

insights

Can health care companies create physician programs while avoiding anti-kickback liability?

Prompted by aggressive enforcement of the Anti-Kickback Statute, many pharmaceutical and medical device companies are reconsidering physician-related programs to avoid potential liability. But while DOJ enforcement remains high, you can create programs that accomplish your company's goals without running afoul of the statute.

The Anti-Kickback Statute makes it a criminal offense to knowingly and willfully solicit, receive, offer, or make a payment to induce or reward referrals for, or orders of, items or services reimbursable by a federal health care program. Civil suits can also be brought under the statute.

We have seen a rise in aggressive DOJ enforcement in recent months. But it is still possible to create programs that comply with the statute without abandoning your company's goals.

Recent DOJ enforcement actions and civil suits

One well-known example of Anti-Kickback enforcement was Purdue Pharma's 2020 guilty plea on two counts of conspiracy to violate the Federal Anti-Kickback Statute and its agreement to a \$2.8 billion in civil settlement related to its drug OxyContin.

In 2021, Athenahealth agreed to pay \$18.25 million to resolve allegations that it paid illegal kickbacks through three marketing programs. These programs included all-expense-paid trips to major sporting and entertainment events, including the Masters Tournament and the Kentucky Derby. In another "lead generation" program, the company paid up to \$3,000 for each physician that signed up for Athena services. In the third scheme, the company paid competitors in the process of discontinuing their services to refer their clients to Athena.

In May 2022, a [federal jury in Dallas convicted](#) the owners and operators of four orthotic brace suppliers in Texas and Arkansas for a \$6.5 million illegal kickback scheme, including violations of the federal Anti-Kickback Statute. According to the DOJ, the defendants concealed the Medicare fraud scheme by entering into sham agreements with purported marketing companies that characterized payments for doctors' orders as "marketing" expenses.

At their sentencing in September 2022, the owners of the orthotic brace supply companies each face 55 years in prison for conspiracy to defraud the U.S., offering and paying illegal health care kickbacks, and seven violations of the Anti-Kickback Statute.

The DOJ's concerns on these issues aren't recent. In November 2020, the Department of Health and Human Services' Office of Inspector General issued a [special fraud alert about "speaker programs,"](#) defined as "company-sponsored events at which a physician or other health care professional (collectively, 'HCP') makes a speech or presentation to other HCPs about a drug or device product or a disease state on behalf of the company." The company typically pays the speaker HCP an honorarium, and often pays remuneration, such as free meals, to attendees.

OIG stated that the alert wasn't intended to discourage "meaningful HCP training and education." But drug and device companies should consider all risks when "assessing whether to offer, pay, solicit, or receive remuneration related to speaker programs."

Tips for how to set up effective programs

So given these recent actions, what can you do about programs involving health care providers?

The devil is in the details. Here is a starting point, but ensure you work with an experienced attorney to structure a potential program and draft documentations and agreements consistent with the proper purposes of the program.

- Ensure any payment to a HCP is tied to a valid reimbursement or expense, or offers the fair market value for the service being offered. For example, if a physician is speaking at event, it's possible to provide payment for travel and the time spent preparing for the presentation.
- Avoid lavish expenditures for food and drink.
- Make sure that any relationship with a physician has a documented, legitimate business purpose.
- Host educational events at a location like a conference center or hotel, instead of resorts or entertainment or sports venues.
- Incorporate new medical or scientific information about the drug or product in any educational event.
- Focus your speakers and guests on individuals with legitimate reasons to attend the program, and discourage the attendance of friends, significant others or family members of the HCP speaker or attendee.
- Although pharmaceutical and device manufacturers may track who orders their products, you may wish to establish a "firewall" so that information does not influence decisions about speaking engagements.
- Remember that although it may be appropriate to provide information and support concerning your product to ensure its appropriate use, you should not provide free or reduced-cost items or services unrelated to your product or that are ordinarily provided by a physician practice within the scope of its day-to-day operations. For example, the OIG has previously warned that laboratory placing phlebotomists in physician practices may run afoul of the Anti-Kickback Statute.

At the end of the day remember that if you provide anything with substantial independent value to a referral source, it may be viewed as a kickback, and the greater the value, the greater the scrutiny you may face. Items or services of de minimus value, or that relate to your product and that may improve patient care are generally permissible. But also keep in mind that the determination of whether a particular arrangement violates the Anti-Kickback Statute depends upon an assessment of factors too numerous to list in this article.

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