CY 2024 Medicare Physician Fee Schedule and Quality Payment Program Proposed Rule

On July 13, 2023, the Centers for Medicare and Medicaid Services (CMS) released the calendar year (CY) 2024 Medicare Physician Fee Schedule (MPFS) proposed rule. CMS notes that this proposed rule 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 access to care, quality, affordability, and innovation. Comments are due by September 11th. For additional information please see CMS's CY 2024 MPFS Fact Sheet. Details on key provisions of the proposed rule are provided below.

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

Proposed Changes

- **Proposed Clarifications and Revisions to the Process for Considering Changes to the Medicare Telehealth Services List**

CMS proposed the following steps of analysis for services under consideration for addition, or removal, or a change in status, as updates to the Medicare Telehealth Services List:

Step 1: Determine whether the service is separately payable under the PFS: When considering whether to add, remove, or change the status of a service on the Medicare Telehealth Services List, CMS proposes to first determine whether the service, as described by the individual HCPCS code, is separately payable under the PFS. CMS further proposes that, if a service identified in a submission is not separately payable under the PFS, CMS would not conduct any further review of that service. CMS would identify the code submitted for consideration and explain that it is not being proposed for addition. Lastly, CMS

proposes to inform each submitter in the confirmation whether the submission was complete, lacking required information, or outside the scope of issues considered under the process for considering changes in the Medicare Telehealth Services List.

Step 2. Determine whether the service is subject to the provisions of section 1834(m) of the Act: If CMS determines at Step 1 that a service is separately payable under the PFS, CMS proposes to apply Step 2 under which they would determine whether the service at issue is subject to the provisions of section 1834(m) of the Act. A service is subject to the provisions of section 1834(m) of the Act when at least some elements of the service, when delivered via telehealth, are a substitute for an in-person, face-to-face encounter, and all of those face-to-face elements of the service are furnished using an interactive telecommunications system.

Step 3. Review the elements of the service as described by the HCPCS code and determine whether each of them is capable of being furnished using an interactive telecommunications system as defined in § 410.78(a)(3): Step 3 is corollary to Step 2, and used to determine whether one or more elements of a service are capable of being delivered via an interactive telecommunication system. In Step 3, CMS considers whether one or more face-to-face component(s) of the service, if furnished via audio-video communications technology, would be equivalent to the service being furnished in-person, and seeks information from submitters to demonstrate evidence of substantial clinical improvement in different beneficiary populations that may benefit from the requested service when furnished via telehealth, including, for example, in rural populations.

Step 4. Consider whether the service elements of the requested service map to the service elements of a service on the list that has a permanent status described in previous final rulemaking: For Step 4, CMS proposes to consider whether the service elements of a code that are being considering for addition to, or removal from, the Medicare Telehealth Services List map to the service elements of a service that is already on the list and has a permanent status, because any code that satisfies this criterion would require no further analysis: if a code describes a service that maps to the service elements of a code that is included on the Medicare Telehealth Services List on a permanent basis, CMS would add the code to the Medicare Telehealth Services List on a permanent basis. CMS further proposes that if the service being considered satisfies Step 4, CMS would end the review and propose to add the service to the Medicare Telehealth Services List on a permanent basis in the next PFS proposed rule. When Step 4 is met, further evidence review is not necessary. If Step 4 is not met, then CMS proposes to continue to Step 5.

Step 5. Consider whether there is evidence of clinical benefit analogous to the clinical benefit of the in-person service when the patient, who is located at a telehealth originating site, receives a service furnished by a physician or practitioner located at a distant site using an interactive telecommunications system: Under proposed Step 5, CMS would review the evidence provided with a submission to determine the clinical benefit of a service. CMS would then compare the clinical benefit of that service, when provided via telehealth, to the clinical benefit of the service if it were to be furnished in person. CMS further proposes that: if there is enough evidence to suggest that further study may demonstrate that the service, when provided via telehealth, is of clinical benefit, CMS would assign the code a "provisional" status on the Medicare Telehealth Services List. Where the clinical benefit of a service, when provided via telehealth, is clearly analogous to the clinical benefit of the service when provided in person, CMS would assign the code "permanent" status on the Medicare Telehealth Services List, even if

the code's service elements do not map to the service elements of a service that already has permanent status.

Proposed Assignment of "permanent" or "provisional" Status to a Service and Changes in Status: CMS proposes to assign "permanent" or "provisional" status to any services for which the service elements map to the service elements of a service on the list that has a permanent status described in previous final rulemaking or for which there is evidence of clinical benefit analogous to the clinical benefit of the in-person service when the service is furnished via telehealth by an eligible Medicare telehealth physician or practitioner.

- **Consolidation of the Categories for Services Currently on the Medicare Telehealth Services List**

CMS is also proposing to consolidate Categories 1, 2, and 3 for all services that are currently on the Medicare Telehealth Services List. For CY 2024, CMS proposes to redesignate any services that are currently on the Medicare Telehealth Services List on a Category 1 or 2 basis and would be on the list for CY 2024 to the proposed new "permanent," category while any services currently added on a "temporary Category 2", or Category 3 basis would be assigned to the "provisional" category.

- **Implementation of Provisions of the Consolidated Appropriations Act of 2023 (CAA, 2023)**

CMS proposes the implementation of the following provisions of the CAA, 2023:

1. In-person Requirements for Mental Health Telehealth: The CAA, 2023 delays the requirement for an in-person visit with the physician or practitioner within 6 months prior to the initial mental health telehealth service, and again at subsequent intervals as the Secretary determines appropriate. In light of this amendment, the in-person requirements for telehealth services furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder will again be effective on January 1, 2025. In addition, the CAA, 2023 similarly delayed in-person visit requirements for mental health visits furnished by Rural Health Clinics and Federally Qualified Health Centers via telecommunications technology.
2. Originating Site Requirements: The CAA, 2023 temporarily expands the telehealth originating sites for any service on the Medicare Telehealth Services List to include any site in the United States where the beneficiary is located at the time of the telehealth service, including an individual's home, beginning on the first day after the end of the PHE for COVID-19 through December 31, 2024.
3. Telehealth Practitioners: The CAA, 2023 requires that qualified occupational therapists, qualified physical therapists, qualified speech-language pathologists, and qualified audiologists continue to be included as telehealth practitioners beginning on the first day after the end of the PHE for COVID-19 through December 31, 2024. CMS proposes to add new paragraphs and to specify that a marriage and family therapist and a mental health counselor are included as distant site practitioners for purposes of furnishing telehealth services.
4. Audio-Only Services: The CAA, 2023 requires that the Secretary shall continue to provide for coverage and payment of telehealth services via an audio-only communications system during the period beginning on the first day after the end of such emergency period and ending on December 31, 2024.

- **Place of Service for Medicare Telehealth Services**

CMS proposes that, beginning in CY 2024, claims billed with POS 10 (Telehealth Provided in Patient's Home) be paid at the non-facility PFS rate. When considering certain practice situations (such as in behavioral health settings, where practitioners have been seeing greater numbers of patients via telehealth), practitioners will typically need to maintain both an in-person practice setting and a robust telehealth setting.

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

As was done to account for the impacts of the COVID-19 PHE, CMS proposes to once again remove certain telehealth frequency limitations beginning CY 2024, which will align with other telehealth-related flexibilities extended by the CAA, 2023. CMS proposes to remove the telehealth frequency limitations for the following codes:

1. *Subsequent Inpatient Visit CPT Codes*: 99231, 99232, 99233
2. *Subsequent Nursing Facility Visit CPT Codes*: 99307, 99308, 99309, 99310
3. *Critical Care Consultation Services: HCPCS Codes*: G0508, G0509

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

Direct Supervision via Use of Two-way Audio/Video Communications Technology: CMS proposes to continue to define direct supervision to permit the presence and "immediate availability" of the supervising practitioner through real-time audio and visual interactive telecommunications through December 31, 2024.

Supervision of Residents in Teaching Settings: CMS proposes to allow the teaching physician to have a virtual presence in all teaching settings, only in clinical instances when the service is furnished virtually (for example, a 3-way telehealth visit, with all parties in separate locations).

Clarification for Remote Monitoring Services: CMS proposes to clarify that the data collection minimums apply to existing remote patient monitoring (RPM) and remote therapist monitoring (RTM) code families for CY 2024. The following remote monitoring codes currently depend on collection of no fewer than 16 days of data in a 30-day period, as defined and specified in the code descriptions: 98976, 98977, 98978, 98980, 98981.

CMS proposes to clarify that RPM and RTM may not be billed together, so that no time is counted twice by billing for concurrent RPM and RTM services. In instances where the same patient receives RPM and RTM services, there may be multiple devices used for monitoring, and in these cases, CMS will to apply the existing rules, which were finalized when establishing the RPM code family, meaning that the services associated with all the medical devices can be billed by only one practitioner, only once per patient, per 30-day period, and only when at least 16 days of data have been collected; and that the services must be reasonable and necessary.

CMS proposes to clarify that, in circumstances where an individual beneficiary may receive a procedure or surgery, and related services, which are covered under a payment for a global period, RPM services or

RTM services (but not both RPM and RTM services concurrently) may be furnished separately to the beneficiary, and the practitioner would receive payment for the RTM or RPM services, separate from the global service payment, so long as other requirements for the global service and any other service during the global period are met.

Telephone Evaluation and Management Services: CMS proposes to continue to assign an active payment status to CPT codes 98966 through 98968 for CY 2024 to align with telehealth-related flexibilities that were extended via the CAA, 2023, which permits the provision of telehealth services through audio-only telecommunications through the end of 2024.

- **Telehealth Originating Site Facility Fee Payment Amount Update**

The proposed Medicare Economic Index (MEI) increase for CY 2024 is 4.5 percent and is based on the expected historical percentage increase of the 2017-based MEI. \ CMS proposes to update the MEI increase for CY 2024 based on historical data through the second quarter of 2023. Therefore, for CY 2024, the proposed payment amount for HCPCS code Q3014 (Telehealth originating site facility fee) is $29.92.

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

CMS is proposing to continue to allow institutional providers to bill for outpatient therapy, diabetes self-management training (DSMT), and medical nutrition therapy (MNT) services when furnished remotely in the same manner they have during the PHE for COVID-19 through the end of CY 2024.

Background/Rationale

- **Proposed Clarifications and Revisions to the Process for Considering Changes to the Medicare Telehealth Services List**

To avoid potential continuing confusion among those who submit requests to add services to the Medicare Telehealth Services List, and as CMS considers the expiration of the Medicare telehealth flexibilities extended by the CAA, 2023 through the end of CY 2024, they believe it would be beneficial to simplify the current taxonomy and multicategory approach to considering submitted requests. Further, CMS believes that simplification toward a binary classification approach could address the confusion from interested parties submitting requests during the PHE. The proposal would restore the simple binary that existed with Category 1 and 2, without displacing or disregarding the flexibility of Category 3.

Therefore, CMS believes the restatement of requirements and corresponding review process is appropriate. CMS also proposes some procedural refinements to the review process, specifically incorporating additional considerations into the evaluation of services, that would serve to maintain scope and focus on a post-PHE context.

- **Consolidation of the Categories for Services Currently on the Medicare Telehealth Services List**

The CMS proposal does not establish any specific timing for considering changes from provisional to permanent status which would avoid a potential situation in which CMS would be forced to remove provisional services from the Medicare Telehealth Services List because the set period tolls, only to later find evidence demonstrating that the removed service should receive permanent status. Under the proposal, CMS would assign a provisional status for codes that satisfy the proposed threshold steps (1, 2, and 3), and then the evidence available leaves a "close call" between permanent and provisional status.

- **Place of Service for Medicare Telehealth Services**

Throughout the PHE for COVID-19, behavioral health services that otherwise would have been furnished in-person have been furnished via telehealth in the patient's home. Now that behavioral health telehealth services may be furnished in a patient's home, which would then serve as an originating site, CMS believes these behavioral health services are most accurately valued the way they would have been valued without the use of telecommunications technology, namely in an office setting. There was an increase in utilization of these mental health services during the PHE that has persisted throughout and after expiration of the PHE for COVID-19. As a result, these practitioners continue to maintain their office presence even as a significant proportion of their practice's utilization may be comprised of telehealth visits. As such, CMS believes practice expenses (PEs) are more accurately reflected by the non-facility rate.

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

When adding some services to the Medicare Telehealth Services List in the past, CMS has included certain restrictions on how frequently a service may be furnished via Medicare telehealth. The frequency limitations that were lifted for the COVID-19 PHE resumed effect beginning on May 12, 2023, (upon expiration of the PHE), in accordance with the March 31, 2020 interim final rule. However, pursuant to existing waiver authority, CMS is exercising enforcement discretion and will not consider these frequency limitations through December 31, 2023; and that CMS anticipated considering the policy further through the rulemaking process.

- **Other Non-Face-to-Face Services Involving Communications Technology under the MPFS:**

Direct Supervision via Use of Two-way Audio/Video Communications Technology: CMS is concerned about an abrupt transition to the pre-PHE policy that defines direct supervision to require the physical presence of the supervising practitioner beginning after December 31, 2023, given that practitioners have established new patterns of practice during the PHE for COVID-19. By proposing additional transitionary time, CMS believes there will be further opportunity to collect information through the coming year to consider an appropriate more permanent approach to direct supervision policy following the PHE for COVID-19.

Supervision of Residents in Teaching Settings: As stated by CMS throughout this proposed rule, there is concern that an abrupt transition to the pre-PHE policy may present a barrier to access to many services, and CMS understands that practitioners have gained clinical experience during the PHE for COVID–19, and could identify circumstances for which the teaching physician can routinely render sufficient personal and identifiable services to the patient, with a virtual presence during the key portion of the telehealth

service. Given these considerations and in alignment with the telehealth policies that were extended under the provisions of the CAA, 2023, CMS is proposing the policy detailed above.

Clarification for Remote Monitoring Services: In recent years, CMS has established payment for two code families that describe certain remote monitoring services: RPM and RTM. CMS has received many questions from interested parties about billing scenarios and requests for clarifications on the appropriate use of these codes in general. Thus, CMS believes it is important to share with all interested parties a restatement/clarification of certain policies.

Telephone Evaluation and Management Services: Previously, CMS finalized separate payment for CPT codes 99441 through 99443 and 98966 through 98968, which describe E/M and assessment and management services furnished via telephone. CPT codes 99441 through 99443 are telehealth services and will remain actively priced through 2024. CPT codes 98966 – 98968, however, describe telephone assessment and management services provided by a qualified non-physician healthcare professional, and they are not telehealth services.

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

The CAA, 2023 extended many of the flexibilities that were available for Medicare telehealth services during the PHE for COVID-19 under emergency waiver authorities, including adding physical and occupational therapists and speech-language pathologists as distant site practitioners through the end of CY 2024. In developing post-PHE guidance, CMS initially took the position that institutions billing for services furnished remotely by their employed practitioners (where the practitioners do not bill for their own services), would end with the PHE for COVID-19 along with the Hospitals Without Walls (HWW) waivers. However, after reviewing input from interested parties, as well as relevant guidance, including applicable billing instructions, CMS is considering whether certain institutions, as the furnishing providers, can bill for certain remotely furnished services personally performed by employed practitioners as proposed above.

Comments

- **Proposed Clarifications and Revisions to the Process for Considering Changes to the Medicare Telehealth Services List**

CMS is soliciting comments on the proposed analysis procedures for additions to, removals from, or changes in status for services on the Medicare Telehealth Services List as described above.

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

Direct Supervision via Use of Two-way Audio/Video Communications Technology: CMS is soliciting comments on whether they should consider extending the definition of direct supervision to permit virtual presence beyond December 31, 2024.

Supervision of Residents in Teaching Settings: CMS seeks comment and information to help consider how telehealth services can be furnished in all residency training locations beyond December 31, 2024, to include what other clinical treatment situations are appropriate to permit the virtual presence of the

teaching physician. CMS also invites commenters to provide data or other information on how the teaching physician's virtual presence could continue to support patient safety, while meeting the clinical needs for all patients, and ensure burden reduction without creating risks to patient care or increasing opportunities for fraud.

Clarification for Remote Monitoring Services: CMS is soliciting comment on the above proposals and clarifications and request general feedback from the public that may be useful in further development of payment policies for remote monitoring services that are separately payable under the current PFS.

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

In the interests of maintaining access to outpatient therapy, DSMT, and MNT services furnished remotely by institutional staff to beneficiaries in their homes consistent with the accessibility of these services when furnished by professionals via Medicare telehealth, CMS is seeking comment on current practice for these services when billed, including how and to what degree they continue to be provided remotely to beneficiaries in their homes. CMS is also seeking comment as to whether these services may fall within the scope of Medicare telehealth or if there are other relevant authorities CMS might consider in future rulemaking.

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

Proposed Changes

- **General Behavioral Health Integration Care Management**

CMS is proposing to increase the work Relative Value Unit (RVU) for the General Behavioral Health Integration Care Management CPT code 99484 and HCPCS code G0323 from 0.61 to 0.93. Additionally, they are proposing to update the CPT 99484 work time to 21 minutes, and the practice expense (PE) inputs as recommended by the Relative Value Scale Update Committee (RUC) without refinement and applying the same changes to the HCPCS code G0323.

- **Caregiver Training Services (CTS)**

CMS is proposing to broadly define caregiver, in the context of Caregiver Training Services, as a family member, friend, or neighbor who provides unpaid assistance to a person with a chronic illness or disabling condition, including individuals assisting or acting as a proxy for a patient with an illness or condition for short or long-term duration, who is involved in episodic, daily, or occasionally managing a patient's complex health care and assistive technology at home, and helping to navigate the patient's transitions between care settings. CMS is proposing to include guardians of minor children and other individuals who are not legally independent within this definition, when warranted.

CMS is proposing to allow treating practitioners to train caregivers in a group setting, simultaneously with other caregivers involved in the care for patients with similar needs to carry out a treatment plan, and the applicable CPT codes (96202, 96203, and 9X017) would be billed once per beneficiary. Additionally, treating practitioners must obtain the patient's (or representative's) consent for one or more specific

caregivers to receive CTS, and documented in the patient's medical record along with the identified need for CTS.

CMS is proposing to establish active payment status for CPT codes 96202 and 96203 (caregiver behavior management/modification training services) 9X015, 9X016, and 9X017 (caregiver training services under a therapy plan of care established by a PT, OT, or SLP). CMS is proposing to require the full 60 minutes of time be performed to report CPT code 96202, and the add on code (96203) may be reported after 75 minutes.

CMS is proposing the work RVU of 0.43 for CPT code 96202, work RVU of 0.12 for CPT code 96203, and RUC-recommended direct PE inputs for both codes. CMS is also proposing the work RVU of 1.00 for CPT code 9X015, work RVU of 0.54 for 9X016, and work RVU of 0.23 per patient service for CPT code 9X017, based on a median group size of five caregivers, and the RUC-recommended direct PE inputs for all three codes.

Background/Rationale

- **General Behavioral Health Integration Care Management**

CMS re-evaluated CPT code 99484 on the recommendation of the RUC, to determine if the code undervalues the care management service. They conducted a survey with 63 respondents and found that the median work RVU was 1.3 and median intra-service time was 21 minutes. CMS also consulted with relevant specialty societies, who recommended using a RVU of 0.93, in alignment with CPT code 99202 (new patient evaluation). Similarly, the RUC recommended utilizing the 25th percentile of survey RVU of 0.85. CMS chose to propose an RVU that aligns with the specialty society recommendation, which they believe also aligns with their goal of ensuring consistent access to these services.

The 2023 MPFS Final Rule established the HCPCS code G0323 based on a direct crosswalk of the work values and direct PE inputs for CPT code 99484, as CMS believed the services mirrored each other. CMS continues to believe the two services are closely aligned on the level, time, and intensity of services provided. Therefore, CMS chose to propose the same updates to HCPCS code G0323 as CPT 99484.

- **Caregiver Training Services**

CMS has historically not covered codes that described services provided to individuals without the patient present to limit Medicare services to those that are reasonable and necessary under section 1862(a)(1)(A) of the Act. However, beginning in CY 2022 the AMA RUC recommended creating new code families to support group behavior management/modification training for caregivers of patients with a mental/physical health diagnosis, caregiver training to facilitate patient functional performance in the community, and an add-on code for group caregiver functional performance training.

CMS previously solicited public comment on how patients may benefit from these caregiver training services and how they may be bundled into existing Medicare-covered services. Commenters generally supported CMS reimbursement for these codes and shared evidence for how caregiver training is a component of standard of care for certain conditions and leads to improved patient outcomes. Commenters also noted that CMS already includes services without direct patient contact in the PFS such as separately billable care management, interprofessional consultations, and caregiver-focused health risk

assessments. In response to these comments, CMS acknowledges the important role caregivers could have in a patient's care.

Additionally, CMS sought to align these proposals with the recent Executive Order on Increasing Access to High-Quality Care and Supporting Caregivers, as part of an HHS review of payment policies to identify opportunities to better account for patient-centered care for the RAISE Family Caregiving Advisory Council, and generally to promote equitable access to medical services through care coordination and team-based care. CMS also believes that under section 1557 of the Affordable Care Act, it is important for providers to use various communication techniques to provide patient centered care. CMS believes that in certain circumstances, caregivers can play a key role in developing and carrying out the treatment plan established by treating practitioners for the patient. As such, CMS believes that Caregiver Training Services (CTS) could be reasonable and necessary to treat the patient's illness or injury as required under section 1862(a)(1)(A) of the Act.

