revisit the date of the initial report and the inclusion of lagged discarded drug data in future rulemaking. Although CMS is not finalizing a date for the transmittal of reports in this final rule, it will send reports to manufacturers containing discard information for each calendar quarter on an annual basis. CMS will issue a preliminary report on estimated discarded amounts based on available claims data from the first 2 quarters of 2023 no later than December 31, 2023.

Due to the enactment of the Inflation Reduction Act on August 16, 2022, and CMS efforts to efficiently implement two statutory provisions that require reporting and deposit mechanisms, discarded drug refunds are to be deposited into the Federal Supplementary Medical Insurance (SMI) Trust Fund. Similarly, the Part B and Part D rebates described in the Inflation Reduction Act also are to be deposited into the Federal SMI Trust Fund. CMS aims to coordinate the collection of these funds in order to minimize the administrative burden on both manufacturers and CMS. This requires an alternative timeline for sending reports to manufacturers and different dates on which funds would be due.

6. Manufacturer Refund Timing

CMS proposed to require manufacturers to provide refunds annually by December 31 based on the report provided to them October 1. In the case of a dispute, payment of the refund is due no later than 30 days after the resolution of the dispute. Per the prior section, CMS is not finalizing the timing for reports to be sent or for refund obligations to be paid in this final rule. It will revisit this issue in future rulemaking.

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 provided an example illustrating how the refund amount would be determined in the proposed rule:

- 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 indicated 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.

Comments/Responses: Comments were in the following categories:

Basing the Refund on a Higher Amount Paid by Medicare. Several commenters expressed concern about a refund amount being based on a higher amount than the provider or supplier was actually paid for the drug or biological. CMS responded that the statute requires the refund amount be calculated based on the product of the Part B drug price per unit and the number of the number of units with the JW modifier. By statute, the price paid to the provider or supplier and the amount used to determine the refund will be the same.

Incomplete Claims Information. There were comments stating that the manufacturer should be able to exclude from the refund calculation claims missing data elements such as provider ID, prescription number, total units billed, or the amount paid in order to ensure that CMS has verifiable information for the calculation of refund payments. CMS responded that claims missing some of this information will be returned to the provider as the lack of information will mean the claim cannot be processed. Other information listed in the comment is not included on the claim and is not needed to determine a refund amount.

Audit Adjustments. Some commenters requested clarification on how CMS will handle audit adjustments after CMS has provided refund reports to manufacturers. Since CMS is not finalizing the timing for reports to be sent or for refund obligations to be paid in this final rule, it will revisit the interaction of claims audits and lagged claims data in future rulemaking. (Nevertheless, this issue was addressed in proposed rulemaking indicating that lagged amounts or changes due to audit adjustments will be reflected in future reports to the manufacturer).

Final Decision: CMS is not making any changes in response to these comments. All proposals will be finalized without modification.

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 requested comments on whether there are other drugs where CMS should raise the applicable percentage.

CMS received numerous requests to increase the applicable percent for drugs with unique circumstances. In response to those comments, CMS took the following actions:

Drugs Reconstituted with a Hydrogel. CMS agrees a drug reconstituted with a hydrogel that has variable dosing based on patient-specific characteristics warrants an increased applicable percentage of 35 percent. Jelmyto® (mitomycin for pyelocalyceal solution) is the only drug that fits this unique circumstance.

Other Products Requested. CMS recognizes that there are other products that may have unique circumstances that warrant an increased applicable percentage that would have to be determined through future notice and comment rulemaking. These drugs may include new drugs that are in their 18-month exemption period. CMS will revisit additional increased applicable percentages for drugs that have unique circumstances, and a process to identify such circumstances, through future notice and comment rulemaking.

Final Decision: CMS is increasing the applicable percentage to 35 percent for a drug that is reconstituted with a hydrogel and has variable dosing based on patient-specific characteristics. It will develop a process through future rulemaking for raising the applicable percentage for other products.

9. Dispute Resolution

A dispute resolution process is not expressly required by section 1847A(h) of the Act. However, CMS proposed 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 proposed to provide a 30-day period following the issuance of its report for the manufacturer to request a change to the refund amount. CMS proposed 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 requested comment on developing an appeal mechanism in future rulemaking.

Comments/Responses: Several commenters requested that the window for manufacturers to file disputes be extended from 30 days to either 60 or 90 days. CMS responded that

information provided in the report is required by statute to include two numbers: (1) the total number of units of the billing and payment code of such drug, if any, that were discarded during such quarter; and (2) the refund amount for which the manufacturer is liable. CMS does not expect that the formulation of a dispute regarding these two numbers should take longer than 30 days since the calculations are straightforward.

Other commenters offered several suggestions regarding the operational aspects of the dispute resolution process. For instance, one commenter requested the process permit manufacturers to dispute as many errors as needed, rather than having to file separate disputes for each error. Several commenters requested that that the dispute resolution process be confidential.

CMS responded that it will further address the dispute resolution process in future rulemaking. With regard to the number of errors that a manufacturer may submit in one filing, CMS proposed that a manufacturer would be able to identify as many errors as they need for each manufacturer report that they dispute. Should a manufacturer receive two reports for two drugs and the manufacturer would like to dispute both, the manufacturer would need to file two disputes, regardless of how many errors they identify in each. CMS will maintain the confidentiality of a manufacturer's proprietary information consistent with applicable law.

Final Decision: Manufacturers will have 30 days after receipt to file a dispute of their report or reports. If following resolution of the dispute, CMS affirms its original calculation or specifies a new discard refund amount, the manufacturer will be required to pay the refund within 30 days of the dispute resolution. CMS is not finalizing the payment of the refund by December 31 of the year the report was issued, since it will be revisiting the timing of reports in future rulemaking. CMs will also revisit the issue of an appeals process 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 proposed that it will periodically audit manufacturers of refundable single-dose container or single-use package drugs consistent with this requirement. CMS requested 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 refundable single-dose container or single-use package drugs. CMS proposed 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 refund amount with respect to such drug for such quarter; and
- 25 percent of such amount.

Comments/Responses: Several commenters requested that the focus of manufacturer audits be limited to the manufacturers' responsibilities under section 1847A(h) of the Act (e.g., their refund obligations. CMS agrees and does not intend to conduct audits beyond determinations that manufacturers have either paid refund obligations or have not.

Some commenters suggested CMS conduct post-claims reviews for providers with unusual JW and JZ modifier reporting patterns. One commenter suggested allowing manufacturers to guide audit efforts by advising of particular issues or trends that warrant attention. CMS agreed with these comments stating that engagement with manufacturers on potential issue areas in discard reporting practices can make the provider audit process more targeted and effective.

One commenter stated that the imposition of civil money penalties should not be set before a manufacturer has had the opportunity to meaningfully engage CMS in a dispute process. CMS agrees that civil money penalties should not be imposed while the window for disputing a refund amount is still open. Civil monetary penalties would not be assessed before a reasonable amount of time has passed since either the report was first sent to the manufacturer or the dispute process concluded with a decision finding that the manufacturer has a refund obligation.

Final Decision: CMS finalizing all of the above proposals without change.

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)

CMS proposed two new HCPCS codes to describe a specified set of pain management and treatment services. The first code (G3002) 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 (G3003) is for each additional 15 minutes of face-to-face time. Another code is being created for GBHI services (G0323) 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 proposed 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 proposed 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 proposed 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. As proposed, the new codes for CPM would be valued using crosswalks to the 2023 PCM services (CPT codes 99424 and 99425), and the payment rate for the new GBHI code would be based on the payment rate for the current general BHI code, 99484.

CMS did 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 noted 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).

Commenters supported the proposal to allow RHCs and FQHCs to furnish CPM services, but they believe CMS should treat HCPCS code G3002 as an encounter and reimburse these services at the RHC AIR or at the FQHC PPS rate, instead of bundling the services under the general care management code, HCPCS code G0511. While CMS agrees that the description of HCPCS code G3002 includes a face-to-face component, it does not believe it is appropriate to pay CPM as a visit. CMS assumes RHC and FQHC practitioners will often discuss chronic pain aspects of the beneficiary's care during a visit, and addressing chronic pain as part of the visit would complete the face-to-face component of CPM. Billing of HCPCS code G0511 would address the non-face-to-face components of CPM. Thus, CMS believes that being able to bill both a face-to-face visit and a non-face-to-face CPM add-on service on the same day mitigates concerns from the commenters; payment for the RHC or FQHC visit accounts for the face-to-face component and payment for non-face-to-face CPM services accounts for the additional time and resources necessary for the unique components of care coordination for non-face-to-face CPM services furnished outside of the face-to-face visit with an RHC or FQHC practitioner.

