CMS PROPOSES RULES TO IMPLEMENT SUPPORT ACT COVERAGE AND REIMBURSEMENT OF OPIOID TREATMENT

Date: 17 September 2019

U.S. Health Care Alert

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Recently, the Centers for Medicare & Medicaid Services ("CMS") published its annual proposed rule outlining potential changes to the Medicare Physician Fee Schedule ("PFS") for upcoming Calendar Year ("CY") 2020 ("Proposed Rule"). [1] In the Proposed Rule, CMS details proposed payment rates and policies under the Medicare PFS, as well as several significant proposals aimed at addressing the national opioid epidemic and implementing provisions of the federal "Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act" or the "SUPPORT for Patients and Communities Act" (referred to herein as the "SUPPORT Act"). [2] In particular, the Proposed Rule describes a new enrollment category and process for opioid treatment programs ("OTPs") to enroll in Medicare, proposes to establish rules to govern Medicare coverage of and payment for opioid use disorder treatment services furnished in such OTPs, and to allow certain face-to-face portions of opioid use disorder treatment services to be covered by Medicare when provided via telehealth communication. Comments on the Proposed Rule are due by September 27, 2019. This Alert provides an overview of CMS's proposals with respect to each topic.

I. NEW ENROLLMENT CATEGORY CREATED FOR OPIOID TREATMENT PROVIDERS

In furtherance of its objectives to help individuals recover from opioid addiction, the SUPPORT Act establishes a new Medicare benefit category for OTPs for the purposes of furnishing opioid use disorder treatment services. [3] Currently, OTPs are not recognized as Medicare providers, meaning that beneficiaries receiving medication-assisted treatment ("MAT") at OTPs for their opioid use disorder must pay out of pocket. In the Proposed Rule, CMS sets forth the eligibility definitions and requirements for OTP enrollment under this newly created benefit category, which will enable OTPs that meet applicable requirements to bill and receive payment under the Medicare program for such services, thereby promoting expanded access to care.

The SUPPORT Act adopted the existing federal regulatory definition of an OTP as meaning "a program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication registered under" the Controlled Substances Act. [4] Beyond meeting such definition, qualifying OTPs must also (i) be accredited by an accrediting body approved by the federal Substance Abuse and Mental Health Services Administration ("SAMHSA"), and (ii) possess SAMHSA certification for their program, which is contingent upon, among other things, adherence to federal opioid treatment standards, compliance with applicable state laws, and compliance with regulations enforced by the Drug Enforcement Administration. [5]

For purposes of enrollment, the SUPPORT Act specifies that OTPs enroll under Section 1866(j) of the Social Security Act, which requires entering into a provider agreement meeting standard Medicare requirements. [6] Further, all typical enrollment processes (e.g., completing an enrollment application) will apply to OTP enrollment, as well as Medicare enrollment regulations designed to give CMS discretion and gatekeeper tools for program integrity purposes to prevent unqualified or potentially fraudulent individuals and entities from being able to enter and inappropriately bill the Medicare program. [7] The Proposed Rule would create a new regulation at 42 C.F.R. § 424.67 incorporating such general enrollment requirements and procedures and further establishing specific enrollment requirements that OTPs must meet to bill Medicare for the provision of opioid use disorder treatment services, including the OTP's submission of a Form CMS-855B with program-specific supplemental information attached. [8] For the supplemental attachment, CMS proposes that the OTP must submit (i) a list of all physicians and other eligible professionals who are legally authorized to prescribe, order, or dispense controlled substances on behalf of the OTP to enable CMS to screen such providers qualifications and prescribing practices; and (ii) a certification that the OTP meets and will continue to meet specific requirements and standards for OTP enrollment, including [9]:

- An OTP must not employ or contract with a prescribing physician or other eligible professional authorized to dispense narcotics (regardless of whether that person will be prescribing or dispensing narcotics at the OTP) who has been convicted within the past 10 years of a federal or state felony that CMS "deem[s] detrimental to the best interests of the Medicare program and its beneficiaries."
- An OTP must not employ or contract with any personnel who is has had their billing privileges under any governmental health care program revoked, is on a preclusion list, or has a current or prior adverse action imposed by a state oversight board for a "case or situation involving patient harm that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries." [10]

