

Vizient Office of Public Policy and Government Relations
Regulatory Update: CMS Proposed Rule – Revisions to Payment Policies under the Medicare
Physician Fee Schedule, Quality Payment Program and Other Revisions to Part B for CY 2020

August 26, 2019

On Monday, July 29, the Centers for Medicare & Medicaid Services (CMS) issued the <u>annual proposed rule</u> to update the calendar year (CY) 2020 Medicare payment and policies for the Physician Fee Schedule (PFS). The rule also proposes changes to the Quality Payment Program (QPP). Comments are due September 27, 2020, and Vizient looks forward to working with members to help inform our letter to the agency.

Background & Summary

This proposed rule revises payment polices under the Medicare PFS and makes other policy changes – including proposals to implement certain provisions of the Bipartisan Budget Act of 2018¹ (BiBA) related to Medicare Part B payment, and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act² (the SUPPORT Act) – applicable to services furnished in CY 2020 and thereafter.

This proposed rule also includes discussions and proposals regarding several other Medicare Part B payment policies, Medicare Shared Savings Program quality reporting requirements, Medicaid Promoting Interoperability Program requirements for eligible professionals, updates to the Quality Payment Program, Medicare enrollment of Opioid Treatment Programs and enhancements to provider enrollment regulations concerning improper prescribing and patient harm. The PFS Addenda along with other supporting documents and tables referenced in the proposed rule are available on the CMS website.

Calculation of the Proposed CY 2020 PFS Conversion Factor

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

CMS is proposing to update PFS rates by 0.14 percent for CY 2020, which includes the zero percent increase as required under current statute³. After this update and the budget-neutrality adjustment required by law to account for changes in relative value units (RVUs), the proposed 2020 PFS conversion factor is \$36.09 (a slight increase from the 2019 conversion factor of \$36.04).

Calculation of the Proposed CY 2020 PFS Conversion Factor			
CY 2019 Conversion Factor		36.0391	
Statutory Update Factor	0.00 percent (1.0000)		
CY 2020 RVU Budget Neutrality Adjustment	0.14 percent (1.0014)		
CY 2020 Conversion Factor		36.0896	

¹ Pub. L. No. 115-123

² Pub. L. No. 115-271

³ Pub. L. No. 114-10, amended by § 53106 of Public Law No. 115-123

Market-Based Supply and Equipment Pricing Update

Last year, CMS finalized proposals to update the PFS direct practice expense inputs (DPEI) for supply and equipment pricing, to be phased in over 4 years. Per this policy, one third of the difference between the CY 2019 price and the final price will be implemented in CY 2020. Table 8 of the proposed rule (pg. 59) provides the complete, fully implemented 4-year phase-in transition from the current to the new pricing. The full list of updated supply and equipment pricing as it will be implemented is made available as a public use file on the CMS website.

Payment for Medicare Telehealth Services - Proposals for CY 2020

In the CY 2003 PFS final rule, CMS established a process of adding services to or deleting services from the list of Medicare telehealth services. Submitted requests are assigned to one of two categories – 1 or 2 – which include services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the list of telehealth services or services that are not similar to those on the current list of telehealth services, respectively. CMS believes that Category 1 criteria streamlines their review process and expedites their ability to identify codes for the telehealth list that resemble services already on that list.

CMS believes that most services under the PFS that can be "appropriately furnished as Medicare telehealth services" have already been added to the Medicare Telehealth list and notes that the agency did not receive any requests from the public for additions to the list for CY 2020. However, CMS states that there are three Healthcare Common Procedure Coding System (HCPCS) G-codes the agency is proposing to adopt for CY 2020 that are "sufficiently similar to services currently on the telehealth list." Thus, for CY 2020, the agency is proposing to add the "face-to-face portions of the following services to the telehealth list on a Category 1 basis":

- HCPCS code GYYY1: Office-based treatment for opioid use disorder, including development of the
 treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70
 minutes in the first calendar month;
- HCPCS code GYYY2: Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month; and
- **HCPCS code GYYY3**: Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes (List separately in addition to code for primary procedure).

CMS believes that adding HCPCS codes GYYY1, GYYY2, and GYYY3 will be supplemental to current policies related to flexibilities in treating substance use disorders (SUDs) under Medicare Telehealth. The list of telehealth services, including the proposed additions described – can be found on the CMS website.

<u>Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (OTPs)</u>

Currently, Medicare covers medications for medication-assisted treatment (MAT), "including buprenorphine, buprenorphine-naloxone combination products, and extended-release injectable naltrexone under Part B or Part D, but does not cover methadone." Additionally, Medicare covers certain counseling and behavioral therapy services furnished by Medicare providers.

The SUPPORT Act⁴ (Section 2005) established a new Part B benefit for opioid use disorder (OUD) treatment services that are furnished by opioid treatment programs (OTPs) beginning on or after January 1, 2020. Previous statute defined OUD treatment services⁵ as "items and services furnished by an OTP⁶ [...] for treatment of OUD." The SUPPORT Act also amended the definition of "medical and other health services" to

⁴ Pub. L. No. 115-271, § 2005

⁵ Section 1861(jjj)(1) of the Act

⁶ As defined in section 1861(jjj)(2)) of the Act

provide for coverage of OUD treatment services – and established a "bundled payment to OTPs for OUD treatment services furnished during an episode of care beginning on or after January 1, 2020."

CMS is making proposals to implement Section 2005 of the SUPPORT Act including: 1) establishing definitions of OUD treatment services and OTP for Medicare; 2) creating a methodology for determining Medicare payment for these services provided by OTPs; and 3) codifying these policies in a new section of regulations⁷.