CMS does not anticipate the caregivers that would receive these services on behalf of a beneficiary would duplicate services provided under another Medicare benefit category or Federal program, including for beneficiaries dually eligible for Medicare and Medicaid.

CPT code 96202 and add-on 96203 were created by the CPT Editorial Panel in February 2021 to report the total duration of face-to-face time spent by practitioners providing group behavior management/modification training to guardians or caregivers of patients. The AMA RUC summary of recommendations noted that this service teaches caregivers how to structure the patient's environment to support and reinforce desired patient behaviors, reduce negative impacts of their diagnosis on their daily life, and develop highly structured technical skills to manage challenging behaviors. Training should be directly relevant to the person-centered treatment plan and each behavior should be clearly identified and documented in the treatment plan.

CPT codes 9X015 and its add-ons 9X016 and 9X017 were created by the CPT Editorial Panel in October 2022 to report the total duration of face-to-face time spend by the practitioner providing individual or group training to caregivers of patients, focusing on improving the patient's ability to perform activities of daily living. Training includes the development of skills like safe activity completion, problem solving, environmental adaptation, training in the use of equipment or assistive devices, or interventions focusing on motor, process, and communication skills.

Comments

- **Caregiver Training Services (CTS)**

CMS is seeking comments on all aspects of the CTS proposal.

CMS is specifically seeking comments on whether States typically cover services similar to CTS under their Medicaid programs, whether coverage would be duplicative, and whether payment is currently available for this service through other programs.

CMS is seeking comments on whether CTS may be delivered simultaneously to multiple caregivers in a group setting and whether multiple sessions of training may be furnished to a caregiver throughout the year.

CMS is seeking comments on the definition of caregiver for the purposes of CTS, and any additional elements they should consider incorporating.

CMS is seeking comments on how clinician and caregiver interactions typically occur, including when the practitioner is dealing with multiple caregivers, and how often these services would be billed for an established treatment plan involving caregivers for a typical patient.

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

Proposed Changes

- **Office/Outpatient (O/O) E/M Visit Complexity Add-on Implementation**

CMS proposes to change the status of HCPCS code G2211 to make it separately payable by assigning the "active" status indicator, effective January 1, 2024.

CMS proposes that the O/O E/N visit complexity add-on code, HCPCS code G2211, would not be payable when the O/O E/M visit is reported with payment modifier-25. After taking into consideration comments by interested parties, CMS estimates that HCPCS code G2211 will be billed with 38 percent of all O/O E/M visits initially. After fully adopted, CMS estimates that HCPCS code G2211 will be billed with 54 percent of all O/O E/M visits.

- **Split (or Shared) Visits**

CMS proposes to delay the implementation of the "substantive portion" as more than half of the total time through at least December 31, 2024. Therefore, CMS proposes to amend 42 CFR 415.140 to revise the definition of "substantive portion" to replace "the year 2022 and 2023" with "years 2022 through 2024" in the interim.

CMS proposes to maintain the current definition of substantive portion for CY 2024 that would allow for use of either one of the three key components (history, exam, or MDM) or more than half of the total time spent to determine who bills the visit.

Background/Rationale

- **Office/Outpatient (O/O) E/M Visit Complexity Add-on Implementation**

In the CY 2021 final rule, CMS refined the O/O E/M visit complexity add-on code, GPC1X, which was placed by HCPCS code G2211, to describe the intensity and complexity of O/O E/M visits associated with medical care services that serve as the focal point for all needed health care services related to a patient's single, serious, or complex condition. Under the final policy, the O/O E/M visit complexity add-on code would be reported with all O/O E/M visit levels; CMS opted to not restrict billing to higher level O/O E/M visits. CMS did not prohibit billing the O/O E/M visit complexity add-on in conjunction with visits that are reported with various modifiers, but did not expect the add-on service to be reported for visits billed with a payment modifier.

There is uncertainty regarding when it would be appropriate to report the O/O E/M visit complexity add-on service, with some parties concerned about potential reductions to the PFS CF and others supportive of

the add-on code to better reflect the resources they use. CMS has historically believed that the O/O E/M visit complexity add-on reflects the time, intensity, and PE resources involved when practitioners furnish the kinds of O/O E/M services that allow them to build longitudinal relationships with all patients. In addition, CMS acknowledged the importance of educating physicians on the appropriate use of the O/O E/M visit complexity add-on code, ongoing implementation of the revisions to the O/O E/M visit code set, electronic health records integration, and the impact of the COVID-19 pandemic. Given this, it is understandable that practitioners that rely on O/O E/< visits to report the majority of their services likely will not report the complexity add-on code with every office visit.

CMS continues to believe that separately identifiable O/O E/M visits occurring on the same day as minor procedures have resources that are sufficiently distinct from the costs associated with furnishing stand-alone O/O E/M visits to warrant different payment. Interested parties have shared that some practitioners would not be likely to report HCPCS code G2211 with every O/O E/M visit they report.

- **Split (or Shared) Visits**

A split (or shared) visit refers to E/M visits performed by both a physician and an NPP in the same group practice. Historically, if the physician performed a substantive portion of the encounter, they could bill for the split (or shared) visit in the facility setting. In CY 2022, CMS defined "substantive portion" as one of the following: either one of the three key E/M elements (history, exam, or MDM) or more than half of total time. For CY 2023, CMS finalized that they would delay implementation of their definition of the substantive portion as more than half of the total practitioner time until January 1, 2024. In addition, in CY 2022, CMS finalized their proposal to create a payment modifier to describe split (or shared) visits to better quantify split (or shared) visits and understand billing patterns. CMS has about one year's worth of claims data from the time the modifier was instituted.

The proposed additional delay allows interested parties to have another opportunity to comment on this policy and gives CMS time to consider more recent feedback and evaluate whether there is a need for additional rulemaking on this aspect of the policy.

Comments

- **Office/Outpatient (O/O) E/M Visit Complexity Add-on Implementation**

CMS seeks comments on their utilization assumptions and the application of this proposed policy for CY 2024. After taking into consideration comments by interested parties, CMS estimates that HCPCS code G2211 will be billed with 38 percent of all O/O E/M visits initially. After fully adopted, CMS estimates that HCPCS code G2211 will be billed with 54 percent of all O/O E/M visits.

- **Evaluating E/M Services More Regularly and Comprehensively**

CMS seeks public comment about the potential range of approaches CMS could take to improve the accuracy of valuing services. In addition, they are interested in information about how CMS might evaluate E/M services with greater specificity, more regularly, and comprehensively. CMS is interested in receiving specific recommendations on ways to improve data collection and ensure accurate payments for E/M and other services. This includes ways to make more timely improvements to methodologies to reflect changes in the Medicare population, treatment guidelines, and new technologies that represent

standards of care. They are interested in recommendations that would ensure data collection from physician practices are as least burdensome as possible, while painting program integrity requirements. CMS is interested in whether commenters believe that the current AMA RUC is the entity that is best positioned to provide recommendations to CMS on resource inputs for work and PE valuations, or if another entity would better serve CMS.

Specifically, CMS seeks comments on the following questions:

1. Do the existing E/M HCPCS codes accurately define the full range of E/M services with appropriate gradations for intensity of services?
2. Are the methods used by the RUC and CMS appropriate to accurately value E/M and other HCPCS codes?
3. Are the current Non-E/M HCPCS codes accurately defined?
4. Are the methods used by the RUC and CMS appropriate to accurately value the non E/M codes?
5. What are the consequences if services described by HCPCS codes are not accurately defined?
6. What are the consequences if services described by HCPCS codes are not accurately valued?
7. Should CMS consider valuation changes to other codes similar to the approach in section II.J.5. of this rule?

- **Split (or Shared) Visits**

CMS seeks public comment on how facilities are currently implementing their split (or shared) services policy in their workflows and how facilities are accounting for services of billing practitioners that are performed split (or shared). In addition, CMS is interested in how to better account for the services of the billing practitioner in teams-based care clinical scenarios. CMS highlighted that the AMA CPT Editorial Panel is considering revisions to aspects of split or shared visits that may impact CMS' policies, and they will review the AMA CPT Editorial Panel's changes if they are available before the final rule. They will consider any changes that are made and their relationship to previous CMS policies.

D. Supervision of Outpatient Therapy Services, KX Modifier Thresholds, Diabetes Self-Management Training (DSMT) Services by Registered Dietitians and Nutrition Professional, and DSMT Telehealth Services (section II.I.)

Proposed Changes

- **Supervision of Outpatient Therapy Services in Private Practices**

CMS is proposing to retain the Occupational Therapists in Private Practices (OTPP) and Physical Therapists in Private Practice (PTPP) direct supervision requirement for unenrolled PTs or OTs by clarifying that the proposed RTM general supervision regulation at §§ 410.59(c)(2) and 410.60(c)(2) applies only to the OTA and PTA and does not include the unenrolled OT or PT.

- **Diabetes Self-Management Training (DSMT) Services Furnished by Registered Dietitians (RDs) and Nutrition Professionals**

CMS proposes to amend the regulation at § 410.72(d) to clarify that a RD or nutrition professional must personally perform Medical Nutrition Therapy (MNT) services. Additionally, they propose to clarify that an RD or nutrition professional may bill for, or on behalf of, the entire DSMT entity as the DSMT certified provider regardless of which professional furnishes the actual education services. CMS further proposes to clarify § 410.72(d) to provide that, except for DSMT services furnished as, or on behalf of, an accredited DSMT entity, registered dietitians and nutrition professionals can be paid for their professional MNT services only when the services have been directly performed by them.

- **DSMT Telehealth Issues (***Distant Site Practitioners)*

To increase access to DSMT telehealth services, CMS is proposing to codify billing rules for DSMT services furnished as Medicare telehealth services at § 410.78(b)(2)(x) to allow distant site practitioners who can appropriately report DSMT services furnished in person by the DSMT entity, such as RDs and nutrition professionals, physicians, nurse practitioners (NPs), physician assistants (PAs), and clinical nurse specialists (CNSs), to also report DSMT services furnished via telehealth by the DSMT entity, including when the services are performed by others as part of the DSMT entity.

- **DSMT Telehealth Issues** (*Telehealth Injection Training for Insulin-Dependent Beneficiaries)*

CMS is proposing to revise their policy at 410.78(e) to allow the 1 hour of in-person training (for initial and/or follow-up training), when required for insulin-dependent beneficiaries, to be provided via telehealth. If finalized, they predict a revision of the Medicare Claims Processing Manual, Pub. 100-04, chapter 12, section 190.3.6 to reflect that flexibility.

Background/Rationale

- **Supervision of Outpatient Therapy Services in Private Practices**

In the CY 2023 PFS final rule, CMS finalized new policies that would allow Medicare payment for remote therapeutic monitoring (RTM) services, including allowing any RTM service to be furnished under their general supervision requirements (87 FR 69649)

The current regulations, however, at §§ 410.59(a)(3)(ii) and 410.60(a)(3)(ii) specify that all occupational and physical therapy services are performed by, or under the direct supervision of, the occupational or physical therapist, respectively, in private practice. These regulations make it difficult for physical therapists in private practice (PTPPs) and occupational therapists in private practice (OTPPs) to bill for the RTM services performed by the physical therapist assistants (PTAs) and occupational therapy assistants (OTAs) they are supervising, since the PTPP or OTPP must remain immediately available when providing direct supervision of PTAs and OTAs.

CMS believes this proposal will increase access to these remotely provided services performed by PTAs and OTAs under the general supervision furnished by PTPPs and OTPPs. This aligns the regulatory text at §§ 410.59 and 410.60 with the RTM general supervision policy that they finalized in their CY 2023 rulemaking.

- **General Supervision for PTs and OTs in Private Practice Comment Solicitation**

Since the CY 2005 PFS, in the private practice setting, CMS has required direct supervision for physical and occupational therapy services when furnished by PTAs and OTAs. Which required a OTPP or PTPP to be immediately available to assist in the performance of procedure. 42 CFR 485.713 specifies that when an OTA or PTA provides services at a location that is off the premises of a clinic, rehabilitation agency, or public health agency, those services are supervised by a qualified occupational or physical therapist who makes an onsite supervisory visit at least once every 30 days.

Over the last several years, interested parties have requested that CMS revise their direct supervision policy for PTPPs and OTPPs to align with the general supervision policy for physical and occupational therapists working in Medicare institutional providers that provide therapy services (for example, outpatient hospitals, rehabilitation agencies, SNFs and CORFs), to allow for the general supervision of their therapy assistants. Additionally, the interested parties have informed them that all but one State allows for general supervision of OTAs and at least 44 States allow for the general supervision of PTAs, via their respective State laws and policies.

- **KX Modifier Thresholds**

Formerly referred to as the therapy cap amounts, the KX modifier thresholds were established through section 50202 of the Bipartisan Budget Act (BBA) of 2018. These per-beneficiary amounts are updated each year based on the percentage increase in the MEI. In the CY 2023 PFS Final Rule, CMS rebased and revised the MEI to a 2017 base year. The amounts are calculated by updating the previous year's amount by the percentage increase in the MEI for the upcoming calendar year and rounding to the nearest $10.00.

Section 1833(g)(7)(B) of the Act describes the targeted medical review (MR) process for services of physical therapy, speech-language pathology, and occupational therapy services. The threshold for targeted MR is $3,000 until CY 2028, when it will be updated by the percentage increase in the MEI. Consequently, for CY 2024, the MR threshold is $3,000 for physical therapy and speech-language pathology services combined and $3,000 for occupational therapy services. Section 1833 (g)(5)(E) of the Act states that CMS will conduct targeted medical review using the factors that may include the following:

1. The therapy provider has had a high claims denial percentage for therapy services under this part or is less compliant with applicable requirements under this title.
2. The therapy provider has a pattern of billing for therapy services under this part that is aberrant compared to peers or otherwise has questionable billing practices for such services, such as billing medically unlikely units of services in a day.
3. The therapy provider is newly enrolled under this title or has not previously furnished therapy services under this part.
4. The services are furnished to treat a type of medical condition.
5. The therapy provider is part of a group that includes another therapy provider identified using the factors described previously in this section.

CMS tracks each beneficiary's incurred expenses for therapy services annually and counts them towards the KX modifier and MR thresholds by applying the PFS rate for each service less any applicable Multiple Procedure Payment Reduction (MPPR) for services that CMS designates as "always therapy services".

- **Diabetes Self-Management Training (DSMT) Services Furnished by Registered Dietitians (RDs) and Nutrition Professionals**

In the CY 2022 PFS rulemaking, CMS adopted a regulation at § 410.72(d) that requires the services that registered dieticians (RDs) and nutrition professionals furnish to beneficiaries to be directly performed by them. They based this on the MNT regulations at subpart G, §§ 410.130 – 410.134. When developing this policy, CMS was only referring to MNT services.

These MNT services are distinct from the DSMT services that RDs or nutrition professionals may furnish when they are or represent an accredited DSMT entity. CMS further notes that the RD or nutrition professional, when named in or a sponsor of an accredited DSMT entity, may act as the DSMT certified provider, which is defined at section 325 1861(qq) of the Act as a physician, or other individual or entity to which Medicare makes payment for other services. RDs and nutrition professionals may qualify as DSMT certified providers within the meaning of the statute since they provide and bill for MNT services. This is reinforced in the sub-regulatory manual provisions (Pub. 100-02, Chapter 15, section 300.2), which specifies that DSMT certified providers may bill and be paid for the entire DSMT program and further clarifies that the RD or nutrition professional is eligible to bill on behalf of an entire DSMT program (or entity) on or after January 1, 2002, after obtaining a Medicare provider number.

Interested parties have alerted CMS that the wording of § 410.72(d) has caused confusion for DSMT entities/suppliers and Part B Medicare Administrative Contractors (MACs) about whether RD or nutrition professions must personal provide DSMT services. With the goal of reducing confusion around § 410.72(d), CMS believes clarification is needed to distinguish between when a RD or nutritional professional is personally providing MNT services, in accordance with MNT regulations, and when they are acting as or on behalf of an accredited DSMT entity and billing for DSMT services that may be provided by a group of other professionals working under an accredited DSMT entity (registered nurses, pharmacists or RDs other than the sponsoring RD).

- **DSMT Telehealth issues – Distant Site Practitioners**

Since 2006, RDs and nutrition professionals have been recognized as distant site practitioners for purposes of Medicare telehealth services under section 1834(m)(4)(E) of the Act. Section 1834(m)(4)(E) of the Act specifies that the practitioners listed at section 1842(b)(18)(C) of the Act, which include RDs and nutrition professionals as of 2006, can serve as distant site practitioners for Medicare telehealth services. Additionally, Medicare Benefit Policy Manual, Pub. 100-02, Chapter 15, section 300.2 clarifies that these certified providers, including RDs or nutrition professionals, may bill for services of the DSMT entity. Since CMS allows RDs and other DSMT certified providers to bill on behalf of the DSMT entity when other professionals personally furnish the service in face-to-face encounters, they believe that this should also be their policy when DSMT is furnished as a Medicare telehealth service.

CMS hopes this proposed revision to the regulation will preserve access to DSMT services via telehealth for Medicare beneficiaries in cases where the DSMT service is provided in accordance with the National Standards for Diabetes Self-management Education Programs (NSDSMEP) quality standards. CMS noted that DSMT services are on the Medicare Telehealth Services List and are subject to the requirements and conditions of payment under section 1834(m) of the Act and §410.78 of their regulations, including originating site and geographic location requirements, when they are in effect.

- **DSMT Telehealth Issues – Telehealth Injection Training for Insulin-Dependent Beneficiaries**

Currently, the manual instruction for Payment for DSMT in the Medicare Claims Processing Manual, Pub. 100-04, chapter 12, section 190.3.6, requires 1 hour of the 10-hour DSMT benefit's initial training and 1 hour of the 2-hour follow-up annual training to be furnished in-person to allow for effective injection training when injection training is applicable for insulin-dependent beneficiaries.

CMS believes that with the expansion of the use of telehealth during the PHE for COVID-19, there have been significant changes in clinical standards, guidelines, and best practices regarding services furnished using interactive telecommunications technology, including for injection training for insulin-dependent patients.

Comments

- **Supervision of Outpatient Therapy Services in Private Practices**

CMS is seeking comments on this specific proposal as they want to know more about how this policy is now functioning with OTs and PTs who are not enrolled and their proposal to maintain this longstanding policy for direct supervision.

- **General Supervision for PTs and OTs in Private Practice Comment Solicitation**

CMS is seeking comment regarding the possibility of changing the physical therapist assistant and occupational therapist assistant supervision policy from direct supervision to general supervision in the private practice setting and the implications of a general supervision policy on the following situations/conditions:

1. Could the general supervision policy raise safety concerns for therapy patients if the PT or OT is not immediately available to assist if needed? Do State laws and policies allow a PTA or OTA to practice without a therapist in a therapy office or in a patient's home?
2. Could any safety concerns be addressed by limiting the types of services permitted under a general supervision policy?
3. Would a general supervision policy be enhanced with a periodic visit by the PT or OT to provide services to the patient? If so, what number of visits or time period should we consider?
4. Would a general supervision policy potentially cause a change in utilization? Would such a change in the supervision policy cause a difference in hiring actions by the PT or OT with respect to therapy assistants?

5. Additionally, they are seeking public comment for their consideration for possible future rulemaking regarding any appropriate exceptions to allowing general supervision in the furnishing of therapy services.

E. Advancing Access to Behavioral Health (section II.J.)

Proposed Changes

- **New Regulation to Codify the Coverage Provision for Marriage and Family Therapist Services and Mental Health Counselor Services**

CMS proposes to define a marriage and family therapist (MFT) at § 410.53 as an individual possessing a master's or doctor's degree that meets the licensure or certification requirements for MFTs according to the state law where the services are provided. Additionally, the individual should have completed at least 2 years or 3,000 hours of post-master's degree clinical supervised experience in marriage and family therapy in settings such as hospitals, skilled nursing facilities (SNFs), private practices, or clinics. Furthermore, the individual must hold a valid license or certification as an MFT in the state where the services are performed.

CMS proposes defining MFT services covered under the Medicare Part B benefit category at § 410.53(b)(1) as those provided by a MFT for the diagnosis and treatment of mental illnesses, where services must be of a type that would be covered if they were provided by a physician or as an incident to a physician's professional service, and at § 410.53(b)(2) excludes services provided to inpatients of a Medicare-participating hospital.

CMS proposes to define a mental health counselor (MHC) at § 410.54 as an individual holding a master's or doctor's degree that qualifies for licensure or certification as a mental health counselor, clinical professional counselor, or professional counselor according to the state law of the state where the services are provided. Additionally, the individual should have completed at least 2 years or 3,000 hours of post-master's degree clinical supervised experience in mental health counseling in settings such as hospitals, skilled nursing facilities, private practices, or clinics. Furthermore, the individual must hold a valid license or certification as an MHC, clinical professional counselor, or professional counselor in the state where the services are performed.

CMS proposes defining MHC services covered under the Medicare Part B benefit category at § 410.54(b)(1) as services provided by a MHC for the diagnosis and treatment of mental illnesses, where services must be of a type that would be covered if they were provided by a physician or as an incident to a physician's professional service, and at §410.54(b)(2) excludes services provided to inpatients of a Medicare-participating hospital.

