CY 2023 Medicare Physician Fee Schedule and Quality Payment Program Proposed Rule

On July 7, 2022 the Centers for Medicare and Medicaid Services (CMS) released the calendar year (CY) 2023 Medicare Physician Fee Schedule (MPFS) proposed rule. CMS notes that the MPFS is one of several proposed rules that reflect a broader Administration-wide strategy to create a more equitable health care system that results in better accessibility, quality, affordability, and innovation. Comments are due by September 6th. For additional information please see CMS's CY 2023 MPFS Fact Sheet. Details on key provisions of the proposed rule are provided below.

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A. Potentially Misvalued Services under the PFS (section II.C.)

Proposed Changes

CMS does not consider home-based visit Current Procedural Terminology (CPT®) codes 99344, 99345, 99349, and 99350 as potentially misvalued.

Background/Rationale

In each proposed rule, CMS seeks nominations from the public of codes that they believe CMS should consider as potentially misvalued. An interested party nominated the home-based visit codes and expressed concern that there is no payment for transportation costs incurred when it is medically necessary for a physician to drive to the home of the patient for a face-to-face-in-home evaluation and management (E/M) visit and that they are not compensated for opportunity loss they incur by seeing fewer patients because they spend time commuting to patients' homes, versus seeing more patients that come to their offices. The nominator also argued that Medicare does not compensate physicians for the work and time associated with assessing a patient's home environment, which provides insight into a patient's overall health and living conditions, also known as the social determinants of health (SDoH).

The nominator requested that CMS increase the overall RVUs for CPT codes 99344, 99345, 99349, and 99350, by including the resources associated with: (1) the physician's transportation costs to patients' homes; (2) lost income opportunity for home versus in-office visits; and (3) in-home SDoH assessment work.

CMS notes that when they establish values for codes or consider whether codes are potentially misvalued, they consider the resources involved in furnishing the specific service as described by the CPT code. They highlighted that historically they do not consider (1) travel costs incurred by the physician or other practitioner; (2) potential opportunity costs to a physician or other practitioner when care is delivered in one setting versus another; or (3) the physician or other practitioner's work and time expended in performing activities that are outside the scope of the specific service as described by the CPT code.

These are not considered to be resources involved in furnishing the service, are not included in establishing payment rates under the fee schedule, and do not provide justification for potential misvaluation of those payments.

Comments: N/A

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

Proposed Changes

- **Changes to the Medicare Telehealth Services List**

CMS is proposing to include several additional services to the Medicare CY 2023 Telehealth Services List on a Category 3 basis. These services include telephone E/M therapy, gastrointestinal tract imaging,

ambulatory continuous glucose monitoring, electronic analysis of implanted neurostimulator pulse generator/transmitter, and adaptive behavior treatment and behavior identification assessment.

- **Requests to Add Services to the Medicare Telehealth Services List for CY 2023**

None of the requests received before the submission deadline (February 10th, 2022) met Category 1 or Category 2 criteria, and therefore CMS is proposing no change to services included in the permanent Categories 1 and 2 Service Lists. The requested services were also considered for addition on a temporary Category 3 basis, with some additions through CY 2023.

CMS is proposing no change to the length of time that temporary Category 3 services will remain on the Medicare Telehealth Services List. Category 3 services will be included through CY 2023 unless the publich health emergency (PHE) extends well into CY 2023, in which case CMS may reconsider.

- **Other Services Proposed for Addition to the Medicare Telehealth Services List**

CMS is proposing to create three new codes to describe prolonged services associated with certain types of E/M services. They are: 1) Healthcare Common Procedural Coding System (HCPCS) code GXXX1*(Prolonged hospital inpatient or observation care evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes 99223, 99233, and 99236 for hospital inpatient or observation care evaluation and management services)*, 2) HCPCS code GXXX2 *(Prolonged nursing facility evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes 99306, 99310 for nursing facility evaluation and management services)*, and 3) HCPCS code GXXX3 *(Prolonged home or residence evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes 99345, 99350 for home or residence evaluation and management services)*.

- **Services Proposed for Removal from the Medicare Telehealth Services List after 151 days following the end of the PHE**

CMS is proposing to continue to include on the Medicare Telehealth Services List the services that are currently set to be removed from the list when the PHE ends (not listed on a Category 1, 2, or 3 basis) for an additional 151 days after the PHE ends. CMS is proposing to align those services that had been planned to stop being available as Medicare telehealth at the end of the PHE with the 151-day extensions of flexibilities enacted in the Consolidated Appropriations Act (CAA), 2022.

- **Implementation of Telehealth Provisions of the Consolidated Appropriations Acts, 2021 and 2022**

Aligning with the flexibilities provided by the CAA, CMS is also proposing to extend Medicare Telehealth Services for 151 days after the expiration of the PHE for certain services that would otherwise not be available for telehealth.

CMS also proposes to revise the regulatory text of CAA to recognize the delay of the in-person requirements for mental health visits furnished by Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) through telecommunications technology under Medicare until the 152nd day after the PHE ends.

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

CMS proposes that Medicare telehealth services furnished on or before the 151st day after the end of the PHE, in alignment with proposed extensions above, will continue to be processed for payment as Medicare telehealth claims when accompanied by the modifier "95". CMS further proposes that providers can continue to report the place of service (POS) code that would have been reported had the service been furnished in-person during the 151-day period after the PHE, as determined on an interim basis by the March 31 IFC.

CMS proposes to align telehealth services taking place within a patient's home (POS "10") and those services not provided in a patient's home (POS "02") to be made at the same facility payment amount.

In addition, CMS is proposing that beginning January 1, 2023, a physician or other qualified health care practitioner billing for telehealth services furnished through audio-only communications technology should append CPT modifier "93". The Agency is also proposing to require RHCs, FQHCs, and Opioid Treatment Programs to use modifier "93" when billing for eligible mental health services via audio-only technology.

Finally, the proposed payment amount for HCPCS code Q3014 is $28.61 (telehealth originating site facility fee).

Background/Rationale

- **Changes to the Medicare Telehealth Services List**

CMS created a third category of telehealth services, Category 3, for those services CMS believed there is a likely clinical benefit when furnished via telehealth, but for which there was not enough clinical data to make it a permanent addition under Category 1 or 2.

To add specific services on a Category 3 basis, CMS required that those services show potential likelihood of clinical benefit when furnished via telehealth based on three factors: (1) Whether, outside of the circumstances of the PHE, there are concerns for patient safety if this service is furnished as a telehealth service, (2) Whether, outside of the circumstances of the PHE, there are concerns about whether the provision of the service via telehealth is likely to jeopardize quality of care, and (3) Whether all elements of the service could fully and effectively be performed by a remotely located clinician using two-way audio-visual communications technology.

The table below represents requested service additions to the Medicare Telehealth Services List for CY 2023.

	Service Type	**Codes**	**Proposed Category 3 Additions for CY 2023**
	Lactation classes	S9443	
Category 3	Telephone E/M	99441-99443	99441-99443
Category 1	Therapy	90901, 97110, 97112, 97116m 97150, 97161-97153, 97164, 97530, 97535, 97537, 97542, 97750, 97755, 97763, 98960-98962	97150, 97530, and 97452, 97537, 97763, 90901, and 98960-98963
Category 3	Gastrointestinal tract imaging	91110	
	Ambulatory continuous glucose monitoring	95251	
Category 1	Electronic analysis of implanted neurostimulator pulse generator/transmitter	95976-95977	
Category 3	Electronic analysis of implanted neurostimulator pulse generator/transmitter	05970, 95983-95984	05970, 95983-95984
Category 2	Adaptive behavior treatment and Behavior identification assessment	97151-97158, 0362T, 0373T	97151-97158, 0362T, 0373T

- **Requests to Add Services to the Medicare Telehealth Services List for CY 2023**

For some of the proposed services, CMS has found sufficient evidence of potential clinical benefit to warrant allowing additional time for interested parties to gather data to support their possible inclusion on the Medicare Telehealth Services List on a permanent Category 1 or Category 2 basis.

CMS believes that the proposed Therapy additions to the Medicare Telehealth Services List on a Category 3 basis can be furnished safely as telehealth through the end of 2023. CMS anticipates that keeping these services on a Category 3 basis would preserve access to care and promote health equity.

CMS acknowledges that audio-only technology can be used to furnish mental health services in certain circumstances after the PHE ends but maintains that audio-visual communication technology is the appropriate standard that will apply to Medicare telehealth services after the PHE and 151-extension period. CMS will assign Telephone E/M visit codes with a "bundled" status after the end of the PHE and extension period, and at that point will post the RUC-recommended RVUs for those codes.

Codes describing the electronic analysis of an implanted neurostimulator pulse generator/transmitter were requested as Category 1 additions. Technology to fully furnish this service remotely is forthcoming, and CMS will consider additional evidence as technology evolves.

- **Other Services Proposed for Addition to the Medicare Telehealth Services List**

The proposed HCPCS G codes are similar to services currently on the Medicare Telehealth Services List, such as CPT codes 99356 and 99357, which were added to the Medicare Telehealth Services List on a Category 1 basis in the CY 2016 rule as well as O/O prolonged service HCPCS code G2212. Similarly, CMS believes that these codes would be sufficiently similar to psychiatric diagnostic procedures or O/O visits currently on the Medicare Telehealth Services List to qualify for inclusion on the list on a Category 1 basis.

- **Services Proposed for Removal from the Medicare Telehealth Services List after 151 days following the end of the PHE**

CMS believes this alignment will simplify the process when these flexibilities end and will minimize potential errors.

- **Implementation of Telehealth Provisions of the Consolidated Appropriations Acts, 2021 and 2022**

CMS believes this approach will ensure a smooth transition after the end of the PHE.

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

CMS believes that the facility payment amount best reflects the practice expenses, direct and indirect, involved in delivering services via telehealth.

CMS believes that using the modifier "93" will simplify billing for audio-only telehealth services, since the same modifier is used by payers outside of Medicare.

Comments

- **Requests to Add Services to the Medicare Telehealth Services List for CY 2023**

CMS is interested in information about Gastrointestinal Tract Imaging and Continuous Glucose monitoring services and seeks comment in order to determine whether these are inherently non-face-to-face services, and therefore may not fit within the scope of services that could be furnished as Medicare telehealth services.

CMS has concerns about general brain nerve neurostimulation codes and is soliciting comments regarding patient safety and whether these services are appropriate for permanent inclusion on the Medicare Telehealth Services List.

CMS is also soliciting comments regarding patient safety for the adaptive behavior treatment and behavior identification assessment codes because this patient population often includes individuals with moderate to severe challenges in oral communication and may require close observation of their movements within all environmental cues.

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

CMS seeks comment on whether the flexibility to meet the immediate availability requirement for direct supervision through the use of real-time, audio/visual technology should be made permanent. Also seeking comment on the possibility of permanently allowing immediate availability for direct supervision through virtual presence for a subset of services, and where patient safety should be a concern.

C. Valuation of Specific Codes (section II.E.)

Proposed Changes

- **Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap**

CMS notes the list of services for the upcoming calendar year that are subject to the MPPR are diagnostic cardiovascular services, diagnostic imaging services, diagnostics ophthalmology services, and therapy services. The public use files and more information regarding the history of the MPPR policy can be found here.

- **Caregiver Behavior Management Training**

Caregiver training codes, CPT codes 96X70 and 96X71, are new codes to be used to report the total duration of face-to-face time spent by providers providing group training to guardians and caregivers of patients. Patients do not attend, but the focus of the session is still related to improving the patient's daily quality of life. This face-to-face time is valuable for caregivers to learn how to structure the patient's environment to support and reinforce desired patient behaviors, reduce negative impacts of the diagnosis on the patient's daily life, and develop technical skills to manage patient behavior.

CPT codes 96X70 and 96X71 are not payable under the physician fee schedule since Medicare payment is generally limited to those items and services that refer to treating the injured or ill patient themselves.

- **Chronic Pain Management and Treatment Bundles**

CMS proposes to create separate coding and payment for Chronic Pain Management and Treatment (CPM) services beginning January 1, 2023, by creating two HCPCS G-codes to describe monthly CPM services. These codes are: 1) GYYY1 (*Chronic pain management and treatment, monthly bundle including, diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, and maintenance of a person-centered care plan that includes*

strengths, goals, clinical needs, and desired outcomes; overall treatment management; facilitation and coordination of any necessary behavioral health treatment; medication management; pain and health literacy counseling; any necessary chronic pain related crisis care; and ongoing communication and care coordination between relevant practitioners furnishing care (e.g. physical therapy and occupational therapy, and community based care), as appropriate. Required initial face-to-face visit at least 30 minutes provided by a physician or other qualified health professional; first 30 minutes personally provided by physician or other qualified health care professional, per calendar month. (When using GYYY1, 30 minutes must be met or exceeded.)) and 2) GYYY2 (*Each additional 15 minutes of chronic pain management and treatment by a physician or other qualified health care professional, per calendar month (List separately in addition to code for GYYY1). (When using GYYY2, 15 minutes must be met or exceeded.)*).

CMS is proposing to include development/revisions to a person-centered care plan that includes goals, clinical needs, and desired outcomes and health literacy counseling as elements of the CPM codes.

These codes could be billed in the same month as a care management service, such as chronic care management or behavioral health integration.

- **Proposed Revisions to the "Incident to" Physician's Services Regulation for Behavioral Health Services**

In support of CMS' 2022 Behavioral Health Strategy to improve access to and quality of mental health care services, CMS proposes to amend the direct supervision requirement under "incident to" legislation to allow behavioral health services to be provided under the general supervision of a physician or nonphysician practitioner (NPP) when these services are provided by auxiliary personnel. CMS believes that this revision may help to reduce existing barriers and make better use of the services of Licensed Professional Counselors and Licensed Marriage and Family Therapists.

In alignment with CMS' 2022 Behavioral Health Strategy goal to increase detection, effective management, and recovery of mental health conditions, CMS is proposing to create a new G code describing General behavioral health integration performed by Clinical Psychologists and Clinical Social Workers to account for monthly care integration. The proposed new code is GBHI1 (*Care management services for behavioral health conditions, at least 20 minutes of clinical psychologist or clinical social worker time, per calendar month, with the following required elements: initial assessment or follow-up monitoring, including the use of applicable validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; facilitating and coordinating treatment such as psychotherapy, coordination with and/or referral to physicians and practitioners who are authorized by Medicare law to prescribe medications and furnish E/M services, counseling and/or psychiatric consultation; and continuity of care with a designated member of the care team*). The payment rate for the new General BHI code would be based on the payment rate for the current general BHI code, 99484.

