COSMOS
Navigate the Compliance Universe

Compliance Today - December 2021
The differences and similarities between American and Italian healthcare fraud, waste, and abuse laws: Part 2

By Pamela Coyle Brecht, Esq.;Avv.Paola Sangiovanni; and Marc Stephen Raspanti, Esq.

Pamela Coyle Brecht (pcb@pietragallo.com) serves as Pietragallo Gordon Alfano Bosick & Raspanti LLP's Practice Chair for the firm's global Qui Tam/False Claims Act Practice Group in Philadelphia, PA. **Paola Sangiovanni** (paola.sangiovanni@grplex.com) is a life sciences lawyer and partner in the law firm of Gitti and Partners, which is located in Milan, Italy. Her clients include med tech, pharma, and healthcare providers. **Marc Stephen Raspanti** (msr@pietragallo.com) is a name partner of Pietragallo Gordon Alfano Bosick & Raspanti LLP, located in Philadelphia, Pennsylvania. He is the founder of the firm's White Collar Criminal Defense Practice Group as well as the firm's Qui Tam/False Claims Act Practice Group.

Part 1 of this article series, published in the November 2021 issue of Compliance Today*, outlined in general the American and Italian healthcare systems. Part 2 outlines America's primary healthcare fraud laws. Part 3 of this series, to be published in the January 2022 issue of* Compliance Today*, will outline Italy's fraud and abuse laws.*

In America, the enforcement landscape is ever evolving. Compliance within this thicket of criminal, civil, and administrative laws and regulations can prove especially challenging. The most used fraud and abuse prevention tools include the federal Anti-Kickback Statute (AKS), the federal False Claims Act (FCA), state false claims acts (FCAs), Stark Law, and more recently the Physician Payments Sunshine Act. In addition to these laws, there are two important industry codes of conduct that govern behavior: the PhRMA Code on Interactions with Health Care Professionals, which covers the pharmaceutical industry, and the AdvaMed Code of Ethics, which covers the medical device industry.

Anti-Kickback Statute and its growing exceptions

The AKS is a powerful federal law that seeks to prevent financial considerations from interfering with the independent medical judgment and purchasing decisions of healthcare providers.[1] In general, this law prohibits a company or individual from offering a healthcare provider, such as a doctor or hospital, incentives (referred to as "inducements") to encourage use of its products or services.

More specifically, the AKS imposes criminal penalties on any person who knowingly and willfully solicits, receives, offers, or pays any "remuneration" (including any kickback, bribe, or rebate) directly or indirectly, in cash or in kind, to any person to induce that person to either:

- refer an individual to a person for the furnishing of an item or service for which payment may be made in whole or in part under a federal healthcare program, or
- purchase, lease, order, or arrange for or recommend the purchasing, leasing, or ordering of any good, facility service, or item for which payment may be made in whole or in part under a federal healthcare program.

Prohibited "remuneration" under the AKS can include prizes, gifts, coupons, discounts, and other goods or services offered to physicians or suppliers. Additionally, a violation of the AKS can occur even if a kickback does

Copyright © 2024 by Society of Corporate Compliance and Ethics (SCCE) & Health Care Compliance Association (HCCA). No claim to original US Government works. All rights reserved. Usage is governed under this website's Terms of Use.

not actually result in a referral or a purchase as the statute prohibits the mere offer or request for something of value with the intent of inducement.

American courts have found that the intent requirement of the AKS is met where "one purpose" of a payment is to induce referrals for, or purchases of, an item or service covered under a federal health program. The "one purpose" test was established in the landmark case *United States v. Greber*.[2] The presence of other good intentions or other purposes for offering, paying, or receiving the payment does not reduce liability.

Exceptions to the Anti-Kickback Statute (safe harbors)

Given its broad scope, the AKS potentially implicates nearly every financial relationship between American healthcare providers, suppliers, and manufacturers and healthcare professionals. U.S. Department of Health & Human Services Office of Inspector General (OIG) has the authority to establish regulatory safe harbors, which are explicit exceptions to the AKS as written. The safe harbors describe activities, which would implicate the AKS but are deemed by the government unlikely to be abusive. If an arrangement falls squarely within one of these safe harbors, it is fully protected from potential AKS exposure. The failure to comply with a safe harbor does not render a practice violative but means only that the practice or arrangement does not have absolute assurance of protection from AKS liability.[3]

Some of the most commonly used AKS safe harbors provide exceptions for investment interests, space or equipment rental, personal services and management contracts, sale of a practice, referral services, warranties, and discounts.[4] AKS safe harbor protection mandates that the payments involved are fair market value, the transactions are commercially reasonable, and they are based on a written agreement signed by the parties or other documented records of the transaction.

As the American healthcare delivery framework becomes more complex and entities seek new and creative ways to conduct business, the OIG will continue to issue guidance beyond the safe harbor regulations. Primary sources for administrative guidance include: (1) OIG guidance on developing compliance programs for pharmaceutical manufacturers, (2) administrative bulletins or OIG special fraud alerts, and (3) advisory opinions. These sources either identify areas of concern or indicate how the OIG would apply the AKS to the particular circumstances of each request.

Special fraud alerts issued by the OIG specifically describe conduct that the OIG views as problematic or impermissible. They put healthcare entities and providers on notice that practices addressed in the alert pose a risk for AKS liability. The OIG also issues advisory opinions upon request when the requesting party provides the OIG with detailed background information on the circumstances of the transaction or other conduct. Essentially, the requestor seeks the "blessing" of the OIG to ensure that they are not engaging in prohibited conduct. OIG must formally "accept" the request before it will render an opinion, the requesting party must reimburse the OIG for the costs of processing the request, and the opinion technically protects only the requestor.

This document is only available to members. Please log in or become a member.

Become a Member Login

Copyright © 2024 by Society of Corporate Compliance and Ethics (SCCE) & Health Care Compliance Association (HCCA). No claim to original US Government works. All rights reserved. Usage is governed under this website's Terms of Use.