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CMS Issues Final Rule to Implement SUPPORT Act Coverage and Reimbursement of Opioid Treatment

By Rebecca Schaefer & Zachary Ernst, K&L Gates LLP

On November 15, 2019, the Centers for Medicare & Medicaid Services (CMS) published its final rule outlining changes to the Medicare Physician Fee Schedule (PFS) for the Calendar Year (CY) 2020 (Final Rule).[1] In the Final Rule, CMS details payment rates and policies under the Medicare PFS, as well as the final version of 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 Final Rule (i) describes a new enrollment category and process for opioid treatment programs (OTPs) to enroll in Medicare, (ii) establishes rules to govern Medicare coverage of and payment for opioid use disorder treatment services furnished in such OTPs, and (iii) allows certain face-to-face portions of opioid use disorder treatment services to be covered by Medicare when provided via telehealth communication. This article discusses where CMS landed following the notice and comment period on the proposed rule (Proposed Rule) issued in August 2019.[3] At a high level, the Final Rule was implemented largely as projected in the Proposed Rule. Notably, the major difference between the Final Rule and the Proposed Rule is the Final Rule's reduced and simplified bundled payment to OTPs for opioid use disorder treatment services, which is discussed in detail below.

New Enrollment Category Created for Opioid Treatment Providers

In furtherance of its objectives to help individuals recover from opioid addiction, the SUPPORT Act established a new Medicare benefit category for OTPs for the purposes of furnishing opioid use disorder treatment services.[4] Prior to the Final Rule, OTPs were not recognized as Medicare providers, meaning that beneficiaries receiving medication-assisted treatment (MAT) at OTPs for their opioid use disorder had to pay out of pocket. In the Final 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.[5] In addition to 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.[6]

For purposes of enrollment, the SUPPORT Act and the Final Rule require that OTPs enroll under Section 1866(j) of the Social Security Act, which requires the entity to enter into a provider agreement that meets standard Medicare requirements.[7] The Final Rule also specifically directs an OTP to have a provider agreement that meets the requirements of Section 1866(a) of the Social Security Act.[8] 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.[9] The Final Rule creates a new regulation at 42 C.F.R. § 424.67 that incorporates these general enrollment requirements and procedures and further establishes specific enrollment requirements that OTPs must meet in order to bill Medicare for the provision of opioid use disorder treatment services.[10] These requirements include submission of a Form CMS-855B with program-specific supplemental information attached, including (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:

1. 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."
2. 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."[11]

CMS finalized the assignment of 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.[12] This designation subjects OTPs to additional screening requirements, which include a site visit and submission of fingerprints for all individuals with greater than 5% ownership in the OTP for purposes of a criminal background check.[13] CMS further requires that, as a condition of reimbursing an OTP claim for a prescribed drug, the ordering provider's National Provider Identifier number must be provided, which enables CMS to monitor the prescribing and dispensing practices occurring at OTP facilities.[14] Commenters were generally supportive of the "high categorical risk" designation and "[s]everal commenters stated that [CMS'] proposed assignment of newly enrolling OTPs to the high categorical risk level was reasonably prudent due to [CMS']: (1) Stated lack of historical information on OTPs; and (2) safety concerns."[15] CMS stated that it plans to closely monitor OTP enrollment over the coming years and, if warranted, consider potential risk level reclassification.[16]

In the Final Rule, CMS includes 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; (iii) failing to satisfy any generally applicable requirements under CMS' existing enrollment denial regulations; and/or (iv) if the physician or other eligible professional[17] has been subject to prior action by a federal or state oversight board based on improper conduct that led to patient harm.[18] An OTP's failure to maintain ongoing compliance with requirements could also be a basis for enrollment revocation.[19] Most notable is that the Final Rule adopted the new and broad sweeping basis to deny or revoke an OTP's enrollment in the event that the physician or other eligible professional has been subject to prior action by a federal or state oversight board based on improper conduct that led to patient harm (nebulously defined).[20]