Background/Rationale

- **Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap**

The public use files and more information regarding the history of the MPPR policy can be found here.

- **Caregiver Behavior Management Training**

These codes are not payable under the MPFS because Medicare does not pay for services that are furnished to parties other than the beneficiary. Medicare payment is generally limited to those items and services that are reasonable and necessary for the diagnosis or treatment of illness or injury or that improve the functioning of a malformed body member.

- **Chronic Pain Management and Treatment Bundles**

The CPM code family has five sets of codes, each with a base code and an add on code. No existing CPT code specifically describes the work of the clinician who performs comprehensive, holistic CPM. The resources involved in providing CPM services to beneficiaries are not appropriately recognized under current coding/payment mechanisms.

CMS expects that creating separate coding and payment for CPM will help facilitate the development of data regarding the prevalence and impact of chronic pain on the Medicare population. CMS believes that the comprehensive care management involved in CPM services may reduce the need for acute services (emergency department care, etc.), and has the potential to reduce the need for concurrent behavioral health disorders.

Adequate health literacy may improve a patient's capability to take responsibility for their health, including pain-related health issues such as adherence to treatment regimens and medical administration. Overall, including CPM health literacy may have a positive influence on health outcomes and reduce health disparities.

Comments

- **Caregiver Behavior Management Training**

CMS is seeking comments about the services described by CPT codes 96X70 and 96X71. They are interested in learning the ways in which a patient may benefit when caregivers receive education about modifying patient behavior. They are also interested in comments on how current Medicare policies regarding these caregiver training services may impact beneficiary health. They are also seeking comments regarding how the services described by these codes may be bundled into Medicare covered services, as some part of care management codes.

- **Chronic Pain Management and Treatment Bundles**

CMS defines chronic pain as "persistent or recurrent pain lasting longer than three months." They are seeking comment as to whether this definition is appropriate, or whether it should consider some other interval or description. They are also interested in comments relating to how chronic pain should be documented in the medical record.

CMS welcomes comments related to conducting initial and subsequent visits (in-person, via telehealth, via telecommunications system, etc.) and any implications for different coding. CMS will also consider comments relating to whether to add CPM codes to the Medicare Telehealth Services List.

CMS believes that most CPM services would be billed by primary care practitioners. They are seeking comments related to permitted billing by non-primary care providers after the GYYY1 has already been

billed in the same month by a different practitioner. They are interested in the number of times the code could be appropriately billed per month, per beneficiary.

CMS is seeking comment as to whether there are elements of CPM care that have not been identified and should be added to the code descriptors.

CMS is seeking comment on which, if any, CPM services could be furnished as "incident to" services.

The proposed work value for HCPCS code GBHI1

CMS is seeking comment as to whether the proposed value for new code GBHI1 (0.61) accurately reflect the resource costs involved in providing behavioral health care, or whether additional coding is needed (i.e. Separate coding for Clinical Psychologists (CPs) and Clinical Social Workers (CSWs), etc.). They are also interested in comments on the proposed requirements for billing GBHI1, including "incident to" requirements and role/responsibilities of CPs and CSWs.

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

CMS is interested in learning how payments between health care providers working with CHWs may have established nontraditional relationships. They are further interested in payments between stakeholders that account for the costs of services provided by CHWs, and how providers ensure that the funding amount is sufficient to cover the full costs of CHW services. They are seeking comment as to whether, and to what extent, CHW services are provided in association with preventative services covered by Medicare.

- **Request for Information: Medicare Potentially Underutilized Services**

CMS is seeking comments on ways to identify specific services and recognize possible barriers to improved access to high value, potentially underutilized services by Medicare beneficiaries. Further seeking comment related to mitigating these obstacles, through conditions of payment, payment rates for these services, or by prioritizing beneficiary and provider education.

CMS is seeking comment on how to best define and identify high-value, potentially underutilized services, as well as what existing services within current Medicare benefits may represent high value care.

CMS is specifically seeking innovative ideas to help broaden perspectives about potential solutions, including educational/marketing strategies, aligning of Medicare and other payer coding, payment, and documentation requirements, enabling of operational flexibility, etc.

- **Comment Solicitation on Payment for Behavioral Health Services under the PFS**

CMS is seeking comment on how best to ensure beneficiary access to behavioral health services, including any potential adjustments to the PFS rate setting methodology.

D. Evaluation and Management Visits (section II.F.)

Proposed Changes

- **Other Evaluation and Management (E/M) Visits**

CMS is proposing to create Medicare-specific coding payment of 'Other E/M' prolonged services, like what CMS adopted in CY 2021 for payment of Office/Outpatient prolonged services. Specifically, CMS is proposing to adopt the general CPT framework for Other E/M visits, so that practitioner time or medical decision making (MDM) would be used to select the E/M visit level. This includes listing the qualifying activities by the physician or nonphysician practitioner (NPP) that count toward the time spent when time is used for the visit level. Notably, history or present illness and a physical exam will only be considered when and to the extent they are medically appropriate and will not impact the Other E/M visit level. A billable unit of time will only be considered attained when more than half of the total time is satisfied by the practitioner who bills the visit.

CMS is proposing to adopt the revised CPT codes and descriptors for Other E/M visits, except for prolonged services, which CMS proposes Medicare-specific coding. Additionally, CMS is proposing to adopt the CPT E/M Guidelines regarding MDM for E/M services.

CMS is proposing to include the new add-on code G2211, which describes the complexity inherent to E/M visits associated with primary care and other similar types of care; this aligns with the values established for the revised O/O E/M CPT codes in the CY 2021 PFS final rule. Notably, the CAA, 2021 delayed Medicare payment for G2211 until at least January 1, 2024.

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

CMS is proposing a work RVU of 1.00 for CPT code 99341, a work RVU of 1.65 for CPT code 99342, a work RVU of 2.87 for CPT code 99344, a work RVU of 3.88 for CPT code 99345, a work RVU of 0.90 for CPT code 99347, a work RVU of 1.50 for CPT code 99348, a work RVU of 2.44 for CPT code 99349, and a work RVU of 3.60 for CPT code 99350.

In addition, CMS is proposing to refine the direct PE inputs by removing supply item SK062 (codes 99341 and 99342). For CPT code 99344, CMS is proposing to refine the direct PE inputs by removing supply items SK062, SJ053, and SJ061. Notably, for CPT codes 99341, 99342, and 99347 CMS is proposing to remove supplies that would be duplicative, such as gloves, alcohol wipes, booklet, and tongue depressors.

- **Prolonged Services for Home or Residence Services (CPT Codes 99358, 99359)**

CMS is proposing that prolonged home or residence services by a physician or NPP would be reportable under GXXX3, which would be reportable when the total time exceeded is by 15 or more minutes. Prolonged services would be reportable as an add-on code to CPT codes 99345 or 00350 once the practitioner spends 15+ minutes beyond the total time finalized for the primary service. Given that CMS is proposing that prolonged services with or without direct patient contact would be reportable under GXXX3, CMS is also proposing that CPT codes 99358, 99359, and 99417 cannot be billed for CPT codes 99345 and 99350. Notably, CMS is proposing to change the status indicator for CPT codes 99358 and 99359 to "I," which indicates that these codes are not valid for Medicare purposes.

- **Split (or Shared) Services**

CMS is proposing to delay the split (or shared) visits policy finalized in CY 2022 for the definition of substantive portion, as more than half of the total time, for one year with a few exceptions. Specifically, CMS is proposing to amend the regulations text at 42 CFR 415.140 to revise the definition of substantive portion and note the current definition of substantive portion applies for visits other than critical care visits furnished in CY 2022 and CY 2023. The proposed paragraph would specify that substantive portion means one of the three key components, history, exam, or MDM or more than half of the total time spent by the physician and NPP performing the split (or shared) visit. Further, CMS is proposing to delay implementation of their definition of the substantive portion as more than half of the total time until January 1, 2024.

Background/Rationale

- **Other E/M Visits**

The AMA CPT Editorial Panel revised the rest of the E/M visit code families, except critical care services to match the general framework of the O/O E/M visits, including inpatient and observation visits, emergency department (ED) visits, nursing facility visits, domiciliary or rest home visits, home visits, and cognitive impairment assessment. These other E/M visit code families are referred to as "Other E/M" visits or CPT codes. The Other E/M visits will parallel the O/O E/M visits, where visit level will be selected based on the amount of practitioner time spent with the patient. Notably, history or present illness and a physical exam will only be considered when and to the extent they are medically appropriate and will not impact the Other E/M visit level. Several Other E/M CPT codes were consolidated, with inpatient and observation visits being combined into a single code set and home and domiciliary visits being combined into a single code set. The number of Other E/M CPT codes will decrease to 50 in 2023, compared to 75 in 2022.

- **Prolonged Services for Home or Residence Services**

CMS is concerned about program integrity, duplicative time, counting time that was not included in the surveyed timeframe, the administrative complexity of having multiple prolonged service codes, and their ability to determine how much time was spent with a patient using claims data. CMS did not propose to accept the CPT coding for prolonged home or residence E/M visits because they would be unable to identify the time spent with patients in the claims data alone. As CMS discussed in CY 2020 PFS final rule, many other codes are available to report prolonged E/M work associated with an E/M visit that occurs outside of the timeframe included in the visit.

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

In February 2021, the CPT Editorial Panel deleted the nine CPT codes in the Domiciliary, Rest Home, or Custodial Care Services code family (CPT codes 99324-99328, and 99334-99337) and one CPT code in the Home Services family (CPT code 99343), to merge with the eight remaining home visit services. The remaining home services CPT codes were revised to describe Home or Residence Services to align with the principles of the O/O E/M visit codes by allowing physicians and NPPs to document and select the level of service based on total practitioner time or MDM level.

For CY 2023, the home and domiciliary E/M code family will be revised by the CPT to include services provided in assisted living facilities, group homes, custodial care facilities, residential substance abuse treatment facilities, and a patient's home. Additionally, the descriptors that allow reporting based on time or MDM level was revised to align with the O/O E/M visit CPT codes.

- **Split (or Shared) Services**

The split (or shared) "substantive portion" policy for services furnished in facility settings was reflected in sub regulatory guidance until it was withdrawn in May 2021, in response to a petition under the Good Guidance regulation. In CY 2022 PFS final rule, a policy for E/M visits furnished in a facility setting allowed payment to a physician for a split (or shared) visit (including prolonged visits), where a physician and NPP provide the services together (not necessarily concurrently) and the billing physician personally performs a substantive portion of the visit.

A split (or shared) visit refers to an E/M visit performed by both a physician and an NPP in the same group practice. Longstanding, CMS policy has been that, for split (or shared) visits in the facility setting, the physician can bill for the services if they perform a substantive portion of the encounter. CMS defined the phrase "substantive portion" in CY 2022 PFS final rule as one of the following: history, or exam, or MDM, or more than half of total time. In CY 2022 PFS final rule, CMS finalized that for CY 2023, the definition of "substantive portion" is more than half of total time.

CMS is aware of concern about the implementation of their phased in approach regarding using only more than half of the total time to define the substantive portion of the visit. Additionally, CMS recognizes the requests to include MDM as the substantive portion. CMS believes it is appropriate to define the substantive portion of a split (or shared) service as more than half of the total time and propose that this policy be effective starting January 1, 2024. With this timeframe that includes delaying implementation, the changes in the coding and payment policies of Other E/M visits would take effect for CY 2023. Despite believing the definition of substantive portion that was finalized in CY 2022 PFS final rule is accurate, CMS recognizes the value in allowing for a one-year transition period for providers and get accustomed to these new changes. This delay also allows interested parties an opportunity to comment on this policy and gives CMS time to consider the potential feedback and made any changes necessary.

Comments: N/A

E. Geographic Practice Cost Indices (GPCI) (section II.G.)

Proposed Changes

- **Phasing in GPCI Adjustment**

CMS proposes to phase in ½ of the proposed GPCI adjustment in CY 2023 and the remaining ½ of the adjustment for CY 2024.

- **Adjustments and Use of Medicare Economic Index (MEI) Cost Share Weights**

CMS is proposing to continue determining the proposed PE GPCI values using the current 2006-based Medicare Economic Index (MEI) cost share weights to weight the four components of the PE GPCI values: employee compensation, office rent, purchased, services, and medical equipment or supplies.

CMS is proposing to rebase and revise the MEI cost share weights for CY 2023, including:

  - Changing the work expense category to 47.261%
  - Changing the practice expense category to 51.341%
  - Changing the employee compensation expense category to 24.716%
  - Changing the office rent expense category to 5.893%
  - Changing the purchased services expense category to 13.914%
  - Changing the equipment, supplies, and other expense category to 6.819%
  - Changing the malpractice insurance expense category to 1.398%

- **Refinement to Unique Fee Schedule Areas in California**

CMS is proposing to identify the Los Angeles-Long Beach-Anaheim metropolitan statistical area (MSA), containing Orange County and Los Angeles County, by one unique locality number, 18, as opposed to two, thus retiring locality number 26, as it is no longer needed. The Los Angeles-Long Beach-Anaheim (Los Angeles Cnty) locality (locality 18) would become Los Angeles-Long Beach-Anaheim (Los Angeles/Orange Cnty).

CMS is proposing to identify the San Francisco-Oakland-Berkely MSA containing San Francisco, San Mateo, Alameda, and Contra Costa counties by one unique locality number, 05, as opposed to four, thus retiring locality numbers 06 and 07, as they are no longer needed. The San Francisco-Oakland-Berkeley (San Francisco Cnty) locality (locality 05) would become San Francisco-Oakland-Berkeley (San Francisco/San Mateo/Alameda/Contra Costa Cnty).

- **Modifications to GPCI Methodology**

CMS is proposing to add two new occupation groups (and their corresponding occupation codes) to the preexisting seven occupation groups for CY 2023: Management Occupations; and Business and Financial Operation Occupations.

CMS is proposing to add four occupation codes to the Computer, Mathematical, Life, and Physical Science group for CY 2023: 15-1212: Information Security Analysts; 15-1257: Web Developers and Digital Interface Designers, 15-1241: Computer Network Architects; and 19-1099: Life Scientists, All Other.

CMS is proposing to add three occupation codes to the Social Science, Community and Social Service, and Legal group for CY 2023: 19-5011: Occupational Health and Safety Specialists; 21-1099: Community and Social Service Specialists, All Other; and 23-1012: Judicial Law Clerks.