CMS finalizes as proposed to include non-face-to-face CPM services described in HCPCS code G3002 in the general care management HCPCS code G0511 when these services are furnished

by RHCs and FQHCs, effective January 1, 2023. Because HCPCS code G3002 is valued using a crosswalk to the PCM CPT code 99424, which is currently one of the CPT codes that comprise HCPCS code G0511, there is no change to the average used to calculate the HCPCS code G0511 payment rate to reflect CPM services. This is in addition to the face-to-face visit component of CPM services.

CMS finalizes the HCPCS code G3002 descriptor with modifications shown in italics:

> Chronic pain management and treatment, monthly bundle including, diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, *and/or* maintenance of a person-centered care plan 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 crisis care; and ongoing communication and care coordination between relevant practitioners furnishing care, for example, physical therapy and occupational therapy, *complementary and integrative approaches*, 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 HCPCS code G3002, 30 minutes must be met or exceeded.)

CMS also finalizes its clarification that when CPs and CSWs provide the services described in HCPCS code G0323 in an RHC or FQHC, they can bill HCPCS code G0511 for dates of service on or after January 1, 2023.

Commenters asked that CMS allow RHCs and FQHCs to provide CCM and GBHI to a patient in the same calendar month and receive the separate reimbursement for each service. CMS notes under the 2021 PFS final rule with comment (86 FR 84699), general care management services furnished in RHCs and FQHCs nay only be billed once per month per beneficiary when at least 20 minutes of CCM services, at least 30 minutes of PCM services, or at least 20 minutes of general BHI services have been furnished and all requirements have been met. Thus, if the requirements for each of these care management services are met, then HCPCS code G0511 can be billed more than once in a calendar month, either alone or with other payable services and the same would apply for CPM and GBHI.

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 proposed applying the 151-day extension of non-in-person visits to all RHC and FQHC mental health visits, and it finalizes conforming changes to the regulations to reflect this policy. [61]

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 will implement these provisions through program instruction or other sub-regulatory means as authorized by CAA, 2022.

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

Beginning April 1, 2021, section 1833(f)(2) raised 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 clarified 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 proposed 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).

[61] 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.

For provider-based RHCs that did not have an AIR established for services furnished in 2020, CMS proposed 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.

Commenters generally supported the use of 12-consecutive month cost reports to establish the payment limit for specified provider-based RHCs. CMS finalizes its proposals without modification.

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 finalizes its proposal to conform its regulations at 42 CFR part 414, subpart G, 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."[62] Many provisions related to the specimen collection fee and travel allowance have only been in manual provisions. CMS proposed 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 final 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 on behalf of an HHA is $25.46.[63] 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 proposed 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 requested 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 proposed to eliminate the manual provision that allows payment for collecting a specimen from ESRD patients.

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[62] 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.

[63] 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.

In codifying its manual provisions, CMS proposed 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 qualified to collect samples and also perform tests to analyze body fluids, tissue, and other substances.

Commenters requested that CMS increase the $3 specimen collection fees to account for labor shortages, wage increases, supplies cost increases, and inflation. CMS reiterates that the statute required the specimen collection fee to be "nominal" and thus not intended to be reimbursement for actual or specific costs. It recognizes, however that updating the $3 amount for inflation is an appropriate way to recognize the specimen collection costs do increase and that increasing the nominal fee by CPI-U will address those growing pressures.

CMS is finalizing a specimen collection fee of $8.57 for 2023 for all specimens collected in one patient encounter. This fee will be increased by $2 ($10.57) for specimen collection from a Medicare beneficiary in a SNF or on behalf of an HHA for all specimens collected in one patient encounter. To establish the nominal specimen collection fee for 2023, CMS first calculated the inflation factor to be applied to the $3.00. It used the historical CPI-U from June of 2022 and divided it by the historical CPI-U for June 1984. It chose June of 1984 as the comparison date because that is the year Congress established the CLFS and the related laboratory specimen collection fees under section 1833(h)(3)(A) of the Act. CMS finalizes beginning January 1, it will update the specimen collection fee amount of $8.57 for each calendar year using the 12-month percentage increase in the CPI-U of the most recent year of data published by BLS, that is for the 12-month period ending June 30th of the year preceding the update year.

These specimen collection fee policies are codified at §414.523(a)(1).

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.[64]

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

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

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

- 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 proposed 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 proposed 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 proposed 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 sought comment on this provision of its proposal.

Many commenters expressed support for the proposals to codify and clarify the CLFS travel allowance policies. Commenters appreciated the clarifications regarding all aspects of the payment policies related to the CLFS travel allowance, including the proposed general requirements, travel allowance bases, travel allowance amount, and travel allowance amount calculations. Several commenters did not agree with the proposal that eligible miles would begin and end at the laboratory. Commenters noted, for example, that travel for specimen collection could being at a location other than the technician's home and could end at a location other than the laboratory, such as a drop-off location for courier or shipping services. One commenter sought clarification on what CMS meant by "trained technician".

CMS states that its belief that the modifications and clarifications to the travel allowance payment policies will improve and simplify the administration of the travel allowance payment policy. It also agrees with commenters that broadening the description of eligible miles will provide flexibility for the types of locations that could serve as the starting or ending point for travel related to specimen collection. CMS clarifies that the phrase "trained technician" refers to those staff providing specimen collection services and related travel. Trained technicians could include a variety of types of specialists with varying levels of training, including a phlebotomist. It clarifies that CMS is not creating qualification requirements for those individuals providing specimen collection services to Medicare beneficiaries.

CMS finalizes the proposed provisions for the laboratory specimen collection fee and travel allowance at 42 CFR part 414, subpart G with refinements to the description of eligible miles such that eligible miles begin at the laboratory or the starting point of the technician's travel for specimen collection and end at the laboratory or the ending point of the technician's travel for specimen collection where the trained technician returns the specimen(s) for testing.

It notes that updates to the travel allowance mileage rate will be issued through subregulatory guidance, specifically the existing CMS change request process, on an annual basis. Updates will be made to the travel allowance mileage rate based upon the most recently published IRS standard mileage rate, as well as the most recently published wage rate for phlebotomist as published by the BLS. The revised travel allowance mileage rate will be effective for the January update of the clinical laboratory fee schedule file. It will also make conforming changes to the Claims Processing Manual, Chapter 16, section 60 to reflect the changes to the travel allowance policies.

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 proposed to use its authority under section 1834(n) of the Act 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 also proposed the same age reduced age limitation for barium enema tests,

blood-based biomarker tests, and screening colonoscopy.[65] CMS did not propose to modify existing conditions of coverage or payment for maximum age limitations and frequency limitations.

Overall, commenters supported the proposals, which CMS finalizes without modification.

2. Complete Colorectal Cancer Screening

Responding to concerns about health equity, low follow-up colonoscopy rates, and patient access barriers, the agency proposed expanding 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.

CMS finalizes its proposal without modification. Effective January 1, 2023, CMS establishes 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. CMS waives the frequency limitations that would otherwise apply for CRC tests for the follow-on screening colonoscopy test when furnished as part of the new complete colorectal cancer screening benefit. Thus, beneficiary cost sharing for the initial screening stool-based test and the follow-on screening colonoscopy test will not apply. Medicare payment for both tests will 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 policy change.

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 is unchanged 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.

Commenters were also supportive of this policy change; they requested specific coding instructions and educational materials for stakeholders. CMS will provide implementation instructions, including coding and payment, through the CMS Transmittals online platform and educational articles through the Medicare Learning Network online platform.

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

3. Authority; Regulatory Impact

CMS cites relevant statutory and regulatory authority for its policy changes, including sections 1861(pp)(1)(D) and 1834(n) of the Act, regulations at §410.37, and NCD 210.3. It emphasizes that finalized policies 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 finalized policies from additional utilization to be approximately $10 million in additional spending.

E. Removal of Selected National Coverage Determinations

In the 2021 PFS final rule[66], 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 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)[67] or 1869(f)[68] 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 coverage, MACs would be able to cover the item or service if the MAC determines such action is appropriate under the statute.

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[66] 85 FR 84472

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

[68] 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.''

CMS finalizes its proposal to remove the NCD for Ambulatory electroencephalographic (EEG).[69] External interested parties recommended removal of this NCD. CMS' rationale for removing 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.

Four commenter, including the original requestors supported removal of the NCD. A beneficiary advocacy organization disagreed with removing this NCD and didn't think CMS should remove any positive coverage NCD as long as beneficiaries use the service because the MACs might develop inconsistent coverage. CMS disagrees and notes that EEG monitoring is a well-established service for which there are already LCDs.

