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Regulatory Update: Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program

August 1, 2023

Background & Summary

On Thursday, July 13, the Centers for Medicare & Medicaid Services (CMS) issued the annual proposed rule to update the Calendar Year (CY) 2024 Medicare payment and policies for the Physician Fee Schedule (PFS) (hereinafter, "Proposed Rule"). The Proposed Rule revises payment polices under the Medicare PFS and makes other policy changes, including delaying split (or shared) billing requirements until CY 2025, changing certain evaluation and management (E/M) visits, and implementing telehealth provisions from the Consolidated Appropriations Act, 2023 to extend COVID-19 public health emergency (PHE) flexibilities. The PFS Addenda, along with supporting documents and tables referenced in the Proposed Rule, are available on the CMS website. The Proposed Rule also includes changes to the Quality Payment Program (QPP) and several significant changes to the Medicare Shared Savings Program (MSSP).

Comments are due **September 11, 2023**, with effective dates for most sections scheduled for January 1, 2024. Vizient looks forward to working with members to help inform our comments to the agency.

Calculation of the Proposed CY 2024 PFS Conversion Factor

There are three components that must be considered to value each service under the PFS – work, practice expense (PE), and malpractice (MP) relative value units (RVUs). Each component is adjusted by geographic price cost indices (GPCIs), which reflect variations in the costs of furnishing services compared to the national average cost for each component. Then, the RVUs are converted to dollar amounts via the application of a conversion factor (CF), which is calculated by CMS's Office of the Actuary (OACT). Finally, the Medicare PFS payment amount (based on the below formula) for a given service and fee schedule area is calculated based on the previously discussed metrics.

$$\text{PFS Payment} = [(\text{WorkRVU} \times \text{WorkGPCI}) + (\text{PERVU} \times \text{PEGPCI}) + (\text{MPRVU} \times \text{MPGPCI})] \times \text{CF}$$

For CY 2024, the proposed CF is $32.75, which is a decrease of $1.14 from the 2023 CF of $33.872, or a 3.3 percent decrease. This decline is in part driven by the inclusion of an add-on payment for complex services, which must be offset to be made budget neutral, as shown in Table 1. The payment impact of the proposed policies by specialty is shown in Table 104 of the Proposed Rule (pg. 1283-1284).

Calculation of the Proposed CY 2024 PFS Conversion Factor		
CY 2023 Conversion Factor		**33.8872**
Conversion Factor without CAA*, 2023 (2.5 Percent Increase for CY 2023)		**33.0607**
CY 2024 RVU Budget Neutrality Adjustment	-2.17 percent (0.9783)	
CY 2024 RVU 1.25 Percent Increase Provided by the CAA, 2023	1.25 percent (1.0125)	
CY 2024 Conversion Factor		**32.7476**

Table 1.
* CAA, Consolidated Appropriations Act of 2023

Practice Expense Relative Value Units

The Practice Expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding malpractice (MP) expenses. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expenses, and all other expenses. PE RVUs are developed considering the direct and indirect practice resources involved in furnishing a service.

CMS allocates indirect costs at the code level based on the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. In addition, CMS incorporates survey data to determine indirect PEs incurred per hour worked (PE/HR) in developing the indirect portion of the PE RVUs.

Clinical Labor Pricing

In the CY 2022 PFS final rule, CMS finalized a four-year, phased-in policy to update clinical labor pricing for CYs 2022 – 2025. Table 5 (pg. 51-52) of the Proposed Rule provides the proposed CY 2024 clinical labor pricing. CMS welcomes additional feedback regarding clinical labor pricing, including any data that will continue to improve the accuracy of the agency's final pricing.

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

In the CY 2023 PFS final rule, CMS solicited public comment on strategies to update the practice expense data collection and methodology. CMS currently uses the AMA's Physician Practice Information Survey (PPIS) to inform PFS rates. Although the AMA is in the process of providing updated data, CMS notes that the current dataset is nearly 20 years old, causing concern among stakeholders that practice expense inputs are not accurate and are impacting PFS ratesetting.

CMS continues to seek feedback on whether, upon completion of the updated PPIS data collection, other alternatives may be necessary and available to address lack of data availability or response rates. **Among other questions, CMS seeks information on aggregation of data and services; how CMS should balance factors driven by a difference in geographic location or setting of care; and whether specific types of outliers may require different analytic approaches.**

Geographic Price Cost Indices (GPCIs)

By statute, CMS must develop separate Geographic Practice Cost Indices (GPCIs) to measure the relative cost difference among localities compared to the national average for the work, practice expense (PE), and malpractice (MP) fee schedule components. CMS is required to review and potentially adjust the GPCIs at least every 3 years. Regarding the GPCI work floor generally, the Consolidated Appropriations Act (CAA), 2021 extended the 1.0 work floor only through December 31, 2023. Therefore, the CY 2024 work GPCIs and Geographic Adjustment Factors (GAFs) in Addenda D and E do not reflect the 1.0 work floor. Addenda D and E of the Proposed Rule, available on the CMS website, include the proposed GPCIs and summarized GAFs.

Medicare Economic Index

The Medicare Economic Index (MEI) reflects the weighted-average annual price change for various inputs involved in furnishing physicians' services. The MEI is a fixed-weight input price index comprised of two broad categories: (1) physicians' own time (compensation); and (2) physicians' practice expense (PE). Additionally, it includes an adjustment for the change in economy-wide, total factor productivity (TFP) (which recently replaced the term multifactor productivity). While the MEI annual percentage change increase is not directly used to update the PFS CF, the MEI cost weights have historically been used to update the GPCI (e.g., weighting the four components of the practice expense GPCI (employee compensation, the office rent, purchased services, and medical equipment, supplies, and other miscellaneous expenses)) and to recalibrate the relativity adjustment to ensure that the total pool of aggregate PE RVUs remains stable relative to the pool of work and MP RVUs.

In CY 2023, CMS finalized, but delayed implementation of, a proposal to rebase and revise the MEI to reflect more current market conditions. CMS proposes to continue to delay implementation of the 2017-based MEI that was finalized in CY 2023. CMS cites the ongoing data collection and updates to AMA's Physician Practice Information Survey (PPIS) and the significant redistributive impacts that MEI updates would have on PFS payments. CMS notes that 2022 data will be available later this year and the agency will monitor that data release and any other data related to physician services' input expenses. Any further changes to the MEI, if appropriate, will be addressed in future rulemaking.[1]

Evaluation and Management (E/M) Visits

Over the past several years, CMS has engaged with the AMA and other stakeholders to update coding and payment for office/outpatient (O/O) evaluation and management (E/M) visits.

For prolonged O/O services, in prior rulemaking, CMS did not accept all of the AMA's revisions. In the CY 2021 PFS final rule, CMS provided that HCPCS add-on code G2211 (O/O E/M visit complexity) could be reported with O/O E/M visits to better account for additional resources associated with primary care or ongoing care related to a patient's single, serious

[1] While the MEI is no longer directly used in calculating the annual update to the PFS conversion factor, it continues to be used for the Medicare telehealth originating site facility fee, targeted medical review threshold amounts, rural health clinic payment limits, geographic practice cost index, and other policies.

condition, or complex condition. However, the CAA, 2021 imposed a moratorium on Medicare payment for the add-on code (G2211) until January 1, 2024.

CMS states that parties have continued to express concerns about the G2211 add-on code, particularly relating to its potential redistributive effects. In response to these concerns, CMS has refined the HCPCS code descriptor to clarify that the code applies to a serious condition rather than any single condition. As the moratorium on the code ends on December 31, 2023, CMS proposes to begin using the code with several refinements. First, CMS proposes to change the status of HCPCS code G2211 to make it separately payable by assigning the "active" status indicator, effective January 1, 2024. Second, CMS proposes that the G2211 code would not be payable when the O/O E/M visit is reported with payment modifier-25.[2]

Initially, CMS estimated that the G2211 code would be used with approximately 58 percent of all office/outpatient E/M visits. Based on the proposed changes, CMS now estimates that this code would be used in approximately 38 percent of all O/O E/M visits initially. In future years which have revised utilization assumptions, CMS estimates the G2211 code will be billed with 54 percent of all O/O E/M visits. **CMS seeks comment on these utilization assumptions and the application of this proposed policy for CY 2024.**

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

Over the last several years, CMS has received feedback from interested parties outside the rulemaking process asking that CMS consider using a different approach for valuing services that rely on research and data outside the AMA RUC's specialty-specific valuation recommendations. Commenters state that the practice of medicine has evolved in such a way that the resource-based relative value scale created three decades ago is no longer appropriate. **CMS seeks comment on the range of approaches it could take to improve the accuracy of valuing services.** Generally, CMS is interested in ways it can improve processes and methodologies to make better and more accurate payment for services. This includes ways to make more timely recommendations and improvements to methodologies to reflect changes in the Medicare population, treatment guidelines, and new technologies. CMS is also interested in whether the AMA Relative Value System (RVS) Update Committee (RUC) is the entity best positioned to provide recommendations to CMS or if another independent entity would better serve this purpose. **Specifically, CMS seeks comment on the accuracy of the existing E/M and non-E/M HCPCS codes, the methods used to value the E/M and non-E/M HCPCS codes, the consequences if services are not accurately defined or valued, and whether CMS should consider valuation changes to other codes.[3]**

Split (or Shared) Visits

A split (or shared) visit refers to an E/M visit that is performed ("split" or "shared") by both a physician and a non-physician practitioner (NPP) who are in the same group. In the Proposed Rule, CMS notes that it in the CY 2022 PFS final rule, it 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 (not

[2] Modifier-25 is used to indicate that a patient's condition required a significant, separately identifiable evaluation and management service above and beyond that associated with another procedure or service being reported by the same physician or other qualified healthcare professional on the same date.
[3] A full list of questions is available on pg. 303-304 of the Proposed Rule.

necessarily concurrently) and the billing physician personally performs a substantive portion of the visit. CMS notes that there were stakeholder concerns regarding the agency's definition of "substantive portion" because only time (i.e., more than half of total time) would have been used for purposes of defining what is the substantive portion of the visit. The CY 2022 split (or shared) visit policy was to take effect January 1, 2024.

CMS continued to hear concerns from stakeholders regarding implementation of the split (or shared) visit policy, and requests that the agency recognize medical decision making (MDM) as included in the substantive portion. After consideration, CMS proposes to delay implementation of the updated substantive portion definition until January 1, 2025. CMS indicates the one-year delay provides another comment opportunity and more time for CMS to consider more recent feedback and evaluate whether there is a need for additional rulemaking on this aspect of the policy. CMS is also interested in how facilities are currently implementing the delayed split/shared services policy. The AMA CPT Editorial Panel is revising aspects of split or shared visits that may impact its policies. CMS may consider whether a revision of the definition of substantive portion is needed through future rulemaking.

In the interim, CMS proposes to revise the definition of "substantive portion" to specify that, "[f]or visits other than critical care visits furnished in calendar years 2022 through 2024, *substantive portion* means either 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."

Telephone Evaluation and Management (E/M) Services

The March 31, 2020 COVID-19 Interim Final Rule established separate payment for CPT codes that describe E/M services furnished via telephone. CPT codes 98966-98968, however, described telephone assessments done by a qualified non-physician healthcare professional, and CMS states that they are not telehealth services. To align with the telehealth-related flexibilities that were extended in the CAA, 2023, CMS proposes to continue using CPT codes 98966-98968 through CY 2024.

Medicare Telehealth Services

Several conditions, such as patient eligibility, originating site, scope of distant site practitioners, and communications methods, must be considered before Medicare will make payments for telehealth services under the PFS. Other services involving communications technology (e.g., remote evaluation of recorded video and/or images submitted by an established patient, brief communication technology-based service (CTBS), online assessment and management) are also covered under the PFS but are different from telehealth services.

In the Proposed Rule, CMS proposes several changes related to telehealth services and implements provisions of the CAA, 2023 which extended various telehealth flexibilities that have been provided during the COVID-19 PHE.

Medicare Telehealth Service List

CMS maintains a Medicare telehealth services list,[4] which currently has three Categories, and has a process for adding or deleting services from the list. However, for CY 2024, CMS proposes to reduce the number of Categories to two: "permanent" and "provisional". Under this proposal, any services in Category 1 or 2 would be added as "permanent." Services listed as temporarily added services (e.g., Category 3) would be assigned to the "provisional" category. CMS provides that services may be redesignated in the future, but CMS does not to set any specific timeline for reevaluation of services added to the Medicare Telehealth Services List on a provisional basis because evidence generation may not align with a timeline.

