

HHS Alert Is Pharma's Guide To Mitigating Anti-Kickback Risk

By Jonathan Ferry and Gene Besen (December 9, 2020)

For years the U.S. Department of Justice and the U.S. Department of Health and Human Services have pursued enforcement cases alleging inducement schemes through medical device and pharmaceutical company programs that pay physicians to talk about their products. Recently, the Office of the Inspector General at the Department of Health and Human Services detailed its position on these programs in a special fraud alert.



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Although many companies won't welcome the OIG's specific callout of essential parts of their marketing plans, the special fraud alert provides a valuable window into the OIG's thinking and will allow companies engaged in these programs to better prepare for potential scrutiny from government enforcement authorities.

Government Enforcement Against Speaker Programs

Two key statutes are the backbone of the government's enforcement actions against speaker programs — the Anti-Kickback Statute and the False Claims Act.



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The AKS is a criminal statute that makes it illegal to offer or ask for anything of benefit — referred to in the statute as remuneration — to induce or reward patient referrals or the generation of business involving any item or service payable by federal health care programs. Simply put, a company cannot pay a doctor to use its devices or prescribe its drugs.

Enforcement authorities also pursue FCA violations hand-in-glove with AKS violations. The government maintains that any claim made on federal health care programs as a result of a service caused by a kickback is a false and fraudulent claim, resulting in treble damages and penalties of approximately \$11,000 to \$22,000 against the violators.

These two statutes have been used to impose crushing liability on multiple device and pharmaceutical companies in recent years, including a recent \$678 million FCA settlement in July of this year.

The government's theory of liability in these cases is fairly straightforward. It believes companies pay bogus speaking fees to physicians and other medical providers to induce them to order, use or prescribe a company's products.

Under the liberal one-purpose test recognized by most courts for AKS violations, the government is emboldened to pursue cases where it believes it can show that just one of several different purposes of a payment to physicians was inducing them to use a company's products. So, although a company may be able to show it paid a physician for the time to give a presentation on the product, if there are other indicia that the company intended the payment to incentivize use of the product, an AKS violation may be established.

The government may also take the position that the company is inducing physician attendees at the presentations if the dinners, drinks and other entertainment are

extravagant enough to lead to such an inference.

The Special Fraud Alert

Although the government has pursued several cases against device and pharmaceutical company speaker programs, the special fraud alert marks the first time the OIG has detailed its specific concerns with these programs. Companies with speaker programs should therefore take note of the alert for several reasons.

First, it puts the industry on notice of suspect characteristics that will attract scrutiny from the OIG and other enforcement authorities. Additionally, the special fraud alerts are routinely used to demonstrate that a company should have known not to engage in the practices they highlight. Enforcement authorities are thus better able to establish the necessary scienter or state of mind for civil and even criminal liability. The special fraud alert may, therefore, portend a more aggressive enforcement environment for speaker programs in the future.

In the alert, the OIG states directly that it "is skeptical about the educational value of [speaker] programs," and suggests that the educational value of such programs can be communicated in other ways, such as publications, online resources, package inserts and third-party educational conferences.

Such suggestions will sound uninformed at best and naïve at worst to experienced marketing and sales business personnel who recognize the value of personal relationships and the endorsement of trusted professionals in the field, but the burden now seems to be on companies to establish the legitimate educational value of their speaker programs.

The special fraud alert, however, also provides valuable information for companies that feature speaker programs as part of their marketing programs. The OIG provides specific features it considers suspect in such programs, including:

- The company sponsors speaker programs where little or no substantive information is actually presented.
- Alcohol is available or a meal exceeding modest value is provided to the attendees of the program — the concern is heightened when the alcohol is free.
- The program is held at a location that is not conducive to the exchange of educational information — e.g., restaurants, or entertainment or sports venues.
- The company sponsors a large number of programs on the same or substantially the same topic or product, especially in situations involving no recent substantive change in relevant information.