CMS is proposing to modify the list of occupation codes used within the first PE GPCI component, Employee Wages to include six occupation codes that were inadvertently excluded. These occupation codes are listed as sources for clinical labor rates used to establish practice expense RVUs in PFS rate setting.

CMS is proposing to use the share of RVUs reflected in recent Medicare utilization data as weights when calculating the CY 2023 Geographic Adjustment Factors (GAFs) as opposed to using the 2006-based MEI cost share weights.

Background/Rationale

- **Phasing in GPCI Adjustment**

In accordance with section 1848(e)(1)(c) of the Act, CMS is required to review and adjust GPCIs at least every three years and if more than one year has elapsed since the date of the last previous GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be ½ of the adjustment that otherwise would be made.

- **Adjustments and Use of Medicare Economic Index (MEI) Cost Share Weights**

CMS believes that implementing these proposals will allow interested parties the opportunity to review and comment on the proposed rebased and revised MEI cost share weights and their potential impacts before the actual use of such weights for purposes of proportion to the work. Additionally, it would maintain consistency in the data used to update both the GPCI and PFS rate setting inputs for CY 2023.

- **Refinement to Unique Fee Schedule Areas in California**

CMS notes that since these areas are not transition areas, they are ineligible for GPCI value incremental phase-in or the hold-harmless provision. Moreover, these localities will receive the same GPCI values, for payment purposes, going forward, making it unnecessary to have multiple locality numbers.

- **Modifications to GPCI Methodology**

These proposals were created in an effort to produce GAF's that more accurately reflect the composite effect of geographic adjustments on payment year over year. Additionally, this will allow the use of current Medicare utilization data that are available each year, as opposed to the MEI cost share weights that are not updated as frequently.

In addition, CMS explains that these proposals are designed to yield improved mathematical precision by providing for a more accurate, full landscape of occupations that should be accounted for, and by aligning the GAF equation weights to use routinely available data.

Comments

- **Adjustments and Use of Medicare Economic Index (MEI) Cost Share Weights**

CMS is seeking comment on the delay in implementation of the MEI cost share weights for the purposes of the CY 2023 and GPCI's and PFS rate setting. CMS is also inviting comments on how best to proceed with implementation of the rebased and revised MEI cost share weights in the future. Specifically, the Agency seeks comment on how best to incorporate the MEI cost share weights into the PE GPCI if they were to implement them outside the statutorily required triennial update in which CMS phases in all aspects of the GPCI update through the 2-year phase-in. Additionally, CMS is seeking comment on potentially incorporating the rebased and revised MEI cost share weights into the CY 2024 GPCIs.

CMS is soliciting comment on whether it would be appropriate to use a multi-year transition to incorporate the rebased and revised MEI cost share weights for purposes of the PE GPCI and PFS rate setting, or if, because the MEI cost share weights only impact the composition of the PE GPCI, such a transition would not be warranted.

CMS is seeking comment on whether it would be appropriate, if CMS were to apply the rebased and revised MEI cost share weights for CY 2025 for the purposes of PE GPCI, to apply a transition to implement the MEI cost share weights for purposes of PFS rate setting as well.

- **Refinement to Unique Fee Schedule Areas in California**

CMS is seeking comment on the proposed technical refinements to consolidate unique fee schedule areas and their locality numbers in California where the unique localities are not operationally necessary. (see proposals IV and V)

F. Determination of Malpractice Relative Value Units (RVUs) (II.H.)

Proposed Changes

- **Revised Methodology for Inputting Risk Factor Values for Specialties with Incomplete Data**

CMS is proposing to revise the methodology for inputting risk factor values for specialties that have incomplete data in insurer filings. Insurer filings sometimes do not include all CMS specialties or use unique specialty names. In the proposed imputation methodology, CMS would use rates from the more commonly reported specialty within the same risk class for specialties with incomplete data. Previously, underrepresented filing data would be excluded. This proposed change would improve collection of risk value input data and help CMS develop a more comprehensive data set.

- **Creation of a Risk Index for the Calculation of MP RVUs**

When calculating MP RVUs, CMS is proposing to use a MP risk index. To calculate the proposed risk index, there would be a ratio of the specialty's national average premium to the volume-weighted national average premium for all specialties. Historically, CMS utilized derived risk factors, which is a ratio of a specialty's national average premium to a single referent specialty's national average premium. The denominator in the ratio was typically based on Allergy/Immunology specialty's national average premium.

- **3-Year Phase-in Reduction of MP RVUs for Specialties with 30 Percent or More Reduction in Risk Index Value**

The proposed methodological improvements in this rule for calculating MP RVUs could result in lower premiums and risk index values for some specialties compared to those that had incomplete data and underwent the revised methodology. CMS identified an approximate 1/3 reduction to the risk index for specialties with the new specialty-specific premium data compared to the information previously used. For specialties with a 30 percent or greater reduction in the CY2023 risk index compared to CY2022 due to the newly available premium data, CMS proposes to phase in a MP RVUs reduction over the three years prior to the next update. The reduction would be 1/3 of the change in MP RVUs for those specialties each year in which the updated methodology results in a 30 percent or more reduction in risk index value.

The list of specialties that would be subject to the phase-in under this proposed policy, and the corresponding risk index values for each specialty is available on the CMS website under downloads for the CY 2023 PFS proposed rule at http://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

Background/Rationale

- **Revised Methodology for Inputting Risk Factor Values for Specialties with Incomplete Data**

CMS is proposing to utilize this small improvement for collecting risk value input data in the future, as this retains as much data as possible and maps specialties more intentionally.

- **Creation of a Risk Index for the Calculation of MP RVUs**

CMS believes that the change is expected to increase consistency in MP RVUs calculation because the MP risk index would reflect changes in payment. CMS does not expect the proposal to impact the pricing of services in the PFS because it does not change relative risk across specialties.

- **3-Year Phase-in Reduction of MP RVUs for Specialties with 30 Percent or More Reduction in Risk Index Value**

We propose to phase in the reduction in MP RVUs over 3 years rather than 2 years because the MP risk index values are updated every 3 years.

Comments:

CMS is soliciting public comment on the proposed list of codes and expected specialties for CY 2023.

G. Proposal to Allow Audiologists to Furnish Certain Diagnostic Services Without a Physician Order (section II.K.)

Proposed Changes

- **Amend Regulations to 410.31(a)(4) to Provide Limited Exception to Physician/NPP Order Requirements for Audiology Services**

CMS is proposing to add a paragraph at § 410.32(a)(4) to remove the physician/NPP requirement for diagnostic hearing testing services furnished personally by audiologists for non-acute hearing conditions. The change excludes balance assessments that are used for patients with disequilibrium. Services may be performed once every 12 months without a physician/NPP order. Beneficiaries may still visit a physician/NPP to receive an order but must otherwise wait 12 months to receive another service without a prior physician/NPP order. All tests provided and the results must be documented in the beneficiaries' medical records.

- **Create HCPCS Code GAUDX to Describe Audiology Services Not Requiring a Physician/NPP Order**

CMS is proposing to create HCPCS code GAUDX, which encompasses audiology services furnished personally by an audiologist without a physician/NPP order for non-acute hearing assessment unrelated to

disequilibrium, or hearing aids or examinations for the purpose of prescribing, fitting, or changing, hearing aids. Audiologists can bill one unit of code GAUDX every 12 months for a beneficiary. The new code is generic, so tests provided could include those split into PC/TC and those that are not.

Background/Rationale

- **Amend Regulations to 410.31(a)(4) to Provide Limited Exception to Physician/NPP Order Requirements for Audiology Services**

In the CY 1997 PFS final rule, CMS established in regulations § 410.31(a), that all diagnostic tests, including audiology tests, must be ordered by the physician who is treating the beneficiary who will use the results to manage the beneficiary's care. These regulations have not been substantively amended since 1997. In 2008, CMS allowed audiologists to enroll in the Medicare program so they could bill independently for their audiology services rather than relying on physicians or other enrolled partitioners to bill on their behalf.

Stakeholders shared a report with CMS showing that the removal of a physician ordering requirement would save Medicare approximately $108 million over a decade. Orders are not required for audiology services by certain public or private health insurers including Medicare Advantage plans and Medicaid.

However, CMS is concerned about patient safety if Medicare patients seek hearing or balance services without involvement from a treating physician or NPP. Therefore, CMS believes that patients with disequilibrium are better served by visiting a physician or NPP first.

- **Create HCPCS Code GAUDX to Describe Audiology Services Not Requiring a Physician/NPP Order**

CMS believes excluding CPT codes for vestibular dysfunction from the HCPCS code GAUDX addresses concerns over patient safety. Providing a limitation on the frequency of these services avoids potential program integrity issues, such as audiologists billing for GAUDX with a greater frequency or providing services that are not reasonable and necessary for the treatment of the patient's illness or injury. CMS chose a 12-month period because six months was too short of a timespan for a new, non-acute hearing condition to arise. Additionally, beneficiaries may still visit their physician or a NPP to receive an order.

CMS believes the proposed HCPCS code GAUDX will allow them to better understand the scope of beneficiary access to these services with or without the order requirement. Additionally, CMS believes the proposed code will help to better assess possible burdens to the beneficiary when attempting to access these services.

Comments:

- **Create HCPCS Code GAUDX to Describe Audiology Services Not Requiring a Physician/NPP Order**

CMS requests comments from interested parties about what settings might represent the typical places of service and which institutional providers might bill for HCPCS code GAUDX.

H. Rebasing and Revising the Medicare Economic Index (MEI) (section II.M.)

Proposed Changes

- **New Data Source for Calculating 2017-based MEI Cost Weights**

CMS is proposing utilizing data from the U.S. Census Bureau's Services Annual Survey (SAS), which is a publicly available data source that incorporates costs from all types of physician practice ownership (i.e. not only self-employed physicians). Supplemental data from the following sources will also be incorporated, to further disaggregate compensation and other residual costs:

  - 2017 Bureau of Labor Statistics (BLS) Occupational Employment and Wage Statistics (OEWS)
  - 2012 Bureau of Economic Analysis (BEA) Benchmark Input-Output data (I/O)
  - 2006 AMA PPIS
  - 2020 AMA Physician Practice Benchmark Survey.

- **New Methodology for Calculating MEI Cost Weights**

CMS is proposing new methodologies for calculating the weights of each of the cost categories used in the MEI. For more details, please refer to pages 464 – 481 in the MPFS proposed rule.

Table 37 summarizes the proposed 2017 price proxies by cost category.

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

Proposed 2017-based Medicare Economic Index		
Cost Category	2017	2017 Price Proxy
MEI Total	**100.000%**	
Physician Compensation	**47.261%**	
Wages and Salaries	39.227%	ECI - Wages and salaries for Private industry workers in Professional and related
Benefits	8.034%	ECI - Total Benefits for Private industry workers in Professional and related
Practice Expense, including PLI	**52.739%**	
Non-physician compensation	**24.716%**	
Non-physician wages	**20.514%**	
Non-health, non-physician wages	12.306%	
Professional and Related wages	1.381%	ECI - Wages and salaries for Private industry workers in Professional and related
Management wages	2.171%	ECI - Wages and Salaries for Private Industry workers in Management, Business, and Financial
Clerical wages	7.947%	ECI - Wages and Salaries for Private Industry workers in Office and Administrative Support
Services wages	0.807%	ECI - Wages and Salaries for Private Industry workers in Service Occupations
Health related, non-physician wages	8.208%	ECI - Wages and salaries for All Civilian workers in Hospitals
Non-physician benefits	**4.202%**	Composite - ECI - Total Benefits for the 5 non-physician wage categories
Other Practice Expense	**28.023%**	
Utilities	0.366%	CPI - Fuels and utilities
All Other Products	2.055%	PPI - Final demand - Finished goods less foods and energy
Telephone	0.471%	CPI - Telephone Services
All Other Professional Services	**13.914%**	
Professional, Scientific, and Technical Services	6.350%	ECI - Total compensation for Private industry workers in Professional, scientific, and technical services
Administrative support & waste	2.341%	ECI - Total compensation for Private industry workers in Office and administrative support
All Other Services	5.223%	ECI - Total compensation for Private industry workers in Service occupations
Capital	**7.748%**	
Fixed Capital	5.527%	PPI - Industry - Lessors of nonresidential buildings
Moveable Capital	2.221%	PPI - Commodity - Machinery and equipment
Professional Liability Insurance	**1.398%**	**CMS - Professional Liability Insurance Index, physicians**
Medical supplies	2.071%	Composite: PPI - Commodity - Medical and surgical appliances and supplies (50%), PPI - Commodity - Surgical and medical instruments (50%)

- **Proposed New MEI Cost Category Weight Changes**

As a result of the new data sources and calculation methodology, several of the proposed 2017 cost weights differ from the 2006-based cost weights. These changes are detailed in Table 30 (pg. 464) and summarized

by the RVU Components in Table 38 (pg. 490). The resulting average calendar year percent change for 2016 to 2023 are illustrated in Table 39 (pg. 490).

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

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

TABLE 38: Percent Distribution of Major Physician Expense Components: 2006 and 2017

	Weight	
RVU Component	Current	Proposed
	2006	2017
Physician Work	50.9%	47.3%
Practice Expense	44.8%	51.3%
Malpractice or PLI	4.3%	1.4%
Total	100.0%	100.0%

TABLE 39: Annual Percent Changes in the 2006-Based and the Proposed 2017-based MEI

Update Year[1]	Proposed 2017-based MEI	2006-based MEI
2016	1.4	1.2
2017	1.3	1.1
2018	1.5	1.4
2019	1.8	1.6
2020	1.9	1.8
2021	1.7	1.5
2022	2.2	2.1
2023	3.8	3.7
Average Change	2.0	1.8

[1]Update year based on historical data through the second quarter of the prior calendar year. For example, the 2020 update is based on historical data through the second quarter 2019.

Background/Rationale

CMS is proposing to delay implementation of the rebased and revised MEI previously described for both the PFS rate setting and proposed CY 2023 GPCIs to allow stakeholders to review the proposal and provide comments.

- **New Data Source for Calculating 2017-based MEI Cost Weights**

The MEI is an index calculated by CMS to reflect the weighted-average annual price change for various economic elements related to physicians' services. It incorporates two categories of expenses: physician compensation and physician practice expenses.

The current MEI is based on data collected in 2006 by the American Medical Association for self-employed physicians through the Physician Practice Information Survey (PPIS). Based on comments from the MEI Technical Advisory Panel, CMS believes that the MEI cost weights need to be updated to reflect more current market conditions and the trend toward larger or hospital-owned practices.

