ALLIANCE for CONNECTED CARE

Summary: Proposed Calendar Year 2021 Physician Fee Schedule

On August 3, 2020, CMS issued the proposed Calendar Year 2021 (CY2021) Physician Fee Schedule (PFS), which makes payment and policy changes under Medicare Part B.

CMS is waiving the 60-day delay in the effective date of the final rule, and is replacing it with a 30-day delay in the effective day of the final rule due to "the significant devotion of resources to the COVID-19 response."

Below is a summary of key payment and policy changes within the rule.

Comments are due by October 5, 2020.

Section II – Provisions of the Proposed Rule for the PFS

D. Telehealth and Other Services Involving Comms Technology

- ***Payment for Medicare Telehealth Services Under Section 1834(m) of the Act***
    - a. Adding services to the Medicare Telehealth Services List.
        - Category 1. Services that are similar to services on the existing Medicare telehealth services list for the roles of, and interactions among, the beneficiary, physician (or other practitioner) at the distant site and, if necessary, the telepresenter.
        - Category 2. Services that are not similar to those on the current Medicare telehealth services list but provide a demonstrated clinical benefit to the patient.
    - b. Requests to Add Services to the Medicare Telehealth Services List for CY 2021

For CY 2021, CMS is proposing to add the following list of services to the Medicare telehealth list on a Category 1 basis.

Service Type	HCPCS Code
Visit complexity inherent to evaluation and management associated with primary medical care services that serve as the continuing focal point for all needed health care services	GPC1X
Group psychotherapy (other than of a multiple-family group)	90853
Neurobehavioral status exam	96121
Prolonged office or other outpatient evaluation and management service(s)	99XXX
Assessment of and care planning for a patient with cognitive impairment	99483
Domiciliary or rest home visit for the evaluation and management of an established patient. Typically, 15 minutes are spent with the patient and/or family or caregiver	99334
Domiciliary or rest home visit for the evaluation and management of an established patient. Typically, 25 minutes are spent with the patient and/or family or caregiver	99335
Home visit for the evaluation and management of an established patient. Typically, 15 minutes are spent face-to-face with the patient and/or family.	99347
Home visit for the evaluation and management of an established patient. Typically, 25 minutes are spent face-to-face with the patient and/or family.	99348

- *Home Visits* - CMS makes special note that it is unable to approve the patient's home as an originating site for telehealth due to statutory restrictions. **However, a patient's home may be used as the originating site for purposes of treatment of a substance use disorder or a co-occurring mental health disorder**. (The SUPPORT for

Patients and Communities Act amended section 1834(m)(4)(C) of the Act and added a new paragraph at section 1834(m)(7) of the Act to remove geographic limitations and authorize the patient's home to serve as a telehealth originating site for purposes of treatment of a substance use disorder or a co-occurring mental health disorder, furnished on or after July 1, 2019, to an individual with a substance use disorder diagnosis.) **Therefore, CMS note that, because the home is not generally a permissible telehealth originating site, these services could be billed when furnished as telehealth services only for treatment of a substance use disorder or co-occurring mental health disorder.**

- c. Proposed Temporary Addition of a Category 3 Basis for Adding to or Deleting Services from the Medicare Telehealth Services List.
  - Category 3. CMS is proposing to create a third category of criteria for adding services to the Medicare telehealth services list on a temporary basis. Any service added under the proposed Category 3 would remain on the Medicare telehealth services list **through the calendar year in which the PHE ends** – recognizing that the PFS schedule may not align with the expiration of the PHE.
    - This list includes services that were added during the PHE for which there is likely to be a clinical benefit when furnished via telehealth, but for which there is not yet evidence available to consider the services as permanent additions under Category 1 or Category 2 criteria. CMS notes that adding services to the Medicare telehealth services list on a Category 3 basis will give the public the opportunity to gather data and generate requests to add certain services to the Medicare telehealth services list permanently during a future rulemaking.
    - When assessing whether there was a potential likelihood of clinical benefit for a service such that it should be added to the Medicare telehealth services list on a Category 3 basis, CMS considered the following factors:
      - Whether, outside of the circumstances of the PHE, there are increased concerns for patient safety if the service is furnished as a telehealth service.
      - Whether, outside of the circumstances of the PHE, there are concerns about whether the provision of the service via telehealth is likely to jeopardize quality of care.
      - Whether all elements of the service could fully and effectively be performed by a remotely located clinician using two-way, audio/video telecommunications technology.

For CY 2021, CMS is proposing to add the following list of services to the Medicare telehealth list on a Category 3 basis.