- **Inclusion of MFT and MHC into Existing Regulation**

CMS proposes amending § 410.10 to add MFT and MHC services to the list of included medical and other health services and amending § 410.150 to add MFTs and MHCs to the list of individuals or entities to whom payment is made.

CMS proposes amending § 410.32(a)(2) to add MFTs and MHCs to the list of practitioners who may order diagnostic tests.

CMS proposes codifying in a new § 414.53 the payment amounts authorized for MFT, MHC, and clinical social worker (CSW) services, where payment amount for CSW, MFT, and MHC services would be 80% of the lesser of the actual charge for the services or 75% of the amount determined for clinical psychologist services under the Physician Fee Schedule (PFS).

CMS also proposes adding MFTs and MHCs to the list of practitioners eligible to provide Medicare telehealth services at the distant site and allowing Addiction Counselors who meet specific requirements to enroll in Medicare as MHCs.

CMS proposes clarifying that the term "mental health" includes the diagnosis and treatment of substance use disorders which applies to MFTs, MHCs, CSWs, and clinical psychologists (CPs) as part of their respective definitions and services.

- **Coding Updates to Allow MFT and MHC Billing**

CMS proposes revising the code descriptor for HCPCS code G0323 as follows: "Care management services for behavioral health conditions, at least 20 minutes of clinical psychologist, clinical social worker, mental health counselor, or marriage and family therapist time, per calendar month." to enable MFTs, MHCs, CPs, and CSWs to bill for monthly care integration services.

CMS proposes conforming updates to the valuation of work and practice expense (PE) inputs for HCPCS code G0323 to align with the proposed changes to the valuation of CPT code 99484, which describes General Behavioral Health Integration.

- **Medicare Enrollment of MFTs and MHCs**

CMS proposes that MFTs and MHCs Medicare enrollment involve completing and submitting the appropriate Form CMS-855 application to the assigned Medicare Administrative Contractor (MAC). And MFTs and MHCs be subject to limited-risk screening, following the provisions outlined in § 424.518 where MFTs and MHCs meeting the finalized requirements in §§ 410.53 and 410.54 utilize the Form CMS-855I application to enroll in Medicare.

- **Implementation of Section 4132 of the CAA, 2023**

CMS proposes the creation of two new G-codes, GPFC1 and GPFC2, to describe psychotherapy for crisis services rendered in any applicable site of service where the non-facility rate for these services is applicable, excluding office settings, and proposes that these codes can be billed when the services are provided in any non-facility place of service except the physician's office setting.

CMS proposes establishing a fee schedule amount for the two new G-codes, GPFC1 and GPFC2, which corresponds to 150% of the current non-facility Relative Value Units (RVUs) for CPT codes 90839 and 90840 and suggests excluding expected expenditures for the new G-codes, GPFC1 and GPFC2, from the budget neutrality calculation for the CY 2024 PFS ratesetting.

- **Health Behavior Assessment and Intervention (HBAI) Services**

CMS proposes allowing CSWs, MFTs, and MHCs to bill for HBAI services described by CPT codes 96156, 96158, 96159, 96164, 96165, 96167, and 96168, and any successor codes, in addition to CPs, where Medicare payment for HBAI services is contingent upon their medical necessity and their contribution to the diagnosis, treatment, or improvement of a patient's condition.

- **Adjustments to Payment for Timed Behavioral Health Services**

CMS proposes applying an adjustment to the work Relative Value Units (RVUs) for psychotherapy codes billed under the Medicare Physician Fee Schedule (PFS). The adjustment would be based on the difference in total work RVUs for office/outpatient Evaluation and Management (E/M) visit codes billed with the proposed inherent complexity add-on code (HCPCS code G2211) compared to visits not billed with this add-on code. The adjustment would be implemented over a 4-year transition period to allow for a gradual change.

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

CMS proposes increasing the current payment rate for HCPCS codes G2086 and G2087 to reflect two individual psychotherapy sessions per month, based on a crosswalk to the work RVUs assigned to CPT code 90834 rather than CPT code 90832, adding 1.08 RVUs to the work value assigned to HCPCS codes G2086 and G2087, which results in a new work RVU of 8.14 for HCPCS code G2086 and 7.97 for HCPCS code G2087, and updating the work RVUs assigned to CPT code 90834 to 2.35.

Background/Rationale

- **New Regulation to Codify the Coverage Provision for Marriage and Family Therapist Services and Mental Health Counselor Services**

CMS is proposing regulatory changes to comply with the Consolidated Appropriations Act (CAA), 2023 which expanded Medicare coverage and payment for marriage and family therapist services (MFTs) and mental health counselor services (MHCs) under Part B of the Medicare program.

CMS believes that the proposed requirement for MFTs to have a minimum of 2 years or 3,000 hours of post-master's degree clinical supervised experience aligns with state licensure requirements. The aim is to establish consistency with the statutory requirement of 2 years of clinical supervised experience. CMS notes that clinical social workers (CSWs) have similar flexibility in their supervised experience requirements, with regulations allowing either 2 years or 3,000 hours of supervised experience. Since both MFTs and CSWs provide services for the diagnosis and treatment of mental illnesses under the same statutory benefit category, the proposed rule seeks to provide similar flexibility in the amount of clinical supervised experience required for both professions.

- **Inclusion of MFT and MHC into Existing Regulation**

CMS notes that proposed changes and additions to regulation to include marriage and family therapists and mental health counselors are part of the implementation of section 4121 of the CAA, 2023. CMS also highlights that the proposal intends to clarify the term "mental health", so the interpretation is consistent with past rulemaking and aligns the interpretation of "mental health" across services.

- **Coding Updates to Allow MFT and MHC Billing**

CMS highlights that the proposed revisions to the code descriptor and valuation of HCPCS code G0323 aim to facilitate billing and reimbursement for care management services provided by MFTs, MHCs, CPs, and CSWs, in line with the expanded Medicare coverage for mental health services.

- **Medicare Enrollment of MFTs and MHCs**

CMS is proposing that MFT and MHC supplier types undergo limited-risk screening under § 424.518, stating that their decision is based on the absence of any justification to categorize these suppliers differently and assign them to a higher screening category compared to other non-physician practitioner types.

- **Implementation of Section 4123 of the CAA, 2023**

CMS states that Section 4123(a)(1) of the CAA, 2023 introduced changes to section 1848 of the Act, adding a new paragraph (b)(12) to address payment for crisis services' psychotherapy furnished in specific locations. It requires the establishment of new HCPCS codes for these services, and the payment amount for these psychotherapy services should be 150 percent of the fee schedule amount for similar codes (e.g., 90839 and 90840) as of January 1, 2022. The proposed G-codes GPFC1 and GPFC2 would describe psychotherapy for crisis services furnished in non-facility places of service other than physician's offices.

CMS also notes that Section 4123(a)(2) of the CAA, 2023 includes a waiver of budget neutrality for subsection (b)(12) under section 1848(c)(2)(B)(ii)(II) for 2024 and expected expenditures for the proposed G-codes will be excluded from the budget neutrality calculation for CY 2024 PFS ratesetting.

- **Health Behavior Assessment and Intervention (HBAI) Services**

In response to the new benefit categories authorized by the CAA, 2023, which allow MFTs and MHCs to provide services for mental illness diagnosis and treatment, CMS re-evaluated whether CSWs, MFTs, and MHCs could furnish and bill for HBAI services. CMS notes that prior to the passage of the CAA, 2023, there was a National Coverage Determination (NCD) that restricted the use of certain CPT codes related to HBAI services to CPs. However, this NCD was retired on December 8, 2022.

CMS recognizes that CSWs, MFTs, and MHCs have the education and training to address psychosocial barriers and can play a vital role in multidisciplinary patient care, particularly for patients with physical health conditions. Mental health professionals like MFTs and MHCs are involved in behavioral management, problem-solving, goal setting, and providing emotional support to patients. Therefore, CMS proposes to allow the billing of HBAI services, including specified CPT codes, by CSWs, MFTs, and MHCs, in addition to CPs, as long as the services are deemed reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member, in accordance with section 1862(a)(1)(A) of the Act.

- **Adjustments to Payment for Timed Behavioral Health Services**

CMS notes that they have been examining the dynamics involved in developing values for behavioral health services under the PFS, especially in light of increasing patient needs and ongoing workforce

shortages. They recognize that services primarily involving person-to-person interactions, such as psychotherapy codes billed in time units, are particularly susceptible to undervaluation due to potential overestimates of time compared to other services. This issue can lead to systemic undervaluation for certain services over time, as efficiencies and improvements in other services are not applicable to one-on-one therapy sessions. This undervaluation may deter professionals from furnishing these services and contribute to the behavioral health workforce shortage.

CMS highlights that the purpose of this adjustment is to address distortions in the valuation process for psychotherapy services and ensure that the relative resources involved in furnishing these services are adequately accounted for. The proposal aims to prevent understated estimates and potential negative impacts on the valuation for psychotherapy services.

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

In response to public comments on the CY 2023 PFS proposed rule, CMS finds that the codes for office-based treatment for SUD should be priced consistently with the crosswalk codes used to value the bundled payments made for Opioid Treatment Program (OTP) services. This is because beneficiaries receiving buprenorphine in non-OTP settings may have similar complex care needs as those receiving SUD treatment services at OTPs.

Comments

- **New Regulation to Codify the Coverage Provision for Marriage and Family Therapist Services and Mental Health Counselor Services**

CMS invites comments regarding:

1. States that have a supervised clinical hour requirement for MFT licensure that is less than 2 years.
2. States that have a supervised clinical hour requirement for MHC licensure that is less than 2 years.
3. Other professionals who may meet the applicable requirements for enrollment as mental health counselors.

- **Coding Updates to Allow MFT and MHC Billing**

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

- **Adjustments to Payment for Timed Behavioral Health Services**

CMS invites comments on the proposed adjustment to the work Relative Value Units, including and especially how the PFS valuation processes for these services and other services with similar characteristics can be improved in the future in order to mitigate distortions in the valuation process for psychotherapy services.

CMS invites comment on whether the minimum value adjustment to the indirect PE for certain services sufficiently accounts for the resources involved in furnishing these services, or whether they should

consider further adjustments, such as applying 50 percent of the calculated minimum value for non-facility indirect PE values for these services, and whether we should consider implementing further changes using a similar 4-year transition.

- **Comment Solicitation on Expanding Access to Behavioral Health Services**

CMS is seeking comments on the following:

1. Ways to expand access to behavioral health services for Medicare beneficiaries.
2. Ways to increase access to behavioral health integration (BHI) services, including the psychiatric collaborative care model.
3. Whether to consider new coding to allow interprofessional consultation to be billed by practitioners who are authorized by statute for the diagnosis and treatment of mental illness; intensive outpatient (IOP) services furnished in settings other than those addressed in the CY 2024 OPPS proposed rule; and how to increase psychiatrist participation in Medicare given their low rate of participation relative to other physician specialties.
4. Whether there is a need for potential separate coding and payment for interventions initiated or furnished in the emergency department or other crisis setting for patients with suicidality or at risk of suicide, such as safety planning interventions and/or telephonic post-discharge follow-up contacts after an emergency department visit or crisis encounter, or whether existing payment mechanisms are sufficient to support furnishing such interventions when indicated.

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

CMS is seeking comments on the following:

1. How practitioners determine which patients might be best served by digital therapeutics and monitor the effectiveness of prescribed interventions, such as, but not limited to, for their patients on an ongoing basis once the intervention has begun.
2. Where digital cognitive behavioral therapy or other digital enabled therapy services are used by clinicians, and how the technology is imbedded in various practice models. For example, how is the patient evaluated and/or how is the treating clinician involved in the services received when the patient participates in digital cognitive behavioral therapy.
3. What standards have interested parties developed or consulted to ensure the physical safety and privacy of beneficiaries utilizing digital cognitive behavioral therapy (CBT) and/or other digital therapeutics for behavioral health.
4. Effective models for distribution/delivery of digital therapeutics and best practices to ensure that patients have the necessary support and training to use applications effectively.
5. What practitioners and auxiliary staff are involved in furnishing RPM and RTM services, including training patients on its use, and to what extent is additional training or supervision of auxiliary staff necessary to provide an appropriate for and/or recommended standard of care in the delivery of these services.

6. How data that is collected by the technology is maintained for recordkeeping and care coordination.
7. What information exists about how an episode of care should be defined, particularly in circumstances when a patient may receive concurrent RTM or digital CBT services from two different clinicians engaged in separate episodes of care.
8. The type and frequency of circumstances that involve multiple medical devices and multiple clinicians and how might allowing multiple, concurrent RTM services for an individual beneficiary affect access to health care, patient out-of-pocket costs, the quality of care, health equity, and program integrity.
9. If interested parties believe digital CBT could be billed using the existing remote therapeutic monitoring codes described by CPT codes 98975, 98980, and 98981 and what impediments may exist to using these codes for digital CBT.
10. Advantages and disadvantages of a generic RTM device code, versus specific RTM codes, if generic device codes undermine or stall progress toward a wider set of specific codes that would provide less ambiguity on reimbursement, and how might generic RTM codes for supply of a device be valued given the broad array of pricing models.
11. Scientific and clinical evidence of effectiveness CMS should consider when determining whether digital therapeutics for behavioral health are reasonable and necessary.
12. Aspects of digital therapeutics for behavioral health to consider when determining whether it fits into a Medicare benefit category, and which category should be used.
13. Aspects of delivering digital cognitive based therapy services should be considered when determining potential Medicare payment? Under current practice models, are these products used as incident-to supplies or are they used independent of a patient visit with a practitioner? If used independently of a clinic visit, does a practitioner issue an order for the services?
14. Barriers to digital CBT reaching underserved populations, and if a supervision requirement impact access to digital CBT for underserved populations.
15. Strategies, if any, within the digital therapeutics for behavioral health support disadvantaged/hard to reach populations in advancing equity in health care services.
16. Potential considerations for protecting the privacy and confidentiality of the patient population in digital therapeutics, including compliance with State behavioral health privacy requirements.

F. Proposals on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Medical Services (section II.K.)

Proposed Changes

- **Dental Services Inextricably Linked to Chemotherapy Services When Used in the Treatment of Cancer**

CMS proposes to amend the regulation at § 411.15(i)(3)(i)(A) to include dental or oral examination performed as part of a comprehensive workup in either the in-patient or outpatient setting prior to Medicare-covered chemotherapy when used in the treatment of cancer; and, medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with chemotherapy when used in the treatment of cancer.

Additionally, CMS proposes to make payment for dental services that are inextricably linked to chemotherapy used in the treatment of cancer with or without the use of other therapy types, including radiation therapy in the treatment of cancer meaning that the proposal is not meant to be limited to cases where chemotherapy in the treatment of cancer is provided without the use of other therapies.

- **Dental Services Inextricably Linked to CAR T-Cell Therapy, When Used in the Treatment of Cancer**

CMS proposes to amend §411.15(i)(3)(i)(A) to include dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered CAR T-cell therapy when used in the treatment of cancer; and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, CAR T-cell therapy when used in the treatment of cancer.

- **Dental Services Inextricably Linked to the Administration of High-Dose Bone-Modifying Agents (antiresorptive therapy) When used in the Treatment of Cancer**

CMS proposes to amend the § 411.15(i)(3)(i)(A) to include dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to the administration of Medicare-covered high-dose bone-modifying agents (antiresorptive therapy), when used in the treatment of cancer; and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, administration of high-dose bone-modifying agents (antiresorptive therapy), when used in the treatment of cancer.

CMS further proposes that payment under the applicable payment system could also be made for services that are ancillary to these dental services, such as x-rays, administration of anesthesia, and use of the operating room as described at § 411.15(i)(3)(ii).

- **Proposed Amendments to Regulations Regarding Dental Services Inextricably Linked to Treatment for Head and Neck Cancer**

CMS proposes to amend § 411.15(i)(3)(i)(A) to allow for payment under Medicare Part A and Part B for (1) dental or oral examination in either the inpatient or outpatient setting prior to the initiation of, or during, Medicare-covered treatments for head and neck cancer; and (2) medically necessary diagnostic and treatment services to eliminate an oral or dental infection in either the inpatient or outpatient setting prior to the initiation of, or during, Medicare-covered treatments for head and neck cancer.

CMS further proposes that payment under the applicable Medicare Parts A and B payment system could also be made for services that are ancillary to these dental services, such as x-rays, administration of anesthesia, and the use of the operating room as described in § 411.15(i)(3)(ii).

Background/Rationale

CMS recognizes that there may be other instances where covered services necessary to diagnose and treat the individual's underlying medical condition and clinical status may require the performance of certain dental services.

- **Dental Services Inextricably Linked to Chemotherapy Services When Used in the Treatment of Cancer**

CMS believes that there is an inextricable link between certain dental and chemotherapy services when used in the treatment of cancer because the standard of care is such that one would not proceed with the medical procedure or service without performing the dental service(s) because the covered medical services would or could be significantly and materially compromised absent the provision of the inextricably-linked dental services and that dental services are a clinical prerequisite to proceeding with the chemotherapy services when used in the treatment of cancer. CMS believes dental services are integral and inextricably linked to chemotherapy when used in the treatment of cancer, and the statutory dental exclusion under section 1862(a)(12) of the Act would not apply.

- **Dental Services Inextricably Linked to CAR T-Cell therapy, When Used in the Treatment of Cancer**

CMS believes that dental services to diagnose and treat infection prior to CAR T-cell therapy are inextricably linked to the clinical success of CAR T-cell therapy and that these services also represent a clinically analogous scenario to dental services for which Medicare payment under Parts A and B is currently permitted when furnished in the inpatient or outpatient setting, such as prior to organ transplant, cardiac valve replacement, or valvuloplasty procedures.

CMS believes there is an inextricable link between dental and CAR T-cell therapy when used in the treatment of cancer because the standard of care is such that one would not proceed with the medical procedure or service without performing the dental service because the covered medical services would or could be significantly and materially compromised absent the provision of inextricably-linked dental services and that dental services are a clinical prerequisite to proceeding with the CAR T-cell therapy when used the treatment of cancer.

CMS believes that proceeding without a dental or oral exam and necessary diagnosis and treatment of any presenting infections of the mouth prior to (CAR) T-cell therapy when used in the treatment of cancer could lead to systemic infections or sepsis, as well as other complications. CMS also believes that oral or dental infection could present a substantial risk to the success of the (CAR) T-cell therapy when used in the treatment of cancer, to the extent that the standard of care would be not to proceed with the procedure. Additionally, CMS believes that dental services furnished to identify, diagnose, and treat oral or dental infections prior to and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or while undergoing (CAR) T-cell therapy when used in the treatment of cancer are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, but instead are inextricably linked to these other covered medical services.

- **Dental Services Inextricably Linked to the Administration of High-Dose Bone-Modifying Agents (antiresorptive therapy) When Used in the Treatment of Cancer**

CMS believes that there is an inextricable link between dental and administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer because the standard of care is such that one would not proceed with the medical procedure or service without performing the dental service because the covered medical services would or could be significantly and materially compromised absent the provision of the inextricably-linked dental services and that dental services are a clinical prerequisite to proceeding with the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer.

- **Proposed Amendments to Regulations Regarding Dental Services Inextricably Linked to Treatment for Head and Neck Cancer**

CMS believes that addressing any oral or dental infection prior to the initiation of treatment serves to minimize the potential development of treatment-induced complications. CMS believes that these treatment-induced complications can occur as a result of and during multiple rounds of treatment.

Comments

- **Dental Services Inextricably Linked to Chemotherapy Services When Used in the Treatment of Cancer**

CMS seeks comments on all aspects of this proposal. Specifically, CMS seeks comment on whether they should consider radiation therapy in the treatment of cancer more broadly as medical services that may be inextricably linked to dental services. CMS seeks comment on whether dental services prior to radiation therapy in the treatment of cancer, when furnished without chemotherapy, such as second-line therapy for metastasized cancer in the head and neck, would be inextricably linked to the radiation therapy services, and therefore payable under Medicare Parts A and B.

- **Dental Services Inextricably Linked to CAR T-Cell Therapy, When Used in the Treatment of Cancer**

CMS seeks comments on all aspects of this proposal. Specifically, CMS seeks comments on whether they should add as an example of dental services in which payment may be made under Medicare Parts A and B other types of lymphodepleting medical services used for cancer treatment, in addition to those used in conjunction with CAR T-cell therapy for cancer treatment.

CMS also requests comment on what specific medical services also involve lymphodepletion and should therefore be considered in addition to CAR T-cell therapy as well as additional information regarding how those specific services might be impacted by dental infections/conditions. CMS seeks comment on whether there is a significant quality of care detriment if certain dental services are not provided prior to these other types of lymphodepleting medical services, and if so, they request a description of that systematic evidence.

- **Dental Services Inextricably Linked to the Administration of High-Dose Bone-Modifying Agents (antiresorptive therapy) When Used in the Treatment of Cancer**

CMS seeks comments on all aspects of this proposal.

- **Proposed Amendments to Regulations Regarding Dental Services Inextricably Linked to Treatment for Head and Neck Cancer**

CMS seeks comments on all aspects of these proposals.

- **Request for Information on Dental Services Integral to Covered Cardiac Interventions**

CMS seeks comments to identify additional cardiac interventions (that is, specific medical services) where the risk of infection posed to beneficiaries is similar to that associated with cardiac valve replacement or valvuloplasty. CMS encourages interested parties to use the public submission process to submit recommendations and relevant clinical evidence for establishing this connection.

