

# Federal Government Shines Spotlight on Speaker Programs

November 20, 2020

The Department of Health and Human Services Office of Inspector General (“OIG”) issued a “Special Fraud Alert” on November 12, 2020, highlighting potential fraud and abuse risks associated with speaker programs operated by drug and device companies.

Speaker programs are company-sponsored events at which a healthcare provider (“HCP”) makes a presentation about a drug or device to other HCPs. Speaker programs are intended to be educational programs that promote a company’s product. The HCP presenter typically is paid an honorarium, while in-person programs often include a meal for attendees. In the Special Fraud Alert, OIG expresses “significant concern” that providing payments or meals to HCPs in connection with speaker programs may be a violation of the federal Anti-Kickback Statute (“AKS”). The AKS makes it a crime to solicit, pay, or receive remuneration (money or other benefits) as an inducement to order products or services reimbursed by federal healthcare programs. In recent years, the Department of Justice and OIG have resolved several high-profile investigations relating to speaker programs for large sums, ranging from tens to hundreds of millions of dollars. Below, we provide an overview of the Special Fraud Alert and considerations for companies moving forward.

## OIG’S CONCERNS ABOUT SPEAKER PROGRAMS

OIG expresses the view that one purpose of the remuneration associated with speaker programs often is to induce or reward referrals for a company’s product. This view is premised largely on OIG’s perception that programs often lack legitimate educational value. OIG also notes that there are many ways for HCPs to learn about drugs and devices that do not involve the receipt of remuneration, such as reviewing a product’s package insert, reading a medical journal, or attending educational events arranged by third parties. OIG identifies the following non-exhaustive list of practices as indicia of attempts to use compensation (to speakers and/or attendees) to drive sales, and thus of particular concern:

- The program offers little or no medically useful information;

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- Speakers are selected because they are high prescribers or users of the company's products;
  - The company's sales and marketing departments influence the selection of speakers or the company selects speakers and attendees based on past or anticipated revenue (potentially through use of a "return on investment" analysis);
  - Speakers are paid fees in excess of fair market value ("FMV") or paid compensation that takes into account the value of past or future business;
  - Events are held at venues that are not conducive to medical education, e.g., expensive restaurants, wineries, golf clubs or sports stadiums;
  - Guests are offered something more than a basic meal, such as expensive food and alcohol (free alcohol raises particular concerns);
  - Guests include individuals with no legitimate reason to be present, e.g., attendees who serve as a company speaker on the same topic, HCPs who recently participated in the same or similar programs, friends or family of the speaker, or staff of the speaker's practice or facilities where the speaker serves as medical director;
  - The company holds many programs on the same product or topic, especially in the absence of new medical/scientific information or new indications approved by the Food and Drug Administration ("FDA").

### **BEST PRACTICES FOR OPERATING SPEAKER PROGRAMS**

The risk factors identified by OIG are not new. These practices have been flagged as potentially problematic in public settlements and Corporate Integrity Agreements. As such, many companies have introduced enhanced controls in recent years to reduce the potential for abuse. Similarly, some institutions have placed limits on faculty members' ability to serve as company speakers, in some cases outright prohibiting them. By issuing this Special Fraud Alert, OIG is taking a public stance in opposition to speaker programs with the likely goal of convincing companies to end them altogether.

In order to reduce the likelihood of being accused of fraud and abuse violations, companies should consider the measures identified below. If adopted, policies and preventive measures should be well documented and training should be provided to impacted employees.

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- Companies should consider implementation of a documented needs assessment to ensure there is a bona fide reason for conducting speaker programs. Particular attention should be paid to product life cycle. Programs are less likely to be viewed as conduits for improper remuneration if there is a demonstrable need to disseminate information to HCPs, such as when a product is newly launched, when a new indication is approved by the FDA, or when new safety information emerges. Speaker programs held several years after a product's launch, when no new clinical information has become available, may be viewed with suspicion.
  - Companies should consider policies that explicitly prohibit the retention of a speaker based on past or future prescribing or product use. Speaker selection should be based on criteria designed to ensure the speakers are appropriately qualified and skilled. This can include academic appointments, scientific publications, thought leadership, and speaking skills. Consideration should be given to policies that prohibit the use of return on investment analyses relating to the selection of speakers, and sales and marketing personnel generally should not have a role in speaker selection.
  - Remuneration provided to speakers should be consistent with FMV, and the FMV determination should be documented. Companies should also consider payment caps to ensure that individual speakers do not earn amounts that might raise concerns for regulators.
  - Program content should be carefully vetted to ensure that meaningful medical information is provided in a fair and balanced manner consistent with the product's package insert, including providing necessary safety information. Presentations should be of a sufficient length to demonstrate that a serious medical exchange has occurred. Presentations lasting for a few minutes may be viewed with skepticism.
  - In-person speaker programs should be held at locations appropriate for medical education. Overly lavish venues or locations associated with entertainment or recreation may be viewed skeptically. Spouses and others with no legitimate medical reason to attend ordinarily should be prohibited. Companies should also monitor the specialties of invited HCPs to ensure the program is not viewed as vehicle for off-label promotion.
  - Companies should consider implementing attendance quotas. Programs attended by one or two HCPs, or even a small handful of HCPs, are viewed by regulators as more likely to be indicative of a social outing than a serious educational program. This can pose a challenge for companies because it is often not possible to guarantee how many HCPs will attend a program. Companies should consider automatic cancellation policies if fewer than a certain number of HCPs show up for a program.

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- Companies should implement measures to prevent “repeat attendees.” Programs attended repeatedly by the same HCP or group of HCPs are viewed skeptically, as likely social occasions at which little or no new information is conveyed. Companies should also consider implementing measures to prevent speakers from attending other speakers’ programs except in exceptional circumstances approved by the compliance or legal department. Speakers should ordinarily not present to members of their own practice.
  - Any meals provided should be modest in nature and alcohol should be limited or prohibited. Companies are well-served by performing audits of speaker programs to ensure that the per-person costs are within company limits. Frequent violations of per-person cost limits may be viewed as a sign that the company does not take its own protocols seriously.
  - Companies should consider having qualified personnel or outside auditors present to ensure that speakers do not make inappropriate statements and that other protocols are followed. The results of monitoring and auditing efforts should be documented.
  - Particularly during the ongoing pandemic, companies should consider using a virtual format for speaker programs, which eliminates meals and reduces the likelihood the program would be viewed as merely a social occasion.

These measures should help ensure that programs provide meaningful educational value to HCPs who have a legitimate reason to attend, and should therefore lessen the risk of accusations of fraud and abuse. We nonetheless expect speakers programs to be subject to increased scrutiny by DOJ and OIG in the coming years.

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Please do not hesitate to contact us with any questions.

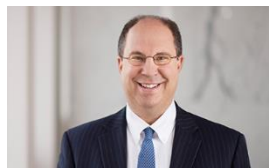
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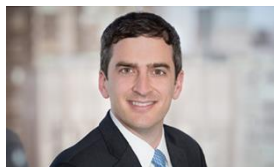
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