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A compliance framework for evaluating medical directorship need

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Physicians around the country are entering into medical directorship agreements with hospitals, health systems, and other healthcare institutions to fill the important role of medical director. Medical directorship agreements help facilitate an organization's ability to comply with regulatory and accreditation guidelines; promote the delivery of quality patient care; and provide clinical and administrative leadership to other physicians, clinical staff, and executive management. However, medical directorships continue to face increasing governmental and regulatory scrutiny, such as that demonstrated by the examples of settlements that follow. Healthcare organizations should be aware of key compliance considerations in evaluating the need for medical directorships.

Noteworthy settlements

- In August 2018, a hospital system paid \$84.5 million to settle claims of Anti-Kickback Statute (AKS) and Stark Law violations.^[1] In addition to other issues, the lawsuit alleged the system paid medical directors multiple times under separate arrangements for the same work; compensated for services not performed; and remunerated for medical directorships that lacked job descriptions, performance standards, or evaluations.^[2]
- In 2019, a home health agency settled two cases of False Claims Act (FCA) infractions.^[3] Allegations included a medical director's approval of care without ever seeing the patients or patient records, "sham medical director agreement[s], and payments to the spouses of referring physicians." The sham medical director agreements also violated the AKS and the Stark Law.
- An orthopedic surgeon paid more than \$470,000 in 2019 to settle allegations of FCA and AKS violations.^[4] For approximately two years, the physician allegedly accepted kickback payments characterized as hourly medical director fees for writing prescriptions for pain creams.
- Similarly, in 2019, a physician agreed to pay approximately \$92,500 for allegedly accepting payments that violated the AKS.^[5] He also prescribed pain cream and facilitated the sale and distribution of the medication in exchange for payments disguised as medical director compensation.
- In 2016, the owner of a home healthcare and hospice company admitted to paying kickbacks to 20 medical directors for obtaining Medicare beneficiary referrals for the organization; however, the medical directors never provided any patient care or oversight at the facilities.^[6] Further, the owner acknowledged that medical director agreements were a tool to conceal the payment. The kickbacks violated the AKS and the FCA, ultimately requiring the owner to pay \$6.8 million.

While the above examples are more recent, the alleged activities related to the first settlement referenced previously started as early as 2004.^[7] Interestingly, on June 9, 2015, the U.S. Department of Health & Human Services Office of Inspector General issued a fraud alert advising that physician compensation arrangements have the potential to violate the AKS.^[8] The alert advised physicians that they have a responsibility to ensure that their relationships, such as medical director agreements, are for “bona fide services the physicians actually provide” and that “those arrangements reflect fair market value.” While most concerns regarding medical directorship agreements may pertain to fair market value compensation amounts, there are additional factors, such as those outlined herein, to consider to ensure regulatory compliance.

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