- **New Methodology for Calculating MEI Cost Weights**

As the SAS data reflects a different provider population, and is structured differently from the PPIS data, CMS needs to correspondingly adapt its previous MEI cost weight calculation. CMS also elected to incorporate additional datasets into its methodology to disaggregate some SAS measures and ensure that cost categories were proportionally estimated and weighted.

- **Proposed New MEI Cost Category Weight Changes**

The proposed 2017-based MEI cost weight for individual cost categories differ from the 2006 cost weights between 0.5 – 8.6 percentage points. CMS states that these differences are due to two key factors: (1) any changes that occurred in the cost to provide physician services between 2006 and 2017, and (2) the SAS data reflects relative costs for all physician ownership practices while the 2006 AMA PPIS data reflected relative costs only for self-employed physician practices.

Comments:

- **New Data Source for Calculating 2017-based MEI Cost Weights**

CMS is soliciting comments on the proposed delay and potential use of the proposed updated MEI cost weights in future years to recalibrate the RVU shares and to update the GPCI cost share weights, which were last realigned to the revised MEI weights in the CY 2014 PFS final rule (78 FR 74380 through 74391).

I. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (section III.B.)

Proposed Changes

- **New Care Management Codes for Chronic Pain Management (CPM) and General Behavioral Health Integration (GBHI)**

CMS is proposing to allow separate payment for CPM services in RHCs and FQHCs to reflect the additional time and resources necessary for the unique components of care coordination services. CMS is not proposing to utilize the add-on HCPCS code GYYY2 for RHC/FQHC payments because RHCs and FQHCs do not pay their practitioners based on additional minutes spent by practitioners. CMS is also proposing to allow clinical psychologists and clinical social works in RHCs and FQHCs to bill for the new GBHI code.

If finalized as proposed, RHCs and FQHCs that furnish the new CPM and GBHI services performed by clinical psychologists and clinical social workers would be able to bill these services using HCPCS code G0511, either alone or with other payable services on an RHC or FQHC claim for dates of service on or after January 1, 2023.

- **Telehealth Flexibilities for Mental Health Visits After the COVID-19 Public Health Emergency (PHE) Ends**

Mental health visits may continue to be provided via telehealth, as established under the PHE, until the 152nd day after the end of the COVID-19 PHE.

Background/Rationale

- **New Care Management Codes for Chronic Pain Management (CPM) and General Behavioral Health Integration (GBHI)**

RHCs generally are paid via an all-inclusive rate (AIR) for all of an individual's medical and mental health services, under a determined payment limit. FQHCs are funded either through prospective payment system (PPS) rate or the center's actual charges, whichever is lower. The AIR and PPS rates were intended to

reflect the total costs of care and supplies that the RHC or FQHC provides to the patient in a single visit, however CMS recognized that these rates did not account for patient complexity, length of stay, or the number of practitioners providing care. Since 2016 CMS has been establishing separate procedural codes for essential and ongoing care management services provided by RHCs and FQHCS including: Chronic Care Management (CCM), Behavioral Health Integration (BHI), and Principal Care Management (PCM).

- **Telehealth Flexibilities for Mental Health Visits After the COVID-19 Public Health Emergency (PHE) Ends**

CMS is making regulatory changes to conform with the CAA, 2022 that temporarily extends a number of Medicare telehealth flexibilities for a limited 151-day period after the end of the COVID-19 PHE. CMS had previously revised regulations that previously required all RHC and FQHC mental health visits to be conducted in-person to allow the use of tele-mental health if the patient had an in-person mental health service within the past six months and the patient must be provided an in-person visit at least annually if they are using telehealth for diagnosis, evaluation, or treatment of mental health disorders. If the provider and patient agree that the risk of an annual in-person visit outweigh the benefits, the requirement may be waived.

CMS notes that they intend to issue program instruction or other subregulatory guidance to implement the provisions of this section of this rule to ensure a smooth transition after the declared end of the PHE for COVID-19.

Comments: N/A

J. Expansion of Coverage for Colorectal Cancer Screening and Reducing Barriers (section III.D.)

Proposed Changes

- **Expanding Access to Colorectal Cancer Screening Services For Individuals 45 and Older**

CMS is proposing to expand Medicare coverage of certain colorectal cancer (CRC) screening tests (gFOBT, iFOBT, and sDNA) by reducing the minimum age payment limitation to 45 years in regulations at §410.37 and National Coverage Determination (NCD) 210.3.

CMS is proposing the modification of the payment limitation for other CRC screening tests in §410.37 and NCD 210.3 to permit coverage for individuals to begin at age 45.

CMS proposes to use its authority under section 1834(n) and 1861(pp)(1)(D) of the Act to modify coverage of certain CRC screening tests to begin when the individual is age 45 or older and expand coverage of certain CRC screening tests to begin for individuals at age 45 for barium enema tests and blood-based biomarker tests, respectively.

CMS proposes to issue formal instructions that would revise the minimum age for the CRC screening tests described in NCD 210.3 from 50 to 45 years.

- **Expanding Definition and Usage of Colorectal Cancer Screening Tests**

CMS is proposing the addition of a non-invasive stool-based test on the list of qualifying procedures as a first step of a complete screening, as part of a larger proposal to modify CRC screening tests within CMS' authority, in consultation with appropriate organizations.

CMS is proposing the expansion of the regulatory definition of CRC screening tests and the exercise of its authority under section 1861(pp)(1)(D) of the Act to expand coverage of to include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based CRC screening test returns a positive result.

CMS is proposing a reversal of frequency limitations described for screening colonoscopy in §410.37(g) to change to being inapplicable in the instance of a follow-on screening colonoscopy test after a positive result from a Medicare covered stool-based test.

CMS is proposing the addition of a new paragraph (k) to §410.37 to state that, effective January 1, 2023, CRC screening tests include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based colorectal cancer screening test returns a positive result.

Background/Rationale

- **Expanding Access to Colorectal Cancer Screening Services For Individuals 45 and Older**

These proposals align with the United States Preventative Services Task Force (USPSTF) May 2021 revised recommendation that those who do not have symptoms of CRC and who are at average risk begin screening at 45.

- **Expanding Definition and Usage of Colorectal Cancer Screening Tests**

The proposal aligns with general medical consensus and USPSTF evidence-based recommendation that there is an association with higher mortality rates and worsened health outcomes from those who do not receive a follow-up colonoscopy after a positive result from stool-based test.

These proposals aim to fully remove beneficiary cost sharing for both stool-based tests and follow-on colonoscopy, encouraging wider utilization of non-invasive CRC screening tests and reducing barriers to screening, prevention, and early detection of CRC. Specifically, this will increase access for individuals with medical complexity and those in rural and underserved communities.

These proposals aim to include text noting the frequency limitations described for screening colonoscopy shall not apply in the instance of a follow-on screening colonoscopy test described in this paragraph.

Comments

CMS is inviting public comment on their proposals to:

- incorporate stool-based testing under Medicare coverage as part of the CRC care process.
- to exercise authority under section 1834(n) of the Act to modify coverage of certain CRC screening tests to begin when the individual is age 45 or older.

In addition to consulting appropriate organizations and recommendations, CMS is soliciting input on the larger idea of changing the minimum age from 50 to 45 for CRC screening tests.

K. Medicare Shared Saving Program (section III.G.)

Proposed Changes

- **Provide Advance Incentive Payments to New Low Revenue ACOs**

CMS is proposing to make advance shared savings payments, referred to as advance investment payments (AIPs), to certain ACOs participating in the Shared Savings Program to improve the quality and efficiency of items and services furnished to Medicare beneficiaries by enhancing the accessibility of the Shared Savings Program. Such payments would be made pursuant to the standards CMS proposes to establish in the new § 425.630.

Additionally, CMS is proposing new broad eligibility requirements for AIPs that will lower the barrier of entry to the Shared Savings Program for low revenue ACOs who are inexperienced with risk. Specifically, CMS is proposing the following criteria for the ACO to be eligible to receive AIPs:

- The ACO is not a renewing ACO or re-entering ACO (as such terms are defined under
- § 425.20).
- The ACO has applied to participate in the Shared Savings Program under any level of the BASIC track glide path and is eligible to participate in the Shared Savings Program.
- The ACO is inexperienced with performance-based risk Medicare ACO initiatives.
- The ACO is a low revenue ACO.

CMS is also proposing to revise §425.611(c)(4) to exclude all Parts A and B fee-for-service payment amounts for a beneficiary's episodes of care for treatment of COVID-19 from expenditure and revenue calculations for purposes of determining an ACO's eligibility to receive AIPs.

- **Allow Applicant ACOs Inexperienced with Performance-Based Risk to Participate in a 5-Year One Sided Shared Savings Model**

CMS is proposing to allow certain ACOs more time under a one-sided model and more flexibility in transitioning to higher levels of risk and potential reward by modifying the participation options available under the Shared Savings Program. For ACOs to be eligible to participate under Level A of the BASIC track for subsequent years of the agreement period as described in § 425.600(a)(4)(i)(C)(3), an ACO must meet the following requirements:

- The ACO is participating in its first agreement period under the BASIC track under § 425.600(a)(4), and
- The ACO is not participating in an agreement period under the BASIC track as a renewing ACO (as defined in § 425.20) or a re-entering ACO (as defined in § 425.20) that previously participated in the BASIC track's glide path under § 425.600(a)(4); and
- The ACO is inexperienced with performance-based risk Medicare ACO initiatives (as defined in § 425.20).

Additionally, CMS is proposing to extend the participation option to re-entering Track 1 ACOs, because they have not previously participated in the BASIC track glide path, and CMS would like to encourage them to begin participating in the program again. Eligibility for this participation option would not consider the ACO's revenue status.

Furthermore, CMS is proposing to add a new § 425.600(g)(1)(i) to provide that an ACO that is inexperienced with performance-based risk Medicare ACO initiatives may participate in the BASIC track glide path for a maximum of 2 agreement periods (once at Level A for all 5 performance years and a second time in progression on the glide path).

CMS also proposes to add a new § 425.600(a)(4)(i)(B)(*2*)(*vi*) to allow currently participating ACOs that are participating in the BASIC track at Level A or Level B for performance year 2022 to elect to continue in their current level of the BASIC track glide path for performance year 2023 and continuing for the remainder of the agreement period. If the ACO does not elect to remain under Level A or Level B, for performance year 2023.

- **Revise the Limitation on the Number of Agreement Periods an ACO can participate in Basic Track Level E**

CMS is proposing to add a new § 425.600(g)(2) to specify that if an ACO is determined to be experienced with performance-based risk Medicare ACO initiatives, the ACO may enter BASIC track Level E under § 425.600(a)(4)(i)(A)(5) for all performance years of the agreement period, or the ENHANCED track under § 425.600(a)(3). These options would be available without regard to the ACO's status as a high or low revenue ACO.

Furthermore, CMS is also proposing that all ACOs would be permitted to participate indefinitely under the BASIC track, Level E, or the ENHANCED track. This would include ACOs currently in the ENHANCED track or that participate under the ENHANCED track in the future. These ACOs would be permitted to enter a new participation agreement under Level E of the BASIC track.

- **Revise the Policies for Determining Beneficiary Assignment**

CMS is proposing to revise the definition of primary care services used for assignment in the Shared Savings Program regulations to include the following additions:

1. Prolonged services HCPCS codes GXXX2 and GXXX3; and
2. Chronic Pain Management HCPCS codes GYYY1 and GYYY2

- **Revise Quality Reporting and Quality Performance Requirements**

CMS is proposing to revise the quality reporting and the quality performance requirements for performance year 2023 and subsequent performance years (section III.G.4. of this proposed rule).

Furthermore, CMS is proposing to establish an alternative quality performance standard for ACOs that do not meet the quality performance standard to share in savings at the maximum rate by reinstating a sliding scale approach for determining shared savings for ACOs, regardless of how they report quality data and revise the approach for determining shared losses for ENHANCED track ACOs.

Additionally, CMS is proposing to establish a health equity adjustment that would upwardly adjust an ACO's quality performance score, to reward ACOs that report all-payer eCQMs/MIPS CQMs, that are high performing on quality, and serve a high proportion of underserved beneficiaries. This proposed adjustment would add up to 10 bonus points to the ACO's MIPS quality performance category score. The resulting

health equity adjusted quality performance score would be used to determine whether the ACO meets the quality performance standard set at the 30th percentile (for performance year 2023) or 40th percentile (for performance year 2024 and subsequent years) across all MIPS quality performance category scores; the final sharing rate for calculating shared savings payments under the BASIC track and the ENHANCED track for an ACO that meets the proposed alternative quality performance standard allowing for application of a sliding scale based on quality performance; and the shared loss rate for calculating shared losses under the ENHANCED track under the proposed modified approach to scaling shared losses.

CMS is also proposing to extend the incentive for reporting eCQMs/MIPS CQMs through performance year 2024 to align with the sunsetting of the CMS Web Interface reporting option.

- **Revise the Benchmarking Methodology**

CMS is proposing to revise the benchmarking methodology to reduce the effect of ACO performance on ACO historical benchmarks, increase opportunities for ACOs caring for medically complex, high-cost beneficiaries, and strengthen incentives for ACOs to enter and remain in the Shared Savings Program, and meet the programmatic goals of improving quality of care and lowering growth in FFS expenditures.

Additionally, CMS is proposing to adjust benchmarks to account for prior savings, helping to mitigate lowering of an ACO's benchmark over time by returning to an ACO's benchmark an amount that reflects its success in lowering growth in expenditures from the previous agreement period. CMS proposes to accomplish this goal by creating a prior savings adjustment with a 50 percent scaling factor for renewing and re-entering ACOs. This proposed change would help to limit the impact of an ACO's performance on its own benchmark.

Further, CMS is proposing to reduce the impact of negative regional adjustments on ACO benchmarks by reducing the cap on negative regional adjustments and gradually decreasing the negative regional adjustment amount as an ACO's weighted-average prospective HCC risk score increases, or the proportion of dually eligible Medicare and Medicaid beneficiaries increases, or both.

- **Change the Calculation of Regional Factors used in Benchmarking**

CMS is proposing to change how they calculate regional factors used in benchmarking to increase internal consistency of benchmark calculations for ACOs under prospective beneficiary assignment by using an assignment window that is consistent with an ACO's selected assignment methodology to identify the assignable population used to calculate regional FFS expenditures.