Service Type	**HCPCS Code**
Domiciliary, Rest Home, or Custodial Care services, Established patients	99336
	99337
Home Visits, Established Patient	99349
	99350

Emergency Department Visits	99281
	99282
	99283
Nursing facilities discharge day management	99315
	99316
Psychological and Neuropsychological Testing	96130
	96131
	96132
	96133

- *Telehealth Services for the PHE That Are Not CY 2021 Medicare Telehealth Proposals. CMS is seeking comment and any evidence supporting their inclusion on either a Category 3 or permanent basis.*

Service Type	**HCPCS Code**
Radiation Treatment Management Services	77247
End-Stage Renal Disease (ESRD) Services	90952 – 90953
	90959
	90962
Psychological and Neuropsychological Testing	96136 – 96139
Therapy Services, Physical and Occupational Therapy, All levels	92521 – 92524
	92507
	97161 – 97168
	97110
	97112
	97116
	97535
	97750
	97755
	97760 – 97761
Hospital, ICU, Emergency care, Observation stays	99217 – 99226
Higher Level Emergency Department Visits	99284 – 99285
Initial and final observation and discharge day management visits	99234 – 99236
	99238 – 99239
Inpatient Neonatal and Pediatric Critical Care	99468 – 99469
	99471 – 99476
Initial and Continuing Intensive Care Services	99477 – 99480
Critical Care Services	99291 – 99292

- d. Comment Solicitation on Medicare Telehealth Services Added on an Interim Basis During the PHE for the COVID-19 Pandemic that CMS is Not Proposing to Retain After the PHE Ends
  - CMS is requesting specific comment on temporary addition to the Medicare telehealth services list through Category 3 criteria including:
    - Whether any ***service*** added to the Medicare telehealth services list for the duration of the PHE for the COVID19 pandemic should be added to the Medicare telehealth services list on a temporary, Category 3 basis
    - Initial and final/discharge interactions (CPT codes 99234-99236 and 99238-99239)
    - Higher level emergency department visits (CPT codes 99284-99285)

        - Hospital, Intensive Care Unit, Emergency care, Observation stays (CPT codes CPT 99217-99220; 99221-99226; 99484-99485, 99468-99472, 99475- 99476, and 99477- 99480)
    - CMS is requesting comment on physical therapy, occupational therapy, and speech-language pathology services: (*CMS notes that statutory restrictions at 1834(m)(E) specify the types of practitioners who may furnish and bill Medicare telehealth services)*
        - Whether physical therapy, occupational therapy, and speech-language pathology services should be added to the Medicare telehealth services list so that, in instances when a practitioner who is eligible to bill for telehealth services furnishes these services via telehealth, they could bill and receive payment for them.
        - CMS is also seeking comment on whether all aspects of physical therapy, occupational therapy, and speech-language pathology services can be fully and effectively furnished via two-way, audio/video telecommunications technology.
    - CMS is requesting comment on critical care services (99291 – 99292):
        - The definition, potential coding and valuation for this kind of remote service
        - Whether current coding (either through the CPT codes describing in-person critical care or the HCPCS G codes describing critical care consults furnished via telehealth) does not reflect additional models of critical care delivery, specifically, models of care delivery that utilize a combination of remote monitoring and clinical staff at the location of the beneficiary to allow, when an onsite practitioner is not available, for a practitioner at a distant site to monitor vital signs and direct in-person care as needed.
        - 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.

- ***Technical Refinement to the Medicare Telehealth Services List to Reflect Current Coding***
    - CMS is proposing to delete CPT codes 96150-96155 from the Medicare telehealth services list and replace them with the following successor codes:
        - CPT code 96156 (Health behavior assessment, including reassessment;
        - CPT code 96158 (Health behavior intervention, individual, face-to-face; initial 30 minutes);
        - CPT code 96159 (Health behavior intervention, individual, face-to-face; each additional 15 minutes;
        - CPT code 96164 (Health behavior intervention, group (2 or more patients), face-to-face; initial 30 minutes);

        - CPT code 96165 (Health behavior intervention, group (2 or more patients), face-to-face; each additional 15 minutes;
        - CPT code 96167 (Health behavior intervention, family (with the patient present), face-to-face; initial 30 minutes);
        - CPT code 96168 (Health behavior intervention, family (with the patient present), face-to-face each additional 15 minutes;
        - CPT code 96170 (Health behavior intervention, family (without the patient present), face-to-face; initial 30 minutes); and
        - CPT code 96171 (Health behavior intervention, family (without the patient present), face-to-face; each additional 15 minutes
    - CMS is also proposing to amend regulations to stipulate that when new codes are issued to replace codes that describe the same clinical services that are currently on the Medicare telehealth services list, CMS will consider those new codes to be successor codes to those that are on the Medicare telehealth services list, and will update the Medicare telehealth services list accordingly.
- ***Furnishing Telehealth Visits in Inpatient and Nursing Facility Settings, and Critical Care Consultations***
    - CMS is seeking comment on whether it would be appropriate to maintain the flexibility during the PHE for the COVID-19 pandemic for physicians and nonphysician practitioners to personally perform required visits for nursing home residents via telehealth. CMS is seeking comment on whether the in-person visit requirement is necessary, or whether two-way, audio/video telecommunications technology would be sufficient in instances when, due to continued exposure risk, workforce capacity, or other factors, the clinician determines an in-person visit is not necessary.
- ***Proposed Technical Amendment to Remove References to Specific Technology***
    - CMS is proposing to remove the second sentence of the regulation at § 410.78(a)(3) which specifies that "[t]elephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system."
- ***Communication Technology-Based Services (CTBS)***
    - CMS is proposing to adopt on a permanent basis that HCPCS codes G2061 through G2063 could be billed by licensed clinical social workers and clinical psychologists, as well as PTs, OTs, and SLPs who bill Medicare directly for their services when the service furnished falls within the scope of these practitioner's benefit categories.
        - CMS is seeking comment on other benefit categories into which these services fall.
    - CMS is proposing to allow billing of other CTBS by certain nonphysician practitioners, consistent with the scope of these practitioners' benefit categories through the creation of two additional HCPCS G codes that can be billed by practitioners who cannot independently bill for E/M services. CMS is proposing to value these services identically to HCPCS codes G2010 and G2012 but is seeking comment on whether CMS should value these services differentially, including potentially increasing the valuation of HCPCS codes G2010 and G2012.
        - G20X0 (Remote assessment of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up

