# PhRMA Issues Updates to Longstanding Code, Addresses OIG's Speaker Program Guidance



PhRMA, the pharmaceutical manufacturer trade association, **announced on Fri. August 6** that it has revised its **longstanding Code on Interactions with Health Care Professionals**. The revisions, which relate to the Code's treatment of speaker programs, track concerns in a **Special Fraud Alert** released late last year by the US Department of Health and Human Services Office of Inspector General. This alert criticized the drug and medical device industry practice of engaging healthcare providers to deliver educational content to potential customers or users of products through so-called "speaker programs." The OIG found in its report that speakers were selected based on past or anticipated business; that attendees of these programs were offered remuneration in the form of lavish meals and alcohol; that programs were often held in high-end locations, often without an agenda, and often without any educational content delivered at all. The OIG also noted its findings that attendees of speaker programs regularly attend the same program more than once, calling into question their educational value. The alert expressly notes OIG's "skepticism" about such programs.

PhRMA appears to be the first of the major medical products trade associations to update its code of ethics based on the OIG's November 2020 alert. The PhRMA Code revisions from August 6 appear to address the criticisms raised by OIG. PhRMA expands its section 7 discussion of Speaker Programs, emphasizing the importance of speaker programs as a real and legitimate avenue of educating customers and product users about the benefits, risks, and science of particular products. Among the revisions:

- The PhRMA Code reiterates that incidental meals of modest value may still be offered to attendees but that they should be subordinate in focus to the educational presentation. The revisions also make it clear that companies should not pay for or provide alcohol at a speaker program, one of the OIG's chief complaints in the November 2020 alert.
- The revisions make clear that the purpose of any speaker program must be to present substantive educational information designed to help address a bona fide educational need among attendees, and that only those with a bona fide educational need should be invited. The revisions also highlight that repeat attendance at a program on the same or substantially same topic is generally not appropriate unless there is a bona fide educational need for the additional information.
- PhRMA emphasizes that the venue should be conducive to informational communication – no extravagant venues, luxury resorts, high-end restaurants, or entertainment/sporting venues.
- Further, the PhRMA Code also spotlights the fact that speakers should be engaged following the guidelines for engaging consultants as described in the PhRMA Code – including selection based on expertise and professional qualifications rather than past or anticipated business.

**Revisions to the new PhRMA Code become effective January 1, 2022.** This gives companies just a few months to evaluate their compliance policies and to update messaging to their employees regarding the appropriate set-up and operation of speaker programs, if any revisions to current practices are required.

If you have questions about this update, please contact Matt Wetzel (**mwetzel@goodwinlaw.com**, (202) 346-4208).