Notably, CMS is proposing to assign newly enrolling OTPs to its "high categorical risk" level under 42 C.F.R. § 424.518, a level currently occupied only by new enrolling home health agencies, DMEPOS suppliers, and diabetes prevention program suppliers. [11] This designation would subject OTPs to additional screening requirements that include undergoing a site visit and submitting fingerprints for all individuals with greater than 5% ownership in the OTP for purposes of a criminal background check. [12] CMS states its rationale for assigning OTPs to this highest level of screening is not only because this is a new enrollment category lacking historical information but also because of concern that "the opioid epidemic has, in [its] view, increased the potential for unscrupulous providers to take advantage of Medicare beneficiaries through fraudulent billing schemes and abusive prescribing practices." [13] CMS also casts a jaundiced view of the provider type in general, citing heightened program integrity risk with OTPs relative to other provider types given the nature of services provided by OTPs (e.g., methadone treatment) and the patient population served (i.e., individuals with opioid addiction). CMS proposes to require that, as a condition of reimbursing an OTP claim for a prescribed drug, the ordering provider's NPI number be listed, in order to enable CMS to monitor the prescribing and dispensing practices occurring at OTP facilities. [14]

Under the Proposed Rule, CMS provides the following grounds to deny an OTP enrollment application: (i) lacking a SAMHSA certification, (ii) failing to meet the new OTP-specific enrollment requirements described above, and/or (iii) failing to satisfy any generally applicable requirements under CMS's existing enrollment denial regulations. [15] The foregoing, as well as failure to maintain ongoing compliance with requirements under the

new rule, as finalized, could also be a basis for enrollment revocation. [16] Notably, CMS additionally proposes to create a new and broad sweeping revocation reason to revoke an OTP's enrollment in the event an individual has been subject to prior action by a federal or state oversight board based on improper conduct that led to patient harm. [17]

Lastly, all Part B-enrolled providers should note that CMS proposes in this FY2020 PFS to expand current denial and revocation regulations applicable under Part D to all providers enrolled under Part B (not just professionals practicing in OTPs). Specifically, CMS would expand its authority, currently established under Part D to Part B as well, to deny or revoke enrollment of a physician or other eligible professional if he/she has a pattern or practice of prescribing drugs that is abusive or represents a threat to beneficiary health and safety. [18]

II. MEDICARE COVERAGE OF OPIOID USE DISORDER TREATMENT SERVICES

CMS notes that prior to the SUPPORT Act, methadone for MAT was not covered by Medicare. Due to the unique manner in which methadone is dispensed and administered, it was not covered by Medicare Part B or Part D, and, as a result, methadone was only permitted to be provided in OTPs (which were not previously eligible for Medicare enrollment). To address this historical gap in Medicare coverage for services furnished by OTPs, the SUPPORT Act established a new Part B benefit category for opioid use disorder treatment services furnished beginning on January 1, 2020, including coverage for medications for MAT, when such services are provided by either an OTP or by a physician or other health care provider in an office-based setting other than an OTP.

Bundled payment to OTPs for opioid use disorder treatment services.

The SUPPORT Act required CMS to begin paying a bundled payment rate for opioid use disorder treatment services furnished by an OTP to an individual during an episode of care beginning on or after January 1, 2020. [19] CMS has proposed that opioid use disorder treatment services that may be furnished by OTPs include: (i) access to each of the three drugs currently approved by the Food and Drug Administration for the treatment of opioid dependence (buprenorphine, methadone, and naltrexone); (ii) the dispensing and administration of such medication, if applicable; (iii) substance use counseling; (iv) individual and group therapy; (v) toxicology testing; and (vi) items and services appropriate to allow the use of telecommunications for certain services. [20] Of note, CMS requests comments as to additional items and services currently covered under Medicare Part B, which CMS should consider covering when provided by an OTP, specifically inquiring whether intake activities, such as the physical exam, initial assessments, and preparation of a treatment plan, should be included in the definition of opioid use disorder treatment services. As reimbursement for such opioid use disorder treatment services furnished by an OTP, the Proposed Rule sets forth a bundled payment methodology, which would be calculated based on the payment rate for the drug component (depending on the specific medication prescribed for MAT) [21] in combination with the payment rate for the nondrug component of services. [22] CMS proposes that the duration of an episode of care would be one week [23] and further declines to specify a maximum number of weeks that a patient may receive opioid use disorder treatment services from an OTP.

