CY 2021 Medicare Physician Fee Schedule and Quality Payment Program Proposed Rule

OVERVIEW OF RULE

On August 3, CMS released the Calendar Year (CY) 2021 Medicare Physician Fee Schedule (MPFS) and Quality Payment Program (QPP) Proposed Rule. The Centers for Medicare and Medicaid (CMS) notes that the policies included in this proposed rule are consistent with and take steps to expand on the President's Executive Order on Improving Rural Health and Telehealth Access, as well as last fall's Executive Order on Protecting and Improving Medicare for Our Nation's Seniors. Additionally, the proposed rule continues to be part of the Administration's multi-year effort to reduce burden under the Patients Over Paperwork initiative. For additional information please see CMS's CY 2021 MPFS Fact Sheet. Details on key provisions of the proposed rule are provided below.

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A. Telehealth Services

Proposed Changes

- **Adding Services to the Medicare Telehealth Services List – Category 1**

After considering public requests for adding Category 1 services to the Medicare telehealth list, identifying services through an internal review for addition to the list, and reviewing the services added on an interim basis during the public health emergency (PHE), CMS is proposing to add the following to the Medicare telehealth services list on a Category 1 basis for CY 2021.

Service Type	Codes
Visit Complexity Associated with Certain Office/Outpatient E/Ms	GPC1X
Prolonged Services	99XXX
Care Planning for Patients with Cognitive Impairment	99483
Domiciliary, Rest Home, or Custodial Care services	99334, 99335
Home Visits	99347, 99348

CMS notes that while the home is generally not a permissible telehealth originating site, the domiciliary/home visit services could be billed as telehealth only for treatment of a substance use disorder or co-occurring mental health disorder under the flexibility afforded by the SUPPORT for Patients and Communities Act.

- **Adding Services to the Medicare Telehealth Services List – Category 3**

CMS is proposing to create a new category of criteria – Category 3 – for adding services to the Medicare telehealth list on a temporary basis through the end of the calendar year in which the PHE ends.

Service Type	Codes
Domiciliary, Rest Home, or Custodial Care services, Established patients	99336, 99337
Home Visits, Established Patients	99350
Emergency Department (ED) Visits	99281, 99282, 99283
Nursing Facilities Discharge Day Management	99315, 99316
Psychological and Neuropsychological Testing	96130, 96131, 96132, 96133

- **Furnishing Telehealth Visits in Inpatient and Nursing Facility (NF) Settings, and Critical Care Consultations**

CMS is proposing to revise the frequency limitation from one visit every 30 days to one visit every 3 days for subsequent NF care services furnished via telehealth.

- **Proposed Technical Amendment to Remove References to Specific Technology**

CMS is proposing to permanently eliminate from the regulations the limitation that ""[t]elephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system." This would allow the use of smart phones and other eligible devices to be used in furnishing telehealth services on a permanent basis, beyond the PHE.

- **"Incident-To" Services and "Direct Supervision" Requirement**

CMS is proposing to clarify that services that may be billed incident-to may be furnished via telehealth incident to a physician's service and under direct supervision.

CMS is extending the policy that "direct supervision" can be satisfied by the virtual presence of the supervising physician or practitioner using interactive audio/video real-time communications technology. CMS is proposing to extend this policy to the later of the end of the calendar year in which the PHE ends or December 31, 2021.

CMS is also clarifying that if audio/visual technology is used to furnish a service when the beneficiary and practitioner are in the same setting, then the service should be billed as if it was furnished in person and not subject to any telehealth requirements.

Background/Rationale

- **Adding Services to the Medicare Telehealth Services List – Category 1**

In the CY 2003 PFS, CMS established a process for adding/deleting services from the Medicare telehealth services list and assigning them one of the following categories: Category 1 – services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the Medicare telehealth services list; or Category 2 – services that are not similar to those on the Medicare telehealth services list but for which there may be a demonstrated clinical benefit to the patient. In reviewing requests for adding services to Category 1, CMS looks for similarities between the requested services and those services already on the Medicare telehealth list for the roles of the different parties involved (e.g., physician, beneficiary, distant site, and telepresenter), as well as similarities in the system and technology used to deliver the service. In response to the PHE, CMS added additional services to the Medicare telehealth list as Category 2 codes on the clinical benefit basis that there "was a patient population that would otherwise not have access to clinically appropriate treatment."

- **Adding Services to the Medicare Telehealth Services List – Category 3**

In response to the PHE, under Section 1135 waiver authority as well as the authority afforded under COVID-19 related legislation, CMS established several telehealth flexibilities, including allowing certain services to be furnished via audio-only and adding services to the Medicare telehealth list on an interim

basis through a sub-regulatory process. However, at the end of the PHE, these waivers and interim policies would expire and payment for telehealth services would be restricted to the routine regulatory process.

CMS notes that the PHE may end before the end of CY 2021 and the timing in such a situation may not allow stakeholders to request additional services to the Medicare telehealth list through the routine regulatory process. Taking this into consideration, as well as not wanting to disrupt clinical practice and beneficiary access to these services, CMS is proposing to create a Category 3 criteria. Services included on a Category 3 basis include those that were added during the PHE, for which there may be a clinical benefit but not yet sufficient evidence to add on a permanent basis under Categories 1 and 2. Any services added on a Category 3 would remain on the Medicare telehealth list through the calendar year in which the PHE ends.

- **Furnishing Telehealth Visits in Inpatient and Nursing Facility Settings, and Critical Care Consultations**

Long-term care facility regulations require that Skilled Nursing Facility (SNF) residents receive an initial visit from a physician, and subsequent periodic visits by either a physician or other nonphysician practitioner (NPP). These visits were required to be in-person, however, during the PHE, CMS waived this requirement allowing the visits to be conducted via telehealth.

Furthermore, CMS currently limits subsequent inpatients telehealth visits to once every 3 days and subsequent nursing facility visits to once every 30 days. CMS has received requests to remove the frequency limitation on subsequent inpatient visits and to revise the NF visits to once every 3 days. While CMS was persuaded by stakeholder concerns that the limitation on subsequent NF visits limited access to care, it was not persuaded to eliminate the limitation on inpatient visits because it continues to believe that a majority of inpatient visits should be furnished in-person for these acutely ill patients.

- **Proposed Technical Amendment to Remove References to Specific Technology**

Prior to the PHE, the regulations stated that telephones, facsimile machines, and electronic mail systems do not meet the definition of interactive telecommunications systems for Medicare telehealth services. CMS modified this requirement on an interim basis so that interactive telecommunications system includes "multimedia communications equipment that includes, at a minimum, audio and visual equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner."

Comments

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

CMS is seeking input on services that should/should not be considered for Category 3, including additional services that were added on an interim basis during the PHE (see Table 11 in the proposed rule). Specifically, CMS seeks input on the following services that were added during the PHE and for which CMS has patient safety concerns outside the context of the PHE.

3. Services we are not proposing to add to the Medicare telehealth services list but are seeking comment on whether they should be added on either a Category 3 basis or permanently.	• Initial nursing facility visits, all levels (Low, Moderate, and High Complexity) (CPT 99304-99306) • Psychological and Neuropsychological Testing (CPT codes 96136-96139) • Therapy Services, Physical and Occupational Therapy, All levels (CPT 97161- 97168; CPT 97110, 97112, 97116, 97535, 97750, 97755, 97760, 97761, 92521- 92524, 92507) • Initial hospital care and hospital discharge day management (CPT 99221-99223; CPT 99238- 99239) • Inpatient Neonatal and Pediatric Critical Care, Initial and Subsequent (CPT 99468- 99472; CPT 99475- 99476) • Initial and Continuing Neonatal Intensive Care Services (CPT 99477-99480) • Critical Care Services (CPT 99291-99292) • End-Stage Renal Disease Monthly Capitation Payment codes (CPT 90952, 90953, 90956, 90959, and 90962) • Radiation Treatment Management Services (CPT 77427) • Emergency Department Visits, Levels 4-5 (CPT 99284-99285) • Domiciliary, Rest Home, or Custodial Care services, New (CPT 99324-99328) • Home Visits, New Patient, all levels (CPT 99341- 99345) • Initial and Subsequent Observation and Observation Discharge Day Management (CPT 99217- 99220; CPT 99224- 99226; CPT 99234-99236)

CMS is seeking additional information on potential Category 3 services including: by and for whom the services are being delivered via telehealth during the PHE; what safeguards in place; how technology is being used to facilitate acquisition of information that would otherwise be obtained by an in-person visit; impact on patient outcomes; etc.

CMS is seeking input on whether physical and occupational therapy and speech-language pathology services should be added to the Medicare telehealth list but only if furnished by an eligible practitioner who can bill for telehealth services, and whether these services can be fully and effectively furnished via two-way, audio/visual telecommunications technology.

CMS is also seeking comments on the following:

- Whether current coding does not reflect models of critical care delivery, specifically models that utilize a combination of remote monitoring and clinical staff at the beneficiary's location when an onsite practitioner is not available.
- How to distinguish the technical component of the remote monitoring portion of the service from the diagnosis-related group (DRG) payment already being provided to the hospital.
- How to provide payment only for monitoring and interventions furnished to Medicare beneficiaries when the remote intensivist is monitoring multiple patients, some of which may not be Medicare beneficiaries.
- How this service intersects with both the critical care consult G codes and the in-person critical care services.

- **Furnishing Telehealth Visits in Inpatient and Nursing Facility Settings, and Critical Care Consultations**

CMS is seeking comment on whether maintain the flexibility allowing physicians and NPPs to conduct their visits via telehealth, and whether two-way, audio/visual technology would be sufficient when an in-person visit is not necessary due to certain factors.

CMS is seeking feedback on whether frequency limitations are more broadly burdensome and limit access to care.

- **Virtual Services**

In recent years, CMS has begun establishing separate payment policies for broader telemedicine services that are not technically telehealth services due to, e.g., the technology utilized, among other factors. These include communication technology-based services (CTBS), virtual check-ins, remote patient monitoring (RPM), etc. CMS is seeking comment on the following regarding additional virtual services that may fall out of the scope and/or definition of existing telehealth and telemedicine services:

  - Whether there are additional services that fall outside the scope of telehealth services where it would be helpful to clarify that the services are inherently non-face-to-face and don't need to be on the Medicare telehealth list in order to be billed and paid for when furnished using telecommunications technology.
  - Use of evolving technologies to improve patient care that are not fully recognized under the current PFS coding and payment system.
  - Impediments that contribute to provider burden and that can result in reluctancy to bill for CTBS.

- **"Direct Supervision" Requirement**

CMS expresses patient safety concerns in regard to permanently extending the flexibility to satisfy the direct supervision requirement virtually. CMS is seeking input on whether additional patient safety guardrails or limitations are necessary, as well as fraud and abuse restrictions, on either a temporary basis or permanently.

CMS is seeking input on risks to beneficiaries who receive care under virtual direct supervision, as well as other potential concerns and data on experience with virtual direct supervision during the PHE.