with the patient within 24 business hours, not originating from a related service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment.)

- G20X2 (Brief communication technology-based service, e.g. virtual check-in, by a qualified health care professional who cannot report evaluation and management services, provided to an established patient, not originating from a related e/m service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion)

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

- ***Comment Solicitation on Continuation of Payment for Audio-only Visits***
  - CMS is not proposing to continue to recognize these codes for payment under the PFS after conclusion of the PHE for the COVID-19 pandemic because, outside of the circumstances of the PHE, we are not able to waive the requirement that telehealth services be furnished using an interactive telecommunications system that includes two-way, audio/video communication technology. CMS notes that the CARES Act allowed its emergency waiver of video technology requirements under 1834m, which will cease at the end of the PHE.
  - CMS is seeking comment on:
    - Whether CMS should develop coding and payment for a service similar to the virtual check-in but for a longer unit of time and with an accordingly higher value.
    - The appropriate duration interval for such services and the resources in both work and PE that would be associated with furnishing them.
    - Whether separate payment for such telephone-only services should be a provisional policy to remain in effect until a year or some other period after the end of the PHE or if it should be PFS payment policy permanently.
- ***Comment Solicitation on Coding and Payment for Virtual Services (remote patient monitoring, virtual check-ins, remote asynchronous service)***
  - CMS is seeking comment on whether there are additional services that fall outside the scope of telehealth services under section 1834(m) of the Act where it would be helpful for CMS to clarify that the services are inherently non-face-to-face, so do not need to be on the Medicare telehealth services list in order to be billed and paid when furnished using telecommunications technology rather than in person with the patient present.
  - CMS is also seeking comment on physicians' services that use evolving technologies to improve patient care that may not be fully recognized by current PFS coding and payment, including, for example, additional or more specific coding for care management services.
  - CMS is broadly seeking comment on any impediments that contribute to healthcare provider burden and that may result in practitioners being reluctant to bill for CTBS.
- ***Proposed Clarification of Existing PFS Policies for Telehealth Services***

  - CMS is proposing to clarify that services that may be billed incident-to may be provided via telehealth incident to a physicians' service and under the direct supervision of the billing professional.
  - CMS is also clarifying that if audio/video technology is used in furnishing a service when the beneficiary and the practitioner are in the same institutional or office setting, then the practitioner should bill for the service furnished as if it was furnished in person, and the service would not be subject to any of the telehealth requirements under section 1834(m) of the Act or § 410.78 of the regulations.
- ***Direct Supervision by Interactive Telecommunications Technology***
  - For the duration of the PHE for the COVID-19 pandemic, CMS adopted an interim final policy revising the definition of direct supervision to include virtual presence of the supervising physician or practitioner using interactive audio/ video real-time communications technology
  - CMS is proposing to extend this policy until the later of the end of the calendar year in which the PHE ends or December 31, 2021
- ***Comment Solicitation on PFS Payment for Specimen Collection for COVID-19 Tests***
  - In the May 1st COVID-19 IFC, CMS finalized on an interim basis that physicians and NPPs may use CPT code 99211 to bill for services furnished incident to their professional services, for both new and established patients, when clinical staff assess symptoms and collect specimens for purposes of COVID–19 testing, if the billing practitioner does not also furnish a higher level E/M service to the patient on the same day.
  - CMS is requesting comment on whether to extend or make permanent the policy to allow physicians and NPPs to use CPT code 99211 to bill for services furnished incident to their professional services, for both new and established patients, when clinical staff assess symptoms and collect specimens for purposes of COVID–19 testing