CMS also seeks comments on whether cardiac interventions such as the implantation of electronic devices in the heart such as pacemakers, cardioverter defibrillators, and monitors are examples of specific medical services for which dental services are inextricably linked to clinical success.

CMS also seeks comment on whether the placement of intracardiac or intravascular foreign material, such as a stent or for hemodialysis, or for a vascular access graft, whereas you would not proceed with the medical service without having first completed a dental evaluation and/or treatment, as determined necessary, would be considered examples of specific medical services for which dental services are inextricably linked to their clinical success. CMS seeks comment on whether preoperative and perioperative dental services are inextricably linked to any other covered cardiac interventions as supported by clinical evidence.

- **Request for Comment on Dental Services Integral to Specific Covered Services to Treat Sickle Cell Disease (SCD) and Hemophilia**

CMS seeks comment on whether certain dental services are inextricably linked to other covered services used in the treatment of SCD, such as, but not limited to, hydroxyurea therapy. CMS seeks comment identifying such covered services for SCD and whether an inextricable link is supported by clinical evidence as described in section II.K.1.c. of the proposed rule.

CMS also seeks comment on whether certain dental services are inextricably linked to certain other covered services for hemophilia, supported by clinical evidence as described in section II.K.1.c. as well as comment identifying such coved services for the treatment of hemophilia. Additionally, CMS seeks comment specifically on whether dental services such as prophylaxis are a standard of care in the management of hemophilia.

- **Request for Information on the Implementation of Payment for Dental Services Inextricably Linked to Other Specific Covered Services**

CMS seeks comments on ways to best continue to improve the implementation of payment policies for dental services as finalized in the CY 2023 PFS final rule. CMS also requests comments on several policies related to the implementation of policies for dental services for which Medicare payments can be made. Specifically, CMS seeks comment on approaches utilized by other plans to mitigate issues with third-party payment, including when Medicare is a secondary payer and when coordinating with state Medicaid programs. CMS seeks comment on the impact of third-party payers, including state Medicaid programs, requiring a Medicare denial for adjudication of primary payment for dental services that are not inextricably linked to another specific covered service.

CMS also seeks comment regarding an informal process on claims denials for the purposes of supporting payment by other payers I currently achieved in practice when using the dental claim form 837d. CMS seeks comment on the practices of other payers related to the submission and claim adjudication with third-party payers as well as the types of guidance, such a s best practices or criteria, that are needed for purposes of coordinating payment for dental services under the policies specified in the rule.

Additionally, CMS seeks comments on what specific information could help inform appropriate payment for dental services (87 FR 69679). CMS seeks comment on whether payment indicators as outlined in the PFS RVU files appropriately align with existing dental billing and coding conventions, or whether edits are necessary. CMS is soliciting comments on whether the current payment indicators included for these CDT codes follow existing dental billing conventions and whether there is a need for additional guidance regarding the submission of claims for services for which payment is permitted under the regulation at § 411.15(i)(3).

CMS seeks comment on whether additional specialty codes should be considered for use in Medicare, and if so, what are the other specific specialties that should be included, CMS also seeks comment on whether these specialty codes may impact the coordination of benefits for dual eligible beneficiaries and how to best coordinate a potential payment policy in this area with respect to state Medicaid plans or private insurance. CMS seeks comment on other coordination of benefits issues, or implementation topics that would be helpful for CMS to address in relation to continuing to implement these PFS payment policies.

G. Drugs and Biological Products Paid Under Medicare Part B (section III.A.)

Proposed Changes

- **Provisions from the Inflation Reduction Act Relating to Drugs and Biologicals Payable Under Medicare Part B**

Payment for Drugs under Medicare Part B During an Initial Period

CMS is proposing changes to the payment limits for drugs based on their wholesale acquisition cost (WAC). Under Section 1847A of the Act, payments for single source drugs or biologicals can be determined using the lesser of the average sales price (ASP) plus 6 percent or WAC plus 6 percent. Historically, WAC-based payment was up to 106 percent of WAC, but CMS adopted a policy to pay up to 103 percent of WAC in the CY 2019 PFS final rule. The Sustaining Excellence in Medicaid Act of 2019 amended the Act to specify a payment limit not to exceed 103 percent of WAC for drugs during an initial period when ASP data is not available.

CMS is proposing to codify these changes to Section 1847A(c)(4) of the Act in § 414.904 by revising the regulatory text for WAC-based payment limits before January 1, 2019, and after January 1, 2019, to align with the requirements of the Sustaining Excellence in Medicaid Act of 2019. They are also proposing to add the payment limit for new biosimilars furnished on or after July 1, 2024, during the initial period as required by Section 1847A(c)(4)(B) of the Act.

Temporary Increase in Medicare Part B Payment for Certain Biosimilar Biological Products

CMS proposes changes to the Medicare Part B payment limit for biosimilar biological products in alignment with Section 1847A(b)(8) of the Act. Currently, the payment limit is set at the Average Sales Price (ASP) plus 6 percent of the reference biological product.

CMS proposes to add definitions of "applicable 5-year period" and "qualifying biosimilar biological product" in § 414.902 to reflect the definitions in the statute. They also propose to make conforming changes to regulatory text at § 414.904(j) by adding paragraphs (j)(1) and (j)(2) to implement the requirements mandated under Section 1847A(b)(8)(B) of the Act for the temporary payment limit increase for qualifying biosimilar biological products.

Inflation-adjusted Beneficiary Coinsurance and Medicare Payment for Medicare Part B Rebatable Drugs

CMS proposes to implement the provisions of Section 11101(a) and (b) of the Inflation Reduction Act (IRA) by adding new subsections to the Act.

Section 11101(a) requires the payment of rebates into the Supplementary Medical Insurance Trust Fund for Part B rebatable drugs if the payment limit amount exceeds the inflation-adjusted payment amount. The inflation-adjusted payment amount is calculated according to the Act. The implementation is being done through program instruction, and CMS issued final guidance for the computation of inflation-adjusted beneficiary coinsurance on February 9, 2023. CMS now proposes to codify the coinsurance amount for Part B rebatable drugs in § 489.30 by adding a new paragraph (b)(6).

Section 11101(b) specifies that if the inflation-adjusted payment amount of a Part B rebatable drug exceeds the payment amount described in the Act, the Part B payment will equal the difference between the payment amount and the inflation-adjusted coinsurance amount, subject to the deductible and sequestration. To implement this, CMS proposes to codify the Medicare payment for Part B rebatable drugs in § 410.152 by adding a new paragraph (m).

Limitations on Monthly Coinsurance and Adjustments to Supplier Payment Under Medicare Part B for Insulin Furnished Through Durable Medical Equipment

CMS proposes to codify changes related to how beneficiaries pay for insulin furnished through covered Durable Medical Equipment (DME) under Medicare Part B. These changes were made under Section 11407 of the IRA and implemented through program instructions for CY 2023.

CMS proposes to codify that the $35 coinsurance limit for a month's supply and the $105 coinsurance limit for 3 months' supply will apply to the duration of the calendar month in which the date of service occurs and the following two calendar months.

- **Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs to Provide Refunds with Respect to Discarded Amounts**

Provision of Information to Manufacturers

CMS proposes several changes related to the discarded drug refund provision. They intend to issue an initial refund report to manufacturers by December 31, 2024, covering all calendar quarters for 2023, separate from the preliminary report issued by December 31, 2023, which will include estimated discarded amounts based on available claims data from the first two quarters of CY 2023. For subsequent annual reports, CMS aims to align the delivery of the refund reports with Part B and Part D inflation rebate reports, sending them around the time they issue the Part B inflation rebate report for the first quarter of the following year. To address the lag in available JW modifier data, they propose including lagged claims data (true-up information) for quarters from 2 calendar years prior in each report, covering eight calendar quarters: four from the previous year (new refund quarters) and four from 2 calendar years prior (updated refund quarters). The reports will provide updated information on the total number of discarded units of the billing and payment code of the drug during the updated refund quarters and the corresponding refund amounts that the manufacturer is liable for. CMS also plans to define "new refund quarter" and "updated refund quarter" in the regulations and revise § 414.940(a)(3) to reflect the inclusion of lagged data in subsequent reports.

Manufacturer Provision of Refund

CMS proposes the following changes related to the timing of manufacturers' refund obligations for the discarded drug refund provision: The initial refund report will be issued no later than December 31, 2024, and the specified refund amounts will be due by February 28, 2025, unless the report is under dispute. Subsequent annual refund reports will be sent by September 30 of each year, and manufacturers must pay the specified refunds by December 31 of the same year, except in case of disputes. If a manufacturer disputes a report, any determined liability upon resolution will be due either by the specified due date or 30 days after resolution, whichever is later. CMS will update § 414.940(b)(1) to reflect these proposed due dates for manufacturers' refund obligations.

Refund Amount: Calculation of Refund Amounts for Updated Quarters

CMS proposes the following changes regarding the calculation of revisions to the manufacturer refund amount for quarters two calendar years prior to the report: Lagged claims data will be included in all reports except the initial report, and the additional lagged JW modifier data will be used for the calculations. The refund calculation with updated data will follow the method finalized in the 2023 PFS final rule, subtracting the refund amount already paid for the drug in the quarter to determine the updated quarter refund amount. The refund amount owed by a manufacturer for an updated refund quarter is determined based on the estimated excess of the total number of discarded units of the drug multiplied by the payment amount over the difference between an applicable percentage of the estimated total allowed charges for the drug during the quarter and the refund amount previously paid for the drug. If the resulting refund calculation for an updated quarter is negative, it will offset any refund owed for other updated quarters or new quarters. To implement this method, § 414.940 will be revised by adding new paragraphs (c)(2) and (3). These proposals aim to ensure accurate and updated calculations for the manufacturer refund amounts while maintaining consistency with the finalized method.

Refund Amount: Calculation of Refund for a drug when there are Multiple Manufacturers

CMS proposes a new method for calculating the refund amount owed by a manufacturer for refundable drugs with multiple manufacturers. The refund amount will be determined based on the estimated excess of the total number of discarded units of the drug multiplied by the payment amount, over the applicable percentage of the estimated total allowed charges for the drug during the quarter (minus the amount paid for packaged drugs). When multiple manufacturers are involved, CMS will identify such drugs using ASP sales data and allocate the financial responsibility for the refund amount based on each manufacturer's proportion of billing unit sales attributed to their respective National Drug Codes (NDCs). The refund amount attributed to each NDC will be calculated as the estimated excess of the total discarded units multiplied by the percentage of billing unit sales for the NDC, and the payment amount, over the applicable percentage of the estimated total allowed charges for the drug during the quarter and the percentage of billing unit sales for the NDC. This proposed calculation method will be applied to calendar quarters in CY 2023 included in the initial refund report, to be sent by December 31, 2024, for both new and updated refund quarters. To implement this proposal, § 414.940 will be revised by adding a new paragraph (c)(4).

TABLE 18: Example of Proportion of Sales Calculation when there are Multiple Manufacturers for a Refundable Drug

NDC	Manufacturer	Refund Quarter Sales (billing units)	Proportion of Sales (percent)
12345-6789-01	Manufacturer 1	5,000	23.81%
23456-7890-01	Manufacturer 2	6,000	28.57%
34567-8901-01	Manufacturer 3	10,000	47.62%
	TOTAL:	21,000	100%

Refund Amount: Increased Applicable Percentage for Drugs with Unique Circumstances

CMS proposes a hybrid approach to determine when an increased applicable percentage is appropriate for a drug with unique circumstances. First, there are two categorical unique circumstances with proposed increased applicable percentages: drugs with a labeled dose of 0.1 mL or less when removed from the vial or container would have a 90% applicable percentage, and rarely utilized orphan drugs furnished to fewer than 100 unique Medicare fee-for-service beneficiaries per year would have a 26% applicable percentage. Secondly, CMS suggests an application process for manufacturers to request an increased applicable percentage for a drug based on its unique circumstances. The proposed applicable percentages for low volume doses range from 90% to 45% based on the labeled dose volume. For rarely utilized orphan drugs, the proposed applicable percentage is 26%. CMS will include drugs with these unique circumstances in the refund report sent to manufacturers and will apply the corresponding increased applicable percentages. Manufacturers may dispute the calculation if they believe an incorrect applicable percentage was applied.

Refund Amount: Proposed Application Process for Individual Drugs

CMS proposes an application process for manufacturers to request an individual drug to be considered for unique circumstances with an increased applicable percentage. Manufacturers must submit a written request, FDA-approved labeling, and justifications for the consideration of an increased applicable percentage based on unique circumstances. The application process will follow notice-and-comment rulemaking, with submissions due by February 1 of the preceding calendar year. CMS will review the

documentation provided for evidence of similar loss of product. Not all circumstances warranting increased applicable percentages, such as weight-based and BSA-based doses, are considered unique at this time. Skin substitutes will have a consistent coding and payment approach, with billing and payment codes excluded from identifying refundable drugs in 2023 and 2024, and their refund obligations revisited in future rulemaking.

TABLE 19: 2021 Discarded Drug Data for Refundable Drugs and Number of Available Package Sizes

Percent Units Discarded	Number of Refundable Drugs	Percentage of Refundable Drugs with Only One Package Size
> 20%	7	100%
15—19.99%	6	83.33%
10—14.99%	20	75%
5—9.99%	22	45.45%
2—4.99%	47	29.79%

Clarification for the Definition of Refundable Drug

Section 1847A(h) of the Act mandates a mechanism to determine discarded amounts of refundable drugs. In the CY 2023 PFS final rule, CMS finalized the policy requiring billing providers to report the JW modifier for separately payable drugs with discarded amounts from single-use vials or packages under Part B, effective January 1, 2023. However, the JW modifier is not required in Medicare Advantage claims for drugs payable under Part B, and there is no similar mechanism to identify discarded units billed to Medicare Advantage plans. CMS clarifies that the JW modifier requirement does not apply to units billed to Medicare Advantage plans, and refund amount calculations under section 1847A(h)(3) of the Act will not include units billed to Medicare Advantage plans.

Use of the JW Modifier and JZ Modifier Policy

In the CY 2023 PFS final rule (87 FR 69723), it was discussed that the JW and JZ modifier policy for reporting discarded drug amounts does not apply to drugs that are self-administered by patients or caregivers in the patient's home. This is because collecting data about discarded amounts from beneficiaries is deemed inappropriate. In an updated FAQ released on January 5, 2023, it was reiterated that suppliers who dispense but do not administer separately payable drugs are not expected to report the JW modifier. However, to avoid claims rejections due to the lack of a claims modifier designating that a drug was dispensed but not administered by the billing supplier, CMS proposes to require that drugs separately payable under Part B from single-dose containers, furnished by a supplier who is not administering the drug, be billed with the JZ modifier.

Background/Rationale

- **Provisions from the Inflation Reduction Act Relating to Drugs and Biologicals Payable Under Medicare Part B**

The Inflation Reduction Act (IRA) includes provisions that impact payment limits and beneficiary costs for certain drugs payable under Medicare Part B. Drugs under Part B fall into three categories: those provided incident to a physician's service, those administered through durable medical equipment (DME), and others specified by statute. Payment amounts for most drugs are determined based on the average sales price (ASP) plus a 6 percent add-on.

Regarding biosimilar biological products ("biosimilars"), two IRA provisions affect payment limits:

1. Section 11402 amends the payment limit for new biosimilars furnished after July 1, 2024, during the initial period when ASP data is unavailable.

2. Section 11403 makes changes to the payment limit for certain biosimilars with an ASP not exceeding that of the reference biological for a 5-year period.

Additionally, two provisions in the IRA impact beneficiary out-of-pocket costs for certain drugs under Part B:

1. Section 11101 requires that beneficiary coinsurance for a Part B rebatable drug be based on the inflation-adjusted payment amount if the Medicare payment amount for a quarter exceeds it, starting April 1, 2023.

2. Section 11407 waives the deductible and limits coinsurance to $35 for a month's supply of insulin furnished through covered DME items on or after July 1, 2023.

The Centers for Medicare & Medicaid Services (CMS) is proposing regulatory changes to codify these provisions and ensure consistency with the IRA requirements.

- **Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs to Provide Refunds with Respect to Discarded Amounts**

Section 90004 of the Infrastructure Investment and Jobs Act amended section 1847A of the Act to require manufacturers to provide a refund to CMS for certain discarded amounts from refundable single-dose container or single-use package drugs. The refund amount is the excess of discarded drug beyond an applicable percentage, which must be at least 10 percent, of total charges for the drug in a calendar quarter.

The CY 2023 PFS final rule implemented these policies and required billing providers to report the JW modifier for drugs with discarded amounts and the JZ modifier for drugs with no discarded amounts. CMS also published the JW Modifier and JZ Modifier Policy FAQ document to address correct modifier usage. Exclusions to the refundable drug definition were established for certain drugs.

Sections 11101 and 11102 of the Inflation Reduction Act (IRA) established new requirements for manufacturers to pay inflation rebates for certain Part B and Part D drugs. Since both the discarded drug refunds and the inflation rebates require payments from manufacturers to the Federal SMI Trust Fund, CMS aligned the operation of these programs to minimize burden.

In this proposed rule, CMS outlines the date for the initial report to manufacturers, subsequent report dates, methods of calculating refunds for discarded amounts, procedures for multiple manufacturers of a refundable drug, and increased applicable percentages for certain drugs with unique circumstances. CMS also proposes a future application process for manufacturers to request an increased applicable percentage for a drug. Additionally, the JW and JZ modifier policy for drugs furnished by suppliers who are not administering the drug is modified.

Comments

- **Request for Information (RFI): Drugs and Biologicals which are Not Usually Self-Administered by the Patient, and Complex Drug Administration Coding (put under comment section)**

This section discusses two policy areas related to Medicare Part B drug payment policies.

1. Self-administered drugs: Medicare Part B covers drugs that are not usually self-administered by the patient, referred to as "incident to" services. The Benefits, Improvements & Protection Act of 2000 (BIPA) amended the relevant sections of the Act to use the term "not usually self-administered" instead of "cannot be self-administered." Each Medicare Administrative Contractor (MAC) maintains a "self-administered drug (SAD) list" for its jurisdiction, which includes drugs excluded from Part B coverage but typically covered under Medicare Part D.

CMS is seeking comments to update and clarify the SAD list guidance to address newly approved drugs and ensure coding and payment consistency.

2. Complex non-chemotherapeutic drug administration: Interested parties have raised concerns that payment for non-chemotherapeutic complex drug administration is inadequate due to existing coding and billing guidelines. They argue that these infusion services are similar to complex chemotherapy administration services but are billed differently.

CMS is seeking comments and information on resources, payment guidelines, and considerations to determine appropriate coding and payment for complex non-chemotherapeutic drug administration. They are also soliciting feedback on potential policy guideline revisions to accurately reflect how these specific infusion services should be furnished and billed.

- **Refund Amount: Calculation of Refund Amounts for Updated Quarters**

CMS is seeking public input on its proposal to include lagged claims data in all reports, except the initial report, for discarded drug amounts (using the JW modifier). They are also requesting feedback on the proposed method of calculating revisions to the manufacturer refund amount based on additional lagged JW modifier data.

- **Refund Amount: Calculation of Refund for a drug when there are Multiple Manufacturers**

CMS is seeking public input on its proposed method for apportioning billing units of a refundable drug sold during a calendar quarter when there are multiple manufacturers for the drug.

- **Refund Amount: Increased Applicable Percentage for Drugs with Unique Circumstances**

CMS is seeking public input on its proposed approach to determining when it is appropriate to increase the applicable percentage for a drug with unique circumstances.

- **Refund Amount: Proposed Application Process for Individual Drugs**

CMS is seeking input on its proposed application process that would allow drug manufacturers to request an individual drug to be considered for unique circumstances and an increased applicable percentage. Specific information they are seeking on the proposed application process, including factors to consider in evaluating applications and appropriate increases to applicable percentages, as well as suggestions for

additional or alternative documentation that may help analyze justifications for increased applicable circumstances.

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

Proposed Changes

- **Section 4113 of the Consolidated Appropriations Act (CAA), 2023**

CMS proposes to make conforming regulatory text changes based on the CAA to applicable RHC and FQHC regulations in 42 CFR part 405 subpart X. Specifically, CMS proposes to include language to delay in-person requirements for mental health visits furnished by RHCs and FQHCs through telecommunication technology under Medicare beginning January 1, 2025.

- **Direct Supervision via Use of Two-way Audio/Video Communications Technology**

CMS proposes to continue to define "immediate availability" as including real-time audio and visual interactive telecommunications through December 31, 2024.

- **Section 4121 of the CAA, 2023**

To implement the CAA, CMS proposes to codify payment provisions for Marriage and Family Therapists (MFTs) and Mental Health Counselors (MHCs) under 42 CFR part 405, subpart X, beginning January 1, 2024. As eligible RHC and FQHC practitioners, MFTs and MHCs would follow the same policies and supervision requirements as a PA, NP, CNM, CP, and CSW.