Two commenters inquired why their requests to remove NCDs had not been discussed. CMS acknowledges receiving a number of NCD removal requests and states it is implicit that it does not agree with these requests because they were not discussed. It will contact interested parties directly for further assistance.

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 Furnished by Opioid Treatment Programs (OTPs)

Section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act[70] 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;

[69] The NCD is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items?CMS014961.
[70] 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[71] 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.[72] 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.[73]
- 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.[74]

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

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

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

[73] Orally administered methadone is not a drug subject to ASP reporting requirements under sections 1927(b)(3)(A)(iii) or 1847A(f)(2)(A) of the Act.

[74] Among comments previously 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.

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 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.

For 2023 and subsequent years, CMS finalizes without modification its proposal 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 will 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 finalizes without modification its proposal for 2023 that the methadone payment amount will be based on the projected increase for the 2-year period from 2021 to 2023. Based on the 2022 Q4 forecast from IHS Global Inc. (IGI), which is updated from the 2022 Q1 forecast in the proposed rule, the 2023 methadone payment amount will be $39.37. This amount is the 2022 payment amount of $37.38 increased by the projected 5.3 percent growth in the applicable PPI from 2021 to 2023 ($37.38 * 1.053 = $39.37).

CMS also finalizes without modification its proposal to do the following:

- For subsequent years, continue to update this rate annually using the PPI for Pharmaceuticals for Human Use (Prescription).
- 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.
- 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 received strong support for the proposal to stabilize the payment rate for methadone. A summary of comments to the 2022 Methadone IFC and CMS' responses appear in section V.A.

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

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 proposed 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. Several commenters supported the proposal.

CMS finalizes the update as proposed. In response to a comment, CMS clarifies that the crosswalk code is being used for the purposes of valuation, not as a requirement regarding the number of minutes spent in an individual therapy session; an OTP would be able to bill for an episode of care, even if the only OUD treatment service was an individual therapy session lasting less than 45 minutes.

One commenter urged CMS to adopt this modification for other SUD bundled payments under the PFS, such as the bundled rate for office-based SUD treatment (HCPCS codes G2086-G2088) and general behavioral health integration (CPT code 99484). The commenter noted that some patients who are prescribed buprenorphine in non-OTP settings will have similarly complex care needs requiring more intensive therapeutic care and that by recognizing the appropriate complexity and intensity of the services in its rate setting, CMS can incentivize more office-based practices to offer these services. CMS noted that such changes are outside of the scope of this specific proposal, which was limited to the payment rate for OUD treatment services when furnished in OTPs, but may consider making similar changes in future rulemaking.

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 finalizes as proposed amending the regulation (42 CFR §410.67(d)(4)(ii)) to clarify 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 also finalizes as proposed applying locality adjustments for services furnished via mobile units as if the service were furnished at the OTP.

Several commenters supported this policy, stating that it will allow OTPs to better serve Medicare beneficiaries and that allowing Medicare payment for services furnished by OTP mobile units is essential to expanding lifesaving access and filling detrimental treatment gaps.

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.[75] 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 (42 CFR §8.12(f)(2)). This exemption will continue only for the duration of the PHE for COVID-19 unless regulations are issued making this flexibility permanent.

Given the flexibilities provided to CMS regarding behavioral health services provided via telehealth (particularly through the SUPPORT Act and CAA 2021), CMS finalizes without modification 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 also finalizes as proposed 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.

In the proposed rule, CMS sought 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. Several commenters advocated CMS continue to allow such audio-only assessments after the end of the PHE, to further promote equity for individuals who are economically disadvantaged, live in rural areas, are racial and ethnic minorities, lack access to reliable broadband or internet access, or do not possess devices with video functions. Because these reassessments are no more complex than initial assessments, one commenter stated they are equally appropriate for audio-video and audio-only care. In addition, a few commenters requested that these flexibilities be extended to treatment with methadone and naltrexone, otherwise CMS will indirectly steer patients toward certain medication.

[75] 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.

After consideration of the comments, CMS is allowing—through the end of 2023—periodic assessments to be furnished audio-only when video is not available, to the extent that it is authorized by SAMHSA and DEA. This will allow continued beneficiary access to these services for 2023, regardless of the PHE, while also allowing additional time for CMS to further consider the issue.

G. Medicare Shared Savings Program – HPA Summary Part II

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 finalizes its proposal to annually update the payment amount for the administration of Part B preventive vaccines based upon the increase in the MEI. CMS also finalizes its proposal 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. Effective January 1, 2023 CMS will 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 4 for use of the EUA for drugs and biological products). Effective January 1 of the year following the year in which the PHE ends, the payment rate for administration of the COVID-19 vaccines will be adjusted to align with the payment amount for the administration of other Part B preventive vaccines.

Commenters had many suggestions for improvement of the Part B preventive vaccine benefit including increasing the vaccine administration payment for all Part B vaccines to $40; expand coverage to include all Medicare-covered vaccines, including those currently covered under Part D; aligning the Part B vaccine benefit to include all vaccines recommended by the CDC's Advisory Committee on Immunization Practices (ACIP); and site neutral payment based on the OPPS payment rates. CMS responds that it did not make any proposals related to expanding the Part B preventive vaccine benefit and refers readers to the 2023 OPPS proposed rule (87 FR 44575-44577) for a discussion on COVID-19 vaccine administration payments in the hospital outpatient setting.

a. Adjustment to the Payment Amount for Geographic Locality

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 GAF values for each fee schedule area are posted in Addendum D to this final 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 finalizes its proposal 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 finalizes the payment adjustments for 2023 and subsequent years.

Commenters were very supportive of the proposal to adjust the payment for the administration of preventive vaccines (influenza, pneumococcal, HBV, and COVID-19).

b. Annual Adjustment to the Payment Amount to Reflect Changes in Cost

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.D). 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.

For 2023 and subsequent years, CMS finalizes its proposal to annually update the payment amount for the administration of Part B preventive vaccines based upon the increase in the MEI.

The 2023 MEI update is 3.8 percent.

- The 2023 payment amount for influenza, pneumococcal, and HBV vaccine administration is $31.14. This amount will be geographically adjusted based upon the fee schedule are where the preventive vaccine is administered using the GAF.
- The 2023 payment amount for COVID-19 vaccine administration is $41.52 through the end of the calendar year in which the current EUA declaration for drugs and biologicals with respect to COVID-19 remains in place.
    - Effective January 1 of the year following the year in which the PHE ends, the payment rate for administration of the COVID-19 vaccines will be adjusted to align with the payment amount for the administration of other Part B preventive vaccines.

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:[76,77]

- The patient has difficulty leaving the home to get the vaccine; difficulty leaving the home could mean any of the following:
    - They have a condition, due to an illness or injury, that restricts their ability to leave home without a supportive device or help from a paid or unpaid caregiver
    - They have a condition that makes them more susceptible to contracting a pandemic disease like COVID-19; or
    - They are generally unable to leave the home, and if they do leave home, it requires a considerable and taxing effort.
- The patient is hard-to-reach because they have a disability or face clinical, socioeconomic, or geographical barriers to getting a COVID-19 vaccine in settings other than their home. These patients face challenges that significantly reduce their ability to get vaccinated outside the home, such as challenges with transportation, communication, or caregiving.
- The sole purpose of the visit is to administer the COVID-19 vaccine. Medicare will not pay the additional amount if the provider or supplier furnished another Medicare covered service in the same home on the same date.
- A home can be a private residence, temporary lodging (e.g., a hotel or motel, campground, hostel, or homeless shelter); an apartment in an apartment complex or a unit in an assisted living facility[78] 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.

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

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

[78] 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.

- 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. Changes for CY 2023

CMS finalizes its proposal 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 finalizes its proposal 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 finalized for the other preventive vaccine administration services.

For 2023, the in-home additional payment amount for COVID-19 administration (HCPCS code M0201) is $36.85 and payment for these services will be adjusted for geographic cost differences using the relevant PFS GAF.

Many commenters supported continuation of the in-home additional payment for COVID-19 vaccine administration and requested this benefit be expanded to include other preventive vaccines and allow home care providers to receive the additional home payment when administering the COVID-19 vaccine with an E/M visit. CMS notes that it did not make any proposals about expanding this in-home benefit but will consider potential policy changes in the future.

