

A summary of the updated PhRMA Code

What actions can organizations take?

On August 6, 2021, the Pharmaceutical Research and Manufacturers of America (PhRMA) announced¹ that it updated its *Code on Interactions with Health Care Professionals*² (“PhRMA Code”). The PhRMA Code was previously updated in 2019 and is a voluntary code of ethics applicable to pharmaceutical company interactions with US health care professionals (HCPs). The updated PhRMA Code will take effect on January 1, 2022.

The changes included in this update primarily focus on company-sponsored speaker programs. Interestingly, in November 2020, The Office of Inspector General (OIG) issued a *Special Fraud Alert: Speaker Programs*.³ The OIG specifically noted that the purpose of its alert was to highlight “the fraud and abuse risks associated with the offer, payment, and solicitation, or receipt of remuneration relating to speaker programs by pharmaceutical and medical device companies.” After reviewing the boundaries of the Anti-kickback Statute, the

OIG listed nine illustrative factors for organizers of speaker programs to consider when evaluating the validity of remuneration agreements with anti-kickback considerations:

1. Presentation of substantive information
2. Availability of alcohol
3. Location of venue
4. Repetitive content
5. Significant time lapse without new information
6. Repetitive attendance by HCPs
7. Attendance by non-HCPs
8. Sales and marketing influence on speaker selection
9. Compensation exceeds Fair Market Value (FMV) or is based on future business

Not surprisingly, the updated PhRMA Code emphasizes each of these nine factors. The following sections highlight the new insertions into the PhRMA Code and other critical changes.

¹ PhRMA, “[Statement on Revisions to the PhRMA Code on Interactions with Health Care Professionals](#),” Speeches & Communication, August 6, 2021.

² PhRMA, “[Code on Interactions with Health Care Professionals](#),” effective January 1, 2022.

³ Office of Inspector General, “[Special Fraud Alert: Speaker Programs](#),” Alerts and Bulletins, November 16, 2020.

Speaker programs and speaker training meetings:

The overarching purpose of company speaker programs remained unchanged; however, the update added new language to the introductory purpose of speaker programs: “Company-sponsored speaker programs provide **substantive educational information** about the benefits, risks, and appropriate uses of company medicines **and related disease states**” (emphasis added).

Diving deeper into the potential fraud and abuse risks related to speaker programs, the PhRMA Code outlines seven new guidelines for companies to follow when providing an incidental meal of modest value during a speaker program. The PhRMA Code explicitly notes that speaker programs without a meal are outside the scope of PhRMA. In short, the following guidelines outline the minimum requirements for speaker programs in the pharmaceutical industry.

1. Purpose is to present substantive educational information
2. Attendees should have a bona fide educational need for the information
3. Incidental meals must be modest and subordinate to the educational presentation
4. Prohibition of alcohol
5. Appropriate venue and presence of an in-person company representative
6. Prohibition for repetitive attendance by attendees
7. Exclusion of attendees’ family, significant others, friends, and guests

In addition to above requirements, the PhRMA Code provides four requirements for compensating or reimbursing HCPs for their time and reasonable expense:

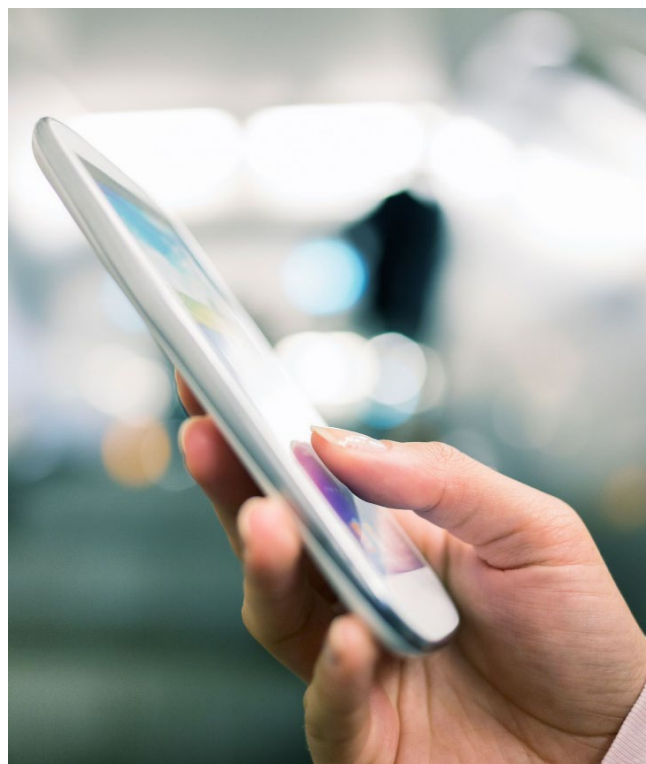
- **Who can be compensated?** The prior version of the code indicated that anyone the company engaged **to participate** was deemed a speaker. This changed to anyone engaged by the company **to speak** was deemed a speaker.
- How can an HCP be compensated? In addition to acknowledging the requirement for knowledge, expertise, reputation, etc., the PhRMA Code now prohibits reimbursement based on “**past revenue that the speaker has generated or future revenue that the speaker could generate by prescribing or ordering company’s products.**”
- What can be compensated? The prior version of the code indicated that a company could compensate based on a **valuable** service. The PhRMA Code update now indicates that compensation must be based on **bona fide** service.
- Where can the services be performed? The recent update added that services cannot be performed at **luxury resorts, high-end restaurants, and entertainment, sporting, or other recreational venues or events.** This new language is further explored in FAQ#13 of the PhRMA Code.