Proposed Definitions of OUD Treatment Services and OTP for Medicare

In addition to items and services listed in current statute⁸, CMS is proposing to define the OUD treatment services that may be furnished by OTPs to specifically include the medications approved by the Food and Drug Administration (FDA)⁹ for the use in treatment of OUD, the dispensing and administration of these medications (if applicable), substance use counseling, individual and group therapy, and toxicology testing. Currently, there are three drugs approved by the FDA for the treatment of opioid dependence – buprenorphine, methadone, and naltrexone¹⁰. Further, CMS is proposing to use the agency's discretion under current statute¹¹ to include "other items and services that the Secretary determines are appropriate" – and considers the use of telecommunications for certain services to be appropriate at this time. As part of the definition of OUD treatment services, CMS is proposing to specify that they are "an item or service that is furnished by an OTP that meets the applicable requirements to participate in the Medicare Program and receive payment."

CMS is seeking feedback on any other items and services – not including meals or transportation, which are statutorily prohibited – that are currently covered under Medicare Part B that should be added to this definition. The agency is requesting evidence supporting the impact of the use of these items and services in the treatment of OUD, as well as detailed information of their costs. Additionally, CMS is particularly interested in feedback regarding whether intake services, which include but are not limited to an initial physical exam and preparation of a treatment plan, should be included in the definition of an OUD treatment service.

Proposed Definition of an OTP

CMS is proposing to define an OTP as an entity that is an opioid treatment program as defined in current statute¹² and meets the applicable requirements for an OTP. Additionally, the agency is proposing that for an OTP to participate and receive payment under Medicare, the OTP must be enrolled under existing requirements¹³, have in effect a certification for their program from the Substance Abuse and Mental Health Services Administration (SAMHSA), and be accredited by an accrediting body approved by SAMHSA. CMS is also proposing that an OTP must have a provider agreement as required currently by law¹⁴.

Proposed Bundled Payments for OUD Treatment Services

The SUPPORT Act¹⁵, directs the agency "to pay to the OTP an amount that is equal to 100 percent of a bundled payment for OUD treatment services that are furnished by the OTP to an individual during an episode of care." CMS is proposing to establish bundled payments for OUD treatment services which would include the treatments and services they are proposing to define (see above). CMS is proposing to calculate the proposed bundled payments by applying separate payment methodologies for the drug component and the non-drug component (i.e., dispensing and administering of medications, substance use counseling, individual and group therapy, and toxicology testing). The agency is proposing to combine the drug component and non-drug components to calculate the full bundled payment rate.

Beginning January 1, 2020, the agency is required to "pay an OTP an amount that is equal to 100 percent of the bundled payment for OUD treatment services furnished by the OTP to an individual during an episode

⁷ At § 410.67

⁸ Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2))

⁹ Section 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 355)

¹⁰ https://www.fda.gov/drugs/information-drug-class/information-about-medication-assisted-treatment-mat

¹¹ Section 1861(jjj)(1)(F) of the Act

¹² 42 CFR 8.2 (or any successor regulation)

¹³ Section 1866(j) of the Act

¹⁴ Section 1866(a) of the Act

¹⁵ Section 1834(w) of the Act, added by section 2005 of the SUPPORT Act

¹⁶ Section 1834(w)(1) of the Act

of care." CMS is proposing that the duration of an episode of care for OUD treatment services would be a week (i.e., any contiguous 7-day period). The agency "recognize[s] that patients receiving MAT are often on this treatment regimen for an indefinite amount of time" – and thus, is "not proposing any maximum number of weeks during an overall course of treatment for OUD." CMS notes that this is similar to how the TRICARE bundled payments to OTPs for methadone are structured¹⁷, as well as payments by some state Medicaid programs. The agency welcomes input on whether they should consider a daily or monthly bundled payment.

Currently, SAMHSA requires 18 OTPs "to have a treatment plan for each patient that identifies the frequency with which items and services are to be provided." CMS notes that there could be a range of service intensity depending on each patient and stage of treatment, and thus a "full weekly bundle" could consist of services varying in frequency - but will still "consider the requirements to bill for the full weekly bundle to be met if the patient is receiving the majority of the services identified in their treatment plan at that time." For the purposes of valuation, CMS "assumed one substance use counseling session, one individual therapy session, and one group therapy session per week and one toxicology test per month." Due to expected changes in the intensity of services over time – based on an individual patient's needs – CMS states that they expect treatment plans to be updated to reflect these changes, or alternatively, noted in the patient's medical record (e.g., in a progress note). CMS is proposing that for cases where "the OTP has furnished the majority (51 percent or more) of the services identified in the patient's current treatment plan (including any changes noted in the patient's medical record) over the course of a week" - that the OTP could bill for a full weekly bundle. When the OTP has furnished at least one of the items or services, but less than 51 percent included in OUD treatment services over the course of a week, CMS is proposing a partial weekly bundle. CMS is proposing to base the OTP bundled payment rates on the type of medication used for treatment. In other words, the agency would categorize the bundled payments by drugs currently approved by the FDA for use in treatment of OUD. Table 15 of the proposed rule (pg. 178) contains the proposed OTP code descriptors, as well as the proposed approximate payment amounts for each. They can also be downloaded from the CMS website.

Bundled Payments Under the PFS for Substance Use Disorders

CMS is proposing to establish bundled payments for the overall treatment of OUD – which will include management, care coordination, psychotherapy, and counseling activities. However, if a patient's treatment includes MAT, this bundled payment would not include payment for the medication itself. Rather, the billing and payment for medications under Medicare Parts B or D would remain unchanged. Additionally, payment for medically necessary toxicology testing would not be included in this proposed bundle, and would continue to be separately billed under the Clinical Lab Fee Schedule. CMS believes that this proposed bundled payment will allow physicians and other providers to bill for a bundle of services that is similar to the OUD treatment services benefit described above but not furnished by an OTP, thus incentivizing greater counseling and care coordination while expanding access to care.

CMS is proposing to implement this new bundled payment through the creation of two new HCPCS G-codes to describe certain monthly bundles of services. These bundles of services consist of overall management, care coordination, individual and group psychotherapy and counseling for office-based OUD treatment. Although the agency did have the option of creating "weekly-reported codes" to describe the bundle of services, which would align with the proposed OTP bundle, CMS concluded that monthly-reported codes are more beneficial for the practice and billing of other types of care management services furnished in office settings and billed under the PFS, such as behavioral health integration services. The agency believes that monthly reported codes reduce the administrative burden on practitioners and are more consistent with care management in the office setting due to the fact that long acting MAT drugs, such as injectable naltrexone or implanted buprenorphine, are being used at a higher rate in the office setting compared to the OTP setting. CMS is proposing to use the same HCPCS codes as above to describe the different stages of treatment: HCPCS codes GYYY1, GYYY2, and GYYY3.

