

Compliance Today – April 2021 Speaker programs highlighted in new HHS OIG special fraud alert

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On November 16, 2020, the Department of Health & Human Services (HHS) Office of Inspector General (OIG) issued an alert entitled “Special Fraud Alert: Speaker Programs.”^[1] The alert was distributed because of 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.”

The alert in brief

At more than six pages in length, OIG’s alert provides a robust description of common speaker programs, previously labeled “speaker bureaus,” as well as the specific regulatory concerns surrounding these programs.

Speaker programs are described as “company-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.” Generous honoraria are paid to the speakers, sometimes amounting to hundreds of thousands of dollars over the course of a year, which can be well above fair market value for the provided speaking services. Such speaking presentations are typically held at upscale venues, usually restaurants, where both speakers and attendees enjoy free meals and beverages, including alcohol. Other settings, such as sporting events, fishing trips, and golf clubs, are also used. Such locations were considered to not be “conducive” to learning by OIG.

The alert highlights OIG’s concern about the fact that “drug and device companies have reported paying nearly \$2 billion to HCPs for speaker-related services” as obtained from the complete 2017, 2018, and 2019 data sets. These data were obtained through the Centers for Medicare & Medicaid Services (CMS) Open Payments system by looking at all compensation under the “Compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program.”^[2]

Additionally, the OIG asserts that these speaker programs are of dubious value. It is understood that these speaker programs do not qualify for continuing education units that are required to maintain HCP licensure. OIG suggests that guidance on the use of medical products and diagnosis of disease be obtained instead from reputable educational outlets such as conferences, medical journals, and package inserts.^[3]

OIG, along with the U.S. Department of Justice, report that they reviewed multiple cases of fraud involving speaker programs that violated the Anti-Kickback Statute. Individuals found guilty of fraud through these programs were subject to civil and criminal penalties, including fines and imprisonment.

Explicitly included in the alert is a warning that “[p]arties involved in speaker programs may be subject to increased scrutiny.” Parties subject to this scrutiny include the company sponsoring the speaker program, the speakers, and attendees who receive items of value such as food and beverages during the program. OIG maintains this view is consistent with their “long expressed concerns over the practice of drug and device companies providing anything of value to HCPs in a position to make or influence referrals to such companies.”

Speaker programs in detail

Several specific components constitute a typical speaker program. Even though the alert provides accurate descriptions of these components, understanding nuanced details about how programs are created, managed, and marketed can help compliance professionals further identify potential compliance concerns.

Speakers

Speaker programs are associated with a number of concerning strategies aimed at speakers. OIG’s alert notably calls out speakers who receive remuneration that is “conditioned” on “sales targets,” which effectively requires speakers to meet a minimum number of prescriptions for a product manufactured by the drug or device company in order to receive payment for their speaking services. However, identifying inappropriate speaker programs extends far beyond monitoring the number of prescriptions issued by speakers.

Potential speakers for these programs are identified directly by the drug or device company, many times through attendance at a company-sponsored event. Alternatively, speakers might be identified through referral by another speaker. Drug and device companies market speakers as subject matter experts or key opinion leaders for their programs, but speakers may be in any stage of their career and may or may not be a well-known expert in the drug, device, or disease about which they are contractually obligated to speak.

After initial conversations about program participation, potential speakers are given consulting or speaking contractual agreements to review and sign. These agreements often include the following sections and stipulations:

- **Training requirement.** Prior to the COVID-19 pandemic, it was not uncommon for new speakers to be provided with all-inclusive trips and financial compensation to attend multiday speaker training events in desirable locations. While this is not currently feasible, it is reasonable to expect that this type of training will resume once the current pandemic ends.
- **Identification of the presentation as promotional.** Another term used to characterize the speaker programs described in the OIG alert is promotional speaking. Given the obvious negative connotation of the word “promotional,” many companies have changed the terminology in their agreements to refer only to speaking programs, but the presentations themselves may still be referred to as promotional.
- **Identification of the presentation as nonpromotional and noneducational.** Companies may state that a presentation, such as a disease-state presentation, is nonpromotional in the agreement. However, the agreement may further clarify that the presentation is not educational or does not meet the criteria to qualify as continuing medical education. The company may also refer to the presentation as informational rather than educational.
- **Presentation materials and content.** The sponsoring company for the speaker program almost always owns the presentation content and all ancillary materials, which will be copyrighted by the sponsor. Alterations to the content and materials are almost never allowed, but if they are, they must be reviewed and approved before inclusion. Presentations may also be identified as specific to a therapeutic product(s) or a disease

state, and speakers might be responsible for providing one or both types of presentations.

