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The shifting federal analysis of referral relationships in healthcare

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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.