Specifically, CMS is proposing to incorporate a prospectively projected administrative growth factor, a variant of the United States Per Capita Cost (USPCC) referred to here as the Accountable Care Prospective Trend (ACPT), into a three-way blend with national and regional growth rates to update an ACO's historical benchmark for each performance year in the ACO's agreement period. Incorporating this prospective trend in the update to the benchmark would insulate a portion of the annual update from any savings occurring as a result of the actions of ACOs participating in the Shared Savings Program and address the impact of increasing market
penetration by ACOs in a regional service area on the existing blended national-regional growth factor.

- **Revise the Application of the Three Percent Cap on Positive Prospective HCC Risk Score Growth**

CMS is proposing to revise how they apply the existing three percent cap on positive prospective HCC risk score growth to better account for medically complex, high-cost populations while continuing to guard against coding initiatives (section III.G.5.e. of this proposed rule).

- **Increase Opportunities for Low Revenue ACOs Participating in the BASIC Track to Share in Savings**

CMS is proposing to expand the eligibility criteria to qualify for shared savings to enable certain low revenue ACOs participating in the BASIC track to share in savings even if the ACO does not meet the MSR as required under section 1899(d)(1)(B)(i) of the Act.

Specifically, CMS is proposing to modify the relevant provisions of § 425.605 to specify that ACOs participating in the BASIC track that do not meet the MSR requirement, but do meet the quality performance standard or the proposed alternative quality performance standard under § 425.512 and otherwise maintain eligibility to participate in the Shared Savings Program, would qualify for a shared savings payment if the following criteria are met:

- The ACO has average per capita Medicare Parts A and B fee-for-service expenditures below the updated benchmark.
- The ACO is a low revenue ACO as defined in § 425.20 at the time of financial reconciliation for the relevant performance year.
- The ACO has at least 5,000 assigned beneficiaries at the time of financial reconciliation for the relevant performance year.

- **Exclude Proposed New Supplemental Payment under the Medicare Hospital Inpatient Prospective Payment System (IPPS) for Indian Health Service (IHS)/Tribal hospitals and hospitals located in Puerto Rico from the determination of Medicare Parts A and B expenditures**

CMS is proposing to exclude the proposed new supplemental payment under the Medicare Hospital Inpatient Prospective Payment System (IPPS) for Indian Health Service (IHS)/Tribal hospitals and hospitals located in Puerto Rico from the determination of Medicare Parts A and B expenditures for purposes of calculations under the Shared Savings Program.

- **Remove Requirement to Submit Marketing Materials Prior to Use**

CMS is proposing to remove the requirement to submit marketing materials prior to use (section III.G.6.b. of this proposed rule). ACOs would be required to submit marketing materials only upon request from CMS, but we would retain the requirement that an ACO must discontinue use of any marketing materials or activities for which CMS has issued a notice of disapproval.

- **Amend the Beneficiary Notification Requirements to Reduce Frequency of Notifications**

CMS is proposing modifications to the beneficiary notification requirements, including to reduce the frequency with which beneficiary information notices are provided to beneficiaries from annually to a

minimum of once per agreement period, with a proposed follow-up beneficiary communication serving to promote beneficiary comprehension of the standardized written notice and occurring no later than 180 days following the date that the standardized written notice was provided to the beneficiary (section III.G.6.c. of this proposed rule).

- **Amend the beneficiary notification requirements to clarify that ACOs and ACO participants are required to post signs in all facilities and make standardized written notices available upon request in all settings in which beneficiaries receive primary care services**

CMS is proposing to amend the beneficiary notification requirements to clarify that ACOs and ACO participants are required to post signs in all facilities and make standardized written notices available upon request in all settings in which beneficiaries receive primary care services (section III.G.6.c. of this proposed rule).

- **Remove the requirement for an ACO to submit certain narratives when applying for the SNF 3-day rule waiver**

CMS is proposing to remove the requirement for an ACO to submit certain narratives when applying for the SNF 3-day rule waiver and replace with a requirement that an ACO submit an attestation that it has established the narratives and will make them available to CMS upon request.

- **Amend regulations to recognize ACOs structured as OHCAs for data sharing purposes**

CMS is proposing to modify the Shared Savings Program data sharing regulations at §§425.702(c)(2) and 425.704(b) to specify that ACOs acting as OHCAs may request aggregate reports and beneficiary identifiable claims data from CMS, respectively. CMS would recognize an OHCA as an additional organizational structure under which an ACO can request data from CMS.

Background/Rationale

- **Provide Advance Incentive Payments to New Low Revenue ACOs**

CMS envisions this new payment option would distribute AIPs to ACOs for two years in order to reduce the financial barriers encountered by small providers and suppliers as they join the Shared Savings Program. These payments would be recouped from any shared savings the ACO earned. Funding the ACOs for two years would align with the policy in AIM. The AIPs are designed to reduce up-front costs that prevent providers and suppliers from forming ACOs, caring for beneficiaries in underserved communities, and achieving long term success in the Shared Savings Program.

Additionally, the AIPs are designed to assist ACOs that face difficulty funding the start-up costs for forming ACOs, caring for beneficiaries in underserved communities, and achieving long term success in the Shared Savings Program. Building upon AIM's success with new ACOs and ACOs inexperienced with performance-based risk Medicare ACO initiatives, we propose to limit the eligibility for these AIPs to these same groups. Our experience administering the Shared Savings Program suggests that re-entering and renewing ACOs have APM experience and would not need, or benefit as significantly from, the start-up funds that AIPs provide because they have already invested in creating an ACO.

- **Allow Applicant ACOs Inexperienced with Performance-Based Risk to Participate in a 5-Year One Sided Shared Savings Model**

To promote the program's goal of ACO accountability for the quality and cost of care furnished to assigned beneficiaries, we believe it would be appropriate to allow certain ACOs in their first agreement period in the program to maintain participation in a one-sided model (with a lower sharing rate) for a longer period of time, rather than risk having those ACOs leave the program altogether to avoid transitioning to two-sided risk before the ACO is confident it has been able to implement the systemic changes necessary to deliver high quality, value-based care.

CMS believes it would be in the best interest of the program and Medicare FFS beneficiaries to permit eligible ACOs to continue participating under the BASIC track Level E, rather than risk significant numbers of experienced, successful ACOs terminating their participation in the program instead of progressing to the higher level of risk and potential reward under the ENHANCED track. CMS' experience shows that ACOs in the BASIC Track Level E and ACOs in the ENHANCED Track have similar performance results.

- **Revise the Limitation on the Number of Agreement Periods an ACO can participate in Basic Track Level E**

CMS believes it would be in the best interest of the program and Medicare FFS beneficiaries to permit eligible ACOs to continue participating under the BASIC track Level E, rather than risk significant numbers of experienced, successful ACOs terminating their participation in the program instead of progressing to the higher level of risk and potential reward under the ENHANCED track. CMS' experiences shows that ACOs in the BASIC Track Level E and ACOs in the ENHANCED Track have similar performance results.

- **Revise the Policies for Determining Beneficiary Assignment**

Section 1899(c)(1) of the Act, as amended by the CURES Act and the Bipartisan Budget Act of 2018, provides that for performance years beginning on or after January 1, 2019, the Secretary shall assign beneficiaries to an ACO based on their utilization of primary care services provided by a physician who is an ACO professional, and all services furnished by Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs). However, the statute does not specify a list of services considered to be primary care services for purposes of beneficiary assignment.

Based on feedback from ACOs and our further review of the HCPCS and CPT codes that are currently recognized for payment under the PFS or that we are proposing to recognize for payment starting in CY 2023, we believe it would be appropriate to amend the definition of primary care services used in the Shared Savings Program assignment methodology to include certain additional codes and to make other technical changes to the definition of primary care services for use in determining beneficiary assignment for the performance year starting on January 1, 2023, and subsequent performance years in order to remain consistent with billing and coding guidance under the PFS.

- **Revise Quality Reporting and Quality Performance Requirements**

CMS is concerned that the current structure of the quality performance standard creates a cliff of "all-or-nothing" scoring where an ACO may be ineligible to share in savings due to a minor difference between its MIPS Quality performance category score and the quality performance standard required to share in savings at the maximum sharing rate for the applicable performance year.

Additionally, CMS has received comments sharing concerns that ACOs are now shifting from being compared against other ACOs to broadening this comparison to include all MIPS eligible clinicians, making it difficult to continue to achieve high quality performance.

- **Revise the Benchmarking Methodology**

Over the 10 years since the Shared Savings Program was first established, CMS has used a variety of approaches for determining the trend and update factors to make an ACO's cost target more independent of its own expenditures, including using factors based on national expenditures, regional expenditures, or both. With these approaches, CMS has maintained a degree of parity between the factors used to trend and update the benchmark, either based on national FFS expenditures, regional FFS expenditures, or a blend of national and regional FFS expenditures.

Further, in earlier rulemaking, CMS acknowledged that the use of factors based on regional FFS expenditures in calculating benchmarks will have varying effects on ACOs depending on each organization's individual circumstances. There is some evidence that certain aspects of the program's benchmarking methodology, notably the regional adjustment to the benchmark, may already deter participation among ACOs with spending above their regional benchmark and those serving medically complex, high-cost populations.

CMS believes that addressing the concerning dynamics in the benchmarking methodology, combined with modifications to the risk adjustment methodology and to participation options targeted at improving participation by ACOs serving medically complex, high-cost populations, would further CMS' goal that 100 percent of people with Original Medicare will be in a care relationship with accountability for quality and total cost of care by 2030.

- **Change the Calculation of Regional Factors used in Benchmarking**

Regional growth rates are computed using expenditures for the ACO's regional service area for Benchmark Year 3 (BY3) and the performance year. To calculate regional expenditures, CMS determines the counties included in the ACO's regional service area based on the ACO's assigned beneficiary population for the year and determine the ACO's regional expenditures as specified under § 425.601(c) and (d).

The regional and national growth rates are then blended together by taking a weighted average of the two. The weight assigned to the national component of the national-regional blend for a given Medicare enrollment type is calculated as the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO for the applicable performance year, calculated by taking a weighted average of county-level shares as specified in § 425.601(a)(5)(v).

ACOs and other interested parties have expressed concerns regarding the dynamic under which an ACO that reduces costs for its own assigned beneficiaries also reduces its average regional costs, resulting in a relatively lower benchmark for the ACO under the blended national-regional growth rates used to trend and update the ACO's historical benchmark. As echoed in public comments, ACOs and other interested parties have suggested that this dynamic particularly disadvantages ACOs with high market penetration in their regional service areas, which may tend to be ACOs operating in rural areas.

- **Revise the application of the Three Percent Cap on Positive Prospective HCC Risk Score Growth**

CMS currently uses prospective HCC risk scores to adjust the historical benchmark for changes in severity and case mix for all assigned beneficiaries, subject to a cap of positive three percent for the agreement period (referred to herein as the "3 percent cap"). This cap is the maximum increase in prospective HCC risk scores allowed for each agreement period, such that any positive adjustment between Benchmark Year three (BY3) and any performance year in the agreement period cannot be larger than three percent.

The three percent cap was finalized through the December 2018 final rule (83 FR 68013) to address concerns with the prior approach for risk adjustment, which used a methodology that differentiated between newly assigned and continuously assigned beneficiaries, as defined in § 425.20. The issues raised by interested parties included concerns that the risk adjustment methodology did not adequately adjust for changes in health status among continuously assigned beneficiaries between the benchmark and performance years and concern that performing risk adjustment separately for newly and continuously assigned beneficiaries created uncertainty around benchmarks and made it difficult for ACOs to anticipate how risk scores would affect their financial performance.

- **Increase Opportunities for Low Revenue ACOs Participating in the BASIC Track to Share in Savings**

CMS believes that while it remains important to ensure performance payments are not based on normal expenditure fluctuations, that modifications to the MSR policy would provide payments to ACOs with the greatest need for shared savings; in particular smaller, rural ACOs which tend to be less capitalized, allowing for investments in care redesign and quality improvement activities. This modification would also align with the other changes to the participation options and financial methodologies under the Shared Savings Program to encourage participation by new ACOs and ACOs that focus on underserved populations, such as the proposal to offer AIPs to new low revenue ACOs joining the BASIC track.

- **Exclude Proposed New Supplemental Payment under the Medicare Hospital Inpatient Prospective Payment System (IPPS) for Indian Health Service (IHS)/Tribal hospitals and hospitals located in Puerto Rico from the determination of Medicare Parts A and B expenditures**

CMS has historically excluded Indirect Medical Education (IME), Disproportionate Share Hospital (DSH) and uncompensated care payments from ACOs' assigned and assignable beneficiary expenditure calculations because CMS does not want to incentivize ACOs to avoid the types of providers that receive these payments. However, CMS has determined that supplemental payment is necessary to avoid causing undue long-term financial disruption to IHS/Tribal hospitals and hospitals located in Puerto Rico as a result of a proposed change in the data used to determine uncompensated care payments for these hospitals beginning in FY 2023.

CMS believes that consistent with their longstanding policy with respect to excluding IME and DSH payments from benchmarking and performance year expenditures, that they will use their authority under section 1899(i)(3) to remove the proposed supplemental payment for IHS/Tribal hospitals and hospitals located in Puerto Rico from performance year expenditures to reward more accurately actual decreases in unnecessary utilization of health care services.

- **Remove Requirement to Submit Marketing Materials Prior to Use**

The Shared Savings Program regulations define "marketing materials and activities" at § 425.20 to include, without limitation, "general audience materials" and activities used or conducted by or on behalf of the ACO, or by ACO participants, or ACO providers/suppliers when used to educate, solicit, notify, or contact Medicare beneficiaries or providers and suppliers about the Shared Savings Program. Further, the Shared Savings Program regulations impose certain marketing requirements at § 425.310 regarding the content and approval of marketing materials and activities. Including that marketing materials and activities are deemed approved after the initial 5-day review period.

As indicated in the November 2011 final rule (74 FR 67948), CMS finalized these marketing policies as an aspect of patient-centeredness, indicating that we believed it would be appropriate and consistent with the purpose and intent of the statute to limit and monitor the use of ACO-related marketing activities and materials to ensure that such communications and marketing are used only for appropriate purposes, such as notification that a beneficiary's healthcare provider is participating in the ACO, issuance of any CMS-required notices, or notification of provider or ACO terminations.

CMS is sensitive to the operational burden imposed on ACOs by these marketing requirements, such as the ACO bearing sole responsibility for collecting and submitting to CMS all marketing materials in use by the ACO, ACO participants, and ACO providers/suppliers, and we noted our desire to balance this burden with the need for appropriate beneficiary protections.

