

September 20, 2021

PhRMA Code 2022: Speaker Programs Enter a Prohibition Era?

Introduction

The Pharmaceutical Research and Manufacturers of America (“PhRMA”) revised its Code on Interactions with Health Care Professionals (the “PhRMA Code”) on August 6, 2021. The PhRMA Code, first published in 2002, is a voluntary code of conduct that establishes generally recognized industry standards for interactions between pharmaceutical companies and health care professionals (“HCPs”). It has been updated over time as government and industry expectations have evolved. The most recent revision implements significant substantive changes that, in some instances, track new HHS Office of Inspector General (“OIG”) guidance, incorporating standards drawn from Department of Justice (“DOJ”) False Claims Act (“FCA”) settlements of Anti-Kickback Statute (“AKS”) allegations.

As discussed more fully below, key changes and clarifications include:

- Speaker programs
 - New: Alcohol should not be served.
 - New: Repeat attendance at a substantially similar event is not appropriate.
 - Clarifying point: Bona fide educational need should exist for each attendee’s presence.
 - Clarifying point: Meals should be not only modest, but also “incidental” to the event.
- Consultant agreements
 - Clarifying Point: Payments to speakers and other HCP consultants should be fair market value, and should not take account of past or future product usage.
- Virtual Events
 - New: PhRMA Code now governs both in-person and virtual continuing medical education events, third-party scientific and educational conferences, and professional meetings.

The revised PhRMA Code takes effect on January 1, 2022. A table attached as an appendix to this Alert summarizes the differences among (1) the current version of the PhRMA Code, (2) the revised version of the PhRMA Code, and (3) the analogous voluntary code of conduct for the medical device industry—the Advanced Medical Technology Association Code of Ethics on Interactions with U.S. Health Care Professionals (the “AdvaMed Code”).

An Enforcement Focus on Speaker Programs

The PhRMA Code revisions respond to a number of DOJ enforcement actions under the AKS and specific guidance from OIG questioning the legitimacy of in-person programs where industry-paid HCPs make educational presentations on products. With respect to DOJ enforcement, recent enforcement actions include:

- In January 2020, a pharmaceutical manufacturer entered into a \$54 million settlement after admitting to allegations that it selected speakers based on prescription activity and that the same individuals repeatedly attended programs.¹

¹ *United States ex rel. Arnstein and Senousy v. Teva Pharmaceuticals USA, Inc.*, No. 1:13-cv-03702-CM-OTW (S.D.N.Y.). See also Jaelyn Jaeger, *Teva to Pay \$54M in FCA Whistleblower Settlement*, Compliance Week (Jan. 7, 2020, 3:01 PM), <https://www.complianceweek.com/whistleblowers/teva-to-pay-54m-in-fca-whistleblower-settlement/28281.article>.

- In July 2020, another pharmaceutical manufacturer entered into a \$642 million settlement with the DOJ regarding its speaker program, admitting that its sales force selected high-prescribing physicians as speakers; that it held events at expensive restaurants, wineries, and golf clubs; and that sales representatives invited prescribers repeatedly to attend the same program.²

With respect to OIG guidance, in November 2020, OIG issued a Special Fraud Alert on Speaker Programs (“Speaker SFA”), indicating that certain speaker program characteristics, many of which were identified in prior speaker program settlements, should now be deemed “suspect” under the AKS. In particular, the Speaker SFA cautioned companies to carefully consider whether to return to in-person speaker programs after the COVID-19 pandemic, or instead, whether to continue conducting programs virtually given that in-person programs have a heightened risk of “suspect” characteristics. As discussed below, the revised PhRMA Code now expressly prohibits, or more strongly discourages, a number of these “suspect” characteristics.

Industry’s Response

Companies have been grappling with how to respond to the Speaker SFA. In Spring 2021, Ropes & Gray conducted an anonymous speaker program benchmarking survey designed to assess pharmaceutical companies’ speaker program policies and practices in response to the enforcement actions and Speaker SFA. A variety of Ropes & Gray clients participated in the survey, and the results indicated that many companies were making notable changes to their speaker program policies in light of the Speaker SFA. In particular, over half of the companies surveyed indicated that they plan to continue in-person speaker programs, but intend to decrease the overall percentage of programs that occur in-person versus virtually. The survey also indicated that some companies are lowering their meal cap and changing their policies around meals given the concerns articulated in the Speaker SFA.

The revised PhRMA Code creates additional pressure for companies to make changes. Although the revised PhRMA Code does not directly address all of the concerns articulated by OIG, it reflects a direct response to several key concerns that are likely to affect important aspects of how speaker programs will be run. The PhRMA Code has always recognized that speaker programs must meet a bona fide educational need, and a number of the revisions are designed to address the government’s skepticism of the educational value of speaker programs. To further combat that skepticism, companies should be prepared to demonstrate the need for speaker programs in any given year through a robust upfront needs assessment process that carefully considers the educational need for speaker programs and documents the support for the proposed programming.

