KING & SPALDING
Client Alert

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For more information, contact:

Brian A. Bohnenkamp
+ 1 202 626 5413
bbohnenkamp@kslaw.com

Nikki Reeves
+1 202 661 7850
nreeves@kslaw.com

Seth H. Lundy
+ 1 202 626 2924
slundy@kslaw.com

Gary C. Messplay
+ 1 202 626 9224
gmessplay@kslaw.com

Sharon Bradley
+1 202 661 7951
sbradley@kslaw.com

Mike Dohmann
+1 202 626 9263
mdohmann@kslaw.com

King & Spalding

Washington, D.C.
1700 Pennsylvania Avenue, NW
Washington, D.C. 20006-4707
Tel: +1 202 737 0500

Revised PhRMA Code Provides Stricter Controls on HCP Speaker Programs

The Revised PhRMA Code Takes Effect January 1, 2022

On August 6, 2021, the Pharmaceutical Research and Manufacturers of America (PhRMA) released highly anticipated revisions to its Code on Interactions with Health Care Professionals ("PhRMA Code" or "the Code"). The PhRMA Code is widely recognized as the industry standard for drug manufacturers' ethical interactions with health care professionals (HCPs). Adopting the Code on a nationwide basis is voluntary, but some states require compliance with the Code, and federal enforcement authorities are less likely to scrutinize interactions with HCPs that comply with the Code.

The revisions, which are to take effect on January 1, 2022, come in the wake of the November 2020 U.S. Department of Health and Human Services, Office of Inspector General ("HHS-OIG") Special Fraud Alert ("SFA"), which identified several "suspect" characteristics of HCP Speaker Programs. (Our client alert analyzing HHS-OIG's Special Fraud Alert is available here.)

Below we summarize key changes to the PhRMA Code and discuss the practical implications.

SUMMARY OF KEY CHANGES

The most significant updates relate to the guidelines around Speaker Programs (Section 7), but there are also notable revisions to Section 2 (meals provided by pharma company representatives), Section 6 (consulting arrangements), and Section 5 (support for third party educational and professional meetings). This alert discusses each in turn and then provides an analysis of the implications arising from these key revisions.

I. Speaker Programs (Section 7)

The revised PhRMA Code includes significant updates related to speaker program meals and speaker selection.

a. Speaker Program Meals

The revised Code provides the following principles for offering incidental meals of modest value to attendees of company-sponsored speaker programs:

- The purpose of the speaker program should be to present substantive educational information designed to help address a bona fide educational need among attendees, taking into account recent substantive changes in relevant information (*e.g.*, new medical or scientific information or a new FDA-approved indication for the product) or the importance of the availability of such educational programming.
- Only those with a bona fide educational need for the information should be invited.
- Incidental meals furnished to attendees must be modest as judged by local standards and subordinate in focus to the educational presentation.
- Companies should not pay for or provide alcohol in connection with the speaker program.
- The speaker program should occur in a venue and manner conducive to informational communication, and a company representative should be physically present. For speaker programs at third-party venues, the third-party venue selected by the company should not be extravagant or the main attraction of the event or perceived as such. Luxury resorts, high-end restaurants, and entertainment, sporting, or other recreational venues or events are not appropriate.
- Repeat attendance at a speaker program on the same or substantially the same topic is generally not appropriate unless the attendee has a bona fide educational need to receive the information presented. Attendance by speakers as participants at programs after speaking on the same or substantially the same topic is generally not appropriate.
- Friends, significant others, family members, and other guests of a speaker or an invited attendee are not appropriate speaker program attendees unless such individuals have an independent, bona fide educational need to receive the information presented.

b. Speaker Selection

The revised Code also incorporates new language adopting existing industry best practices for selecting speakers. Specifically, the revised Code provides that "[c]ompanies should not select a health care professional to serve as a speaker based on past revenue that the speaker has generated or potential future revenue that the speaker could generate by prescribing or ordering a company's products."

II. Informational Presentations by Pharma Company Representatives and Accompanying Meals (Section 2)

The revised PhRMA Code maintains much of the previous guidance regarding the provision of meals to HCPs incidental to an informational presentation by a company representative, including that meals provided by field sales representatives or their immediate managers should be limited to in-office or in-hospital settings. The revised Code provides additional emphasis regarding attendee requirements, noting that "[i]ncidental 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." The Code also prohibits so-called "grab-and-go" meals.