E. Care Management Services and Remote Physiologic Monitoring Services

- ***Digitally Stored Data Services/Remote Physiologic Monitoring/Treatment Management Services (RPM)***
  - CMS is proposing on a permanent basis to allow consent to be obtained at the time that RPM services are furnished.
  - CMS is also proposing to allow auxiliary personnel (which includes other individuals who are not clinical staff but are employees, or leased or contracted employees) to furnish services described by CPT codes 99453 and 99454 under the general supervision of the billing physician or practitioner.
  - CMS is clarifying that only physicians and or nonphysician practitioners (NPPs) who are eligible to furnish E/M services may order bill RPM services (99453, 99454, 99091, 99457, and 99458).
  - CMS is clarifying that practitioners may furnish RPM services to patients with acute conditions as well as patients with chronic conditions.
  - CMS is clarifying that "interactive communication" for purposes of CPT codes 99457 and 99458 involves, at a minimum, a real-time synchronous, two-way audio interaction that is capable of being enhanced with video or other kinds of data transmission.

  - CMS is clarifying that when the PHE for the COVID-19 pandemic ends, CMS will again require that an established patient-physician relationship exist for RPM services to be furnished.
  - CMS is seeking comment on whether the current RPM coding accurately and adequately describes the full range of clinical scenarios where RPM services may be of benefit to patients.
- ***Transitional Care Management***
  - CMS is proposing to remove 14 additional actively priced (not bundled or non-covered) HCPCS codes from the list of remaining HCPCS codes that cannot be billed concurrently with TCM.
  - CMS is also proposing to allow the new Chronic Care Management code HCPCS code G2058 to be billed concurrently with TCM when reasonable and necessary.
- ***Psychiatric Collaborative Care Model (CoCM) Services (HCPCS code GCOL1)***
  - CMS is proposing to establish a G-code to describe 30 minutes of behavioral health care manager time. The proposed work RVU for the new proposed code is 0.77. CMS is proposing this code could be used for either the initial month or subsequent months. CMS proposes to add HCPCS code GCOL1 to the list of designate care management services for which CMS allows general supervision. The required elements listed for CPT code 99493 would also be required elements for billing GCOL1.
    - The proposed code is: 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.

F. 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

- ***Time Values for Levels 2-5 Office/Outpatient E/M Visit Codes***: CMS proposes beginning for CY 2021 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 Monthly Capitation Payment Services: CMS proposes 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 build into each code.
  - TCM Services: Because both TCM codes include a required face-to-face E/M visit (either a level 4 or 5 office/outpatient E/M visit), CMS proposes 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.
  - Maternity Services: CMS proposes to increase the work RVUs, physician time, and PE inputs in the form of clinical staff time associated with the maternity packages by accepting the revaluation recommendation from the AMA RUC.
  - Assessment and Care Planning for Patients with Cognitive Impairment (CPT code 99483): CMS notes that the revaluation finalized in the CY 2020 PFS final rule for CPT code 99205

effective beginning CY 2021, 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. CMS doesn't believe this is appropriate, so proposes to update the work, time, and PE in the form of clinical staff time for CPT code 99483.

- Initial Preventive Physical Examination (IPPE) and Initial and Subsequent Annual Wellness Visits: CMS proposes to adjust upward the work, physician time, and direct PE inputs for HCPCS codes G0428 and G0402.
- Emergency Department Visits: CMS proposes to update the values for ED visits to reflect the relativity with office/outpatient E/M visits, per recommendations from the American College of Emergency Physicians.
- Therapy Evaluations: CMS proposes 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. CMS calculates this adjustment based on a volume-weighted average of the increases to the office/outpatient E/M visit work RVUs from CY 2020 to CY 2021.
- Behavioral Healthcare Services: 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 add-on psychotherapy services with equivalent times. CMS proposes to increase the work RVU for CPT code 90834 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 min of psychotherapy, CMS proposes to increase its work RVU based on the increase to CPT code 99213. For CPT code 90837, which describes 60 min of psychotherapy, CMS proposes to increase the work RVU based on the proportional increase to CPT codes 99214 and 90838.
- Ophthalmological Services: CMS was asked to reevaluate these services, but they do not propose to revalue these services because they are not sufficiently analogous or connected to the office/outpatient E/M visit codes.

- ***Comment Solicitation on the Definition of HCPCS code GPC1X***
  - CMS continues to believe that the typical visit described by the revised and revalued office/outpatient E/M visit code set still does not adequately describe or reflect the resources associated with primary care and certain types of specialty visits.
  - In the CY 2020 PFS final rule, CMS finalized the HCPCS add-on code GPC1X which describes the "visit complexity inherent to E/M 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." Since the publication of the CY 2020 PFS, some specialty societies have stated that the definition is unclear.
  - CMS is soliciting comments with additional, more specific information regarding what aspects of the definition of HCPCS add-on code GPC1X are unclear, how CMS might address those concerns, and how CMS might refine its utilization assumptions for the code.
- ***Prolonged Office/Outpatient E/M Visits (CPT code 99XXX)***

- CMS previously finalized CPT code 99XXX *(Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each additional 15 minutes (List separately in addition to CPT codes 99204, 99215 for office or other outpatient E/M services)*, and indicated that the code could be reported when the physician's or NPP's time is used for code level section and the time for a level 5 office/outpatient E/M visit is exceeded by 15 minutes or more.
- In this rule, CMS states that it believes that 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. CMS proposes 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.