Additional updates:

While most of the updates focus on speaker programs and associated topics, there are several other updates that require a company’s careful review. Many of these changes relate to modernization of terminology throughout all the sections of the PhRMA Code, including:

- “**Spouse**” was updated to “significant other”
- “**Unimpeachable**” was updated to “**modest as judged by local standards**”
- “**Resort**” was updated to “**luxury resort**”
- **Music CDs** was removed as a prohibition of non-educational items
- **DVD/CD player** was removed, and **laptop** was added as an educational item that may have an independent value to an HCP and is, therefore, inappropriate
- References to **digital platforms** and **virtual** CMEs were included in the Pharmaceutical Company Support for Continuing Medical Education section

The last change to highlight comes from the section-- **Informational Presentations by Pharmaceutical Company Representatives and Accompanying Meals.** The word **Incidental** was added as a qualifier for providing meals. The PhRMA Code now provides a narrower definition of these permissible meals. It notes that Incidental meals “can be provided only where there is a reasonable expectation, and reasonable steps are taken to confirm, that each attendee has a substantive interaction or discussion with the company representative.” This new language that defines incidental meals is further explored in FAQ #9 of the PhRMA Code.



What does this mean?

Regulatory enforcement and cynicism for industry-based speaker programs will likely increase. In fact, OIG expressed skepticism surrounding the educational merit of speaker programs and cited a statistic that life science companies spent \$2 billion on HCPs between 2017–2019 for speaker-program services. Although the pandemic may have temporarily halted in-person speaker programs, the OIG recognizes that companies will likely ramp up in-person speaker programs post-pandemic. The revised PhRMA Code signifies the industry’s ongoing efforts to reduce the perception and incidence of fraud and abuse whenever payments and other transfers of value are offered or made to HCPs.

As a result of these changes, companies should consider maturing, modifying, and monitoring both front-end and back-end controls related to their interactions and remuneration to HCPs. On the front end, organizations should look to policies, procedures, risk assessments, and training that address the changes summarized above. On the back end, organizations should document that auditing and monitoring practices are running optimally, and that incidents of non-compliance are mitigated and addressed in a timely and compliant manner. The following are examples of potential actions companies should consider to help mitigate the risks associated with speaker programs:

Front-end controls:

- Establish modest meal limits based on local standards and train relevant employees and company representatives on these limits.
- Prohibit sales and marketing personnel from any involvement in the selection of speakers
- Require pre-approval for venue locations
- Require legal review of speaker program contracts
- Include speaker program fraud and abuse activities in the company’s legal and compliance risk assessment process

Back-end controls:

- Confirm that attendees (through the review of sign-in sheets and other program-related documents) are not attending more than one speaker program on the same or substantially the same topic
- Review itemized receipts to confirm that alcohol was not purchased or served
- Require in-person company representatives to physically sign the attendee sign-in sheet
- Review last names and titles of attendees to help identify potential family members in attendance
- Monitor speaker program agendas and presentations to ensure program materials are continually refreshed to include substantive changes in relevant information

As a final consideration, life sciences organizations should think about engaging experienced professionals with demonstrated methodologies to help design, execute, manage, and report on auditing and monitoring activities to further mitigate the emerging risks that surround speaker programs.

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