COSMOS
Navigate the Compliance Universe

Compliance Today - August 2019
The shifting federal analysis of referral relationships in healthcare

By Stacy Harper, JD, MHSA, CPC

Stacy Harper (sharper@spencerfane.com) is a Partner at Spencer Fane LLP in the firm's Overland Park, KS office.

- linkedin.com/in/stacy-harper-aab27b20

The compliance analysis necessary to structure financial arrangements between potential healthcare referral sources and referral recipients has been complex for decades. Unlike other industries, healthcare organizations face a myriad of overlapping state and federal laws that restrict the financial relationships and associated referrals, each with their own definitions, triggers, intent, and exceptions or safe harbors.

At the federal level, these compliance obligations have typically applied only to financial relationships in which the referral source is referring patients where care will be reimbursed by a federal healthcare program. However, the implementation of the Eliminating Kickbacks in Recovery Act of 2018 (EKRA) and recent enforcement activity by the Department of Justice in the Forest Park Medical Center bribery case[1] are shifting the scope of the federal compliance obligations to include additional layers of federal and state laws, each applicable in the absence of reimbursement by federal healthcare programs.

As such, if a relationship with physicians or other referral sources has been structured to carve out federal healthcare program beneficiaries to avoid triggering federal law requirements, it is time to review its compliance.

The historic federal analysis

The primary enforcement against financial arrangements between referral sources and referral recipients at the federal level has historically arisen under either the Stark Law or the Anti-Kickback Statute (AKS).

Stark Law

Section 1877 of the Social Security Act, also known as Stark Law or the physician self-referral law, prohibits a physician from referring a Medicare or Medicaid patient for designated health services (DHS)[2] to an entity with which the physician or his immediate family member has a financial relationship, unless an exception is met.[3] "Physician," for purposes of the Stark Law, is defined as doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor. DHS include clinical laboratory services; physical therapy, occupational therapy, and outpatient speech-language pathology services; radiology and certain other imaging services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services.

A financial relationship includes direct or indirect investment or ownership interest or direct or indirect compensation arrangements. The Stark Law is a strict liability statute, requiring no proof of ill intent by the parties to the relationship. As such, each financial relationship must satisfy all elements of an exception to the Stark Law for the DHS entity to be permitted to accept a referral from the physician for the provision of DHS to a

Medicare or Medicaid beneficiary.

When analyzing a financial relationship under the Stark Law, the analysis typically follows this simplified set of steps:

1. Is there a physician involved?
2. Does the physician order or refer DHS?
3. Are the DHS billed to Medicare?
4. Does the physician have a financial relationship with the entity providing the DHS?

If the answers to all four questions are yes, then a Stark Law exception must be satisfied to allow the DHS claims to Medicare.

Anti-Kickback Statute

Section 1128B of the Social Security Act, commonly referred to as the Anti-Kickback Statute, prohibits the solicitation, receipt, offer, or payment of remuneration in exchange for the referral of a service or item reimbursed by a federal health care program.[4] The AKS is violated where one purpose of the remuneration is to pay for the referral.[5] "Remuneration" includes a kickback, bribe, or rebate.[6]

Thus, the simplified analysis of a financial relationship under the AKS is:

1. Is there a payment or transfer of value from a person or entity providing healthcare services or supplies to an individual?
2. Is there a referral from the individual to the provider of healthcare services or supplies?
3. Are the services or supplies billed to a federal healthcare program?

If the answer to all three questions is yes, then the AKS is implicated and compliance then turns on the fourth question: Is a purpose of the arrangement to induce or reward the referral of federal healthcare program beneficiaries? If the financial arrangement is structured to comply with an AKS safe harbor, then the answer to the fourth question is deemed to be no, and the arrangement complies with the AKS. If all elements of a safe harbor cannot be satisfied, then the arrangement may be subject to federal scrutiny and compliance will turn on the intent of the parties.

Thus, a complete absence of claims to federal healthcare programs may avoid triggering compliance obligations under the Stark Law and AKS.

