# CMS Proposes Changes to Telehealth Reimbursement, Stark, Substance Use Disorder Treatment Reimbursement, and Evaluation & Management Reimbursement in the CY 2019 Physician Fee Schedule Proposed Rule

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On Thursday, July 12, 2018, the Centers for Medicare & Medicaid Services (CMS) released the 2019 Physician Fee Schedule (PFS) Proposed Rule (the Proposed Rule). In it, CMS proposes a number of changes of note, including permitting Medicare reimbursement for certain communication technology-based and remote evaluation services that do not satisfy Medicare's requirements for telehealth services, clarifying the requirements for written agreements and signatures under the Stark law, and revising the documentation requirements and payment levels for evaluation and management (E/M) visits. The Proposed Rule also solicits comments on a bundled episode of care for substance use disorder (SUD) treatment. We are following these and other proposed changes, and will be separately publishing articles on the changes for telehealth services and substance use disorder treatment services on our HLB Health Law & Policy Blog and in our monthly newsletter, *HLB Perspectives*.

**PROPOSED TELEHEALTH REIMBURSEMENT CHANGES**

The Proposed Rule includes a number of proposed changes relevant to telehealth. *First*, CMS proposes distinguishing between Medicare telehealth services and "communication technology-based and remote evaluation services." This distinction would permit Medicare reimbursement for three services that are colloquially referred to as types of telehealth services but that do not meet the statutory requirements for Medicare-reimbursable telehealth services. The particular types of communication technology-based and remote evaluation services that CMS proposes covering are discussed further below.

*Second*, CMS proposes adding prolonged preventive services (HCPCS Codes G0513 and G0514) to the enumerated list of Medicare telehealth services that can be reimbursed when provided via telehealth and in compliance with CMS' reimbursement requirements for telehealth services, including originating site restrictions and geographic requirements. *Lastly*, CMS proposes regulations implementing sections 40302 and 50325 of the Bipartisan Budget Act of 2018, which requires changes to the telehealth originating site and geographic requirements for home dialysis patients' monthly clinical assessments and acute stroke services.

***Communication Technology-Based and Remote Evaluation Services.*** CMS proposes providing separate Medicare reimbursement for three types of communication technology-based and remote evaluation services as follows:

- ***Virtual Check-Ins (HCPCS Code GVCI1).*** Virtual check-ins are "brief check-in services furnished using communication technology that are used to evaluate whether or not an office visit or other service is warranted." Under CMS' proposal, virtual check-ins would be eligible for separate payment, but these services would not be billable if they originated from or led to another, related evaluation and management service by the same physician or qualified health care professional. CMS has specifically requested comments on other coverage requirements-for example, restrictions on the frequency or modality of the virtual check-ins. Patient consent and an existing practitioner-patient relationship would be required for virtual check-ins. As discussed further below, the Proposed Rule specifically calls

attention to the potential value of virtual check-ins as part of a substance use disorder treatment regimen.

- ***Store and Forward Services (HCPCS Code GRAS1)***. CMS proposes to create specific coding that describes "the remote professional evaluation of patient-transmitted information conducted via pre-recorded 'store and forward' video or image technology." Like virtual check-ins, these "store and forward" services would not be billable if they originated from or led to another, related evaluation and management service by the physician or qualified health care professional. CMS is seeking comment as to whether these services should be limited to established patients or whether certain practitioners (e.g., dermatologists or ophthalmologists) could evaluate and determine if a new patient requires an in-person visit utilizing "store and forward" communications.

- ***Interprofessional Consultations (CPT Codes 994X6, 994X0, 99446 – 49).*** Although CMS has previously taken the position that interprofessional consultations are considered bundled and are therefore not separately billable, CMS recognizes that the absence of separate payment for interprofessional consults "means that specialist input is often sought through [a separate patient visit] when a phone or internet-based interaction between the treating practitioner and the consulting practitioner would have been sufficient." Therefore, CMS proposes allowing separate payment for interprofessional consultations provided via communication technology with verbal consent from the beneficiary. CMS acknowledges that separate payment for these services "will contribute to payment accuracy for primary care and care management services," but also expresses concern about (1) distinguishing between payable interprofessional consultations taken for the benefit of the patient and nonpayable consultations taken for the benefit of the practitioner and (2) the potential program integrity concerns associated with these consultations. CMS expressly seeks comment on these concerns and potential controls or limitations that can be put in place to address them.