Consistent with SAMHSA requirements, the payment methodology set forth in the Proposed Rule requires an OTP to have a treatment plan in place for each patient identifying the frequency with which items and services are to be provided. Notably however, the proposed payment bundle for opioid use disorder treatment services

provided by an OTP does not require a particular intensity or frequency of specific services and would instead be based on the percentage of services included in the patient's treatment plan, which the OTP actually furnished during the week. In other words, the OTP-developed treatment plan is the lynchpin for the proposed bundled payment methodology, which includes:

- CMS indicates that an OTP may bill the full weekly bundled payment so long as the patient has received the majority (51% or more) of the services outlined in the current treatment plan (regardless of the frequency or intensity of services included in such treatment plan). [24]
- In the event that, for any reason (e.g., the patient's choice, an inpatient hospitalization, inclement weather), an OTP furnishes at least one service but less than a majority of the items or services identified in a patient's treatment plan, the OTP can submit a bill for a partial episode of care (specifying whether the patient received MAT or not during the partial week). CMS seeks comments regarding the minimum threshold that should be applied to determine when a partial episode could be billed.
- Alternatively, in the event a patient requires substantially more counseling, including individual or group therapy, than the amount specified in the patient's individualized treatment plan, CMS has proposed that the OTP could bill an add-on code to adjust the bundled payment rate. [25]

CMS notes it expects that OTPs will ensure treatment plans reflect the full scope of services that an OTP anticipates furnishing during an episode of care, and the OTP will regularly update a patient's treatment plans to reflect any changes, thus obviating the OTP's need to bill the add-on code on a long-term basis and likely reducing the frequency of which an OTP bills for a partial episode instead of a full episode of care. While the Proposed Rule emphasizes CMS's desire for the bundled payment methodology to encourage efficient care by mitigating incentives tied to the volume of services furnished, CMS indicates it is interested in comments regarding ways CMS "might better stratify the coding for [opioid use disorder] treatment to reflect the varying needs of patients (based on complexity or frequency of services, for example) while maintaining the full advantage of the bundled payment, including increased efficiency and flexibility in furnishing care." [26]

CMS acknowledges the mandate in the SUPPORT Act that CMS ensure no duplicative payments are made under Part B or Part D for items and services furnished by an OTP, further recognizing that the items included in the OTP bundle may appropriately be available to Medicare beneficiaries from other providers. CMS states that it believes a beneficiary may receive counseling or therapy both as part of an OTP bundle and also through medically necessary services provided by a physician, and the patient's receipt of counseling and therapy services from multiple providers during the same time period would not necessarily result in a prohibited duplication of services. However, CMS indicates that duplicative payments would likely result from the submission of claims to Medicare for drugs furnished to a Medicare beneficiary (as well as the administration of such drugs) on a certain date of service by both an OTP and another provider or supplier, in which case CMS will consider the payment for such medications furnished by the OTP to be duplicative. CMS encourages OTPs to "take reasonable steps to ensure that the items and services furnished under their care are not reported or billed under a different Medicare benefit" and proposes to ultimately recoup any duplicative payment for such medication from the OTP given that the OTP is responsible for managing the beneficiary's overall opioid use disorder treatment. [27] However, in light of the strict disclosure prohibitions and confidentiality requirements imposed as to substance use disorder patient records under 42 C.F.R. Part 2, OTPs may be prohibited or impaired from

obtaining the information necessary to ensure that duplicative services are not provided to a patient under its care, particularly if the OTP is restricted from communicating with other Medicare providers regarding the patient.

Bundled payment under PFS for office-based opioid use disorder treatment services.

