

A PUBLICATION OF THE HEALTH CARE COMPLIANCE ASSOCIATION

WWW.HCCA-INFO.ORG

Gearing up for future challenges

an interview with Tom Twinem

Director, Corporate Compliance / Privacy Officer Children's Hospital of Wisconsin

See page 16

25

Medical directorship arrangements: Increased government enforcement and best practices for compliance

Wade Miller and Kimyatta McClary

31 Establishing a baseline compliance pulse for hospital and physician groups: Evaluations by outside counsel

Ann Bittinger, William J. Holahan, and Caroline Kubovy

43 Advanced practice providers: Top three compliance problems Carolyn Buppert **49** OIG 2014 Work Plan explores new compliance projects Nathaniel Lacktman

This article, published in Compliance Today, appears here with permission from the Health Care Compliance Association. Call HCCA at 888-580-8373 with reprint requests.

by Wade Miller and Kimyatta McClary

Medical directorship arrangements: Increased government enforcement and best practices for compliance

- » The OIG continues to increase enforcement related to medical directorship arrangements.
- » Paying medical directors for referrals of patients is illegal under the Anti-Kickback Statute and may result in False Claims Act liability.
- » Ensure that medical directorship arrangements are in writing, compensate the physician at fair market value, and outline the services the physician is to perform, as well as the compensation for such services.
- » Maintain documentation of services the medical director performs, such as time logs or other accounts.
- » Implement a systematic and thorough compliance program that routinely monitors and provides oversight of physician/provider relationships.

Wade Miller (wade.miller@alston.com) is a Partner and **Kimyatta McClary** (kimyatta.mcclary@alston.com) is a Senior Associate in Alston & Bird LLP's Litigation & Trial Practice Group in Atlanta. The authors are grateful to Kendall Short, an Associate in Alston & Bird LLP's Litigation & Trial Practice Group, for her assistance in researching this article.

edical directors are often in a prime position to generate business for the healthcare providers who pay them. As a result, the government is looking at these relationships with heightened scrutiny.

In April 2006, the Office of the Inspector General (OIG) published "An Open Letter to Health Care Providers"¹ offering the OIG's views on provider/physician compliance with the Anti-Kickback Statute (AKS), the Physician Self-Referral Law (Stark Law), and the False Claims Act (FCA).² In the letter, the OIG makes clear that questionable medical directorship arrangements between providers and physicians would be subject to greater scrutiny and possible enforcement actions in the near future.

Over the past few years, the federal government has done just that. We have seen numerous investigations and prosecutions targeting improper medical directorship arrangements between physicians and healthcare providers (e.g., hospital, hospice, home health, nursing, and long-term care facilities). Many of these actions have resulted in staggering financial tolls, administrative sanctions, and, in some cases, criminal liability against both physicians and providers.

With the increase in enforcement activity by the OIG against questionable medical directorship arrangements, it is important that providers and physicians understand what the law requires for compliance when entering into medical direc-

torship arrangements, and that these parties implement thorough compliance programs to avoid potential liability. This article provides an overview of the relevant healthcare fraud and abuse laws, highlights recent government enforcement activity related to medical



Miller



Compliance Today April 2014

McClary

directorship arrangements, and discusses best practices that providers and physicians can implement in order to avoid violations of the healthcare fraud and abuse laws when entering into medical directorship arrangements.

The role of the medical director

Medical directors can play important roles in overseeing clinical care, providing education and training to staff, participating in administrative decision-making, developing

policies and procedures, and improving overall quality of care. The roles and responsibilities of medical directors vary depending on the type of provider they work for.

Regardless of the type of services the medical director is to provide, when a healthcare provider contracts with a physician for a medi...when a healthcare provider contracts with a physician for a medical director position, both sides must carefully contemplate the federal requirements under the healthcare fraud and abuse laws.

compensation for medical directorships or consulting engagements. The statute covers those who offer or pay remuneration as well as those who solicit or receive remuneration. Each party's "knowing and willful" intent is a key element of their liability under the AKS. Criminal penalties and administrative sanctions for violating the AKS include fines, jail terms, and exclusion from participation in the federal healthcare programs.

The Stark Law prohibits physicians from

referring patients who receive healthcare services that are payable by Medicare or Medicaid to entities with which the physician has a financial relationship, unless an exception applies. Financial relationships include both ownership/investment interests and compensation arrangements, such as medical

directorships. The Stark Law is a strict liability statute, which means proof of specific intent to violate the law is not required. The Stark Law prohibits the submission, or causing the submission, of claims in violation of the law's restrictions on referrals. Additionally, the Stark Law requires that physicians must be paid at fair market value and that the provider/physician arrangement is commercially reasonable. Penalties for violations of the Stark Law include fines as well as exclusion from participation in the federal healthcare programs, which can cut off a significant source of funding.

The FCA creates liability for any person who "(A) knowingly presents, or causes to be presented, a false or fraudulent claim for

cal director position, both sides must carefully contemplate the federal requirements under the healthcare fraud and abuse laws. The three primary federal fraud and abuse laws that apply to physician/provider medical directorship arrangements are the AKS, the Stark Law, and the FCA.