These three communication technology-based and remote evaluation services do not satisfy the requirements for Medicare telehealth services as set forth in section 1834(m) of the Social Security Act, 42 U.S.C. § 1395m(m), but in the Proposed Rule, CMS takes the view that the Medicare telehealth standards do not apply to services that "inherently involve the use of communication technology." In particular, CMS states:

We have come to believe that section 1834(m) of the Act does not apply to all kinds of physicians' services whereby a medical professional interacts with a patient via remote communication technology. Instead, we believe that section 1834(m) of the Act applies to a discrete set of physicians' services …. For CY 2019, we are aiming to increase access for Medicare beneficiaries to physicians' services that are routinely furnished via communication technology by clearly recognizing a discrete set of services that are defined by and inherently involve the use of communication technology.

CMS' willingness to consider providing Medicare reimbursement for services that do not meet the statutory requirements for Medicare telehealth services but do involve the use of communication technology or remote evaluation appears to signal a general recognition of the value that these services can offer, including earlier and more cost-effective intervention. Although it is too early to draw large conclusions from this proposal, it may also signal the prioritization of regulatory flexibility and a more specific receptiveness to future proposals for other communication technology-based and remote evaluation services.

**PROPOSED CLARIFICATIONS TO STARK WRITTEN AGREEMENT AND SIGNATURE REQUIREMENTS**

The Proposed Rule envisions refining the Stark regulations to tighten and clarify (but not change) the existing law with respect to what qualifies as a written agreement and when a signature must be secured. Specifically, the proposed changes would add regulatory provisions specifying that (1) the writing requirement contained in various compensation arrangement exceptions can be satisfied by "a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties" and (2) the signature requirement can be satisfied if the compensation arrangement meets all of the other requirements of the exception, and the required signatures are obtained within "90 consecutive calendar days immediately following the date" a signature was required but not yet secured.

In the 2016 final PFS rule, CMS had explained its position on what qualifies as a written agreement, and indicated that it was merely clarifying what had been its longstanding interpretation. CMS explained this position in the preamble, but without codifying this in the regulations themselves. That final rule also allowed parties 90 days to secure a signature, but limited it to once every three years with the same physician. However, in 2018, Congress amended the statute itself to provide that a collection of documents can qualify as a writing and to give parties 90 days to secure a signature, and notably did not limit parties who are tardy in gathering signatures to once every three years with the same physician. Thus, these proposed changes would effectively codify, in regulation, what is already the law, pursuant to the statute.

**OPIOD USE DISORDER TREATMENT AND OTHER SUBSTANCE USE DISORDER (SUD) TREATMENT**

In the Proposed Rule, CMS reiterated its commitment to make combatting the opioid epidemic a top priority for the agency and to align its efforts with the Department of Health and Human Services' (HHS) opioid initiative. In support of that commitment, CMS is considering, and seeking comment on, the creation of a bundled episode of care for SUD treatment that would include components of Medication Assisted Treatment (MAT) such as management and counseling treatment, treatment planning, and medication management or observing drug dosing for treatment of SUDs. CMS has expressed hope that such bundling could expand access to treatment for SUDs, and thus, be effective in preventing the need for more acute services, such as hospitalization. Further opportunities also exist to leverage communication technology, such as CMS' proposal to provide separate payment for certain "virtual check-ins" (discussed above) provided for particular components of MAT. Finally, in addition to bundling, CMS also requested comments on whether the counseling portion or other MAT components could be provided by qualified practitioners "incident to" services of the billing physician.

CMS has also proposed adding two new Promoting Interoperability measures to the e-Prescribing objective for clinicians eligible for Merit-Based Incentive Payment System (MIPS): (1) Query of Prescription Drug Monitoring Programs (PDMPs); and (2) Verify Opioid Treatment Agreement. These measures are intended to support HHS opioid initiatives by helping health care providers avoid inappropriate prescriptions, improving coordination of prescribing amongst health care providers and focusing on the advanced use of EHR technology. CMS also proposed corresponding changes to the measures for eligible hospitals in the FY 2019 Inpatient Prospective Payment System (IPPS) Proposed Rule.