CMS also proposes to allow addiction counselors that meet all of the applicable requirements of clinical supervised experience in mental health counseling, and that are licensed or certified as MHCs, clinical professional counselors, or professional counselors by the State in which the services are furnished) to enroll in Medicare as MHCs. To remain consistent with payment policies for professionals billing Medicare under the PFS, CMS proposes that the definitions established for MFTs and MHCs under the PFS would also apply for RHCs and FQHCs. CMS also proposes to clarify that when MFTs and MHCs provide the services described in HCPCS code G0323 in an RHC or FQHC, the RHC or FQHC can bill HCPCS code G0511. Finally, CMS proposes to make several confirming regulatory changes to applicable RHC and FQHC regulations in 42 CFR part 405, subpart X.

- **Updates to Supervision Requirements for Behavioral Health Services furnished at RHCs and FQHCs**

CMS proposes to change the required level of supervision for behavioral health services furnished "incident to" a physician or NPP's services at RHCs and FQHCs to allow general supervision, rather than direct supervision. Accordingly, CMS proposes to revise the regulations at §§ 405.2413 and 405.2415 to reflect that behavioral health services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided by auxiliary personnel incident to the services of a physician (or another practitioner).

- **General Care Management Services in RHCs and FQHCs**

CMS proposes to include the CPT codes associated with the suite of services that comprise RPM and RTM in the general care management HCPCS code G0511 when these services are furnished by RHCs and FQHCs. RHCs and FQHCs that furnish RPM and RTM services 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, 2024.

- **Payment for Community Heath Integration (CHI) and Principal Illness Navigation (PIN) Services in RHCs and FQHC**

CMS proposes to allow separate payment for CHI and PIN services in RHCs and FQHCs under the general care management HCPCS code G0511. Both CHI and PIN involve a person-centered assessment to better understand a patient's needs. CHI addresses unmet SDOH needs that affect the diagnosis and treatment of the patient's medical problems (e.g., facilitating access to community-based services, building self-advocacy skills). Principal Illness Navigation helps individuals who are diagnosed with high-risk conditions (for example, mental health conditions, substance use disorder, and cancer) identify and connect with appropriate clinical and support resources.

- **Proposed Revision to the Calculation of the Payment Amount for the General Care Management HCPCS Code G0511**

CMS proposes to revise the method of calculating HCPCS code G0511 so that payment for general care management is more appropriate, given the expansion of billable services under the code to include RPM, RTM, CHI, and PIN.

Specifically, CMS proposes to take the weighted average of the base code and add-on code pairs, in addition to the individual base codes for all of the services that comprise HCPCS code G0511 by using the CY 2021 PFS utilization to calculate the payment rate for the general care management services furnished in RHCs and FQHCs on or after January 1, 2024. To calculate the weighted average, CMS multiplies the non-facility payment rate times the non-facility utilization for each code, sums the total, and then divides by the summed non-facility utilization for the codes included in the average.

- **Chronic Care Management (CCM) Services and Virtual Communication Services Requirement for Obtaining Beneficiary Consent**

CMS proposes to clarify when, how and by whom beneficiary consent for CCM services can be obtained. Specifically, informed consent to receive CCM services must be obtained prior to the start of CCM services. Consent does not have to be obtained at the required initiating visit for CCM that must be performed by the RHC or FQHC practitioner, but it can be obtained at that time. Since the RHC or FQHC practitioner discusses CCM with the beneficiary during the initiating visit, if consent is separately obtained, it may be obtained under general supervision, and can be verbal as long as it is documented in the medical record and includes notification of the required information. That is, beneficiary consent can be obtained at the same time that the CCM service is initiated by auxiliary staff who work to furnish the CCM services. Further, there need not be an employment relationship between the person obtaining the consent and the RHC or FQHC practitioner. That is, the clinical staff obtaining the verbal or written consent can be under contract with the RHC or FQHC. CMS also will require the beneficiary be informed on the availability of CCM services; that only one practitioner can furnish and be paid for these services during a calendar month; and of the right to stop the CCM services at any time.

Regarding virtual communication, CMS proposes to clarify that the consent from the beneficiary to receive virtual communication services can be documented by auxiliary staff under general supervision, as well as by the billing practitioner.

Background/Rationale

- **Implementation of the Consolidated Appropriations Act (CAA), 2023**

Section 4113(d) of the CAA, 2023 also continues to delay the in-person requirements under Medicare for mental health services furnished through telehealth under the PFS and for mental health visits furnished by RHCs and FQHCs via telecommunications technology. That is, for RHCs and FQHCs, in person visits will not be required until January 1, 2025 or, if later, the first day after the end of the PHE for COVID-19. Therefore, CMS continues to apply the delay of the in-person requirements under Medicare for mental health services furnished by RHCs and FQHCs.

- **Direct Supervision via Use of Two-way Audio/Video Communications Technology**

CMS believes the extension would align the timeframe of this policy with many of the PHE-related telehealth policies that were extended under provisions of the CAA, 2023. CMS is also concerned about an abrupt transition to the pre-PHE policy of requiring the physical presence of the supervising practitioner beginning after December 31, 2023, given that RHCs and FQHCs have established new patterns of practice during the PHE for COVID-19. CMS also believes that RHCs and FQHCs will need time to reorganize their practices established during the PHE to reimplement the pre-PHE approach to direct supervision without the use of audio/video technology.

- **Section 4121 of the CAA, 2023**

CMS is implementing provisions as required under the CAA, as well as ensuring RHC and FQHC billing practices align with those billing Medicare under PFS.

- **Updates to Supervision Requirements for Behavioral Health Services furnished at RHCs and FQHCs**

CMS proposes the change to better align with applicable policies under PFS implemented in 2023.

- **General Care Management Services in RHCs and FQHCs**

Requirements for RPM and RTM services are similar to the non-face-to-face requirements for the general care management services furnished in RHCs and FQHCs. The care coordination included in services, such as office visits, do not always adequately describe the non-face-to-face care management work involved in primary care. Payment for in-person encounters may not reflect all the services and resources required to furnish comprehensive, coordinated care management.

- **Payment for Community Heath Integration (CHI) and Principal Illness Navigation (PIN) Services in RHCs and FQHC**

CMS believes proposed CHI and PIN services are similar to the requirements for the general care management services furnished by RHCs and FQHCs. As such, we believe the level of care coordination resources required in addressing the particular SDOH need(s) that are interfering with, or presenting a

barrier to, diagnosis or treatment of the patient's problem(s) addressed in the CHI initiating visit are not captured in the RHC AIR or the FQHC PPS payment, particularly for the rural and/or low-income populations served by RHCs and FQHCs. Allowing a separate payment for CHI and PIN services in RHCs and FQHCs is intended to reflect the additional time and resources necessary for the unique components of care coordination services. It also supports the CMS pillars for equity, inclusion, and access to care for the Medicare population, and improve patient outcomes, including for underserved and low-income populations where there is a disparity in access to quality care.

- **Proposed Revision to the Calculation of the Payment Amount for the General Care Management HCPCS Code G0511**

CMS notes that calculating the average of the non-facility rates but adding in RPM and RTM services base codes would result in a lower payment amount for HCPCS code G0511 compared to the current payment amount. They add that while the policy may address providing a payment for furnishing non-face-to-face services, the magnitude of the value may not appropriately account for the costs. Therefore, they proposed a revised methodology for the calculation by looking at the actual utilization of the services. CMS does not have data on utilization of the services that comprise HCPCS code G0511 for RHCs and FQHCs since HCPCS code G0511 accounts for a variety of services. Therefore, CMS uses the physician office setting as a proxy for utilization of these services in the absence of actual data because this setting most closely aligns with the types of services furnished in RHCs and FQHCs since they typically furnish primary care.

- **Chronic Care Management (CCM) Services and Virtual Communication Services Requirement for Obtaining Beneficiary Consent**

While CMS has stated its intent to ensure CCM requirements for RHCs and FQHCs are not more burdensome than those billing under PFS believes its guidance could be clearer, especially given the comments it received form the 2022 PFS and the end of the COVID-19 PHE.

Regarding virtual communication, while CMS continues to believe that beneficiary consent is necessary so that the beneficiary is notified of cost sharing when receiving these services, they do not believe that the timing or manner in which beneficiary consent is acquired should interfere with the provision of one of these services.

Comments

- **Direct Supervision via Use of Two-way Audio/Video Communications Technology**

CMS seeks comment on whether they should consider extending the definition of direct supervision to permit virtual presence beyond December 31, 2024. CMS also seeks comment on potential patient safety or quality concerns when direct supervision occurs virtually in RHCs and FQHCs; for instance, if certain types of services are more or less likely to present patient safety concerns, or if this flexibility would be more appropriate when certain types of auxiliary personnel are performing the supervised service. CMS is also interested in potential program integrity concerns such as overutilization or fraud and abuse that interested parties may have in regard to this policy.

- **Proposed Revision to the Calculation of the Payment Amount for the General Care Management HCPCS Code G0511**

CMS welcomes comments on the proposed methodology.

I. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) Conditions for Certification or Coverage (CfCs) (section III.C.)

Proposed Changes

- **Definitions**

In order to reflect the statute, CMS proposes adding conforming changes to the CfCs to include MFT and MHC services to indicate that RHC and FQHCs can offer these services under their Medicare certification. At § 491.2, Definitions, CMS proposes adding a definition of MFTs and MHCs by cross-referencing the definitions proposed at §§ 410.53 and 410.54. CMS also proposes to add CP, CSW, and CNM professionals to § 491.2, Definitions, and cross-reference the definitions established in the payment requirements at § 410.77(a), §410.71(d), §410.73(a) respectively.

CMS proposes revising the existing "nurse practitioner" (NP) definition at § 491.2(1) to require that an NP be certified as a primary care nurse practitioner at the time of provision of services by a recognized national certifying body that has established standards for nurse practitioners and possess a master's degree in nursing or a Doctor of Nursing Practice (DNP) doctoral degree.

CMS proposes adding the education requirement to clause (1) of the definition of NP because the American Nurses Association has stated that for someone to become an NP, one must be a registered nurse or have a bachelor of science in nursing (BSN), complete an NP-focused master's or doctoral nursing program, and pass the National NP Certification Board Exam. CMS propose to retain paragraphs (2) and (3) of the current NP definition, which provides alternative certification and education requirements an NP can meet to furnish services in an RHC or FQHC if (1) is not met.

- **Staffing and Staff Responsibilities**

At § 491.8(a)(3), CMS proposes to add MFT and MHC to the list of staffing and staff responsibilities, allowing them to be the owner, employee, or furnish services under contract to the clinic or center. CMS also proposes adding MFTs and MHCs to the list of other practitioners who can provide services when the clinic or center is open and operating. CMS also proposes to update § 491.8(a)(6) to include MFTs and MHCs to the list of other practitioners who are eligible to furnish services and who can provide services, within the scope of practice, when the clinic or center is open and operating.

Background/Rationale

- **Definitions**

The CAA established a new benefit category for MFT services and MHC services. Section 4121(b)(1) of the CAA amended section 1861(aa)(1)(B) of the Act to add MFT and MHC services as services that can be furnished by RHCs, which is incorporated into FQHC services through section 1861(aa)(3) of the Act. The proposals codify these changes.

CMS proposes adding the education requirement to clause (1) of the definition of NP because the American Nurses Association has stated that for someone to become an NP, one must be a registered nurse or have a Bachelor of Science in nursing (BSN), complete an NP-focused master's or doctoral nursing program, and pass the National NP Certification Board Exam.

- **Staffing and Staff Responsibilities**

Section 4121(b)(1) of the CAA amends section 1861(aa)(1)(B) of the Act by including MFT and MHCs to the list of other practitioners whose services, when provided in RHCs and FQHCs, are entitled to payment under the Medicare program. To implement these changes, CMS proposes modifying their CfCs to include MFT and MHCs as recognized staff for RHC and FQHCs.

CMS notes that if MFTs and MHCs can provide reimbursable services under the Medicare program, the pool of mental health professionals who can help address practitioner shortages in rural communities can expand.

Comments

- **Definitions**

CMS seeks comments regarding the current definition of NPs at § 491.2(1). Specifically, they are interested in feedback on whether the definition of NPs should specify that an NP's certification be in the area of primary care, or whether this distinction should be removed.

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

Proposed Changes

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

CMS proposes to allow Shared Savings Program ACOs the option to report quality measures, including the CAHPS for MIPS survey, under the Alternative Payment Model Performance Pathway (APP) on only their Medicare beneficiaries through Medicare Clinical Quality Measures (CQMs).

CMS proposes to amend the definition of "Collection Type" in section IV.A.4.f.(1)(b) of this proposed rule to include the Medicare CQM as an available collection type in MIPS for ACOs that participate in the Shared Savings Program. Additionally, CMS proposes to establish data submission and completeness criteria pertaining to the Medicare CQMs for the MIPS quality performance category.

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

- A Medicare fee-for-service beneficiary who meets the criteria for a beneficiary to be assigned to an ACO described at § 425.401(a); and
- Had at least one claim with a date of service during the measurement period from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a PA, NP, or CNS.

- A Medicare fee-for-service beneficiary who is assigned to an ACO in accordance with § 425.402(e) because the beneficiary designated an ACO professional participating in an ACO as responsible for coordinating their overall care.

CMS proposes to establish the data completeness criteria threshold for the Medicare CQM collection type, in which a Shared Savings Program ACO that meets the reporting requirements under the APP would submit quality measure data for Medicare CQMs on the APM Entity's applicable beneficiaries eligible for the Medicare CQM, as proposed at § 425.20, who meet the measure's denominator criteria. Specifically, CMS is proposing the following data completeness criteria thresholds for Medicare CQMs:

- At least 75 percent for the CY 2024, CY 2025, and CY 2026 performance periods; and 2026, 2027, and 2028 MIPS payment years.
- At least 80 percent for the CY 2027 performance period/2029 MIPS payment year.

CMS proposes to add three measures as Medicare CQMs to the APP measure set for Shared Savings Program ACOs beginning with performance year 2024 and subsequent performance years. ACOs may report the 3 Medicare CQMs, or a combination of eCQMs/MIPS CQMs/Medicare CQMs, to meet the Shared Savings Program quality reporting requirement at § 425.510(b) and the quality performance standard at § 425.512(a)(5). The three measures are:

- Quality ID#: 001 Diabetes: Hemoglobin A1c (HbA1c) Poor Control;
- Quality ID#: 134 Preventive Care and Screening: Screening for Depression and Follow-Up Plan; and
- Quality ID#: 236 Controlling High Blood Pressure

CMS proposes that for the first performance year of an ACO's first agreement period under the Shared Savings Program, if the ACO reports data via the APP and meets MIPS data completeness requirement at § 414.1340 and receives a MIPS Quality performance category score under § 414.1380(b)(1), the ACO will meet the quality performance standard under the Shared Savings Program, if:

- For performance year 2024. The ACO reports the 10 CMS Web Interface measures or the 3 eCQMs/MIPS CQMs/Medicare CQMs, and administers a CAHPS for MIPS survey under the APP.
- For performance year 2025 and subsequent performance years. The ACO reports the 3 eCQMs/MIPS CQMs/Medicare CQMs and administers a CAHPS for MIPS survey under the APP.

Additionally, CMS is proposing that an ACO would not meet the quality performance standard or the alternative quality performance standard if:

- For performance year 2024, if an ACO
    - does not report any of the 10 CMS Web Interface measures or any of the three eCQMs/MIPS CQMs/Medicare CQMs and
    - does not administer a CAHPS for MIPS survey under the APP.
- For performance year 2025 and subsequent performance years, if an ACO
    - does not report any of the three eCQMs/MIPS CQMs/Medicare CQMs and

- does not administer a CAHPS for MIPS survey under the APP.

CMS proposes that new benchmarks for scoring ACOs on the Medicare CQMs under MIPS would be developed in alignment with MIPS benchmarking policies. Specifically, CMS proposes for performance year 2024 and 2025 to score Medicare CQMs using performance period benchmarks. For PY 2026 and subsequent years, CMS proposes to transition using historical benchmarks for Medicare CQMs when baseline period data are available to establish historical benchmarks in a manner that is consistent with the MIPS benchmarking policies at § 414.1380(b)(1)(ii).

- **Expanding the Health Equity Adjustment to Medicare CQMs**

CMS proposes that ACOs that report Medicare CQMs would be eligible for the health equity adjustment to their quality performance category score when calculating shared savings payments. Specifically, CMS proposes to revise § 425.512(b) to specify that, for PY 2024 and subsequent PYs, they would calculate a health equity adjusted quality performance score for an ACO that reports the three Medicare CQMs or a combination of eCQMs/MIPS CQMs/Medicare CQMs in the APP measure set, meeting the data completeness requirement at § 414.1340 for each measure, and administers the CAHPS for MIPS survey.

CMS proposes to revise the underserved multiplier calculation to specify the calculations in more detail and bring greater consistency between the calculation of the proportion of ACOs' assigned beneficiaries residing in a census block group with an ADI national percentile rank of at least 85 and the proportion of ACOs' assigned beneficiaries who are enrolled in Medicare Part D LIS or are dually eligible for Medicare and Medicaid.

CMS proposes to remove beneficiaries who do not have a numeric national percentile rank available for ADI from the health equity adjustment calculation for performance year 2023 and subsequent performance years. Beneficiaries without a national percentile ADI rank would appear neither in the numerator nor in the denominator of the proportion.

CMS proposes to modify the calculation of the proportion of assigned beneficiaries dually eligible for Medicare and Medicaid and the calculation of the proportion of assigned beneficiaries enrolled in LIS to use the number of beneficiaries rather than person years for calculating the proportion of the ACO's assigned beneficiaries who are enrolled in LIS or who are dually eligible for Medicare and Medicaid starting in performance year 2024.

For performance year 2024 and subsequent performance years, CMS proposes to use historical submission-level MIPS Quality performance category scores to calculate the 40th percentile MIPS Quality performance category score. CMS proposes to use a rolling 3-performance year average with a lag of 1-performance year. CMS proposes that for PY 2024 and subsequent performance years, if

1. an ACO reports all required measures under the APP and meets the data completeness requirement at § 414.1340 for all required measures and receives a MIPS Quality performance category score under § 414.1380(b)(1), and
2. the ACO's total available measure achievement points used to calculate the ACO's MIPS Quality performance category score for the performance year is reduced due to measure exclusion under § 414.1380(b)(1)(vii)(A),

CMS would use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, to determine whether the ACO meets the quality performance standard required to share in savings at the maximum rate under its track for the relevant performance year.

CMS proposes to revise § 425.512(b)(3)(ii)(B) to state that CMS assigns a value of 0 for each measure that CMS does not evaluate because the measure is unscored. These changes would be effective for performance year 2023 and subsequent performance years.

CMS proposes that quality measures impacted by the MIPS policy at § 414.1380(b)(1)(vii)(A) are unscored measures for the purposes of calculating the health equity adjustment; therefore, excluded measures would not render an ACO ineligible for the health equity adjustment as long as the ACO reports all required measures under the APP and meets the data completeness requirement at § 414.1340 for all required measures and receives a MIPS Quality performance category score.

CMS proposes a change to the MIPS policy to remove the 10 percent threshold for changes to codes, clinical guidelines, or measure specifications for all measure types.

- **Proposals to Align CEHRT Requirements for Shared Savings Program ACOs with MIPS**

CMS proposes to require Spanish language administration of the CAHPS for MIPS survey for MIPS eligible clinicians reporting MIPS. Specifically, they propose to require MIPS eligible clinicians to contract with a CMS-approved survey vendor that, in addition to administering the survey in English, will administer the Spanish survey translation to Spanish-preferring patients using the procedures detailed in the CAHPS for MIPS Quality Assurance Guidelines beginning with 2024 survey administration.

CMS proposes to sunset the Shared Savings Program CEHRT threshold requirements and modify regulations at § 425.506(f) to indicate they will be applicable only through PY 2023. Further, CMS proposes, for PYs beginning on or after January 1, 2024, to require that all MIPS eligible clinicians, Qualifying APM Participants (QPs), and Partial Qualifying APM Participants (Partial QPs) participating in the ACO, regardless of track, satisfy all the following:

- Report the MIPS Promoting Interoperability (PI) performance category measures and requirements to MIPS as either of the following;
    - All MIPS eligible clinicians, QPs, and partial QPs participating in the ACO as an individual, group, or virtual group; or
    - The ACO as an APM entity.
- Earn a MIPS performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level. A MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity may be excluded from the requirements proposed at § 425.507(a) if the MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity
    - Does not exceed the low volume threshold set forth at § 414.1310(b)(1)(iii);
    - Is an eligible clinician as defined at § 414.1305 who is not a MIPS eligible clinician and has opted to voluntarily report measures and activities for MIPS.
    - Has not earned a performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level.

A MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity may be excluded from the requirements proposed at § 425.507(a) if the MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity:

- Does not exceed the low volume threshold;
- Is an eligible clinician as defined at § 414.1305 who is not a MIPS eligible clinician and has opted to voluntarily report measures and activities for MIPS; or
- Has not earned a performance category score for the MIPS Promoting Interoperability performance category because the MIPS Promoting Interoperability performance category has been reweighted.

CMS proposes that any requirements applicable to MIPS eligible clinicians reporting on objectives and measures specified by CMS for the MIPS PI category would apply to MIPS eligible clinicians, QPs, and Partial QPs participating in an ACO at § 425.507(a).