III. Consulting Arrangements (Section 6)

The revised Code's guidance around HCP consulting arrangements is largely unchanged from the previous version. However, the revised Code now explicitly provides that consultant "[s]election should not take into account the volume or value of past business that may have been or potential business that could be generated for the company by the HCP consultant." The Code also clarifies that high-end restaurants and entertainment, sporting, or other recreational venues or events are not appropriate venues for consulting/advisor meetings.

IV. Pharmaceutical Company Support for Third-Party Educational or Professional Meetings (Section 5)

The revised PhRMA Code retains the provisions of the previous version regarding industry support for third-party events and meetings. But the Code now recognizes that many of these events have transitioned to hybrid models that include virtual components. The revised Code makes clear that "Section 5 applies to in-person third-party scientific and educational conferences or professional meetings and virtual meetings conducted via a digital platform (with audio and/or video conferencing capabilities) with or without an associated in-person event." Notably, this is the Code's only mention of virtual interactions.

ANALYSIS AND PRACTICAL IMPLICATIONS

The revised Code represents PhRMA's reaction to HHS-OIG's SFA, likely as part of an effort to help ensure that widely adopted industry standards remain consistent with guidance from federal enforcement authorities. There are, however, a handful of differences remaining between the two documents. Most notably, the revised Code does not prohibit alcohol from being available for purchase by attendees at a speaker program, whereas the SFA indicates that the mere availability of alcohol—even if not provided by a manufacturer—is "suspect."

In addition, the revised PhRMA Code does not prohibit sales and marketing business units from influencing speaker selection but instead focuses more on the underlying key compliance considerations for speaker selection, noting that "[c]ompanies should not select a health care professional to serve as a speaker based on past revenue that the speaker has generated or potential future revenue that the speaker could generate by prescribing or ordering a company's products." The SFA more bluntly notes as a suspect characteristic that "a company's sales or marketing business units influence the selection of speakers . . ."

The Code also specifically calls out and more clearly restricts "high-end restaurants" for meeting venues and notes that speaker program venues "should not be extravagant or the main attraction of the event or perceived as such." Manufacturers should consider whether their speaker program venue policies and practices might need to be updated to help avoid utilizing a venue that might be viewed as "high-end."

Manufacturers should also note that the revised Code emphasizes the need for representatives to have meaningful interactions with each recipient of a meal and consider whether additional measures might be needed to help ensure meaningful interactions will all meal recipients, including non-prescriber office staff who receive meals.

The revised Code notably does not provide guidance governing manufacturers' interactions with HCPs in a virtual environment, beyond noting that the rules around third-party conferences are the same for both in-person and virtual conferences. PhRMA, however, in June 2020, published a "Statement on Application of PhRMA Code Section 2 During Emergency Periods," which addresses some key questions around virtual meals, including that the "presence" requirement can be met through virtual "presence" of the representative. However, that guidance only applies during a "national public health emergency period" and does not address many of the operational details around virtual interactions, which will remain at the discretion of each manufacturer.

In response to the recently published revisions, manufacturers should assess their current policies and procedures against the revised PhRMA Code and determine whether updates may be needed before January 1, 2022, when the revised Code takes effect. Although the Code is not the law, complying with the PhRMA Code is generally viewed as protective to help avoid scrutiny by government enforcement authorities with respect to complying with key federal laws, including the Anti-Kickback Statute. There are also several states that mandate compliance with the PhRMA Code, including laws in California, Connecticut, the District of Columbia (which requires licensed representatives to comply with the PhRMA Code), Massachusetts (which has a state-authored code that is based on the PhRMA Code), and Nevada. Therefore, even in cases where a manufacturer may decide not to incorporate the PhRMA Code revisions into its U.S. health care compliance policies generally, it will still need to consider the implications under those state legal obligations.

King & Spalding regularly assists pharmaceutical manufacturers in designing and implementing comprehensive compliance programs, including the development of policies and procedures that facilitate compliance with the PhRMA Code while also taking into account the unique aspects of each manufacturer's business operations. We are happy to help companies further consider the implications of these revisions for their compliance programs and speaker programs in particular.