CMS also proposes to establish bundled payments for opioid use disorder treatment services that are furnished by physicians and other health professionals (not just by an OTP). Similar to the OTP payment bundle, the proposed bundle for Part B providers includes management, care coordination, psychotherapy, and counseling activities. Notably, the PFS bundled payment excludes payment for the medication used in MAT (which under the Proposed Rule would be paid under Medicare Part B or Part D), and further excludes payment for medically necessary toxicology testing (which would continue to be separately billed under the Clinical Lab Fee Schedule). Unlike the weekly bundle proposed for OTPs, the PFS-bundled payment for opioid use disorder treatment services furnished in an office setting covers a monthly bundle of services for opioid use disorder treatment, which CMS explains is intended to better align with the practice and billing of other types of care management services furnished in office settings (noting in particular the increased use of long-acting MAT drugs in an office setting compared to an OTP setting). [28]

In the Proposed Rule, CMS suggests a code to describe the bundle of services provided in the initial month, which would cover intake activities, development of a treatment plan, care coordination, and individual and group therapy, as well as a code to describe the care coordination, therapy, and counseling provided in subsequent months of opioid use disorder treatment. Further, CMS proposes an "add-on" code for coverage of opioid use disorder treatment services when the total time spent by the billing professional and clinical staff exceeds double the minimum amount of time required to bill the base code for the month, in the event that medically necessary opioid use disorder treatment services for a particular patient substantially exceed the resources included in the base code.

CMS acknowledges the possibility that beneficiaries with opioid use disorder have comorbidities and may require medically necessary psychotherapy services for other behavioral health services. CMS indicates that in order to avoid duplicative billing of such opioid use disorder treatment services, certain CPT codes may not be reported by the same practitioner for the same beneficiary during the same month that the newly added bundled payment codes are billed.

III. TELEHEALTH SERVICES

Furthering the aim to increase access to opioid use disorder treatment services and provide greater flexibility to providers in furnishing face-to-face encounters to patients, the Proposed Rule adds several therapy and counseling services to Medicare's list of approved services that may be provided via telehealth:

- CMS proposes to allow the face-to-face portions of any of the individual therapy, group therapy, and counseling services included in three HCPCS codes covering a physician or other practitioner's provision of office-based treatment for opioid use disorder to be provided via telehealth. [29] CMS anticipates that these services would often be billed by addiction specialty practitioners, but notes in the Proposed Rule that these codes are not limited to any particular physician or nonphysician practitioner specialty. Further, CMS does not propose requiring consultation with a specialist as a condition of payment for these codes.

- Similarly, in order to increase access to care for beneficiaries receiving opioid use disorder treatment services from an OTP, the Proposed Rule would allow OTPs to furnish the substance use counseling, individual therapy, and group therapy included in the payment bundle via two-way interactive audio-video communication technology, as clinically appropriate.

In addition, the Proposed Rule implements the provisions of the SUPPORT Act, which removed the geographic limitations for telehealth services furnished on or after July 1, 2019 to an individual with a substance use disorder diagnosis, for the purposes of treating such disorder or a co-occurring mental health disorder. Also recall, the SUPPORT Act amended requirements applicable to the telehealth originating site to allow telehealth services for treatment of a diagnosed substance use disorder or co-occurring mental health disorder to be furnished to a patient from any originating site (not just a rural site and including the patient's home). [30]

IV. CONCLUSION

Overall, the Proposed Rule makes good on CMS's obligation under the SUPPORT Act to address the nationwide opioid epidemic crisis through its proposed implementation of the various mandates to expand Medicare coverage for opioid use disorder treatment services. With the exception of CMS's proposal to include OTPs in the "high categorical risk" level for purposes of enrollment, the proposals outlined in the Proposed Rule reflect an overall attempt by CMS to provide greater flexibility to OTPs—for example, by declining to articulate more than a handful of new enrollment qualifications for OTPs over the criteria already required by SAMHSA; declining to create additional conditions of participation for OTPs; basing bundled payment methodologies on the scope of services the OTP anticipates a patient requires through its OTP-developed treatment plan, without strict requirements as to the required frequency or intensity of services; and generally expanding access to opioid use disorder treatment services through greater telehealth access.

K&L Gates' health care practice is closely monitoring the nationwide opioid crisis, including federal and state statutory and regulatory proposals aimed to expand and improve coverage for opioid use disorder treatment services. We routinely assist residential, outpatient, and facility-based treatment providers and private equity investors in behavioral health, as well as health systems and hospitals, and other providers and suppliers with legal advice, including licensure, certification, reimbursement, regulatory compliance, transactional due diligence, and strategic considerations.

In this regard, and as noted above, comments on the Proposed Rule are due by September 27, 2019. Providers contemplating receiving reimbursement for opioid use disorder services or enrolling as an OTP should consider whether to submit comments to CMS on the Proposed Rule. K&L Gates' health care practice and public policy and law practice regularly facilitate stakeholder engagement with Congress and the administration, including through the development and submission of public comments.