- There has been a significant period of time with no new medical or scientific information, nor a new U.S. Food and Drug Administration approval or cleared indication for the product.
- Health care providers attend programs on the same or substantially the same topics more than once — as either a repeat attendee, or as an attendee after being a speaker on the same or substantially the same topic.
- Attendees include individuals who do not have a legitimate business reason to attend the program, including friends, significant others, or family members of the speaker or attendee; employees or medical professionals who are members of the speaker's own medical practice; staff of facilities for which the speaker is a medical director; or other individuals with no use for the information.
- The company's sales or marketing business units influence the selection of speakers, or the company selects speakers or attendees based on past revenue or expected revenue that the speakers or attendees have generated or will generate by prescribing or ordering the company's products — e.g., a return on investment analysis is considered in identifying participants.
- The company pays speakers more than fair market value for the speaking service or pays compensation that takes into account the volume or value of past business generated, or potential future business generated, by the health care providers.

Compliance and Speaker Programs

While the OIG has put companies on notice of its concerns about speaker programs, it has also provided a framework of specific suspect characteristics that companies should address in order to avoid or withstand eventual enforcement scrutiny. Companies are thus in a position to tailor their speaker programs and compliance programs to address the OIG's concerns.

Given the OIG's stated skepticism with respect to these programs, such work on the front end may save enormous costs when the OIG or the DOJ question the legitimacy of a company's program. Companies can and should take some basic measures to guard against liability.

The OIG's concerns are clustered into three categories: (1) the nature of the events themselves; (2) whether the events are repetitive; and (3) the selection and remuneration of the speakers. Speaker programs should be structured and monitored to address each category of concern.

With respect to the nature of events, companies should consider the educational content, venue, attendees and overall extravagance of the event. Companies should ensure that valuable clinical information is always conveyed to attendees. The OIG specifically cites restaurants and sports venues as potentially problematic, as well as high-value meals, free alcohol, and invitations to a physician's friends and family as other areas of concern.

Companies should take a wholistic view of this guidance. Each suspect characteristic pointed out by the OIG constitutes a piece of the enforcement puzzle.

For example, any event held at a professional sporting venue might be immediately suspect as the potential for legitimate educational activity at such an event may seem facially minimal. But an event with well-documented educational content held at a restaurant at moderate cost, even if some wine is provided with dinner, may be of less concern.

At minimum, companies should be able to document the legitimate educational content of the program, and avoid extravagance that would undermine the educational justification for the program.

The OIG also believes that repetitive programs and repeat attendees cast doubt on the educational value of a program. Obvious red flags, such as physicians providing the same presentation to the same attendees, clearly fall into this category.

Less obvious may be programs that provide information already well established in the medical community, such that the OIG would question the educational need for the program. Companies should thus be able to document the information conveyed and the attendees at each event to demonstrate the legitimate educational value of the program. If information is not fresh or if the programs are repetitive, companies should have an articulable justification for the event.

Finally, the OIG takes aim at suspect practices of internal management of speaker programs. In particular, control or a high degree of influence by sales and marketing business units can raise serious red flags for enforcement authorities. Any links between paid speaking opportunities and volume of use of a company's products can cause serious concern.

Additionally, sales representatives' requests for favored physicians to speak or attend events will also trigger enforcement attention. Although, marketing unit involvement in speaker programs is perhaps necessary and inevitable, checks and balances from the clinical side of the company, and strong and well-publicized compliance policies are necessary to mitigate the risks inherent in such involvement.

Conclusion

The OIG's recent special fraud alert on speaker programs notes the inherent tension between legitimate educational activity and illegal physician inducement that can exist in these programs. The alert suggests that speaker programs are at risk for investigation and that a company may need to justify them to a skeptical OIG.

Evaluation of speaker programs in light of this recent guidance, and addressing any areas of concern, will position a company to better withstand any such review by the OIG, the DOJ or other enforcement authorities.

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