

OIG Fraud Alert on Speaker Programs Warns Providers They Risk Kickback Implications

In a <u>special fraud alert</u> issued November 16, 2020, the HHS Office of Inspector General (OIG) places providers on notice they could be accused of accepting kickbacks from pharmaceutical companies and medical device manufacturers by participating in their speaker programs.

HHS OIG questions the value of speaker programs when providers are generously compensated to speak at programs offered at venues that don't necessarily lend themselves to education (e.g. restaurants) and when the same or similar information provided at the speaker program can be assessed elsewhere (e.g., medical journals, package insert, etc.).

Federal Anti-Kickback Statute ("AKS")

It is a violation of the AKS to knowingly receive anything of value that induces a provider to use or purchase products or services (e.g., drugs or devices) that are paid for by Medicare, Medicaid or other government programs. The AKS ascribes criminal liability to all parties to an impermissible "kickback" transaction and violation is a felony punishable by a maximum fine of \$100,000, imprisonment up to 10 years, or both. Criminal conviction will also lead to mandatory exclusion from Medicare and Medicaid.

"Suspect Characteristics" Could Indicate a Violation of the AKS

According to the OIG, whether a speaker program violates the AKS depends on the facts, circumstances, and intent of the parties. The fraud alert lists the following "suspect characteristics" that could implicate the AKS:

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 education information (e.g., restaurants, 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;



Providers 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, employees or medical professionals who are members of the speaker's own medical practice; staff of facilities for which the speaker is a medical director; and other individuals with no use for the information;
The company's sales or marketing business units influence the selection of speakers or the company selects 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 products(s) (e.g., a return on investment analysis is considered in identifying participants); and
The company pays 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 provider.

What Does this Mean for CCH Faculty?

Presumably the OIG issued this fraud alert during the pandemic emergency when in-person speaking programs have decreased to encourage providers to consider the risks of future speaking programs and evaluate their individual circumstances against the "suspect characteristics" listed above. I encourage providers to do the same and remind providers that all remuneration received by industry is available to the public through CMS's Open Payments Search Tool. If you are unfamiliar with Open Payments, please see new feature video.

Dual Employment

As a reminder, prior to your participation in speaker bureau events as a speaker or if you are invited to attend a commercially sponsored CME activity, you need to report these activities:

- 1. First to your leadership;
- 2. Once you have leadership approval, contact Corporate Compliance at compliance@cookcountyhhs.org for additional guidance before acceptance; and
- 3. Annually on the Dual Employment Survey.