NOTES:

[1] Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection

System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations, 84 Fed. Reg. 40482 (Aug. 14, 2019), https://www.govinfo.gov/content/pkg/FR-2019-08-14/pdf/2019-16041.pdf (hereinafter, "Proposed Rule").
[2] Support for Patients and Communities Act, Pub. L. 115-271 (hereinafter, "SUPPORT Act").
[3] SUPPORT Act § 2005(d).
[4] *Id.* § 2005(b); 42 C.F.R. § 8.2; see also 21 U.S.C. § 823(g)(1).
[5] SUPPORT Act § 2005(b); and 42 C.F.R. § 8.11.
[6] SUPPORT Act § 2005(b); *see also* 42 U.S.C. § 1395cc.
[7] *Proposed Rule* at 40717.
[8] CMS acknowledges that Form CMS-855B is typically completed by suppliers rather than providers, but believes it is the most appropriate and the most suitable enrollment application, since OTPs would only bill Part B (while at the same time stating OTPs will meet the definition of an institutional provider). *Id.* at 40718-19.
[9] *Id.*
[10] *Id.* at 40720.
[11] *Id.* at 40719.
[12] *See* 42 C.F.R. § 424.518.
[13] *Proposed Rule* at 40719.
[14] *Id*. at 40722.
[15] *See* 42 C.F.R. § 424.530.
[16] Providers should note that the Proposed Rule would not supplant or eliminate an OTP's obligation to maintain compliance with all existing and applicable provisions of 42 C.F.R. Part 8.
[17] *Proposed Rule* at 40723. Note, CMS cites potentially tenuous legal authority for this revocation reason ("We currently lack the legal basis to take administrative action against a physician or other eligible professional for a matter related to patient harm based solely on an IRO determination or an administrative action (excluding a state medical license suspension or revocation) imposed by a state oversight board, a federal or state health care program, or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. We believe, however, that our general rulemaking authority under sections 1102, 1866(j)(1)(A), and 1871 of the Act gives us the ability to establish such legal grounds.").
[18] *Id*. at 40722.
[19] SUPPORT Act § 1834(w)(1); *Proposed Rule* at 40525.
[20] *Proposed Rule* at 40520.
[21] The Proposed Rule outlines several potential approaches to value the drug component, including basing payments on average sales price ("ASP") and, when ASP data is not available, referencing Medicare Part D and TRICARE payment rates, wholesale acquisition costs, and/or national drug pricing benchmark data included in Medicaid's NADAC survey. See *id*. at 40530–35.
[22] To price the nondrug component, CMS has proposed referencing the nondrug component of the TRICARE weekly bundled rate for services furnished when a patient is prescribed methadone, noting that the TRICARE rate describes a generally similar bundle of services as the bundle proposed for an OTP. *Id.* at 40535.
[23] SUPPORT Act § 1834(w)(1). CMS clarifies in the Proposed Rule that the one-week period is defined as "a contiguous 7-day period that may start on any day of the week." *Proposed Rule* at 40525.
[24] *Id.* Though CMS acknowledges the wide variation in the intensity and frequency of opioid use disorder

treatment services provided to a patient depending on the severity of the patient's opioid use disorder and their stage of opioid use disorder treatment, for purposes of valuing the bundled payment, CMS assumed a week of services would include one substance use counseling session, one individual therapy session, and one group therapy session, with one toxicology test per month.
[25] In explaining the rationale for providing an add-on code to provide additional reimbursement for services that were not expected and not included in the patient's treatment plan, CMS states: "we recognize that counseling and therapy are important components of MAT and that patients may need to receive counseling and/or therapy more frequently at certain points in their treatment. We seek to ensure that patients have access to these needed services." *Id.* at 40527.
[26] *Id.* at 40543.
[27] *Id.* at 40539.
[28] *Id.* at 40542.
[29] In particular, HCPCS code GYYY1 covers at least 70 minutes of such services in the first calendar month, HCPCS code GYYY2 covers at least 60 minutes of such services in a subsequent calendar month, and HCPCS code GYYY3 covers each additional 30 minutes beyond the first 120 minutes. See *id.* at 40543.
[30] SUPPORT Act § 2001(a).

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