CMS recognizes that OUD treatment is quite variable and that certain treatment courses may be more resource intensive than others. For that reason, CMS is seeking input on how best to mitigate this issue, including whether or not they should create a separately billable code or codes to describe additional

¹⁷ 81 FR 61079

¹⁸ § 8.12(f)(4))

resources involved in furnishing OUD treatment-related services after the first month. CMS expresses concern that bundles could inadvertently limit the appropriate amount of OUD care furnished to patients who may have more complex and varying medical needs.

To help alleviate these concerns, the agency is proposing to create an <u>add-on code</u> which would make the appropriate payment for additional resource costs that might be limited by the bundled OUD payment. CMS is also seeking feedback on ways to maximize efficiency and flexibility in furnishing care, the positive consequences of the bundled payment, while still reflecting the varying needs of patients based on complexity or frequency of services in the coding for OUD treatment.

Although these codes are not limited to any particular physician or nonphysician practitioner specialty, the agency anticipates that these services would most often be billed by addiction specialty practitioners. CMS is also proposing not to require consultation with a psychiatric consultant or specialist as a condition of payment for these codes.

CMS recognizes that in some cases, OUD first becomes apparent to practitioners in the emergency department (ED) setting. The agency acknowledges that currently, there is not specific coding that describes the diagnosis of OUD or the referral for MAT in these situations. Thus, CMS is seeking input on the use of MAT in the ED setting – which includes the initiation of MAT, the potential for referral or follow-up care and the potential for the administration of long-acting MAT agents in this setting. Feedback received will help CMS understand typical practice patterns, and inform the agency on whether or not it should consider making separate payment for such services in future rulemaking.

Physician Supervision for Physician Assistant (PA) Services

Current law allows for services to be furnished by a physician assistant (PA) under the supervision of a physician. CMS has interpreted this to mean that PA services must be supervised according to the "general supervision" requirement, which is under a physician's "overall direction and control, but the physician's presence is not required during the performance of PA services." After receiving significant feedback from commenters stating that PAs now practice more autonomously and in states with more relaxed requirements, CMS is proposing to revise current regulations¹⁹ and proposing that the statutory physician supervision requirement for PA services²⁰ "would be met when a PA furnishes their services in accordance with state law and state scope of practice rules for PAs in the state in which the services are furnished, with medical direction and appropriate supervision as provided by state law in which the services are performed."

If there is no state law governing physician supervision of PA services, CMS is proposing that the requirement by Medicare for PA services would be "evidenced by documentation in the medical record of the PA's approach to working with physicians in furnishing their services." Additionally, uniform with current rules – the documentation would need to be available upon request to CMS. These proposed changes would significantly align these regulations with current regulations²¹ on physician collaboration for nurse practitioner (NP) and clinical nurse specialist (CNS) services.

Review and Verification of Medical Record Documentation

CMS notes that nonphysician practitioners (NPPs) who are authorized under Medicare Part B to furnish and be paid for all levels of evaluation and management (E/M) services would benefit from a relaxing of the "burdensome E/M documentation requirements that would allow them to review and verify medical record notes made by their students, rather than having to re-document the information." Types of nonphysician practitioners include NPs, CNSs, and certified nurse-midwives (CNMs) – which CMS collectively refers to for purposes of this proposal as advanced practice registered nurses (APRNs) and as PAs.

CMS believes that it would be appropriate to provide more flexibility to providers (including physicians, PAs, and APRNs) who document medical records and are paid under the PFS. Thus, the agency is proposing to establish a "general principle to allow the physician, the PA, or the APRN who furnishes and bills for their

^{19 § 410.74} and § 410.74(a)(2)

²⁰ Section 1861(s)(2)(K)(i) of the Act

²¹ §§ 410.75(c)(3) and 410.76(c)(3)

professional services to review and verify, rather than re-document, information included in the medical record by physicians, residents, nurses, students or other members of the medical team." This proposal would apply to all settings for Medicare-covered services that are paid under the PFS. However, CMS notes that while this proposal addresses who may document services in the medical record (subject to review and verification by the furnishing and billing clinician) – it does not change the scope of or the standards for documentation that is required in the medical record to demonstrate medical necessity of services, or any other requirements for appropriate medical recordkeeping.

Care Management Services

CMS continues to update PFS payment policies to improve payment for care management and care coordination – including expanding the suite of codes describing these services. Additional information regarding recent new codes and associated PFS payment rules is available on the CMS website. In this proposed rule, CMS is proposing a code set refinement related to transitional care management (TCM) services and chronic care management (CCM) services. Additionally, the agency is proposing new coding for principal care management (PCM) services, and addressing chronic care remote physiologic monitoring (RPM) services. A high level summary of the proposed requirements is available on the CMS website.

Transitional Care Management (TCM) Services

CMS reviewed TCM billing requirements, and found that under prior rulemaking²², the agency had established a list of 57 HCPCS codes that cannot be billed during the 30-day period covered by TCM services by the same practitioner reporting TCM. The agency found fourteen (14) codes on the list that represent active codes that are currently paid separately under the PFS. CMS now believes that these codes may not substantially overlap with TCM services, and thus should be separately payable along with TCM. For CY 2020, CMS is proposing to remove the billing restrictions associated with these 14 HCPCS codes. Furthermore, CMS believes that these codes – when medically necessary – could complement TCM services, and not overlap or duplicate services.