B. Communication Technology-Based Services (CTBS)

Proposed Changes

- **NPP Billing of CTBS**

CTBS are those services furnished via telecommunications technology but are not considered Medicare telehealth services. In response to the PHE, CMS permitted G2061-G2063 to be billed by licensed clinical

social workers and clinical psychologists, as well as PTs, OTs, and SLPs within their scope of service. CMS is proposing to adopt this policy on a permanent basis.

CMS is also proposing to allow HCPCS codes G20X0 and G20X2 to be billed by NPP, consistent with their scope or practice. These services will be valued identically to G2010 and G2012, respectively.

- **"Sometimes Therapy" Designation**

CMS is proposing to designate HCPCS codes G20X0, G20X2, G2061, G2062, and G2063 as "sometimes therapy" services. When billed by private practice PT, OT, or SLP, the codes would need to include the corresponding GO, GP, or GN therapy modifier to indicate that the service was furnished as therapy under an OT, PT, or SLP plan of care.

- **Consent**

CMS is clarifying that consent for all CTBS can be documented by the billing provider and auxiliary staff under general supervision. CMS continues to believe that beneficiary consent is necessary, but does not believe the timing or manner in which consent is acquired should interfere with the provision of the service.

- **CTBS Originating from an E/M Service within Previous 7 Days**

CMS is also retaining that when a CTBS originates from a related E/M service within 7 days by the same physician or other qualified health care professional, the CTBS is bundled into the E/M service and not separately billable.

Background/Rationale

- **NPP Billing of CTBS**

CTBS are those services furnished via telecommunications technology but are not considered Medicare telehealth services. In response to the PHE, CMS has permitted these services to be billed by licensed clinical social workers and clinical psychologists, as well as PTs, OTs, and SLPs within their scope of service.

C. Audio-Only Visits

Proposed Changes

- **Telephone E/M Services**

CMS is proposing to stop recognizing these codes as covered services under the PFS after the end of the PHE because, outside the context of the PHE, CMS is unable to waive the requirement that telehealth services be furnished using interactive telecommunications systems that include two-way, audio/visual communication technology.

Background/Rationale

- **Telephone E/M Services**

On an interim basis for the duration of the PHE, CMS established that it will separately pay for telephone E/M services that were previously considered non-covered services under PFS. These are identified as CPT codes 98966-98968 (telephone assessment and management services provided by qualified nonphysician health care professionals for established patients, parent, or guardian not originating from a related E/M service provided in previous 7 days nor leading to an E/M service or procedure within 24 hours or soonest available appointment), 99441-99443 (telephone E/M by a physician or other qualified health care professional who may report E/M services for established patients, parent, or guardian not originating from a related E/M service provided in previous 7 days nor leading to an E/M service or procedure within 24 hours or soonest available appointment). These services are currently available for both new and established payments.

Comments

CMS recognizes that longer phone conversations may be necessary than are currently afforded under a virtual check-in. Therefore, CMS is seeking input on whether to develop coding/payment for a service similar to virtual check-ins but for a longer unit of time, and the appropriate interval for such services.

CMS is seeking input on whether separate payment for telephone-only services should be a provisional policy that remains in effect for a duration of time after the end of the PHE or whether it should be a permanent policy beyond the PHE.

D. Remote Physiologic Monitoring (RPM) Services

Proposed Changes

CMS is proposing to permanently allow consent to be obtained at the time the RPM service is furnished.

CMS is proposing to allow auxiliary personnel to furnish services described by CPT codes 99453 and 99454 under general supervision of the billing physician or practitioner.

After the end of the PHE, CMS will revert to requiring that these services are furnished to established patients and require that 16 days of data be collected within 30 days to meet the requirements for CPT codes 99453 and 99454.

CMS provides clarification on RPM CPT codes 99453, 99454, 99091, 99457, and 99458. CMS is clarifying that these codes can only be billed by physicians or NPPs who are eligible to bill for Medicare E/M services, and that these services can be furnished to patients with acute conditions in addition to patients with chronic conditions.

CPT Codes 99453 and 99454

- CMS clarifies that, even when multiple medical devices are provided, the services associated for all the medical devices can be billed only once per patient per 30-day period and only when at least 16 days of data have been collected.
- 99453 can be billed only once per episode of care when an episode is defined as "beginning when the [RPM] service is initiated and ends with attainment of targeted treatment goals."

Medical Devices

- CMS clarifies that medical devices must meet the FDA's definition of "medical device," and that it has found no language that indicating that the device must be FDA cleared or prescribed by a physician.
- For 99454, the medical device should digitally (i.e., automatically) upload patient physiologic data (i.e., not be patient self-recorded and/or self-reported).
- Medical devices that digitally collect and transmit data must be medically reasonable and necessary and be used to collect and transmit reliable data that allows understanding of a patient's health status to develop and manage a treatment plan.

CPT Code 99091

- This service can be billed by physicians and other qualified healthcare professionals whose scope of practice and Medicare benefit category include the service and who are authorized to independently bill Medicare for the service.

CPT Codes 99457 and 99458

- These services can be furnished by clinical staff under the general supervision of a physician or NPP, and that these services are not considered to be diagnostic tests.
- CMS clarifies that it reads "interactive communication" to mean, at a minimum, real-time synchronous, two-way audio interaction that is capable of being enhanced with video or other kinds of data transmission.
- For 99457, the interactive communication must total at least 20 minutes of interactive time with the patient over the course of a calendar month; each additional 20 minutes is reported using 99458. Time is interpreted to mean "the time spent in direct, real-time interactive communication with the patient."

Background/Rationale

RPM includes the collection and analysis of patient physiologic data that are used to develop and manage a treatment plan for chronic and/or acute health illness or conditions. Stakeholders have requested clarification on these codes, including who can furnish these services, using which medical devices, how data can be collected, and how "interactive communication" is defined. Additionally, these services could only be furnished to patients with chronic conditions.

Comments

CMS is seeking comment on whether the current RPM coding accurately and adequately describes the full range of clinical scenarios that RPM services may benefit patients. Specifically, CMS notes that some patients may not require remote monitoring for 16 days or more in a 30-day period, and that for some patients, continuous short-term monitoring might be more appropriate (e.g., several times a day, over a period of 10 days, etc.).

E. Transitional Care Management (TCM)

Proposed Changes

CMS is proposing to remove 14 actively priced HCPCS codes from the list of remaining HCPCS codes that cannot be billed concurrently with TCM services when reasonable and necessary.

CMS is also allowing the new Chronic Care Management code, HCPCS code G2058, to be billed concurrently with TCM when reasonable and necessary.

TABLE 14: 15 Additional Codes That Could Be Billed Concurrently with TCM

Code Family	CPT Code	Descriptor
End Stage Renal Disease Services (for ages less than 2 months through 20+ years)	90951	ESRD related services with 4 or more face-to-face visits per month; for patients <2 months of age
	90954	ESRD related services with 4 or more face-to-face visits per month; for patients 2-11 years
	90955	ESRD related services with 2-3 face-to-face visits per month; for patients 2-11 years
	90956	ESRD related services with 1 face-to-face visit per month; for patients 2-11 years
	90957	ESRD related services with 4 or more face-to-face visits per month; for patients 12-19 years
	90958	ESRD related services with 2-3 face-to-face visits per month; for patients 12-19 years
	90959	ESRD related services with 1 face-to-face visit per month; for patients 12-19 years
	90963	ESRD related services for home dialysis per full month; for patients <2 years of age
	90964	ESRD related services for home dialysis per full month; for patients 2-11 years
	90965	ESRD related services for home dialysis per full month; for patients 12-19 years
	90966	ESRD related services for home dialysis per full month; for patients 20 years and older
	90967	ESRD related services for dialysis less than a full month of service; per day; for patients <2 years of age
	90968	ESRD related services for dialysis less than a full month of service; per day; for patients 2-11 years
	90969	ESRD related services for dialysis less than a full month of service; per day; for patients 12-19 years
Complex Chronic Care Management Services	G2058	Chronic care management services, each additional 20 minutes of clinical staff time directed by a physician or other qualified healthcare professional, per calendar month

Background/Rationale

CMS originally identified a list of 57 HCPCS codes and related services that could not be billed concurrently with TCM services because of potential duplication of services. For CY 2020, CMS modified its policy and removed 16 HCPCS codes from that list.

Comments

CMS is seeking input on the additional services it is proposing can be billed concurrently with TCM.

F. Psychiatric Collaborative Care Model (CoCM) Services (HCPCS Code GCOL1)

Proposed Changes

CMS is proposing to establish a new G-code to describe 30 minutes of behavioral health care manager time, and to price this code based on one half the work and direct PE inputs for CPT Code 99493 (which is assigned a work RVU of 1.53).

- GCOL1: Initial or subsequent psychiatric collaborative care management, first 30 minutes in a month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional.

CMS is also proposing that all the required elements for 99493 would also be required for GCOL1, under general supervision, and that the time rules would apply consistent with the guidance for CPT Codes 99492-99494. Furthermore, CMS is proposing the GCOL1 could be billed during the same month as CCM and TCM service, but that patient consent requirement would apply to each service independently.

Background/Rationale

CoCM is "an evidence-based approach to behavioral health integration that enhances "usual" primary care by adding care management support and regular psychiatric inter-specialty consultation." Stakeholders requested additional coding to capture shorter increments of time when patient is seen for services but is then hospitalized or referred for specialized care.

Comments

CMS is seeking input on the additional service and proposed valuation.

G. Refinements to Values for Certain Services to Reflect Revisions to Payment for Office/Outpatient Evaluation and Management (E/M) Visits and Promote Payment Stability during the COVID-19 Pandemic

Proposed Changes

- **Time Values for Levels 2-5 Office/Outpatient E/M Visit Codes**

Beginning calendar year 2021, CMS is proposing to adopt the actual total times (defined as the sum of the component times) rather than the total times recommended by the RUC for CPT codes 99202 through 99215.

- **Revaluing Services that are Analogous to Office/Outpatient E/M Visits – End-Stage Renal Disease (ESRD) Monthly Capitation Payment (MCP) Services**

CMS states that the ESRD MCP codes should be updated to more accurately account for the associated office/outpatient E/M visits. The Administration has initiatives focused on improving kidney health and their objective here is that by improving the payment accuracy for the ESRD MCP codes, they would also be supporting broader efforts at advancing kidney health. CMS is proposing to increase the work, physician time, and PE inputs in the form of clinical staff time of the ESRD MCP codes based on the marginal difference between the 2020 and 2021 office/outpatient E/M visit work, physician time, and PE inputs built into each code, as summarized in the Tables 19 and 20.

- **TCM Services (CPT codes 99495 and 99496)**

CMS is proposing to increase the work RVUs associated with the TCM codes commensurate with the new valuations for the level 4 (CPT code 99214) and level 5 (CPT code 99215) office/outpatient E/M visits for established patients. Tables 19 and 20 include long descriptors, as well as current and proposed work RVUs, physician time, and clinical staff time, for the TCM codes.