The AKS is a criminal law that prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by the federal healthcare programs (e.g., drugs, supplies, or healthcare services for Medicare or Medicaid patients). Remuneration includes anything of value, including, for example, cash, free office space, expensive hotel stays and meals, and excessive payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or] (C) conspires to commit a violation of [the FCA]." FCA violations include claims that are fraudulent on their face (e.g., overcharging the government for services rendered, charging for services not performed) as well as accurate claims for completed services that are rendered in violation of other laws, such as the AKS and the Stark Law.

Given these strict laws, payments to medical directors in exchange for referrals can present a significant problem for both the physicians and the facilities since medical directors are often big referral sources for providers. If medical directors are receiving compensation above fair market value or are failing to provide legitimate services in exchange for their payments, the government may consider these referrals to be illegal kickbacks in violation of the AKS or Stark Law. If a claim that resulted from a kickback is then subsequently submitted to Medicaid or Medicare for payment, the provider and physician may then also be liable under the FCA.

Recent government enforcement

The federal government, with the OIG and the Department of Justice (DOJ) at the helm, is increasingly initiating investigations and prosecutions targeting "sham" physician/provider medical directorship arrangements that allegedly violate the FCA, the AKS, the Stark Law, and other fraud and abuse laws. Some examples of recent enforcement actions include:

Dr. Gustave Drivas was sentenced to 151 months in prison in September 2013 and had his medical license revoked in New York for his role as a "no show" doctor in a \$77 million Medicare fraud scheme. Dr. Drivas knowingly authorized his coconspirators to use his Medicare billing number to charge Medicare for more than \$20 million for medical procedures and services that were never performed. From 2005 to 2010, Dr. Drivas served as the medical director of a clinic in Brooklyn, but he almost never visited the clinic except to collect his checks, ultimately receiving more than \$500,000. He was convicted of healthcare fraud conspiracy. In addition to the prison term, Dr. Drivas was also sentenced to three years of supervised release, exclusion from Medicare, Medicaid, and all federal health programs, forfeiture of \$511,000, and payment of restitution of \$50.9 million.³

- Dr. Eugene Goldman was convicted in June 2013 of one count of conspiring to violate the AKS and four counts of violating the AKS arising from his work as medical director at Home Care Hospice Inc. (HCH) in Philadelphia. He regularly referred Medicare and Medicaid patients to HCH between December 2000 and July 2011 in exchange for more than \$263,000 in kickbacks.⁴
- Tuomey Health Care System in Sumter, South Carolina, engaged in a number of part-time employment arrangements that were found to have no other purpose than to induce referrals. The hospital paid physicians compensation amounts far exceeding market value for parttime employment services that were not needed. In May 2013, a federal jury found the hospital guilty of violating the Stark Law and returned a \$39 million verdict. The hospital was also found guilty of violating the FCA, entitling the government to seek treble damages plus certain other penalties.⁵
- McAllen Hospitals L.P., d/b/a/ South Texas Health System, a hospital group based in McAllen, Texas, agreed in October 2009 to pay the government \$27.5 million to settle claims that it violated the

FCA, the AKS, and the Stark Law between 1999 and 2006. The government alleged that the defendants had entered into illegal financial relationships with several doctors in McAllen in order to induce them to refer patients to hospitals within the group. These payments were purportedly disguised through a series of sham contracts, including medical directorships and lease agreements.⁶

- University of Medicine and Dentistry of New Jersey entered into clinical assistant professorship agreements with several cardiologists. These contracts technically required the doctors to perform teaching-related services in exchange for between \$50,000 and \$180,000 per year in compensation. The United States argued that the agreements were primarily for the physicians to refer patients for private cardiology services to the hospital, and there was little indication that the services described in the agreements were ever performed. The court found that the arrangements violated the Stark Law, because they failed the fair market value and commercial reasonableness requirements. The hospital settled with the government in September 2009 for \$8.3 million.7
- Ferrell-Duncan Clinic, Inc., a physician group practice in Springfield, Missouri, paid the government \$1 million and entered into a 5-year Corporate Integrity Agreement to settle alleged violations of the AKS, FCA, and Stark Law. Allegedly, the physician group practice entered into medical directorship agreements with Cox Medical Centers that were not in writing, the physicians were paid more than fair market value for their services, and the amounts paid were based on the value of referrals the physicians sent to the medical center.⁸