- **Updating Public Reporting Requirements**

CMS proposes that MIPS eligible clinicians, QPs, and Partial QPs who would be excluded from reporting under the proposed regulation at § 425.507(b) may be excluded from the number of MIPS eligible clinicians, QPs, or Partial QPs that the ACO publicly reports under proposed regulation at § 425.308(b)(9). However, if such MIPS eligible clinicians, QPs, and Partial QPs do report the MIPS PI performance category as an individual, group, or virtual group or the ACO reports the MIPS PI performance category as an APM entity, the MIPS eligible clinicians, QPs, and Partial QPs should be included in the number of MIPS eligible clinicians, QPs, and Partial QPs that the ACO publicly reports.

- **Updating Annual Certification Requirements**

CMS proposes to sunset the CEHRT certification requirement in the Shared Savings Program by amending regulations to no longer require ACO clinicians to report the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable percentage specified at § 425.506(f).

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

CMS proposes to include health status information such as risk profile and chronic condition subgroups to the extent that such data would aid ACOs in identifying patients that meet the denominator criteria for the Medicare CQM Specifications. CMS would also provide technical assistance to ACOs when reporting the Medicare CQMs, including providing technical resource documents.

- **Revise the Requirement to Meet the Case Minimum Requirement for Quality**

CMS proposes to replace the references to meeting the case minimum requirement at § 414.1380 with the requirement that the ACO must receive a MIPS Quality performance category score under § 414.1380(b)(1) to meet the quality performance standard.

- **Determining Beneficiary Assignment Under the Shared Savings Program**

CMS proposes to use an expanded window for assignment in a new step three to the claims-based assignment process to identify additional beneficiaries for ACO assignment. CMS is also proposing to modify the definition of "assignable beneficiary" to be consistent with the use of an expanded window for assignment to identify additional beneficiaries to include in the assignable population after application of the existing methodology

CMS proposes to add a new definition of "Expanded window for assignment" in § 425.20 to mean the 24-month period used to assign beneficiaries to an ACO, or to identify assignable beneficiaries, or both that includes the applicable 12-month assignment window and the preceding 12 months.

CMS proposes the addition of a step three to the beneficiary assignment methodology would occur after the current steps one and two and would apply only to beneficiaries who do not meet the pre-step requirement but who received at least one primary care service during the proposed expanded window for assignment with an ACO professional who is a primary care physician or a physician who has one of the specialty designations included in § 425.402(c).

- Beneficiaries qualifying for step three would be assigned based on the plurality of allowed charges for primary care services during this expanded window for assignment.
- Second, the proposed revision to the definition of an assignable beneficiary would similarly include beneficiaries who receive at least one primary care service during the proposed expanded window for assignment from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c).
- In combination with using the expanded window for assignment for identifying beneficiaries who received at least one primary care service from a primary care physician or a physician whose specialty designation is used in assignment, under both the proposed step three for assignment and proposed revised definition of an assignable beneficiary, CMS would continue to consider whether beneficiaries received at least one primary care service during the 12-month assignment window.
- CMS proposes that these changes would be effective for the performance year beginning on January 1, 2025, and subsequent performance years.

CMS proposes to modify the regulations at § 425.400(c)(2)(i) and (ii) to incorporate references to the expanded window for assignment, such that CMS would apply the additional primary care service codes to all months of the assignment window or applicable expanded window for assignment when the assignment window or applicable expanded window for assignment includes any month(s) during the COVID-19 PHE.

- **Revise the Definition of an Assignable Beneficiary**

CMS proposes that a Medicare fee-for-service beneficiary who does not meet assignment requirements but who meets both of the following criteria would also be considered an assignable beneficiary:

- Receives at least one primary care service with a date of service during a specified 24-month expanded window for assignment from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c).
- Receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled practitioner who is a nurse practitioner, physician assistant, or a clinical nurse specialist.

CMS proposes to specify that the assignable population would be identified for the relevant benchmark year, or the performance year (as applicable) using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii):

- In §§ 425.652(a)(5)(v)(A) and (b)(2)(iv)(A), provisions on calculating the county-level share of assignable beneficiaries who are assigned to the ACO for each county in the ACO's regional service area for purposes of calculating the blended national-regional growth rates used in trending and updating the benchmark.
- In the provision on redetermination of the regional adjustment for the second or each subsequent performance year during the term of the agreement period in § 425.652(a)(9)(ii).
- In the provision on the calculation of average county FFS expenditures for assignable beneficiaries in each county in the ACO's regional service area in § 425.654(a)(1)(i).
- In the provision on adjusting for differences in severity and case mix between the ACO's assigned beneficiary population for BY3 and the assignable beneficiary population for the ACO's regional service area for BY3, in calculating average per capita expenditures for the ACO's regional service area, in § 425.656(b)(3).

CMS proposes to specify in the proposed new provision at § 425.655(b)(1) that the assignable population that would be used to calculate average county prospective HCC and demographic risk scores for purposes of calculating the proposed regional risk score growth cap adjustment factor would be identified for the relevant benchmark year or the performance year (as applicable) using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

- **Revise the Definition of Primary Care Services used in Shared Savings**

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

1. Smoking and Tobacco-use Cessation Counseling Services CPT codes 99406 and 99407;
2. Remote Physiologic Monitoring CPT codes 99457 and 99458;
3. Cervical or Vaginal Cancer Screening HCPCS code G0101;
4. Office-Based Opioid Use Disorder Services HCPCS codes G2086, G2087, and G2088;
5. Complex Evaluation and Management Services Add-on HCPCS code G2211, if finalized under Medicare FFS payment policy;
6. Community Health Integration services HCPCS codes GXXX1 and GXXX2, if finalized under Medicare FFS payment policy;
7. Principal Illness Navigation (PIN) services HCPCS codes GXXX3 and GXXX4, if finalized under Medicare FFS payment policy;
8. SDOH Risk Assessment HCPCS code GXXX5, if finalized under Medicare FFS payment policy;
9. Caregiver Behavior Management Training CPT Codes 96202 and 96203, if finalized under Medicare FFS payment policy; and
10. Caregiver Training Services CPT codes 9X015, 9X016, and 9X017

CMS further proposes to specify a revised definition of primary care services in a new provision of the Shared Savings Program regulations at § 425.400(c)(1)(viii) to include the list of HCPCS and CPT codes specified which would be applicable for use in determining beneficiary assignment for the performance year starting on January 1, 2024, and subsequent performance years The proposed additional CPT codes:

1. 99406 and 99407; and
2. 99457 and 99458; and
3. 96202 and 96203

- **Revise the Policies on the Shared Savings Program's Benchmarking Methodology**

CMS proposes to revise the Shared Savings Program regulations governing the calculation of the regional growth rate when updating the historical benchmark between Benchmark Year (BY) 3 and the performance year at § 425.652(c) to incorporate a regional risk score growth cap adjustment factor.

CMS proposes the following approach to calculate and apply the regional adjustment, or the regional adjustment in combination with the prior savings adjustment, if applicable, for ACOs in agreement periods starting on January 1, 2024, and in subsequent years:

- CMS would continue to calculate the original uncapped regional adjustment by Medicare enrollment type using the applicable percentage phase-in weight based on whether the ACO has lower or higher spending compared to its regional service area and the ACO's agreement period subject to a regional adjustment as described in § 425.656(d).
- CMS would continue to apply the 5 percent cap on positive regional adjustments and the -1.5 percent cap and offset factor on negative regional adjustments at the enrollment type level, as finalized in the CY 2023 PFS final rule and described in § 425.656(c). For the performance year beginning on January 1, 2025, and subsequent performance years, the national assignable fee-for-service population used to calculate the caps would reflect the revised definition of assignable beneficiary that incorporates the expanded window for assignment as proposed in section III.G.3.a of this proposed rule.
- After applying the cap and offset factor (if applicable), CMS would express the regional adjustment as a single per capita value by calculating a person year weighted average of the Medicare enrollment type-specific regional adjustment values.
- If the ACO's regional adjustment amount (expressed as a single per capita value) is positive, the ACO would receive a regional adjustment, according to the approach we finalized in the CY 2023 PFS final rule. CMS would apply the enrollment type-specific regional adjustment amounts separately to the historical benchmark expenditures for each Medicare enrollment type.
    - If the ACO is also eligible for a prior savings adjustment, the ACO would receive the higher of the two adjustments.
    - If the regional adjustment amount (expressed as a single per capita value) is higher, CMS would apply the enrollment type-specific regional adjustment amounts separately to the historical benchmark expenditures for each Medicare enrollment type.
    - If the prior savings adjustment is higher, CMS would apply the adjustment in the manner finalized in the CY 2023 PFS final rule as a flat dollar amount applied separately to the historical benchmark expenditures for each Medicare enrollment type.

- If the ACO's regional adjustment amount (expressed as a single per capita value) is negative, the ACO would receive no regional adjustment to its benchmark for any enrollment type.
    - If the ACO is eligible for a prior savings adjustment, it would receive the prior savings adjustment as its final adjustment, without any offsetting reduction for the negative regional adjustment.

CMS proposes to implement the changes described in this section through revisions to §§ 425.652, 425.656, and 425.658. Specifically, within § 425.652, CMS proposes revisions to describe how CMS would determine and apply the adjustment to an ACO's benchmark depending on whether the ACO is eligible for a prior savings adjustment and whether the ACO's regional adjustment, expressed as a single value, is positive or negative. This provision would also establish that if an ACO is not eligible to receive a prior savings adjustment and has a regional adjustment, expressed as a single value that is negative or zero, the ACO will not receive an adjustment to its benchmark.

CMS propose to revise § 425.656 (which describes the calculation of the regional adjustment) and § 425.658 (which describes the calculation of the prior savings adjustment) to include certain elements of each calculation that were previously described in § 425.652(a)(8). Specifically, CMSs propose to revise § 425.656 to redesignate paragraphs (d) and (e) as paragraphs (e) and (f) (respectively) and to specify in a new paragraph (d) that we would express the regional adjustment as a single value, and use this value in determining whether a regional adjustment or a prior savings adjustment would be applied to the ACO's benchmark in accordance with § 425.652(a)(8) (as revised under this proposed rule).

CMS proposes to add a new paragraph (c) under § 425.658 specifying that CMS would calculate the per capita savings adjustment as the lesser of 50 percent of the pro-rated average per capita savings amount and the cap equal to 5 percent of national per capita FFS expenditures for assignable beneficiaries for BY3 expressed as a single value by taking a person-year weighted average of the Medicare enrollment-type specific values.

CMS proposes to modify the calculation of the regional update factor used to update the historical benchmark between benchmark year (BY) 3 and the performance year by capping an ACO's regional service area risk score growth through use of an adjustment factor to provide more equitable treatment for ACOs and for symmetry with the cap on ACO risk score growth.

CMS proposes to further mitigate the impact of the negative regional adjustment on the benchmark to encourage participation by ACOs caring for medically complex, high-cost beneficiaries.

CMS proposes to specify the circumstances in which CMS would recalculate the prior savings adjustment for changes in values used in benchmark calculations due to compliance action taken to address avoidance of at-risk beneficiaries, or as a result of the issuance of a revised initial determination of financial performance for a previous performance year.

CMS proposes to specify use of the CMS-HCC risk adjustment methodology applicable to the calendar year corresponding to the performance year in calculating prospective HCC risk scores for Medicare FFS beneficiaries for the performance year, and for each benchmark year of the ACO's agreement period.

- **Modify Prior Savings Adjustment**

CMS proposes to modify the list of circumstances for adjusting an ACO's historical benchmark in § 425.652(a)(9) to include two additional scenarios:

1. A change in savings earned by an ACO in a benchmark year in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries, or
2. A change in the amount of savings or losses for a benchmark year due to a reopening of a prior determination of ACO shared savings or shared losses and the issuance of a revised initial determination under § 425.315

CMS proposes that for an adjusted benchmark due to the two conditions being considered to be used in financial reconciliation for a performance year, any determination that changes the amount of the ACO's savings or losses in any of the benchmark years under §§ 425.315 or 425.316(b)(2)(ii)(B) or (C) must be issued no later than the date of the initial determination of shared savings or shared losses through financial reconciliation for the relevant performance year under § 425.605(e) or § 425.610(h).

CMS proposes to consider whether this prior ACO is impacted by the following when determining whether to issue an adjusted benchmark:

1) A change in the amount of savings calculated for any of the ACO's benchmark years eligible for inclusion in the prior savings adjustment in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries; or
2) A revised initial determination issued under § 425.315 that impacts the determination of the ACO's savings or losses for one of the benchmark years.

- **Refine How Benchmark Years are Risk Adjusted**

CMS proposes to codify paragraph (b) of § 425.659 their approach to determining Medicare FFS beneficiary prospective HCC risk scores for Shared Savings Program benchmark and performance year calculations. Specifically, CMS proposes to codify:

- The current practice of calculating risk scores for Medicare FFS beneficiaries for a performance year, which provides that CMS uses the CMS-HCC risk adjustment methodology applicable for the corresponding calendar year.
- The current practice for agreement periods beginning before January 1, 2024, of applying the CMS-HCC risk adjustment methodology for the calendar year corresponding to benchmark year in calculating risk scores for Medicare FFS beneficiaries for each benchmark year of the agreement period.
- For agreement periods beginning on January 1, 2024, and in subsequent years, CMS would apply the CMS-HCC risk adjustment methodology for the calendar year corresponding to the performance year in calculating risk scores for Medicare FFS beneficiaries for each benchmark year of the agreement period.

CMS proposes at § 425.659(b)(2) to codify current practices for calculating prospective HCC risk scores for a benchmark or performance year. Specifically, CMS proposes to:

- Remove the MA coding intensity adjustment, if applicable.

- Renormalize prospective HCC risk scores by Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries) based on a national assignable FFS population for the relevant benchmark or performance year.
- Calculate the average prospective HCC risk score by Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries) to risk adjust benchmark calculations also performed by Medicare enrollment type.

CMS proposes to adjust the benchmark to account for CMS-HCC risk adjustment model changes during the term of the agreement period to maintain uniformity between the calculation of prospective HCC risk scores for the performance year and each benchmark year.

CMS proposes to revise the list of circumstances for adjusting the historical benchmark for the second and each subsequent performance year during the term of the agreement period at § 425.652(a)(9) to include a change in the CMS-HCC risk adjustment methodology used to calculate prospective HCC risk scores.

- **Modify AIP Eligibility Requirements to Allow ACOs to Advance to Performance-Based Risk During the 5-Year Agreement Period**

CMS proposes to modify Advance Investment Payments (AIP) eligibility requirements to allow an ACO receiving advance investment payments to transition to two-sided risk within its 5-year agreement period under the BASIC track's glide path. Specifically, CMS proposes to modify § 425.630(b)(2) and (3) to allow an eligible ACO receiving advance investment payments to advance to performance-based risk beginning in PY3 of the ACO's agreement period.

CMS also proposes to modify § 425.316(e)(2) to specify that CMS would cease payment of advance investment payments if CMS determines that an ACO approved for AIP became experienced with performance-based risk Medicare ACO initiatives during the first or second performance year of its agreement period or became a high revenue ACO during any performance year of the agreement period in which it received advance investment payments.

- CMS also proposes to modify § 425.316(e)(2)(i) to specify that CMS will cease payment of advance investment payments no later than the quarter after the ACO became experienced with performance-based risk Medicare ACO initiatives or became a high revenue ACO.
- CMS proposes that this policy would be effective January 1, 2024. Under this proposal, an ACO could not use advance investment payments to fund repayment mechanisms or repay shared losses. This limitation also reduces the risk that ACOs stretch themselves beyond their financial capacity while receiving advance investment payments by taking on large amounts of risk.

CMS proposes to Modify ACO reporting requirements to require ACOs to submit spending plan updates to CMS in addition to publicly reporting spend plan updates.

- **Modify AIP Recoupment and Recovery Policies for Early Renewing ACOs**

CMS proposes to amend § 425.630(g)(4) to create a limited exception to the policy of recovering advance investment payments from an ACO that voluntarily terminates its participation agreement for the agreement period during which it received advance investment payments. Under this proposal, CMS would not seek to collect all advance investment payments received from an ACO, if the ACO voluntarily terminates its participation agreement at the end of PY2 or later during the agreement period in which it received advance investment payments, provided that the ACO immediately enters into a new participation agreement with CMS under any level of the BASIC track's glide path or the ENHANCED track. Rather, CMS would carry forward any remaining balance of advance investment payments owed by the early renewing ACO into the ACO's new agreement period.

CMS further proposes to allow an ACO approved for AIP to early renew its participation agreement before the expiration of its current agreement if the ACO terminates its current participation agreement effective on or after December 31 of the ACO's second performance year. By requiring the ACO to maintain its current agreement period for the first two years, the ACO will receive all its advance investment payments prior to renewing its participation agreement.

CMS further proposes that in such circumstances, the early renewing ACO must continue to repay the advance investment payments through shared savings earned in the subsequent agreement period. If an ACO early renews prior to PY3, it will no longer comply with the eligibility requirements for receiving payments and may be subject to compliance actions under §§ 425.216 and 425.218. An ACO may spend an advance investment payment over its entire agreement period.

CMS proposes to amend § 425.630(e)(3) to permit an early renewing ACO to spend advance investment payments in its second agreement period so long as the advance investment payments are spent within 5 performance years of when it began to receive advance investment payments. If the ACO does not spend all the advance investment payments received by the end of the fifth performance year, the ACO must repay any unspent funds to CMS.

CMS proposes to permit CMS to terminate advance investment payments for future quarters to an ACO that has provided CMS with notice of termination in accordance with § 425.220(a) if the ACO will not immediately enter a new agreement period. This avoids distributing advance investment payments to an ACO from which CMS would subsequently need to recover such payments. If finalized, these proposed changes would be effective January 1, 2024.

- **Permit Reconsideration Review of Quarterly Payment Calculations**

CMS proposes to permit an ACO to request a reconsideration review for all advance investment payment quarterly payment calculations, not just instances where no payments were distributed.

CMS further proposes to revise § 425.630(f) to provide that CMS would notify in writing each ACO of its determination of the amount of advance investment payment it will receive and that such notice would inform the ACO of its right to request reconsideration review.

- **Update Shared Savings Program Eligibility Requirements**

CMS proposes to remove the option under § 425.106(c)(5) for ACOs to request an exception to the requirement specified in § 425.106(c)(3) that 75 percent control of the ACO's governing body must be

held by ACO participants. Additionally, CMS proposes a corresponding revision to remove the option for ACOs to request an exception to the 75 percent control requirement as part of their Shared Savings Program applications.

CMS proposes to codify the current operational approach for determining whether an ACO participant has participated in a performance-based risk Medicare ACO initiative. Under the current operational approach, an ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if its TIN was or will be used to calculate financial reconciliation for the entity participating in such ACO initiative. In general, if an ACO participant was included on an Initiative ACO's participant list for a performance year during the 5 most recent performance years before the ACO's agreement start date, and the Initiative ACO is, or will be, financially reconciled for that performance year, the ACO participant will be considered to have participated in the Initiative ACO.

CMS proposes to modify the existing definitions for "experienced with performance-based risk Medicare ACO initiatives" and "inexperienced with performance-based risk Medicare ACO initiatives" at § 425.20 to include the following new sentence at the end of each definition: "An ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if the ACO participant TIN was or will be included in financial reconciliation for a performance year under such initiative during any of the five most recent performance years" effective on January 1, 2024.

CMS proposes to correct the error in the definition for "Rural health center (RHC)" at § 425.20 by replacing the word "center" with the word "clinic".

Background/Rationale

In combination, the above MSSP proposals are anticipated to improve the incentive for ACOs to sustainably participate and earn shared savings in the program. On net, total program spending is estimated to decrease by $330 million over the 10-year period 2024 through 2033. These changes are anticipated to support the goals outlined in the CY 2023 PFS final rule for growing the program with a particular focus on including underserved beneficiaries.

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

Medicare CQMs would serve as a transition collection type to help some ACOs build the infrastructure, skills, knowledge, and expertise necessary to report all payer/all patient MIPS CQMs and eCQMs by defining a population of beneficiaries that exist within the all payer/all patient MIPS CQM Specifications and tethering that population to claims encounters with ACO professionals with specialties used in assignment.

The proposed definition for beneficiary eligible for Medicare CQMs is intended to create alignment with the all payer/all patient MIPS CQM Specifications. The HCPCS and revenue center codes designated under § 425.400(c) as primary care services for purposes of assignment under the Shared Savings Program only partially over-lap with the codes designated as eligible encounters used to identify the eligible population in all payer/all patient MIPS CQM Specifications. Additionally, only applying the 12-month period used in assignment or deferring to the basic assignment methodology under Subpart E to identify the beneficiaries eligible for Medicare CQMs would have the unintended result of reducing the beneficiaries eligible for Medicare CQMs to only patients that had an eligible encounter during the overlap of the assignment window as defined at § 425.20 and the measurement period as defined in the Medicare CQM Specifications.

CMS believes the proposal to establish the Medicare CQM collection type would address the concerns from ACOs regarding the capability of meeting the data completeness requirement for all payer data. Specifically, the proposal to define Beneficiaries eligible for Medicare CQMs aims to focus ACOs' reporting efforts on beneficiaries with an encounter with an ACO professional with a specialty used in assignment and thereby reduce the potential for missing or un-matched patient data.

CMS also believes the proposal to create Medicare CQMs is intended to support ACOs through the transition to reporting the all payer/all patient eCQMs/MIPS CQMs and to facilitate quality assessment improvement activities since we would provide ACOs with a list of beneficiaries eligible for Medicare CQM reporting to aid in patient matching and data deduplication.