However, given the breakdown of marketing material review dispositions, the time and resources CMS currently expends to review all submitted marketing materials, and the additional effort for ACOs to submit these materials prior to use, we believe the current submission requirements create an unnecessary administrative burden for both CMS and ACOs that is not outweighed by the benefits of the current policy.

- **Amend the Beneficiary Notification Requirements to Reduce Frequency of Notifications**

CMS remains committed to program transparency and believes that beneficiary notices are important communication tools, and CMS believes that ACOs are in the best position to communicate with beneficiaries regarding their care and the purposes for Medicare claims data sharing. CMS wants to ensure that beneficiaries understand the advantages of their participation in ACOs, that their data is secure, that only the minimum necessary data is collected, and how this data is used for purposes of improving the quality of care for beneficiaries in the Shared Savings Program. Thus, CMS is working to improve the beneficiary notice to ensure that the content of the notice utilizes plain language and is beneficiary-friendly, as well as affirming patient choice and clarifying the beneficiary's opportunity to decline claims data sharing.

In addition to providing standardized written notices to beneficiaries upon request, ACOs and ACO participants are currently required to furnish standardized written notices prior to or at the first primary care visit of the performance year (§ 425.312(a)(2)(iii), (iv)). CMS continues to believe that requiring periodic beneficiary notifications affords ACOs and ACO participants an opportunity for direct engagement with the beneficiary, thereby serving to strengthen the beneficiary's relationship with the ACO and ACO participants from whom the beneficiary may receive care. This requirement promotes program transparency and empowers patients with the knowledge of the ACO's mission, data sharing requirements, and ACO operations, thereby allowing patients to make informed decisions about where they receive care. Therefore, CMS intends to retain the beneficiary notification policies, but in the interest of an overall reduction in

administrative burden, CMS is proposing to modify § 425.312(a) to reduce the frequency with which an ACO or ACO participant must furnish standardized written notifications to beneficiaries from up to five times per agreement period to once per agreement period.

- **Amend the beneficiary notification requirements to clarify that ACOs and ACO participants are required to post signs in all facilities and make standardized written notices available upon request in all settings in which beneficiaries receive primary care services**

ACOs and ACO participants frequently ask whether CMS requires signage to be posted in all facilities or only those where primary care services are provided. Although CMS believes the existing regulation text is clear on this point, CMS wishes to provide clarification that ACO participants are required to post beneficiary notification signs in all of their facilities, whether or not primary care services are provided in every facility

- **Remove the requirement for an ACO to submit certain narratives when applying for the SNF 3-day rule waiver**

CMS is committed to reducing unnecessary application and/or program burden where possible and consider application attestations as a way of streamlining processes when appropriate. The submission of the three remaining narratives has largely functioned as a mechanism for ACOs to confirm they have established operations for communicating between the ACO and its SNF affiliates, establishing a care management plan, and beneficiary evaluation and admission plan. The existence of the three narrative plans provides some assurance of an ACO's capacity to identify and manage beneficiaries who may be admitted to a SNF affiliate. However, as a payer, CMS does not have the experience that would be required to evaluate the appropriateness of the contents of these plans.

- **Amend regulations to recognize ACOs structured as OHCAs for data sharing purposes**

CMS believes that an Organized Health Care Arrangement (OHCA) structure potentially could address some of the concerns that commenters have raised about ACOs collecting and reporting all-payer data to CMS as required under the APP. However, CMS notes that this proposal is limited to the Shared Savings Program regulations governing CMS' data sharing with ACOs and is not intended to affect or modify any existing obligations under the HIPAA Privacy Rule. Furthermore, it is the ACOs' responsibility to consult with their legal counsel and others as necessary to determine how to structure their arrangements with their ACO participants and ACO providers/suppliers to comply with HIPAA requirements.

Comments:

CMS is inviting public comment on:

- Their proposal to create and distribute Advance Incentive Payments (AIPs) to low revenue ACOs.
- All aspects of the proposal for recoupment of the AIPs made to ACOs.
- The foregoing proposals for ACO participation options in the Shared Savings program.
- Whether to extend the proposed option for certain ACOs inexperienced with performance-based risk Medicare ACO initiatives to spend an entire five year agreement period under the one-sided model of the BASIC track for an additional agreement period for low revenue ACOs that enter the BASIC track as a new legal entity so that these ACOs would be eligible for a second one-sided

only agreement period followed by a third agreement period in the BASIC track glide path, which would include an additional 2 years under the one-sided model (for a total of 12 years under the one-sided model) before progressing to two-sided risk.

- The alternative approach under which we would permit low revenue ACOs to remain in a one-sided only model of the BASIC Track for a second agreement period before entering the BASIC Track glide path in their third agreement.
- Two potential social determinants of health (SDOH) measures for future measure development, and the addition of new Consumer Assessment of Healthcare Providers and Systems (CAHPS) for the Merit-based Incentive Payment System (MIPS) Survey Questions.
- An alternative approach to calculating ACO historical benchmarks that would use administratively-set benchmarks that are decoupled from ongoing observed FFS spending.
- The proposed changes to the definition of primary care services used for assigning beneficiaries to Shared Savings Program ACOs for the performance year starting on January 1, 2023, and subsequent performance years.
- Any other existing HCPCS or CPT codes and new HCPCS or CPT codes proposed elsewhere that CMS should consider adding to the definition of primary care services for purposes of assignment in future rulemaking.
- All aspects of the proposal to identify all CCN's associated with ACP participant TINs for use in assignment and other operations prior to determining historical benchmarks, running quarterly assignments, and financial reconciliation in addition to developing a mechanism for reporting to ACO's all CCNs used in assignment and for purposes of program operations.
- Proposals to scale shared savings and shared losses discussed in sections III.G.4.b.(2) through (5) of this proposed rule, including the alternative approach if the proposed changes to § 414.1415(b)(2) and (b)(3) are not finalized:
    - Proposal to reinstate a modified sliding scale approach for determining shared savings for all ACOs regardless of how they report quality data.
    - Proposal that if an ACO fails to meet the existing criteria under the quality performance standard to qualify for the maximum sharing rate but the ACO achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set then the ACO would share in savings at a lower rate that reflects the ACO's quality performance score.
    - Proposal to revise § 425.512(a)(4) and (5) to provide for a quality performance standard that an ACO must meet in order to share in savings at the maximum sharing rate under its track.
    - Proposal to apply the sliding scale approach to determine shared savings for all qualifying ACOs and to determine shared losses for ENHANCED track ACOs regardless of how they report quality data to CMS.
- Proposal to update the eCQM/MIPS CQM incentive for performance year 2024 to include:
    - A quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set, the ACO will meet the quality performance standard used to determine eligibility for shared savings and to avoid maximum shared losses.

  - If an ACO achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set.
  - If an ACO reports the three eCQMs/MIPS CQMs, meets the data completeness requirement at § 414.1340 and the case minimum requirement at § 414.1380 for all three eCQMs/MIPS CQMs.
- Whether CMS should incorporate the proposed amendments to § 414.1415(b)(2) and (b)(3) described in section IV.A.4.a into the eCQM/MIPS CQM incentive.
- Alternative approach to calculating the underserved multiplier as the sum of an ACO's proportion of assigned beneficiaries residing in areas of high socioeconomic disadvantage and an ACO's proportion of dually eligible Medicare and Medicaid assigned beneficiaries.
- The proposal to use two alternative approaches to calculating underserved multipliers, including:
  - Use of the LIS indicator in place of, or in addition to, a beneficiary's dual Medicare and Medicaid enrollment status.
  - Using the higher of either ACO's assigned beneficiary population residing in a census block group with an ADI national percentile rank of at least 85, the proportion of the ACO's assigned beneficiaries that are dually eligible for Medicare and Medicaid, or the proportion of the ACO's assigned beneficiaries receiving LIS.
- The proposal to use a three-tiered approach to determine the values assigned to each measure of the health equity adjusted quality performance score.
- The scale of values attributed to the performance groups, as well as the proposal to limit the overall amount of the health equity adjustment to a maximum of 10 bonus points.
- The proposed requirement that an ACO's underserved multiplier be at least 20 percent for an ACO to be eligible for health equity adjustment bonus points.
- Proposed alternative methodologies for calculating the underserved multiplier.
- Incorporating into the methodology for calculating the ACO's underserved multiplier whether ACO assigned beneficiaries are eligible for the LIS available under the Medicare Part D prescription drug program, including use of a LIS indicator in place of a beneficiary's dual enrollment status.
- The proposal for Preventative Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID# 226) and the Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID 134) to be scored using flat percentage benchmarks for the 2022 performance year.
- The proposal clarification of when CMS would exercise its discretion to reopen for good cause when either an initial determination or a final agency determination regarding an ACO's financial performance needs to be corrected as a result of any corrections made to MIPS Quality performance category scores that affect the determination of whether an ACO is eligible for shared savings, the amount of shared savings due to the ACO, or the amount of shared losses owed by the ACO.
- The potential future inclusion of two new structural measures in the APP measure set: Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health,
  - How to best implement the measures and how they could further drive health equity and health outcomes under the Shared Savings Program?

  - What are the possible barriers to implementation of the measures in the Shared Savings Program?
  - What impact would the implementation of these measures in the Shared Savings Program have on the quality of care provided for underserved populations?
  - What type of flexibility with respect to the social screening tools should be considered should the measures be implemented?
  - While supporting flexibility, how can we advance the use of standardized, coded health data within screening tools?
  - Should the measures, if implemented in the future, be considered pay-for-reporting measures?
- The proposal to shorten the MIPS survey to remove survey items that are relevant only to primary care providers.
- Alternatives to the combination of policies proposed in sections III.G.5.c.(3) through (5).
- A potential longer-term approach for use of administratively set benchmarks that are decoupled from ongoing observed FFS spending.
- The proposal to use a three-way blend that incorporates the ACPT to update an ACO's historical benchmark for agreement periods beginning on January 1, 2024, and in subsequent years.
  - Specific elements of this approach, including our proposal to calculate the ACPT on a risk adjusted flat dollar basis, to institute a guardrail to protect ACOs, and to retain discretion to adjust the weight applied to the ACPT and the two-way blend in the event of unforeseen circumstances.
- The proposal to adjust the ACO's historical benchmark for savings generated in the ACO's prior agreement period.
- The proposed changes to the calculation of the regional adjustment for agreement periods beginning on January 1, 2024, and in subsequent years.
- The alternative options with interested parties now having the opportunity to consider their merits relative to the package of policies we are proposing in sections III.G.5.c.(3) through (5) of this proposed rule.
  - On certain operational factors that we would need to address with greater specificity if we were to finalize any of the alternatives.
- The proposals specified in the proposed new regulations at §§425.652, 425.654, and 425.656
- The proposal to use the authority granted by section 1899(d)(1)(B)(ii) of the Act to adjust the benchmark for beneficiary characteristics and other such factors as the Secretary determines to be appropriate, to modify the existing 3 percent cap on risk score growth using the first option.
- The proposed changes to the risk adjustment methodology for agreement periods beginning on or after January 1, 2024.
  - On the two alternatives considered.
- The proposal to expand the criteria ACOs can meet to qualify for shared savings under the BASIC track.
- The analysis regarding the impact of the PHE for COVID-19 on Shared Savings Program ACOs' expenditures.

- The proposed change to the determination of Medicare Parts A and B expenditures for purposes of calculations under the Shared Savings Program, including the determination of benchmark and performance year expenditures, as well as the calculation of ACO participant revenue.
- The proposed frequency of the notification and whether CMS' proposal will reduce net burden and mitigate any potential beneficiary confusion.
- A modified benchmarking methodology which may boost participation, increase savings to the Medicare Trust Fund and make long-term participation in the Shared Savings Program possible for more ACOs.
- The proposed broader changes to the benchmarking methodology that may be needed to further strengthen incentives for providers and suppliers to participate in the Shared Savings Program and generate savings while preserving a mechanism for convergence to a consistent regional benchmarking approach that does not elicit selective participation.
- The direction for future benchmarking that is designed to create a sustainable pathway for long term program savings for both ACOs and CMS and to address interested parties' concerns around ratcheting.
- The stages for implementing such an approach within the Shared Savings Program.
    - Particularly on an initial convergence phase and a post-convergence phase, and any other considerations related to this approach that we have not addressed in this proposed rule.
- Any additional modifications to the design of the Shared Savings Program that should be considered in conjunction with administratively set benchmarks.
- The extent to which the use of administratively set benchmarks might have the potential to improve the quality and efficiency of care furnished to Medicare beneficiaries and any anticipated impact on Medicare expenditures.
- Considerations for calculating an ACPT to be used as an administratively set benchmark update factor.
- The proposed 5-year intervals for establishing an ACPT, and alternative approaches that would tie the ACPT to an ACO's agreement period.
- Approaches to accounting for price growth and demographic factors versus volume/intensity and considerations for guardrails to protect against projection error.
- Approaches to updating the ACPT that would ensure it does not overly reflect ACOs' collective impact on spending.
- The approach of subtracting a modest annual discount factor from the fixed 5-year ACPT growth trend based on the relative efficiency of the ACO.
- The approach for calculating and applying a discount factor in determining the amount of an ACO's benchmark update.
- The intervals of the discount we described, and alternative approaches such as use of a sliding scale in determining the discount amount.
- Approaches to ensuring the discount is reflective of the ACO's regional efficiency, including the approach of recalculating the discount factor to reflect changes in an ACO's regional efficiency as a result of changes in the ACO's composition during its agreement period.
- Considerations related to removing the negative regional adjustment in establishing the ACO's historical benchmark under an administratively established benchmark approach.

- Considerations for limiting disincentives for efficient ACOs to add less efficient providers and suppliers.
- The following proposals as it relates to benchmarking updates:
    - Considerations for the design of a regionally consistent benchmarking approach, including how to set fair and accurate risk-standardized benchmarks, the process for annual updates to regional rates, and how to distinguish between enrollment types.
    - Considerations for the required conditions and timing for reaching this post-convergence phase with the use of regionally consistent benchmarks, as well as incentives to promote ACO spending convergence within a region.
    - Approaches to addressing rebasing effects for renewing and re-entering ACOs in subsequent agreement periods during the convergence phase.
    - Considerations for converging to nationally consistent spending versus regionally consistent spending.