We will explore CMS's proposals related to opioid use disorders in more detail in a future article on our HLB Health Law & Policy Blog and in our monthly newsletter, *HLB Perspectives*.

**EVALUATION AND MANAGEMENT (E/M) DOCUMENTATION AND PAYMENT**

The Proposed Rule offers a number of significant changes for physicians and other practitioners paid under the Medicare PFS for E/M services. Stakeholders have long maintained that the 1995 and 1997 E/M Documentation Guidelines that practitioners rely on are administratively burdensome, outdated, and ought to be revised and revalued. The Proposed Rule includes a number of changes related to E/M documentation and payment, including proposals to:

- Pay a single-PFS rate for E/M visit levels 2 through 5 for new and established patients, and minimize documentation standards so that practitioners would only need to document the information to support level 2. The Proposed Rule acknowledges that certain E/M visits differ from typical visits (for example, in time and complexity), and proposes associated add-on payments and ratesetting adjustments.
- Provide practitioners a choice in documentation, and determining the appropriate level the office/outpatient E/M visits, based on: (1) the 1995 or 1997 Documentation Guidelines; (2) Medical Decision-Making (MDM); or (3) time.
- Expand on current history and exam policy by allowing practitioners to focus their documentation on what has changed since the last visit or on pertinent items that have not changed, rather than re-documenting information.
- Allow practitioners to review and verify certain information in the medical record that is entered by staff or the beneficiary, rather than re-entering it.

Past proposed changes to E/M guidelines and payment rules have faced difficulties due to the lack of consensus among stakeholders. Because the anticipated impact of the foregoing proposals will vary widely by specialty and other practice factors, we expect that stakeholder comments will sharply diverge, particularly with regard to the proposed single-PFS rate with add-on payment and ratesetting adjustments.

**OTHER ISSUES OF NOTE**

- ***Teaching Physician E/M Documentation Requirements***. CMS proposes changes to E/M documentation requirements for teaching physicians in an effort to reduce administrative burdens. The proposed rule would loosen the reins on how a teaching physician's presence during E/M services can be demonstrated. The proposal would remove the current requirement that the teaching physician has to document his or her participation in the review and direction of the E/M services furnished and replace it with a new requirement whereby the extent of the teaching physician's participation in the review and direction of services furnished may now be demonstrated solely from the notes in the medical records made by a physician, medical resident, or nurse.

- ***Section 603.*** The Proposed Rule would retain the 40 percent PFS relativity factor used to determine the facility fee for nonexcepted items and services furnished in an off-campus, provider-based, outpatient department.

- ***Part B Drug Pricing.*** The Proposed Rule would change the Wholesale Acquisition Cost (WAC)-based payment rate for Part B drugs from 106 percent of WAC to 103 percent of WAC, consistent with MedPAC's recommendation in its June 2017 report to Congress. Most drugs are paid based on 106 percent of the average sales price (ASP), and this proposal would not alter ASP-based payment rates. It would also not impact the payment methodology used for drugs furnished in hospital outpatient departments, or the payment for single-source drugs, which is set by statute at 106 percent of the lesser of ASP or WAC.

- ***Price Transparency.*** CMS has also requested information on price transparency. Although the Proposed Rule does not set forth any specific proposals, CMS states that it is considering potential actions to promote provider-side efforts "to engage in consumer-friendly communication of their charges" so that patients understand their potential financial liability for services and can compare charges between provider. This request for information was also included in the FY 2019 IPPS Proposed Rule.

The foregoing is a sampling of key highlights found among the more than 1,400 pages of the Proposed Rule. Comments on CMS' proposals are due on September 10, 2018. The Proposed Rule will be published in the Federal Register on July 27, 2018 at https://federalregister.gov/d/2018-14985. In the interim, the unpublished version is available at https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-14985.pdf.

*For more information on the PFS, Telemedicine, Stark, Opioid Use Disorder Treatment, and E/M Guidelines and Payment, please contact: Amy Joseph or Jeremy Sherer in Boston at 617.532.2700; Katrina Pagonis in San Francisco at 415.875.8515; Charles Oppenheim, Alicia Macklin, or Paul Garcia in Los Angeles at 310.551.8111; Martin Corry, Keith Fontenot, or David Vernon in Washington, D.C. at 202.580.770; or your regular Hooper, Lundy & Bookman contact.*

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