14 HCPCS Codes that Currently Cannot be Billed Concurrently with TCM by the Same Practitioner & are Active Codes Payable by Medicare PFS

Code Family	HCPCS Code	Descriptor
Prolonged Services without Direct	99358	Prolonged E/M service before and/or after direct patient care; first hour; non-face-to-face time spent by a physician or other qualified health care professional on a given date providing prolonged service
Patient Contact	99359	Prolonged E/M service before and/or after direct patient care; each additional 30 minutes beyond the first hour of prolonged services
Home and 93792 Outpatient		Patient/caregiver training for initiation of home INR monitoring
International Normalized Ratio (INR) Monitoring Services	93793	Anticoagulant management for a patient taking warfarin; includes review and interpretation of a new home, office, or lab INR test result, patient instructions, dosage adjustment and scheduling of additional test(s)
End Stage Renal	90960	ESRD related services monthly with 4 or more face-to-face visits per month; for patients 20 years and older
Disease Services (patients who are 20+ years)	90961	ESRD related services monthly with 2-3 face-to-face visits per month; for patients 20 years and older
	90962	ESRD related services with 1 face-to-face visit per month; for patients 20 years and older

	90966	ESRD related services for home dialysis per full month; for patients 20 years and older	
	90970	ESRD related services for dialysis less than a full month of service; per day; for patient 20 years and older	
Interpretation of Physiological Data	99091	Collection & interpretation of physiologic data, requiring a minimum of 30 minutes each 30 days	
Complex Chronic Care	99487	Complex Chronic Care with 60 minutes of clinical staff time per calendar month	
Management Services	99489	Complex Chronic Care; additional 30 minutes of clinical staff time per month	
Care Plan Oversight Services	G0181	Physician supervision of a patient receiving Medicare-covered services provided by a participating home health agency (patient not present) requiring complex and multidisciplinary care modalities within a calendar month; 30+ minutes	
	G0182	Physician supervision of a patient receiving Medicare-covered hospice services (Pt not present) requiring complex and multidisciplinary care modalities; within a calendar month; 30+ minutes	

CMS is proposing to revise current billing requirements for TCM by allowing TCM codes to be billed concurrently with any of the above 14 HCPCS codes. However, before finalizing this proposal – CMS is seeking feedback on if an overlap of services exists – and if so, which services should be restricted from being billed concurrently with TCM. Additionally, CMS is requesting input on if any overlap would depend on if the same or a different practitioner is reporting the services. Finally, because Current Procedural Terminology (CPT) reporting rules generally apply at the practitioner level – the agency is seeking input as to if this proposed policy should differ based on if it is the same or a different practitioner reporting the services.

Chronic Care Management (CCM) Services

CCM services are furnished by a physician or NPP managing overall patient care and their clinical staff — and include comprehensive care coordination services per calendar month, for patients with two or more serious chronic conditions. Currently, there are two subsets of codes — one for non-complex chronic care management and one for complex chronic care management. CMS notes that CCM services increase patient and provider satisfaction as well as save costs but that CCM services are still underutilized. In order to "improve payment accuracy, reduce unnecessary burden, and help ensure that beneficiaries have access", for CY 2020, CMS is proposing changes to the CCM code set.

For complex CCM services, the current CPT codes include in the code descriptors a requirement for establishment or substantial revision of the comprehensive care plan. Additionally, they include moderate to high complexity medical decision-making as an explicit part of the services. For complex CCM codes, CMS is proposing to adopt two new G codes to be used for billing under the PFS instead of CPT codes 99487 and 99489. These new codes explicitly do not include the service component of substantial care plan revision, since patients who require moderate to high complex medical decision making inherently need and receive care plan revisions, thus making the service component of a substantial care plan revision duplicative. CMS is proposing to 1) adopt HCPCS code GCCC3 instead of CPT code 99487, and 2) adopt HCPCS code GCCC4 instead of code 99489.

CMS believes that identifying additional time increments would improve payment accuracy for non-complex CCM services and, as such, is proposing to adopt two new G codes with new increments of clinical staff time – rather than the existing single CPT code (99490). The first G code (GCCC1) would describe the initial 20 minutes of clinical staff time, and the second G code (GCCC2) would describe each additional 20 minutes thereafter. The new G codes would be used for payment under the PFS rather than CPT code 99490. CMS intends for these G codes to be temporary – but they will remain in place until the CPT Editorial Panel can consider revising the current code descriptors for complex CCM services.

Additionally, CMS believes there are aspects of the Typical Care Plan language for CCM services that are "redundant or potentially unduly burdensome." Thus, the agency is proposing to eliminate the phrase "community/social services ordered, how the services of agencies and specialists unconnected to the practice will be directed/coordinated, identify the individuals responsible for each intervention" and insert the

phrase "interaction and coordination with outside resources and practitioners and providers." The agency believes simplifying the language appropriately describes the "important work of interacting and coordinating with resources external to the practice." The proposed new language would read: "The comprehensive care plan for all health issues typically includes, but is not limited to, the following elements:

- Problem list
- Expected outcome and prognosis
- Measurable treatment goals
- Cognitive and functional assessment
- Symptom management
- Planned interventions
- Medical management
- Environmental evaluation
- Caregiver assessment
- Interaction and coordination with outside resources and practitioners and providers
- Requirements for periodic review
- When applicable, revision of the care plan."

Principal Care Management (PCM) Services

Currently, CCM codes require patients to have two or more chronic conditions; however, CMS believes there is a gap in coding and payment for care management services for patients with only one chronic condition. Thus, CMS is proposing a separate coding and payment for principal care management (PCM) services, which would describe care management services for one serious chronic condition. CMS notes that a "qualifying condition would typically be expected to last between three months and a year, or until the death of the patient, may have led to a recent hospitalization, and/or place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline." CMS is not proposing any restrictions on the specialties that could bill for PCM, but notes that the agency expects the majority of these services would be "billed by specialists who are focused on managing patients with a single complex chronic condition requiring substantial care management."

