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MEMORANDUM

Re: Revised PhRMA Code

Today the Pharmaceutical Research and Manufacturers of America (PhRMA) released a revised "Code on Interactions with Health Care Professionals."¹ The revised Code, which will become effective on January 1, 2009, is substantially more restrictive than the July 2002 version of the Code. The most significant changes are summarized below.

Informational Presentations and Meals (2)

- *Meals at presentations by sales representatives and managers:* Like the 2002 version of the Code, the new version permits company representatives to offer occasional meals to healthcare professionals and their staffs in connection with an informational presentation or discussion. However, in a significant departure from the prior version, any such meals offered by field representatives or their immediate managers must be limited to in-office or in-hospital settings. An FAQ elaborates that even providing a meal to healthcare professional at a restaurant down the street from the professional's office is not permissible. If a hospital practitioner does not have an office conducive to informational communication, a presentation and modest lunch may be provided in a hospital cafeteria or other meeting space in the hospital (FAQ 8). As before, the meals must be modest by local standards (an FAQ gives the example of an in-office sandwich or pizza lunch), not be part of an entertainment or recreational event, and be provided in a manner conducive to informational communication.

¹ The revised Code is available on PhRMA's web site at <http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf>.

- *Meals at presentations by other company employees:* Because the in-office restriction on meals is limited to sales representatives and their immediate managers, the revised Code still permits other company employees (an FAQ gives the example of a senior business executive) to provide occasional, modest meals to a healthcare professional outside the office or hospital in connection with an informational presentation. Such meals must be modest as judged by local standards, not be part of an entertainment or recreational event, and take place in a venue and manner conducive to informational communication.
- *Meals at speaker programs:* An FAQ explains that modest meals are still permitted for a group of healthcare professionals outside the office or hospital if provided in connection with an information presentation by a healthcare professional retained by the company, as long as the venue is conducive to discussion (FAQ 13).

Gifts to Healthcare Professionals (10 and 11)

- *Minimal value items prohibited:* The revised Code no longer permits the offer of minimal value, practice related items such as pens, clipboards, note pads, mugs, and other reminder items. This prohibition also applies to minimal value items offered at third-party professional or scientific meetings (FAQ 2).
- *Modest value items for education only:* The 2002 Code permitted the occasional offer to healthcare professionals of modest value (\$100 or less) items if they were primarily for the benefit of patients. The revised Code limits the offer of modest value items to those designed primarily for the education of patients or healthcare professionals. For example, stethoscopes and other medical equipment, which were permitted under the 2002 Code, are now prohibited because they relate to patient treatment rather than patient education (FAQ 1). For similar reasons, non-educational items to be given to patients – such as pedometers, stopwatches, or general fitness items -- are prohibited (FAQ 4). Examples of permissible items primarily for the education of healthcare professionals are medical texts, a subscription to a scientific journal, or clinical treatment guidelines (FAQ 3). Examples of permissible items primarily for the education of patients are anatomical models for examination rooms, patient self-assessment and tracking tools, written informational materials, and patient starter kits (FAQ 4).

Entertainment and Recreation Prohibited (3)

- The 2002 Code prohibited the offer of entertainment or recreational events to healthcare professionals except in the context of advisory board and other consultant meetings and speaker training meetings. The revised Code removes this exception and prohibits entertainment, recreational items, and vacation trips from being offered to any healthcare professional who is not a salaried employee of the company.

Consultant Meetings at Resorts Prohibited (6)

- As before, the Code permits Companies to retain bona fide consultants as advisors and to pay them fair market value compensation and reimbursement for reasonable travel, lodging, and meal expenses. The factors supporting a bona fide consulting arrangement are similar to those in the prior version of the Code, with the notable exception that consultant meetings may not be held at resort locations. Also, as discussed above, recreation or entertainment events may not be provided at these meetings.

Speaker Programs and Speaker Training Meetings (7)

- *No resorts, entertainment, or recreation for speaker training meetings:* As before, the Code permits companies to pay reasonable compensation to healthcare professionals for time, travel, lodging, and meal expenses in connection with speaker training meetings. However, as with other consultant meetings, resort venues are now prohibited, as are entertainment and recreation.
- *Speaker program procedures and disclosure:* The revised Code contains several guidelines for speaker programs that were not formerly addressed:
 - Companies should cap the total amount of annual compensation it will pay to an individual healthcare professional speaker.
 - Companies should develop speaker program policies, including those addressing the appropriate number engagements for any individual speaker.
 - Companies should appropriately train speakers, and monitor their speaker programs for compliance with FDA requirements.
 - Companies should ensure that their speakers and their materials disclose that the speaker is presenting on behalf of the company and that the speaker is presenting information consistent with FDA guidelines.