Although CMS received several requests for services to be permanently added to the Medicare Telehealth Services List for CY 2024, after review, the agency did not propose permanently adding any services to the list. However, of requested codes that CMS reviewed, the agency proposes to add three Health and Well-being Coaching services[5] to the list on a temporary[6] basis for CY 2024.

In addition, as described below, CMS proposes a new stand-alone HCPCS G code (GXXX5: Administration of a standardized, evidence-based Social Determinants of Health (SDOH) Risk Assessment tool for 5-15 minutes) to identify and value the work involved in a SDOH risk assessment when medically reasonable and necessary in relation to an E/M visit. As a result, CMS proposes to add GXXX5, if finalized as proposed, to the Medicare Telehealth Services List on a permanent basis.

Proposed Clarifications and Revisions to the Process for Considering Changes to the Medicare Telehealth Service List

With the expiration of the PHE and the expansion of the Medicare Telehealth Services List in recent years, CMS also proposes to simplify the assessment for adding services to the Medicare Telehealth Services List. If finalized, the new assessment would be implemented in CY 2025. CMS proposes the following five-step assessment for determining whether a service should be added to the Medicare Telehealth Services list:

- Step 1: CMS determines if the service is separately payable under the PFS and if it meets the criteria for telehealth services. If not, further review is not conducted.
- Step 2: CMS checks if the service (or at least some element of the service), when delivered via telehealth, can substitute for an in-person, face-to-face encounter, and if

[4] The Medicare Telehealth Services List currently consists of three categories. Category 1: Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the Medicare Telehealth Services List; Category 2: Services that are not similar to those on the current Medicare Telehealth Services List; and Category 3: Services added on a temporary basis that will ultimately need to meet the criteria under Category 1 or 2 in order to be permanently added to the Medicare Telehealth Services List. To add a specific service on a Category 3 basis, CMS conduced a clinical assessment to identify those services for which CMS could foresee a reasonable potential likelihood of clinical benefit when furnished via telehealth.

[5] Three Health and Well-being Coaching services that CMS proposes to add to the telehealth list on a temporary basis for CY 2024: CPT code 0591T (Health and well-being coaching face-to-face; individual, initial assessment); CPT code 0592T (Health and well-being coaching face-to-face; individual, follow-up session, at least 30 minutes); and CPT code 0593T (Health and well-being coaching face-to-face; group (2 or more individuals), at least 30 minutes)

[6] Since, in the Proposed Rule, CMS proposes "permanent" and "provisional" categories, the agency proposes adding services to the Medicare Telehealth Services List on temporary basis, however, if the new categories are finalized as proposed, the three Health and Well-being Coaching services would be provisional services.

all face-to-face elements can be furnished using an approved interactive telecommunications system.

- Step 3: CMS reviews the service elements described by the HCPCS code to see if they can be provided using interactive telecommunications. Also, at this step, CMS reviews evidence of a substantial clinical improvement in different beneficiary populations who may benefit from the requested service when furnished via telehealth.
- Step 4: CMS compares the requested service's elements to those of a service already on the Medicare Telehealth Services List with permanent status. If the code aligns, the new service is added on a permanent basis in the next PFS rule. If Step 4 is not met, CMS will proceed to Step 5.
- Step 5: CMS assesses whether there is clinical evidence of benefit similar to an in-person visit when the service is provided through telehealth. If there is enough evidence, the code is assigned "provisional" status. Alternatively, if the clinical benefit is clearly analogous to an in-person visit, it is assigned "permanent" status, even if the service elements do not map to the service elements of an existing permanent telehealth service.

CMS notes that the timeline for nominating services under this new assessment framework would remain the same. For example, requests to add services to the Medicare Telehealth Services List for CY 2025 should be received no later than February 10, 2024. **CMS seeks comments on this proposed assessment for adding services to the Medicare Telehealth Services List.**

Implementation of Provisions of the CAA, 2023

On December 29, 2022, the CAA, 2023 was signed into law, which extended several telehealth flexibilities until December 31, 2024. In the Proposed Rule, CMS updates regulations to implement the law.

In-Person Requirements for Mental Health Telehealth

In the PFS 2022 final rule, CMS implemented a statutory requirement that patients must be seen in-person (i.e., without the use of telecommunications technology) within a 6-month period before an initial mental health telehealth service can be provided and annually thereafter. In addition, the agency provided exceptions to this in-person requirement and clarified other elements of this policy. The CAA, 2023, delays until December 31, 2024, this in-person requirement. The requirement for subsequent in-person visits was also delayed, along with the in-person visit requirements for mental health visits furnished by Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) delivered through telehealth. To implement these provisions of the CAA, 2023, CMS proposes regulatory changes to delay these in-person visit requirements from going into effect until December 31, 2024.

Originating Site Requirements

CMS also proposes to implement the CAA, 2023, provision which permits telehealth services to be provided at any site in the United States where the beneficiary is located at the time of the telehealth service, including the individual’s home, until December 31, 2024.

Telehealth Practitioners

The CAA, 2023 expanded the definition of eligible telehealth practitioners to include qualified occupational therapists, qualified physical therapists, qualified speech-language pathologists,

and qualified audiologists until December 31, 2024. Beginning January 1, 2024, CMS will also recognize marriage and family therapists (MFT) and mental health counselors (MHC) as telehealth practitioners. CMS proposes to specify that MFTs and MHCs as proposed to be defined (pg. 332-334 of the Proposed Rule) are included as distant site practitioners for purposes of furnishing telehealth services.

Audio-only services

The CAA, 2023 also requires temporary coverage of audio-only telehealth services included on the Medicare Telehealth Services List. CMS reiterates that only those telehealth services that are designated as eligible to be furnished via audio-only technology as of March 15, 2020, will continue to be covered until December 31, 2024. A list of services that involved audio-only interaction that were included on the Medicare Telehealth Services List.

Place of Service for Medicare Telehealth Services

Under the PFS, there are two payment rates for many physicians' services: the facility rate and the non-facility rate (or office rate). When a physician or practitioner submits a claim for their services, including telehealth services, a Place of Service (POS) code is required because it is used to determine whether a service is paid at the facility or non-facility rate. The PFS facility rate is the amount generally paid to a physician or practitioner when a service is furnished in a facility (e.g., hospital or skilled nursing facility); Medicare also makes a separate payment ("facility fee") to the facility for the costs associated with the service (e.g., clinical staff, equipment, overhead). Alternatively, the PFS non-facility rate applies when the service is furnished in an office or other setting.

To make appropriate payment for telehealth services during the PHE, CMS instructed providers billing for Medicare telehealth services to report the POS code that would have been reported had the service been performed in person and requested that modifier "95" be used to indicate a service was furnished via telehealth. In the CY 2023 PFS final rule, CMS finalized a policy that would go into effect at the end of the calendar year in which the PHE ends (2023), where physicians and practitioners would no longer bill claims with both modifier 95 and a POS code. Instead, physicians and practitioners would bill for services using only POS 02 (Telehealth provided other than in the patient's home) or POS 10 (Telehealth provided in the patient's home). In the Proposed Rule, CMS notes that because many practitioners are providing services both in the office and through telehealth, it believes these practitioners must maintain an office presence, even if they are providing a substantial amount of telehealth visits to patient's located in their homes. As such, CMS believes these practitioners' practice expense (PE) costs are more accurately reflected by the non-facility rate. As a result, CMS proposes that claims billed with POS 10 (Telehealth provided in patient's home) be paid at the non-facility PFS rate. Also, for CY 2024, CMS proposes that claims billed with POS 02 (Telehealth provided other than in patient's home) will continue to be paid at the PFS facility rate. In the Proposed Rule, CMS indicates, "the facility rate more accurately reflects the PE of these telehealth services; this applies to non-home originating sites such as physician's offices and hospitals."

Telehealth Originating Site Facility Fee Payment Amount Update

The telehealth originating site fee is increased annually by the percentage increase in the Medicare Economic Index (MEI), which is proposed to be 4.5% for CY 2024. For CY 2024, the proposed payment amount for HCPCS code Q3014 (telehealth originating site facility fee) is $29.92.

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

In previous years, services added to the Medicare Services Telehealth List have been subject to limitations on how frequently a service can be furnished through telehealth. During the PHE, CMS removed frequency limitations for certain subsequent inpatient visits, subsequent nursing facility visits, and for critical care consultations furnished via telehealth. The frequency limitations resumed on May 12, 2023, following the expiration of the PHE. However, CMS stated it would exercise enforcement discretion regarding these limitations through December 31, 2023.

For CY 2024, CMS proposes to remove the telehealth frequency limitations for several codes[7] until December 31, 2024, to align with other telehealth-related flexibilities extended by the CAA, 2023. **CMS is seeking information from interested parties on how practitioners have been ensuring that Medicare beneficiaries receive these visits after the expiration of the PHE.**

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

Direct Supervision via Use of Two-Way Audio/Video Telecommunications Technology

Under Medicare Part B, certain types of services, including diagnostic tests and services furnished incident to a physician's or practitioner's professional services, must be furnished under specific minimum levels of supervision. One level of supervision is direct supervision, which requires the immediate availability of the supervising physician or other practitioner.

During the PHE, CMS expanded the definition of "direct supervision" for diagnostic tests, physicians' services and some hospital outpatient services to allow the supervising professional to be immediately available using real-time audio/video technology ("virtual presence"), as opposed to requiring their physical presence. CMS proposes to continue allowing direct supervision requirements to be met through real-time audio/video telecommunications (excluding audio-only) through December 31, 2024.

CMS is soliciting comments on whether it should consider extending this definition after December 31, 2024. Specifically, CMS is interested in input from parties on potential patient safety or quality concerns when direct supervision occurs virtually, if this flexibility would be more appropriate for certain types of services, and feedback on potential program integrity concerns. CMS also requests feedback on an approach to direct supervision which permanently establishes this virtual presence flexibility by presuming that the services are nearly always performed in entirety by auxiliary personnel.

[7] The list of codes (Subsequent Inpatient Visit CPT Codes: 99231-99233; Subsequent Nursing Facility Visit CPT Codes: 99307-99310; and Critical Care Consultation Services: HCPCS Codes: G0508 and G0509) and descriptors can be found on pg. 133-135 of the Proposed Rule.

Supervision of Residents in Teaching Settings

In the CY 2021 PFS final rule, CMS established a policy that, after the end of the PHE, teaching physicians may meet the requirements to be present for the key or critical portions of services furnished involving residents through a virtual presence, but only for services furnished in residency training sites located outside of a Metropolitan Statistical Area (MSA). After the PHE ended, CMS announced it would use enforcement discretion so that this flexibility would continue for physicians in all resident training sites through December 31, 2023. For CY 2024, CMS proposes to continue this policy through December 31, 2024.

CMS seeks comment on the expansion of virtual presence for all residency training sites after December 31, 2024. Specifically, CMS requests feedback on what other clinical treatment situations (e.g., various types of teaching physician services) are appropriate for virtual presence of the teaching physician and invites commenters to share data or other information on how virtual presence supports patient safety, meets the clinical needs for all patients and ensures burden reduction, without creating risks for patient care or increasing opportunities for fraud.

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

During the COVID-19 PHE, outpatient therapy services, diabetes self-management training (DSMT), and Medical Nutrition Training (MNT) could be furnished through telehealth to beneficiaries in their homes. These services would be paid either separately or as part of a bundled payment, when provided by the billing practitioner or provided by institutional staff and billed for by institutions (e.g., HOPDs, SNFs, and HHAs). For telehealth services more broadly, during the PHE, CMS allowed more types of practitioners (e.g., PTs, OTs and SLPs) to provide telehealth services and the agency waived telehealth originating site requirements.