- **Maternity Services**

When revaluing the maternity packages, CMS used a methodology that added in the marginal differences in work, physician time, and practice expense (PE) in the form of clinical staff time between the current and 2021 E/M values. They found this method accurately accounts for the increase in valuation relative to the office/outpatient E/M visits.

- **Assessment and Care Planning for Patients with Cognitive Impairment (CPT code 99483)**

CMS proposes to adjust the work, time, and PE in the form of clinical staff time for CPT code 99483 from 3.44 RVUs in CY 2020 to 3.80 RVUs in CY 2021.

- **Initial Preventive Physical Examination (IPPE) and Initial and Subsequent Annual Wellness (AWV) Visits**

In this section, CMS proposes to change the work, physician time, and direct PE inputs for HCPCS codes G0438 and G0439 and CPT codes 99204 and 99214. Specifically, CMS is proposing to increase the RVUs for G0438 from 2.43 to 2.60 and for G0439 from 1.50 to 1.92.

- **Emergency Department (ED) Visits**

CMS is proposing to increase the values for ED Visit CPT codes to be consistent with the principle that the levels 1-3 ED visits should remain the same as the levels 1-3 new patient office visits but the levels 4-5 ED visits should have a higher value than the corresponding office visits, due to the complexity of the patients requiring that level of emergency care. Specifically, CMS is proposing to increase the RVUs for 99283 from 1.42 to 1.60, for 99284 from 2.60 to 2.74, and for 99285 from 3.80 to 4.00.

- **Therapy Evaluations Description**

CMS is proposing to adjust the work RVUs for these services based on a broad-based estimate of the overall change in the work associated with assessment and management to mirror the overall increase in the work of the office/outpatient E/M visits. More specifically, they are proposing to apply a percentage increase,

estimated to be approximately 28 percent, to the work RVUs for the therapy evaluation and psychiatric diagnostic evaluation services codes.

- **Behavioral Healthcare Services**

CMS is proposing to increase the work RVU for CPT code 90834 from 2.00 to 2.25 based on the marginal increase in work value for CPT code 99214 from CY 2020 to CY 2021.

Similarly, for CPT code 90832, which describes 30 minutes of psychotherapy, and is proposing to increase the work RVU based on the increase to CPT code 99213, which is commonly billed with the 30 minutes of psychotherapy add-on, CPT code 90833.

For CPT code 90837, which describes 60 minutes of psychotherapy, CMS is proposing to increase the work RVU based on the proportional increase to CPT codes 99214 and 90838, which is the office/outpatient E/M visit code most frequently billed with the 60 minutes of psychotherapy add-on. Table 21 provides a summary of the current and proposed RVUs for these services.

- **Prolonged Office/Outpatient E/M Visits (CPT code 99XXX)**

CMS is proposing that when the time of the reporting physician or NPP is used to select office/outpatient E/M visit level, CPT code 99XXX could be reported when the maximum time for the level 5 office/outpatient E/M visit is exceeded by at least 15 minutes on the date of service. The tables below are examples of how this would be applied.

TABLE 22: Proposed Prolonged Office/Outpatient E/M Visit Reporting - New Patient

CPT Code(s)	Total Time Required for Reporting*
99205	60-74 minutes
99205 x 1 and 99XXX x 1	89-103 minutes
99205 x 1 and 99XXX x 2	104-118 minutes
99205 x 1 and 99XXX x 3 or more for each additional 15 minutes.	119 or more

*Total time is the sum of all time, including prolonged time, spent by the reporting practitioner on the date of service of the visit.

TABLE 23: Proposed Prolonged Office/Outpatient E/M Visit Reporting – Established Patient

CPT Code(s)	Total Time Required for Reporting*
99215	40-54 minutes
99215 x 1 and 99XXX x 1	69-83 minutes
99215 x 1 and 99XXX x 2	84- 98 minutes
99215 x 1 and 99XXX x 3 or more for each additional 15 minutes.	99 or more

*Total time is the sum of all time, including prolonged time, spent by the reporting practitioner on the date of service of the visit.

Background/Rationale

- **Time Values for Levels 2-5 Office/Outpatient E/M Visit Codes**

In the CY 2020 PFS final rule, CMS finalized adoption of the RUC-recommended times, but stated that they would continue to consider whether this issue has implications for the PFS broadly. Since then they found the approach used by the AMA RUC sometimes resulted in two conflicting sets of times: the

component times as surveyed and the total time as surveyed. CMS made this change to avoid conflicting times.

- **Revaluing Services that are Analogous to Office/Outpatient E/M Visits**

In the CY 2020 PFS proposed rule, CMS recognized that there are services other than the global surgical codes for which the values are closely tied to the values of the office/outpatient E/M visit codes. They specifically identified transitional care management (TCM) services (CPT codes 99495, 99496); cognitive impairment assessment and care planning (CPT code 99483); certain end-stage renal disease (ESRD) services (CPT codes 90951 through 90970); and the annual wellness visit (AWV) and initial preventive physical exam (IPPE) (HCPCS codes G0402, G0438, G0439) are codes with values closely tied to the values of the office/outpatient E/M visit codes. Overall, CMS believes that the magnitude of the changes to the values of the office/outpatient E/M visit codes and the associated redefinitions of the codes themselves are significant enough to warrant an assessment of the accuracy of the values of services containing, or closely analogous to, office/outpatient E/M visits.

- **Assessment and Care Planning for Patients with Cognitive Impairment (CPT code 99483)**

When CMS conducted their revaluation finalized in the CY 2020 PFS final rule for CPT code 99205, they found the current work RVU for CPT code 99483 would have a lower work RVU than a new patient level 5 office/outpatient E/M visit, which would create a rank order anomaly between the two codes that they did not consider to be appropriate. Since CPT code 99483 was valued in relation to a level 5 office/outpatient E/M visit, they found that an adjustment to the work, physician time, and PE was necessary to reflect the marginal difference between the value of the level 5 new patient office/outpatient E/M visit in CY 2020 and CY 2021 would be appropriate to maintain payment accuracy.

- **Emergency Department Visits**

CMS proposed these changes in response to stakeholders' concerns that the work RVUs for these services have been undervalued given the increased acuity of the patient population and the heterogeneity of the sites, such as freestanding and off-campus EDs, where ED visits are furnished (82 FR 53018).

- **Behavioral Healthcare Services**

As the values for the office/outpatient E/M visits are increasing, CMS states there will be an increase in the overall value for psychotherapy furnished in conjunction with office/outpatient E/M visits. CMS believes that it is important, both in terms of supporting access to behavioral health services through appropriate payment and maintaining relativity within this code family, to increase the values for the standalone psychotherapy services to reflect changes to the value of the office/outpatient E/M visits which are most commonly furnished with the addon psychotherapy services with equivalent times.

- **Prolonged Office/Outpatient E/M Visits (CPT code 99XXX)**

CMS provides clarification regarding the reporting of prolonged office/outpatient E/M visits as the intent of the CPT Editorial Panel was unclear because of the use of the terms "total time" and "usual service" in the CPT code descriptor. The term "total time" is unclear because office/outpatient E/M visits now represent a range of time, and "total" time could be interpreted as including prolonged time. Further, the term, "usual

service" is undefined. There is no longer a typical time in the code descriptor that could be used as point of reference for when the "usual time" is exceeded for all practitioners, and there would be variation if applied at the individual practitioner level. CMS believes this clarification is necessary because allowing reporting of CPT code 99XXX after the minimum time for the level 5 visit is exceeded by at least 15 minutes would result in double counting time.

Comments

- **Revaluing Services that are Analogous to Office/Outpatient E/M Visits – End-Stage Renal Disease (ESRD) Monthly Capitation Payment (MCP) Services**

CMS believes the majority of the visits included in the ESRD MCP bundles are being furnished, but they are seeking comment on whether there are instances where the number and level of visits being furnished are not consistent with the number and level of visits built into the valuation of the code.

- **Therapy Evaluations Description**

CMS recognizes that it did not use the methodology typically used to value services under the PFS and is seeking comment on potential alternative methodologies or specific values for these services, particularly about whether stakeholders believe it would be better to develop values using comparator codes from the office/outpatient E/M visit code set, and if so, why.

- **Definition of HCPCS code GPC1X**

In the CY 2020 PFS final rule, CMS finalized the HCPCS add-on code GPC1X which describes the "visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex condition."

CMS believes the inclusion of HCPCS add-on code GPC1X appropriately recognizes the resources involved when practitioners furnish services that are best-suited to patients' ongoing care needs and potentially evolving illness, and that it inherently distinct from existing coding that describes preventive and care management services. In the context of specialty care, GPC1X could recognize the resources inherent in engaging the patient in a continuous and active collaborative plan of care related to an identified health condition which requires management by a clinician with specialized clinical knowledge, skill and experience. Such collaborative care includes patient education, expectations and responsibilities, shared decision-making around therapeutic goals, and shared commitments to achieve those goals.

CMS requests comments to provide additional, more specific information regarding what aspects of the definition of HCPCS add-on code GPC1X are unclear, how they might address those concerns, and how they might refine the utilization assumptions for the code.

H. Scopes of Practice and Related Issues

Proposed Changes

- **Supervision of Diagnostic Tests by Certain NPPs**

CMS is proposes to amend the regulations on a permanent basis to specify that supervision of diagnostic psychological and neuropsychological testing services can be done by nurse practitioners (NPs), certified nurse specialists (CNSs), physician assistants (PAs), or certified nurse-midwives (CNMs) to the extent that they are authorized to perform the tests under applicable State law and scope of practice, in addition to physicians and clinical practitioners (CPs) who are currently authorized to supervise these tests.

CMS proposes to amend on a permanent basis to specify that diagnostic tests performed by a PA in accordance with their scope of practice and State law do not require the specified level of supervision assigned to individual tests, because the relationship of PAs with physicians under § 410.74 would continue to apply.

CMS is also proposing to make permanent the removal of the requirement for a general level of physician supervision for diagnostic tests performed by a PA.

- **Pharmacists Providing Services Incident to Physicians' Services**

CMS clarifies that pharmacists may provide services incident to the services, and under the appropriate level of supervision, of the billing physician or NPP, if payment for the services is not made under the Medicare Part D benefit. This includes providing the services incident to the services of the billing physician or NPP and in accordance with the pharmacist's state scope of practice and applicable state law. Medication management is covered under both Medicare Part B and Part D. CMS reiterates that pharmacists fall within the regulatory definition of auxiliary personnel.

- **Provision of Maintenance Therapy by Therapy Assistants**

CMS is proposing to make permanent the Part B policy for maintenance therapy services effective January 1, 2021, in order to create greater conformity in payment policy for maintenance therapy services that are furnished and paid under Part B with those in SNF and home health (HH) settings under Part A. If adopted, the policy would dovetail with the amended interim policy set forth in response to the PHE that grants PTs and OTs the discretion to delegate maintenance therapy services to the PTAs and OTAs, as clinically appropriate, for the duration of the PHE.