Key areas that are specifically addressed are:

- *Alcohol Prohibition.* The Speaker SFA identified the serving of alcohol, particularly when provided for free, as a suspect characteristic in speaker programs. Consistent with that guidance, the revised PhRMA Code now prohibits pharmaceutical companies from paying for or providing alcohol in connection with speaker programs. This represents a significant change in how the pharmaceutical industry has historically executed these programs.
- *Modest and Incidental Meals.* As with alcohol, the Speaker SFA identified meals exceeding “modest” value as suspect. The current PhRMA Code already requires that meals provided during speaker programs and other informational presentations be modest as judged by local standards. The revised PhRMA Code also expects that such meals will be incidental (subordinate in focus to the educational presentation) and 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. Accordingly, the revised PhRMA Code reaffirms that meals offered in grab-and-go containers are prohibited, and reminds the hosts of speaker programs to ensure (if

² Press Release, Department of Justice, *Novartis Pays Over \$642 Million to Settle Allegations of Improper Payments to Patients and Physicians* (July 1, 2020), <https://www.justice.gov/opa/pr/novartis-pays-over-642-million-settle-allegations-improper-payments-patients-and-physicians>.

not document) that meals are both modest and served solely to those with substantive interactions with company representatives.

- *Attendees.* The revised PhRMA Code now makes clear that only individuals with a bona fide educational need for the information should attend, and repeat attendance for events covering substantially the same information is not considered appropriate. The revised PhRMA Code also reiterates previous guidance prohibiting significant others and guests at speaker programs. This change emphasizes the need for hosts of speaker programs to police both invitations and attendance. Note that the revised PhRMA Code limits application of the enhanced standards on attendance to speaker programs where a meal is provided, suggesting the concern is the potential “inducement” provided in the form of a meal.
- *Speaker Selection and Compensation.* The revised PhRMA Code reaffirms that, when HCPs are speaking on behalf of a company, they may be compensated for their time and reimbursed for certain reasonable travel, lodging, and meal expenses incurred in connection with company-sponsored speaker programs. The PhRMA Code now also expressly prohibits pharmaceutical companies from selecting an HCP to serve as a speaker based on past revenue that the speaker has generated, or based on potential future revenue that the speaker could generate by prescribing or ordering a company’s products. Pharmaceutical companies have historically expected that a speaker will have first-hand experience with a product (i.e., the speaker has prescribed a product in the past, and thus has seen the effects of its use on patients) in order to speak creditably about the product. The revised PhRMA Code’s prohibition on taking into account past or future revenue presumably still would allow companies to expect some familiarity with a product. To demonstrate compliance with this revised standard, pharmaceutical companies should consider enhanced documentation of how a speaker was selected for a given presentation.
- *In-Person and Virtual Events.* Recognizing that the virtual presentation of educational programs as a result of the COVID-19 pandemic will likely become a permanent option for educational events and professional meetings, the revised PhRMA Code now makes clear that its guidance is applicable to both in-person and virtual educational events and professional meetings, but it does not address the use of virtual speaker programs. Notably, the revised PhRMA Code does not adopt the more extreme position taken in the Speaker SFA, which suggested a general skepticism of any need for live speaker events in light of the availability of relevant information online or via virtual platforms.

Changes to Consultant Arrangements

Although the revised PhRMA Code will not fundamentally revise the rules for engaging HCPs as speakers and for other consulting arrangements, the revisions suggest more care is needed in selecting HCPs for engagements and documenting the basis for selection. Specifically, the revisions appear to incorporate another longstanding DOJ position, that compensation impermissibly takes into account the volume or value of referrals if it is based on the volume or value of past business that may have been, or potential future business that could be, generated for the company by the HCP consultant. Previously, the PhRMA Code simply stated that compensation should be reasonable and based on fair market value.

With respect to events hosted for HCP consultants of pharmaceutical companies, the revised PhRMA Code makes clear that, as with speaker programs, consultants should not be hosted at high-end restaurants, and that entertainment, sporting, or other recreational venues or events are not appropriate. Previous guidance had prohibited hosting events at luxury resorts. The new PhRMA Code makes the somewhat broader statement that ancillary benefits provided to consultants must be minimal.

Conclusion

This update to the PhRMA Code may prompt a notable change in the way pharmaceutical companies design and conduct speaker programs. In order to comply with the updated guidance, pharmaceutical companies may need to make certain adjustments to their speaker programs, and may further need to enhance their existing approaches to documenting the appropriateness of interactions. The most high-profile change is that pharmaceutical companies may no longer serve or provide alcohol at events. The revised PhRMA Code also reaffirms that pharmaceutical manufacturers must ensure that meals provided at speaker programs not only are “modest as judged by local standards,” but also “incidental” to the substantive program, and that guests are not invited (or brought along). Although speakers may continue to be compensated for their time and services, the PhRMA Code now makes clear that they may not be selected based on, and that even fair market value compensation should not take into account, their past or potential future generation of referrals.

