

Healthcare Law Alert: OIG Special Fraud Alert on “Educational” Stipends

On November 16, 2020, the Office of the Inspector General for the United States Department of Health and Human Services (OIG) issued a Special Fraud Alert to reiterate and highlight its previous warnings to both health care professionals and pharmaceutical and device manufacturers about outsized and/or questionable payments to referring providers for conducting or attending “educational” programs.

Referring back to its guidance on mandatory compliance programs for pharmaceutical manufacturers (2003) and small physicians practices (2000), as well as its “Roadmap For New Physicians” (2010), the OIG reminded the health care community of its long-standing concern regarding financial arrangements with, or the transfer of extraordinary in-kind benefits to, physicians and other health care professionals who are in a position to refer patients for pharmaceuticals and/or medical devices. Referencing data that manufacturers are required to report to the Centers for Medicare & Medicaid Services, the OIG noted that for 2017, 2018 and 2019, nearly \$2 billion had been paid by such manufacturers to individual health care providers for certain non-consultative services – including serving as faculty for educational programs sponsored by a manufacturer and acting as speakers in more informal settings. The OIG highlighted examples of questionable behavior, including:

- selecting high-prescribing providers to serve as speakers (thus entitling such recipients to sometimes outsized speaker fees);
- conditioning the offer of speaker roles on reaching sales targets, such as writing a specific number of prescriptions;
- holding speaker programs at entertainment venues that are inconsistent with serious educational activity (such as golf events, winery tours and sports stadiums); and
- inviting health care professionals to attend multiple events with identical or very similar “educational” topics and including spouses, significant others, friends, or other family members in such invitations.

The Alert summarizes the applicable federal kickback laws and regulations, pointing out that civil and criminal penalties can be imposed on manufacturers’ employees as well as individual health care providers for participation in illegal educational events whether the benefit provided is cash or in kind. Violations of the statute are felonies punishable by fines of up to \$10,000, imprisonment of up to 10 years, or both. The OIG can also initiate administrative proceedings which can adversely impact continuing Medicare and Medicaid participation status, as well as result in the imposition of civil monetary penalties. While the Alert references various voluntary ethical guidelines promulgated by the pharmaceutical and device manufacturing industries, it also expresses the OIG’s great skepticism about the educational value of many so-called “educational programs” that are asserted as the basis for the cash and/or in-kind benefits. It also reminds providers and manufacturers that even if only one of several purposes of an educational event is to induce or reward referrals, the cash or benefit

exchanged can still be considered an illegal kickback. The Alert calls on health care providers who are in a position to refer or influence the referral of patients to take responsibility for assessing the validity of any educational relationship proposed by a manufacturer and making an objective determination as to whether or not the offer is conditioned upon, or is a reward for, the providers' referral pattern.

In addition, the Alert gives a laundry list of "suspect characteristics" which may call into question the underlying purposes of the educational event, including:

- inappropriate venues (sporting or entertainment events);
- lack of substantive programming;
- availability of alcohol;
- programs on medications that have been in wide use for some time without new information about medical efficacy or use; and
- repeatedly inviting the same health care providers, who happen to be high referral sources for the sponsoring manufacturer, to such programs.

Finally, the Alert warns that during the current public health emergency, in-person meetings have decreased, implying that health-related educational events have been thriving online. It suggests that greater scrutiny may be given to manufacturers who restart sponsored in-person programs as opposed to using less risky means of transmitting educational content.

A copy of the Special Fraud Alert may be found at [SFA speaker programs_11.13 v2 \(hhs.gov\)](#)