CMS is proposing to allow on a permanent basis, therapists to delegate performance of maintenance therapy services to an OTA or PTA for outpatient occupational and physical therapy services in Part B settings beginning January 1, 2021. CMS is also proposing to revise sections 220.2, 230.1 and 230.2 of chapter 15 of the Medicare Benefit Policy Manual to clarify that PTs and OTs no longer need to personally perform maintenance therapy services and to specifically remove the prohibitions on PTAs and OTAs from furnishing such services.

- **Medical Record Documentation**

CMS reiterates that as established in the CY 2020 PFS final rule and similarly expressed in the COVID-19 interim final rule with comment period (IFC), any individual who is authorized under Medicare law to furnish and bill for their professional services, whether or not they are acting in a teaching role, may review and verify (sign and date) the medical record for the services they bill, rather than re-document, notes in the medical record made by physicians, residents, nurses, and students (including students in therapy or other clinical disciplines), or other members of the medical team.

Specifically, CMS clarifies that the broad policy principle that allows billing clinicians to review and verify documentation added to the medical record for their services by other members of the medical team also applies to therapists.

Background/Rationale

CMS' changes were in response to stakeholder feedback on identifying Medicare regulations that contain more restrictive supervision requirements than existing state scope of practice laws, or that limit health professionals from practicing at the top of their license. Furthermore,

Comments

- **Teaching Physician and Resident Moonlighting Policies; Supervision of Residents in Teaching Settings through Audio/Video Real-Time Communications Technology; and Virtual Teaching Physician Presence during Medicare Telehealth Services**

In response to the PHE, CMS implemented several policies on an interim final basis related to PFS payment for the services of teaching physicians involving residents and resident moonlighting regulations, supervision of residents, and virtual teaching physician. CMS is soliciting comments on whether these policies should continue once the PHE ends, be temporarily extended through December 31, 2021, or made permanent.

- **Primary Care Exception Policies**

In response to the PHE, CMS permitted all levels of office/outpatient E/M visits to be furnished by the resident and billed by the teaching physician under the primary care exception. The list of services included in the primary care exception was subsequently further expanded and CMS allowed PFS payment to the teaching physician for services furnished by residents via telehealth under the primary care exception if the services were also on the list of Medicare telehealth services. CMS is seeking comments on whether these policies should continue once the PHE ends. CMS is also considering whether specific services added under the primary care exception should be extended temporarily or made permanent and are soliciting public comment on whether these services should continue as part of the primary care exception once the PHE ends.

I. Payment for Primary Care Management Services in Rural Health Centers (RHCs) and Federally Qualified Health Centers (FQHCs)

Proposed Changes

- **Proposal on RHC and FQHC Payment Codes**

In response to stakeholder requests that RHCs be allowed to furnish and bill for PCM services, CMS proposes that HCPCS codes G2064 and G2065 can be added to G0511 as a comprehensive care management service for RHCs and FQHCs starting January 1, 2021. CMS believes that there can be significant resources involved in care management for a single high0risk disease or complex chronic condition, and that the requirements for the new PCM codes are similar to the requirements for the care management services described by HCPCS code G0511.

Background/Rationale

- **Proposal on RHC and FQHC Payment Codes**

In the CY 2018 final rule, CMS finalized revisions to the payment methodology for CCM services furnished by RHCs and FQHCs and established requirements for general Behavioral Health Integration (BHI) and psychiatric Collaborative Care Management (CoCM) services furnished in RHCs and FQHCs. Specifically, they made revisions to permit RHCs and FQHCs to bill for care management services (HCPCS codes G0511 and G0512).

In the CY 2020 PFS final rule, CMS established a separate payment for PCM services. PCM services include comprehensive care management services for a single high-risk disease or complex condition, typically expected to last at least 3 months, possibly have led to a recent hospitalization, and/or placed the patient at significant risk of death. Beginning January 1, 2020, practitioners billing under the PFS can bill for PCM services using HCPCS codes G2064 or G2065.

J. Comprehensive Screenings for Seniors: Section 2002 of the Substance Use-Disorder Prevention that Promote Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act)

Proposed Changes

- **Proposal on Section 2002 of the SUPPORT Act Requirements**

CMS is proposing that the requirements of section 2002 of the SUPPORT Act be added to current regulations for the Initial Preventive Physical Examination (IPPE) and Annual Wellness Visit (AWV). Specifically, CMS is proposing to implement enacting regulations to reflect these changes at 42 CFR § 410.15 for AWV and 42 CFR § 410.16 for IPPE. Each of these sections will be amended by: 1) adding the term "screening for potential substance use disorders;" 2) adding the term "a review of any current opioid prescriptions" and its definition; and 3) revising the "initial preventive physical examination," "first annual wellness visit providing personalized prevention plan services," and "subsequent annual wellness visit providing personalized prevention plan services."

Background/Rationale

- **Proposal on Section 2002 of the SUPPORT Act Requirements**

The SUPPORT Act (enacted in October of 2018) is intended to provide for opioid use disorder prevention, treatment and recovery. Section 2002 of the SUPPORT Act, Comprehensive Screening for Seniors, required that the Initial Preventive Physical Examination (IPPE) and Annual Wellness Visit (AWV) include screening protocols for potential substance use disorders (SUDs) and a review of any current opioid prescriptions.

CMS believes that these provisions are complementary to existing components of the IPPE and AWV, and they propose that these new elements be added to IPPE and AWV regulations. CMS believes that adding these screening provisions will draw attention to their importance, and further, fulfil the requirements spelled out in section 2002 of the SUPPORT Act

Comments

CMS is seeking public comment on this proposal.

K. Medicare Shared Savings Program (MSSP)

Proposed Changes

- **Establishing a Smaller Measure Set for ACOs**

CMS is proposing to decrease the number of measures from 23 to 6, and the number of actively reportable measures from 10 to 3. This would reduce the burden for reporting requirements. Reporting for these measures would begin in January 2022 for the 2021 performance year. This would align with the CMS proposal to implement the Alternative Payment Model Performance Pathway (APP) under the Quality Payment Program (QPP)'s Merit-Based Incentive Payment System (MIPS). The proposed APP would replace the current Shared Savings program quality measure set to simplify reporting requirements. CMS hopes that using a single methodology to measures quality under the Shared Savings Program as well as MIPS would encourage ACOs to focus efforts on improving the value of care and engaging patients.

The new APP framework would also be weighted different, with quality accounting for 50 percent, PI accounting for 30 percent, IA accounting for 20 percent, and cost accounting for 0 percent. ACOs would be scored on the measures they choose to report but would receive zero points for those they do not report. Further, CMS proposes to remove the phase in approach for quality reporting. Regardless of performance year and agreement period, all ACOs would be scored on the same 3 actively reportable quality measures: 1) Diabetes: Hemoglobin A1C Poor Control (>9%); 2) Preventive Care and Screening: Screening for Depression and Follow-Up Plan; and 3) Controlling High Blood Pressure.

The CMS Web Interface would be removed by the 2021 MIPS performance year and data would be reported via a submission method of the ACOs' choosing. ACOs would receive a score between 3 to 10 points for each measure and ACOs would be required to field a MIPS patient survey.

- **Revising the Sharing Savings Program Quality Performance Standard**

CMS is proposing to raise the quality performance standard for all ACOs from the 30th percentile to the 40th percentile across all MIPS quality performance category scores, with the exclusion of providers eligible for facility-based scoring. CMS conducted a data analysis using 2018 reporting data that showed 95 percent of ACOs would meet the new 40th percentile requirement.

- **Methodology for Determining Shared Savings/Losses based on ACO Quality Performance**

For all tracks, CMS is proposing to revise the regulations and requirements that ACOs must meet to qualify for a shared savings payment beginning on January 1, 2021. If the ACO is eligible to share in savings and meets the proposed quality performance standard, the ACO will receive the maximum sharing rate up to the performance payment limit. However, if an ACO fails to meet the proposed quality performance standard, the ACO would be ineligible to share in savings. CMS is also proposing to modify the methodology for determining shared losses under Track 2 and the ENHANCED track. The new calculation for calculating shared losses would begin on January 1, 2021. The quality score of the ACO will also be used to calculate shared losses.

- **Revising the Approach to Monitoring ACO Quality Performance and Addressing ACOs that Fail to Meet the Quality Performance Standard**

CMS is proposing to broaden their ability to terminate contracts with ACOs on the basis of noncompliance. The modified text would state that CMS would review an ACO's submission of quality measurement data to identify noncompliance. CMS would be able to request additional documentation to prove compliance. There are currently no regulations on what actions CMS can take if ACOs do not meet quality measures for multiple years. However, CMS is proposing a new monitoring approach to allow it to address continued noncompliance. If ACOs do not meet quality measures for 2 consecutive performance years or fail to meet quality standards for any 3 performance years within an agreement period, the contract will be terminated. Also, a contract could be terminated at the discretion of CMS if quality measures are not met. Different termination policies will be applied to re-entering ACOs and new ACOs. The new policies would take effect in 2021. If the contract is terminated, the ACO will no longer receive shared savings.

- **Updating the Process Used to Validate ACO Quality Data Reporting**

CMS believes that the current audit process is burdensome and time-consuming for ACOs. CMS is proposing to streamline the data delivery method for ACOs into one validation process. The audit data would be used for both the Shared Savings Program and MIPS. CMS proposes retaining the right to audit and validate the data reported by the ACO.

- **Updating the Extreme and Uncontrollable Circumstances Policy**

CMS is proposing to change the quality performance standard for the Shared Savings Program. However, CMS believes that extreme and uncontrollable circumstances affect an ACO's ability to report data. Starting in 2021, the minimum quality performance score for an ACO affected by an extreme and uncontrollable circumstance would be equal to the 40th percentile MIPS quality performance score. If an ACO cannot report data, CMS would apply the 40th percentile MIPS quality performance score. ACOs in Track 2 and

the ENHANCED track would also eligible for relief from shared losses under the new policy. The data used to determine the percentile will come from the quarter 4 list of assigned beneficiaries. CMS also proposes specifying what would and would not be considered an extreme and uncontrollable circumstance and, subsequently, the affected geographic areas.

- **Updating the Definition of Primary Care Services Used in Beneficiary Assignment**

CMS is proposing to include certain codes for technical changes to the definition of primary care starting January 1, 2021. CMS is proposing to revise the following primary care services codes to account for online digital E/M, assessment of and care planning for patients with cognitive impairment, chronic care management, non-complex chronic care management, principal care management, and psychiatric collaborative care management. CMS defines online digital evaluation, or e-visits, to be non-face-to-face, patient-initiated communications using online patient portals. CMS believes that this definition should be expanded beyond the public health emergency to account for a wider, diverse range of care. The chronic disease management code requires two or more chronic conditions that place the patient at a significant risk of death or co-morbidities. Other requirements are applied to the following new codes: non-complex chronic care management, principal care management, and psychiatric collaborative care management.