- HealthSouth Corporation and Drs. James Andrews and Lawrence Lemak of Birmingham, Alabama paid a total of \$14.9 million to settle allegations related to improper medical directorship arrangements. HealthSouth paid \$14.2 million, while the two orthopedic surgeons paid \$450,000 and \$250,000 respectively. Under the agreements, HealthSouth purportedly provided the physicians with valuable compensation, including free use of the corporate jet, and required the physicians to render only limited services in return. The medical director agreements allegedly called for redundant services and encouraged the physicians to refer their patients to HealthSouth facilities.9
- Covenant Medical Center in Waterloo, Iowa allegedly violated the Stark Law by paying five physicians commercially unreasonable compensation, well above fair market value, to refer their patients to Covenant for treatment. The government noted that "[t]hese physicians were among the highest paid hospital-employed physicians not just in Iowa, but in the entire United States." The hospital agreed to pay the government \$4.5 million to resolve allegations that it violated the FCA and the Stark Law.¹⁰

The increase of government enforcement in this area, coupled with the risk of financial tolls, administrative sanctions, and in some cases, criminal liability, highlights the importance of a thorough compliance program to mitigate the risk of potential violations of the healthcare fraud and abuse laws when entering into medical directorship arrangements.

Recommended best practices

The healthcare fraud and abuse laws themselves are the most helpful resources for developing best practices for physician/provider medical directorship arrangements. For example, the AKS has certain "safe harbors" that protect arrangements from prosecution if they meet certain criteria. The "personal services and management contracts" safe harbor, under which most medical directorship agreements fall, includes the following requirements and suggests the best practices for medical directorship arrangements:

- The agreement must be in writing and signed by both parties for a term of at least one year.
- The agreement must cover all of the ser-vices to be provided for the term of the agreement and must specify what services the medical director will provide.
- If the agreement is for services that are periodic or sporadic in nature, the agreement must delineate the time intervals in which the services will be performed and the exact charge for such intervals.
- The aggregate compensation for the services must be set in advance, be consistent with fair market value, and not take into account the volume or value of referrals from the physician to the hospital.
- The proposed services must be commercially reasonable and cannot involve the counseling or promotion of a business arrangement.
- The aggregate services contracted for do not exceed those that are reasonably necessary to accomplish the commercially reasonable business purpose of the services.¹¹

OIG guidance materials, as well as the liability evidence revealed in recent enforcement actions, are also good resources for determining best practices when entering into physician/provider medical directorship arrangements. In addition to the practices outlined above, physicians and providers should also:

- Maintain and regularly review documentation such as time logs or other accounts of services performed by the medical director.
- Only hire the number of medical directors that are reasonably needed for legitimate purposes.
- Be aware of state law requirements regarding medical directorships.
- Implement a systematic and thorough compliance program that routinely monitors and provides oversight of physician/provider relationships.

Conclusion

The legal risks associated with "sham" physician/provider medical directorship arrangements are significant for all parties. With the increase in government enforcement action in this area, it is imperative that providers and physicians become educated on the requirements of the FCA, the AKS, and the Stark Law, and that they implement robust compliance programs that prevent possible civil and criminal violations of the healthcare fraud and abuse laws.

- DHHS Office of Inspector General: An Open Letter to Health Care Providers, April 24, 2006. Available at http://l.usa.gov/1gkYhy3
 The Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b); the Physician Self-Referral Law (Stark Law), 42 U.S.C. § 1395nn; and the False Claims Act (FCA), 31 U.S.C. §§ 3729–3733.
 U.S. Department of Justice press release: "No Show" Doctor Sentenced to 151 Months in Prison in Connection with \$77 Million Medicare Devel Conterprise 12 Conterprise 12 Conterprise
- Medicare Fraud Scheme. September 16, 2013. Available at http://1.usa.gov/N6JlYX
- 4. U.S. Department of Justice press release: Doctor Convicted in Kickback Scheme Involving a Philadelphia Hospice. June 3, 2013.
- Available at http://l.usa.gov/lgkYSjd
 U.S. Department of Justice press release: Jury Returns \$39 Million Verdict Against Hospital for Violating Stark & False Claims Act. May 10, 2013. Available at http://l.usa.gov/lkMpfSx
 U.S. Department of Justice press release: Texas Hospital Group Pays U.S. \$27.5 Million to Settle False Claims Act Allegations. October 30, 2009. Available at http://l.usa.gov/lfTXTh7
- 2009. Available at http://l.usa.gov/lfTXTb7 United States v. Campbell, 2011 U.S. Dist. LEXIS 1207 (D.N.J. Jan. 4, 2011).
- U.S. Attorney's Office press release: Physician's Group Signs 8. 51 Million Settlement Agreement. October 30, 2008. Available at http://l.usa.gov/liAHdTw. Additional information available at
- http://1.usa.gov/1oMBbRO
- U.S. Department of Justice press release: HealthSouth and Physicians Pay \$14.9 Million to Settle Health Care Fraud Claims. December 14, 2007. Available at http://l.usa.gov/O26Lj5. Additional information available at http://l.usa.gov/10MBbRO
 U.S. Department of Justice press release: Covenant Medical Center to Pay U.S. \$4.5 Million to Resolve False Claim Act Allegations. August 25, 2000. Available at http://l.usa.gov/IMEAN
- 25, 2009. Available at http://1.usa.gov/1fuwBqN 11. 42 C.F.R. § 1001.952(d).