4. 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.[79] In contrast, an EUA continues until specifically terminated.[80] 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, four 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. FDA has limited authorized use of the Janssen-manufactured COVID-19 vaccine. Recently, FDA issued an EIA for emergency use of the Novavax COVID-19 vaccine. 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.[81]

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 final rule and summarizes these clarifications in Tables 85 and 86 (reproduced below). Table 85 displays the 2023 Part B payment for preventive vaccine administration if the EUA declaration continues into calendar year 2023 and Table 86 displays

[79] https://www.phe.gov/emergency/news/healthactions/phe/PAges/default.aspx
[80] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/faqs-what-happens-euas-when-public-health-emergency-ends.
[81] Details are discussed in the COVID-19 Monoclonal Toolkit available at https://www.cms.gov/monoclonal.

the Part B payment for preventive vaccine administration beginning January 1, 2023 if the EUA declaration ends on or before December 31, 2022.

Table 85: 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]	$31.14	MEI	GAF
COVID-19 Vaccine[2,4]	$41.52	MEI	GAF
In-Home Additional Payment for COVID-19 Vaccine Administration (M0201)	$36.85	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 2023 PFS final rule, this product is only available under EUA as injection.

Table 86: 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[1,3]	$31.14	MEI	GAF
COVID-19[2,3]	$31.14	MEI	GAF
In-Home Additional Payment for COVID-19 Vaccine Administration (M0201)	$36.85	MEI	GAF
COVID-19 Monoclonal Antibodies (for Treatment or Post-Exposure Prophylaxis)	Medicare payment under the applicable payment system		
COVID-19 Monoclonal Antibodies (for Pre-Exposure Prophylaxis)[3,4]	$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]Beneficiary coinsurance and deductible are not applicable.
[4]There are no monoclonal antibody products for pre-exposure prophylaxis of COVID-19 that have marketing authorization at this time.

Many commenters were supportive of CMS proposal to cover and pay for monoclonal antibody products used for treatment or post-exposure prophylaxis of COVID-19 under the Part D preventive vaccine benefit through the end of the year in which the EUA declaration for drugs and biologicals is terminated. Several commenters objected to the proposal to end the current payment for these products even following the year in which the EUA ends. Commenters stated that healthcare providers will continue to need extensive resources to treat patients after the EUA ends. Commenters requested that CMS provide sufficient notice and clear guidance before a payment transition begins for COVID-19 monoclonal antibody products and that CMS consider ways to minimize out-of-pocket costs for beneficiaries who will be charged cost-sharing for these therapies. Several commenters objected to not providing an annual update to monoclonal antibody products.

CMS believes it should continue payment and coverage of COVID-19 monoclonal antibodies under the Part B preventive vaccine benefit until the end of the calendar year in which the EUA declaration ends, rather than the end of the calendar year in which the PHE for COVID-19 ends. CMS will continue to assess the pandemic in considering whether further policy changes are warranted through additional rulemaking. CMS plans to notify vaccine providers and beneficiaries and develop guidance in advance of the transition in payment policies. CMS also believes that the payment amount for COVID-19 monoclonal antibody administration is appropriate for these services through the period they will remain in effect.

In response to reimbursement questions, CMS states that during the EUA declaration for drugs and biological products, Medicare will not pay for COVID-19 monoclonal antibody products that health care providers receive free. CMS sets the Medicare payment rate for products based on 95 percent of the AWP for those settings that are not paid under reasonable costs for vaccine products. Specifically for products furnished incident to a physician's service, the payment limit amounts for most drugs and biologicals separately payable under Part B are based on the ASP plus a statutorily mandated 6 percent add-on. The add-on percentage for WAC-based payments determined by MACs for new drugs before an ASP-based payment limit is available is up to 3 percent.[82]

Several commenters recommended that CMS continue to distinguish between preventive monoclonal antibody products used as pre-exposure prophylaxis and monoclonal antibody products used for treatment or post-exposure prophylaxis. One commenter requested that we cover monoclonal antibodies used for pre-exposure prophylaxis for infectious diseases other than COVID-19 under the Part B preventive vaccine benefit. CMS will consider these comments for future rulemaking; CMS notes that the comments for monoclonal antibodies for diseases other than COVID-19 are outside the scope of this rulemaking.

5. Regulatory Updates and Conforming Changes

In the November 6, 2020 interim final rule with comment (IFC)[83], "Additional Policy and Regulatory Revisions in Response to COVID-19 PHE", CMS published several changes to the

[82] https://www.cms.gov/files/document/r11572CP.pdf.
[83] 85 FR 71147

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.

Regulatory Impact
For 2023, CMS estimates approximately a $40 million increase in spending related to updating the payment amount for the administration of vaccines by the MEI (3.8%). Approximately $30 million of the increase represents the administration of the COVID-19 vaccine and the remaining $10 million represents the other preventive vaccines.

I. Medical Necessity and Documentation Requirements for Nonemergency, Scheduled, Repetitive Ambulance Services (§410.40(e)(2)(ii))

CMS finalizes as proposed 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 reads 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 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 reports receiving few comments and that they were overwhelmingly supportive. CMS describes questions raised and offers the following clarifications.

- No new documentation requirements are being set for use of specific forms.
- The revised language applies to all non-emergent, scheduled, repetitive ambulance transport services not only those subject to prior authorization requirements under the Repetitive, Scheduled, Non-Emergent Ambulance Transport (RSNAT) Prior Authorization model.[84] CMS notes that this CMS Innovation Center model has been expanded and as of August 1, 2022 is fully operational nationwide.
- The PCS and additional medical necessity documentation must be prepared and retained for every non-emergency, repetitive, scheduled, ambulance service. It is not required to be submitted with every claim but must be available on request.

[84] 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.

CMS categorizes several requests and suggestions from commenters as outside of the scope of this rule, such as allowing nonphysician practitioners to certify patient necessity for non-emergency, repetitive, scheduled, ambulance services and investing RSNAT model savings into providing payment for physician oversight of Emergency Medical System services.

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 finalizes several changes to its existing Medicare provider enrollment regulations.

2. Medicare Enrollment Provisions

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

i. OIG Exclusions

CMS finalizes its proposal 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."

ii. Felony Convictions

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 expands these two regulatory provisions to include managing organizations, officers, and directors. It also adds new paragraphs at §§424.530(a)(3)(iii) and 424.535(a)(3)(iv) to clarify that these two provisions also apply to contracted parties.

iii. Definitions

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

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

Commenters were generally supportive of the proposed changes. One commenter expressed concern about the requirement that volunteer board members of NPCs disclose their social security numbers on CMS enrollment applications. CMS notes in its reply that section 1124(a) of the Act makes no distinction between for-profit and non-profit entities or between paid and voluntary board members, and thus social security numbers of NPC board members must be disclosed.

b. 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).

Commenters were generally supportive of the proposed changes. CMS finalizes the revisions as proposed.

c. 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 finalizes its proposal 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).

Several commenters expressed support for the proposed change. One commenter expressed a concern that this would shorten the period in which a provider or supplier can appeal a revocation or enrollment. CMS states that the added language does not reduce the timeframe for filing an appeal it merely clarifies that if no appeal is filed within the prescribed timeframe, the revocation becomes effective.

d. 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 finalizes the following changes to §424.518. CMS first adds 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 clarifies 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 the provider or supplier 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 adds a new paragraph (c)(4). CMS states that any adjustment under paragraph (c)(3) also applies 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.

Several commenters cautioned CMS against implementing proposed §424.518(c)(4), as well as the expansion of §424.518 to include ownership changes, until these provisions' potential impacts and burdens on providers, the MACs, and beneficiary access to care are assessed. They expressed particular concern about the burden on owners of multiple providers and suppliers. CMS replies that it carefully considered the possible impacts of this policy and its estimates indicate that less than 3,000 providers and suppliers per year would be affected by these changes. It does not believe that the changes will result in delays in enrollment application processing but will monitor this provision for any significant undue burden. CMS finalizes all provisions in this section as proposed.

e. 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 finalizes its proposal 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 will 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.

Several commenters expressed support for the proposal. Others contended that CMS lacked the statutory authority for its proposal to move SNFs to the high screening category. CMS replies that is proposal was not intended to use the increase in the screening level of SNFs to detect compliance with the SNF CoPs under 42 CFR 483. Rather, it was to more closely monitor SNF owners and operators for having engaged in criminal activity that threatens Medicare beneficiaries and the Trust Funds. CMS believes this falls within the authority granted to the Secretary under section 1866(j)(1)(A) of the Act. Other commenters expressed general concern about the necessity of these provisions and the potential burden on the owners and operators of SNFs. CMS believes these additions are necessary to protect the Medicare program from fraud, waste, and abuse. CMS finalizes the revisions as proposed.

f. 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 finalizes its proposal to add a new condition of payment in paragraph (b)(6) in §424.57. This states 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.