For CY 2020, CMS is proposing to make separate payment for PCM services via two new G codes: 1) HCPCS code GPPP1, and 2) HCPCS code GPPP2. The first G code, HCPCS code GPPP1, "would be reported when, during the calendar month, at least 30 minutes of physician or other qualified health care provider time is spent on comprehensive care management for a single high risk disease or complex chronic condition." The second, HCPCS code GPPP2, "would be reported when, during the calendar month, at least 30 minutes of clinical staff time is spent on comprehensive management for a single high risk disease or complex chronic condition." Additionally, CMS is proposing that the full CCM scope of service requirements would apply to PCM services – including documenting the patient's verbal consent in the medical record.

Chronic Care Remote Physiologic Monitoring Services

Remote physiologic monitoring (RPM) services are chronic care management services involving digitally collected physiologic data that are monitored remotely. Currently, RPM services require direct supervision. CMS is proposing that RPM services (CPT codes 99457 and 994X0) may be furnished under general supervision, and that these codes should be included as designated care management services.

Payment for Evaluation and Management (E/M) Visits

In the CY 2019 PFS final rule²³, CMS finalized payment, coding, and documentation changes for evaluation and management (E/M) office/outpatient visits – scheduled to go into effect in CY 2021. Following the final rule, the American Medical Association (AMA) engaged with CMS, and the "AMA/CPT established the Joint AMA CPT Workgroup on E/M to develop an alternative solution." The workgroup's alternative approach for office/outpatient was "approved by the CPT Editorial Panel in February 2019, with an effective date of January 1, 2021" and is available on the AMA's website. CMS is largely proposing to adopt this alternative approach. However, the CPT coding changes will require additional changes to CMS' policies. Additionally,

CMS is proposing to accept the new values for codes as revised by the AMA Relative Value Scale Update Committee (RUC), as well as an add-on code for prolonged service time.

Proposed Policies for CY 2021 for Office/Outpatient E/M Visits

For CY 2021, CMS is proposing to "adopt the new coding, prefatory language, and interpretive guidance framework that has been <u>issued by the AMA/CPT</u>" for office/outpatient E/M visits (CPT codes 99201-99215). The agency notes "that this includes deletion of CPT code 99201 (Level 1 office/outpatient visit, new patient), which the CPT Editorial Panel decided to eliminate as CPT codes 99201 and 99202 are both straightforward medical decision-making (MDM) and only differentiated by history and exam elements." Additionally, under the new framework – history and exam would no longer select the visit level for office/outpatient E/M visits. Rather, an office/outpatient E/M visit would include a medically appropriate history and exam, when performed.

For levels 2 through 5 office/outpatient E/M visits, the code level reported would be decided based on either: 1) the level of MDM as redefined in the new AMA/CPT guidance or 2) time, meaning the "total time personally spent by the reporting practitioner on the day of the visit (including face-to-face and non-face-to-face time)." CMS would no longer adopt the minimum supporting documentation associated with level 2 office/outpatient E/M visits (as finalized in last year's rulemaking) because they are no longer planning to assign a blended payment rate.

CMS is proposing to adopt the new time ranges within the CPT codes as revised by the CPT Editorial Panel. There would be "a single add-on CPT code for prolonged office/outpatient E/M visits (CPT code 99XXX) that would only be reported when time is used for code level selection and the time for a level 5 office/outpatient visit (the floor of the level 5 time range) is exceeded by 15 minutes or more on the date of service." CMS is proposing a payment rate of approximately \$35 for this new prolonged services code for additional time spent with patients beyond the level 5 visit.

In April 2019, the AMA Relative Value Scale Update Committee (RUC) provided CMS the "results of its review, and recommendations for work RVUs, practice expense inputs and physician time (number of minutes) for the revised office/outpatient E/M code set." These proposed changes in coding and values are for the revised office/outpatient E/M code set, as well as the new 15-minute prolonged services code. This code set and the proposed values will be effective in CY 2021.

Additionally, CMS is proposing to consolidate the two add-on HCPCS G codes that were finalized in last year's rulemaking for primary care and certain non-procedural specialty care into a single code. This code would describe the work associated with visits that are part of ongoing, comprehensive primary care and/or visits that are part of ongoing care related to a patient's single, serious, or complex chronic condition. CMS is proposing a payment rate of approximately \$17 for this service.

The tables below reflect both the previously finalized payment rates, as well as the newly proposed payment rates (for new and established patients, respectively) for CY 2021:

Proposed Payment for Office/Outpatient Based E/M Visits - New Patients

Level	Current Payment* (new patient)	Approximate Payment Rates Finalized in 2019 for CY 2021	Proposed Payment**
1	\$45	\$44	N/A
2	\$76		\$77
3	\$110	\$135	\$119
4	\$167		\$177
5	\$211	\$211	\$232

^{*} Current payment for CY 2019

^{**} Proposed payment based on the CY 2020 proposed RVUs and the CY 2019 payment rate

Proposed Payment for Office/Outpatient Based E/M Visits – Established Patients

Level	Current Payment* (established patient)	Approximate Payment Rates Finalized in 2019 for CY 2021	Proposed Payment**
1	\$22	\$24	\$24
2	\$45		\$60
3	\$74	\$93	\$96
4	\$109		\$136
5	\$148	\$148	\$190

^{*} Current payment for CY 2019

Comment Solicitation on Consent for Communication Technology-Based Services

In the CY 2019 PFS Final Rule²⁴, CMS finalized several services that could be furnished via telecommunications technology, as well as separate payments for them. Additionally, CMS specified that "verbal consent must be documented in the medical record for each service furnished so that the beneficiary is aware of any applicable cost sharing." CMS has heard from stakeholders that for HCPCS codes G2010 and G2012 that it is "difficult and burdensome to obtain consent at the outset of each of what are meant to be brief check-in services." The agency has heard from clinicians that for CPT codes 99446-99449, 99451, and 99452 – that it is "particularly difficult for the consulting practitioner to obtain consent from a patient they have never seen."