The CAA, 2023 extended this COVID-19 related flexibility by allowing PTs, OTs and SLPs to serve as distant site practitioners through the end of CY 2024. However, other COVID-19 related waivers and flexibilities (e.g., institutions billing for services furnished remotely by their employed practitioners and Hospital Without Walls waivers) would end with the PHE, resulting in ambiguity regarding access to outpatient therapy, DSMT, and MNT services when furnished remotely by institutional staff to beneficiaries in their homes. CMS proposes to continue to allow institutional providers to bill for these services when furnished remotely as done during the PHE through the end of CY 2024. **CMS seeks comment on current practice for these services when billed, including how and to what degree they continue to be provided remotely to beneficiaries in their homes.**

For DSMT, CMS notes that this is often provided by staff that are not those typically authorized to furnish Medicare telehealth services. CMS has released sub-regulatory guidance that it will use enforcement discretion when reviewing the telehealth eligibility status of the practitioner providing any part of a remote DSMT service, so long as that person is otherwise qualified to provide the service.

Clarification for Remote Monitoring Services

The CY 2021 PFS final rule finalized policies for Remote Physiologic Monitoring (RPM) and Remote Therapeutic Monitoring (RTM) that would have expired at the end of the PHE. Since

the PHE ended on May 11, 2023, CMS provides clarity, as outlined in Table 2, regarding these policies in the Proposed Rule.

Topic	Clarification
New versus Established Patient Requirements	Since the end of the PHE, RPM services must be furnished only to established patients. CMS considers a patient who received initial RPM services during the PHE to be an established patients for the new patient requirement.
Data Collection Requirements	During the PHE, CMS finalized an interim policy to permit billing for remote monitoring codes which require data collection for at least 16 days in a 30-day period when less than 16 days of data are collected within a given 30-day period. In the CY 2021 PFS final rule, CMS finalized the expiration of this policy with the end of the PHE. Therefore, as of the end of the PHE, the 16-day monitoring requirement went back into effect. In the Proposed Rule, CMS clarifies that the data collection minimums apply to existing RPM and RTM code families for CY 2024.
Use of RPM, RTM, in Conjunction with Other Services	Currently, practitioners may bill RPM or RTM, but not both, concurrently with certain care management services.[8] CMS proposes to clarify that RPM and RTM may not be billed together, so that no time is counted twice by billing for concurrent RPM and RTM services.
Other Clarifications for Appropriate Billing	CMS proposes to clarify that, in circumstances where a beneficiary may receive a procedure or surgery and related services which are covered under a global payment, RPM or RTM services (but not both) may be furnished separately to the beneficiary from the global payment, so long as other requirements for the global service are met. CMS clarifies that the remote monitoring services must be unrelated to the diagnosis for which the global procedure is performed and must be for an episode of care that is separate and distinct from the episode of care for the global procedure. **CMS seeks comment on this proposal and requests general feedback that may inform future payment policies for remote monitoring services.**

Table 2.

Advancing Access to Behavioral Health

Marriage and Family Therapists (MFT), Mental Health Counselors (MHC) and Clinical Social Workers (CSW)

In the Proposed Rule, CMS implements provisions of the CAA, 2023 which provide for Medicare Part B coverage for MFTs and MHCs. Consistent with the statute, CMS proposes to add definitions of MFTs and MHCs into the regulations to codify their coverage provisions.

CMS proposes to define “marriage and family therapist services” as services furnished by a marriage and family therapist for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the marriage and family therapist is

[8] The following care management services are eligible to be billed concurrently with either RPM or RTM: Chronic Care Management, Transitional Care Management, Behavioral Health Integration, Principal Care Management, and Chronic Pain Management and Treatment Services.

legally authorized to perform under state law (or the state regulatory mechanism provided by state law) of the state in which such services are furnished. CMS is also proposing that the services must be of a type that would be covered if they were furnished by a physician or as an incident to a physician's professional service. The agency proposes that services furnished by an MFT to an inpatient of a Medicare-participating hospital would not be covered.

CMS proposes to define "mental health counselor services" as services furnished by a mental health counselor for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the mental health counselor is legally authorized to perform under state law (or the state regulatory mechanism provided by state law) of the state in which such services are furnished. The services must be of a type that would be covered if they were furnished by a physician or as an incident to a physician's professional services. The agency proposes that services furnished by an MHC to an inpatient of a Medicare-participating hospital would not be covered. Also, CMS proposes to allow Addiction Counselors who meet all the applicable requirements of an MHC to enroll as an MHC.

CMS proposes to add MFTs and MHCs to the list of practitioners who can order diagnostic tests to the extent that the MFT or MHC is legally authorized to perform the service under state law in the state in which such services are furnished. In addition, CMS proposes to allow MFTs, MHCs and CSWs to bill for health behavior assessment and intervention (HBAI) services.

CMS is also proposing to codify new payment amounts for MFT, MHC, and CSW services as 80 percent of the lesser of the actual charge for the services or 75 percent of the amount determined for clinical psychologist services under the PFS. The agency also proposes to add MFTs and MHCs to the list of practitioners who are eligible to furnish Medicare telehealth services at a distant site. In addition, CMS proposes to revise the code descriptor for HCPCS code G0323 (care management services for behavioral health conditions, at least 20 minutes of clinical psychologist or clinical social worker time, per calendar month) in order to allow MFTs and MHCs to bill for this monthly care integration services.

Mobile Crisis Care in Medicare

The CAA, 2023 created a new payment mechanism for psychotherapy for crisis services furnished in an applicable site of service. The CAA, 2023 requires the Secretary to establish new HCPCS codes under the PFS for services furnished on or after January 1, 2024. These services will be paid equal to 150 percent of the fee schedule amount for non-facility sites of services for each year for the services identified.[9]

An applicable site of service is defined as a site of service other than a site where the facility rate under the PFS applies, and other than an office setting. CMS proposes two new G-codes describing psychotherapy for crisis services furnished in any place of service at which the non-facility rate for psychotherapy for crisis services applies, other than the office setting: HCPCS codes GPFC1 and GPFC2, as outlined in Table 3. The agency proposes that these two new G-codes can be billed when the services are furnished in any non-facility place of service other than the physician's office setting. The statute provides a waiver of budget neutrality and CMS proposes that these codes would be excluded from the budget neutrality

[9] HCPCS codes 90389 (*psychotherapy for crisis; first 60 minutes*); and 90840 (*psychotherapy for crisis; each additional 30 minutes (list separately in addition to code for primary service*).

calculation for PFS ratesetting. Also, the statute directs CMS to educate providers that auxiliary personnel are eligible to participate in the furnishing of these "psychotherapy for crisis situation" services. CMS notes that there are varying definitions of "peer support specialist" and other auxiliary personnel. To be inclusive of available auxiliary personnel, CMS is not proposing a definition of auxiliary personnel that can participate in these services.

Code	Descriptor
GPFC1	Psychotherapy for crisis furnished in an applicable site of service (any place of service at which the non-facility rate for psychotherapy for crisis services applies, other than the office setting); first 60 minutes
GPFC2	Psychotherapy for crisis furnished in an applicable site of service (any place of service at which the non-facility rate for psychotherapy for crisis services applies, other than the office setting); each additional 30 minutes (list separately in addition to code for primary service)

Table 3.

Ensuring Adequate Coverage of Outpatient Mental Health Services

The CAA, 2023 established Medicare coverage and payment for intensive outpatient services (IOP) for individuals with mental health needs when furnished by hospital outpatient departments, community mental health centers, RHCs, and FQHCs, effective January 1, 2024. The proposed implementation is discussed in the CY 2024 OPPS proposed rule (Vizient's summary of the CY 2024 OPPS proposed rule).

Adjustments to Payment for Timed Behavioral Services

The agency has received feedback regarding the valuation of services that primarily involve conversational interactions rather than physical interactions because these services require minimal equipment and supplies compared to other services. As a result, valuation is based almost entirely on the practitioner's work (rather than estimates of typical time that is usually based on survey data). Based on research, CMS notes that where valuation is based on practitioner's work, this may lead to overvaluation, and by implication, undervaluation of other services. Also, CMS indicates that undervaluation could be because these time-based codes, which reflect one-on-one time with the patient, are highly unlikely to become more efficient over multiple years, unlike surgical procedures which could gain operational improvements and benefit from new technology.

CMS proposes to address the need in valuation for timed psychotherapy services by applying an adjustment to the work RVUs for the psychotherapy codes payable under the PFS. This adjustment would be based on the difference in total work RVUs for office/outpatient (O/O) E/M visit codes[10] billed with the proposed inherent complexity add-on code (G2211), compared to the total work RVUs for visits that are not billed with G2211. CMS estimates that this would result in an upward adjustment of 19.1 percent for work RVUs for these services. CMS is proposing to implement this change with the CPT codes list in Table 4.

[10] CPT Code 99202-99205 and 99211-99215.

Code	Descriptor
90832	Psychotherapy, 30 minutes with patient
90834	Psychotherapy, 45 minutes with patient
90837	Psychotherapy, 60 minutes with patient
90839	Psychotherapy for crisis; first 60 minutes
90840	Psychotherapy for crisis each additional 30 minutes (list separately in addition to code for primary service)
90845	Psychoanalysis
90846	Family psychotherapy (without the patient present); 50 minutes
90847	Family psychotherapy (conjoint psychotherapy) (with patient present); 50 minutes
90849	Multiple-family group psychotherapy
90853	Group psychotherapy (other than of a multiple-family group)
GPFC1*	See above
GPFC2*	See above

Table 4.

*These two codes are proposed in the CY 2024 PFS Proposed Rule.

Update to the Payment Rate for the PFS Substance Use Disorder (SUD) Bundle (HCPCS codes G2086-G2088)

In the CY 2023 PFS final rule, CMS finalized a change to the payment rate for the non-drug component of the bundled payment for episodes of care under the Opioid Treatment Program (OTP). This change modified the crosswalk for individual therapy from a code reflecting a 30-minute session to a 45-minute session. CMS received feedback requesting an expansion of this modification for other bundled payments for SUD under the PFS.

CMS proposes to update the valuation of HCPCS SUD codes G2086 and G2087 by increasing the current payment rate to reflect two individual psychotherapy sessions per month, based on a crosswalk to the work RVU for CPT code 90834[11] (psychotherapy, 45 minutes with patients) rather than CPT code 90832 (psychotherapy, 30 minutes with patients. If all proposals are finalized, this results in an update to the work RVU of 8.36 for HCPCS code G2086 and a work RVU of 8.19 for HCPCS code G2087.

Comment Solicitation on Expanding Access to Behavioral Health Services

As part of its efforts to increase access to behavioral health services, the agency welcomes feedback, including on ways to increase access to behavioral health integration (BHI) services, including the psychiatric collaborative care model; whether it could consider new coding to allow interprofessional consultation to be billed by practitioners who are authorized by statute for the diagnosis and treatment of mental illness; intensive outpatient (IOP) services furnished in settings other than those addressed in the CY 2024 OPPS proposed rule; and how to increase psychiatrist participation in Medicare given their low rate of participation relative to other physician specialties. **CMS also seeks comment on the need for separate coding and payment for interventions initiated or furnished in the emergency department or other crisis setting for patients with suicidality, such as safety planning**

[11] CMS notes that it is proposing to increase the work RVUs of this code in the Proposed Rule, so the final work RVUs could change based on what is finalized.

interventions, or whether existing payment mechanisms are sufficient to support furnishing such interventions when needed.

Request for Information on Digital Therapies such as, but not limited to, Digital Cognitive Behavioral Therapy

As CMS continues to gather information on how remote monitoring services are used in clinical practice and experience with coding and payment policies for these codes, it requests information on the use of digital cognitive behavioral therapy and other digital therapeutics, including how practitioners determine which patients are best served by these technologies, how practitioners ensure the safety of patients when using digital technologies, how data that are collected by the technology are stored, and other practical information about the use of these technologies in a care setting. A complete list of questions is available in the Proposed Rule (pg. 358-361).

Services Addressing Health-Related Social Needs (Community Health Integration Services, Social Determinants of Health Risk Assessment, and Principal Illness Navigation Services)

For CY 2024, CMS seeks to better recognize how an interdisciplinary team (including community health workers (CHWs)) is involved in treatment of Medicare beneficiaries by updating coding and payment policies to accurately reflect that involvement. Accordingly, CMS is proposing three new services to address health-related social needs: Community Health Integration (CHI) Services, Social Determinants of Health (SDOH) Risk Assessments, and Principal Illness Navigation Services.