Commenters were supportive of the proposal. CMS replied that a beneficiary would not have any financial liability or responsibility for expenses in cases where a provider's or supplier's billing privileges are deactivated, denied, or revoked. CMS finalizes the revisions as proposed.

g. 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 sought 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 proposed 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. In the proposed rule, 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 Medicaid 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.

Several commenters expressed support for the proposal, and CMS is finalizing it as proposed.

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 proposed 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.

3. Changes to Exceptions

CMS finalizes without modification its proposed changes to the two exceptions described above.

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

CMS previously established a policy 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 previously established, the availability of the exception for the year involved was determined by examining PDE claims as of December 31 of the prior year.

In this final rule, CMS changes 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 is 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.

CMS acknowledges that neither it nor the individual prescriber will 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. CMS is concerned that 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.
A few commenters objected to the proposed change to use the current year as the evaluation period. They believe it will be overly confusing to the prescribers in small practices and difficult for prescribers to track. They worry about that prescribers may be unduly subject to compliance actions because they may be unaware of the number of Part D controlled substance prescriptions they have written, and concern was expressed about access to these medications, especially in medically underserved areas.

To address these concerns, CMS intends to provide feedback to prescribers through an online dashboard that will contain a variety of EPCS elements, which will be developed as soon as technically feasible. Initially, the EPCS dashboard will include whether a prescriber was determined to be compliant or non-compliant, and the agency anticipates adding information that defines the type of exceptions and provides more detail about prescribers' EPCS status so that they can see the number of prescriptions for Medicare Part D controlled substances they issued in the evaluated year. However, due to the lag in claims data, that information would not be available until after the PDE submission deadline, which is generally 6 months after the end of the calendar year being evaluated. CMS indicates that, through the 2024 EPCS compliance year, the only consequence of non-compliance is a notice informing the prescriber of the prescriber's non-compliance, and the agency will provide prescribers who do not meet the small prescriber

exception with at least two separate notices that they do not meet the exception, with information included about how they can come into compliance before a compliance action (other than a notice) would be imposed.

CMS does not believe the change in the evaluation period will impact access to these medications, but it intends to monitor both the impact of the policy change as well as other factors that could affect access.

CMS does not believe it is operationally feasible for it to notify prescribers that they are approaching the 100-prescription threshold, and it notes that prescribers are not required to track the number of controlled substance prescriptions for Part D drugs they issue.

The finalized policy is effective for 2023 and subsequent years. CMS notes that the only noncompliance action it would take in 2023 and 2024 for violations of the exception requirements is the issuance of a noncompliance letter; the agency believes that the risk to prescribers of this policy change will be minimal.

b. Cases of Recognized Emergencies

CMS previously established 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 proposed 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 proposed using the prescriber address in the National Plan and Provider Enumeration System (NPPES) database.

CMS finalizes its proposals without modification.

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 finalizes its proposal 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 will be the issuance of a noncompliance letter. CMS clarifies that these notices would be sent by e-mail, when possible, to all available e-mail addresses in PECOS and NPPES and by regular mail if there is no e-mail address in PECOS or and no e-mail address in NPPES.

Commenters supported extending the policy of only sending noncompliance letters through the 2024 EPCS program implementation year; they noted that the extension will give vendors and practices time to implement EPCS and adjust products and technology to align with DEA EPCS requirements and regulations. Some commenters objected to the extension because they felt that timely enforcement was necessary to combat drug abuse and diversion and that all parties had more than enough time to become compliant. Because CMS is concerned about unintended consequences for prescribers who still need additional time to implement EPCS, it is satisfied that noncompliance letters will encourage prescribers to conduct EPCS as soon as possible.

CMS sought comment on other appropriate types of compliance actions after 2024 and noted that any penalties would not go into effect sooner than January 1, 2025. CMS will consider all input as it develops future regulatory proposals. CMS indicates that any updates to specific requirements related to potential EPCS penalties or actions may be addressed through separate and future notice-and-comment rulemaking.

5. Regulatory Impact

CMS does not anticipate that the finalized policies will 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 (GADSC)

Medicare makes payment for ambulance services based on the ambulance fee schedule. Section 1834(l)(17) of the Act required CMS to develop a data collection system on ambulance costs, revenues and other information by December 31, 2019. CMS is also required 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.

The survey is in place and CMS has had some learning experiences, as well as questions and feedback from the field, that have resulted in process changes and improvements to the survey instrument. The final rule lists these changes in detail. A draft of the instrument that includes the 2023 changes is posted on the CMS website at https://www.cms.gov/files/document/medicare-

ground-ambulance-data-collection-instrument-draft.pdf. CMS is making one additional refinement to the printable instrument in response to a comment.

As discussed in the proposed rule, CMS is in the process of developing the web-based GADCS portal and programmed survey instrument that ground ambulance organizations will use to report the data. CMS states the changes to the printable instrument will better match current plans and expectations for the programmed instrument. The final rule also details changes to the programmed instrument. The questions in the web-based, programmed system will be identical to the printable instrument that will ultimately be posted on CMS' Ambulances Services Center website when this final rule is published.

Ambulance providers and suppliers 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 (§414.626(d)). In addition, the ambulance provider or supplier may request an informal review of a decision by CMS to apply the 10 percent penalty (§414.626(e)(2)). 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). Since then, CMS has sought ways to streamline the request process and has determined the most efficient method is a web-based form via the Medicare Ground Ambulance Data Collection System rather than via the Ambulance ODF mailbox. CMS said it intends to launch the web-based portal that ground ambulance organizations can use to submit their hardship exemption and informal review requests in late 2022 and will share more information when available. To accommodate either approach (or any future approach), CMS is finalizing as proposed that requests must be submitted in the form and manner specified by CMS.

N. Revisions to HCPCS Level II Coding for Skin Substitutes

CMS describes the process for creating and revising HCPCS codes and also the FDA approval processes skin substitutes. Some skin substitute products are regulated by the FDA as 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 skin substitutes 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 skin substitutes.[85] Prior to 2021, all of these products, including those regulated by the FDA as devices, were assigned a Q code as they were generally treated as 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.

[85] 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 (ambulance) and medical and surgical supplies.

Beginning in 2020, CMS required each HCPCS code application for an HCT/P skin substitute to include a letter from the FDA's Tissue Reference Group (TRG) indicating that the product meets the criteria for regulation under the HCT/P FDA regulatory pathway. The proposed rule indicated 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 skin substitutes. CMS directed that these products would be contractor-priced by the MACs rather than as drugs and biologicals.

Proposals: CMS proposed to:

- Assign A codes to all skin substitutes that are not drugs or biological products. This proposal would be for all skin substitute products previously assigned Q codes and new skin substitutes requesting a new HCPCS code.
- Evaluate code applications for all skin substitutes 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 skin substitutes 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 skin substitutes with an existing Q code seeking an A code) to furnish a letter from the TRG indicating how the product is regulated by the FDA.

Table 88 of the final rule lists all skin substitutes that currently have Q codes where CMS proposed to retire the code on January 1, 2024 and the manufacturer of the product would need to reapply for A code under CMS' proposal. Manufacturers of these products would have had 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 89 of the final rule lists skin substitutes that currently have Q codes where CMS proposed that the code would be retired on January 1, 2024. For these codes, the manufacturer has already furnished TRG information on how these products are regulated by the FDA. Under CMS' proposal, manufacturers of these products would have been granted an A code effective January 1, 2024 without having to reapply for a HCPCS code.

Final Decision: The coding proposals were one part of CMS' overall proposed approach to refining how CMS treats skin substitutes furnished in the physician office setting for purposes of coding and payment under Medicare as described more fully in section II.J. As CMS is not finalizing its payment proposals with respect to these products, the coding proposals are also not being finalized. Commenters will be summarized and responded to in future rulemaking.

IV. Updates to the Quality Payment Program – HPA Summary Part III

V. Finalizing Provisions from the Interim Final Rules

A. Finalizing the CY 2022 Methadone Payment Exception for OTPs

As mentioned in section III.F., CMS issued the Methadone IFC in November 2021 regarding the payment rate for methadone under the Medicare Opioid Treatment Program (OTP) benefit for 2022. The Methadone IFC froze the payment rate to OTPs for methadone in 2022 at the 2021 payment rate. This section summarizes the issues, public comments from the IFC, and the final policies adopted for payment to OTPs for methadone in 2022. CMS is finalizing the 2022 policies without modification.

