

OIG Skeptical of Medical Device and Pharmaceutical Speaker Programs

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by Ross C. D'Emanuele

The Department of Health and Human Services Office of Inspector General (“OIG”) has issued a [Special Fraud Alert](#) to highlight what it views as inherent risks associated with speaker programs that pharmaceutical and medical device companies organize and fund.

These programs are typically company-sponsored events at which one or more physicians or other health care professionals make presentations about a device or drug product or disease state. The company will usually pay the speaker an honorarium and expenses, and may pay travel or other costs of attendees.



Using unusually strong language, the OIG states that it is “skeptical about the educational value of such programs.” Numerous investigations have revealed to the OIG that, often, health care professionals receive generous compensation to speak at these programs, and that the programs are offered under circumstances uncondusive to learning, or involve audience members who have no

legitimate reason to attend. These cases cause the OIG to conclude that in many circumstances at least one purpose of the compensation paid to the speaker (and to the attendees), is to induce or reward referrals of the company’s products. Any payment made purposefully to induce or reward referrals of items payable by a federal health care program is a violation of the federal anti-kickback statute, which is a felony punishable by a fine of up to \$100,000, imprisonment for 10 years, or both. Violation of the anti-kickback statute can also lead to liability under the federal civil false claims act, civil monetary penalties, and exclusion from federal health care programs. Health care

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professionals who solicit or accept such payments are also at risk of violating the anti-kickback statute.

Some of the characteristics of suspect speaker programs include:

- Sales or marketing personnel influence speaker selection;
- Health care professionals attend multiple programs on the same topic;
- The company sponsors numerous programs on the same or similar topics, particularly without a recent substantive change in the information;
- Significant time elapses with no new medical or scientific information nor new FDA-approved or cleared indication for a product;
- The company pays more than fair market value for the speaking services or pays compensation that takes into account the volume or value of past or potential future business generated by the health care professionals;
- Attendees include those without a legitimate business reason to attend;
- The location of the program is not conducive to the exchange of education information; or
- Alcohol (particularly free alcohol), or a meal exceeding modest value is provided to attendees.

The OIG points out that many other ways exist for health care professionals to obtain information about drug or device products, such as online resources, third-party educational conferences, medical journals, and others. The existence of these other resources that do not involve payment to health care professionals suggests to the OIG that at least one purpose of payment associated with speaker programs is often to induce or reward referrals.

The current pandemic emergency has put many in-person speaking programs on hold. When in-person speaking programs resume, it will be important for medical device and pharmaceutical companies to review their speaker program practices, and take into account the OIG's strong skepticism. Both the OIG fraud alert and the alternative ways that health care professionals have learned about drug and device products during the pandemic have altered the landscape for speaker programs: speaker program sponsors should take notice.

If you have questions about the topic addressed here, please contact the author of any member of the Dorsey & Whitney Health Care Transactions & Regulations Practice Group.