G. Scope of Practice and Related Issues

- ***Virtual Teaching Physician Presence during Medicare Telehealth Services*** – CMS is considering whether this policy should be extended on a temporary basis (that is, if the PHE ends in 2021, this policy could be extended to December 31, 2021 to allow for a transition period before reverting to status quo policy) or be made permanent, and are soliciting public comments on whether this policy should continue once the PHE ends.
- ***Primary Care Exception Policies*** – CMS also 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 similarly considering an extension like above.

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

- The SUPPORT Act established a new Medicare Part B benefit category for OUD treatment services furnished by OTPs during an episode of care, beginning on or after January 1, 2020. For CY2021, CMS is proposing several refinements and seek to provide clarification on certain issues:
  - ***Definition of OUD Treatment Services*** – CMS is proposing to add opioid antagonist medications, such as Naloxone, to the list of covered OUD treatment services.
  - ***Proposed Adjustment to the Bundled Payments for OUD Treatment Services*** – CMS proposes to adjust the bundled payment rates through the use of add-on codes to account for instances in which OTPs provide Medicare beneficiaries with Naloxone.
    - CMS proposes to adopt two add-on G codes:
      - *HCPCS code GOTP1*: Take-home supply of nasal naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.
      - *HCPCS code GOTP2*: Take-home supply of auto-injector naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.

- Drug Pricing for Nasal Naloxone – payment will be ASP + 0.
- Drug Pricing for Auto-Injector Naloxone – payment will be the lower of ASP + 0, WAC + 0, or NADAC.
- Frequency Limit – CMS proposes to apply a limit on the frequency of the add-on payment for Naloxone dispensed by OTPs to one add-on code every 30 days to the extent that it is medically reasonable and necessary.

- ***WAC Pricing*** – Section 1834(w) of the Act gives the Secretary discretion to establish bundled payment rates for OUD treatment services. In the CY2020 PFS final rule, CMS limited payments to OTPs for injectable and implantable drugs to 100 ASP. The Act allows CMS to use other payment methodologies when ASP is now available, including WAC and AMP. Now, CMS is amending the OTP drug pricing methodology to limit WAC-based payments to 100 percent of WAC.
- ***Billing and Payment Policies –***
  - Institutional Claim Forms – CMS is exploring claims processing flexibilities requested by some OTPs that would allow them to bill services on institutional claims, rather than professional claim forms.
  - Periodic Assessments – CMS has received inquiries from stakeholders related to what activities would qualify to bill the add-on code for periodic assessments, HCPCS code G2077. CMS originally stated that the services need to be medically reasonable and necessary and that OTPs should document the rationale for billing the add-on code in the patient's medical record. Now, CMS proposes that to bill for G2077, a face-to-face medical exam or biopsychosocial assessment needs to have been performed. Additionally, CMS notes that in the May 8 IFC, it allowed periodic assessments to be furnished during the PHE via two-way interactive audio-visual communication technology. CMS is now also proposing to allow periodic assessments to be furnished via two-way interactive audio-visual communication technology moving forward. Note – use of audio-only calls will not be extended beyond the PHE.
  - Date of Service – In the CY2020 PFS, CMS defined an episode of care as a 1-week period, but has received questions about how that aligns with "standard billing cycles." CMS proposes that OTPs may choose to apply a standard billing cycle by setting a particular day of the week to begin all episodes of care.
  - Coding – CMS welcomes comments on how it may better account for differences in resource costs among patients over the course of treatment in coding adjustments.
  - Annual Updates – CMS notes that the payment for the non-drug component of the bundled payment for OUD treatment services will be updated annually based on the Medicare Economic Index.

Section III – Other Provisions of the Proposed Rule

F. Medicaid Promoting Interoperability Program Requirements for Eligible Professional (EP)

- CMS is proposing to amend the list of available electronic clinical quality measures (eCQMs) available to Medicaid Eligible Professionals (EPs) participating in the Medicaid Promoting Interoperability Program so that they align with those available to eligible clinicians in MIPS.

- CMS is also maintaining its requirement that Medicaid EPs report on any six eCQMs that are relevant to their scope of practice, regardless of whether they report via attestation or electronically, and including one outcome measure.
    - The eCQMs that would be available for Medicaid EPs to report in 2021, that are both part of the Core Sets and on the MIPS list of eCQMs, and that would be considered high priority measures under our proposal are: CMS2, "Preventive Care and Screening: Screening for Depression and Follow-Up Plan"; CMS122, "Diabetes: Hemoglobin A1c (HbA1c) Poor Control (> 9%)"; CMS125, "Breast Cancer Screening"; CMS128, "Anti-depressant Medication Management"; CMS136, "Follow-Up Care for Children Prescribed ADHD Medication (ADD)"; CMS137, "Initiation and Engagement of Alcohol and Other Drug Dependence Treatment"; CMS153, "Chlamydia Screening for Women"; CMS155, "Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents"; and CMS165, "Controlling High Blood Pressure."