CMS provides background on the three FDA-approved medications for opioid use disorder (MOUD)—methadone, buprenorphine, and naltrexone. Unlike the other medications, methadone cannot be dispensed by a pharmacy because it is a schedule II controlled substance. As a result, it is not covered by Part D. Approximately 74 percent of individuals receiving services from OTPs receive methadone for OUD treatment, with the vast majority of the remainder receiving buprenorphine. Among beneficiaries using OTP services under the relatively new Medicare benefit, the percentage receiving methadone is closer to 95 percent. Medication-assisted treatment (MAT) combines MOUD with counseling and behavioral therapies to provide a whole-patient approach to OUD care. CMS cites research that MAT has been shown to improve patient survival and increase retention in treatment.

Overdose deaths further accelerated during the pandemic, particularly among racial and ethnic minorities, as noted in public comments. CMS cited a comment that these spikes in substance use and overdose deaths reflect a combination of increasingly deadly illicit drug supplies, treatment disruptions, social isolation, and other hardships related to the COVID-19 pandemic, but also reflect the longstanding inadequacy of the medical infrastructure when it comes to preventing and treating SUD. According to CMS, 2.8 percent of Medicare FFS beneficiaries had an OUD in 2018—more than 1 million individuals. OUD-related problems are compounded in the Medicare population by chronic pain-associated conditions more common in later life, as well as the increased prevalence of multiple comorbidities and polypharmacy risks among older adults.

CMS restates the pricing and reporting issues already described in section III.F., which would have reduced 2022 payments for oral methadone to $17.64, from its 2021 level of $37.38. Instead, CMS froze the amount for 2022 at the 2021 rate, revised regulations accordingly (§410.67(d)(2)(i)(B)), and requested comment. The majority of commenters were supportive. CMS agrees that the payment exception was important to promote MOUD accessibility and to allow additional time to evaluate utilization to inform the payment rate for methadone furnished in OTPs for 2023 and future years. A few commenters raised concerns that freezing the payments at 2021 rates could be inadequate given supply-chain and inflation-related issues. CMS took this feedback into account as it reflects inflation from 2021 for 2023 and subsequent years using PPI, as described in section III.F.

Several commenters stated that oral concentrate methadone, which is the most preferred modality, is more costly to provide to patients than methadone tablets and that should be

reflected in pricing. For example, commenters noted that some states require full-time pharmacists be present to dose the oral concentrate formulation, and that supplies used in dispensing the oral concentrate—such as electric pumps and pipettes, and their related software—require maintenance, replacement, acquisition, and storage. While CMS may consider addressing these issues in future rulemaking, it believes the methodology for 2023 and future years reflecting PPI is an appropriate factor to account for changes in methadone costs and CMS is revising regulations accordingly.

B. Policy and Regulatory Revisions in Medicare and Medicaid in Response to the COVID-19 Public Health Emergency

1. Improving Access to Virtual Communication Services Furnished by Rural Health Clinics (RHC) and Federally Qualified Health Centers (FQHC)

In this final rule, CMS responds to public comments and finalizes policies from the April 2020 IFC on Medicare and Medicaid policy and regulatory revisions in response to the PHE.

To minimize risks associated with exposure to COVID-19, the IFC expanded services that can be included in the payment for virtual communications[86] in RHCs and FQHCs:

- CPT code 99421 (Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5–10 minutes);
- CPT code 99422 (Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11– 20 minutes); and
- CPT code 99423 (Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes).

In addition, effective on or after March 1, 2020 and throughout the PHE, the payment rate for HCPCS code G0071 is the average of the PFS national non-facility payment rate for HCPCS code G2012 (communication technology-based services), HCPCS code G2010 (remote evaluation services), CPT code 99421, CPT code 99422, and CPT code 99423.[87] Previously, HCPCS code G0071 was set at the average of the national non-facility PFS payment rates for HCPCS code G2012 services) and HCPCS code G2010 (remote evaluation services), updated annually based on the PFS national non-facility payment rate for these codes. Under the IFC, all virtual communication services billed by HCPCS code G0071 would be available to new patients not seen by the RHC or FQHC within the previous months. The IFC also removed the requirement that patient consent had to be obtained both before the G0071 service is furnished and before these services are billed; consent can be obtained when services are furnished, including consent obtained by staff under the general supervision of the RHC or FQHC practitioner for the virtual communication codes during the PHE.

[86] Virtual communications and telehealth are distinct services. Telehealth services are considered a substitute for an in-person visit. Virtual communications are brief discussions with the RHC or FQHC practitioner to determine if a visit is necessary (CMS FAQ).

[87] The description for HCPCS code G0071 is Payment for communication technology-based services for 5 minutes or more of a virtual (non-face-to-face) communication between a rural health clinic (rhc) or federally qualified health center (fqhc) practitioner and rhc or fqhc patient, or 5 minutes or more of remote evaluation of recorded video and/or images by an rhc or fqhc practitioner, occurring in lieu of an office visit; rhc or fqhc only.

Comments/Responses: Most commenters supported these flexibilities as allowing providers to better meet patients' needs and ensuring access to care during the pandemic. One commenter noted that the ability to bill HCPCS code G0071 for new patients would better help Urban Indian Organizations (UIOs) serve AI/AN communities, which often face challenges accessing medical professionals regularly within a 12-month span since they need to travel longer distances to reach dispersed reservation-based Indian Health Services (IHS) or tribal health services. A few commenters requested the flexibility be extended beyond the PHE. CMS expressed appreciation for the policy but said it does not intend to extend the flexibilities past the PHE. However, CMS will continue to evaluate the effectiveness of these flexibilities and, in the event that future circumstances warrant additional flexibilities, will reconsider these issues in future rulemaking.

Final Decision: CMS is finalizing the policy without modification. When the PHE ends, CPT codes 99421, 99422 and 99423 will no longer be included in the payment for HCPCS code G0071, virtual communication services will only be available to patients that have been seen in the RHC or FQHC within the previous 12 months, and beneficiary consent for these services must be acquired under direct supervision and prior to the services being furnished.

2. Revision of Home Health Agency Shortage Area Requirements for Furnishing Visiting Nursing Services by RHCs and FQHCs

The April 2020 IFC modified requirements for visiting nursing services furnished in the home by RHCs and FQHCs. Prior to the PHE, visiting nursing services were only covered if the following conditions were met:

- The RHC or FQHC was located in an area designated by the Secretary to have a shortage of HHAs;
- If rendered to a homebound individual; and
- Other conditions at §405.2416.

Under the IFC, during the PHE, any area typically served by the RHC, and any area that is included in the FQHC's service area plan, was determined to have a shortage of HHAs with no request for this determination required. However, CMS mandated RHCs and FQHCs to check the HIPAA Eligibility Transaction System (HETS) before providing visiting nursing services to ensure the patient was not already under a home health plan of care. If the patient was under a home health plan of care, the HHA had to provide optimal care to achieve the goals and outcomes identified in the patient's plan of care, for each patient's medical, nursing, and rehabilitative needs (in accordance with §484.105). RHC and FQHC visiting nursing services could not be covered by Medicare if they overlapped with a 30-day period of home health care.

Comments/Responses: CMS received a few comments, including one that expressed support but also concern that expanding these services would exacerbate existing shortages of home healthcare professionals since the policy broadened eligible service areas and consequently the number of patients within these areas needing services. CMS acknowledges the shortage of home healthcare workers and the PHE's impact on underserved rural and urban communities.

CMS believes this flexibility is important for patient access to nursing services in the home and the potential for HHAs that may be overwhelmed during COVID–19 PHE.

Final Decision: CMS is finalizing the policy without modification. After the PHE ends, visiting nurse services will only be covered if the RHC or FQHC is located in an area designated by the Secretary to have a shortage of HHAs and the services meet the other conditions in §405.2416.

C. Additional Policy and Regulatory Revisions in Response to the COVID-19 PHE

1. Revision of Bed Count Methodology for Determining Provider-Based RHCs' Exemption from the RHC Payment Limit[88]

On May 8, 2020, CMS published an IFC titled "Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program" (85 FR 27550). In that IFC, CMS implemented a policy affecting the calculation of the bed count methodology that determined when a provider-based RHC was exempted from the national RHC per-visit payment limit.

Generally, an RHC that is provider-based to a hospital with fewer than 50 beds is excepted from the national RHC per-visit payment limit and is reimbursed based on actual reasonable costs. Due to the PHE, many hospitals increased inpatient bed capacity to address the surge, which could have affected payment for provider-based RHCs if their associated hospital had expanded beyond 50 beds, thus making them ineligible for the limit exception. To address this, CMS modified regulations to use the number of beds from the cost reporting period prior to the start of the PHE as the official hospital bed count for determining provider-based RHCs exempted from the RHC payment limit. Once the PHE ends, a hospital will need to lower its bed count to less than 50 beds to maintain the RHC exception.