- **Revising the Policy for Determining the Amount of Repayment Mechanism Arrangements for Certain ACOs Renewing to Continue their Participation Under a Two-Sided Model**

CMS proposes establishing 2 policies to allow ACOs to benefit from a lower repayment mechanism than allowable by current policies. First, renewing ACOs could use an existing repayment mechanism to establish its ability to repay CMS. The amount must be equal to the lesser of either the 1 percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's beneficiaries or 2 percent of the total Medicare Parts A and B FFS revenue. Second, ACOs' agreements that began July 1, 2019, or January 1, 2020, can reduce the amount of their repayment mechanisms. CMS is also proposing to allow a one-time opportunity for a repayment mechanism decreased for eligible ACOs that renewed an agreement beginning on either July 1, 2019 or January 1, 2020. CMS proposes that an ACO must demonstrate its repayment mechanism before any change to its terms and type of repayment mechanism.

Background/Rationale

In response to COVID-19, CMS loosened restrictions on the application of the Shared Savings Program extreme and uncontrollable circumstances policy to offer relief to all ACOs that may be unable to accurately report quality data for 2019. Also, on May 8, 2020, CMS changed Shared Savings Program policies to: allow ACOs to extend their existing agreement period by 1-year; allow ACOs to maintain their current level of participation for performance year 2021; adjust program calculations to remove payment amounts for COVID-19 treatment; expand the definition of primary care to include telehealth, e-visits, and other forms of virtual communication.

Comments

CMS generally seeks comment on the proposals outline above and is specifically soliciting comments on an alternative to the new extreme and uncontrollable circumstances policy for performance year 2022 and beyond. The alternative approach would use a scaling model to calculate the maximum possible shared

savings, instead of using the baseline of at least 20 percent of beneficiaries located in an area impacted by an extreme and uncontrollable circumstance.

- **Updating the Definition of Primary Care Services Used in Beneficiary Assignment**

CMS considered adding HCPCS codes G2010 to the definition of primary care, which is a short 5 to 10-minute discussion for remote evaluation. However, CMS decided against including the HCPCS codes G2010 and G2012 to the definition of primary care because they believe in-person visits will replace these interactions after the public health emergency is over. CMS is soliciting comments on the issue of including these codes in the definition of primary care.

CMS seeks comments on the whether to exclude advance care planning services identify by CPT codes.

L. Notification of Infusion Therapy Options Available Prior to Furnishing Home Infusion Therapy Services

Proposed Changes

CMS is proposing that for home infusion therapy services effective beginning CY 2021, physicians are expected to continue their current practice of discussing options available for furnishing infusion therapy under Part B and documenting their discussions in their patients' medical records prior to establishing a home infusion therapy plan of care. There will not be a mandatory form or guideline on how physicians need to inform their patients.

Background/Rationale

Physicians routinely discuss infusion therapy options with their patients and document discussions in their patients' medical records. CMS acknowledges that there are also various forms, manners, and frequencies in which physicians may use to inform patients of their options.

M. Modifications to Quality Reporting Requirements and Comment Solicitation on Modifications to the Extreme and Uncontrollable Circumstances Policy for Performance Year 2020

Proposed Changes

- **CAHPS for ACOs Reporting Requirements:**

CMS is proposing to remove the requirement that ACOs complete a Consumer Assessment of Healthcare Providers and Systems (CAHPS) for performance year (PY) 2020. ACOs would automatically receive full points for each of the CAHPS survey measures within the patient/caregiver experience domain.

- **Modifications to the Extreme and Uncontrollable Circumstances Policy**

CMS is proposing an alternative approach to scoring ACOs for PY 2020, using the higher of an ACO's 2020 quality performance score or its 2019 quality performance score for ACOs that completely report quality data for 2020. The modifications specify that for new ACOs that completely report quality data,

CMS will continue to score them as pay-for-reporting and assign a quality score of 100 percent. As for new ACOs that do not, they would receive the 2020 ACO mean quality performance score. This includes re-entering ACOs that terminated in its first agreement period and is now in its first performance year of a new agreement period.

For ACOs in a second or subsequent performance year that completely and accurately report the measures for PY 2020, the ACO will receive the higher of its performance year 2020 ACO quality performance score. For ACOs that do not, they will receive the 2020 ACO mean quality performance score. This includes re-entering ACOs that terminated in its second or subsequent agreement period.

Background/Rationale

- **CAHPS for ACOs Reporting Requirements:**

CMS is aware that the potential negative impacts of the COVID-19 can lead to challenges in benchmarking and computing quality improvement scores for 2020. Since the PHE for the COVID-19 pandemic is applied to all counties, all ACOs are considered affected by an extreme and uncontrollable circumstance. CMS is concerned with a decrease in primary care services which may impact beneficiaries' ability to fully complete the survey. A recently published Commonwealth Health Study showed a decrease in the number of primary care visits in the 2nd quarter of 2020 even with the uptick in telehealth visits. The pandemic can also impact survey administration procedures and response rates if certain vendor-specific revisions are needed (i.e. allowing mail-only surveys), introducing a lack of standardization in survey administration and difficulties with comparability of data.

- **Modifications to the Extreme and Uncontrollable Circumstances Policy**

While CMS recognizes the concerns regarding the potential impacts of COVID-19 on quality reporting, they strongly encourage ACOs to report quality data in order to be held accountable for the quality of care they provide to their beneficiaries. This alternative proposal encourages all ACOs to report quality for PY 2020 while offering protections for ACOs if they believe their performance scores will be adversely impacted by COVID-19. The modification would continue to benefit ACOs that perform well during 2020 and help to mitigate the impact for those that do not.

Comments

CMS seeks comment on their proposal to waive the CAHPS for ACOs reporting requirement and to provide ACOs automatic credit for the survey measures for performance year 2020. They also seek comment on their modifications to the extreme and uncontrollable circumstances policy and welcome comments that propose an alternative approach to scoring ACOs under the policy.

N. Proposal to Remove Selected National Coverage Determinations (NCDs)

Proposed Changes

CMS is proposing to remove the following 9 outdated NCDs:

- Extracorporeal Immunoadsorption (ECI) using Protein A Columns

- Electrosleep Therapy
- Implantation of Gastroesophageal Reflux Device
- Apheresis (Therapeutic Pheresis)
- Abarelix for the Treatment of Prostate Cancer
- Histocompatibility Testing
- Cytogenetic Studies
- Magnetic Resonance Spectroscopy
- FDG PET for Inflammation and Infection

Background/Rationale

In a 2013 Federal Register notice, CMS established an expedited administrative process to remove NCDs older than 10 years, allowing local Medicare Administrative Contractors (MAC) to determine coverage. The rationale for the removal of each of the NCDs is provided below, with the majority suggested by external stakeholders to be outdated:

- Extracorporeal Immunoadsorption (ECI) using Protein A Columns: The therapeutic use of ECI constrained by the parameters of the NCD as scientific evidence has continued to evolve. Removing the NCD and leaving it to contractor discretion would provide flexibility for coverage considerations that may be more responsive to the evolving evidentiary base.
- Electrosleep Therapy: The NCD predates the current NCD public notice standards with no decision memorandum, evidence review, and bibliography. The FDA's class level assigned to electrosleep therapy has also changed over time for indications of anxiety and/or insomnia. Removing the NCD will allow local contractors to consider coverage of new technologies.
- Implantation of Gastroesophageal Reflux Device: Some devices have a limited evidence base with respect to improving long-term patient outcomes. Local contractor discretion would provide an immediate avenue to potential coverage in appropriate candidates.
- Apheresis (Therapeutic Pheresis): This NCD predates the current NCD public notice standards. No evidence review was published to justify the specific list of conditions covered. The scope of indications for apheresis has also continued to develop since the origin of the NCD. Leaving the determination to local contractor discretion will provide flexibility for coverage considerations that may be more responsive to the evolving evidentiary base.
- Abarelix for the Treatment of Prostate Cancer: In reports to systemic allergic reactions, Abarelix was voluntarily withdrawn from the market. The NCD is generally considered to be obsolete and is no longer marketed in the U.S. As a result, the NCD no longer contains clinically pertinent and current information.
- Histocompatibility Testing: External stakeholders suggested that the texts within this NCD are now less frequently utilized and raised concerns of reducing provider burden. Techniques have evolved; therefore, clinicians need to make sophisticated assessments related to the indication, their access to testing approaches, and appropriate avenues for billing. Removing the NCD and allowing contractor discretion will accommodate clinical flexibility to better serve needs of beneficiaries.

- Cytogenetic Studies: The NCD has been superseded by subsequent Medicare policy. The focus of NCDs has shifted from cytogenetic studies to genetic sequencing when seeking genetic information of interest.
- Magnetic Resonance Spectroscopy: Although MRS is generally used in assessing brain tissue, there is potential applicability to other types of cancers. The 2004 broad noncoverage determination for all indications was based on evidentiary review for solely one indication, diagnosis of brain tumors. As the evidence evolves and clinical utility develops across various indications, the 2004 NCD may prohibit appropriate local coverage determinations.
- FDG PET for Inflammation and Infection: There is no overall agreement in the current literature regarding added value of FDG PET for some inflammatory and infectious conditions. Leaving the NCD to local contractor discretion allows flexibility in tailoring coverage decisions to a specific patient's case.

Comments

CMS is soliciting comments on the removal of each of the nine NCDs as well as comments recommending other NCDs for future removal. They also seek public comments that may identify other reasons for proposing to remove NCDs and whether the time-based threshold of "older" (designated as 10 years in the 2013 notice) continues to be appropriate. CMS requests that comments include a rationale for support.

O. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D drug under a prescription drug plan or an MA-PD plan

Proposed Changes

CMS is proposing, pursuant to the SUPPORT Act, to delay the mandatory implementation of Electronic Prescribing for Schedule II, III, IV, or V controlled substance (EPCS) under Medicare Part D, to a January 1, 2022 start date to provide additional time for Medicare prescribers to adjust (especially given limitations related to COVID-19).

Additionally, CMS is proposing clarifications that, beginning on and proceeding this January 1, 2022, start date, prescribers must use the National Council for Prescription Drug Programs (NCPDP) SCRIPT 2017071 standard when performing EPCS because "they are already required to use this standard when conducting e-prescribing for covered Part D drugs for Part D eligible individuals."

Background/Rationale

Section 2003 of the SUPPORT Act generally mandates that the prescribing of a Schedule II, III, IV, or V controlled substance under Medicare Part D be done electronically in accordance with an electronic prescription drug program **beginning January 1, 2021, subject to any exceptions, which HHS may specify**. Section 2003 of the SUPPORT Act requires that the Secretary use rulemaking to specify circumstances and processes by which the Secretary may waive the EPCS requirement and provides the Secretary with authority to enforce and specify appropriate penalties for non-compliance with EPCS. The SUPPORT Act specifies some circumstances under which the Secretary may waive the electronic

prescribing requirement with respect to controlled substances that are covered Part D drugs and also permits HHS to develop other appropriate exceptions.

