

## Compliance Today – March 2021 Are paid speaker programs worth the risk?

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By Crystal M. Singleton, JD, CHC, CRCR

Crystal Singleton ([crystal.m.singleton@osfhealthcare.org](mailto:crystal.m.singleton@osfhealthcare.org)) is Vice President, Compliance Services, at OSF Healthcare System in Peoria, IL.

- [linkedin.com/in/crystal-singleton-3a6b7b9](https://www.linkedin.com/in/crystal-singleton-3a6b7b9)

In a rare move, the U.S. Department of Health & Human Services Office of Inspector General (OIG) issued a special fraud alert on speaker programs on November 16, 2020.<sup>[1]</sup> The alert warns the provider, pharmaceutical, and medical device industries of the risks associated with payments for speaker programs. Speaker programs are company-sponsored events where physicians or other healthcare professionals (collectively, HCPs) make speeches or presentations to other HCPs about a drug, device product, or disease state on behalf of the company. The company generally pays the speakers an honorarium, and attendees often receive remunerations such as free meals.

The timing of the announcement amid the various stay-at-home orders and cancellations is ironic yet telling of what we can expect from the OIG as the industry begins to reemerge into the world of educational events, travel, and conferences. OIG acknowledges that the pandemic has “necessarily curtail[ed]” many in-person activities but clarifies that the “risks remain whenever payments are offered or made to HCPs who generate Federal health care program business.” This statement by the OIG clearly signals that virtual events are within the scope of the alert’s guidance.

### The risks of paid speaker programs

In the alert, the OIG continues to express its long-held concern that inappropriate financial incentives to HCPs for participation in speaker programs tend to induce referrals and carry the potential of inappropriately influencing patient care. OIG’s view is supported by recent research on the impact of payments on physician prescribing and by the OIG’s own recent enforcement activities and investigations. While the OIG states that the purpose of the alert is not to “discourage meaningful HCP training,” the OIG has unmistakably expressed its skepticism about the “educational value” of some programs. OIG pointed to several “suspect characteristics” that should raise a red flag for any organization or HCP who is considering a potential speaker program or educational event. These “suspect characteristics” include:

- “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 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 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...;
- “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.”

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