CMS determined that the one comment received related to this policy was out of scope and finalizes the policy without modification.

D. Origin and Destination Requirements Under the Ambulance Fee Schedule[89]

Ambulance services are Part B services permitted where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations (section 1861(s)(7) of the Act). CMS reviews the content of those regulations (42 CFR §410.40), including the following modifications made in the April 2020 IFC.

The April 2020 IFC expanded the list of destinations (§410.40(f)) during the COVID-19 PHE for which Medicare covers ambulance transportation to include all destinations, from any point of origin, that are equipped to treat the condition of the patient consistent with Emergency Medical Services (EMS) protocols established by state and/or local laws where the services will be

[88] This subsection 1 is the only subsection under this final rule's section V.C.
[89] In the final rule, this section appears as V.E., and there is no V.D.

furnished. Based on these protocols, a patient suspected of having COVID-19 that requires a medically necessary transport may be transported to a testing facility to get tested for COVID-19 instead of a hospital. Such destinations may include an alternative site determined to be part of a hospital, CAH or SNF, community mental health centers, FQHCs, RHCs, physicians' offices, urgent care facilities, ambulatory surgery centers (ASCs), any location furnishing dialysis services outside of an ESRD facility when an ESRD facility is not available, and the beneficiary's home.

Comments/Responses: CMS received 17 comments supporting the temporary expansion of the list of covered ground ambulance destinations. Two commenters sought clarification if the temporary expanded list of covered destinations applies to any beneficiary, not only beneficiaries experiencing a COVID-19 related clinical presentation. CMS states the expanded list during the PHE applies to beneficiary, with or without a COVID-19 related clinical presentation.

Two commenters inquired whether including the beneficiary's home as an appropriate alternate destination means that a clinically appropriate treatment-in-place determination—such as contemplated in CMS' Emergency Triage, Treatment and Transport (ET3) payment model, where the beneficiary can be appropriately managed in the home, without ambulance transport—is a covered benefit. First, CMS states that, consistent with section 1861(s)(7) of the Act, there must be a medically necessary ground transport of a patient in order for an ambulance service to be covered, with various circumstances that the IFC spoke to. CMS then notes that section 9832 of the American Rescue Plan Act of 2021 gave the Secretary authority to implement a waiver applicable to ground ambulance services during the PHE. With this authority, effective March 1, 2020 through the end of the PHE for the COVID-19, CMS is waiving requirements (under sections 1861(s)(7) and 1834(l) of the Act) that an ambulance service include the transport of an individual to the extent necessary to allow payment for ground ambulance services furnished in response to a 911 call (or the equivalent in areas without a 911 call system) in cases in which an individual would have been transported to a destination permitted under §410.40(f) but such transport did not occur as a result of community-wide EMS protocols due to the PHE for the COVID-19. CMS then refers the reader to the COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing document for further information at https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf.

Three commenters recommended that CMS evaluate the effectiveness of this interim expansion and consider developing permanent revisions. CMS responded that the ET3 model is designed to evaluate the potential benefits described by the commenters in circumstances outside of the PHE. CMS continues to believe that the current regulatory requirements governing coverage of ambulance services are appropriate under non-PHE circumstances.

Final Decision: CMS is finalizing the policy without modification. After the PHE ends, the regulations will still reflect the long-standing ambulance services coverage (with the exception of REHs, which are new) for the following destinations: hospital, CAH, REH (effective with services on or after January 1, 2023), SNF, beneficiary's home, and dialysis facility for an ESRD patient who requires dialysis. Any future refinements will be addressed in rulemaking with an opportunity for public comment.

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 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 CF for 2023 is $33.0607, 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 -1.60 percent. Overall, the 2023 CF is nearly 4.5% lower than the 2022 CF. The 2023 anesthesia conversion factor is $20.6097, 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 146 and 147 from the final rule, reproduced below.

Table 146: Calculation of the 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	-1.60 percent (0.9840)	
2023 Conversion Factor		**$33.0607**

Table 147: Calculation of the 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	-1.60 percent (0.9840)	
2023 Practice Expense and Malpractice Adjustment	0.06 percent (1.0005)	
2023 Conversion Factor		**$20.6097**

Table 148 (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 148. 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 7 percent for diagnostic testing facility, increase of 4 percent for infectious disease, increase of 3 percent for internal medicine, and increase of 2 percent for physical medicine, geriatrics, and psychiatry to a decrease of 3 percent for interventional radiology and vascular surgery, and a decrease of 2 percent for sixteen other specialties. Other factors that could impact changes include 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 148 (reproduced below) shows the estimated 2023 combined impact on total allowed charges by specialty of all the RVU and other changes. For this year, CMS provides an additional impact table (table 149 in the final rule) that includes a facility/non-facility breakout of payment changes.

Table 148: 2023 Final 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
Allergy/Immunology	$233	0%	-1%	0%	-2%
Anesthesiology	$1,749	-1%	0%	0%	-2%
Audiologist	$71	-1%	0%	-1%	-2%
Cardiac Surgery	$199	-1%	-1%	0%	-2%
Cardiology	$6,331	0%	-1%	0%	-1%
Chiropractic	$674	-1%	1%	0%	0%
Clinical Psychologist	$791	-1%	0%	-1%	-2%
Clinical Social Worker	$861	-1%	0%	-1%	-2%
Colon and Rectal Surgery	$156	-1%	-1%	0%	-2%
Critical Care	$354	1%	0%	0%	1%
Dermatology	$3,760	-1%	0%	0%	-1%
Diagnostic Testing Facility	$817	0%	7%	0%	7%
Emergency Medicine	$2,544	0%	0%	0%	0%
Endocrinology	$534	0%	0%	0%	0%
Family Practice	$5,817	0%	0%	0%	0%
Gastroenterology	$1,595	0%	-1%	0%	-1%
General Practice	$378	0%	0%	0%	0%
General Surgery	$1,772	-1%	-1%	0%	-2%
Geriatrics	$177	2%	0%	0%	2%
Hand Surgery	$256	-1%	0%	0%	-1%
Hematology/Oncology	$1,713	0%	-1%	0%	-1%
Independent Laboratory	$600	0%	0%	0%	0%
Infectious Disease	$590	4%	0%	0%	4%
Internal Medicine	$9,881	2%	0%	0%	3%
Interventional Pain Mgmt	$929	-1%	-1%	0%	-2%
Interventional Radiology	$467	-1%	-3%	0%	-3%
Multispecialty Clinic/Other Phys	$151	0%	-1%	0%	-1%
Nephrology	$2,032	1%	0%	0%	1%
Neurology	$1,406	0%	-1%	0%	-1%
Neurosurgery	$732	-1%	0%	0%	-1%
Nuclear Medicine	$54	-1%	-1%	0%	-2%
Nurse Anes / Anes Asst	$1,122	-1%	0%	0%	-2%
Nurse Practitioner	$5,842	1%	0%	0%	1%
Obstetrics/Gynecology	$596	-1%	0%	0%	-1%
Ophthalmology	$4,849	-1%	0%	0%	-1%
Optometry	$1,316	-1%	0%	0%	-1%
Oral/Maxillofacial Surgery	$74	-1%	-1%	0%	-2%
Orthopedic Surgery	$3,476	-1%	0%	0%	-1%
Other	$59	0%	-1%	0%	-2%
Otolaryngology	$1,139	-1%	0%	0%	-1%
Pathology	$1,173	-1%	0%	0%	-1%
Pediatrics	$58	0%	0%	0%	0%
Physical Medicine	$1,097	2%	0%	0%	2%
Physical/Occupational Therapy	$4,925	-1%	1%	-1%	-1%
Physician Assistant	$3,182	0%	0%	0%	0%

Table 148: 2023 Final 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**
Plastic Surgery	$324	-1%	0%	0%	-1%
Podiatry	$2,013	-1%	-1%	0%	-1%
Portable X-Ray Supplier	$78	0%	2%	0%	1%
Psychiatry	$990	1%	0%	0%	2%
Pulmonary Disease	$1,402	1%	0%	0%	1%
Radiation Oncology and Radiation Therapy Centers	$1,615	-1%	0%	0%	-1%
Radiology	$4,734	-1%	-1%	0%	-2%
Rheumatology	$548	-1%	-1%	0%	-2%
Thoracic Surgery	$318	-1%	-1%	0%	-2%
Urology	$1,758	-1%	-1%	0%	-1%
Vascular Surgery	$1,104	0%	-3%	0%	-3%
Total	$91,414	0%	0%	0%	0%

The following is an explanation of the information for Table 148:

- 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 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 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 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 Provisions

The expected impacts of some of the changes in this rule (other than those associated with changes in RVUs or the update factor) are discussed in previous sections of this summary. This includes the effect of changes related to 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, policies related to skin substitute products, effects of policies for Medicare Part A and B payment for dental services, among others.

