

# Special Fraud Alert: Speaker Programs

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In November 2020, the Department of Health and Human Services Office of Inspector General (OIG) issued a Special Fraud Alert related to speaker programs sponsored by pharmaceutical and medical device companies. Specifically, the Alert centered on the OIG's significant and longstanding concerns regarding fraud and abuse risks associated with remuneration for such programs.

Speaker programs—events at which physicians or other health care professionals (HCPs) speak or present about a drug, device, or disease state on the company's behalf—are inherently susceptible to violating the Anti-Kickback Statute (AKS).

Both those who offer or pay the prohibited remuneration (i.e., pharmaceutical and medical device companies) and those who solicit or receive it (i.e., individual HCPs as program speakers or attendees) are subject to criminal liability pursuant to the AKS and may also face civil and administrative enforcement actions.

The OIG expressed significant concern regarding speaker program remuneration, noting that total program payments by pharmaceutical and medical device companies approximated \$2 billion in the last three years. It further noted its skepticism about the education value of such programs and the numerous cases it has investigated and pursued alleging AKS violations under such arrangements.

The OIG went on to identify the following sampling of “suspect characteristics” that may indicate an AKS violation:

- 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 program attendees;
- The program is held at a location that is not conducive to the exchange of educational information;



- 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;
- Attendees include individuals who don't have a legitimate business reason to attend the program;
- 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);
- The company pays HCP speakers more than fair market value or pays compensation that takes into account the volume or value of past or potential future business generated by the HCPs.

HCPs and pharmaceutical and medical device companies should consider these examples when structuring a speaker program arrangement:

- Hold the program in a location conducive to learning. Avoid entertainment, recreation, travel, meals or other benefits, if possible.
- Include only audience members who have a legitimate reason to attend.
- Select a speaking topic that is new and substantive or substantively different than information already known to the attendees.
- Reconsider the need for the program if HCPs can obtain the information about the drug, device, or disease states through other means (e.g., online resources, product's package inserts, third-party educational conferences, medical journals).
- Consider the OIG's heightened scrutiny as companies resume in-person programs halted by the COVID-19 pandemic.
- Obtain a third-party opinion to assure that the compensation is consistent with fair market value. ●