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## OIG Warns of Risks Associated with Speaker Programs

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On November 16, 2020, the U.S. Department of Health and Human Services Office of Inspector General (OIG) released a Special Fraud Alert<sup>[1]</sup> highlighting what it views as the significant fraud and abuse concerns associated with speaker programs, which for purposes of the Alert, OIG defines as:

[C]ompany-sponsored events at which a physician or other health care professional (collectively, “HCP”) makes a speech or presentation to other HCPs about a drug or device product or a disease state on behalf of the company. The company generally pays the speaker HCP an honorarium, and often pays remuneration (for example, free meals) to attendees.

According to the Alert, “[i]n the last three years, drug and device companies have reported paying nearly \$2 billion to HCPs for speaker-related services.”<sup>[2]</sup>

OIG’s Alert discusses the fact that both OIG and the Department of Justice (DOJ) have conducted numerous fraud investigations related to speaker programs. Specifically, the Alert warns that payments to a health care provider made in connection with a speaker program could violate the federal Anti-Kickback Statute (AKS), which makes it a federal crime to, among other things, knowingly and willfully solicit, receive, pay, or offer any remuneration in return for a referral payable in whole or in part by a federal health care program.<sup>[3]</sup>

Although OIG cited an unnamed pharmaceutical trade group, which explained that individuals participate in speaker programs to educate other health care professions, OIG expressed skepticism regarding “the educational value of such programs.” OIG cites multiple studies for the proposition that health care professionals who receive remuneration from a company are more likely to prescribe or order that company’s products. According to OIG “[t]his remuneration to HCPs may skew their clinical decision making in favor of their own and the company’s financial interests, rather than the patient’s best interests.”

OIG also notes that “[t]here are many other ways for HCPs to obtain information about drug and device products and disease states that do not involve remuneration to HCPs,” including online resources, product package inserts, third-party educational conferences, and medical journals. According to OIG, “[t]he availability of this information through means that do not involve remuneration to HCPs further suggests that at least one purpose of remuneration associated with speaker programs is often to induce or reward referrals.”

In its Alert, OIG provided a non-exhaustive list of “suspect characteristics” of speaker programs, including:

1. The company sponsors speaker programs where little or no substantive information is presented.
2. 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).

3. 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).
4. The company sponsors many programs on the same or substantially the same topic or product, especially in situations involving no recent substantive change in information.
5. There has been a significant period with no new medical or scientific information nor a new FDA-approved or cleared indication for the product.
6. 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).
7. Attendees include individuals without 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 medical practice; staff of facilities for which the speaker is a medical director; and other individuals with no use for the information.
8. 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).
9. The company pays HCP speakers more than fair market value for the speaking service or pays compensation that considers the volume or value of past business generated or potential future business generated by the HCPs.

The Alert provides a clear warning to any health care professional receiving remuneration in connection with a speaker program. If the requisite intent is present, OIG warns that the company and the health care professional “may be subject to criminal, civil, and administrative enforcement actions” for improper speaker program arrangements.

Recent enforcement activity makes clear that OIG’s Alert should not be considered an idle warning. For example, in July 2020, DOJ announced that Novartis Pharmaceuticals had agreed to pay over \$640 million to resolve separate False Claims Act (FCA) investigations, which included allegations that Novartis paid kickbacks to doctors under the guise of speaker programs in order to induce those doctors to prescribe Novartis’ drugs.<sup>[4]</sup> The following month, DOJ announced that medical device maker Merit Medical agreed to pay \$18 million to settle an FCA investigation related to allegations that Merit paid kickbacks to ordering physicians under the guise of a similar program.<sup>[5]</sup>

OIG’s Alert, combined with these recent multi-million dollar settlements, should serve as a blunt reminder to health care providers and their counsel to carefully analyze the fraud and abuse risk associated with participating in speaker programs before any remuneration is paid.

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

[2] Drug and device companies are required to report this data to the Centers for Medicare & Medicaid Services (CMS) for publication on CMS’ Open Payments website, <https://www.cms.gov/OpenPayments/Explore-the-Data/Explore-the-Data>.

[3] 42 U.S.C. § 1320a-7b(b).

[4] <https://www.justice.gov/opa/pr/novartis-pays-over-642-million-settle-allegations-improper-payments-patients-and-physicians>.

[5] <https://www.justice.gov/opa/pr/medical-device-maker-merit-medical-pay-18-million-settle-allegations-improper-payments>.

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