G. Medicare Shared Savings Program

- ***Quality and Other Reporting Requirements***
    - **Applying the Alternative Payment Model (APM) Performance Pathway (APP) to Shared Savings Program ACOs:**
        - CMS proposes that ACOs would only need to report one set of quality metrics that would satisfy the reporting requirements under both MIPS and MSSP. Under this proposal, for PY 2021 and subsequent performance years, ACOs would be assessed on a smaller measure set. ACOs will be scored on 6 measures, and would be required to actively report on the following 3 measures:
            - Diabetes: Hemoglobin A1c Poor Control
            - Preventive Care and Screening: Screening for Depression and Follow-Up Plan
            - Controlling High Blood Pressure
        - ACOs would also still be required to field a CAHPS for MIPS survey and would be measure on two-claims based measures: the Hospital-Wide, 30-day, All-Cause Unplanned Readmission Rate for MIPS Eligible Clinician Groups; and the All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions.
        - If an ACO does not report any of the three APP measures it is required to actively report and does not field a CAHPS for MIPS survey the ACO would not meet the quality performance standard for purposes of MSSP and would not be able to share in savings and would own maximum losses, if applicable. For MIPS scoring purposes, an ACO that fails to report via the APP would receive a zero in the Quality performance category under MIPS.
        - In addition to the six measures included in the proposed APP, CMS notes that it is also considering a adding a "Days at Home" measure. This measure is currently under development and may be added to the APP core measure set in future years once it has been through the MAP pre-rulemaking process.
        - CMS is seeking comment on an alternative approach that could be used in the event the three measures ACOs are required to actively report on are not applicable to their beneficiary population and there are more appropriate measures available under

MIPs.

Under the alternative approach, ACOs could opt out of APP and report to MIPS as an APM entity. If an ACO decides to report to MIPS, the CAHPS survey would become optional, but the ACO would be required to report Promoting Interoperability and Clinical Improvement Activities and would also be subject to the Cost component.

- ***MSSP Quality Performance Standard***
  - CMS proposes to increase the quality performance standard for all ACOs to achievement of a quality performance score equivalent to the 40th percentile or above across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring. CMS previously had a quality performance standard from the 30th percentile on one measure in each domain.
- ***Use of ACO Quality Performance In Determining Shared Savings and Shared Losses***
  - CMS proposes that to qualify for shared savings, an ACO must meet the minimum savings rate requirements established for the track/level, meet the proposed quality performance standard, and otherwise maintain its eligibility to participate in MSSP.
  - CMS proposes modifications for the methodology for determining shared losses under Track 2 and the ENHANCED Track for PYs beginning on or after January 1, 2021 to account for the proposed revisions to the quality performance standard. Under the proposed approach, for an ACO that meet the quality performance standard, CMS would take into consideration the ACO's quality score when determining the ACO's share of losses.
  - CMS proposes that if the ACO fails to meet the quality performance standard as proposed, the shared loss rate would be 60 percent under Track 2 or 75 percent under the ENHANCED Track.
- ***Compliance with the Quality Performance Standard***
  - CMS proposes a new approach for monitoring and addressing an ACO's continued noncompliance with the applicable quality performance standard for PYs beginning on or after January 1, 2021.
  - CMS proposes that when CMS determines an ACO fails to meet the quality performance standard, CMS may take the actions prior to termination and may terminate the ACO's participation agreement.
  - CMS proposes to terminate an ACO's participation agreement when the ACO fails to meet the quality performance standard for 2 consecutive performance years within an agreement period or fails to meet the quality performance standard for any 3 performance years within an agreement period, regardless of whether the years are in consecutive order.
  - CMS proposes that it will terminate the participation agreement of a renewing ACO or a re-entering ACO if the ACO fails to meet the quality performance standard for 2 consecutive performance years across 2 agreement periods, specifically the last performance year of the ACO's previous agreement period and the first performance year of the ACO's new agreement period.
  - CMS also proposes that it will terminate the participation agreement of a renewing ACO or a re-entering ACO if the ACO fails to meet the quality performance standard for the last performance year of the ACO's previous agreement period and this occurrence was either the second consecutive performance year of failed quality performance or the third

nonconsecutive performance year of failed quality performance during the previous agreement period.

