



Office of Inspector General releases special fraud alert for speaker programs

On November 16, 2020, The Office of Inspector General ("OIG") of the Department of Health and Human Services released Special Fraud Alert: Speaker Programs to "highlight the fraud and abuse risks associated with the offer, payment, solicitation, or receipt of remuneration relating to speaker programs by pharmaceutical and medical device companies."¹

OIG releases Special Fraud Alerts to bring awareness to risks it frequently identifies during government investigations. Accordingly, this Special Fraud Alert comes after recent allegations that drug and device companies paid physicians or other health care professionals (collectively, "HCPs") who spoke at or attended company speaker events to induce them to prescribe certain products. Further, the Special Fraud Alert notes that Open Payments data from the last three years reflects that drug and device companies paid nearly \$2 billion to HCPs for speaker-related services.

Highlights from the special fraud alert

Through the Special Fraud Alert, OIG expresses skepticism about the educational value of speaker programs. The Special Fraud Alert notes that the OIG and Department of Justice ("DOJ") have investigated numerous allegations of speaker-related activity violating the Federal Anti-Kickback Statute ("AKS"). The AKS is a criminal statute that prohibits the exchange (or offer to exchange) of anything of value, in an effort to induce (or reward) the referral of business reimbursable by Federal healthcare programs.² Congress enacted the AKS, in part, to ensure that physicians are making referrals based on scientific and medical merits, not financial incentives.

The Special Fraud Alert notes that these government investigations have identified the following examples of alleged activity by drug and device companies involving speaker programs:

- Selecting high-prescribing HCPs to be speakers and rewarding those HCPs with lucrative speaker deals;
- Conditioning speaker remuneration on sales targets;
- Holding speaker programs at entertainment venues or during recreational events or otherwise in a manner not conducive to an educational presentation;
- Holding programs at high-end restaurants where expensive meals and alcohol were served; and
- Inviting an audience of HCP attendees who had previously attended the same program or HCPs' friends, significant others, or family members who did not have a legitimate business reason to attend the program.

The Special Fraud Alert notes that facts, circumstances, and the intent of the parties play a significant role in OIG's assessment of whether a company has violated the AKS. OIG believes that intent "may be evidenced by the speaker program's characteristics and the actual conduct of the parties involved."

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1. OIG, "Special Fraud Alert: Speaker Programs," November, 16, 2020, <https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/SpecialFraudAlertSpeakerPrograms.pdf>

2. 42 U.S. Code § 1320a-7b

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The Special Fraud Alert identifies the following characteristics that potentially indicate an inappropriate intent and could lead to a violation of AKS:

- 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, 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;
- 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) (e.g., a return on investment analysis is considered in identifying participants);
- The company pays HCP 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 HCPs.

Conclusion

OIG acknowledges that this Special Fraud Alert has been released during a pandemic, and many companies may not be hosting traditional speaker programs; however, the underlying drivers of risk remain the same. Whenever payments are offered or made to HCPs who prescribe to patients covered by Federal health care programs, such payments can present undue influence. Further, should a company choose to return to traditional speaker programs, the Special Fraud Alert notes "[risk] will become more

pronounced if companies resume in-person speaker programs or increase speaker program-related remuneration to HCPs."

Because of the risks associated with speaker programs and the scrutiny drug and device companies will continue to face, Deloitte believes that risk assessments and auditing and monitoring of speaker-related activity is imperative--now more than ever--and that life sciences organizations should consider enlisting seasoned practitioners with tested methodologies, knowledge, and experience to help confirm that speaker programs are designed and executed in a compliant manner and that risks identified can be mitigated and/or addressed in a timely manner.

If a company or HCP has questions about a specific speaker program arrangement involving remuneration to referral sources, the OIG Advisory Opinion process remains available. Information about that process may be found at: <https://oig.hhs.gov/faqs/advisory-opinions-faq.asp> To view the complete Special Fraud Alert, visit <https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/SpecialFraudAlertSpeakerPrograms.pdf>

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