Comments

CMS is seeking general comments on this proposal, including the feasibility for prescribers to meet the proposed January 1, 2022 deadline. CMS is also soliciting comments on the impact of this proposal on overall interoperability and the impact on medical record systems, as well as comments on whether the proposed change would be significant enough for a January 1 implementation date, which is required for all significant changes affecting Part D plans.

P. Medicare Part B Drug Payment for Drugs Approved Through the Pathway Established Under Section 505(b)(2) of the Food, Drug, and Cosmetic Act

Proposed Changes

CMS is proposing to amend regulation text at 42 CFR 414.902 by stating that "multiple source drugs may include drug products described under section 505(b)(2) of the FFDCA" and adding § 414.904(k) that describes the framework for determining such products as "multiple source drugs."

Background/Rationale

Section 505(b)(2) of the FFDCA describes new drug applications (NDAs) that contain full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. In more practical terms, these drugs sometimes reflect new versions of pre-existing multiple source drugs but are presented/structured in ways that would warrant an NDA (and, thus, higher single-source drug prices when entering the Medicare market).

For certain developers, this pathway is more market-driven than science-driven. Such developers usually look to have their own single-source HCPCs code attributed to their 505(b)(2) product, despite similarities to other approved products covered under cheaper multiple-source HCPCs codes (that reimburse at the volume-weighted average ASP offered for all included brand name and generic products covered under the code).

When possible, CMS has looked to attribute 505(b)(2) products to existing multiple source drug codes to reduce cost for beneficiaries and the program. This proposed rule codifies in regulation this practice, and defines the process used for determining when a 505(b)(2) product can still be lumped under existing multiple-source drug HCPCs codes.

Comments

CMS is soliciting comment on this general process, as well as ways to best improve the determination process.

Q. Updates to the Certified Electronic Health Record Technology (CEHRT) due to the 21st Century Cures Act Final Rule

Proposed Changes:

- **CEHRT Requirements in the Promoting Interoperability Program and QPP**

CMS is proposing that the technology used by healthcare providers to satisfy the definitions of CEHRT at must be certified under the Certification Program in accordance with the updated 2015 Edition of health IT certification criteria as finalized in the 21st Century Cures Act final rule. This includes technology used to meet the 2015 Edition base EHR definition § 170.102, technology certified to the criteria necessary to be a meaningful EHR user under the Promoting Interoperability Programs, and technology certified to the criteria necessary to report on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category. Healthcare providers participating in the Promoting Interoperability Programs or QPP would be required to use only technology that is considered certified under the ONC Health IT Certification Program according to the timelines established in the Cures Act final rule.

CMS also proposes to revise two definitions of under § 414.1305. First, under the definitions of CEHRT, they propose to replace the reference to the "Advancing Care Information" performance category with the "Promoting Interoperability" performance category. The same would be done under the definition of Meaningful EHR user for MIPS.

- **Certification Requirements under the Hospital Inpatient Quality Reporting (IQR) Program**

Beginning with CY 2020 reporting period/FY 2023 payment determination and for subsequent years, CMS proposes expanding flexibility to allow hospitals to uses either: 1) technology certified to the 2015 Edition criteria for CEHRT as was previously finalized in the FY 2019 IPPS/LTCH final rule; or 2) technology certified to the 2015 Edition Cures Update standards as finalized in the 21st Century Cures Act final rule.

Background/Rationale

- **CEHRT Requirements in the Promoting Interoperability Program and QPP**

The 21st Century Cures Act final rule established timelines for: 1) a transition period where technology certified to not-yet updated or updated versions of the same certification criteria would be considered certified; and 2) the date for which technology certified to only the updated version would be considered certified. CMS affirms that each of their proposals support their focus on promoting interoperability and continued alignment, reduce healthcare provider burden, and provide flexibility for providers to pursue innovative applications that improve care delivery.

- **Certification Requirements under the Hospital IQR Program**

CMS aims to align electronic quality measure requirements of the Hospital IQR Program with other Medicare and Medicaid programs in order to reduce reporting burden on healthcare providers. In adopting this approach, CMS will encourage hospitals to implement the most up-to-date, standards-based structured data capture while also maintaining alignment with the Promoting Interoperability Program proposal. This

allows early adopters of health IT certified to the 2015 Edition Cures Update criteria for CEHRT to implement changes while still meeting Hospital IQR Program requirements.

Comments

CMS seeks public comments on the changes to the CEHRT Requirements in the Promoting Interoperability Program and QPP and certification requirements under the Hospital IQR Program.

R. MIPS Value Pathways (MVPs)

Proposed Changes

- **Timeline for MVP Implementation**

Due to the COVID-19 PHE, CMS is delaying the implementation of MVPs to the 2022 performance year (this would be moved from the original 2021 performance year start date).

- **MVP Guiding Principles**

CMS is proposing updates to the MVP guiding principles, development criteria, and process that would guide MVP implementation beginning with the 2022 MIPS performance period/2024 MIPS payment year.

The updated guiding principles for MVPs are proposed as follows (with changes shown in italics):

1. MVPs should consist of limited, *connected complementary* sets of measures and activities that are meaningful to clinicians, which will reduce clinician burden, *align* scoring, and lead to sufficient comparative data.
2. MVPs should include measures and activities that would result in providing comparative performance data that is valuable to patients and caregivers in evaluating clinician performance and making choices about their care; *MVPs will enhance this comparative performance data as they allow subgroup reporting that comprehensively reflects the services provided by multispecialty groups.*
3. MVPs should include measures *selected using the Meaningful Measures approach and, wherever possible, the patient voice must be included*, to encourage performance improvements in high priority areas.
4. MVPs should reduce barriers to APM participation by including measures that are part of APMs where feasible, and by linking cost and quality measurement.
5. *MVPs should support the transition to digital quality measures*.

- **M MVP Candidates Criteria**

As stated in previous rulemaking, CMS is allowing stakeholders to submit their own MVP candidates for consideration. As such, CMS is proposing to develop and select MVPs using criteria in the following topics (this will be applied to all MVP candidates—developed by CMS and/or stakeholders).

    - Utilization of Measures and Activities across Performance Categories
    - Intent of Measurement

- Measure and Activity Linkages with the MVP
- Appropriateness
- Comprehensibility
- Incorporation of the Patient Voice
- Measures and Improvement Activities Considerations: MIPS Quality Measures (not meant to be prescriptive on the number of quality measures included)
- Measures and Improvement Activities Considerations: Cost Measures
- Measures and Improvement Activities Considerations: Improvement Activities
- Measures and Improvement Activities Considerations: Promoting Interoperability (PI) Measures

Additionally, CMS is proposing that, beginning with the 2022 performance period, stakeholders that are developing candidate MVPs would be required to include patients as a part of the development process (incorporating patients and/or patient representatives through means that may include, but are not limited to technical expert panels or an advisory committee).

- **MVP Candidate Proposal Process**

CMS states that an MVP Candidate Application template will be posted on the QPP Resource Library, and applications will be accepted likely on a rolling basis once a streamlined process of application/review is established. It will be at Agency's discretion to determine if proposed MVP candidates will be approved for the following performance year; all MVP candidates would have to meet the criteria described above and include patient input.

In addition, CMS states that they will "vet the quality and cost measures from a technical perspective to validate that the coding in the quality measures and cost measure(s) include the clinician type being measured, and whether all potential specialty specific quality measures or cost measure were considered, with the most appropriate included." CMS would reserve the right to reach out to select stakeholders whose candidate MVP may be feasible for the upcoming performance period, to schedule a "feedback loop meeting to discuss feedback, and next steps that may include recommended modifications to the MVP candidate." Notably, MVPs must be established through rulemaking, therefore, CMS will not communicate to the stakeholder whether an MVP candidate has been approved, disapproved, or is being considered for a future year, prior to the publication of the proposed rule.

- **Implementing Meaningful Measures in MVPs**

Similar to the 2020 MPFS proposed rule, CMS is considering the use of claims-based population health data for quality measurement under the MVP framework—despite pushback from certain stakeholders over concerns of reliability, validity, attribution, and/or risk adjustment related to such measures. CMS is also proposing to allow the use of QCDR measures, despite pushback from certain stakeholders that allowing such measures would place additional reporting and financial burdens for clinicians looking to participate in MVPs that contain such measures. Any QCDR and/or claims-based measures would still have to meet the criteria proposed.

To this end, CMS is also proposing to allow third party intermediaries (i.e. QCDRs, qualified registries, and Health IT vendors) to support MVPs.

Background/Rationale

- **Transforming MIPS: MIPS Value Pathways**

CMS originally proposed MVPs to reduce clinician burden relating to MIPS reporting requirements, and to incentivize clinicians' transition to value-based payment models and risk-bearing APMs. MVPs represent a smaller subset of reporting requirements and quality metrics that are tailored to a specific patient population/condition and/or practice specialty—the primary goal of the MVP track (from CMS' perspective) is to standardize performance measurement of a specialty or a medical condition and reduce the "siloed nature" of the traditional MIPS participation experience. Stakeholders have complained that the vast number of quality measurement options and activities available to MIPS ECs limits the ability of the program to truly assess and compare clinician quality and performance (such stakeholders have referenced the 98% positive payment adjustment rate as a key sign that the program does little to differentiate ECs based on quality). These adjusted guiding principles for the MVP pathway are informed by previous RFIs within the 2020 MPFS proposed rule.

- **MVP Development: Process of Developing and Reviewing MVP Candidates**

The proposed MVP development process by CMS is in response to substantial stakeholder feedback. Notably, the Agency has made an effort to showcase their commitment to involving stakeholder input and collaboration in the MVP development process and will continue to seek feedback prior to PY 2022.

Comments

CMS is seeking, but not limiting, general stakeholder input on: 1) the updated guiding principles for MVPs; 2) the defined criteria for developing MVPs; 3) ways to improve the MVP candidate application/review process and to improve process transparency; 4) concerns/support for allowing administrative claims-based population health measures and QCDR measures, as well as allowing third party intermediaries to support MVPs.

S. APM Performance Pathway (APP)

Proposed Changes

- **General Proposals for APP**

CMS is proposing at § 414.1367 to establish an APM Performance Pathway (APP) under MIPS, beginning in the 2021 MIPS performance year, that would replace the current APM Scoring Standard. Duly, the APP would serve as an optional MIPS reporting and scoring pathway for MIPS eligible clinicians (ECs) identified on the Participation List or Affiliated Practitioner List of any APM Entity participating in any MIPS APM on any of the four snapshot dates (March 31, June 30, August 31, and December 31) during a performance period. The APP would also be required for MSSP quality determinations for ACOs. The APP may be reported by the individual EC, group (TIN), or APM Entity.

The APP consists of a fixed set of measures for the quality performance category (listed below). Additionally, the Cost performance would be weighted to 0%, similar to other APMs; Improvement Activities scores would automatically be assigned based on the requirements of the MIPS APM (and it's

use of MIPS Improvement Activities, described in further detail below), with all APM participants reporting through the APP in 2021 earning a score of 100%; and, Promoting Interoperability requirements and scoring would remain the same.