Healthcare Professionals who are Members of Formulary or
Clinical Practice Guideline Committees (8)

- In a new section, the revised Code provides that companies should require healthcare professionals who are speakers or consultants for the company, and who also sit on formulary committees or clinical practice guideline committees, to disclose their affiliation with the company to their committees. This disclosure requirement extends for two years beyond the termination of the speaker or consultant agreement.

Support for CME and Third-Party Educational or Professional Meetings (4 and 5)

- *New section on support for CME:* Like the prior version, the revised Code permits financial support of third-party educational or professional meetings where the third-party sponsor controls the content, faculty, educational methods, materials, and venue, and where the costs of non-faculty attendees are not subsidized (except that costs of professionals-in-training may be subsidized under certain circumstances). However, the revised Code also adds a new section specifically addressing support for continuing medical education (CME). Among the guidelines for CME support are the following:
 - The company should separate its CME grant making functions from its sales and marketing departments, and establish objective criteria for making CME grant decision. These guidelines track recommendations contained in the OIG Compliance Program Guidance for Pharmaceutical Manufacturers.²
 - The company should follow standards for commercial support issued by the Accreditation Council for Continuing Medical Education (ACCME Standards)³ or other accrediting entities.
 - The company should not provide a CME program provider with advice or guidance on the content or faculty for a specific funded program, even if asked. This is consistent with a change in the ACCME Standards that was implemented in October 2007. However, an FAQ explains that this does

² 68 Fed. Reg. 23731, 23735 (May 5, 2003).

³ Available at http://www.accme.org/dir_docs/doc_upload/700a1624-d6f0-46d8-a4bc-88e12a56eca2_uploaddocument.htm.

not prevent a company from publicizing that it will consider funding meetings on a general topic (e.g., disease management techniques in diabetes) (FAQ 21).

- *Meals and receptions at CME:* The 2002 Code permitted companies to provide meals or receptions at funded scientific and educational meetings, either directly or by providing funding for this purpose to the program provider. Under the revised Code, a company should not provide a meal directly at a CME program, nor should it provide the CME program provider with funding earmarked for meals (FAQ 19). However, at a third-party conference or professional meeting at which CME activities comprise only part of the meeting, a company may sponsor a meal or reception if it is permitted by the sponsor of the meeting and is clearly separate from the CME portions of the meeting (FAQ 20).

Use of Prescriber Data (12)

- A new section of the Code provides that companies that use non-patient identifiable prescriber data for marketing and other purposes should do so responsibly. This involves respecting the confidentiality of the data, and following the rules of voluntary programs that allow prescribers to choose not to make their prescribing information available to drug companies. It also involves developing policies for use of the prescribing data and educating employees on the policies, designating an internal contact person to handle inquiries about the use of the data, and establishing disciplinary actions for misuse of data.

Sales Representative Training (14)

- Another new section provides that all sales representatives should be trained in applicable laws, regulations, and industry codes, including the PhRMA Code, and should also be trained sufficiently to provide accurate, up-to-date product information consistent with FDA requirements. Companies should monitor the compliance of their representatives with company policies and standards of conduct, and take appropriate action where violations are found.

Adherence to the Code (15)

- *Certification program:* PhRMA is establishing a program under which companies who certify annually that they have policies and procedures in place to foster compliance with the Code will be identified on a public web site, along with contact information for their Chief Compliance Officers.

- *External verification of compliance:* The Code encourages companies to seek external verification, at least every three years, that the company has policies and procedures in place to foster compliance with the Code. PhRMA will identify on its web site if a company has done so. PhRMA will also issue general guidance for such external verification.

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It is important to note that, although the PhRMA Code is a voluntary industry code, it is currently incorporated into the laws governing drug marketing compliance in two states. California requires pharmaceutical companies to adopt a comprehensive compliance program that includes, among other things, policies for compliance with the PhRMA Code, and to update their compliance programs within six months after any revision of the PhRMA Code.⁴ In Nevada, the Board of Pharmacy in January 2008 adopted the PhRMA Code by reference, including any subsequent revisions in the PhRMA Code that are not disapproved by the Board. Any drug manufacturer or wholesaler who employs a person to sell or market a drug in Nevada must annually submit to the Board either a statement that it uses the PhRMA Code as its marketing code of conduct, or, if it uses a modified version of the Code or does not use the Code, a copy of its marketing code of conduct. If a wholesaler or manufacturer does not use the PhRMA Code unaltered, it may be required to make changes in its marketing code of conduct if the Board finds it deficient.⁵

Please contact Alan Kirschenbaum (202-737-4283, amk@hpm.com), Jeff Wasserstein (202-737-9627, jnw@hpm.com), or Michelle Butler (202-737-7551, mlb@hpm.com) if you have any questions about the revised PhRMA Code.

⁴ Cal. Health & Safety Code § 119402(b).

⁵ Nev. Rev. Stat § 639.570; Nev. Board of Pharmacy Rule R-122-07 (eff. Jan. 30, 2008).