PUBLICATION

The Nightmare Came True: Minor Licensing Actions Could Lead to Disastrous Collateral Damages

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As forewarned, CMS's finalization of the Calendar Year (CY) 2020 Physician Fee Schedule, effective January 1, 2020, brings significant changes to its authority to deny or revoke a Medicare enrollment for physicians and other eligible professionals based on minor licensing disputes, such as a fine or reprimand by a state licensing board. These new bases for denial or revocation of enrollment, coupled with the new disclosure requirements for providers and suppliers related to affiliations with disclosable events, demonstrate that CMS is sticking to its promise to end 'pay and chase' in federal health care fraud efforts by greatly enhancing its enforcement efforts in enrollment and revocation.

Regulatory Changes

So, what will happen beginning on January 1, 2020? CMS may now deny or revoke the current enrollment of any professional eligible to enroll in Medicare if the professional has been:

Subject to prior action from a State oversight board, Federal or State health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm.
42 C.F.R. §§ 424.530(a)(15), 424.535(a)(22).

In determining whether patient harm exists, CMS will consider the following factors:

- The nature of the patient harm.
- The nature of the physician's or other eligible professional's conduct.
- The number and type(s) of sanctions or disciplinary actions that have been imposed against the physician or other eligible professional by a state oversight board, IRO, Federal or State health care program, or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. These actions can include, but are not limited to in scope or degree:
  - License restriction(s) pertaining to certain procedures or practices.
  - Required compliance appearances before State oversight board members.
  - License restriction(s) regarding the ability to treat certain types of patients (for example, cannot be alone with members of a different gender after a sexual offense charge).
  - Administrative/monetary penalties.
  - Formal reprimand(s).
- If applicable, the nature of the IRO determination(s).
- The number of patients impacted by the physician's or other eligible professional's conduct and the degree of harm thereto or impact upon.
  42 C.F.R. §§ 424.530(a)(15), 424.535(a)(22).

Non-Finalized Provisions

In the proposed rule, CMS originally included the following actions in its determination of what constitutes patient harm:

- Required participation in rehabilitation or mental/behavioral health programs; or
- Required abstinence from drugs or alcohol and random drug testing.
  84 Fed. Reg. 62568, 62926 (Final Rule, November 15, 2019).

Commenters expressed a number of concerns regarding CMS's consideration of these actions, including that physicians and other eligible professionals could be discouraged from seeking help for health problems and not self-reporting to medical boards to obtain assistance. Commenters expressed concern that these proposed changes appeared to specifically target individuals engaged in mental/behavioral health and/or substance use disorder treatment for medical problems, in programs that already have appropriate monitoring to prevent harm. 84 Fed. Reg. at 62928. In its response to these comments, CMS stated why it would no longer consider those two actions as circumstances under which it would find patient harm:

We do not wish to discourage physicians and other eligible professionals from seeking whatever help they may need. . . . However, we note that the action or order must be restricted to required participation in a rehabilitation or mental/behavioral health program or abstinence from drugs or alcohol and random drug testing. If the action involves either of these directives as well as an additional sanction that involves patient harm, the latter (but not the rehabilitation, abstinence, or testing portion of the directive) could involve [denial or revocation of the enrollment].
Id.

CMS included three examples of how this might work operationally:

Example 1 – In a case involving patient harm, a state oversight board requires Dr. X to enter a rehabilitation program. There are no other sanctions in the state's order. Since the state's action is restricted exclusively to rehabilitation, [the denial or revocation of enrollment provisions] would not apply.

Example 2 – In a case not involving patient harm, a state oversight board issues a decision pertaining to Dr. X that: (1) Requires him to enter a rehabilitation program; and (2) imposes a fine on him. [The denial or revocation of enrollment provisions] would not apply in any event because no patient harm was present.

Example 3 – In a case involving patient harm, a state oversight board issues a decision pertaining to Dr. X that: (1) Requires him to enter a rehabilitation program; and (2) restricts his license for a 60-day period due to sexual misconduct. CMS would consider the board decision under [the denial or revocation of enrollment provisions], as applicable, because of the license restriction based on sexual misconduct.
Id.

CMS also removed a proposed catch-all provision that it would consider "any other information [it] deem[s] relevant" in its determination of patient harm. *Id*. at 62929. However, CMS explained that even if this language was not contained in the regulation, this removal "will not affect our continued inclusion of this same factor in several of our existing denial and revocation reasons" and that it was not "precluding its use in possible future provisions." *Id*.

Stakeholder Comments and CMS's Response

If CMS had not buried the proposed regulations in a single paragraph on 808 pages of a proposed rule focused primary on fee schedule changes, public outcry to the proposed rules might have been greater. Burying the provisions in a section specific to opioid treatment providers certainly does not appear to be consistent with

notice and comment rulemaking. This likely explains the limited number of responses to the proposed regulatory changes.