Structuring compliance through a "carve out" of federal healthcare programs can be a risky option, because the billing of a single claim to a federal healthcare program could trigger the obligations and the administrative processes to ensure no claims are submitted can be burdensome. However, the exclusion of federal healthcare programs is not an entirely uncommon strategy for addressing possible Stark Law and AKS compliance.

State law considerations

Outside Stark Law and AKS obligations, the compliance requirements for arrangements between healthcare organizations have significantly varied under state law.

Some states focus their restrictions on financial relationships between referral sources and referral recipients on the involvement of Medicaid claims. Other states have laws that restrict relationships between referral sources and referral recipients related to only specific types of services (frequently laboratory or physical therapy services), and still other states have laws that mirror the Stark Law or AKS but apply to all payment sources.

Because of the variance at the state law level, the impact of the new federal compliance considerations will have more significant affects in certain states.

If a healthcare organization is located in a state that has a state law version of the Stark Law or AKS applicable to all payers, the healthcare organization is less likely to have structured an arrangement based on exclusion of federal payers, because the arrangement would have raised compliance problems at the state level. In states where there is no all-payer limitation or where there has been an absence of enforcement, healthcare organizations are more likely to have carve out relationships that need re-assessment.

The new layers

In the last year, a new statute and new case law has added additional layers to the compliance analysis for financial relationships between healthcare organizations.

EKRA

Effective in October 2018, EKRA imposed new federal requirements on healthcare organizations that provide recovery home, clinical treatment facility, or laboratory services.[7] EKRA prohibits the knowing and willful solicitation, receipt, offer, or payment of any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory.[8]

Like the AKS, EKRA is an intent-based statute that provides several safe harbors to guarantee compliance, although the safe harbors under EKRA do not align entirely with the safe harbors under the AKS. For example, the AKS provides a safe harbor for all payments made to a bona fide employee.[9]

However, employee safe harbor under EKRA only protects arrangements where the employee's payment is not determined by or does not vary by the number of individuals referred, the number of tests or procedures performed, or the amount billed to or received for the services provided.[10] Further, unlike the Stark Law and AKS, EKRA is not limited to any particular payer and applies to arrangements that do not include federal healthcare programs.

Forest Park

In 2016, the Department of Justice indicted 21 individuals associated with Dallas-based Forest Park Medical Center for kickback violations. The indictment included alleged violations of the AKS based on claims to Tricare and federal employee benefit plans, but the alleged damages were significantly broader than the Tricare and federal employee benefit claims, based on the additional claim for violations of the Federal Travel Act, which forbids engaging in certain criminal acts involving the use of the U.S. mail or interstate or foreign travel.[11]

The Forest Park case is the second time the Department of Justice has used the Federal Travel Act to exercise jurisdiction in a healthcare-related indictment. The Travel Act was also used in 2016 to indict Bernard Greenspan, D.O. for an alleged laboratory bribery scheme. The indictment of Dr. Greenspan involved claims to Medicare, and he was convicted in 2017 of violations of both the Travel Act and AKS.[12]

Forest Park Medical Center was a group of physician-owned hospitals that filed for bankruptcy in 2015 and 2016. Because the hospitals were physician-owned, the Stark Law prevented the hospitals from enrolling in Medicare or Medicaid, and the hospitals primarily provided out-of-network services to patients insured through other healthcare programs.

The conduct giving rise to the kickback indictment included a complex structure of various companies, consulting agreements, marketing arrangements, waiver of out-of-network copayments, and other arrangements that would likely be subject to scrutiny under the Stark Law and AKS if Medicare and Medicaid claims were involved. Because Forest Park Medical Center did not provide services to Medicare or Medicaid beneficiaries, it argued that the Stark Law and AKS did not apply.

At trial, several of the defendants asserted that they obtained legal opinions as to the compliance of the arrangements based on the absence of Medicare and Medicaid patients.

Following the initial indictment, ten of the defendants pleaded guilty and only nine defendants continued to trial. In April, the jury found seven of the nine defendants guilty on at least some counts, primarily related to conspiracy, bribery, and paying kickbacks. One of the physician defendants was acquitted and a mistrial was declared for one defendant. Although only one defendant was affirmatively convicted at trial under the Travel Act, the law is seen as having had a significant impact on the case.