Community Health Integration (CHI) Services

CMS proposes to establish two new G-Codes describing CHI services performed by certified or trained auxiliary personnel, which may include a CHW, incident to the professional services and under the general supervision of the billing practitioner. CHI services address unmet SDOH needs that affect the diagnosis and treatment of the patient's medical problems.

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

CMS proposes two codes (GXXX1[12] and GXXX2[13]) with complete descriptions available in the Proposed Rule (pg. 241-242).

CMS seeks comment on whether the proposed descriptor times are appropriate and reflect typical service times, and whether a frequency limit is relevant for the add-on code. The agency seeks comment on the typical amount of time practitioners spend

[12] GXXX1: Community health integration services performed by certified or trained auxiliary personnel, which may include a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address social determinants of health (SDOH) need(s) that are significantly limiting ability to diagnose or treat problem(s) addressed in an initiating E/M visit.
[13] GXXX2 Community health integration services, each additional 30 minutes per calendar month.

per month furnishing CHI services to address SDOH needs. CMS also seeks to better understand the typical duration of CHI services.

CMS proposes that all auxiliary personnel who provide CHI services must be certified or trained to perform all included service elements and authorized to perform them under applicable state law and regulations. In states where there are no applicable licensure laws, CMS proposes to require auxiliary personnel furnishing CHI services to be trained to provide them. Training must include patient and family communication, interpersonal and relationship-building, patient and family capacity-building, service coordination and system navigation, patient advocacy, facilitation, individual and community assessment, professionalism and ethical conduct, and the development of an appropriate knowledge base, including of local and community-based services. **CMS seeks comment on whether to include the number of hours of required training, as well as the training content and who should supply the training.**

To avoid care fragmentation, CMS proposes that only one practitioner per beneficiary per month could bill for CHI services, but the same practitioner could bill for other care management services during the same month as CHI services. The agency also seeks comment on other service elements not included in the proposed CHI service codes that should be included or are more important in addressing unmet SDOH needs and where CMS could consider coding and payment in the future.

Social Determinants of Health (SDOH) – Proposal to Establish a Stand-Alone G-Code

CMS notes that assessing SDOH needs is a vital part of patient care and that the resources involved in these activities are not appropriately reflected in current coding. As a result, CMS proposes to add a new standalone G-Code, GXXX5 to increase the frequency of SDOH risk assessments and to promote standardization of such assessments.[14]

In the Proposed Rule, CMS notes that the SDOH risk assessment must be furnished by the practitioner on the same date as an E/M visit and the identified SDOH needs must be documented in the medical record. **CMS seeks comment on whether, as a condition of payment, the practitioner also has the capacity to furnish appropriate care management services to address the identified SDOH needs.**

CMS also proposes adding this code to the Medicare Telehealth Services List, as CMS believes this assessment may be conducted via telehealth. **CMS seeks comment on where and how these services would typically be provided.**

Principal Illness Navigation (PIN) Services

In the Proposed Rule, CMS notes that experts on navigation of treatment for cancer and other high-risk, serious illnesses have demonstrated the benefits of navigation services for patients experiencing severe conditions, especially those with unmet social needs.

[14] GXXX5: Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5-15 minutes

As a result, CMS proposes two new codes, GXXX3[15] and GXXX4[16], for Principal Illness Navigation (PIN) services, when trained or certified auxiliary personnel under the direction of a billing practitioner (which may include a patient navigator or peer specialist) are involved in a patient's health care navigation as part of the treatment plan for a serious, high-risk disease expected to last at least 3 months, that places the patient at significant risk of morbidity or mortality (e.g., cancer, COPD, congestive heart failure, HIV/AIDS, several mental illness, and substance use disorder).

Similar to the framework for billing care management and CHI services, the same practitioner would furnish and bill for both the PIN initiating visit and the PIN services, and PIN services must be furnished in accordance with the "incident to" regulations. An initiating E/M visit would not be required every month that PIN services are billed, only prior to commencing PIN services, to establish the treatment plan, specifically how PIN services would help accomplish that plan, and establish the PIN services as incident to the billing practitioner's service. CMS proposes to designate PIN services as care management services furnished under general supervision. **CMS seeks comment on whether other professional services should be considered the prerequisite initiating visit for PIN services, including the annual wellness visit (AWV).**

CMS proposes that all auxiliary personnel who provide PIN services must be certified or trained to perform all included service elements and authorized to perform them under applicable state law and regulations.

In states where there are no applicable licensure laws, CMS proposes to require auxiliary personnel furnishing PIN services to be trained to provide them. **CMS seeks comment on whether to include the number of hours of required training, as well as the training content and who should supply the training.**

CMS proposes that PIN visits could not be billed while the patient is under a home health plan of care because of the significant overlap in services furnished in home health and PIN. CMS notes that when Medicare and Medicaid cover the same services, Medicare is generally the primary payer. **The agency also seeks comment on other service elements not included in the proposed PIN service codes that should be included or are more important in addressing unmet SDOH needs, and where CMS could consider coding and payment in the future.**

Social Determinants of Health Risk Assessment in the Annual Wellness Visit (AWV)

The AWV includes the establishment or update of a patient's medical and family history, application of a health risk assessment, and the establishment or update of a personalized prevention plan. CMS proposes adding a new SDOH Risk Assessment as an optional, additional element of the AWV with an additional payment. CMS proposes that the SDOH Risk Assessment may be separately payable with no beneficiary cost sharing when furnished as part of the same visit with the same date of services as the AWV.

[15] GXXX3: Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, which may include a patient navigator or certified peer specialist; 60 minutes per calendar month, in the following activities

[16] Principal Illness Navigation services, additional 30 minutes per calendar month

The agency proposes that the SDOH Risk Assessment service include the administration of a standardized, evidence-based SDOH risk assessment tool furnished in a manner that all communication with the patient be appropriate for the patient's education, developmental and health literacy level, and be culturally and linguistically appropriate.

CMS invites public comment on this proposal, specifically on whether an SDOH Risk Assessment would ultimately inform and result in the development of steps to address and integrate SDOH in the patient's AWV health assessment and personalized prevention plan.

CMS proposes that Medicare would pay 100 percent of the fee schedule amount for the SDOH Risk Assessment service (no beneficiary cost-sharing) when this risk assessment is furnished to a Medicare beneficiary at the individuals AWV. The proposal to include SDOH Risk Assessment is optional for both the beneficiary and the clinicians.

Payment for Caregiver Training Services

In CYs 2022 and 2023, CMS received recommendations for new caregiver training codes. Although CMS has historically taken the position that codes describing services furnished to individuals without the patient's presence are not covered under Medicare, CMS indicated in the CY 2023 PFS final rule that there could be circumstances where separate payment for caregiver training services may be appropriate.

For CY 2024, CMS proposes to pay practitioners when they train and involve caregivers to support patients with certain diseases or illnesses. CMS proposes to pay for these services when furnished by a physician, non-physician practitioner, or therapist under an individualized treatment plan or therapy plan of care. **CMS has broadly defined caregiver to include a family member, friend, or neighbor who provides unpaid assistance to a person with a chronic illness or disabling condition and seeks public comment on this definition.** CMS notes that a patient-centered treatment plan should account for clinical circumstances where the treating practitioner believes the involvement of a caregiver is necessary to ensure a successful outcome for the patient and the patient agrees to caregiver involvement.

CMS proposes to establish an active payment status for CPT codes 96202 and 96203 (caregiver behavior management/modification training services) and CPT codes 9X015, 9X016, and 9X017 (caregiver training services under a therapy plan of care established by a PT, OT, SLP). The proposed payment will be made when the treating practitioner identifies a need to involve a caregiver. CMS proposes that the practitioner must get patient consent for involving and training a caregiver, and that specific times must be met to report these codes.[17] **CMS seeks public comment on all of these proposals.**

Payment for Skin Substitutes

In the CY 2023 PFS final rule, CMS indicated its interest in refining skin substitute policies and noted that such refinements could be phased in over several years as the agency learns how to incorporate skin substitutes as supplies under the PFS ratesetting methodology. CMS determines the direct PE for a specific service by adding the costs of the direct resources (clinical staff, medical supplies and medical equipment) typically involved with furnishing that

[17] CPT 96202 requires 60 minutes. CPT code 96203 requires 75 minutes of total time.

service. In the Proposed Rule, CMS is considering how to identify appropriate PE direct costs for skin substitute products. More specifically, CMS is reviewing price information, performing market research, assessing invoices from stakeholders, and evaluating cost information on Medicare claims. CMS also considers supply and equipment prices submitted through the invoice submission process to understand typical market prices of products. **CMS seeks comment on this variety of cost-gathering approaches to continue to appropriately develop payment rates for skin substitute services and products.**

In addition, CMS is considering different approaches to billing for skin substitutes. For example, CMS is considering an approach like that in OPPS, where skin substitute products are grouped and billed as either high-cost or low-cost with specific procedure codes. Additionally, for services performed too infrequently for grouping, CMS is considering a separate procedure coding system to inform specificity and account for cost variability of products. This approach could also include billed units of measurement or establishment of direct cost inputs with similarly resourced services to produce RVUs for a service and product together (the 'crosswalk' method). **CMS seeks comment on how these potential methods may inform the resource costs involved in skin substitute products and services.**

Drugs and Biological Products Paid Under Medicare Part B

The Inflation Reduction Act (IRA) contains several provisions that affect payment limits or beneficiaries' out-of-pocket costs for certain drugs payable under Part B. CMS proposes to codify and conform the regulatory text to reflect these changes.

Section 11402 of the IRA amends the payment limit for new biosimilars furnished to beneficiaries on or after July 1, 2024 during the initial period when Average Sales Price (ASP) data is not available, setting the payment limit as the lesser of (1) an amount not to exceed 103 percent of the Wholesale Acquisition Cost (WAC) of the biosimilar or the Medicare Part B drug payment methodology in effect November 1, 2003; or (2) 106 percent of the lesser of the WAC or ASP of the reference biological, or in the case of a selected drug during a price applicability period, 106 percent of the maximum fair price of the reference biological. CMS proposes to codify these changes.

Section 11403 of the IRA temporarily increases the payment limit for certain biosimilars with an ASP that is not more than the ASP of the reference biological for a period of five years. This section requires that a qualifying biosimilar be paid at ASP plus 8 percent of the reference biological's ASP, rather than 6 percent, during the applicable 5-year period that begins October 1, 2022. CMS proposes to add the definitions of "applicable 5-year period" and "qualifying biosimilar biological product" to the regulation. The agency also proposes to make conforming changes to the regulatory text for the temporary payment limit increase for qualifying biosimilar biological products.

Section 11101 requires that beneficiary coinsurance for a Part B rebatable drug is to be based on the inflation-adjusted payment amount if the Medicare payment amount for a calendar quarter exceeds the inflation adjusted payment amount, beginning on April 1, 2023. CMS issued initial guidance implementing this provision on February 9, 2023. The agency proposes to adopt conforming changes to the regulatory text.

Section 11407 provides that for insulin furnished through an item of Durable Medical Equipment (DME) on or after July 1, 2023, the deductible is waived and coinsurance is limited to $35 for a month's supply of insulin furnished through a covered item of DME. CMS has

implemented this provision under program instruction for 2023. The agency proposes to codify this provision.

RFI: Drugs and Biologicals Which are Not Usually Self-Administered by the Patient, and Complex Drug Administration Coding

Medicare pays for services and supplies, including drugs and biologics, that are not usually self-administered by the patient, which are furnished as "incident to" a physician's professional service. Drugs that are usually self-administered are thus statutorily excluded from coverage and payment under Part B under the "incident to" benefit.

CMS is soliciting comments on two policy areas. **First, CMS seeks comment and information regarding the relevant resources involved, as well as inputs and payment guidelines and/or considerations that could be used in determining appropriate coding and payment for complex non-chemotherapeutic drug administration. CMS seeks comment on whether the agency should revise the policy guidelines to better reflect how these specific infusion services are furnished and should be billed.**

Second, CMS is soliciting comments regarding the policies on the exclusion of coverage for certain drugs under Part B which are usually self-administered by the patient. The agency specifically requests feedback on definitions of the terms "administered," "self-administered," "usually," and "by the patient." CMS is also soliciting feedback on the process for determining which drugs are not usually self-administered by the patient; the process for issuing determinations on which drugs are classified as not usually self-administered by the patient; the relevant resources involved that could be used in determining appropriate coding and payment for complex non-chemotherapeutic drug administration; and whether CMS should revise its policy guidelines to better reflect how complex non-chemotherapeutic drug administration infusion services are furnished and billed.