Lastly, all Part B-enrolled providers should note that CMS finalized expansion of the current denial and revocation regulations applicable under Part D to include all providers enrolled under Part B (not just professionals practicing in OTPs).[21] Specifically, CMS expanded its authority, currently established under Part D to now include Part B as well, to deny or revoke enrollment of a physician or other eligible professional if the physician has a pattern or practice of prescribing drugs that is

abusive or represents a threat to beneficiary health and safety.[22]

With the release of the Final Rule, OTPs fully certified by SAMHSA and accredited by a SAMHSA-approved accrediting body could begin enrolling in the Medicare program to bill for services starting January 1, 2020.[23] CMS encourages OTPs to begin the enrollment process as soon as possible. At least one newly enrolled provider of opioid treatment services has released a press release regarding their acceptance of Medicare.[24]

Medicare Coverage of Opioid Use Disorder Treatment Services

CMS notes that prior to the SUPPORT Act, methadone for MAT was not covered by Medicare.[25] 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).[26] 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.[27]

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.[28] CMS finalized its proposal to define the opioid use disorder treatment services that are furnished by OTPs to 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; (vi) intake activities, such as the physical exam, initial assessments, and preparation of a treatment plan; (vii) periodic assessment of services; and (viii) items and services appropriate to allow the use of telecommunications for certain services.[29]

As reimbursement for such opioid use disorder treatment services furnished by an OTP, the Final Rule sets forth a bundled payment methodology calculated based on the payment rate for the drug component (depending on the specific medication prescribed for MAT), in combination with the payment rate for the non-drug component of services.[30] The Final Rule provides that the duration of an episode of care would be one week and did not specify a maximum number of weeks that a patient may receive opioid use disorder treatment services from an OTP.[31]

Consistent with SAMHSA requirements, the payment methodology set forth in the Final 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.[32] The Final Rule positions OTP-developed treatment plan as the lynchpin for the bundled payment methodology.

In the Proposed Rule, CMS proposed the following in regard to the bundled payment methodology: (i) the 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; and (ii) 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.[33]

However, in the Final Rule, CMS altered its plan for the bundled payment methodology.[34] Based

on concerns raised by commenters, CMS noted that "many OTPs would need to change their documentation patterns to operationalize the proposed threshold for determining when to bill a full episode versus a partial episode and that having to make such changes in a short amount of time could be burdensome and potentially create barriers to providing care." CMS goes on to state that "[i]n the interest of combating the opioid crisis and in the best interest of beneficiaries, [CMS'] goal is to minimize barriers to OTPs enrolling in Medicare and beginning to furnish services to Medicare beneficiaries."[35] Accordingly, CMS only finalized a proposal to establish full weekly bundled payments and included a lower threshold to bill an episode of care. Specifically, the Final Rule contains the following notable requirements for the bundled payment methodology:

1. As a threshold to bill a full episode, that at least one service was furnished (from either the drug or non-drug component) to the patient during the week that corresponds to the episode of care. CMS will be monitoring for abuse given this low threshold for billing for a full weekly bundled payment. CMS remains interested in implementing a payment policy for partial episodes at some point in the future but decided against including the partial episode payment in the Final Rule.
2. 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, the Final Rule allows for the OTP to bill an add-on code to adjust the bundled payment rate.[36]

CMS notes it expects that OTPs will ensure treatment plans reflect the full scope of services an OTP anticipates furnishing during an episode of care, and the OTP will regularly update a patient's treatment plans to reflect any changes.[37] While the Final Rule emphasizes CMS' desire for the bundled payment methodology as a way to encourage efficient care by mitigating incentives tied to the volume of services furnished, CMS reiterated in the discussion regarding bundled payments under the PFS for substance use disorders that 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."[38]

