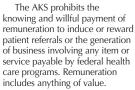
Navigating Anti-Kickback Statute Risks in Offering Free Services to Health Care Providers

By William P. Keefer and Louis Q. Reynolds Phillips Lytle LLP

ne area that continues to raise red flags across the health care fraud and abuse landscape is the

provision of free services to health care providers by health care entities, including hospitals, laboratory testing companies and pharmaceutical companies. While such offerings may be beneficial to patient care, they can trigger serious concerns under the federal Anti-Kickback Statute (AKS).1



An AKS violation requires a showing of intent to induce the referral of federal health care program business. In analyzing intent under the AKS, courts have adopted the "one purpose" test to determine whether the AKS has been violated. Under the "one purpose" test, only one purpose. and not necessarily the primary



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purpose of remuneration, need be to induce the referral of federal health care program business to demonstrate an AKS violation

Violations of the AKS can result in criminal penalties, civil fines and exclusion from federal programs.

Slippery Slope

Health care organizations often offer free items or services to health care providers—such as data analytics tools, administrative support or access to proprietary software. These items or services may enhance efficiency or improve patient outcomes. They also, however, carry the risk of being viewed as kickbacks if they influence referrals of federal health care business.

For example, a laboratory company may offer to pay for the implementation of a software program used by health care providers to order tests from that laboratory company. If that software program can be used for many other purposes beyond ordering specific lab tests from the laboratory company, there may be a higher risk of scrutiny from regulators under the AKS.

Similarly, providing free billing support or staff to a physician's office could be interpreted as relieving the physician of a financial burden, thereby constituting remuneration under the AKS.

Risk Factors

Features of arrangements involving free items or services that (provided an intent to induce referrals of federal health care program business is present) pose a higher risk of violating the AKS include, but are not limited to, the following:

- · Free items or services are only offered to highreferring physicians or those with the potential to generate referrals.
- The items or services offered for free have substantial. independent economic value to a physician referral source, or have no connection to the clinical and operational activities of a physician referral source.

Risk Mitigation

Offering or accepting a free item or service is not a per se violation of the AKS. Facts and circumstances of each arrangement should be carefully reviewed to assess potential risk under the AKS, considering the following risk

Offering free items or services to physician referral sources may also implicate the federal Physician Self-Referral Law (the "Stark Law").

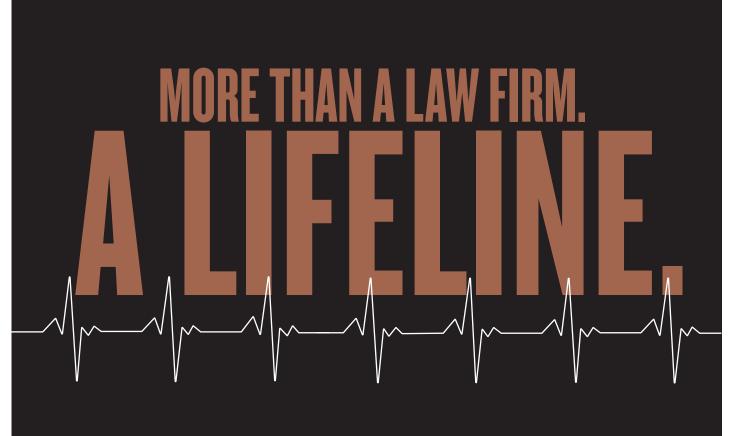
- · Clearly outline the purpose of the item or service, its fair market value and how it supports legitimate clinical or operational goals.
- Offer items or services based on objective, nonreferral-based criteria to avoid the appearance of favoring high-volume physician referral sources.
- Conduct audits to help ensure that free items or services are not influencing referral behavior.

by simply charging and paying the fair market value for items or services, instead of offering and accepting

While providing free items or services to physicians can foster collaboration and improve care delivery, the arrangements must be structured with rigorous attention. to legal boundaries. The Anti-Kickback Statute casts a wide net, and even well-meaning arrangements can lead to significant liability if not carefully managed.

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