- Other policy adjustments that should be considered for benchmark setting in the post-convergence phase.
    - Approaches, generally, to addressing health inequities via the benchmark methodology for the Shared Savings Program, and specifically to incentivize ACOs to serve historically underserved communities.
    - Considerations for what data would need to be collected on Medicare beneficiaries and their communities (for example, need for and access to health care providers, transportation, and social services) and what factors should be considered to identify underserved communities and adjust ACO benchmarks.
    - Considerations for including a health equity benchmark adjustment in the Shared Savings Program in the near term comparable to the equity adjustment being tested within the ACO REACH Model.
    - Considerations for addressing health inequities in the context of the benchmarking concept outlined in this section of this proposed rule.
    - Considerations for monitoring and program integrity tools that would track the use of any health equity benchmark adjustments for the intended purposes.
    - Considerations for whether benchmark adjustments for ACOs that include CAHs, RHCs, FQHCs, and REHs as ACO participants would improve care for rural and underserved populations and increase participation by these providers and suppliers in the Medicare Shared Savings Program.

L. Medicare Part B Payment for Preventive Vaccine Administration Services (section III.H.)

Proposed Changes

- **Proposed Adjustment to the Payment Amount for Administration of Preventive Vaccines for Geographic Locality**

CMS proposes applying a geographic adjustment policy to preventive vaccine administration services for CY 2023 and subsequent years. Historically, vaccine administration rates were established through rulemaking using a crosswalk to the payment rate for similar services paid under the PFS. In CY 2022, CMS decoupled payment for these vaccine administration services from the PFS crosswalk. To implement the adjustment, CMS proposes using a GAF for each PFS fee schedule area to reflect the costs of administering preventative vaccines.

Additionally, CMS proposes amending regulation § 410.152 to codify the use of the GAFs for each PFS fee schedule area to reflect the geographic cost differences. Specifically, CMS would revise § 410.152 to adjust the payment amount using GAF for the administration of influenza, pneumococcal, HBV vaccines, and COVID-19 vaccines beginning January 1, 2023. Revisions would also include alignment of the payment rate for administration of COVID-19 vaccines with the rates for the administration of other Part B preventative vaccines effective January 1 of the year following the year in which the PHE ends.

- **Proposed Annual Adjustment to the Payment Amount for Administration of Preventive Vaccines to Reflect Changes in Cost**

CMS is proposing to update the payment amount of preventative vaccines to reflect cost changes using the annual increase in the MEI. Based on the proposed change, the COVID-19 vaccine administration payment amount would also be based on the MEI. The proposal includes an annual update to the payment amount for the administration of vaccines based on the MEI.

- **Continuing the Additional Payment for At-home COVID-19 Vaccinations**

In June 2021, CMS announced an additional payment of approximately $35 when a COVID-19 vaccine is administered in the home. For CY 2023, CMS proposes to continue the additional payment of $35.50 and adjust the payment for geographic cost variation, similar to the payment methodology for preventive vaccine administration service. The at-home payment would also reflect changes in the MEI. CMS proposes that the additional payment no longer be tied to the end of the PHE.

- **Payment Rates for COVID-19 Vaccines**

The current payment rate for administration of the COVID-19 vaccine of $40 per dose will continue through the end of the calendar year in which the emergency use authorization (EUA) declaration for drugs and biological products ends.

- **Continuation of Payment for COVID-19 Monoclonal Antibody Products under Medicare Part B**

For monoclonal antibody products used for treatment or for post-exposure prophylaxis of COVID-19, CMS proposes a continuation of those payments under the Medicare Part B vaccine benefit through the end of the calendar year in which the EUA declaration ends. Until the end of the EUA declaration, CMS will maintain the payment rates for administering those products in a healthcare setting and in the home. Additionally, CMS proposes, beginning January 1, 2023, applying the GAF to the payment amount for those products used for treatment or post-exposure prophylaxis. CMS would not extend the proposal to update the payment based on the MEI.

CMS also proposes including coverage and payment for the monoclonal antibody products that are used for pre-exposure prophylaxis for prevention of COVID-19. The GAF would also apply to the payment amount the administration of those products. CMS would continue the existing payment policy under the Part B vaccine benefit for these products even after the EUA declaration ends, as long as the products have authorization.

Background/Rationale

- **Proposed Adjustment to the Payment Amount for Administration of Preventive Vaccines for Geographic Locality**

Costs for suppliers can vary significantly across geographic areas due to differences in rent and wages. The use of the GAFs is preferred to the PFS GPCIs because the former is a single adjustment factor that could be more easily applied to the flat payment rates for the administration of vaccines. In contrast, PFS GPCIs reflect geographic cost differences for each of the three distinct components of PFS services. Calculation of GAF incorporates structures like those in PFS GPCIs and results in similar payment, but GAF is a more streamlined approach.

- **Proposed Annual Adjustment to the Payment Amount for Administration of Preventive Vaccines to Reflect Changes in Cost**

The MEI is used in other healthcare settings; it is a fixed-weight input price index that reflects the physicians' time and practice expenses. The MEI also adjusts for economic factors. CMS also considered the Consumer Price Index for All Items (CPI-U) and the Employment Cost Index (ECI). Compared to the CPI-U which measures inflation, the MEI is healthcare-specific and would better reflect the prices of goods and services in vaccine administration. Compared to the ECI which measures wages and salaries, the MEI considers additional factors for suppliers that administer preventive vaccines.

- **Continuing the Additional Payment for At-home COVID-19 Vaccinations**

The initial establishment of the additional payment for at-home COVID-19 vaccinations was to account for the time that health care professionals must monitor the patient after administration of the vaccine. Additional payments would continue to provide access to beneficiaries who might not be able receive the vaccine otherwise. CMS does not propose extending additional payments to the administration of other vaccines at home because the post-administration monitoring of the patient for COVID-19 vaccines is not the general administration protocol for other vaccines.

- **Payment Rates for COVID-19 Vaccines**

Following the end of the EUA declaration for drugs and biological products, the payment rate for administration of the COVID-19 vaccine with align with the rate for the administration of other Part B preventive vaccines.

- **Continuation of Payment for COVID-19 Monoclonal Antibody Products under Medicare Part B**

For the GAF application to the payment amount for the administration of monoclonal antibody products used for treatment of COVID-19, CMS stated that it is appropriate to continue to adjust the payment amount to reflect geographic cost differences.

The Part B vaccine benefit would continue to cover the use of monoclonal antibody products for prevention because for certain individuals, these pre-exposure prophylactic products may be their only preventive option against COVID-19.

Comments:

- **Proposed Adjustment to the Payment Amount for Administration of Preventive Vaccines for Geographic Locality**

CMS is inviting comment on the proposal to use the GAF to adjust the payment amount for the administration of preventive vaccines for geographic cost variations. CMS is welcoming comment on additional factors that could make the payment reflect cost differences across localities. They are soliciting comment on the codification of these changes and the proposed amendments to § 410.152.

- **Proposed Annual Adjustment to the Payment Amount for Administration of Preventive Vaccines to Reflect Changes in Cost**

CMS invites comments on the proposal including on potential approaches other than MEI to update payment rates for the administration of preventive vaccines.

- **Continuing the Additional Payment for At-home COVID-19 Vaccinations**

CMS is soliciting comments and suggestions on how to improve program integrity and protect beneficiaries with payments for administering preventive vaccines at home.

- **Continuation of Payment for COVID-19 Monoclonal Antibody Products under Medicare Part B**

CMS seeks comment on how best to refine the payment rates for the administration of monoclonal antibody products for pre- and post- exposure prophylaxis for COVID-19.

M. State Options for Implementing Medicaid Provider Enrollment Affiliation Provision (section III.K.)

Proposed Changes

- **Flexibility for States to Change their Approach to Medicaid Provider Enrollment Affiliation Disclosures**

This proposal would allow states greater flexibility in creating their phased-in approach to implementing the requirement for providers who are not enrolled in Medicare to provide the disclosures to the state as required under the Program Integrity Enhancements to the Provider Enrollment Process Act.

States that are currently using the disclosure process described in § 455.107(b)(2)(ii) where providers must disclose only upon request from the state, can opt to transition to the process described in § 455.107(b)(2)(i) where all providers who are initially enrolling, or revalidating their Medicaid or CHIP enrollment information must disclose their affiliations to the state. States cannot transition from the latter process to the former.

Background/Rationale

- **Flexibility for States to Change their Approach to Medicaid Provider Enrollment Affiliation Disclosures**

The Program Integrity Enhancements to the Provider Enrollment Process requires Medicare, Medicaid, and Children's Health Insurance Program (CHIP) providers and suppliers to disclose any current or previous direct or indirect affiliation with a provider or supplier that:

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

These disclosures are required to be submitted when a provider applies for enrollment or revalidation of enrollment in Medicare, Medicaid, or CHIP.

To limit the potential burden on providers, CMS, and states phased-in the implementation of this requirement. For Medicare enrollment, providers must submit affiliation disclosures only upon CMS's request. CMS provided states with two options for states to implement the requirements:

- Providers not enrolled in Medicare must submit affiliation disclosures to the state when initially enrolling in Medicaid and CHIP; or
- Providers not enrolled in Medicare must submit affiliation disclosures only upon request from the state.

The second option mirrors the process being used for Medicare providers and permits the state to utilize a slower implementation process.

Initially, under § 455.107(b)(1)(ii) states were not allowed to change between the two reporting options, as CMS was concerned this would cause undue logistical complications and confusion among the provider community. However, after consultation with the states and reviewing disclosure submission data, CMS believes that requiring states to continue utilizing the process initially selected by the state may hinder its operations or program integrity efforts.

Additionally, CMS notes that all states that choose the second option will eventually be required to collect affiliation disclosures from their providers upon the submission of each initial and revalidation application.

Comments: N/A

N. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD Plan (section 2003 of the SUPPORT Act) (section III.L.)

Proposed Changes

- **Extend Existing Non-Compliance Action of Sending Letters to Non-Compliant Prescribers for the EPCS Program Implementation Year**

CMS is proposing to extend the existing non-compliance action of sending letters to non-compliant prescribers for the CY 2023 EPCS program implementation year (January 1, 2023, through December 31, 2023) to the following year (January 1, 2024, through December 31, 2024). Starting in CY 2025, CMS plans to begin increasing the severity of penalties for non-compliant prescribers, from issuance of non-compliance letters to other penalties.

- **Change Data Source Used to Identify Geographic Location of Prescribers to Inform Recognized Emergency Exception**

CMS is proposing to use the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) address instead of the National Council for Prescription Drug Programs (NCPDP) Pharmacy Database address to determine whether the exception at § 423.160(a)(5)(iii) is applicable. In situations where prescribers do not have a PECOS address, CMS proposes to use the prescriber address in the National Plan and Provider Enumeration System (NPPES) data.

- **Use PDE Data From Current Evaluated Year to Determine Provider Exceptions Based on Number of Part D Controlled Substance Claims**

CMS is proposing to change the year from which prescription drug event (PDE) data is used from the preceding year to the current evaluated year when determining whether a prescriber qualifies for an exception based on the number of Part D controlled substance claims. Prescribers issuing 100 or fewer Part D controlled substance prescriptions meet the exception. Additionally, a prescriber's compliance status would be evaluated based on PDE data with a 'Date of Service' within the evaluated calendar year using PDE data, which Part D sponsors must submit by mid-way through the following year.

Background/Rationale

- **Extend Existing Non-Compliance Action of Sending Letters to Non-Compliant Prescribers for the EPCS Program Implementation Year**

CMS notes several advantages of EPCS including enhanced patient safety through patient identity checks, safety alerts, medication menus, electronic history files, and medication recommendations that lower the risk of errors and potentially harmful interactions.

- **Change Data Source Used to Identify Geographic Location of Prescribers to Inform Recognized Emergency Exception**

CMS believes PECOS would have the most current address information for prescribers who are enrolled in Medicare, making it the best data source for identifying provider location.

- **Use PDE Data From Current Evaluated Year to Determine Provider Exceptions Based on Number of Part D Controlled Substance Claims**

CMS believes it is consistent to consider the prescriptions issued during the evaluation period, rather than the previous year, in case there are year-over-year changes. CMS believes this proposal will better identify small prescribers for purpose of EPCS compliance and simplify the program by aligning the time periods of the exceptions. CMS also believes providers will more clearly be able to understand their Medicare Part D controlled substance prescribing patterns throughout the first two years of the EPCS program, where the only action for non-compliance is a letter.

Comments:

- **Extend Existing Non-Compliance Action of Sending Letters to Non-Compliant Prescribers for the EPCS Program Implementation Year**

CMS is seeking comment on additional penalties that CMS may impose to enforce the EPCS requirement.

CMS is seeking comment from interested parties on options they may suggest for penalties to enforce EPCS compliance.

- **Change Data Source Used to Identify Geographic Location of Prescribers to Inform Recognized Emergency Exception**

CMS is seeking public comment on whether using NPPES, NCPDP, or some other database is appropriate when there is no prescriber address in PECOS.

CMS is seeking comment on an alternative of using NPPES as the source for all prescribers. Additionally, CMS is seeking comment on other potential data sources that could be used to verify a prescriber's address.

- **Use PDE Data From Current Evaluated Year to Determine Provider Exceptions Based on Number of Part D Controlled Substance Claims**

CMS is seeking comment on its proposal to modify the exception at §423.160(a)(5)(ii) and on the possibility that prescribers would avoid prescribing controlled substances to Medicare beneficiaries, particularly where

they are approaching the 100 Part D controlled substances prescription threshold late in a calendar year, in order to remain a small prescriber.

CMS is also seeking comment on an alternative for CY 2023 only, because some prescribers are expecting CMS to use the CY 2022 PDE to assess whether the exception at §423.160(a)(5)(ii) applies for purposes of CY 2023 EPCS compliance.

O. Updates to the Quality Payment Program (section IV.)

Proposed Changes

- **Subgroup Reporting**

CMS proposes the following for subgroup reporting:

  - For the subgroup description requirement, a group must submit a description of each subgroup at the time of registration.
  - An individual eligible clinician, as represented by a TIN/NPI combination, may register for no more than one subgroup within a group's TIN.
  - Apply the low volume threshold criteria for a subgroup using information from the first segment of the applicable MIPS determination period.
  - Score subgroups on each selected population health measure based on their affiliated group score, if available and that if the subgroup's affiliated group score is not available, each such measure is excluded from the subgroup's total measure achievement points and total available measure achievement points.
  - Score subgroups on the cost measures included in the MIPS Value Pathways (MVP) that they select, based on their affiliated group score, if available. If the affiliated group score is not available, the measure is excluded from the subgroup's total measure achievement points and total available measure achievement points.
  - Will not assign a score for subgroups that register but do not submit data for an applicable performance period.