Requiring Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts

The Infrastructure Investment and Jobs Act, which was signed into law on November 15, 2021, requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The refund amount is the amount of discarded drug that exceeds an applicable percentage, which is required to be at least 10 percent, of total charges for the drug in a given calendar quarter. The agency finalized many of its proposals in the CY 2023 PFS final rule but declined to finalize certain policies related to the timing of reports and other operational aspects of the program, which it addresses in the Proposed Rule.

In the Proposed Rule, CMS addresses the provision of information to manufacturers, manufacturer provision of refunds, a framework to have an increased applicable percentage for drugs with unique circumstances, and clarification regarding the definition of refundable drug. In addition, CMS clarifies policy related to the use of modifiers. Specifically, CMS clarifies that the JW modifier requirement does not apply to units billed to MA plans and that refund amounts will not include units billed to MA plans.

CMS also notes that in the CY 2023 PFS final rule, the agency discussed the applicability of the JW and JZ modifier policy to drugs that are not administered by the billing supplier. In these cases, suppliers who dispense but do not actually administer the separately payable drug are not expected to report the JW modifier. Beginning October 1, 2023, CMS will begin

editing for correct use of the JW and JZ modifier. The agency acknowledges that there is no claims modifier to designate that a drug was dispensed, but not administered, by the billing supplier, which may result in claims rejections without a modification. Therefore, CMS proposes to require that drugs separately payable under Part B from single-dose containers that are furnished by a supplier who is not administering the drug be billed with the JZ modifier.

Medicare Part B Payment for Preventive Vaccine Administration Services

Medicare Part B covers both the vaccine and its administration for specified preventive vaccines – influenza, pneumococcal, and hepatitis B virus (HBV). In addition, there is no applicable beneficiary coinsurance, and the annual Part B deductible does not apply for these vaccinations or the services to administer them. Payment for these vaccines is based on 95 percent of the Average Wholesale Price (AWP) for a particular vaccine product, except when furnished in settings for which payment is based on reasonable cost, such as a hospital outpatient department.

In the CY 2022 PFS final rule, CMS finalized an add-on payment of $35.50 for administration of the COVID-19 vaccine in a beneficiary's home. Throughout the duration of the PHE, CMS has received significant feedback requesting that this add-on payment become permanent for the COVID-19 vaccine, as well as for other Medicare Part B preventive vaccines. Based on an internal evaluation, CMS has concluded that the data shows that this add-on payment increased healthcare access to vaccines, particularly those in underserved populations. Accordingly, CMS proposes to maintain the in-home additional payment for the COVID-19 vaccine administration under the Part B preventive vaccine benefit. Additionally, CMS proposes to extend the additional payment to the administration of the pneumococcal, influenza, and hepatitis B vaccines when administered in the home. Notably, the additional payment can only be billed once per visit, even if multiple vaccines are administered. This additional payment amount would be annually updated using the percentage increase in the MEI and adjusted to reflect geographic cost variations using the PFS GAF which reflects cost differences for the geographic locality based upon the fee schedule area where the preventive vaccine is administered. **CMS seeks comment on these proposals.**

Also, in the CY 2022 PFS final rule, CMS outlined the conditions required for a vaccine administered in the home to qualify for this add-on payment. In the conditions, CMS specifies that multi-dwelling units (including group homes, communal spaces, skilled nursing facilities etc.) may be considered a home for purposes of the add-on payment. However, as noted in the code descriptor, Medicare pays the additional payment amount for up to a maximum of 5 vaccine administration services per home unit or communal space within a single group living location; but only when fewer than 10 Medicare patients receive a COVID-19 vaccine dose on the same day at the same group living situation. **With the expansion of the add-on payment policy to other vaccines, CMS seeks comment on this condition and whether this policy for defining what qualifies as a "home" should be applicable to all Part B preventive vaccines.**

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

The Medicare Improvements for Patients and Providers Act of 2008 provided coverage of Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR), and Intensive Cardiac Rehabilitation (ICR) under Medicare Part B. The Balanced Budget Act (BBA) of 2018 directs CMS to add to the types of practitioners who may supervise PR, CR, and ICR programs to

also include PAs, NPs, and Clinical Nurse Specialists (CNS). These provisions are effective January 1, 2024. CMS proposes several changes to implement this section of the BBA.

CMS proposes adding a new term, nonphysician practitioner (NPP), which would be defined as a PA, NP, or CNS, as those terms are defined in the Social Security Act. CMS also proposes to amend the term "supervising physician" to mean a physician or NPP. Finally, CMS proposes to amend the definitions of PR, CR, and ICR to specify that these are physician or NPP-supervised programs.

The agency also proposes to specify that all settings must have a physician or NPP immediately available and accessible for medical consultations and emergencies at all times when items and services are furnished under the programs.

Proposals on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Services

Medicare Payment for Dental Services

Although the Social Security Act precludes payment under Medicare Parts A or B for dental services, CMS clarified in the CY 2023 PFS final rule that certain clinical scenarios may be eligible for payment under Medicare Parts A and B. CMS notes that this clarification acknowledges that certain underlying medical conditions may require dental services and are inextricably linked to other covered services when hospitalization is required for a severe dental procedure or underlying dental-related medical condition, therefore, the Medicare Part A exception applies. In the CY 2023 PFS final rule, CMS also established a process for the public to submit additional dental services that may be linked to covered services for review and created a policy to permit payment for certain dental services beginning in CY 2024. CMS is proposing to codify additional policies to permit payment for certain dental services inextricably linked to other covered services.

CMS has identified scenarios where dental services are inextricably linked to a primary medical service covered by Medicare not precluded by statute. Dental services are considered integral to the clinical success of the following medical services used to treat cancer: chemotherapy, CAR T-Cell therapy, and administration of high-dose bone-modifying agents. Therefore, CMS proposes to permit payment under Medicare Parts A and B for:

(1) Dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered: chemotherapy, CAR T-cell therapy, and the administration of high-dose bone-modifying agents when any of these treatments is used in the treatment of cancer; and
(2) Medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with: chemotherapy, CAR T-cell therapy, and the administration of high-dose bone-modifying agents when any of these treatments is used in the treatment of cancer.

CMS further proposes that payment under the applicable payment system could also be made for services that are ancillary to these dental services, such as x-rays, administration of anesthesia, and the use of the operating room.

In addition, CMS provides a request for information on dental services integral to covered cardiac interventions, a request for comment on dental services integral to specific covered services to treat sickle cell disease and hemophilia, and comments on

dental services possibly inextricably linked to other Medicare-covered services. CMS also seeks feedback on implementation and payment.

Medicare Diabetes Prevention Program

The Medicare Diabetes Prevention Program (MDPP) is an evidence-based behavioral intervention that aims to prevent or delay the onset of type 2 diabetes for eligible Medicare beneficiaries diagnosed with pre-diabetes. During the PHE, CMS granted flexibility to the program, allowing coaches to provide services virtually through distance learning. CMS believes that extending the flexibilities granted during the PHE will boost access to the MDPP services. As such, CMS is proposing to extend those flexibilities through December 31, 2027. CMS also proposes to simplify the MDPP's current performance-based payment structure by allowing fee-for-service payments for beneficiary attendance.

Expand Diabetes Screening and Diabetes Definitions

Statute requires coverage of diabetes screening tests in the Medicare Part B program. Recently revised guidance from the US Preventative Service Task Force (USPSTF) recommends the Hemoglobin A1C (HbA1c) test for diabetes screening, which is not currently covered by Medicare. For CY 2024, CMS proposes to expand coverage of diabetes screening tests to include the Hemoglobin A1C (HbA1c) test; expand and simplify the frequency limitations for diabetes screening; and simplify the regulatory definition of diabetes for diabetes screening under MNT and DSMT.

Under these proposed changes, the regulatory definition of diabetes would be updated to remove the codified clinical test requirements. By changing this definition, CMS will be able to change coverage for diabetes under the MNT without modifying the national coverage determination. The proposed revised definition of diabetes for the DSMT would remove the codified clinical test requirements and be shortened to define diabetes as a condition of abnormal glucose metabolism. CMS believes these changes reflect the evolving criteria for diagnosing diabetes that is more reflective of the current standard used for diagnosis.

Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan

In the CY 2021 PFS final rule, CMS provided a January 1, 2022, compliance date for electronic prescribing (e-prescribing) of controlled substance (EPCS) for a covered Part D drug under a prescription drug plan or an MA-PD plan. In the Proposed Rule, CMS proposes changes to clarify implementation and enforcement of the EPCS requirements.

Standards for the Same Legal Entity

In the CY 2022 PFS final rule, CMS finalized an exception for prescriptions issued where the prescriber and dispensing pharmacy are the same entity (the same entity exception). During implementation of the same entity exception, CMS has noted that the Prescription Drug Event (PDE) data does not have a field that consistently and accurately identifies prescribers and dispensing pharmacies that are part of the same entity. However, the Medicare E-Prescribing and Prescription Drug Program final rule codified standards that could be used when all parties to a transaction are employed by and part of the same legal entity.

CMS proposes to remove the same entity exception from the CMS EPCS requirements, and to add language adopting the regulations from the Medicare E-Prescribing final rule. Under

this proposed change, prescriptions that are prescribed and dispensed within the same legal entity would be included in the CMS EPCS Program compliance calculations.[18] **CMS believes that this proposal would provide flexibility where prescriptions are transmitted within the same legal entity, but seeks comment on these proposals.**

Definition of Prescriptions for Compliance Calculation

In the CY 2022 PFS final rule, CMS finalized the compliance threshold requirement for the CMS EPCS Program such that prescribers are required to prescribe at least 70 percent of their Part D Schedule II-V controlled substance prescriptions. However, CMS did not define how prescriptions with multiple fills would affect the compliance threshold.

In the Proposed Rule, CMS states that for purposes of the EPCS Program, the agency will count unique prescriptions in the measurement year using the prescription number assigned by the pharmacy and included in the Part D claims data. CMS clarifies renewals will be counted as an additional prescription in the compliance threshold, but CMS will not count refills as an additional prescription in the CMS EPCS Program compliance threshold calculation unless the refill is the first occurrence of the unique prescription in the measurement year.

Updates to the CMS EPCS Program Exceptions for Cases of Recognized Emergencies and Extraordinary Circumstances

In the CY 2022 PFS final rule, CMS finalized two exceptions related to exceptional circumstances that may prevent prescribers from being able to conduct EPCS. The first is for prescribers prescribing during a recognized emergency. The second exception is for prescribers who receive a CMS waiver for facing emergency circumstances when not in a recognized emergency. CMS proposes to update the circumstances applicable for the recognized emergency and extraordinary circumstances waiver by modifying the definition of "extraordinary circumstance" to mean a situation outside of the control of a prescriber that prevents the prescriber from electronically prescribing a Schedule II-V controlled substance that is a Part D drug. CMS also proposes modifying the exception so that CMS will identify which events trigger the recognized emergency exception. **CMS seeks comment on these proposals.**

CMS also proposes that prescribers impacted by a recognized emergency exception would be excepted for the entire measurement year, and not just the duration of the emergency. For prescribers recognized under a waiver, CMS proposes that a prescriber has a period of 60 days from the date of the notice of the non-compliance to request a waiver, and approved waivers would apply to prescriptions written by a prescriber for the entire measurement year. **CMS seeks comment on these proposals.**

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

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act established a new Medicare Part B benefit

[18] See 42 CFR § 423.160(a)(5) and (a)(3)(iii).

category for opioid use disorder (OUD) treatment services furnished by opioid treatment programs (OTPs).

To better align coverage provided by OTPs with the provisions outlined in the CAA, 2023, CMS proposes to extend the audio-only flexibilities for periodic assessments furnished by OTPs through the end of CY 2024. Audio-only will be allowed only when video is not available to the extent that use of audio-only communications technology is permitted under the applicable SAMHSA and DEA requirements at the time the service is furnished, and when all other applicable requirements are met. CMS believes that this extension will minimize disruption to beneficiary access.

