PUBLICATION

Most Restrictive Medicare Enrollment Rules Proposed for Opioid Treatment Programs

August 29, 2019

Grounded in the bipartisan Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act designed to "alleviate the nationwide opioid crisis," CMS's proposed requirements in the 2020 Physician Fee Schedule for opioid treatment programs (OTPs) extend far beyond the enrollment and revocation rules for any other types of Medicare providers and suppliers. This article discusses some of the more significant proposed requirements.

OTPs – High Risk

CMS justifies these additional enrollment requirements because of its proposed assignment of "newly enrolling OTPs to the high categorical risk level." 84 Fed. Reg. 40482, 40719 (August 14, 2019 Proposed Rule). CMS has provided two main reasons for its "high" risk assignment for OTPs. First, because OTP services are an entirely new Medicare benefit, CMS has no historical information on OTPs (either from an enrollment, billing, or claims perspective) upon which it "can fairly estimate the degree of risk they may pose." *Id*. Next and perhaps more insightful is the acknowledgement by CMS that industry abuses have occurred. CMS particularly highlights that the "opioid epidemic has . . . increased the potential for unscrupulous providers to take advantage of Medicare beneficiaries through fraudulent billing schemes and abusive prescribing practices; recent examples include 'patient brokers' in Massachusetts, as well as excessive stays in 'sober homes' in Florida." *Id*. CMS also notes the "heightened risk" that OTPs present because of the nature of the "core service" at the facilities (prescribing and dispensing of methadone and other opioids as part of treatment for opioid addiction) and the "nature of the patients" at OTPs since these individuals are "grappling with opioid addiction." *Id*.

Unique Enrollment Requirements for OTPs

Even though other provider or supplier types fall within the same "high" risk categorical assignment as newly enrolling home health agencies, durable medical equipment, prosthetics, orthotics, supplies suppliers and Medicare Diabetes Prevention Program suppliers, CMS has imposed a number of unique requirements for OTPs. For example, CMS has explicitly stated that it intends to utilize a more thorough screening of OTPs than that currently utilized by the Substance Abuse and Mental Health Services Administration (SAMSHA). *Id.* In a general discussion about the SAMHSA certification process, CMS notes that although "SAMHSA's approved accreditation bodies do verify that these individuals have appropriate licensure, they do not collect this information on a form, screen against federal databases, or have a database that keeps this information. <u>CMS, however, intends to conduct these activities</u> [for OTPs]." *Id*. (emphasis added).

With respect to the SAMHSA certification process, CMS proposes that to enroll in Medicare, "an OTP must have in effect a current, valid certification by SAMHSA for such a program." *Id*. at 40720. This means, however, that CMS will not accept a "provisional" certification or accreditation in lieu of a current, valid SAMHSA certification or accreditation by an accrediting body or other entity approved by SAMHSA for an OTP to enroll in Medicare. *Id*. at 40716, 40720. Thus, OTPs who have applied for accreditation and/or certification and would be eligible to receive a provisional certification for up to one year would <u>not</u> be eligible for enrollment in Medicare until the process was complete. *Id*.

CMS is also proposing, as an effort to ensure that "problematic" providers and personnel are not prescribing or dispensing drugs on behalf of an OTP, that OTPs

Must not employ or contract with a prescribing or ordering physician or other eligible professional or with any individual legally authorized to dispense narcotics who, within the preceding 10 years, has been convicted . . . of a federal or state felony that we deem detrimental to the best interests of the Medicare program and its beneficiaries, based on the same categories of detrimental felonies, as well as case-by-case detrimental determinations, found at 42 C.F.R. 424.535(a)(3). This provision would apply irrespective of whether the individual in question is (1) [c]urrently dispensing narcotics at or on behalf of the OTP; or (2) a W-2 employee of the OTP.

Id. at 40720.

This restriction on individuals with an adverse history also would apply to any individual on the preclusion list under 42 C.F.R. §§ 422.222 or 423.120(c)(6), as well as any employee or independent contractor who has a "current or prior adverse action imposed by a state oversight board, including, but not limited to, a reprimand, fine, or restriction, for a case or situation involving patient harm that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries." *Id*. As discussed in great detail in the Professionals Beware Article, CMS's new enrollment denial or revocation basis for this type of current or prior adverse action would apply to all providers and suppliers, not just OTPs, and represents arguably one of the most significant changes to the Medicare enrollment rules since 2006.

Finally, under the proposed rule, OTPs must also specifically report an OTP's medical director and its program sponsor as managing employees. *Id*. Historically, CMS has required all "managing employees" to be reported, but CMS did not specifically identify any categories of employees who would by default be considered managing employees. Rather, CMS typically refers to the regulatory definition in 42 C.F.R. § 424.502, confirming the need for at least one managing employee but requiring all managing employees to be reported. OTPs, however, will be required to list, among others, the "OTP's medical director and program sponsor." 84 Fed. Reg. at 40720.

OTPs as Providers

Since the statute identified OTPs as providers, CMS proposes to follow other regulatory requirements for providers but has identified the CMS 855B form as the application form that OTP providers will complete. OTPs will be subject to the application fees due to their identification as a provider.

Comments on the proposed rule are due by September 27, 2019.

Baker Donelson Comments

These proposed rules for OTPs present restrictions not yet seen before in the Medicare enrollment space and raise many questions and concerns for existing and new OTPs seeking enrollment in Medicare. Among those questions and concerns:

- CMS has not explained in any detail how it intends to conduct its screening activities, which federal databases it will use, or how long it will keep its own database of information.
- New and existing OTPs would need to wait for the entire SAMHSA certification process to be complete instead of operating under a provisional certification and providing much-needed recovery and treatment services to an underserved community for up to a year. Further, if anything should happen to a current OTP's SAMHSA certification or accreditation, then, based on these proposed

rules, an OTP may face harsh repercussions.

- The fact that an OTP may not employ or contract with an individual who has certain current or prior adverse actions is more far reaching than the restrictions for other providers or suppliers that must report adverse actions for individuals in ownership or control positions but not front line staff.
- The proposed reporting of disciplinary actions imposed by a state oversight board, including, but not limited to, a reprimand, fine, or other restriction, has far reaching implications as discussed more fully in the article appearing in the Professionals Beware Article.
- With respect to disclosure during the enrollment process, OTP staff preparing Medicare applications (initial enrollment and updates) should focus on CMS's unusual specificity with respect to managing employees and the proposed mandatory reporting of the medical director and program sponsor.

The comment period for the proposed rule ends on **September 27, 2019**. Time is of the essence for OTPs to respond to CMS's proposed restrictions and requirements for Medicare enrollment. OTPs should contact professional and trade associations to alert those organizations to these proposed changes.

For more information, please contact any member of Baker Donelson's Health Law Reimbursement Group.