- **Quality**

ECs scored under the APP would be scored on the quality measure set defined in the box below

Measure ID	Measure Title
Quality: 321	CAHPS for MIPS
Quality: 001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control
Quality: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan
Quality: 236	Controlling High Blood Pressure
TBD	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS EC Groups
TBD	Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs

- **Improvement Activities**

CMS is proposing to retain similar scoring for this category as is currently afforded under the APM Scoring Standard. Specifically, that CMS would publish the assigned improvement activities scores for each MIPS APM prior to the start of the PY.

- **Performance Category Weights**

MIPS ECs reporting through the APP would be scored under the same methodology established for MIPS generally.

Category	Weight	Reweighting Policy
Quality	50%	If reweighted to 0% due to E&UC, Promoting Interoperability would equal 75%, and Improvement Activities would equal 25%
Cost	0%	N/A
Promoting Interoperability	30%	If reweighted to 0% due to E&UC, Quality would equal 75%, and Improvement Activities would equal 25%
Improvement Activities	20%	N/A

- **Technical amendments to MIPS APM Definition**

CMS is proposing conforming amendments to the definition of MIPS APMs to reflect options made available through APP—namely, to reflect the ability to report on either the APM entity or individual level and the ability for ECs on an Affiliated Practitioner List to participate. This includes: not depending on the availability of quality measure data reported directly to the APM; not requiring MIPS APMs be in operation and therefore collecting quality data for the entirety of the performance year; and expanding the definition of MIPS APM to include APMs in which there is only an Affiliated Practitioner List.

Background/Rationale

CMS is proposing the APP as a replacement for the current APM Scoring Standard (and to run alongside implementation of the MVP framework). Similarly, the APP has been established for purposes of burden reduction and meaningful measurement among MIPS eligible clinicians who already participate in APMs but elect to participate in MIPS or fall below the applicable Partial QP threshold. Specifically, CMS hopes that the APP, similar to the MVP pathway, will provide a more predictable and consistent MIPS reporting standard to "reduce reporting burden and encourage continued APM participation."

Comments:

CMS is seeking input on all aspects of the proposed APP discussed above.

T. MIPS Quality Category

Proposed Changes

CMS is proposing the following changes to the MIPS performance category measures and related activities. Generally, the proposed category weights for the 2023 and 2024 payment years (2021 and 2022 performance years, respectively) are listed in the table below.

Performance Category	2023 MIPS Payment Year (Proposed)	2024 and Future MIPS Payment Years (Proposed)
Quality	40%	30%
Cost	20%	30%
Improvement Activities	15%	15%
Promoting Interoperability	25%	25%

- **CMS Web Interface**

CMS is proposing to sunset the CMS Web Interface measures as a collection type for groups and virtual groups with 25 or more eligible clinicians starting with the 2021 performance period.

- **MIPS Quality Measure Set**

CMS is proposing the addition of new measures, updates to specialty sets, removal of existing measures, and substantive changes to existing measures. In summary, CMS is proposing to add 2 new administrative claims outcomes measures (i.e. Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the MIPS EC Groups; and, Risk-Standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty(TKA) for NIPS ECs); modify existing specialty sets and propose new specialty sets; remove 14 MIPS quality measures (2 that are extremely topped out; 1 MIPS quality measure that is duplicative to another current measure; 1 measure that is duplicative to a newly proposed measure; 2 measures that do not align with the Meaningful Measures Initiative; 5 measures that are no longer stewarded or maintains; 1 measure that does not meet current clinical guidelines; and 2 measures that are under the topped out lifecycle); and, make substantive changes to 112 existing quality measures.

- **Separate Performance Periods for Administrative Claims Measures**

CMS is proposing to allow for longer performance periods for certain administrative claims measures on an individual basis. For example, the newly proposed measure *'RSCR Following Elective Primary THA and/or TKA'* was developed and tested using a performance period that was longer than a full calendar year in order to provide larger sample sizes; beginning with the 2021 performance year, if this proposed change passes, this measure would a have a 3-year performance period that would start on October 1 of the calendar year 3 years prior to the applicable performance year and conclude on September 30 of the calendar year of the applicable performance year, with a 90-day numerator assessment period followed by a 60-day claims run-out period.

- **Changes the CAHPS for MIPS Survey to Address the Increased Use of Telehealth Care**

CMS is proposing the following changes related to the CAHPS for MIPS survey to address the increased use of telehealth care during COVID-19:

  - Integrate one telehealth item into the CAHPS for MIPS Survey that assesses patient-reported usage of telehealth services.
  - Propose revisions to the CAHPS for MIPS Survey cover page to include a reference to care received in telehealth settings.

- **Telehealth Codes Used in Beneficiary Assignment for the CAHPS for MIPS Survey**

In response to the PHE and to address the increased use of telehealth, CMS is proposing to revise the definition of "primary care services" used in the MIPS assignment methodology for the 2021 CAHPS for MIPS survey, and for any subsequent performance year, to include the following additions:

  - CPT codes: 99421, 99422, and 99423 (codes for online digital E/M services (e-visits)); 99441, 99442, and 99443 (codes for telephone E/M services); and 96160 and 96161 (codes for administration of health risk assessment); and
  - HCPCS codes: G2010 (code for remote evaluation of patient video/images) and G2012 (code for virtual check-in)."

Background/Rationale

- **CMS Web Interface**

This is due to a reported decrease in utilization of the CMS Web Interface by groups and virtual groups since 2017. Furthermore, ACOs participating in the MSSP or Next Gen ACO Model account for more than 80 percent of organizations utilizing the CMS Web Interface measures, and such entities are transitioning to APP participation which does not include such measures.

- **Telehealth Codes Used in Beneficiary Assignment for the CAHPS for MIPS Survey**

CMS expects that the utilization of such services will substantially increase not only during the PHE for the COVID-19 pandemic, but also thereafter. Accordingly, CMS proposes to include virtual primary care

visits and telehealth visits to determine patient assignment to groups for purposes of the CAHPS for MIPS Survey for 2021 and subsequent performance years.

Comments

CMS is seeking general comment on all aspects of these proposed changes as well as any alternatives to consider.

U. MIPS Cost and Improvement Activities Categories

Proposed Changes

- **Cost Category – Telehealth Services**

CMS is proposing to add the costs associated with telehealth services to the previously established cost measures. Notably, CMS states that they do not consider this addition an alteration to the original intent of the cost measures and do not believe this captures a new category of cost. For more information on the codes added, please visit: https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback.

- **Improvement Activities – Modifying Existing Improvement Activities**

CMS is proposing specific and technical alterations to the following two improvement activities: "Engagement of patient through implementation of improvements in patient portal;" and, "Comprehensive Eye Exams."

Background/Rationale

Comments

CMS is seeking general comment on all aspects of these proposed changes as well as any alternatives to consider.

V. MIPS Promoting Interoperability Category

Proposed Changes

- **Query of Prescription Drug Monitoring Program (PDMP) Measure**

CMS is proposing to retain this measure as an optional measure and propose to make it worth 10 bonus points.

- **Optional Health Information Exchange (HIE) Bi-Directional Exchange Measure**

CMS is proposing to add the following new measure under the HIE objective beginning with the performance period in 2021: *Health Information Exchange (HIE) Bi-Directional Exchange*. CMS is proposing the HIE Bi-Directional Exchange measure would be reported by attestation and would require a yes/no response to the following questions: (1) I participate in an HIE in order to enable secure, bi-

directional exchange to occur for every patient encounter, transition or referral, and record stored or maintained in the EHR during the performance period; (2) The HIE that I participate in is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and does not engage in exclusionary behavior when determining exchange partners; and (3) I use the functions of CEHRT for this measure, which may include technology certified to criteria at 45 CFR 170.315(b)(1), (b)(2), (g)(8), or (g)(10).

Background/Rationale

- **Query of Prescription Drug Monitoring Program (PDMP) Measure**

CMS acknowledges that further efforts are needed to improve the technical foundation for EHR-PDMP integration, and acknowledges stakeholder concerns about the current readiness across states for the implementation of this measure (or lack thereof); thus, they are not requiring a Query of PDMP measure for performance-based scoring yet.

- **Optional Health Information Exchange (HIE) Bi-Directional Exchange Measure**

CMS is proposing this measure to incentivize MIPS eligible clinicians to engage in bi-directional exchange through an HIE. Notably, this new HIE Bi-Directional Exchange measure would serve as an optional alternative to the two existing measures (the Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure) and would be worth 40 points.

Comments

CMS is seeking general comment on all aspects of these proposed changes as well as any alternatives to consider.

W. MIPS APM Scoring Standard

Proposed Changes

- **Elimination of APM Scoring Standard**

Due to a considerable amount of negative feedback by the stakeholder community, CMS is proposing to terminate the APM scoring standard and replace it with the proposed MIPS APM Performance Pathway (APP) and scoring rules, as previously discussed. Subsequently, CMS is proposing the following changes and adjustments:

  - Re-designating the regulation that describes APM Entity group determinations so that CMS may retain certain APM Entity group reporting policies that were established and finalized for reporting and scoring under MIPS beginning with 2021;
  - Ending the full-TIN APM policy, which allows for an APM Entity group to include ECs on the Participation List in a full-TIN APM on December 31 of the MIPS performance Period only if the APM is a full-TIN APM;

- Allowing MIPS ECs identified on the Participation List or Affiliated Practitioner List of any APM Entity participating in any MIPS APM on any of the three snapshot dates (March 31, June 30, August 31), as well as December 31 during a performance period, beginning in the 2021 MIPS performance period, to be considered participants in an APM Entity group;
- Terminating the APM Entity level low-volume threshold determinations
- (Continue past APM entity group scoring methodologies)

- **Reweighting based on Extreme and Uncontrollable Circumstances for APM Entity Groups**

CMS is proposing to allow APM Entities to apply for reweighting of one or more MIPS performance categories due to extreme and uncontrollable circumstances, beginning with the 2020 performance period (2022 payment period). This would be applicable to all four performance categories and all MIPS ECs in the APM Entity group.

Background/Rationale

- **Reweighting based on Extreme and Uncontrollable Circumstances for APM Entity Groups**

If approved this exception would not be offset by subsequent data submissions in the performance year for the APM Entity. Notably, CMS is also proposing that APM Entities would have to demonstrate in the application to CMS that greater than 75 percent of its participant MIPS ECs would be eligible for reweighting the Promoting Interoperability performance category for the applicable performance period.

Comments

CMS is seeking general comment on all aspects of these proposed changes as well as any alternatives to consider.

X. MIPS Final Score Methodology

Proposed Changes

- **Reducing the MIPS Performance Threshold**

CMS is proposing to reduce the finalized MIPS Performance threshold, that determines positive/negative payment adjustments, from 60 to 50 for the 2021 performance year (the 2023 payment year).

- **Scoring Flexibility for Quality Measures**

Beginning with the 2021 performance period, CMS is proposing a policy to truncate the performance period or suppress a quality measure if CMS determines that "revised clinical guidelines, measure specifications or codes impact the clinician's ability to submit the measure or may lead to potentially misleading results."

