

OIG ISSUES SPECIAL FRAUD ALERT REITERATING CONCERNS REGARDING SPEAKER PROGRAMS

On November 16, 2020, the U.S. Department of Health and Human Services, Office of the Inspector General (the "OIG") issued a Special Fraud Alert ("SFA") emphasizing the fraud and abuse risks inherent in speaker programs run by pharmaceutical and medical device companies.

The SFA specifically focuses on pharmaceutical and medical device company-sponsored events at which a physician or other health care professional (collectively, "HCP") makes a speech or presentation to other HCPs on behalf of the company regarding a drug or device, or a disease state. In return, the company pays the speaker an "honorarium" and, often, other remuneration, such as free meals.

The OIG has a longstanding concern that such speaker programs may violate the Federal Anti-kickback Statute (the "AKS"). As stated in the SFA, under the AKS, it is a "criminal offense to knowingly and willfully solicit, receive, offer, or pay any remuneration to induce or reward, among other things, referrals for, or orders of, items or services reimbursable by a Federal health care program." As the SFA notes, there have been a number of Federal civil and criminal cases against companies and HCPs involved in speaker programs. Among other things, these cases have involved allegations that the drug and device companies:

- selected high-prescribing HCPs as speakers as a means of rewarding them with lucrative deals (for instance, paying them hundreds of thousands of dollars for speaking);
- conditioned speaker remuneration on hitting certain sales targets (such as requiring HCPs to write a minimum number of prescriptions in order to receive the speaker honoraria);
- held speaker programs in a manner not conducive to educational presentations, such as holding them at wineries, sports stadia, adult entertainment facilities and fishing or golf trips, or at high-end restaurants where alcohol and expensive meals were served; and
- invited HCPs who had previously attended the same program or their friends, significant others or family who did not have a legitimate reason to attend.

The OIG's main concern with such speaker programs is whether the drug and device companies are organizing them with the intent to induce HCPs to order or prescribe the companies' products. That said, the OIG recognizes that the lawfulness of any remunerative arrangement under the AKS is dependent on the particular facts and circumstances involved, as well as the intent of the parties. As a result, in the SFA, the OIG lays out a number of "characteristics, which, taken separately or together, potentially indicate a speaker program arrangement that could violate" the AKS.

The OIG's list of "suspect characteristics" in a speaker program (which is illustrative only, and neither exhaustive nor determinative) includes the following. HCPs, pharmaceutical companies, medical device companies and others should be on the lookout for arrangements in which:

- "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 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 changes 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;”
- “HCPs 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 HCP 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 HCP 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)” and
- “The company pays HCP speakers more than fair market value for the speaking services or pays compensation that takes into account the volume or value of past business generated or potential business generated by the HCPs.”

Violating the AKS violations is a felony offense punishable by a fine of up to \$100,000, 10 years in jail, or both. A criminal conviction under the AKS will also lead to mandatory exclusion from Federal health care programs (including, but not limited to, Medicare and Medicaid). Proceedings to exclude persons from Federal health care programs and civil money penalties may also result from an AKS conviction.

The OIG’s Special Fraud Alert may be found here:

<https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/SpecialFraudAlertSpeakerPrograms.pdf>

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Garfunkel Wild’s attorneys are prepared to assist you in addressing and analyzing speaker-related programs. Should you have any questions regarding the above, please contact the [Garfunkel Wild attorney](#) with whom you regularly work or send an email to info@garfunkelwild.com.

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