Appropriate Use Criteria for Advanced Diagnostic Imaging

Appropriate Use Criteria (AUC) are evidence-based guidelines that assist clinicians in selecting the imaging studies most likely to improve health outcomes for patients based on their individual criteria. Under this program, a practitioner who orders an advanced diagnostic imaging service for a Medicare beneficiary in an applicable setting is required to consult an AUC using a qualified clinical decision support mechanism, and the practitioner must report the AUC consultation on the Medicare claim. CMS established the program in the CY 2018 rulemaking cycle, with an intended start date of January 1, 2020. In response to the COVID-19 PHE, CMS extended the operational testing period, ultimately delaying the payment penalty phase. For CY 2024, CMS proposes to indefinitely pause the program to allow the agency to re-evaluate and consider next steps. **In addition, CMS proposes to stop the testing and education period and rescind the regulations governing the program.**

Clinical Laboratory Fee Schedule (CLFS)

The Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for clinical diagnostic laboratory tests (CDLTs) under CLFS. Under a 2016 Medicare CLFS final rule, CMS required that "reporting entities" report to CMS during a "data reporting period" "applicable information" collected during a "data collection period" for their "component applicable laboratories".[19] In subsequent years, CMS gained stakeholder feedback and made policy modifications, such as changes to the definition of "applicable laboratory." In general, since 2018, the payment amount for each CDLT on the CLFS is based on the applicable information collected and reported to CMS during the data reporting period and is equal to the weighted median of the private payor rates for the test. The payment amounts under the CLFS are not subject to any other adjustment. In addition, the law provided a four-year phase-in of payment reductions, limiting the amount the CLFS rates for each CDLT can be reduced compared to the prior year. Specifically, from CY 2018-2020 the reduction could not be more than 10 percent per year, and for CY 2021-2023 the reduction could not be more than 15 percent per year. Also, for CDLTs that are not Advanced Diagnostic Laboratory Tests (ADLTs) (among other changes, ADLT payment rate updates occur annually), the data collection period, data reporting period, and payment rate are to occur every three years.

[19] The first data collection period occurred from January 1, 2016, through June 30, 2016. The first data reporting period occurred from January 1, 2017, through March 31, 2017.

Since 2019, several legislative changes occurred, including changes to the data reporting requirements, without modifying the data collection period (January 1, 2019 – June 30, 2019) and extending the phase-in of payment reductions under CLFS.

The CAA, 2023 made further revisions to the CLFS requirements for the next data reporting period for CDLTs that are not ADLTs, delaying the applicable data reporting period for one year, so that data reporting would be required from January 1, 2024 through March 31, 2024, instead of January 1, 2023 through March 31, 2023. The three-year data reporting cycle for CDLTs that are not ADLTs would resume after that data reporting period.

The CAA, 2023 also extends the statutory phase-in of payment reductions resulting from private payer rate implementation until CY 2026. The legislation also specifies that the applicable percent for CY 2023 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2023 shall not result in any reduction in payment as compared to the payment amount for that test in CY 2022. The applicable percent of 15 percent will apply for CYs 2024 through 2026. The CLFS payment rates for CY 2025 through CY 2027 will be based on applicable information collected during January 1, 2019 through June 30, 2019 and reported to CMS during the data reporting period of January 1, 2024 through March 31, 2024.

CMS proposes conforming regulatory changes to implement these provisions of the CAA, 2023.

Request for Information (RFI): Histopathology, Cytology, and Clinical Cytogenetics Regulations Under the Clinical Laboratory Improvement Amendments (CLIA) of 1988

CMS seeks comment on ways to update CLIA requirements to align with new histopathology innovations and technologies, as the regulations have not been updated since 1992. The RFI focuses on the areas of histopathology, cytology, and clinical cytogenetics of CLIA as it looks to update standards for conducting laboratory activities. Specifically, CMS seeks input on including slide preparation and staining under CLIA regulations, supervision and documentation of gross tissue examination, cytology screening location requirements, remote examination of cytology and histopathology slides, CLIA certification requirements for laboratories, and technician qualification requirements. **CMS seeks public feedback on these questions.**

Medicare Enrollment

As noted in the Proposed Rule, CMS may revoke a Medicare provider's or supplier's enrollment for any reason specified in statute, for example, the failure to adhere to Medicare enrollment requirements, exclusion by the HHS Office of the Inspector General, felony convictions within the past 10 years, a pattern of improper or abusive billing, and/or termination by another Federal health care program. When a provider or supplier is revoked, they are barred from reenrolling in the program for 1 to 10 years. CMS proposes several changes to the revocation policies, such as those related to non-compliance revocation grounds, misdemeanor convictions, and False Claims Act civil judgments, among other topics. Also, CMS proposes policy related to the effective date of the revocation and timeframe for the reversing a revocation.

Updates to the Definitions of Certified Electronic Health Record Technology

As authorized under law, CMS makes incentive payments to eligible professionals, eligible hospitals, critical access hospitals (CAHs), and Medicare Advantage organizations to promote

the adoption and meaningful use of Certified Electronic Health Record Technology (CEHRT). In the CY 2021 PFS final rule, CMS finalized a requirement that the technology used by health care providers to satisfy the definitions of CEHRT must be certified under the ONC Health IT Certification Program.

In April 2023, ONC released a proposed rule (HT-1) in which the agency proposed removing "editions" from the ONC Health IT Certification Program. Accordingly, CMS proposes revisions to the CEHRT definitions in the Medicare Promoting Interoperability Program and the Quality Payment Program (which includes the Shared Savings Program) to support the transition ONC proposed in the HT-1 proposed rule. CMS proposes to revise the definitions of CEHRT so these definitions are consistent with the updates to the Health IT Certification Program in the ONC HT-1 proposed rule, should the ONC proposals become final. Additionally, CMS notes that these proposals do not rely on the finalization of the proposals in the ONC HT-1 proposed rule.

Shared Savings Program

Eligible groups of providers and suppliers, including physicians, hospitals, and other healthcare providers, may participate in the Shared Savings Program (SSP) by forming or joining an accountable care organization (ACO). Under the SSP, providers and suppliers that participate in an ACO continue to receive traditional Medicare FFS payments, and the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements, and in some instances, may be required to share in losses if it increases health care spending. Under the SSP, there are different participation tracks (i.e., BASIC[20] or ENHANCED[21]) that allow ACOs to assume various levels of risk.

In the Proposed Rule, CMS addresses changes to the SSP to further advance Medicare's overall value-based care strategy of growth, alignment, and equity. CMS proposes changes to the quality performance standard and reporting requirements under the Alternative Payment Model (APM) Performance Pathway (APP), updates the definition of primary care services, refines the financial benchmarking methodology for ACOs, and refines the newly established advance investment payments (AIPs), among other changes. **CMS also seeks comment on future potential developments to the SSP, including a new track that would offer a higher level of risk and potential reward than currently available under the ENHANCED track.**

Proposal for Shared Savings Program ACOs to Report Medicare CQMs

In prior rulemaking, CMS finalized policy for performance year (PY) 2025 and subsequent PYs that ACOs must report the three eCQMs/ Merit-based Incentive Payment System (MIPS) (MIPS) Clinical Quality Measures (CQMs) and the CAHPS for MIPS survey. In the Proposed Rule, CMS acknowledges prior stakeholder comments regarding the requirement to report all payer measures because the measure ties performance to patients that the ACO does not actively manage and increases the difficulty of meeting data completeness requirements. However, in the Proposed Rule, CMS reiterated that as the transition to reporting all-payer

[20] The BASIC track offers a glide path for eligible ACOs to transition from a one-sided shared savings-only model to progressively higher increments of financial risk and potential reward under two-sided shared savings (otherwise referred to as performance-based risk) and shared losses models within a single 5-year agreement period.
[21] The ENHANCED track offers ACOs the opportunity to accept greater financial risk for their assigned beneficiaries in exchange for potentially higher financial rewards.

eCQMs/MIPS CQMs continues, the health equity adjustment that was finalized in the CY 2023 PFS final rule will help support ACOs experiencing a challenge with the new quality report requirements. CMS also notes that it previously extended the eCQM/MIPS CQM reporting incentive through PY 2024 to incent ACOs to report the eCQMs/MIPS CQMs before full reporting of these measures is required, beginning in PY 2025. While CMS notes that it is continuing to monitor the impact of these finalized policies that may be addressed in future rulemaking, the agency also proposes a new collection type to help some ACOs be better positioned to eventually report all payer/all MIPS CQM and eCQMs.

New Proposed Collection Type: Medicare CQM

The new proposed collection type, which is for SSP ACOs only, is the Medicare CQMs for Accountable Care Organizations Participating in the Medicare Shared Savings Program ("Medicare CQMs") which is for SSP ACOs under the APP. Notably, Medicare CQMs would define a population of beneficiaries that exist within the all payer/all MIPS CQM specifications and linking that population to claims encounters with ACO professionals with specialties used in assignment. As a result, CMS believes ACOs would be able to more effectively identify the ACO's eligible population, particularly for ACOs with a higher proportion of specialty practices and/or multiple EHRs. In the Proposed Rule, CMS clarifies that if finalized, in performance year 2024, ACOs would have the option to report by using the CMS Web Interface measures, eCQMS, MIPS CQM collection types and/or Medicare CQMs. However, in PY 2025 and subsequent PYs, ACOs would no longer be able to use the CMS Web Interface measures.

Additionally, as outlined in Table 5, CMS proposes to establish data submission and completeness criteria pertaining to the Medicare CQMs for the MIPS quality performance category and a definition of a beneficiary eligible for Medicare CQM.[22] Table 25 (pg. 537) of the Proposed Rule provides the Proposed APP reporting requirements and quality performance standard for PY 2024 and subsequent performance years.

Topic	Proposal
Data completeness threshold*	- At least 75 percent for the CY 2024- 2026 performance periods/2026-2028 payment years - At least 80 percent for the CY 2027 performance period/2029 MIPS payment year
Benchmarking Policy**	- For PY 2024 and 2025, Medicare CQMs to be scored using performance period benchmarks - For PY 2026 and subsequent PYs, Medicare CQMs to be scored using historical benchmarks when baseline period data are available (historical benchcmark to be established in a manner that is consistent with MIPS benchmarking policies
Expanding the Health Equity	- Beginning PY 2026, CMS to begin calculating health equity adjusted quality performance score for an ACO reporting and

[22] CMS proposes to define a beneficiary eligible for Medicare CQM at § 425.20 as a beneficiary identified for purposes of reporting Medicare CQMs for ACOs participating in the Medicare Shared Savings Program (Medicare CQMs) who is either of the following:

- A Medicare fee-for-service beneficiary (as defined at § 425.20) who:
  - Meets the criteria for a beneficiary to be assigned to an ACO described at § 425.401(a); and
  - Had at least one claim with a date of service during the measurement period from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a PA, NP, or CNS.
- A Medicare fee-for-service beneficiary who is assigned to an ACO in accordance with § 425.402(e) because the beneficiary designated an ACO professional participating in an ACO as responsible for coordinating their overall care.

Adjustment to Medicare CQMs	meeting data completeness requirements for the three Medicare CQMs, or a combination of eCQMs/MIPS CQMs/Medicare CQMs in the APP measure set, and administering the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS survey.

Table 5.

*To aid ACOs in the process of patient matching and data aggregation necessary to report Medicare CQMs, CMS would provide the ACO a list of beneficiaries who are eligible for Medicare CQMs annually, at the beginning of the quality data submission period. However, CMS indicates this list would likely not be complete and so would need to ensure beneficiaries are appropriately included on an ACOs Medicare CQMs reporting.

**CMS indicates that benchmarks for scoring ACOs on the Medicare CQMs under MIPS would be developed in alignment with MIPS benchmarking policies

Proposal to Align CEHRT Requirements for SSPs ACOs with MIPS

Currently, the MIPS CEHRT requirements are more comprehensive than the SSP requirements. To align the SSP with MIPS, CMS proposes to remove the SSP CEHRT threshold requirements beginning PY 2024 and add a new requirement for PYs beginning on or after January 1, 2024. Under this proposal, all MIPS eligible clinicals, Qualifying APM Practitioners (QPs), and Partial QPs participating in the ACO would report the MIPS Promoting Interoperability (PI) performance category measures and requirements to MIPS, at the individual, group, virtual group, or APM level, and earn a MIPS performance category score.