CMS is requesting feedback on whether a "single advance beneficiary consent" could be acquired for certain communication technology-based services. This policy is in line with the agency's overarching goals of reducing the burden on beneficiaries and encouraging the use of these technology-based services. To obtain consent, the practitioner would have to make clear that the use of these services would result in a cost sharing obligation for the beneficiary. Additionally, CMS is seeking input on the suitable period that this "advance beneficiary consent" would cover before a practitioner would be forced to obtain new consent, and whether or not this period would be based on the number of services provided or a specific time frame. There are certain integrity concerns relating to advance consent, and the agency is requesting feedback on how best to minimize these concerns while still reducing beneficiary burden.

Comment Solicitation on Opportunities for Bundled Payments under the PFS

For a majority of services under the PFS, payment is made based on rates established for individual services, individually described by a CPT code. CMS has made "identifying and developing appropriate payment policies that aim to achieve better care and improved health for Medicare beneficiaries" a priority. Subsequently – the agency is exploring new options for establishing PFS payment rates or adjustments for services that are furnished or grouped together (i.e., bundled payments). CMS is requesting feedback on opportunities to expand the concept of bundling to "recognize efficiencies among physicians' services paid under the PFS." The agency believes that existing statute – while requiring CMS reimburse "physicians' services based on the relative resources involved in furnishing the service, [also] allows considerable flexibility for developing payments under the PFS."

Proposed Updates to the Quality Payment Program (QPP) for CY 2020

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established the QPP for eligible clinicians. Under the QPP, eligible clinicians can participate via one of two tracks – the Merit-based Incentive Payment System (MIPS) or the Advanced Alternative Payment Models (Advanced APMs). CMS began implementing the QPP through rulemaking for CY 2017, known as the transition year. The proposed updates to the QPP include changes effective January 1, 2020 (the 2020 performance period). CMS is proposing

^{**} Proposed payment based on the CY 2020 proposed RVUs and the CY 2019 payment rate

minor changes that intend to simplify participation and create flexibilities in the MIPS program for the 2020 performance year. However, the agency states that their approach is to maintain the majority of the requirements from the 2019 performance year. Further, CMS notes that these proposed policies will "gradually prepare clinicians for the 2022 performance period and the 2024 MIPS payment year. The CMS website has a detailed Quality Payment Program Proposed Rule Fact Sheet.

MIPS Value Pathways – Request for Information

CMS is making significant proposals to apply a new participation framework – the MIPS Value Pathways (MVPs) – beginning with the 2021 performance year. CMS acknowledges that the MIPS MVPs would be a substantial change in the way clinicians could participate in MIPS, and plans to work closely with all stakeholders as they establish this new framework. The agency is encouraging "clinicians, patients, specialty societies, stakeholders, third parties and others" to review the proposed rule's Request for Information (RFI) regarding "Transforming MIPS: MIPS Value Pathways" as well as their illustrative diagram.

CMS states that the MVP framework will "connect quality, cost, and improvement activities performance categories to drive toward value." Additionally, the proposed policies intend to reduce any barriers clinicians may face when moving into an Advanced APM. In order to decrease clinician burden and improve performance data quality – while still taking into account different types of specialties and practices – the proposed framework would further reduce the number of performance measures and activities clinicians may select. CMS is seeking feedback on the four guiding principles they are proposing to define MVPs:

- 1. MVPs should include a limited set of measures/activities meaningful to clinicians which are meant to reduce or eliminate clinician burden related to measure selection and activities
- 2. MVPs should include measures and activities that would provide comparative performance data valuable to patients and caregivers when evaluating clinician performance
- 3. MVPs should include measures to encourage performance improvement in high priory areas
- 4. MVPs should reduce barriers to APM participation

CMS believes that the most important change with MVPs is that it will eventually prohibit all MIPS-eligible clinicians from selecting quality measures from a single inventory and, instead, measures and activities in an MVP would be connected around a clinician specialty or condition. CMS is further seeking feedback on how to construct MVPs, how to select measures and activities for MVPs, how to determine MVP assignment and how to transition to MVPs. Examples of possible MIPS Value Pathways are available on Table 34 (page 732) of the proposed rule.

Major MIPS Proposals

In addition to the MVP framework, CMS is making two significant proposals for the 2020 MIPS performance period. First, CMS is making proposals to improve the Qualified Clinical Data Registry (QCDR) measure standards "to require measure testing, harmonization, and clinician feedback." The agency notes that these proposals are being made to enhance the quality of QCDR measures that are available for reporting. These policies relate to CY 2020 and CY 2021 for QCDRs. Second, CMS is proposing to add new episode-based measures in the cost performance category in order to "more accurately reflect the cost of care that specialists provide." Additionally, the agency is proposing to make revisions to both the total per capita cost and the Medicare Spending Per Beneficiary (MSPB) measures.

CMS is proposing updates to the public reporting of MIPS data. The agency is proposing to publicly report on the Physician Compare website aggregate MIPS data – beginning with Year 2 – including the minimum and maximum MIPS performance category and final scores. In other words, the aggregate performance Year 2 data (CY 2018 data, available in late CY 2019) will be publicly reported "as technically feasible." Additionally, CMS is proposing that if a MIPS eligible clinician is scored using facility-based measurement – the agency would make this information publicly available via an "indicator on the Physician Compare profile page or downloadable database." Furthermore, the agency is proposing to provide a link to facility-based measure-level information for these clinicians on the Hospital Compare website, "as technically feasible." In other words, the agency will post an indicator for facility-based MIPS clinicians on Physician Compare with the linkage to Hospital Compare. CMS is making this proposal beginning with CY 2019 performance period data available for public reporting starting in late CY 2020 and for all future years – and is seeking feedback on this proposal.