- **Contractual limitation on extemporaneous Q&As.** The agreement may include a prohibition against answering any questions from attendees in a way that is unflattering to the company, deviates from a provided script or talking points, or reflects on the speaker's clinical experience beyond what is preapproved by the company.
- **Presentation scheduling obligations.** Speakers are customarily held to a minimum number of speaking events to be conducted during the year.
- **Compensation amounts.** Compensation per speaking event, travel reimbursements, and payment terms are all commonly included in an agreement's scope of work. This section routinely defines expenses that will and will not be reimbursed.
- **Reporting in CMS Open Payments.** The agreement will likely state that payment for services and other attributions of value will be made publicly available in CMS Open Payments.
- **Regulatory oversight.** Food and Drug Administration (FDA) regulations 21 C.F.R. § 202.1 (prescription drug advertising) and 21 U.S.C. § 352 (misbranded drugs and devices) are commonly cited in agreements. This establishes that speakers are limited in their discussions to only the FDA-approved indications for the drug being discussed. Due to differences in medical advertising regulation between drugs and devices, the regulatory references in speaking agreements for devices may be less specific than for drugs. Even though the regulations are applicable only to drug- or device-focused presentations, the citations are included in agreements for disease-state presentations (see below for additional discussion). Unfortunately, the inclusion of such a regulatory reference often confused HCPs, who mistakenly conclude that the regulatory oversight indicates that these programs are allowed by the government and/or should be allowed by their employer.
- **Marketing sign-off.** Almost all speaker programs are managed by a drug or device manufacturer's marketing department. The OIG alert also highlights this.

HCPs were not expressly defined in the alert. Although physicians have traditionally been a target, advanced practice providers (APPs) are frequently sought after as speakers by drug and device companies. As a group, APPs include physician assistants; nurse practitioners; certified nurse midwives; certified nurse specialists; and certified registered nurse anesthetists, including anesthesiologist assistants. APPs have also been known to participate in less common speaking programs focused on patient populations.^[4] Speaking programs in which the audience consists primarily of patients are not mentioned in the OIG alert.

Presentation focus

Presentations focused on a specific therapeutic product differ from disease-state presentations. Therapeutic product-focused presentations will usually describe the sponsoring company's product (drug, device, or biologic) that has gained FDA approval for marketing relative to a particular indication. For example, the presentation may have a title that highlights the use of a specific drug in hypertensive patients to decrease the risk of stroke. Using research supplied by the sponsoring company as well as selected studies from the peer-reviewed literature, copious quantitative research is reviewed in the presentation to substantiate the stated indication and use of the product. Little or no information about competing products is provided.

Disease-state presentations have another purpose separate from therapeutic product-focused presentations. The goal of the disease-state content is to provide the attendee with a fuller understanding of a disease,

particularly an aspect of a disease, syndrome, or other disorder that happens to be related to one or more therapeutic products that are manufactured by the sponsoring company. Individual therapeutics may or may not be mentioned, and the presentation may be branded or unbranded. If any of the sponsoring company's products are featured, it is not uncommon for competing products to also be discussed. However, to keep the disease state status, any discussions about product use are minimal and brief.

Both types of presentations generally include the sponsoring company's logo and an indication of the company's copyright (ownership) of the content. Sometimes the logo and copyright notice will appear on each slide of the presentation used. Disease-state presentations may not include a company's logo but will include a disclosure that the talk was sponsored by the company.

Related activities

Experienced and well-received speakers are often asked to participate in other activities related to speaker programs, such as serving as a trainer for other speakers and/or developing presentations for the exclusive use of sponsoring company speaker programs. Similar to the speaker compensation arrangements, serving as a trainer or content developer is associated with generous compensation and potentially lavish trips.⁵¹ (There is a passing reference to training in the alert, but it's not specifically addressed.) Prior to the COVID-19 pandemic, one or more trips to sought-after locales for associated meetings might have also been included.

Trainers are only allowed to train based on sponsoring company-provided materials and procedures, and they cannot deviate from those standards. Content developers have more leeway when creating presentations and other training materials, but they have no ownership of any work product. All ownership and associated rights are assigned to the sponsoring company, and this assignment will be outlined in the personal agreement.

These other speaker program-related activities are not mentioned in the OIG alert. However, HCP employers looking to develop, strengthen, and/or enforce policies regarding speaker program participation will need to determine if partaking in these related activities constitutes the same level of risk as serving as a speaker. If so, limits must also be placed on these related activities.

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