CMS also proposes to require that the ACO publicly report the number of MIPS eligible clinicians, QPs, and partial QPs participating in the ACO that earn a MIPS performance category score for the MIPS PI performance category at the individual, group, virtual group, or APM entity level.

MIPS Value Pathway (MVP) Reporting for Specialists in Shared Savings Program ACOs- Request for Information

Beginning in CY 2023, specialists who reported under MIPS, including specialists in SSP ACOs, had the option to register to report MVPs for the applicable performance period as a group, subgroup, or individual and to report on relevant MVP quality measures. CMS states that there is a need to allow specialists to report more relevant data to allow patients and referring clinicians to make more informed decisions regarding the specialists involved in a patient's care.

CMS indicates that its overarching intent is to have specialists participate in ACOs in a meaningful way and to collect quality data that is comparable to data reported by other specialty providers in quality MVPs. Among several other questions in the Proposed Rule, **CMS seeks feedback on how the agency could encourage the reporting of MVPs to collect quality data that is comparable to data reported by other specialty providers in quality MVPs and how CMS should provide ACOs with bonus points to their health equity adjusted quality performance score when an ACO's specialty clinicians report MVPs.**

Proposal to Modify the Health Equity Adjustment Underserved Multiplier

In the CY 2023 PFS final rule, CMS finalized a health equity adjustment to reward providers who provided high quality care to vulnerable populations. As a correction to the calculation to better account for these vulnerable patients, CMS proposes to use the number of beneficiaries, rather than person years, for calculating the proportion of the ACO's assigned

beneficiaries who are enrolled in the low-income subsidy (LIS) program or who are dually eligible for Medicare and Medicaid, starting in performance year 2024. CMS indicates the proposed policy recognizes more eligible beneficiaries and provides increased incentives for ACOs to help facilitate LIS enrollment for beneficiaries who are eligible for the program.

Proposal to Use Historical Data to Establish the 40th Percentile MIPS Quality Performance Category Score

Beginning in performance year 2024, CMS proposes to use historical submission-level MIPS quality performance category scores on a three-year rolling basis (with a one-year lag) to calculate the 40th percentile MIPS Quality performance category score. For example, for PY 2024, the quality performance standard would be based on averaging the 40th percentile MIPS Quality performance scores from performance years 2020 through 2022. CMS would release quality performance standard on the SSP website in December prior to the performance year.

Proposal to Apply a SSP Scoring Policy for Excluded APP Measures

CMS proposes that, for performance year 2024 and subsequent performance years, if (1) an ACO reports all required measures under the APP, meets the data completeness requirements, and receives a MIPS Quality performance category score; and (2) the ACO's total available measure achievement points used to calculate the ACO's MIPS Quality performance category score for the performance year is reduced due to measure exclusion, then CMS will use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS quality performance category score, to determine whether the ACO meets the quality performance standard required to share in savings at the maximum rate under its track for the relevant performance year.

Proposal to Revise the Requirement to Meet the Case Minimum Requirement for Quality Performance Standard Determinations

CMS requires ACOs to meet certain case minimum requirement to determine the quality performance standard for ACOs in the first performance year of their first agreement period, for the eCQM/MIPS CQM incentive for PY 2024, and for the extreme and uncontrollable circumstances policy. In the Proposed Rule, CMS notes that regulations referencing "case minimum" are not sufficiently clear to describe the policy's intent of applying the MIPS Quality performance category scoring policies in determining the ACO quality performance standard. To alleviate confusion regarding the reference to case minimum requirement for the ACO quality performance standard, beginning in PY 2024, CMS proposes replacing any reference to "meeting the case minimum requirement" with a requirement that "the ACO must receive a MIPS Quality performance category score". CMS states that this policy incorporates the applications of case minimums into the MIPS Quality performance category scoring policies to determine an ACO's quality performance standard under the SSP. In the Proposed Rule (pg. 574-578), CMS provides examples of application of the proposed policy clarification and specific regulatory changes.

Proposals to Improve ACO Risk Adjustment and Alignment

Proposal to Cap Regional Service Area Risk Score Growth for Symmetry with ACO Risk Score Cap

CMS proposes to modify the calculation of the regional component of the three-way blended benchmark update factor[23] for agreement periods beginning on January 1, 2024. The proposal would cap prospective Hierarchical Condition Coding (HCC) risk score growth in an ACO's regional service area between benchmarking year three and the performance year using a similar methodology as the one adopted in the CY 2023 PFS final rule for capping ACO risk score growth. This cap on regional risk score growth would be applied independently of the cap on an ACO's own prospective HCC risk score growth. CMS states that this proposal would maintain a disincentive against coding intensity for ACOs with high market share by adjusting the regional risk score growth cap based on ACO market share.

Proposal to Update How Benchmarks are Risk Adjusted

In the CY 2024 MA Capitation Rates and Part C and Part D Payment Policies final rule, CMS finalized the transition to a revised CMS-HCC risk adjustment model (V28). When the CMS-HCC risk adjustment model changes, CMS notes that this complicates SSP performance year and benchmark year comparisons, which tend to negatively impact ACOs with the highest average risk scores, ACOs participating in two-sided models, and ACOs that have been in the SSP longer. CMS conducted an initial analysis (pg. 699-704) of the V28 CMS-HCC model on the SSP calculations using the current approach and an alternative approach to calculating benchmark year risk scores. To minimize the risk of distortion from using different CMS-HCC risk scores for benchmark years and the performance year that could occur under the current policy, among other changes, CMS proposes an alternative approach to making such calculations for agreement periods beginning on January 1, 2024.

Proposal to Mitigate the Impact of the Negative Regional Adjustment on the Benchmark to Encourage Participation by ACOs Caring for Medically Complex, High-Cost Beneficiaries

CMS states that the policies finalized in the CY 2023 PFS final rule sought to reduce the impact of negative regional adjustments for agreement periods beginning on January 1, 2024, and subsequent years. These policies were intended to incentivize ACOs that serve high-cost beneficiaries to join or continue to participate in the SSP.

To further incentivize ACO participation, CMS proposes to modify the policies adopted in the CY 2023 PFS final rule to prevent any ACO from receiving an adjustment that would cause its benchmark to be lower than it would have been in the absence of a regional adjustment.[24] CMS expects that all ACOs would benefit from this proposal and that no ACO would be made

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[23] Weighted one-third accountable care prospective trend (ACPT) and two-thirds national-regional blend.

[24] Under this updated methodology, CMS would continue to calculate the original uncapped regional adjustment, continue to apply the 5 percent cap on positive regional adjustments, and the -1.5 percent cap and offset factor on negative regional adjustments. After these two adjustments, CMS would express the regional adjustment as a single per capita value. If the ACO's regional adjustment amount is positive, the ACO would receive a regional adjustment through the approach finalized in the CY 2023 PFS final rule. If the ACO's regional adjustment is negative, the ACO would receive no regional adjustment to its benchmark for any enrollment type. If the ACO is eligible for a prior savings adjustment, it would receive the prior savings adjustment as its final adjustment.

worse off by the proposed policy. Tables 37 and 38 (pg. 671-672) of the Proposed Rule offer hypothetical examples of ACOs that would be impacted by this proposal.

Shared Governance Requirement

In prior rulemaking, CMS finalized a policy that a SSP ACO's governing body must be at least 75% controlled by ACO participants, with an option for ACOs to seek an exception to this shared governance requirement. CMS has not granted any exceptions since this policy was finalized, and accordingly, CMS proposes to remove the option for ACOs to request an exception to this shared governance requirement.

Proposed Modifications to Advance Investment Payments Policies

In the CY 2023 OPPS final rule, CMS established Advance Investment Payment (AIP) policies to provide funding to smaller ACOs, enabling them to form high-performing networks and address the health needs of underserved communities. This new payment option is for eligible SSP ACOs entering agreement periods beginning on or after January 1, 2024. In the Proposed Rule, CMS provides modifications to refine several AIP policies to better prepare for initial implementation of AIP beginning with ACOs entering agreement periods on January 1, 2024.

In summary, CMS proposes to allow ACOs to advance to two-sided model levels within the BASIC track's glide path beginning in PY3 of the agreement period in which they receive advance investment payments. CMS also proposes to recoup AIPs from shared savings for ACOs that wish to renew to continue their participation in the SSP. CMS indicates it would terminate AIPs for future quarters to ACOs that elect to terminate their participation in the SSP. In addition, CMS proposes to require ACOs to report spend plan updates and actual spend information to CMS in addition to publicly reporting such information. The agency also proposes that ACOs receiving AIPs may seek reconsideration review of all payment calculations. If finalized as proposed, the changes would go into effect January 1, 2024.

Comment Solicitation on Potential Future Developments to the SSP Policies

CMS seeks comment to inform future policy developments to advance progress towards its goal of having all Medicare beneficiaries enrolled in value-based care models by 2030. Specifically, CMS seeks information on the following: (1) incorporating a higher risk track than the ENHANCED track; (2) modifying the amount of the prior savings adjustment through changes to the 50% scaling factor used in determining the adjustment, as well as considerations for potential modifications to the positive regional adjustment to reduce the possibility of inflating the benchmark; (3) potential refinements to the Accountable Care Prospective Trend (ACPT) and the three-way blended benchmark factor update; and (4) approaches to promote ACO and community-based organization (CBO) collaboration.

Updates to the Quality Payment Program

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established the QPP for eligible clinicians. Under the QPP, MIPS eligible clinicians can participate via one of two tracks – the MIPS (reporting available beginning CY 2023 via traditional MIPS or MIPS Value Pathways (MVPs)) and APMs. Generally, the Proposed Rule sets forth changes to the QPP starting January 1, 2024. CMS also provides a several resources regarding the Proposed Rule the Quality Payment Program website.

Traditional MIPS

Traditional MIPS is the original reporting option available for MIPS eligible clinicians. Performance in MIPS is measured across four areas: quality, improvement activities (IA), Promoting Interoperability (PI), and Cost. Often, proposed changes to Traditional MIPs also apply to MVP policy.

Performance Areas

Quality Performance Category

CMS proposes the following key modifications to the quality performance category and seeks comments regarding these potential changes:

- Expanding the definition of the collection type to include Medicare CQMs for ACOs participating in the MSSP.
- Establishing the quality performance category data submission criteria for eCQMs that requires the utilization of CEHRT.
- Establishing the data submission criteria for Medicare CQMs.
- Requiring administration of the CAHPS survey in Spanish.
- Maintaining the data completeness criteria threshold to at least 75 percent for the CY 2026 performance period/2028 MIPS payment year and increasing the data completeness criteria to at least 80 percent for the CY 2027 performance period/2029 MIPS payment year.
- Establishing data completeness criteria for Medicare CQMs.
- Establishing a measure set inventory of 200 MIPS quality measures, which can be found in Table Group A of the Proposed Rule (pg. 1536-1558)
    - CMS also proposes modification to existing specialty sets and new specialty sets as described in Table Group B of the Proposed Rule (pg. 1559-1880).

Cost Performance Category

As required under current regulations, CMS specifies cost measures (e.g., episode-based measures coverage a range of conditions and procedures and two population-based measures) for a performance period to assess the performance of MIPS eligible clinicians on the cost performance category. CMS proposes adding five new episode-based measures to the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year. These measures are Depression, Emergency Medicine, Heart Failure, Low Back Pain, and Psychoses and Related Conditions. CMS proposes a 20-episode case minimum if a MIPS eligible clinician is to be assessed on such a measure. CMS also proposes to remove the Simple Pneumonia with Hospitalization episode-based measure beginning with the CY 2024 performance period/2026 MIPS payment year. More information on the development and evaluation of these measures is available on the QPP cost measures page.

Improvement Activities (IA) Category

In the Proposed Rule, CMS notes that while it is not proposing changes to the traditional MIPS improvement activities policies for the CY 2024 performance period/2026 MIPS payment year, the agency is proposing policy for group reporting in MVPs as noted below.

Also, CMS proposes to add five new IAs, modify one existing IA, and remove three existing IAs[25] from the inventory for the CY 2024 performance period/2025 MIPs payment year and future years. The five new measures include measures for HIV prevention, cervical cancer screening, behavioral/mental health and substance use screening for pregnant and postpartum women, behavioral/mental health and substance use screening for older adults, and practice-wide quality improvement in the MIPS Value Pathways Program. CMS refers readers to Appendix 2 (pg.1968) of the Proposed Rule for more details on these measures.