CMS acknowledges the mandate in the SUPPORT Act for CMS to 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.[39] CMS states that it believes a beneficiary may receive counseling and/or therapy 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.[40] However, CMS indicated in the Proposed Rule 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.[41] In the Final Rule, 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 plans 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.[42] The Final Rule states that in cases where a payment for drugs used as part of an OTP's treatment plan is identified as being a duplicative payment because a claim for the same medications for the same beneficiary on the same date of service was paid under a different Medicare benefit, CMS will generally recoup the duplicative payment made to the OTP.[43]

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

In the Final Rule, CMS also establishes bundled payments for opioid use disorder treatment services that are furnished by physicians and other health professionals (not just by an OTP).[44] Similar to the OTP payment bundle, the bundle for Part B providers includes management, care coordination, psychotherapy, and counseling activities.[45] Notably, the PFS bundled payment excludes payment for the medication used in MAT (which under the Final Rule is 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).[46] Unlike the weekly bundle 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).[47]

In the Final Rule, CMS codified an adjustment to the OTP bundled payment to cover services provided in the initial month that includes intake activities, development of a treatment plan, care coordination, and individual and group therapy.[48] CMS additionally finalized a code to describe the care coordination, therapy, and counseling provided in subsequent months of opioid use disorder treatment.[49] Lastly, CMS went forward with 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.[50]

CMS acknowledges the possibility that beneficiaries with opioid use disorder have comorbidities and may require medically necessary psychotherapy services for other behavioral health services.[51] CMS finalized 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.[52]

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 Final Rule adds several therapy and counseling services to Medicare's list of approved services that may be provided via telehealth:

1. CMS now allows 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.[53] CMS anticipates that these services would often be billed by addiction specialty practitioners, but notes in the Final Rule that these codes are not limited to any particular physician or nonphysician practitioner specialty.[54] Further, CMS does not require consultation with a specialist as a condition of payment for these codes.[55]

2. Similarly, in order to increase access to care for beneficiaries receiving opioid use disorder treatment services from an OTP, the Final Rule allows 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.[56]

In addition, for the purposes of treating such disorder or a co-occurring mental health disorder, the Final Rule implements the provisions of the SUPPORT Act that removed the geographic limitations

for telehealth services furnished on or after July 1, 2019 to an individual with a substance use disorder diagnosis.[57] 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).[58]

Conclusion

Overall, the Final Rule makes good on CMS' obligation under the SUPPORT Act to address the nationwide opioid epidemic crisis through its implementation of the various mandates to expand Medicare coverage for opioid use disorder treatment services. With the exception of CMS including OTPs in the "high categorical risk" level for purposes of enrollment, the Final Rule reflects 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; and generally expanding access to opioid use disorder treatment services through greater telehealth access.

Authors

Rebecca Schaefer is a partner in K&L Gates' health care and FDA practice group, focusing her practice on healthcare regulatory and transactional matters. Ms. Schaefer has specialized knowledge of issues affecting academic medical centers, including those related to faculty physician practices, clinical research, mission support, and privacy and she presently advises hospital, health system, academic medicine, pharmacy and other healthcare clients on myriad compliance matters and strategic initiatives. Prior to joining K&L Gates, Ms. Schaefer served as associate university counsel at The University of North Carolina at Chapel Hill, where she was the senior health care attorney for the UNC School of Medicine and UNC Faculty Physicians. In this capacity, Ms. Schaefer advised campus and school-based leadership on various regulatory, transactional, institutional policy, and governance matters, including in the areas of healthcare fraud and abuse, privacy, human subjects research, and life sciences regulation. Her transactional experience includes hospital acquisitions, strategic affiliations, joint ventures and physician practice acquisitions, as well as professional service, data use and other types of agreements. Ms. Schaefer has also counseled on faculty physician employment matters, including physician compensation plans, employment agreements, and restrictive covenants. Prior to UNC-Chapel Hill, Ms. Schaefer was in private practice in Washington, D.C. advising clients from various sectors of the health care industry on matters such as clinical trial agreements, FDA regulatory compliance counseling, health care transactional due diligence, and the research, analysis, and compilation of legal and policy positions to comment on various agencies' rulemaking.