Within MIPS, the performance threshold is the minimum number of points an eligible clinician must obtain to avoid a negative payment adjustment. CMS is proposing to increase the performance threshold – currently

30 points – to 45 points for the CY 2020 and 60 points for CY 2021 performance periods (payment years 2022 and 2023). Additionally, the agency is proposing to increase the additional performance threshold for "exceptional performance" to 80 points for the 2022 MIPS payment year and 85 points for the 2023 MIPS payment year. CMS takes the combined score across the categories to calculate the MIPS "final score". Based on their final score, eligible clinicians receive a performance-based payment adjustment under the PFS. For the 2020, 2021, and 2022 performance years (payment years 2022, 2023 and 2024), the category weights are proposed as follows:

Proposed Weights by MIPS Performance Category for the 2022 through 2024 MIPS Payment Years

Performance Category	2022 MIPS Payment Year (Proposed)	2023 MIPS Payment Year (Proposed)	2024 MIPS Payment Year (Proposed)
Quality	40%	35%	30%
Improvement Activities	15%	15%	15%
Promoting Interoperability	25%	25%	25%
Cost	20%	25%	30%

Quality Performance Category

CMS is proposing to reduce the Quality performance category weight to 40 percent, then 35, then 30 in 2020, 2021, and 2022 respectively. The agency is also proposing to remove "low bar, standard of care, process measures" and instead focus on outcome measures, while adding new specialty sets (e.g., Speech Language Pathology, Audiology, Clinical Social Work, Chiropractic Medicine, Pulmonary, Nutrition/Dietician and Endocrinology).

Table 36 of the proposed rule (pg. 772) contains the summary of data completeness requirements and performance period by collection type for the 2020 MIPS performance period. The new MIPS quality measures proposed for inclusion in MIPS for the 2020 performance period and future years are found in Table Group A of Appendix 1 of the-proposed rule (pg. 1345). The new specialty measures sets proposed for addition and modification can be found in Table Group B of Appendix 1 (pg. 1353). Additionally, MIPS quality measures with proposed substantive changes can be found in Table Group D of Appendix 1 (pg. 1598), and MIPS quality measures proposed for removal can be found in Table Group C of Appendix 1 (pg. 1570). The new specialty measures sets proposed for addition and modification can be found in Table Group B of Appendix 1 (pg. 1353). All of these measures are stratified by collection type in the table below – as well as counts of new, removed, and substantively changed measures:

Summary of Quality Measures for the 2020 MIPS Performance Period

Collection Type	# Measures Proposed as New	# Measures Proposed for Removal	# Measures Proposed with a Substantive Change*	# Measures Remaining for CY 2020
Medicare Part B Claims Specifications	0	17	22	47
MIPS CQMs Specifications	3	52	77	184
eCQM Specifications	1	6	33	45
Survey - CSV	0	0	0	1
CMS Web Interface Measure Specifications	1	1	9	10
Administrative Claims	0	0	0	1
Total**	4	55	95	206

^{*} This column includes all measures that have a requested substantive change from the measure stewards. The total of 95 substantive changes reflects both measures that will continue and a subset of measures that have been proposed for removal for PY 2020. There are 73 substantive changes that are proposed in Appendix 1 for measures not being proposed for removal.

^{**} A measure may be specified under multiple collection types but will only be counted once in the total.

Cost Performance Category

CMS is proposing to increase the Cost Performance category weight to 20 percent, then 25, then 30 in 2020, 2021, and 2022 respectively and is also proposing to add 10 new episode-based measures and revise the current measures (Medicare Spending Per Beneficiary Clinician (MSPB) measure and Total Per Capita Cost Measure (TPCC)). The goal of these proposed changes is to assign responsibility for services to a larger number of clinicians, improve risk-adjusted timelines, and avoid assigning costs incurred prior to a clinician providing services to patients. CMS is proposing to steadily increase the weight of the cost performance category from the current 15 percent to 30 percent, beginning with the 2024 MIPS payment year and expects that the cost performance category will make up 20 percent of a MIPS eligible clinician's final score for the 2022 MIPS payment year.

In addition to proposals related to the weight of the cost performance category, CMS is proposing to change their approach – for this year and in future rulemaking – to the attribution methodology for each cost performance category measure in the measure specifications. These are available for review and public comment (until September 27) on the CMS website; they will be available on the QPP website as finalized after publication of the final rule. Additionally, CMS is proposing that measure attribution would be different for individuals and groups – and would be defined in the measure specifications.

As previously mentioned, CMS is proposing modifications to the TPCC and MSPB measures. CMS is proposing that the TPCC measure would require E/M services to have an associated primary care service — or a follow up E/M service from the same clinician group. Attribution for TPCC would exclude clinicians who predominantly deliver non-primary care services (e.g., general surgery). For the MSPB measure, CMS is proposing to rename it to the "MSPB Clinician (MSPB-C)" measure. Additionally, the agency is proposing to revise the measure so that clinician attribution changes would have different methodologies for surgical and medical patients. Further details are available in the measure specification documents. Information about the proposed changes to the TPCC measure, as well as a comparison to the measure as currently specified, is available in the revised TPCC zip file. A cost measure methodology document and a measure codes list file for the revised MSPB measure is available in the revised MSPB clinician zip file.

Beginning with the 2020 performance period and subsequent performance periods, CMS is proposing to add 10 newly developed episode-based measures to the cost performance category. CMS developed these measures to show the cost to both the Medicare program as well as beneficiaries for the items and services furnished during an episode of care. These measures "compare clinicians on the basis of the cost of care are clinically related to their initial treatment of a patient and provided during the episode's timeframe." CMS is specifically defining cost based on the allowed amounts on Medicare claims – which include both Medicare payments as well as beneficiary deductible and coinsurance amounts. Table 37 of the proposed rule (pg. 799) lists the 10 episode-based measures, and detailed specifications for each measure are available on the CMS website.

Improvement Activities Performance Category

CMS is proposing to add 2 new Improvement Activities, modify 7 of the existing Improvement Activities, and remove 15 of the existing Improvement Activities. Appendix 2 in the-proposed rule (pg. 1690) includes the comprehensive changes proposed to the Improvement Activities inventory. The CMS "Study on Factors Associated with Reporting Quality Measures" is concluding with CY 2019 – and the agency will not continue the study during the 2020 performance period. CMS indicates in the proposed rule that the final study results will be "shared at a later date."

For the Improvement Activities performance category, CMS is proposing to redefine the definition of a rural area. The agency is proposing that the definition of a "rural area" would mean a ZIP code designated as rural by the Federal Office of Rural Health Policy (FORHP) using the most recent FOHRP Eligible Zip Code file available. Previously, CMS used the most recent Health Resources and Services Administration (HRSA) Area Health Resource File data set available.