- **Expanding the Health Equity Adjustment to Medicare CQMs**

Under the goals of the CMS National Quality Strategy, CMS is moving towards a building-block approach to streamline quality measures across CMS quality programs for the adult and pediatric populations. This "Universal Foundation" of quality measure will focus provider attention, reduce burden, identify disparities in care, prioritize development of interoperable, digital quality measures, allow for cross-comparisons across programs, and help identify measurement gaps.

The goal of the health equity adjustment is to reward ACOs serving a high proportion of underserved beneficiaries, with high performance scores on quality measures, and support ACOs with the transition to eCQMs/MIPS CQMs.

CMS believes that applying the health equity adjustment to an ACO's quality performance category score when reporting Medicare CQMs would encourage ACOs to treat underserved populations.

The underserved multiplier is a proportion ranging from zero-to-one of the ACO's assigned beneficiary population for the performance year that is considered underserved based on the highest of:

1. the proportion of the ACO's assigned beneficiaries residing in a census block group with an Area Deprivation Index (ADI) national percentile rank of at least 85; or
2. the proportion of the ACO's assigned beneficiaries who are enrolled in Medicare Part D low-income subsidy (LIS) or are dually eligible for Medicare and Medicaid.

The use of both the ADI and Medicare and Medicaid dual eligibility or LIS status to assess underserved populations in the health equity adjustment allows CMS to consider both broader neighborhood level characteristics and individual characteristics among CMS beneficiaries.

Removal of beneficiaries without a national percentile ADI rank from the health equity adjustment is more equitable because it will remove a beneficiary without an ADI rank from the denominator and the numerator of the calculation of an ACO's underserved multiplier instead of penalizing ACOs that have such beneficiaries.

CMS believes the proposal to use the number of beneficiaries instead of person years would bring greater consistency between the two proportions used in determining the underserved multiplier. It also acknowledges that beneficiaries with partial year as compared to 546 full year LIS enrollment or dual eligibility are also socioeconomically vulnerable and strengthens incentives for ACOs to serve this population. Further, inclusion of beneficiaries with partial year LIS enrollment in the underserved

multiplier provides increased incentive for ACOs to help facilitate LIS enrollment for beneficiaries who meet eligibility criteria.

CMS believes the proposal to use a 3-year historical average for base years would mitigate issues that may arise from using a single year historical reference such as scoring, policy, and/or performance anomalies, such as a pandemic, specific to the historical base year.

- **Proposals to Align CEHRT Requirements for Shared Savings Program ACOs with MIPS**

CMS believes that incorporating MIPS PI performance category's requirements into the Shared Savings Program will alleviate the burden that the current policy creates for ACOs. Because the Shared Savings Program CEHRT attestation requirement and the MIPS PI category requirements are not the same, ACOs have the burden of managing compliance with two different CEHRT program requirements.

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

CMS believes the proposed use of an expanded window for assignment in an enhanced stepwise assignment methodology would result in a greater overall number of beneficiaries assigned to ACOs. All beneficiaries who are assigned to an ACO under the current methodology would continue to be assigned to an ACO under the proposed methodology. Under the proposed methodology, a beneficiary who does not meet the current pre-step requirement would also be eligible to be assigned to an ACO if they (a) received at least one primary care service from a nurse practitioner, physician assistant, or clinical nurse specialist who is an ACO professional in the ACO during the applicable assignment window and (b) received at least one primary care service from a primary care physician or physician with a specialty used in assignment who is an ACO professional in the ACO during the applicable expanded window for assignment.

- **Revise the Policies on the Shared Savings Program's Benchmarking Methodology**

CMS believes this proposed policy update to the regional update factor would help increase for ACOs operating in regional service areas with high-risk score growth, including those serving more medically complex beneficiaries, therefore increasing incentives for ACOs to form or continue participation in such areas. At the same time, CMS believes that incorporating the market share adjustment helps to mitigate concerns related to coding intensity for ACOs with high market share and thus a relatively high level of influence over risk scores in the ACOs regional service area.

CMS believes the adoption of the alternative approach to calculating prospective HCC risk scores for the performance year and each benchmark year of an ACO's agreement period would allow CMS to measure the change more accurately in severity and case mix for an ACO's assigned beneficiary population or the assignable beneficiary population. Under such an approach, there would be no potential for distortion from using different CMS-HCC risk adjustment models in calculating prospective HCC risk scores for benchmark years and the performance year that could occur under the current policy.

- **Modify AIP Recoupment and Recovery Policies for Early Renewing ACOs**

CMS believes that the proposed Advance Investment Payment changes would help ensure that CMS efficiently obtains information in a consistent manner from all ACOs receiving advance investment payments and thereby support CMS's monitoring and analysis of the use these payments. CMS believes

that these proposed changes will impose little to no administrative burden on participating ACOs, which are already required to publicly report this information by § 425.308(b)(8).

- **Update Shared Savings Program Eligibility Requirements**

CMS continues to believe that ACO participants should drive ACO leadership to move toward improved quality of care and patient outcomes, and that this is a key component of ACO success and ability to earn shared savings. The 75 percent participant control threshold is critical to ensuring that governing bodies are participant-led and best positioned to meet program goals, while allowing for partnership with non-Medicare enrolled entities to provide needed capital and infrastructure for ACO formation and administration. Over the years, a few ACOs have requested an exception to form a governing body with less than 75 percent participant control. CMS discussed the exemption requests with the interested ACOs and ultimately the ACOs adjusted comply with the 75 percent participant control requirement. To date, CMS has not granted an ACO an exception to this requirement, despite the flexibility provided in current regulation. Accordingly, CMS believes that there is no reason to continue to offer an exception to the requirement, as ACOs have demonstrated that they can appropriately meet the 75 percent participant control requirement without utilizing this flexibility since its establishment in the November 2011 final rule.

Comments

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

CMS seeks comment on their proposal to use a 3-performance year rolling average with a lag of 1-performance year to calculate the 40th percentile MIPS Quality performance category score used for the quality performance standard for performance year 2024 and subsequent performance years.

- **Expanding the Health Equity Adjustment to Medicare CQMs**

CMS seeks comments on their proposals to revise the calculation of the health equity adjustment underserved multiplier and the use of the number of beneficiaries enrolled in Low-Income Subsidy (LIS) rather than person years.

CMS is soliciting comments on scoring incentives that would be applied to an ACO's health equity adjusted quality performance score beginning in performance year 2025 when specialists who participate in the ACO report quality MVPs as described at § 414.1365(c)(1).

CMS seeks comment on the factors that affect the administration of survey translations where there is need for one or more of the available translations.

- **Proposals to Align CEHRT Requirements for Shared Savings Program ACOs with MIPS**

CMS seeks public comment on their proposal to require all MIPS eligible clinicians, Qualifying APM participants, and Partial Qualifying APM Participants, regardless of track, satisfy all MIPS Promoting Interoperability (PI) performance category measures and requirements to MIPS.

CMS seeks public comment on an alternative proposal that ACOs report the measures and requirements under the MIPS PI performance category, in accordance with regulations at 42 CFR part 414 subpart O, at the APM entity level. This alternative proposal would remove the option for MIPS eligible clinicians, Qualifying APM Participants (QPs), and Partial Qualifying APM Participants (Partial QPs) participating

in the ACO to report the MIPS PI performance category at the individual, group, or virtual group level for purposes of satisfying the proposal at § 425.507.

- **Updating Annual Certification Requirements**

CMS seeks public comment on the proposal to sunset the CEHRT certification requirement in the Shared Savings Program at §§ 425.302(a)(3)(iii) and 425.506(f) and to add new requirements at § 425.507, for performance years beginning on or after January 1, 2024, unless otherwise excluded, to require that all MIPS eligible clinicians, Qualifying APM Participants (QPs), and Partial Qualifying APM Participants (Partial QPs) participating in the ACO, regardless of track, satisfy all new MIP reporting requirements.

- **Updating Public Reporting Requirements**

CMS seeks comment on the proposal to add a new requirement for public reporting in § 425.308(b)(9), requiring that the ACO must publicly report the number of MIPS eligible clinicians, Qualifying APM Participants (QPs), and Partial Qualifying APM Participants (Partial QPs) participating in the ACO that earn a MIPS performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level MIPS Value Pathway (MVP) Reporting for Specialists in Shared Savings Program ACOs.

- **Revise the Requirement to Meet the Case Minimum Requirement for Quality**

CMS also seeks feedback on the following aspects of MVP reporting for specialists in Shared Savings Program ACOs:

- In order to highlight specialty clinical practice within ACOs, how should CMS encourage specialist reporting of MVPs?
- How should CMS encourage the reporting of MVPs to collect quality data that is comparable to data reported by other specialty providers in quality MVPs and to address clinician concerns over measure appropriateness?
- How should CMS consider encouraging specialists to report the MVP that is most relevant to their clinical practice?
- How should CMS distinguish bonus points for ACOs that report on a larger volume of patients through MVPs?
- How should CMS provide ACOs with bonus points to their health equity adjusted quality performance score when an ACO's specialty clinicians report MVPs?
- What concerns and considerations should CMS be aware of when assessing ACOs for quality performance based on reporting quality measures within MVPs?
- Would incentivizing specialty MVPs create a disincentive for ACOs to report primary care focused APP and/or MVP measures?
- In the event that MIPS quality measures in MVPs are excluded under § 414.1380(b)(1)(vii)(A), should CMS apply the proposed Shared Savings Program scoring policy for excluded APP measures as described in section III.G.2.f. of this proposed rule?

CMS seeks comment on how long we should have bonus points in place in order to incentivize MVP reporting.

CMS seeks comments on if and how CMS should consider assessing overall specialty performance as part of the APP in the future.

CMS seeks comment on how long we should have bonus points in place in order to incentivize MVP reporting.

CMS seeks comments on if and how CMS should consider assessing overall specialty performance as part of the APP in the future.

- **Revise the Definition of an Assignable Beneficiary**

CMS seeks comment on proposed modifications to § 425.20, to revise the definition of "assignable beneficiary," "assignment window," and add a new definition of "expanded window for assignment.

CMS seeks comment on additional policies they should consider for potential future rulemaking regarding assignment methodology, with the goal of increasing the number of Original Medicare fee-for-service beneficiaries assigned to an ACO, particularly in underserved communities.

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

CMS welcomes comments on any aspects of the proposed changes, including the length of the expanded window for assignment.

CMS seeks comment on proposed modifications to the definition of assignable beneficiary in § 425.20.

- **Determining Beneficiary Assignment Under the Shared Savings Program**

CMS also seeks comment on proposed technical and conforming changes to references to the identification of assignable beneficiaries in subpart G of the Shared Savings Program regulations, as well as in the proposed new regulation at § 425.655—on calculating the regional risk score growth cap adjustment factor, to incorporate the use of the assignment window or expanded window for assignment in identification of the assignable beneficiary population.

- **Revise the Policies on the Shared Savings Program's Benchmarking Methodology**

CMS seeks comment on the proposed changes to establish a new defined term in § 425.20, expanded window for assignment, for use in a proposed additional step three in the beneficiary assignment methodology and in identifying the assignable beneficiary population, revisions to the definition of assignable beneficiary, as well as proposed technical and conforming changes to provisions of the Shared Savings Program regulations, including the definition of assignment window under § 425.20, and provisions within subpart E and subpart G.

CMS seeks comment on the proposed changes to the calculation of the regional component of the update factor for agreement periods beginning on or after January 1, 2024.

- **Revise the Definition of Primary Care Services used in Shared Savings**

CMS seeks comment on 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, 2024, and subsequent performance years.

CMS also welcomes comments on any other existing HCPCS or CPT codes and new HCPCS or CPT codes proposed elsewhere in this proposed rule that we should consider adding to the definition of primary care services for purposes of assignment in future rulemaking.

- **Modify AIP Recoupment and Recovery Policies for Early Renewing ACOs**

CMS seeks comment on the proposals to amend AIP policies and require that all AIP ACOs be inexperienced with performance-based risk Medicare ACO initiatives while the ACO receives advance investment payments during PY1 and PY2 of the agreement period – and to allow ACOs to progress to performance-based risk under the BASIC track's glide path beginning with PY3 of the same agreement period.

CMS seeks comment on the proposed changes to § 425.630(e)(3) and § 425.630(g)(4). d. to Amend Termination Policies to Allow CMS to Cease Distribution of Advance Investment Payments Following an ACO's Notification of Voluntary Termination.

CMS seeks public comments on the appropriateness of the proposed policy refinement and elimination of the exception process.

- **Modify AIP Eligibility Requirements to Allow ACOs to Advance to Performance-Based Risk During the 5-Year Agreement Period**

CMS seeks comments on the proposed definition of "experience with performance-based risk Medicare ACO initiatives".

CMS seeks public comments on the appropriateness of the proposed policy refinement and elimination of the exception process. Specifically, the revised regulation text would state: "In cases in which the composition of the ACO's governing body does not meet the requirements of paragraph (c)(2) of this section, the ACO must describe why it seeks to differ from these requirements and how the ACO will provide meaningful representation in ACO governance by Medicare beneficiaries.

CMS seeks comment on the following:

1. policies/model design elements that could be implemented so that a higher risk track could be offered without increasing program expenditures;
2. ways to protect ACOs serving high-risk beneficiaries from expenditure outliers and reduce incentives for ACOs to avoid high-risk beneficiaries; and
3. the impact that higher sharing rates could have on care delivery redesign, specialty integration, and ACO investment in health care providers and practices.

- **Modify Prior Savings Adjustment**

CMS seeks comments on potential changes to the 50 percent scaling factor used in determining the prior savings adjustment.

- **Refine How Benchmark Years are Risk Adjusted**

CMS also seeks comments on potential changes to the positive regional adjustment to reduce the possibility of inflating the benchmark while still mitigating potential ratchet effects on ACO benchmark.

CMS seeks comment on the following potential refinements to the ACPT and the three-way blended benchmark update factor as CMS works toward broad implementation of administrative benchmarks:

1. replacing the national component of the two-way blend with the ACPT; and
2. scaling the weight given to the ACPT in a two-way blend for each ACO based on the collective market share of multiple ACOs within the ACO's regional service area.

CMS seeks comments on the proposed changes to regional benchmarking adjustments.

CMS seeks comments on the proposal to adjust the historical benchmarking to reflect changes in savings or losses for a performance year that constitutes a benchmark year for an ACO's current agreement period. These changes would be applicable for agreement periods beginning on or after January 1, 2024.

CMS seeks comment on the proposals regarding the prospective HCC risk scores to be used in risk adjustment for purposes of benchmark calculations under the Shared Savings Program.

- **Update Shared Savings Program Eligibility Requirements**

CMS seeks public comment on potential future developments to Shared Savings Program policies including: incorporating a track with higher risk and potential reward than the Enhanced track; modifying the amount of the prior savings adjustment through potential changes to the 50 percent scaling factor used in determining the adjustment, as well as considerations for potential modifications to the positive regional adjustment to reduce the possibility of inflating the benchmark; potential refinements to the ACPT and the three-way blended benchmark update factor over time to further mitigate potential ratchet effects within the update factor; and policies to promote ACO and CBO collaboration.

CMS seeks comment on ways to improve and incentivize collaboration between ACOs and interested parties in the community or CBOs (public or private not-for-profit entities that provide specific services to the community or targeted populations in the community to address the health and social needs of those populations).

CMS seeks comments on approaches, generally, for encouraging or incentivizing increased collaboration between ACOs and CBOs, including any policies specifically designed to encourage ACOs to partner with CBOs and address unmet health-related social needs.

CMS also seeks comments on potential changes CMS could make to the patient-centered care requirements in § 425.112 to strengthen partnerships between ACOs and interested parties in the community, including CBOs, to address unmet health-related social needs.

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

Proposed Changes

Effective January 1, 2024, the payment policy allowing for additional payment for the administration of a COVID-19 vaccine in the home would be extended to include the other three preventive vaccines included in the Part B preventive vaccine benefit (pneumococcal, influenza, and hepatitis B vaccines), and the payment amount for all four vaccines would be identical. That is, beginning January 1, 2024, the Medicare Part B will pay the same additional payment amount to providers and suppliers that administer a pneumococcal, influenza, hepatitis B, or COVID-19 vaccine in the home, under certain circumstances.

This additional payment amount would be annually updated using the percentage increase in the MEI and adjusted to reflect geographic cost variations using the PFS GAF.

- CMS proposes to limit the additional payment to one payment per home visit, even if multiple vaccines are administered during the same home visit.
- CMS proposes revisions to the relevant regulations to include monoclonal antibodies that are used for PreP of COVID-19 under the Part B preventive vaccine benefit.

CMS neglected to include the effective date for the MEI policy in the regulation text. Therefore, they are proposing the following correction, and they are reorganizing other elements of the regulation text at § 410.152(h) as they codify the in-home additional payment:

- At § 410.152, at paragraph (h)(5), they propose to add that the paragraph is effective beginning January 1, 2023.
- At § 410.152, they propose to combine the existing paragraph (h)(2) and (h)(3) into a new paragraph (h)(2), with subparagraphs (h)(2)(i) and (h)(2)(ii)
- At § 410.152, at a revised paragraph (h)(3), they propose new regulations regarding the in-home additional payment for preventive vaccine administration, as described in this section of the proposed rule in section III.H.3.c.

Background/Rationale

Recent study results have allowed CMS to conclude that the in-home additional payment improved healthcare access to vaccines for these often-underserved Medicare populations. From an analysis of the data, the in-home additional payment is being billed significantly more frequently for beneficiaries that are harder to reach and that may be less likely to otherwise receive these preventive benefits. Therefore, they are proposing to maintain the in-home additional payment for COVID-19 vaccine administration under the Part B preventive vaccine benefit.

CMS' statutory authority at section 1861(s)(10) of the Act to regulate Part B preventive vaccine administration is identical for all four preventive vaccines, and the payment has been shown to positively impact health equity and healthcare access, therefore they are extending the additional payment to the administration included in the Part B preventive vaccine benefit.

CMS emphasizes that every vaccine dose that is furnished would still receive its own unique vaccine administration payment. They intend to continue to monitor utilization of the M0201 billing code for the

in-home additional payment, and they plan to revisit the policy should they observe inappropriate use or abuse of the code.

For CY 2024, the proposed growth rate of the 2017-based MEI is estimated to be 4.5 percent, based on the IHS Global, Inc. (IGI) first quarter 2023 forecast with historical data through fourth quarter 2022. Therefore, CMS would multiply the 768 CY 2023 in-home additional payment amount for Part B preventive vaccine administration of $36.85 by the proposed CY 2024 percentage increase in the MEI of 4.5 percent, which would result in a proposed CY 2024 in-home additional payment for Part B preventive vaccine administration of $38.51 ($36.85 x 1.045 = $38.51).

Comments

CMS seeks comment on the policy condition mentioned in section III.H.3.b of this proposed rule regarding Medicare payment of the in-home additional payment amount for up to a maximum of 5 vaccine administration services per home unit or communal space within a single group living location, but only when fewer than 10 Medicare patients receive a COVID-19 vaccine dose on the same day at the same group living location. CMS solicits comments on these proposals and the proposed amendments to the regulation text.

L. 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.M.)

Proposed Changes

CMS proposes that based on the existing regulatory text at § 423.160(a)(5), the CMS EPCS Program will automatically adopt the electronic prescribing standards at § 423.160(b) as they are updated. As a result, any finalized proposals from the CY 2024 Medicare Advantage and Part D Policy and Technical Changes proposed rule to standards at § 423.160(b) would apply to electronic prescribing for the CMS EPCS program as well.

CMS proposes to integrate the provision at § 423.160(a)(3)(iii) in the CY 2008 PFS final rule (72 FR 66405) into the CMS electronic prescribing of controlled substances (EPCS) program requirements at § 423.160(a)(5). The provision at § 423.160(a)(3)(iii) in the CY 2008 PFS final rule (72 FR 66405) permits the use of either HL7 messages or the NCPDP SCRIPT Standard to transmit prescriptions when all parties are part of the same legal entity while maintaining e-prescribing requirements. CMS proposes to remove the same entity exception at § 423.160(a)(5)(i) from the CMS EPCS Program requirements. CMS proposes to add "subject to the exemption in paragraph (a)(3)(iii) of this section" to § 423.160(a)(5).

CMS proposes to specify how prescriptions with multiple fills within the same year would impact the calculation of the compliance threshold. For the CMS EPCS Program compliance threshold calculation, CMS proposes to count refills as an additional prescription and not count refills as an additional prescription unless the refill is the first occurrence of the unique prescription in the measurement year.

CMS proposes to modify the rules for when the two EPCS Program exceptions apply and the duration of both exceptions. CMS proposes that prescribers apply for waivers in times of emergency and disaster and

limiting the circumstances that would trigger the exception. Specifically, CMS proposes to modify the definition of "extraordinary circumstance" at § 423.160(a)(5)(iv) to mean a situation outside of the control of a prescriber that prevents the prescriber from electronically prescribing a Schedule II-V controlled substance that is a Part D drug. CMS also proposes to modify the recognized emergency exception at § 423.160(a)(5)(iii) so that CMS will identify which events trigger the recognized emergency exception.

CMS proposes to modify the timeframe under CMS EPCS Program waivers to be one measurement year. CMS proposes that prescribers who need a waiver beyond December 31 of a measurement year would need to complete a new waiver application. CMS is also proposing that from the date of the non-compliance notice, prescribers have 60 days to request a waiver.