The Travel Act is a federal racketeering statute implemented in 1961 that prohibits the use of interstate commerce in the commission of an "unlawful activity," including bribery in violation of the laws of the state where committed. The Travel Act is not limited to healthcare and does not require any payment from or claim to the federal government.

In the Forest Park case, the Travel Act's application was based on alleged violations of the Texas commercial bribery statute that prohibits the: (1) intentional or knowing (2) offering, conferring, solicitation or acceptance of a benefit (3) to or by a fiduciary, (4) without the consent of the fiduciary's beneficiary (5) where acceptance of such benefit will influence the conduct of the fiduciary in relation to the affairs of his or her beneficiary.[13] A "fiduciary" under the statute includes, among others, "a lawyer, physician, accountant, appraiser or other professional advisor."[14]

The majority of states have some form of commercial bribery statute that, like Texas, focuses on the acceptance of value in exchange for violating a fiduciary relationship owed to an individual. Many of these statutes specifically include a physician or other professional advisor as a fiduciary. Many of these statutes are drafted in a manner that requires only proof of the intentional offer, payment, solicitation or acceptance of a value, without approval of the beneficiary, that will impact the fiduciary relationship. In many states, there is little-to-no case law interpreting the statutes, and many do not appear to require that the intent be to actually influence the decisions of the fiduciary.

Further, unlike the Stark Law, AKS, and EKRA, the Travel Act does not provide any exceptions or safe harbors to guarantee an arrangement free from scrutiny.

The new analysis

Both EKRA and the Travel Act are intent-based statutes. As such, they do not automatically make every relationship that has carved out federal healthcare programs improper. They instead add layers to the analysis that must be conducted.

Although the involvement of federal healthcare programs continues to be a relevant question for determining

Stark Law and AKS application, the absence of these claims to these programs no longer ends the analysis. Consideration of state law requirements—not only within the healthcare-specific laws, but also general laws relating to financial relationships such as a commercial bribery statute—has increased importance.

For physicians and other healthcare organizations desiring to structure collaborative arrangements, consideration should continue to be given to the Stark Law and AKS. The parties should now also consider EKRA, the applicable state laws, and the extent to which the relationship may influence the physician or other provider's fiduciary obligations to the patient. Where arrangements have been previously structured to comply with the AKS and Stark Law by avoiding federal healthcare programs, these arrangements should be re-evaluated for compliance with EKRA and the Travel Act.

Takeaways

- Relationships between physicians and/or referral sources should be reviewed to ensure compliance in wake of the Forest Park verdicts.
- Structuring compliance through a "carve out" can be a risky option because the billing of a single claim to a federal healthcare program could trigger obligations and administrative processes.
- Outside of federal regulations, the compliance requirements for arrangements between healthcare organizations significantly varies under state law.
- In the last year, a new statute and new case law have added additional layers to the compliance analysis for financial relationships between healthcare organizations.
- Intent-based statutes do not automatically make every relationship that has carved out federal healthcare programs improper, but EKRA and the Travel Act add layers to necessary compliance efforts.

1 Department of Justice press release, Northern Disctrict of Texas. "Seven Guilty in Forest Park Healthcare Fraud Trial" April 10, 2019. https://bit.ly/2WZU1kv
2 42 C.F.R. 411.351 - Definitions
3 42 U.S.C. 1395nn(a)(1) - Limitation on certain physician referrals
4 42 U.S.C. 1320a-7b(b) - Illegal remunerations
5 See U.S. v. McClatchey, 217 F.3d 823 (2000).
6 Ibid, Ref #5
7 18 U.S.C. 220 Illegal remunerations for referrals to recovery homes, clinical treatment facilities, and laboratories
8 18 U.S.C. 220(a).
9 42 C.F.R. 1001.952(i) - Exceptions
10 18 U.S.C. 220(b)(2).
11 18 U.S.C. § 1952. Interstate and foreign travel or transportation in aid of racketeering enterprises.
12 2017 WL 894809. The Travel Act
13 Texas Penal Code 32.43 Commercial Bribery
14 Texas Penal Code 32.43(a)(2), definition of "fiduciary"