Aside from the new alcohol prohibition, the revised PhRMA Code’s most notable change is an increased burden on pharmaceutical companies to justify attendance (or repeat attendance) by certain individuals, and to ensure the modest nature of venues and meals. Process and recordkeeping changes may be required to continue hosting in-person events.

The revised PhRMA Code will likely move the pharmaceutical industry toward more moderate, education-forward speaker programs, a change the OIG clearly supports.

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Provision	Current PhRMA Code	Revised PhRMA Code	Applicable AdvaMed Code
Revisions to Existing PhRMA Code Sections			
Defined Purpose of a Speaker Program	Health care professionals participate in company-sponsored speaker programs in order to help educate and inform other HCPs about the benefits, risks and appropriate uses of company medicines.	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.	All company-conducted programs and meetings with HCPs should be conducted in a manner conducive to the exchange of information, and all attendees must have a legitimate need to attend the program or meeting.
Venues	[R]esorts are not appropriate venues.	Venues should not be renowned, 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.	The setting should be centrally located and easily accessible (for example, considering proximity to airports and highways) in relation to the place of origin of the invited participants. Companies should not select a setting because of its entertainment or recreational facilities (considering, for example, the season or time of year of the event). Companies should avoid top category or luxury hotels or resort facilities without an appropriate justification. Ski resorts, island or beach resorts, and other resorts in geographic locations renowned primarily as

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			seasonal vacation destinations may not be appropriate during the season in question.
Venue for Training	Speaker training sessions should be held in venues and locations . . . that are appropriate and conducive to informational communication and training about medical information.	The speaker program should occur in a venue and manner conducive to informational communication, and a company representative should be physically present.	Companies should conduct live or virtual training and education programs in settings that are conducive to the effective transmission of information. These may include clinical, educational, conference, or other settings, such as hotels or other commercially available meeting facilities.
Take-Out Meals	Offering “take-out” meals or meals to be eaten without a company representative being present (such as “dine & dash” programs) is not appropriate.	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. Offering “grab-and-go” meals is not appropriate.	A Company may not provide a meal or refreshments: . . . [i]f a Company representative is not present (such as a “dine & dash” program).
Meals for Spouses and Guests	Inclusion of a HCP’s spouse or other guest in a meal accompanying an informational presentation made by or on behalf of a company is not appropriate.	Inclusion of an attendee’s significant other or guest in a meal accompanying an informational presentation made by or on behalf of a company is not appropriate.	A Company may not provide a meal or refreshments . . . [f]or guests of Health Care Professionals or for any other person who does not have a bona fide professional interest in the information being shared at the meeting.
Bona Fide Purpose of Invitees	It is not appropriate to include a spouse or guest at a meal in connection with an informational presentation, regardless of who pays for their meal, unless the spouse or guest would independently	Only those with a bona fide educational need for the information should be invited.	HCPs must have a legitimate need to attend a company-conducted training or education program.

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	qualify as a healthcare professional for whom the informational presentation is appropriate.		
Specific Educational Information	Interactions should be focused on informing HCPs about products, providing scientific and educational information and supporting medical education.	Company-sponsored speaker programs provide substantive educational information about the benefits, risks, and appropriate uses of company medicines and related disease states.	HCPs need training and education on disease states and treatment options, patient selection criteria, clinical treatment standards and outcomes, care pathways, and how medical technologies benefit certain patient populations, among other important topics.
Remuneration for Speakers	Any compensation or reimbursement made to an HCP in conjunction with a speaking arrangement should be reasonable and based on fair market value.	It is appropriate for companies to offer HCPs speaking on behalf of a company compensation for their time and reimbursement of certain reasonable travel, lodging, and meal expenses incurred in connection with company-sponsored speaker programs.	Companies may pay for an HCP's modest and reasonable travel and lodging costs to attend a company-conducted program or meeting under certain circumstances. In all instances, there must be objective, legitimate reasons that support the need for travel and lodging for HCPs.
Prohibition on Selection Based on Referrals	Companies should continue to ensure that speaking arrangements are neither inducements nor rewards for prescribing a particular medicine or course of treatment.	Companies should not select an HCP 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.	Companies are prohibited from selecting consultants on the basis of generating business or rewarding referrals from an HCP or anyone affiliated with the HCP.
Consultant Compensation	Any compensation or reimbursement made in conjunction with a consulting arrangement should be	Any compensation or reimbursement made in conjunction with a consulting arrangement should be reasonable and	A company should compensate a consultant consistent with the fair market value in an arm's length transaction of the

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	reasonable and based on fair market value.	based on fair market value and should not take into account the volume or value of past business that may have been or potential future business that could be generated for the company by the HCP consultant.	services provided. A company should not base compensation on the volume or value of the consultant's past, present or anticipated business.

New PhRMA Code Sections			
Alcohol	N/A	Companies should not pay for or provide alcohol in connection with the speaker program.	N/A
Repeated Attendance	N/A	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.	N/A
Virtual Events	N/A	This Section . . . applies to in-person CME events and virtual CME events conducted via a digital platform (with audio and/or video conferencing capabilities) with or without an associated in-person event.	N/A