- ***Updating the Process Used to Validate ACO Quality Data Reporting***
  - Rather than continuing to validate ACO quality data reporting under MSSP, CMS believes that it would be more appropriate for MIPS to validate the data submitted by ACOs for the three measures in the APP framework, as ACOs will be able to select the submission method for these measures and the MIPS DVA is based on submission method.
- ***Changes to the Extreme and Uncontrollable Circumstances Policy for PY 2021***
  - CMS proposes to update the extreme and uncontrollable circumstances policy under MSSP consistent with its proposal to align the quality reporting requirements for MSSP with the proposed APP.
  - For PY 2021 and subsequent PYs, CMS would set the minimum quality performance score for an ACO affected by an extreme and uncontrollable circumstance during the PY, including the applicable quality data reporting period for the PY, to equal the 40th percentile MIPS Quality performance category score.
  - If the ACO is able to report quality data and meet the MIPS data completeness and case minimum requirements, we would use the higher of the ACO's MIPS Quality performance category score or the 40th percentile MIPS Quality performance score.
  - If an ACO is unable to report quality data and meet the MIPS Quality data completeness and case minimum requirements due to extreme and uncontrollable circumstance, CMS would apply the 40th percentile MIPS Quality performance category cores.
  - CMS proposes to determine the percentage of the ACO's performance year assigned beneficiary population that was affected by an extreme and uncontrollable circumstances based on the quarter four list of assigned beneficiaries, rather than the list of assigned beneficiaries used to generate the CMS Web Interface, which is currently used.
  - CMS is soliciting comment on a potential extreme and uncontrollable circumstances policy for PY 2022 and beyond that would continue to incentivize reporting but also acknowledge the challenges presented by extreme and uncontrollable circumstances. CMS is considering creating a methodology that would adjust the amount of shared savings determined for affected ACOs that complete quality reporting but do not meet the quality performance standard or that are unable to complete quality reporting.
- ***Revisions to the Definitions of Primary Care Services used in MSSP Beneficiary Assignment***
  - CMS proposes to revise the definition of primary care services in the MSSP regulations to include the following additions:
    - Online digital evaluation and management CPT codes 99421, 99422, and 00423
    - Assessment of and care planning for patients with cognitive impairment CPT code 99483
    - Chronic care management code CPT code 99491
    - Non-complex chronic care management HCPCS code G2058 and its proposed replacement CPT code, if finalized through the CY 2021 PFS rulemaking
    - Principal care management HCPCS codes G2064 and G2065; and
    - Psychiatric collaborative care model HCPCS code GCOL1, if finalized through CY 2021 PFS rulemaking.

- CMS seeks comments on the idea of permanently includes HCPCS codes G2010 (code for remote evaluation of recorded video and/or images submitted by an established patient) and G2012 (code for brief communication technology-based service) in the definition of primary care used in assignment.
- CMS proposes to modify the definition of primary care services for purposes of assignment in MSSP to exclude advance care planning CPT code 99497 and the add-on code 99498 when billed in an inpatient care setting, for use in determining beneficiary assignment for the PY starting January 1, 2021 and subsequent PYs. CMS seeks comments on determining operationally whether advance care planning services are provided in an inpatient care setting.

- ***Exclusion from Assignment of Certain Services Reported by FQHCs or RHCs When Furnished in SNFs***
  - CMS proposes to revise the existing exclusion for professional services billed under CPT codes 99304 through 99318 that are furnished in a SNF to include services reported on an FQHC or RHC claim that includes CPT codes 99304 through 99318, when those services are furnished in a SNF. Operationally, the exclusion would occur when the following conditions are met:
    - Either a professional service is billed under CPT codes 99304 through 99318, or an FQHC/RHC submits a claim including a qualifier CPT code 99304 through 99318; and
    - A SNF facility claim is in CMS claims files with dates of service that overlap with the date of service for the professional service or FQHC/RHC service.
- ***Reducing the Amount of Repayment Mechanisms for Eligible ACOs***
  - CMS proposes two policies that would allow certain ACOs to benefit from a lower repayment mechanism amount than would otherwise be required under the current regulations.
  - CMS proposes to allow a renewing ACO that wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for PYs in the new agreement period to have a repayment mechanism equal to or lesser than the following: 1) 1 percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent CY for which 12 months of data is available; or 2) 2 percent of the total Medicare Parts A and B FFS revenue of its ACO participants, based on revenue for the most recent CY for which 12 months of data are available.
  - CMS also proposes to establish a policy that allows certain ACOs a one-time opportunity to decrease the amount of their repayment mechanisms. Under this proposal, an ACO that renewed its agreement period beginning on July 1,2 019 or January 1, 2020, may elect to decrease the amount of its repayment mechanism if 1) upon renewal, it elected to use an existing repayment mechanism to establish its ability to repay any shared losses incurred in its new agreement period and the amount of that repayment mechanism was greater than the repayment mechanism amount estimated for the ACO's new agreement period; and 2) the recalculated repayment mechanism amount for PY 2021 is less than the existing repayment mechanism amount.
- ***Applicability of Policies to Track 1+ Model ACOs***
  - CMS states that, unless otherwise specified, the proposed changes to MSSP regulations apply to ACOs in the Track 1+ Model in the same way that they apply to ACOs in Track 1, so long as the applicable regulation has not been waived under the Track 1+ Model. Similarly, to the extent that certain requirements of the regulations that apply to ACOs under Track 2 or the

ENHANCED Track have been incorporated for ACOs in the Track 1+ Model under the terms of the Track 1+ Model Participation Agreement, any proposed changes to those regulations would also apply to ACOs in the Track 1+ Model in the same way that they apply to ACOs in Track 2 or the ENHANCED Track.

