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OIG Special Fraud Alert Questions the Need for Industry-Sponsored Speaker Programs

On November 16, the Department of Health and Human Services Office of Inspector General (OIG) issued a Special Fraud Alert challenging the educational value of industry-sponsored speaker programs and questioning the continued need for such in-person events.

Notably, the alert goes beyond merely identifying program characteristics that OIG might consider abusive and concludes that at least one purpose of the remuneration to speakers (in the form of honoraria) and attendees (in the form of free meals) could be to induce or reward referrals, even though information about disease states, drugs, and devices is readily available through means that do not require remuneration to healthcare professionals (HCPs) (e.g., online, in package inserts, at third-party educational conferences, in medical journals). In response to the trade group PhRMA's assertion that HCPs participate in company-sponsored speaker programs in order to educate and inform other HCPs, the alert states, "OIG is skeptical about the educational value of such programs." The alert concludes that companies should assess the need for in-person programs, given the inherent risks of such programs and the available alternatives for conducting quality programs virtually, as demonstrated during the pandemic.

In general, a speaker program is a company-sponsored event where an HCP is paid to present information or clinical studies related to a drug, device, or disease state to other HCP attendees, often over a meal paid for by the company. Companies commonly rely on interactive speaker programs to disseminate information about their products and related disease states. The federal anti-kickback statute is violated when remuneration is paid or received to induce or reward referrals of items or services reimbursable by a federal healthcare program.

The alert delivers a harsh criticism of in-person, HCP-led programs and comes on the heels of recent fraud cases alleging improper payments to HCPs in connection with such programs. While speaking arrangements have long been identified as an area of potential risk under the anti-kickback statute, the alert, coupled with recent Department of Justice settlements that include extensive corporate integrity agreements relating to speaker programs, reflects increasing scrutiny of speaker programs by regulators and suggests that companies should likewise turn their focus to assessing the guardrails around their speaker programs and, whenever possible, document the need for in-person programs.

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