Additionally, CMS is proposing to establish removal factors for consideration when proposing to remove certain improvement activities from the Inventory. An activity would be considered for removal if it is duplicative of another activity; an alternate activity exists with a stronger relationship to quality care or improvements in clinical practice; the activity does not align with current clinical guidelines or practice; the activity does not align with at least on meaningful measures area; the activity does not align with Quality, Cost, or Promoting Interoperability performance categories; there have been no attestations of the activity for 3 consecutive years; and/or the activity is obsolete.

Finally, CMS is proposing to require that for the Improvement Activity Credit for groups – groups or virtual groups – would be able to attest to an improvement activity when at least 50 percent of MIPS eligible clinicians in the group participate in or perform the activity. Additionally, at least 50 percent of a group's National Provider Identifier (NPI) must perform the same activity for the same continuous 90 days in a performance period.

Promoting Interoperability (PI) Performance Category

For scoring the Promoting Interoperability performance category (weighted at 25 percent of the MIPS Final Score) for 2022 payment year, the agency did not propose significant changes. In this proposed rule, however, CMS is focused on several proposals:

- 1. Establishing a performance period (effective for the 2023 MIPS payment year) of a minimum of a continuous 90 day period within CY 2021, up to and including the full calendar year
- 2. Making the Query of Prescription Drug Monitoring Program (PDMP) measure optional in CY 2020 (and possibly making the e-Prescribing measure worth up to 10 points in CY 2020)
- 3. Removing the numerator and denominator for the Query of PDMP measure and instead using a yes or no response beginning in CY 2019
- 4. Removing the Verify Opioid Treatment Agreement measure in CY 2020
- 5. Redistributing points for the Support Electronic Referral Loops by Sending Health Information measure to the Provide Patients Access to their Health Information measure if an exclusion is claimed (in CY 2019)
- 6. Revising the description of the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure exclusion to more clearly capture CMS's intended policy (CY 2019)
- 7. Continuing the current policy of reweighting the Promoting Interoperability performance category for certain non-physician practitioner MIPS eligible clinicians for the 2020 performance period and
- 8. Additional proposals related to hospital-based MIPS clinicians and non-patient facing MIPS eligible clinicians in groups

The following table reflects these proposals – although the maximum points available do not include points that would be redistributed in the event that an exclusion is claimed.

Proposed Scoring Methodology for the Performance Period in 2020

Objectives	Measures	Maximum Points
o Proceribing	e-Prescribing**	10 points
e-Prescribing	Query of PDMP	5 points (bonus)
Health Information	Support Electronic Referral Loops by Sending Health Information	20 points
Exchange	Support Electronic Referral Loops by Receiving and Incorporating Health Information**	20 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points
Public Health and Clinical Data Exchange	Report to two different public health agencies or clinical data registries for any of the following: Immunization Registry Reporting** Electronic Case Reporting** Public Health Registry Reporting** Clinical Data Registry Reporting** Syndromic Surveillance Reporting**	10 points

^{**} Exclusion available

CMS has also included several Requests for Information related to the above proposals including:

- 1. Potential Opioid Measure to be included in this category
- 2. NQF and CDC Opioid Quality Measures

- 3. A Metric to improve the efficiency of providers within electronic health records
- 4. The provider to patient exchange objective
- 5. Integration of patient-generated health data into electronic health records using Certified Electronic Health Record Technology
- 6. Engaging in activities that promote the safety of electronic health records

Advanced Alternative Payment Models (Advanced APMs)

The following APMs are expected to be Advanced APMs for the 2020 QP Performance Period: Next Generation ACO Model; Comprehensive Primary Care Plus (CPC+) Model; Comprehensive ESRD Care (CEC) Model (Two-Sided Risk Arrangement); Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative); Comprehensive Care for Joint Replacement Payment Model (CEHRT Track); Oncology Care Model (Two-Sided Risk Arrangements); Medicare ACO Track 1+ Model; Bundled Payments for Care Improvement Advanced; Maryland Total Cost of Care Model (Maryland Care Redesign Program; Maryland Primary Care Program); Primary Care First; and Medicare Shared Savings Program (Track 2, Basic Track Level E, and the ENHANCED Track). CMS is proposing policies regarding "several aspects of the Advanced APM criterion on bearing financial risk for monetary losses." Specifically, the agency is amending their definition of expected expenditures, and is seeking input on whether "certain items and services should be excluded from the capitation rate for the definition of full capitation arrangements."

Additionally, CMS is proposing that for Partial Qualifying APM Participants (Partial QPs) – Partial QP status will apply only to the Taxpayer Identification Number (TIN)/National Provider Identifier (NPI) combination(s) through which an individual eligible clinician attains Partial QP status, beginning with the 2020 QP Performance Period. Further, CMS is proposing to revise existing statute to state "that an eligible clinician is not a QP or a Partial QP for the year when an APM Entity terminates from an Advanced APM at a date on which with APM Entity would not bear financial risk under the terms of the Advanced APM for the year in which the QP Performance Period occurs."

What's Next?

CMS publishes the final PFS/QPP regulation in early November, 2019 and the majority of changes are effective at the beginning of the following calendar year (Jan. 1, 2020). The 60-day comment period closes on September 27, 2019. Vizient's Office of Public Policy and Government Relations looks forward to hearing continued member feedback on this proposed rule. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions or regarding any aspects of this proposed regulation – both positive reactions and provisions that cause you concern.

It is possible there will be substantial shifts between the proposed and final rule based on public comments and further analysis by CMS. Look for more information from our office when the final rule is released in November.

<u>Additional Resources</u>

<u>Chelsea Arnone</u>, Regulatory Affairs and Government Relations Director in Vizient's Washington, D.C. office, can be reached at (202) 354-2608, and is monitoring this rule and other regulatory developments. Please reach out to her if you have any questions or if Vizient can provide any assistance as you consider these issues.