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New Stark Regulation May Spark Reviews of Medical Directorships

By Nina Youngstrom

Between recent changes to Stark regulations[1] and Medicare watchdogs' long-time concern about fair market value and commercial reasonableness, hospitals may want to revisit their medical director agreements. There's a limit to how many medical director agreements are defensible and how much physicians should be paid for the administrative services they provide.

"Make sure each medical directorship serves a legitimate business purpose and there is no duplication," advises Lyle Oelrich, a principal with PYA. He recommends performing a medical director needs assessment.[2]

In the revised Stark regulation, CMS for the first time defined commercial reasonableness, which is a pillar of many common exceptions to the Stark Law, along with fair market value. CMS says commercially reasonable means "the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty." Also, an arrangement doesn't have to be profitable to be commercially reasonable. In the context of medical director agreements, CMS cautions that looks can be deceiving. "Arrangements that, on their face, appear to further a legitimate business purpose of the parties may not be commercially reasonable if they merely duplicate other facially legitimate arrangements (84 FR 55790)," the rule stated. "For example, a hospital may enter into an arrangement for the personal services of a physician to oversee its oncology department. If the hospital needs only one medical director for the oncology department, but later enters into a second arrangement with another physician for oversight of the department, the second arrangement merely duplicates the already-obtained medical directorship services and may not be commercially reasonable. Although the evaluation of compliance with the physician self-referral law always requires a review of the facts and circumstances of the financial relationship between the parties, the commercial reasonableness of multiple arrangements for the same services is questionable."

CMS is letting entities that provide designated health services know they shouldn't pay for more medical directorships than absolutely necessary, Oelrich said. "It's not a major change in the way the government views it, but they are making their point more clearly in the new Stark regulation."

Some Medical Directorships Are Required

Not all medical director agreements are put in place for the same reason, Oelrich explained. Some are required to meet federal and/or state regulatory requirements. For example, the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program requires a medical directorship for bariatric surgical programs to be a Center of Excellence, he said. "However, the need for such medical directorships is not always that clear. For example, in the cardiology department at a hospital, you may find a congestive heart failure medical director, a chest pain medical director, a cardiac rehabilitation medical director, a coronary catheterization laboratory medical director, an electrophysiology medical director, and an electrocardiogram medical director," Oelrich said. In these situations, medical directorships are potentially duplicative, and he suggests hospitals evaluate whether some administrative services can be consolidated or restructured. "However, ultimately, each

individual medical directorship may be supportable as any formal analysis of medical directorship need is facts and circumstances specific," he said.

Medical director agreements have been on the government's radar for years. In a 2015 fraud alert,[3] the HHS Office of Inspector General stated that "physicians who enter into compensation arrangements such as medical directorships must ensure that those arrangements reflect fair market value for bona fide services the physicians actually provide. Although many compensation arrangements are legitimate, a compensation arrangement may violate the anti-kickback statute if even one purpose of the arrangement is to compensate a physician for his or her past or future referrals of Federal health care program business."

Medical director agreements also pop up in civil monetary penalty and False Claims Act (FCA) cases. For example, Sutter Health in California agreed to pay $30.5 million in a 2019 FCA settlement[4] for allegedly overpaying Sacramento Cardiovascular Surgeons Medical Group for physician assistants and medical director agreements in violation of the Stark Law. The case was set in motion by a former compliance officer at Sutter Medical Center.

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1 Nina Youngstrom, "Final Stark Rule Makes Room for 'Imperfect Performance,' Has VBC Exceptions Like OIG's," *Report on Medicare Compliance* 29, no. 43 (December 7, 2020), https://bit.ly/3sLfudL.
2 Nina Youngstrom, "Checklist: Evaluating Medical Directorships," *Report on Medicare Compliance* 30, no. 10 (March 15, 2021).
3 HHS Office of Inspector General, "Fraud Alert: Physician Compensation Arrangements May Result in Significant Liability," June 9, 2015, https://bit.ly/3exPf30.
4 Nina Youngstrom, "A Compliance Officer Is the Whistleblower in Sutter Health Case; Settlement Is $30.5M," *Report on Medicare Compliance* 28, no. 41 (November 18, 2019), http://bit.ly/3bxZ2qQ.