CMS proposes to continue the practice of issuing a prescriber notice of non-compliance as a non-compliance action for subsequent measurement years.

Background/Rationale

CMS provides the rationale that this proposal would improve alignment of electronic prescribing policies and would provide prescribers in the lame legal entities with several ways to conduct electronic transmittals for Schedule II, III, IV, and V controlled substances that are Part D drugs. As a result, CMS explains that the prescribers' prescriptions should be included in the CMS EPCS Program compliance calculation. In the CMS EPCS program, prescribers are required (at § 423.160(a)(5)) to conduct prescribing for at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs electronically each measurement year (January 1 - December 31).

CMS provides the rationale for removing the same entity exception that the agency would no longer need to separately identify and apply different methodology based on whether the prescriber and dispensing pharmacy are the same entity. Previously, CMS was concerned that requiring the use of NCPDP SCRIPT standard version 2017071 within a closed system could increase the rate of performance errors and costs. In implementing the same entity exception, CMS explains that it was impossible to exclude same entity prescriptions from compliance calculations due to the format of Prescription Drug Event (PDE) data, and it found that it can circumvent concerns related to performance errors and costs within a closed system if it removes the requirement to use the NCPDP SCRIPT standard listed in § 423.160(b). CMS also provides the rationale that the proposal could reduce the administrative burden for prescribers within the same legal entity. Under the proposed changes, prescriptions that are prescribed and dispensed within the same legal entity would be included in CMS EPCS Program compliance calculations as part of the 70 percent compliance threshold at § 423.160(a)(5).

CMS proposes that renewals, and not refills, will count as additional prescriptions for the CMS EPCS Program compliance threshold calculation because renewals require prescribers to generate a new prescription while refills are documented as a part of the original prescription transmittal. CMS states that including every fill of prescriptions could increase the burden place on small prescribers, and many would no longer qualify for the small prescriber exception at § 423.160(a)(5)(ii).

CMS provides the rationale for the proposed changes to the recognized emergency and extraordinary circumstances waiver exceptions that the new proposal would improve alignment with other CMS emergency policies for quality reporting and performance. CMS also states that CMS may not be able to

identify every local or state emergency, and, as a result, some prescribers may not be able to receive an exception when they need it. In addition, CMS explains that the exception should not be automatic because not every emergency may impact the ability of prescribers to conduct EPCS.

CMS proposes to modify the duration and timing of extraordinary waiver exceptions to clarify the attestation process for prescribers to request a waiver established in the CY 2022 PFS final rule.

CMS' rationale for the proposal to continue to send-non-compliance notices in subsequent measurement years is that it would support EPCS adherence and would be more effective than establishing burdensome penalties for prescribers. CMS explains that it believes that it can mitigate the risk of waste or abuse without further penalties.

Comments

CMS seeks comments on the proposals to remove the same entity exception and expand available standards for same legal entities within the CMS EPCS Program.

CMS solicits comments on the proposed circumstances applicable for exceptions under the recognized emergency and extraordinary circumstances waiver.

CMS seeks comments on the proposed duration for exceptions due to recognized emergencies and the timing of waivers.

CMS solicits comments on its proposal to continue sending notice to non-compliant prescribers.

M. Hospice: Changes to the Hospice Conditions of Participation (section III.O.)

Proposed Changes

The CAA 2023 established a new Medicare benefit category for marriage and family therapist (MFT) services and mental health counselor (MHC) services furnished by and directly billed by MFTs and MHCs, respectively. CAA 2023 specifically adds these services to covered hospice care services. In order to implement this provision of the CAA 2023, CMS proposes to modify the requirements for the hospice conditions of participation (CoPs) "Interdisciplinary group (IDG), care planning and coordination of service" and "Personnel qualifications." This statutorily required modification allows MHCs or MFTs to serve as members of the IDG. In addition, CMS proposes to modify the hospice personnel qualification to also include qualifications for an MFT and an MHC.

Background/Rationale

In accordance with the statute, CMS proposes to revise the statute to specify that the IDG must include a social worker (SW), an MFT, or an MHC. In addition, CMS believes that with the introduction of MHC and MFT into the hospice CoPs, it is important to also include these new disciplines in the personnel qualifications. Currently the requirement establishes the requirements for several disciplines that work in hospices including but not limited to social worker, nurse and therapist. In this rule, CMS proposes to add both MHC and MFT to the provider requirements.

Comments

None.

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

Proposed Changes

- **Development and Maintenance of MIPS Value Pathways (MVPs)**

CMS is proposing 5 new MVPs to be available for the 2024 performance year, along with revisions to all previously finalized MVPs. The 5 newly proposed MVPs are:

1. Focusing on Women's Health
2. Quality Care for the Treatment of Ear, Nose, and Throat Disorders
3. Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV
4. Quality Care in Mental Health and Substance Use Disorders
5. Rehabilitative Support for Musculoskeletal Care.

- **Third Party Intermediaries**

CMS is proposing to eliminate the health IT vendor category beginning with the CY 2025 performance period. In order to submit data on behalf of clinicians, a health IT vendor would need to meet the requirements of and self-nominate to become a qualified registry or QCDR. They can continue to facilitate data collection and support clinicians and groups in the sign in and upload and sign in and attest submission types.

CMS is proposing to clarify that a QCDR or a qualified registry must support all measures and improvement activities available in the MVP with 2 exceptions:

1. If an MVP includes several specialties, then the QCDR or qualified registry is only expected to support the measures that are pertinent to the specialty of their clinicians.
2. QCDR measures are only required to be reported by the QCDR measure owner. In instances where a QCDR doesn't own the QCDR measures in the MVP, the QCDR can only support the QCDR measures if they have the appropriate permissions.

CMS is proposing the following policies related to third party intermediaries:

1. CMS would indicate in the public qualified postings that a third-party intermediary has been placed on a remedial action plan or terminated.
2. CMS could take remedial action, including termination, for third party intermediaries that fail to maintain up-to-date contact information.
3. Third party intermediaries would be required to notify CMS when a CAP has been successfully completed.
4. CMS could initiate termination of third-party intermediaries that are on remedial action for two consecutive years.

- **Public Reporting**

CMS is proposing to modify existing policy about publicly reporting procedure utilization data on individual clinician profile pages by incorporating Medicare Advantage (MA) data.

- **Quality Category**

CMS is proposing changes to the quality measures inventory that would result in a total of 200 quality measures for the 2024 performance period. These proposals reflect the:

1. Addition of 14 quality measures, including 1 composite measure and 7 high priority measures, of which 4 are patient-reported outcome measures.
2. Removal of 12 quality measures from the MIPS quality measure inventory.
3. Partial removal of 3 quality measures from the MIPS quality measure inventory.
4. Substantive changes to 59 existing quality measures.

CMS is proposing the following data completeness thresholds for subsequent performance periods (for eCQMs, MIPS CQMs, Medicare Part B claims measures, and QCDR measures):

1. 75% for the 2026 performance period.
2. 80% for the 2027 performance period.

CMS also proposes the following data completeness criteria thresholds for Medicare CQMs:

1. 75% for the 2024,2025 and 2026 performance periods.
2. 80% for the 2027 performance period

CMS is proposing to require groups, virtual groups, subgroups, and APM Entities to contract with a CAHPS for MIPS survey vendor to administer the Spanish survey translation to Spanish-preferring patients using the procedures detailed in the CAHPS for MIPS Quality Assurance Guidelines. They are also recommending that groups, virtual groups, subgroups, and APM Entities administer the CAHPS for MIPS Survey in the other available translations.

- **Cost Performance Category**

CMS is proposing to calculate improvement scoring for the cost performance category at the category level without using statistical significance beginning with the CY 2023 performance period/2025 MIPS payment year.

CMS is proposing that the maximum cost improvement score of 1 percentage point out of 100 percentage points will be available beginning with the CY 2023 performance period/2025 MIPS payment year. They are also proposing that the maximum cost improvement score available for the CY 2022 performance period/2024 MIPS payment year will be 0 percentage points.

CMS is proposing to add 5 new episode-based cost measures beginning with the CY 2024 performance period, each with a 20-episode case minimum. The measures are: an acute inpatient medical condition measure (Psychoses and Related Conditions), three chronic condition measures (Depression, Heart Failure, and Low Back Pain), and a measure focusing on care provided in the emergency department setting (Emergency Medicine).

CMS is also proposing to remove the acute inpatient medical condition measure Simple Pneumonia with Hospitalization, beginning with the CY 2024 performance period/2026 MIPS payment year.

- **Improvement Activities Performance Category**

CMS is proposing to add 5 new improvement activities. These proposals include an MVP-specific improvement activity titled "Practice-Wide Quality Improvement in MIPS Value Pathways". CMS is also proposing to modify 1 existing improvement activity and remove 3 existing improvement activities.

- **Promoting Interoperability Performance Category**

CMS proposes to update the CEHRT definition to align with the Office of the National Coordinator for Health IT (ONC)'s regulations.

CMS is proposing to continue automatic reweighting for clinical social workers in the 2024 performance period.

CMS is proposing to increase the performance period to a minimum of 180 continuous days within the calendar year.

CMS is proposing to require a "yes" response for the SAFER Guide measure beginning with the CY 2024 performance period.

- **Final Scoring**

CMS is proposing a policy to clarify that they will not calculate a facility-based score at the subgroup level. Facility-based scores are only calculated as part of a final score in traditional MIPS* which isn't an available reporting option for subgroups.

CMS is proposing to clarify that beginning with the 2023 performance period/2025 MIPS payment year, subgroups would receive their affiliated group's complex patient bonus, if available.

CMS proposes increasing the performance threshold from 75 to 82 points for the 2024 MIPS performance period/2026 MIPS payment year. CMS is using the mean of final scores from the 2017 – 2019 MIPS performance periods/2019 – 2021 MIPS payment years to set the MIPS performance threshold.

CMS is proposing to open the targeted review submission period upon release of MIPS final scores and to keep it open for 30 days after MIPS payment adjustments are released. This would maintain an approximately 60-day period for requesting a targeted review.

CMS is also proposing that, if CMS requests additional information under the targeted review process, that additional information must be provided to and received by CMS within 15 days of receipt of such request.

CMS is proposing to add subgroups and virtual groups to the list of entities that may submit a request for a targeted review for the MIPS payment adjustment factor beginning with the 2023 MIPS performance period/2025 MIPS payment year.

- **Advanced APMs**

CMS is proposing to remove the numerical 75% threshold and have the Advanced APM require the use of the certified electronic health record technology (CEHRT) for Qualifying APM Participant (QP) performance periods beginning in 2024.

CMS is proposing to make QP determinations at the individual eligible clinician level only, instead of the APM Entity level.

Under current statute, the QP threshold percentages will increase beginning with the 2024 performance year/2026 payment year.

1. Medicare payments:
    a. QP threshold increasing from 50% to 75%
    b. Partial QP threshold increasing from 40% to 50%
2. Medicare patients:
    a. QP threshold increasing from 35% to 50%
    b. Partial QP threshold increasing from 25% to 35%

Beginning for the 2024 performance year/2026 payment year, QPs will receive a higher MPFS update ("qualifying APM conversion factor") of 0.75% compared to non-QPs, who will receive a 0.25% Medicare PFS update, which will result in a differentially higher PFS payment rate for eligible clinicians who are QPs. Eligible clinicians who are QPs for a year will continue to be excluded from MIPS reporting and payment adjustments for the year.

Background/Rationale

- **Development and Maintenance of MVPs**

CMS notes that the implementation of MVPS aligns with many of the objectives and goals the CMS National Quality Strategy and the Universal Foundation strive to achieve. Through their development processes for new MVPs, CMS aims to gradually develop new MVPs that are relevant and meaningful for all clinicians who participate in MIPs.

- **Health IT Vendors**

CMS believes that eliminating the category of health IT vendor as a distinct type of third-party intermediary will improve the integrity of program data, by ensuring consistent data validation and audit requirements for all third-party intermediaries.

- **Performance Threshold**

CMS notes that this increase aligns with their goal to provide practices with a greater return on their investment in MIPS participation by giving an opportunity to achieve a higher positive payment adjustment.

- **Public Reporting**

CMS notes that they are incorporating this data for a more accurate representation of procedure volumes.

- **Quality Category**

CMS notes that for the administration of the CAHPS for MIPS survey, their analysis of historic CAHPS data indicates that the use of survey translations has not been widespread and there is unmet need for access to surveys in the 7 available translations. The proposal and recommendation would make the survey more accessible to survey respondents who can only respond in Spanish or another available translation and provide an opportunity to better understand their experiences of care and any disparities in care.

CMS states the incorporation of higher data completeness criteria thresholds in future years ensures a more accurate assessment of a MIPS eligible clinician's performance on quality measures and prevents selection bias to the extent possible. CMS believes it is feasible for eligible clinicians and groups to achieve a higher data completeness criteria threshold without jeopardizing their ability to successfully participate and perform in MIPS.

- **Cost Performance Category**

CMS states that this updated methodology would ensure mathematical and operational feasibility to allow for improvement to be scored in the cost performance category starting with the 2023 performance period/2025 MIPS payment year. This update would also align with their methodology for scoring improvement in the quality performance category.

CMS highlights that these proposed measures cover clinical topics and MIPS eligible clinicians currently with limited or no applicable cost measures. As such, these proposed measures would help fill gaps in the cost performance category's measure set. In addition, these proposed measures would support the transition from traditional MIPS to MIPS Value Pathways (MVPs) by allowing for new MVPs to be created and enhancing existing MVPs.

- **Improvement Activities Performance Category**

CMS notes the proposed new and modified activities will help fill gaps they have identified in the Inventory, while the removal of three activities will help ensure that the Inventory reflects current clinical practice.

- **Promoting Interoperability Performance Category**

CMS notes that in a recent proposed rule, ONC signaled a move away from the "edition" construct for certification criteria. Instead, all certification criteria will be maintained and updated at 45 CFR 170.315. CMS aims to align with this new definition of CEHRT for QPP and the Medicare Promoting Interoperability Program.

CMS notes their proposal to increase the performance period to 180 continuous days ensures that the MIPS Promoting Interoperability performance category continues to align with the Medicare Promoting Interoperability Program for eligible hospitals and critical access hospitals. CMS believes that having additional data available from a longer performance period is beneficial to further improve the Promoting Interoperability performance category, and an integral step towards promoting health information exchange.

CMS highlights that the SAFER Guides measure is intended to encourage MIPS eligible clinicians to use the High Priority Practices SAFER Guide, annually, to assess their progress and status on important facets

of patient safety, including CEHRT implementation, safety and effectiveness, identifying vulnerabilities, and developing a "culture of safety" within their organization.

- **Final Scoring**

CMS states their proposal to increase the threshold stems from their reinterpretation of "prior period", within statutory language, such that it could mean a time span of 3 consecutive performance periods. CMS believes continuing a gradual and incremental increase in the performance threshold by establishing the performance threshold for the CY 2024 performance period/2026 MIPS payment year at 82 will provide stability to MIPS eligible clinicians. They also believe the performance threshold of 82 strikes an appropriate balance of using more robust data and yet accounting for clinician practices that are still recovering from the impacts of the COVID-19 PHE.

CMS notes the targeted review process has allowed them to review and address concerns about whether a clinician qualifies for QP designation. It's essential to compiling an accurate list of QPs, which is necessary for purposes of determining who will receive the application of the higher MPFS conversion factor (also known as "qualifying APM conversion factor") of 0.75 percent (versus non-QPs, who will receive 0.25 percent) beginning in the 2026 payment year.

- **Advanced APMs**

Regarding CEHRT for Advanced APMs, CMS now believes that the standard for CEHRT use for Advanced APMs may have been unnecessarily burdensome, imposing unwarranted barriers to organization of and participation in Advanced APMs, and not clinically relevant for many prospective and current participants in Advanced APMs. CMS states it is important both to apply a rigorous standard for use of CEHRT and to allow sufficient flexibility to Advanced APMs to specify CEHRT modules that are clinically relevant for their participants.

CMS notes their proposed regulations to revise the QP and Partial QP thresholds and change the APM incentive payment are to align with regulations made by the Consolidated Appropriations Act of 2023.

Comments

CMS is seeking comments on:

- Potential approaches to, and considerations for, public reporting.
- Scoring incentives that would be applied to an ACO's health equity adjusted quality performance score beginning in the 2025 performance year when specialists who participate in the ACO report quality MVPs.
- Their proposal to require a continuous 180-day performance period for the Promoting Interoperability performance category beginning with the CY 2024 performance period/2026 MIPS payment year, and the proposed changes to the regulation text.
- The proposals to modify the quality performance category measure set, a measure set of 200 MIPS quality measures in the inventory for the CY 2024 performance period.
- The proposal to require the administration of CAHPS for MIPS Survey in the Spanish translation. In addition, CMS is interested in comments from organizations that administer the CAHPS for MIPS

Survey on whether they consider contracting with vendors to administer the survey in one or more of the available survey translations based on the language preferences of patients.

- How CMS might be able to change performance standards to encourage clinicians to continuously improve care, particularly clinicians with little room for improvement under MIPS. Specifically, they are asking for feedback to the following questions:
    - What potential policies in the MIPS program would provide opportunities for clinicians to continuously improve care?
    - Should CMS consider, in future rulemaking, changes in policies to assess performance to ensure ongoing opportunities for continuous performance improvement?
    - Should CMS consider, for example, increasing the reporting requirements or requiring that specific measures are reported once MVPs are mandatory?
    - Should CMS consider creating additional incentives to join APMs in order to foster continuous improvement, and if so, what should these incentives be?
    - What changes to policies should CMS consider assessing continuous performance improvement and clinicians interested in transitioning from MIPS to APMs?
    - CMS acknowledges the potential increase in burden associated with increasing measure reporting or performance standards. How should they balance consideration of reporting burden with creating continuous opportunities for performance improvement?
    - While they are aware of potential benefits of establishing more rigorous policies, requirements, and performance standards, such as developing an approach for some clinicians to demonstrate improvement, they are also mindful that this will result in an increasing challenge for some clinicians to meet the performance threshold. Are there ways to mitigate any unintended consequences of implementing such policies, requirements, and performance standards?

O. Social Determinants of Health Risk Assessment in the Annual Wellness Visit (section III.S.)

Proposed Changes

CMS proposes to add regulatory text at § 410.15 that will include a new Social Determinants of Health (SDOH) Risk Assessment as an optional, additional element of the Annual Wellness Visit (AWV) with an additional payment. This proposal builds upon CMS' separate proposal to establish a stand-alone G code (GXXX5) for SDOH Risk Assessment furnished in conjunction with an Evaluation and Management (E/M) visit.

CMS proposes that the SDOH Risk Assessment be:

- Separately payable with no beneficiary cost sharing when furnished as part of the same visit with the same date of service as the AWV.
- Paid at 100 percent of the fee schedule amount of the risk assessment.
- Inclusive of the administration of a standardized, evidence based SDOH risk assessment tool.
- Furnished in a manner that all communication with the patient be appropriate for the patient's educational, developmental, and health literacy level, and be culturally and linguistically appropriate.

- Furnished as part of the same visit and on the same date of service as the AWV, so as to inform the care the patient is receiving during the visit.
- Optional for both the health professional and the beneficiary to empower clinicians and patients to employ this assessment only when appropriate and desired.

Background/Rationale

The AWV includes the establishment (or update) of the patient's medical and family history, application of a health risk assessment and the establishment (or update) of a personalized prevention plan. Given the significant impact of SDOH on health, the health care system broadly has been working to take these factors into account when providing care and rendering services. This work to better address the impact that SDOH has on patients ties in heavily with HHS's Strategic Approach to Addressing Social Determinants of Health to Advance Health Equity, the CMS Strategic Pillar to advance equity, and the CMS Innovation Center Accountable Health Communities (AHC) Model that ended in 2022. Additionally, CMS is aware of concerns regarding barriers to completing the AWV, AWV's "one size fits all" approach, and research finding that underserved patients were less likely to receive an AWV and that practices serving underserved and sicker populations were less likely to provide such visits to their patients. CMS increasingly understands the importance that SDOH be considered in the care process and believes that this proposal will reduce barriers, expand access, promote health equity, and improve care for populations that have historically been underserved.

Comments

CMS invites public comment on its proposal, including whether a SDOH Risk Assessment would ultimately inform and result in the development of steps to address and integrate SDOH in the patient's AWV health assessment and personalized prevention plan. CMS has received feedback that the AWV may be more effectively furnished if elements were allowed to be completed over multiple visits and days, or prior to the AWV visit. CMS invites public comment on this issue for consideration in the rulemaking.

P. Regulatory Impact Analysis (section VII.)

Proposed Changes

CMS estimates the CY 2024 MPFS conversion factor to be $32.75, a decrease of $1.14 (or 3.34%) from the CY 2023 conversion factor of $33.89.

TABLE 102: Calculation of the CY 2024 PFS Conversion Factor

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

RVUs: Table 104 (CY 2024 PFS Estimated Impact on Total Allowed Charges by Specialty) on page 1193 of the proposed rule summarizes the impact of Work, PE, and MP RVU changes on total allowed charges across specialties.

Facility vs. Non-Facility Break Out of Payment Changes: Note, for the 2024 MPFS rulemaking cycle, beginning on page 1196, CMS is providing in Table 105 (CY 2024 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.