Notably, the proposed modified measure is titled "Use decision support and standardized treatment protocols to manage workflow in the team to meet patient needs" and its validation criteria explicitly promotes the use of clinical decision support (CDS), particularly open-source, freely available, interoperable CDS.

Promoting Interoperability Performance Category

The Social Security Act includes a provision requiring the meaningful use of certified electronic health record (EHR) technology (CEHRT) as a performance category under MIPS (referred to as the Promoting Interoperability performance category).

CMS proposes the following modifications for the Promoting Interoperability performance category:

- Lengthen the performance period for this category from a minimum of any continuous 90-day period in a calendar year to any continuous 180-day period within CY 2024;
- Modify one of the exclusions for the Query of Prescription Drug Monitoring Program (PDMP) measure;
- Provide a technical update to the e-Prescribing measure's description to ensure it clearly reflects previously finalized policy;
- Modify the Safety Assurance Factors for Electronic Health Record Resilience (SAFER) Guide measure to require MIPS eligible clinicians to affirmatively attest to completion of the self-assessment of their implementation of safety practices; and
- Continue to reweight this performance category at zero percent for CSWs for the CY 2024 performance period/2026 MIPS payment year.

Table 45 (pg. 1044-1049) of the Proposed Rule outlines objectives and measures for the promoting interoperability performance category for the CY 2024 performance period. **CMS seeks feedback on these proposals, specifically CMS seeks input on the continuous 180-day performance period for the Promoting Interoperability performance category.**

MIPS Final Scoring Methodology and Scores

CMS proposes several changes related to the MIPS Final Scoring Methodology.

Regarding cost, CMS proposes to determine each MIPS eligible clinician's cost improvement score at the category level instead of the current measure level, beginning with the CY 2023

[25] CMS proposes removing the following measures: Implementation of co-location PCP and Mental Health Services; Consulting Appropriate Use Criteria (AUC) Using Clinical Decision Support when Ordering Advanced Diagnostic Imaging; and Obtain or Renew an Approved Waiver for Provision of Buprenorphine as Medication-Assisted Treatment for Opioid Use Disorder.

performance period/2025 MIPS payment year. Additionally, CMS proposes to modify the cost improvement scoring methodology to remove the requirement that requires comparing measures with a "statistically significant change (improvement or decline) in performance" beginning in CY 2023 performance period/2025 MIPS payment year.[26]

Table 46 (pg. 1050) of the Proposed Rule outlines the scoring methodology for the Promoting Interoperability performance category for the CY 2024 performance period.

To alleviate confusion associated with prior rulemaking, CMS proposes that in order to initiate the baseline score for the IA performance category, a MIPS eligible clinician or group with APM Participation must have submitted data for two performance categories or attest to having completed an improvement activity. CMS also proposes that the agency will not apply a baseline score if it has also approved a request for performance category reweighting or hardship exception affecting the improvement activities performance categories.

MIPS Targeted Review

CMS proposes to add virtual groups and subgroups as eligible to submit a request for targeted review. The agency also proposes to permit submission of a request for targeted review beginning on the day CMS makes the MIPS final score available and ending 30 days after publication of the MIPS payment adjustment factors for the MIPS payment year. If the agency requests additional information under the targeted review process, CMS proposes that additional information must be provided to and received by CMS within 15 days of receipt of such request (the current timeline is 30 days).

Third Party Intermediaries

CMS proposes to: (1) add requirements for third party intermediaries to obtain documentation of their authority to submit on behalf of a MIPS eligible clinician; (2) specify the use of a simplified self-nomination process for existing Quality Clinical Data Registries (QCDRs) and qualified registries; (3) add requirements for QCDRs and qualified registries to provide measure numbers and identifiers for performance categories; (4) add a requirement for QCDRs and qualified registries to attest that the information contained in the qualified posting about them is correct; (5) modify requirements for QCDRs and qualified registries to support MVP reporting to increase flexibility for measures supported; (6) specify requirements for a transition plan for QCDRs and qualified registries withdrawing from the program; (7) specify requirements for data validation audits; (8) add additional criteria for rejecting QCDR measures; (9) add a requirement for QCDR measure specifications to be displayed throughout the performance period and data submission period; (10) eliminate the Health IT vendor category; (11) add failure to maintain updated contact information as criteria for remedial action; (12) revise corrective action plan requirements; (13) specify the process for publicly posting remedial action; and (14) specify the criteria for audits.

[26] CMS is proposing instead to determine the cost improvement score at the category level by subtracting the cost performance category score of the previous performance period from the cost performance category score of the current performance period, and then dividing the difference by the cost performance category score of the previous performance period and dividing by 100.

Public Reporting on Compare Tools

To expand the information publicly available, CMS proposes to include the telehealth indicator to identify the telehealth services provided on clinician profile pages and utilization data showing a more complete scope of a clinician's experience. **CMS seeks feedback on ways to publicly report data submitted on measures under the MIPS cost performance category on the Compare tool**.

MIPS Payment Adjustments

CMS uses a final score to determine MIPS payment adjustments. Beginning with the CY 2024 performance period/2026 MIPS payment period, CMS proposes to revise the policy for identifying the "prior period" used for establishing the performance threshold. This updated definition would define the "prior period" as three performance periods instead of a single performance period. CMS proposes to use the CY 2017 performance period/2019 MIPS payment year through CY 2019 performance period/2021 MIPS payment year as the prior period for CY 2024 performance year/2026 MIPS payment year. The intention of this proposal is to create consistency and stability by succinctly identifying the prior period. **CMS requests feedback on this proposal.**

Based on the proposed definition of "prior period", CMS included means of final scores for MIPS eligible clinicians spanning over three performance periods. Because of issues related to data from CY 2020 and 2021 during the PHE, CMS proposes to use the CY 2017-CY 2019 performance periods/2019-2021 MIPS payment years as the prior period (with its mean of 82 points) for the purpose of establishing the performance threshold for the CY 2024 performance period/2026 MIPS payment year. In the regulatory impact analysis, CMS believes that 46 percent of MIPS eligible clinicians would receive a negative payment adjustment for the CY 2024 performance year/2026 MIPS payment year if the policies proposed are finalized. **CMS seeks feedback on these proposals, including whether the agency should use means of final scores from alternative years to set the performance threshold for the CY 2024 performance period/2026 MIPS payment year.**

2023 Performance Period*		2024 Performance Period*	
Final Score Points	**MIPS Adjustment**	**Final Score Points**	**MIPS Adjustment**
0.0-18.75	Negative 9%	0.0-20.5	Negative 9%
18.76-74.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale	20.51-81.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale
75.0	0% adjustment	82.0	0% adjustment
75.01-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 75.00 to 100.00 This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.	82.01-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 86.00 to 100.00 This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.

Table 6.

*Illustration of point system and associated adjustments comparison between the CY 2023 performance period/2025 MIPS payment year and the proposed CY 2024 performance period/2026 MIPS payment year

MIPS Value Pathways (MVPs)

In the CY 2020 PFS final rule, CMS established MVPs, which are a subset of measures and activities that are relevant to a specialty, medical condition, or specific patient population, and can be used to meet MIPS reporting requirements. In the CY 2022 and 2023 PFS final rules, CMS finalized and refined policies regarding MVP reporting by subgroup and reporting policies, among several other policies.

New MVPs and Modifications to Existing MVPs

The agency proposes five new MVPs to be available within the 2024 performance year. These proposed MVPs are: (1) focusing on women's health; (2) quality care for the treatment of ear, nose, and throat disorders; (3) prevention and treatment of infectious disease including Hepatitis C and HIV; (4) quality care in mental health and substance use disorders; and (5) rehabilitative support for musculoskeletal care. More information regarding the proposed new MVPs is available in the Proposed Rule (pg. 1982-2002).

In addition, CMS notes that one of the goals of the CMS National Quality Strategy is to implement a "Universal Foundation" of impactful measures across all CMS quality and value-based programs. Among other changes, CMS proposes to consolidate the previously finalized Promoting Wellness MVP and Optimizing Chronic Disease Management MVP into a single primary care MVP (titled Value in Primary Care MVP) that aligns with the adult core set from the Universal Foundation.

Subgroup Reporting

Notably, CMS also proposes changes related to subgroup reporting (the option for clinicians to participate as subgroups for reporting MVPs beginning in the CY 2023 performance period/2025 MIPS payment year). Among other changes, CMS proposes to update the subgroup policy for reweighting of MVP performance categories; update the facility-based scoring and complex patient bonus for subgroups under the final score calculation; update the targeted review policy for subgroups; and codify in regulation policies finalized in previous years' rules. Notably, some of the proposed changes would apply retroactively due to operational implementation issues. More information regarding proposed changes to previously finalized MVPs for the CY 2023 performance period/2025 MIPS payment year and future years is available in the Proposed Rule (pg. 2003-2033).

Also, CMS clarifies the relationship between a subgroup's successful completion of an IA and its impact on the affiliated group. If a subgroup consists of 50 percent or more of the clinicians in the affiliated group, and the subgroup attests to completing an activity, then the group would receive credit for this improvement activity, as this meets the agency's standard for a group's completion of an improvement activity.

APM Performance Pathway (APP)

As noted above, CMS proposes including the Medicare CQM for ACOs participating in the MSSP collection type in the APM Performance Pathway (APP) measure set.

In addition, CMS proposes to end the use of APM Entity-level QP determinations and instead make all QP determinations at the individual eligible clinician level. CMS is also proposing to modify the "sixth criterion" under the definition of "attribution-eligible beneficiary" by including any beneficiary who has received a covered professional service furnished by the National Provider Identifier (NPI) for the purpose of making QP determinations.

CMS proposes to align the requirements for QP and Partial QP threshold percentages for both the payment amount and patient count methods under the Medicare Option and the All-Payer option with the CAA, 2023 requirements for the 2025 payment year. This new threshold will be 3.5 percent of the eligible clinician's estimated aggregate payments for covered professional services. CMS also proposes adjusting the Targeted Review period to address operational challenges.

Advanced APMs

CMS proposes to modify the CEHRT use criterion for Advanced APMs effective CY 2024. CMS will no longer apply the 75 percent CEHRT use minimum for Advanced APMs, and instead specifies that the APM must require all APM participants to use CEHRT as defined in the proposed change to the definition of CEHRT discussed above. Similarly, CMS also proposes to amend the Other-Payer Advanced AOM CEHRT use criterion due the proposed change to the definition of CEHRT.

Transforming the Quality Payment Program

The CMS National Quality Strategy addresses the urgent need for transformative action to advance a more equitable, safe, and outcomes-based health care system for all individuals. Three of the National Quality Strategy goals highlighted in the Proposed Rule are: (1)

Increasing alignment across value-based programs; (2) Advancing health equity; and (3) Accelerating interoperability.

With these strategies in mind**, CMS seeks feedback on how the agency can modify policies under the QPP to foster clinicians' continuous performance improvement and positively impact care outcomes for Medicare beneficiaries. CMS seeks specific feedback on MIPS policies, increasing reporting requirements, adding additional incentives, minimizing provider burden and other feedback related to increasing participation in value-based care.** A full list of questions is available in the Proposed Rule on pg. 965-966.

Regulatory Impact Analysis

CMS seeks, in both the CY 2024 PFS and OPPS Proposed Rules, feedback on how the agency can best quantify the impact of proposed rules on vulnerable populations. CMS identifies demographic factors such as income, race, neighborhood, and health status (i.e., end-stage rental disease) that might be relevant to assessing the impact of proposed payment changes and policies in the various CMS rules. Specifically, for PFS, CMS seeks comment on the best way to analyze these impacts across the various specialties. A full analysis of the impact by specialty is available on pg. 1304 of the Proposed Rule.

What's Next?

CMS typically publishes the PFS final rule by early November, with effective dates of most policies being January 1, 2024. The comment period closes on September 11, 2023.

Vizient's Office of Public Policy and Government Relations looks forward to hearing continued member feedback on this proposed rule. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions or regarding any aspects of this proposed regulation – both positive reactions and provisions that cause you concern. Please direct your feedback to Emily Jones, Regulatory Affairs and Administration Policy Director, in Vizient's Washington, D.C. office.