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

- The 21st Century Cures Act created a separate Medicare Part B benefit and payment to cover home infusion therapy-associated professional services for certain drugs and biologicals administered intravenously or subcutaneously through a pump that is an item of durable medical equipment, effective January 1, 2021.
- CMS proposes that for home infusion therapy services effective beginning CY 2021, physicians may continue with their current practice of discussing options available for furnishing home infusion therapy under Part B and annotating these discussions in their patients' medical records prior to establishing a home infusion therapy plan of care. CMS is not proposing any additional required forms or frequency of notifications.

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

- The SUPPORT Act mandates that the prescribing of controlled substances under Part D be done electronically in accordance with an electronic prescription drug program, beginning January 1, 2021. The SUPPORT Act provides HHS with authority to specify circumstances and processes by which the Secretary may waive the EPCS requirement and to enforce and specify appropriate penalties for non-compliance.
- CMS plans on using the public feedback from the Medicare Program Electronic Prescribing for Controlled Substances (EPCS) Request for Information released on August 4, 2020 on the appropriate waivers and whether CMS should impose penalties for noncompliance with the EPCS mandate to inform future standalone rulemaking.
- In this proposed rule, CMS encourages all prescribers to conduct EPCS as soon as is feasible for them. Given the logistical challenges in operationalizing EPCS and the time required to analyze comments from the RFI, CMS proposes to move the deadline for prescriber adoption of EPCS to January 1, 2022.
- CMS also proposes that prescribers must use the NCPDP SCRIPT 2017071 standard since they are already required to use this when e-prescribing for covered Part D drugs and CMS believes prescribers should use the same standard for e-prescribing controlled substances.
- CMS seeks comments on the feasibility for prescribers to meet the proposed January 1, 2022 deadline, the impact of this proposal on overall interoperability and the impact on medical record systems. CMS is also interested in 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.

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

- Currently, payment for most separately payable Medicare Part B drugs and biologicals is determined using the methodology in section 1847A of the Act, and is largely paid based on ASP + 6%. Drugs largely into two categories: multiple source drugs, and single source drugs.

- However, there is a subset of drugs that do not easily fall into one of those two categories. These drugs, which are approved under section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, are not required to have the same labeling as other drugs. Although CMS has assigned some such products to separate single source billing and payment codes, some new drugs approved under this pathway correspond to existing products that are assigned to and paid under a multiple source drug code.
- CMS proposes to continue assigning certain section 505(b)(2) drug products to existing multiple source drug codes if the products are described by existing multiple source drug codes consistent with its interpretation of the definition of multiple source drugs.

M. Updates to Certified Electronic Health Record Technology due to the 21st Century Cures Act Final Rule

- ***Clarifications****:*
    - ONC proposed to remove several additional certification criteria associated with measures under the Promoting Interoperability Programs and MIPS from the 2015 Edition:
        - "Drug formulary and preferred drug check lists" at 170.315(a)(10)
        - "Secure messaging" at 170.315(e)(2); and
        - "Patient-specific education resource" at 170.315(a)(13).
    - "Secure messaging" and "patient-specific education resource" are necessary for participants to meet two of the measures in the Medicaid Promoting Interoperability Program. CMS is not proposing any chances to the measures as the final year of the Medicaid Promoting Interoperability Program is 2021, and ONC stated in its final rule that ONC-ACBs may continue to issue certification certificates for these criteria until January 1, 2022. CMS notes that "[h]ealth IT developers are encouraged to maintain the certified functionality for those two criteria through 2021, even if they move forward with updates to other criteria."
    - "Drug formulary and preferred drug check lists" criteria will be retired after January 1, 2022, so CMS states that this criteria would no longer be required for reporting e-prescribing measures for the Medicare Promoting Interoperability Program and MIPS, beginning in CY 2021.
- ***Proposals****:*
    - CMS proposes that the technology used by health care providers to satisfy the definitions of CEHRT 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.
    - CMS proposes that health care providers participating in the Promoting Interoperability Programs or QPP could be required to use only technology that is considered certified under the ONC Health IT Certification Program according to the times in the ONC final rule. During the 3 month period in which ONC is using enforcement discretion to extend certification timelines, health care providers may be certified to either version.

<u>Section IV – Quality Payment Program</u>

A. CY 2021 Updates to QPP

- Within the MIPS Cost performance category, CMS is proposing to Update existing measure specifications to include telehealth services that are directly applicable to existing episode-based cost measures and the TPCC measure.

- For a fact sheet on the CY 2021 Quality Payment Program proposed rule, please visit: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1100/2021%20QPP%20Proposed%20Rule%20Fact%20Sheet.pdf