- **Benchmarks and Topped Out Scoring Policies**

To adjust for the potential lack in historical data, CMS is instead proposing to use benchmarks for the CY 2021 performance period that are based on the actual data submitted during the CY 2021 performance period (as opposed to historic 2019 data).

Alternatively, CMS is also considering using the historic benchmarks from the 2020 MIPS performance period for the CY 2021 performance period. CMS acknowledges that this option would allow clinicians to continue to receive advance notice for benchmarks to set clear performance goals; however, they remain concerned over the notion of using outdated data.

- **Scoring for All Administrative Claims-Based Measures**

CMS is proposing to amend the regulatory text to allow for more flexible adjustments to minimum case requirements applicable to administrative claims-based measures. Specifically, the proposed regulation would allow the minimum case requirement for such measures to be defined annually in the list of MIPS measures (as opposed to limiting such requirements to amounts listed in regulation; e.g., for non-administrative claims measures, the minimum case requirement is 20 cases).

- **Assigning Measure Achievement Points for Topped Out Measures**

Since CMS is proposing to utilize performance period benchmarks (as opposed to historic benchmarks) for the 2021 MIPS performance period, the Agency will not be able to identify topped-out measures (measures that have been topped-out for 2 or more consecutive years for purposes of the topped out scoring of 7 measure achievement points). As a result, CMS is instead proposing, for the 2021 performance year, to apply the 7 measures achievement point cap to measures that meet the following two criteria:

1. Measures that have been topped out for 2 or more periods based on the published 2020 MIPS performance period historic benchmarks; and,
2. Measures that remain topped out after the 2021 MIPS performance period benchmarks have been calculated.

- **Complex Patient Bonus**

CMS is proposing to continue the complex patient bonus for the 2021 performance period (2023 payment period). Furthermore, to adjust for the increased complexity due to the COVID-19 PHE, CMS is proposing to double the complex patient bonus score ECs can receive during the 2020 performance period (2022 payment period), with a cap at 10 points. For example, if a MIPS eligible clinician would receive 4 complex patient bonus points under the existing formulas, the MIPS EC would receive 8 complex patient bonus points for the 2020 performance period added to the final score.

Background/Rationale

- **Scoring Flexibility for Quality Measures**

This proposed change is to adjust for changes to clinical guidelines, measure specifications, inadvertent deletions, or revisions of codes that cannot be anticipated (unlike an ICD-10 code change, for instance). CMS would retain the flexibility to instead assess the measure on 9 consecutive months of data and

suppress the measure if 9 consecutive months of data are not available. CMS would publish a list of measures requiring the truncated 9-month assessment period on the CMS website "as soon as technically feasible, but no later than the beginning of the data submission period."

- **Benchmarks and Topped Out Scoring Policies**

Due to flexibilities provided to MIPS ECs to allow for no data submission for the 2019 performance period, CMS believes that it may not have a representative sample of data to base quality measure benchmarks for the 2021 performance year. CMS is aware that this presents limitations, as ECs will not have the ability to view quality measure benchmarks in advance under this proposal.

- **Scoring for All Administrative Claims-Based Measures**

CMS is looking to establish less rigid requirements since the agency is proposing to add additional administrative claims measures (that would yield different case minimum requirements) in the 2021 performance year.

Comments

CMS is seeking general comment on all aspects of these proposed changes as well as any alternatives to consider.

Y. Third-Party Intermediaries

Proposed Changes

CMS is proposing multiple changes to requirements for third party intermediaries, including qualified clinical data registries (QCDRs), and qualified registries, as well as changes to remedial action (not encompassed in this summary). These changes are being proposed, partly, to support third party intermediaries interested in supporting MVPs in the future, as well as those involved in APP reporting.

- **Involvement of Third-Party Intermediaries in MVPs and APP reporting**

CMS verifies that QCDRs, qualified registries, and health IT vendors who support the Quality, Promoting Interoperability, and Improvement Activities performance categories may also support the reporting of MVPs. Additionally, CMS verifies that such parties (specifically, qualified registries and health IT vendors) may play a role in APP reporting, as three quality measures encompassed in APP use the MIPS CQM and eCQM collection types.

- **Approval and Audit of Third-Party Intermediaries; QCDR Measure Requirements**

CMS is proposing to amend current policies for the approval of third-party intermediaries. CMS specifically outlines new criteria for third party intermediary approval and reserves the right to audit such entities at any time. This includes the addition of the following criterions: 1) entities must demonstrate compliance with the requirements for any prior MIPS performance period for which it was approved as a third party intermediary; and 2) the entity must not have provided inaccurate information to clinicians

regarding QPP requirements. Furthermore, CMS is proposing to mandate that third-party intermediaries must attend and complete training and support sessions as specified by CMS.

CMS is also proposing to codify in federal regulation requirements that, beginning with the 2023 MIPS payment year, as a condition of approval QCDRs and Qualified registries would be responsible for conducting annual data validation audits (with specific obligations), as well as targeted audits (with specific obligations) if deficiencies are identified through data validation. (The specific requirements and details of each audit would be further defined in federal regulation.)

Background/Rationale

- **Approval and Audit of Third-Party Intermediaries; QCDR Measure Requirements**

This is in response to feedback and trends indicating that certain intermediaries' practices adversely impact clinician data reporting and potentially misrepresent clinician data.

Comments

- **Approval and Audit of Third-Party Intermediaries; QCDR Measure Requirements**

CMS is soliciting feedback on whether they should impose data validation requirements on health IT vendors as part of the third party intermediary approval process, and if so, how the data validation for health IT vendors should differ, if at all, from those proposed for QCDRs and qualified registries. CMS is also soliciting feedback if such requirements should also be applied to CMS-approved survey vendors, such as CAHPS for MIPS vendors.

Z. APM Incentive Payment Disbursement

Proposed Changes

- **Revised approach to identifying TIN(s) for the APM Incentive Payment**

CMS is proposing a revised approach to identifying TIN(s) associated with ECs that achieve QP status for purposes of the APM incentive payment. Specifically, the approach would involve the following updated hierarchy.

1. Any TIN associated with the QP that, during the QP Performance Period, is associated with an APM Entity through which the EC achieved QP status;
2. Any TIN associated with the QP that, during the APM Incentive Payment base period, is associated with an APM Entity through which the EC achieved QP status;
3. Any TIN associated with the QP that, during the APM Incentive Payment base period, is associated with an APM Entity participating in an Advanced APM through which the EC had achieved QP status;
4. Any TIN associated with the QP that, during the APM Incentive Payment base period, participated in an APM Entity in an Advanced APM;

5. Any TIN associated with the QP that, during the APM Incentive Payment base period, participated with an APM Entity in any track of the APM through which the EC achieved QP status;
6. Any TIN associated with the QP that, during the APM Incentive Payment base period, participated with an APM Entity in an APM other than an Advanced APM;
7. Any TIN associated with the QP that submitted a claim for covered professional services furnished by the QP during the APM Incentive Payment base period, even if such TIN has no relationship to any APM Entity or APM; then
8. (If CMS has not identified any TIN associated with the QP to which we can make the APM Incentive Payment, CMS will attempt to contact the QP via a public notice to request their Medicare payment information) The QPs identified in the public notice, or any other eligible clinicians who believe that they are entitled to an APM Incentive Payment. Such QPs must notify CMS of their claim as directed in the public notice by November 1 of the payment year, or 60 days after CMS announces that initial payments for the year have been made, whichever is later. After that time, any claims by a QP to an APM Incentive Payment will be forfeited for such payment year.

Background/Rationale

CMS has proposed several changes to the APM payment and determination processes to adjust for the current COVID-19 PHE, as well as pre-existing issues. Notably, outside of these proposed changes, QP and PQ payment amount thresholds are still scheduled to increase to 75 percent and 50 percent, respectively, for CY 2021 (for the 2023 payment year).

Comments

CMS is seeking general comment on all aspects of these proposed changes as well as potential alternatives to consider.

AA. Qualifying APM Participant (QP) and Partial QP Determinations

Proposed Changes

- **Attribution and Threshold Score Calculations**

CMS is proposing to redefine beneficiary attribution requirements for APM Entities to ensure that beneficiaries who have been prospectively attributed to an APM Entity for a QP Performance Period will be excluded from the attribution-eligible beneficiary count for any other APM Entity that is participating in an APM where that beneficiary would be ineligible to be added to the APM Entity's attributed beneficiary list.

- **Targeted Review of QP Determinations**

CMS is proposing to establish a targeted review process for limited circumstances surrounding QP determinations that would provide a systematic opportunity for ECs to request further determination review. Such targeted reviews could only be made if the EC or APM Entity believe in good faith that, due

to a CMS clerical error, an EC was omitted from a Participation List used for purposes of QP determinations (this would not be extended to omissions from the Affiliated Practitioner Lists). If CMS determines a clerical error was made, they are proposing to assign the omitted EC the most favorable QP status that was determined at the APM Entity level on any snapshot dates for the relevant QP performance Period on which the EC participated in the APM Entity.

- **COVID-19 PHE Advanced APM Determination and QP Determinations**

CMS is proposing the following changes to APM determination and QP determination processes:

- CMS will not reconsider the Advanced APM determinations of APMs which have already been evaluated and determined to meet the Advanced APM criteria for CY 2020, even in the event that the APMs make changes to their governing documents or operations in such a way that, if there were a redetermination, they would no longer meet the criteria to be an Advanced APM.
- CMS will evaluate all APMs in future years with the understanding that any provisions of the Participation Agreement or governing regulation designed in response to the COVID-19 PHE will not be considered to the extent they would prevent the APM from meeting the Advanced APM criteria for a year.
- CMS will not revoke the QP status of EC participants in an Advanced APM if the APMs governing documents are amended to initiate an earlier end date

To reduce burden for individual ECs and allow APM Entities to have a "centralized source of feedback as to the statuses of their individual EC participants," CMS is also proposing to allow an APM Entity to make the Partial QP election on behalf of all of the individual ECs associated with such Entity. CMS acknowledges, however, that allowing this may cause election conflicts.

Background/Rationale

- **Attribution and Threshold Score Calculations**

CMS notes that, under the current methodology for calculating Threshold Scores, eligible beneficiaries can be attributed to the denominator of the calculation for some APM Entities for whom those same beneficiaries could never be included in the numerator. This may happen in a scenario where a beneficiary is prospectively attributed to an APM Entity and as a result is precluded, by the applicable rules for one or more APMs, from attribution to other APM Entities in certain other APMs.

- **Targeted Review of QP Determinations**

CMS looks to align the targeted review process with that of the MIPS targeted review process codified at § 414.1385. Either an EC or APM Entity may submit a request for targeted review.

- **COVID-19 PHE Advanced APM Determination and QP Determinations**

CMS is proposing these changes in response to the demands of the COVID-19 PHE, and the systematic alterations occurring across certain APMs

Comments

CMS is seeking general comment on all aspects of these proposed changes as well as potential alternatives to consider.