- **Major Alternative Payment Model (APM) Provisions**

CMS proposes the following major APM provisions:

  - Introduce the option for APM Entities to report the Promoting Interoperability performance category at that APM Entity level.
  - Introduce a voluntary reporting option for APM Entities to report the promoting interoperability performance category at the APM Entity level beginning with the 2023 performance period.
  - Revisions to the regulations to clarify that the criterion for Advanced APMs that payment must be based on quality measures can be met through the use of a single quality measure that meets the criteria specified.
  - Permanently establish the generally applicable revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and

suppliers in participating APM Entities for the applicable QP Performance Period, beginning with the 2023 QP Performance Period.
- Apply the 50 eligible clinician limit directly to the APM Entity participating in the Medical Home Model, and to no longer look to the parent organization for the APM Entity.

- **Quality Performance Category**

CMS is proposing the following:

- Expand the definition of the term high priority measure to include health equity quality measures.
- Change the CAHPS for MIPS case-mix adjustor for "Asian language survey completion" to use instead the "language other than English spoken at home" variable.
- Increase the data completeness criteria threshold from 70 percent to 75 percent for the CY 2024 and 2025 performance periods/2026 and 2027 MIPS payment years.
- Finalize a set of 195 quality measures, which include: the addition of new measures; updates to specialty sets; removal of existing measures, and substantive changes to existing measures

- **Cost Performance Category**

CMS is proposing the following:

- Update the operational list of care episode and patient condition groups and codes by adding the Medicare Spending Per Beneficiary (MSPB) Clinician cost measure as a care episode group.

- **Improvement Activities Performance Category**

CMS is proposing the following:

- Add four new, modify five existing, and remove five existing improvement activities from the Inventory.
- Removal of five activities, both to align with current clinical guidelines and practice as well as to eliminate duplication, so that the Inventory offers flexibility and choice without a potentially burdensome number of activities available.

- **Promoting Interoperability Performance Category**

CMS is proposing the following:

- Require and modify the Electronic Prescribing Objective's Query of Prescription Drug Monitoring Program (PDMP) measure while maintaining the associated points at 10 points.
- Expand the Query of PDMP measure to include not only Schedule II opioids, but also Schedule III, and IV drugs.
- Add a new Health Information Exchange (HIE) Objective option, the Enabling Exchange under the Trusted Exchange Framework and Common Agreement (TEFCA) measure (requiring a yes/no response), as an optional alternative to fulfill the objective.

- Consolidate the current options from three to two levels of active engagement for the Public Health and Clinical Data Exchange Objective and to require the reporting of active engagement for the measures under the objective.
- Modify the scoring methodology for the Promoting Interoperability performance category
- Continue to reweight the Promoting Interoperability performance category for certain types of non-physician practitioner MIPS eligible clinicians.

- **Third Party Intermediaries**

CMS is proposing the following:

- Update the definition of third-party intermediary consistent with existing policies and to make other minor technical edits to the regulation text governing third party intermediaries accordingly.
- Revise qualified clinical data registry (QCDR) measure self-nomination and measure approval requirements, including proposing to delay the QCDR measure testing requirement for traditional MIPS by an additional year, until the CY 2024 performance period/2026 MIPS payment year.
- Continue delaying this requirement based on their recognition of the continuing impact of the COVID-19 public health emergency on the ability of QCDRs to test measures.
- Revise remedial action and termination policies.

- **MIPS Value Pathways (MVP) Development**

CMS is proposing to modify the MVP development process such that they would evaluate a submitted candidate MVP through the MVP development process, and if they determine it is "ready" for feedback, they will post a draft version of the submitted candidate MVP on the Quality Payment Program website and solicit feedback for a 30-day period.

CMS is also proposing to modify the MVP maintenance process such that interested parties and the public would be able to submit their recommendations for potential revisions to established MVPs on a rolling basis throughout the year. CMS would then review the submitted recommendations and determine whether any are potentially feasible and appropriate.

CMS is proposing revisions to seven MVPs (*Advancing Rheumatology Patient Care; Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes; Advancing Care for Heart Disease; Optimizing Chronic Disease Management; Adopting Best Practices and Promoting Patient Safety within Emergency Medicine; Improving Care for Lower Extremity Joint Repair; and Patient Safety and Support of Positive Experiences with Anesthesia*) based on the proposed removals of certain activities from the improvement activities inventory and the addition of other relevant existing quality measures for MVP participants to select from.

CMS is proposing to develop five new MVPs: Advancing Cancer Care, Optimal Care for Kidney Health, Optimal Care for Neurological Conditions, Supportive Care for Cognitive-Based Neurological Conditions; and Promoting Wellness.

- **APM Performance Pathway (APP)**

CMS is proposing to remove the reference to subgroup scoring of the APP, and therefore, disallow reporting of the APP by a subset of a group.

- **MIPS Final Score Methodology**

CMS proposes the following:

  - Amend the benchmarking policy to score administrative claims measures in the quality performance category using a benchmark calculated from performance period data.
  - Clarify the topped-out measure policy and update the topped-out measure life cycle for scoring topped-out measures in the quality performance category.
  - Establish a maximum cost improvement score of 1 percentage point out of 100 percentage points available for the cost performance category beginning with the CY 2022 performance period/2024 MIPS payment year.
  - Use the CY 2019 MIPS payment year as the prior period and the rounded mean final score of 75 points from that prior period as the performance threshold for the CY 2025 MIPS payment year.
  - A facility-based MIPS eligible clinician would be eligible to receive the complex patient bonus.
  - Virtual groups would be eligible for facility-based measurement.
  - Changes to the definition of a facility-based MIPS eligible clinician.

Background/Rationale

- **Subgroup Reporting**

CMS believes that the subgroup description will help them understand the underlying rationale for how groups placed clinicians in a subgroup and help us utilize these characteristics to shape subgroup criteria in the future. CMS believes that these policies would help address the issues identified with assessing performance of the administrative claims measures at the subgroup level.

- **Major Alternative Payment Model (APM) Provisions**

CMS is proposing to introduce a voluntary reporting option for APM entities to report the promoting interoperability performance category at the APM entity level because it is their understanding it is possible that an APM Entity may represent only a single practice site or specialty within a larger multi-specialty TIN. They believe that in these circumstances the APM Entity may have both the ability and desire to report on the promoting interoperability performance category at the APM Entity level, thereby excluding data generated by the rest of the larger TIN, in cases where the APM Entity itself performed above average relative to the rest of that TIN.

- **Quality Performance Category**

CMS highlights that as significant and persistent inequities in healthcare outcomes exist in the United States, they are committed to developing innovative solutions that support access to high quality care and promote health equity, including the exploration of solutions to measure health equity within MIPS. Health equity is a priority area across CMS programs, including MIPS.

CMS notes that only a small percentage of CAHPS for MIPS Survey participants who report speaking a language other than English at home actually complete the survey in that language. We believe that collecting information on the language spoken by the participant at home as a case-mix adjustor rather than the language used by the respondent to complete the survey is likely to capture language preference more accurately, as well as response patterns of participants with similar experiences, for a more meaningful comparison of performance between MIPS groups.

CMS continues to believe that it is important to incrementally increase the data completeness criteria as MIPS eligible clinicians, groups, and virtual groups gain experience with MIPS. They state that the incorporation of higher data completeness thresholds in future years ensures a more accurate assessment of a MIPS eligible clinician's performance on quality measures and prevent selection bias to the extent possible.

- **Improvement Activities Performance Category**

CMS believes the new and modified activities help fill gaps they have identified in the Inventory as well as seek to ensure that activities reflect current clinical practice across the category. All four of the new activities being proposed relate to CMS Six Health Equity Priorities for Reducing Disparities in Health. CMS believes that all of their proposed new improvement activities are responsive to the Administration's goal of advancing health equity for all.

- **Promoting Interoperability Performance Category**

CMS believes that PDMPs play an important role in patient safety by assisting in the identification of patients who have multiple prescriptions for controlled substances or may be misusing or overusing them. Querying the PDMP is important for tracking dispensed controlled substances and improving prescribing practices. Efforts to expand the use of PDMPs and integrate PDMPs with health information technology systems are supported by Federal interested parties including ONC, the Centers for Disease Control and Prevention (CDC), the Department of Justice (DOJ), and the Substance Abuse and Mental Health Services Administration (SAMHSA). The Query of PDMP measure offers a way to reward health care providers who participate in current PDMP initiatives, including those supported by Federal partners.

CMS also states that they believe the new measure for Enabling Exchange Under TEFCA that they are proposing would incentivize MIPS eligible clinicians to exchange information by connecting directly or indirectly to a qualified health information network (QHIN) and support health information exchange at a national level.

- **MIPS Value Pathways (MVP) Development**

CMS notes identification of priorities for MVP development includes consideration of the various specialties and subspecialties that currently participate in MIPS, and identification of priorities of the Biden-Harris Administration, Department, and Agency.

- **APM Performance Pathway (APP)**

CMS notes that this proposed change is not intended as a change in policy; it was not their intent to permit MIPS eligible clinicians within an APM entity to be scored at a level in between a group and the individual clinician.

- **MIPS Final Score Methodology**

CMS believes that using a performance period benchmark to score these measures would allow for scores that are more reflective of current performance, while adding no additional burden to clinicians. They do not believe using performance period benchmarks would increase burden to clinicians. They believe that clinicians prefer to have historical benchmarks to aid in measure selection and have performance targets. Additionally, population health administrative claims measures in MIPS are not subject to case minimum policies reducing the risk in being scored on these measures.

CMS states they believe the maximum cost improvement score proposal is appropriate because although there are many opportunities for clinicians to actively work on improving their performance on cost measures, such as through more active care management or reductions in certain services, we recognize that many clinicians are still learning about cost. measurement under MIPS. They aim to continue to educate clinicians about cost measurement and develop opportunities for robust feedback and measures that better recognize the role of clinicians.

CMS highlights that continuing to use the mean final score from the CY 2019 MIPS payment year to determine the performance threshold for the CY 2025 MIPS payment year would maintain stability in the program. They believe continuing to use the mean final score from the CY 2019 MIPS payment year would provide predictability to MIPS eligible clinicians during a program year in which they might be affected by those prior policy changes as well as potentially scored on performance categories that were previously reweighted due to the COVID-19 PHE.

Although individual facility-based MIPS eligible clinicians are not required to submit data for at least one MIPS performance category, and it is possible they may choose not to submit data voluntarily, CMS believes they should be eligible to receive the complex patient bonus.

Comments:

CMS is seeking comments on the following:

- Sunsetting the use of APM Entity level qualifying participant (QP) determinations and instead making QP determinations at the individual eligible clinician level only.
- The gap in statutory financial incentives for QPs in the 2025 payment year, and the difference in potential financial incentives between QPs and MIPS eligible clinicians in payment years beginning in 2026.
- The addition of questions related to health disparities and price transparency to the CAHPS for MIPS Survey.
- Development and implementation of health equity quality measures.
- Development and implementation of quality measures that address amputation avoidance in diabetic patients.
- Which additional risk indicators and data sources CMS should consider for the complex patient bonus to better assess the social and medical complexity for the patients of MIPS eligible clinicians.
- Third party intermediary support of MVPs and national Continuing Medical Education (CME) organizations becoming a new type of third-party intermediary.

- How should they use MVPs to obtain more meaningful performance data from both primary care and specialty clinicians and drive improvements for APP reporters and APM participants? What are the associated pros and cons for the suggested solution(s)?
- How should they better align clinician experience with MVPs and APMs, and ensure that MVP reporting serves as a bridge to APM participation?
- How should they best limit burden and develop scoring policies for APM participants in multispecialty groups who choose to participate in MVPs and report specialty care performance data? Should they require APP participants to focus on those clinicians who work in the associated quality measurement clinical area and require subgroup reporting of relevant MVPs for others? Should they develop a process for a composite score that incorporates both APP measures and other MVP specialty measures?
- Other policy options for MIPS specialty clinician performance data reporting they should consider.
- Potential future inclusion of two new measures in the APP measure set: MUC21-136: Screening for Social Drivers of Health and MUC21-134: Screen Positive Rate for Social Drivers of Health.

P. Regulatory Impact Analysis (section VII.)

Proposed Changes

- **Proposed Change to Conversion Factor (CF) and RVUs for CY 2023**

Conversation Factor (see Table 136 below):

- CMS estimates the CY 2023 PFS CF to be 33.0775 which reflects the budget neutrality adjustment, the 0.00 percent update adjustment factor, and the expiration of the 3.00 percent increase for services furnished in CY 2022, as provided in the CAA. As displayed in the table, the conversion factor for CY 2023 is a decrease of approximately $1.53 to the CY 2022 CF, which generally means a reduction in reimbursement across a wide range of Medicare services.

TABLE 136: Calculation of the CY 2023 PFS Conversion Factor

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

RVUs: Table 138 (CY 2023 PFS Estimated Impact on Total Allowed Charges by Specialty) on page 1439 of the proposed rule summarizes the impact of Work, PE, and MP RVU changes on total allowed charges across specialties. The combined impact of all RVU changes across specialties with respect to Medicare spending is 0%.

Note, the changes per specialty are typically driven by the valuation of a relatively small number of new or potentially misvalued codes and therefore the impact of the RVU change is not uniform across the specialty – as explained, Table 138 percentage changes are based upon aggregated estimated PFS allowed charges

summed across all services furnished by Medicare providers within a specialty compared to previous CY. Therefore, they are averages, and may not necessarily be representative of what is happening to the particular services furnished by a single practitioner within any given specialty.

CMS updated their current suite of public use files (PUFs) by including a new file that shows estimated specialty payment impacts at a more granular level, specifically by showing ranges of impact for practitioners within a specialty.

This file is available on the CMS website under downloads for the CY 2023 PFS proposed rule at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFSFederal-Regulation-Notices.html.

Facility vs. Non-Facility Break Out of Payment Changes: Note, for the 2023 MPFS rulemaking cycle, on pages 1442-1446, CMS is providing in Table 139 (CY 2023 PFS Estimated Impact on Total Allowed Charges by Setting) more granular information that separates the specialty-specific impacts by site of service in response to concerns that Medicare payment policies are directly responsible for the consolidation of privately owned physician practices and free standing supplier facilities into larger health systems.