

OIG Issues Special Fraud Alert on Drug and Device Companies' Speaker Programs

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On November 16, 2020, the Department of Health and Human Services Office of Inspector General (OIG) issued a Special Fraud Alert (Alert) regarding speaker programs sponsored by pharmaceutical and medical device companies. This is a significant development involving fraud and abuse guidance from the OIG, as it marks just the sixth publication of a Special Fraud Alert in the last 20 years. All of the OIG's Special Fraud Alerts are available at this link: [OIG Special Fraud Alerts](#).

The Alert specifically addresses speaker programs as pharmaceutical or medical device company-sponsored events at which a physician or other health care professional collectively, (Professional) makes a speech or presentation to other healthcare professionals about a drug, device, product, or disease state on behalf of the company. As a part of the event, the company usually pays the speaking professional and provides meals and/or some other benefits to the attendees, who are often Professionals as well. Such payments or other benefits to Professionals, whether speakers or attendees, by the company implicate the federal anti-kickback statute (AKS) if the Professionals are in a position to generate federal healthcare program business for the company, through direct referrals or otherwise.

The AKS is a federal law that makes it a criminal offense to knowingly and willfully solicit, receive, offer, or pay any remuneration^[1] to induce or reward, among other things, referrals for, or orders of, items or services reimbursable by a Federal health care program.^[2] When remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. Critically for Professionals who may be involved in speaking programs, the AKS provides for criminal liability to all parties to an impermissible "kickback" transaction -- those who solicit or receive prohibited remuneration as well as those who offer or pay the prohibited remuneration.

According to the Special Fraud Alert, there have been numerous fraud and abuse investigations involving allegations that drug and device companies

organize and pay for speaker programs with the intent to induce Professionals to prescribe or order (or recommend the prescription or ordering of) the companies' products. Acknowledging that speaking program sponsors would argue that speaker programs are intended to help educate and inform other Professionals about the benefits, risks, and appropriate uses of company drugs or products, the OIG asserts that generous remuneration is often paid to Professionals speaking at or attending speaking programs under circumstances that suggest that at least one purpose of the remuneration is to induce or reward referrals generated by the Professionals.

As a result, the OIG makes clear in the Special Fraud Alert that parties involved in speaker programs may be subject to increased scrutiny. These include any drug or device company that organizes or pays remuneration associated with a speaking program, any Professional who is paid to speak, and any Professional attendees who receive remuneration from the company (e.g., free food and drink or any other benefit). This reflects a continuation of the OIG's long-standing concerns over the practice of drug and device companies providing anything of value to Professionals in a position to make or influence referrals to such companies' products covered by federal healthcare programs. In prior guidance reiterated in the Special Fraud Alert, the OIG has cautioned physicians to consider the propriety of any proposed relationship with a drug or device company and be advised that "if the basis for a physician's compensation 'is your ability to prescribe a drug or use a medical device or refer your patients for particular services or supplies, the proposed consulting arrangement likely is one you should avoid as it could violate fraud and abuse laws.'" Heeding this advice is critical for Professionals because they could very well face liability under the AKS for knowingly and willfully soliciting or receiving remuneration in connection with speaker programs in return for prescribing or ordering products reimbursable by a federal healthcare program.

To provide practical guidance to potential speaking program participants or sponsors, the OIG in the Special Fraud Alert describes certain characteristics of a speaking program, which, taken separately or together, potentially indicate an arrangement that could violate the AKS. A violation of the AKS depends on the facts and circumstances of each arrangement and the intent of the parties on a case-by-case basis, and the presence or absence of one of these characteristics alone is not determinative of an AKS violation, but the Special Fraud Alert provides the following indicators of a potentially problematic speaking program arrangement:

- 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 FDA-approved or cleared indication for the product;
- Professionals 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 don't have a legitimate business reason to attend the program, including, for example, friends, significant others, or family members of the speaker or Professional 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; and 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 Professional speakers or attendees based on past or expected revenue that the speakers or attendees have or will generate by prescribing or ordering the company's product(s) (e.g., a return on investment analysis is considered in identifying participants);
- The company pays Professional 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

In parting, the OIG notes that the Special Fraud Alert is not intended to discourage meaningful training and education of Professionals; rather, its purpose is to highlight certain inherent risks of remuneration related to speaker programs. Professionals and drug and device companies should carefully consider such risks when evaluating whether to offer, pay, solicit, or receive remuneration related to speaker programs.

If you have any questions or would like more information, please contact Chandler Martin or your Nexsen Pruet attorney.

[1] For purposes of the AKS, the "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

[2] See 42 U.S.C. § 1320a-7b(b)(1)–(2). The anti-kickback statute applies broadly to remuneration to induce or reward referrals of patients as well as the payment of remuneration intended to induce or reward the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any item or service reimbursable by any Federal health care program. For purposes of the AKS, the term "referral" includes the full range of these types of activities (including ordering or prescribing items).