In response to comments from approximately 30 stakeholders, CMS reiterated its promise to deny or revoke only if there was a determination by a state oversight board or similar body that involved patient harm. *Id*. at 62727. Some of the commenters indicated that the proposed changes were "overly vague" and would "unfairly impose harsh and disproportionate sanctions on providers for potentially minor violations." *Id*. Commenters also expressed concern that the proposed changes would particularly harm young and inexperienced physicians who could be punished by CMS for modest transgressions and that these changes generally could devastate individual medical practices, since a Medicare revocation would trigger an automatic Medicaid enrollment termination as well as termination from private payer programs. *Id*. Finally, commenters stated that these changes would negatively affect Medicare beneficiaries' access to health services because:

1. A revoked provider's patients would have to seek care elsewhere; and
2. The number of available physicians and other eligible professionals (including, perhaps the group practices with which they are affiliated) will be unnecessarily reduced, leading to provider shortages. *Id*.

On this note, commenters stated that provider shortages "could be especially problematic in remote and underserved areas and with specialized services" and that the "patient harm CMS seeks to deter could actually increase through a restriction of available care." *Id*. CMS did not agree that this type of action would reduce access to available care since CMS believes that expansion of its denial and revocation authority would affect only a "very small number" of professionals eligible to enroll. *Id*. at 62928.

In responding to these comments, CMS again reiterated that patient harm is key to any action it might take under these new rules, refuting the assumption by some commenters that the "action itself, regardless of any impact on a patient, would be sufficient for CMS to invoke these provisions," and further stated "Patient harm must be a result." *Id*. However, that is not always the case under the current regulations, such as when CMS revokes billing privileges for a handful of unpaid claims that inadvertently included the name of a deceased beneficiary that was the same or very similar to the living beneficiary who received the services. Where is the patient harm in this situation?

In rejection of a suggestion that CMS's preamble discussion be included in the regulatory text to ensure that CMS keeps its promise that "modest sanctions would not automatically result in a revocation," CMS explained that this language was not suitable for regulatory text but that these discussions should make clear that the revocation authority will be applied:

3. With great care and circumspection;
4. in a non-arbitrary manner;
5. infrequently; and
6. only when the conduct and resulting patient harm were significant in nature. *Id*. at 62929.

A number of commenters addressed the subtle way these rules were proposed – buried within the enrollment rules relating to opioid treatment programs and not as a stand-alone section – increasing the chance that many provider organizations were unaware of these changes or might believe the provisions only applied to opioid treatment programs. *Id*. at 62930. CMS rejected this notion, finding about 30 comments to be evidence that "sufficient public notice was furnished regarding these provisions." *Id*. at 62931.

Commenters also argued that state oversight boards, not the federal government, are the "appropriate entities for monitoring and disciplining physicians and, if warranted, restricting their authority to treat patients." *Id*. at 62930. CMS acknowledged the "very crucial role" of state oversight boards in, *inter alia*, protecting the health of patients, but believes that it too has responsibility for "safeguarding the welfare of individuals" receiving Medicare benefits and that this responsibility is the "overriding principle . . . behind our patient harm provisions." *Id*. This response does not, however, take into account that charges in an order may not be sustained during the disciplinary dispute process and that facts may not be substantiated. And, CMS will not be privy to the settlement discussions that occur in these types of matters and thus will not know whether allegations of harm were actually substantiated or not.

Unlike state oversight boards that have processes that offer due process protections, such as to offer rebuttal evidence in response to allegations, CMS's rules do not afford a physician or practitioner the same due process considerations. A revocation is similar to a summary suspension in that the revocation action is taken and then appeal rights are provided. And, there is no expedited appeal process if there is uncontroverted proof that no patient harm occurred. CMS justifies its process because it "must be able to take prompt action, using [its] independent judgment, to halt potential threats to Medicare patients and the Trust Funds." *Id*. at 62931. Further, as a federal agency, CMS believes it "is not bound to utilize the same administrative processes and mechanisms that state oversight boards do." *Id*.

So, although stakeholders raised concerns regarding not only the substance of the new rules but the manner in which CMS provided "notice" of the new rules, CMS stood its ground and moved forward on finalizing rules lacking in any due process protections to get a prompt resolution to an arbitrary determination regarding harm.

Implications for Health Care Professionals

To the extent that you are a professional facing a licensing board action, it will be incredibly important for your counsel in the matter to understand the potential collateral damages from agreeing to settle the dispute by accepting a minor sanction. Similarly, the credentialing staff for professional practices should consider how to analyze the potential implications for a soon-to-be-hired staff member with a minor past licensing sanction.

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