C. Changes Due to the Quality Payment Program

CMS estimates that approximately 42 percent of the nearly 1.7 million clinicians billing to Part B (719,516) will be assigned a MIPS score because others will be ineligible for or excluded from MIPS. Table 154, 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 154: Description of MIPS Eligibility Status for 2023 Performance Period/2025 MIPS Payment Year Using the 2023 PFS Final Rule Assumptions**

		CY 2023 PFS Final Rule Estimates	
Eligibility Status	**Predicted Participation Status in MIPS Among Clinicians**	**Number of Clinicians**	**PFS Allowed Charges ($ in mil)*****
Required eligibility (always subject to a MIPS payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria)	Engaged in MIPS *	120,887	32,372
	Did not engage in 2021 but engaged in 2019	17,529	5,120
	Did not engage in 2021 and did not engage 2019 (or did not have data in 2019)*	13,368	3,499
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low-volume threshold in all 3 criteria)	Had a group submission	560,211	14,633
Opt-In eligibility assumptions (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)	Engaged in MIPS	7,442	$417
	Do not engage in MIPS	79	$4
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**719,516**	**$56,045**

Table 154: Description of MIPS Eligibility Status for 2023 Performance Period/2025 MIPS Payment Year Using the 2023 PFS Final Rule Assumptions**			
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	475,882	$11,990
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	98,909	$657
Excluded for other reasons (Non-eligible clinician type, newly enrolled, QP)	Not applicable	403,980	$18,506
Total Number of Clinicians Not MIPS Eligible		**978,771**	**$31,153**
Total Number of Clinicians (MIPS and Not MIPS Eligible)		**1,698,287**	**$87,198**

*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.

CMS notes that it does not have the ability to assess the 2019 data supplement clinicians on performance in its model, so it used the final score from the CY 2023 PFS proposed rule baseline model and used that same score for this final rule's baseline and final policies models. CMS has therefore separated the "required eligibility" into three buckets this year: (1)"Engaged in MIPS"; (2) "Did not engage in 2021 did engage in 2019"; and (3)"Did not engage in either 2021 or 2019" so that it can isolate both the effects of its final policies which are modeled using 2021 data, the effect of the 2019 data supplement, and model the population of clinicians who did not engage in either year.

In the aggregate, CMS estimates that for the 2025 payment year, it would redistribute about $700 million in payment adjustments on a budget neutral basis. CMS estimates that the maximum positive payment adjustment is about 6.09 percent. The overall proportion of clinicians receiving a positive or neutral payment adjustment is 63 percent and 37 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 156, 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 one 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. CMS states that all practices sizes saw either minimal change or a modest increase in the percentage of clinicians receiving either a positive or neutral adjustment

Table 156: 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 Allowed Charges*** **
Baseline model among clinicians who engage **with MIPS** **				
1) Solo	10,417	55.39%	44.61%	0.50%
2) 2-15	67,932	65.03%	34.97%	1.41%
3) 16-99	147,832	56.64%	43.36%	1.10%
4) 100+	461,769	64.26%	34.74%	2.22%
Overall	687,950	62.56%	37.44%	1.64%
Final policies model among clinicians who engage with MIPS**				
1) Solo	10,417	56.38%	43.62%	0.52%
2) 2-15#	67,932	66.04%	33.96%	1.42%
3) 16-99#	147,832	56.78%	43.22%	1.04%
4) 100+#	461,769	65.21%	34.79%	2.25%
Overall	687,950	63.35%	36.65%	1.64%

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

**2021 and 2019 data used to estimate CY 2023 performance period /2025 MIPS payment adjustments. Payment estimates trended to 2025 dollars.

***The 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.

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. The scoring model results presented in the proposed rule assume that 2021 data submissions are representative of 2023 performance. Likewise, CMS states that it is difficult to predict whether clinicians will elect to opt-in to participate into the MIPS program.

D. Alternatives Considered

The final rule contains a range of potential policies, and CMS provides a discussion of alternatives considered for some of these policies. 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 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 47.5 percent work RVUs, 51.2 percent PE RVUs, and 1.3 percent MP RVUs (this would represent a significant shift from the current weights of 50.9 percent for Work RVUs, 44.8 percent PE RVUs, and 4.3 percent MP RVUs). This shift would result in significant specialty specific impacts and a reduction in the PFS CF.

Table 158 in the final rule (extract reproduced here) illustrates specialty-specific impacts if CMS had used the rebased and revised MEI cost share weights to adjust the RVUs to match the PE share of the MEI.

Extract From Table 158: 2023 PFS Estimated Impact on Total Allowed Charges by Specialty using Rebased and Revised MEI Cost Share Weights for 2023					
(A) Specialty	**(B) Total: Non-Facility/Facility**	**(C) Allowed Charges (mil)**	**(D) Combined Impact No MEI Changes** (same as shown in Table 149)	**(E) Combined Impact Year 1 MEI Transition**	**(F) Combined Impact Full MEI Changes**
Estimated Conversion Factor			**$33.0607**	**$33.642**	**$31.834**
TOTAL	*TOTAL*	$91,046	-2%	0%	0%
	Non-Facility	$61,291	-2%	-1%	2%
	Facility	$29,755	-1%	1%	-4%
ALLERGY/IMMUNOLOGY	*TOTAL*	$232	-2%	0%	5%
CARDIAC SURGERY	*TOTAL*	$197	-1%	-3%	-9%
CARDIOLOGY	*TOTAL*	$6,310	0%	-1%	-1%
DIAGNOSTIC TESTING FACILITY	*TOTAL*	$822	0%	5%	16%
EMERGENCY MEDICINE	*TOTAL*	$2,531	0%	-1%	-7%
GENERAL SURGERY	*TOTAL*	$1,760	2%	-2%	-5%
INDEPENDENT LABORATORY	*TOTAL*	$594	4%	1%	10%
INTERNAL MEDICINE	*TOTAL*	$9,813	-2%	3%	1%
NEUROSURGERY	*TOTAL*	$727	-2%	-2%	-8%

Extract From Table 158: 2023 PFS Estimated Impact on Total Allowed Charges by Specialty using Rebased and Revised MEI Cost Share Weights for 2023					
(A) Specialty	**(B) Total: Non-Facility/Facility**	**(C) Allowed Charges (mil)**	**(D) Combined Impact No MEI Changes** (same as shown in Table 149)	**(E) Combined Impact Year 1 MEI Transition**	**(F) Combined Impact Full MEI Changes**
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	*TOTAL*	$1,608	-2%	1%	6%
RADIOLOGY	*TOTAL*	$4,712	-2%	-3%	-2%
THORACIC SURGERY	*TOTAL*	$314	-1%	-2%	-8%

The impact of the rebased and revised MEI cost share weights compared with the current weights would have had significant specialty-specific impacts. 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 3.7% to $31.834.[90]

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 policies 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 delayed these adjustments to allow public comment and finalization of the 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 will maintain the use of the current 2006-based MEI cost share weights for the 2023 GPCIs.

As an alternative to using the current 2006-based cost share weights, CMS examined using the 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 updating the employee compensation component from 16.553 percent to 24.716

[90] The estimated impact was a decrease of almost 6.5 percent in the proposed rule and it appears CMS did not update its analysis as it is nonsensical that the estimated conversion factor would be higher in year one of a four-year transition than the 2023 conversion factor of $33.0607

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 159 in the final rule).

CMS notes that the use of the rebased and revised MEI cost share weights only impacts the PE GPCI and maintaining 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.

E. Impact on Beneficiaries

CMS believes that a number of changes in this final rule will increase participation in a more sustainable way for ACOs serving medical complex, high-cost beneficiaries. These 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 will lead to meaningful feedback to beneficiaries on the type and scope of care provided. It also believes that several of the new quality measures include patient-reported outcome-based measures, which may be used to help patients make more informed decisions about treatment options.

F. Estimating Regulatory Costs

Because regulations impose administrative costs on private entities, CMS estimates the cost associated with regulatory review, such as the time needed to read and interpret the final rule. CMS assumes that the total number of unique reviewers for this year's rule will be comparable to the number of unique commenters on last year's final 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 final 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 $21.5 million ($931.35 x 23,341 reviewers on last year's final rule).