Zachary Ernst is a third-year associate in the firm's Research Triangle Park office. Mr. Ernst's focuses his practice on a variety of health law issues, including health care regulatory, compliance, and transactional issues for hospitals, health systems, academic medical centers, and other health care providers. His scope of work includes analysis of potential Stark Law and Anti-Kickback matters; government investigation and inquiries; federal regulatory compliance, including Stark and anti-kickback statutes, EMTALA, HIPAA, and the Affordable Care Act; and assisting clients with various operational matters, including contracting, medical staff issues, and risk management issues.

Endnotes

[1] 84 Fed. Reg. 62568 (Nov. 15, 2019), https://www.govinfo.gov/content/pkg/FR-2019-11-15/pdf/2019-24086.pdf (hereinafter, Final Rule).

[2] Support for Patients and Communities Act, Pub. L. No. 115-271 (hereinafter, "SUPPORT Act").

[3] 84 Fed. Reg. 40482 (Aug. 14, 2019), https://www.govinfo.gov/content/pkg/FR-2019-08-14/pdf/2019-16041.pdf (hereinafter, Proposed Rule).

[4] SUPPORT Act § 2005(d).

[5] *Id.* § 2005(b); 42 C.F.R. § 8.2; see also 21 U.S.C. § 823(g)(1).

[6] SUPPORT Act § 2005(b); and 42 C.F.R. § 8.11.

[7] SUPPORT Act § 2005(b); *see also* 42 U.S.C. § 1395cc.

[8] Final Rule at 62637.

[9] *Id*. at 62920.

[10] *Id.* at 63202–05.

[11] *Id.*

[12] *Id.* at 63208.

[13] *Id.* at 62922.

[14] *Id.* at 62923.

[15] *Id.* at 62922.

[16] *Id.*

[17] The Final Rule defines "eligible professional" as the term is defined in Section 1848(k)(3)(B) of the Social Security Act. Section 1848(k)(3)(B) of the Social Security Act defines term "eligible professional" as any of the following:

(i) A physician;

(ii) A practitioner described in section 1842(b)(18)(C) of the Social Security Act;

(iii) A physical or occupational therapist or a qualified speech-language pathologist; or

(iv) Beginning with 2009, a qualified audiologist (as defined in section 1861(ll)(3)(B)).

[18] *Final Rule* at 63203–4.

[19] *Id.* at 63203.

[20] *Id.* at 63203–4.

[21] *Id.* at 63204.

[22] *Id.*

[23] CMS, *Letter to OTP Program Sponsors and State Opioid Treatment Authorities*,https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Opioid-Treatment-Program.

[24] PRWeb, *BayMark Health Services Opioid Treatment Programs Nationwide Now Accept Medicare* (Jan. 8, 2020), https://www.prweb.com/releases/baymark_health_services_opioid_treatment_programs_nationwide_now_accept_medicare/prweb16817719.htm.

[25] *Final Rule* at 62630.

[26] *Id*.

[27] *Id.* at 62630–31.

[28] *Id*.

[29] *Id.* at 63189.

[30] *Id.* at 62639.

[31] *Id.* at 62640–41.

[32] *Id.* at 62641.

[33] *Proposed Rule* at 40525.

[34] *Final Rule* at 62645.

[35] *Id*.

[36] *Id*.

[37] *Id*.

[38] *Id.* at 62674.

[39] *Id.* at 62664.

[40] *Id.* at 62634.

[41] *Proposed Rule* at 40539.

[42] *Final Rule* at 62664.

[43] *Id*.

[44] *Id.* at 62674.

[45] *Id.*

[46] *Id.* at 62673.

[47] *Id.*

[48] *Id.* at 62676.

[49] *Id.* at 62674.

[50] *Id.*

[51] *Id.* at 62675.

[52] *Id.* at 62677.

[53] *Id.* at 62675–76.

[54] *Id.* at 62674.

[55] *Id.* at 62674.

[56] *Id.* at 62646.

[57] *Id.* at 62676.

[58] *Id.* at 62628–29.

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