

HEALTH LAW

Update

NEWS FOR THE CLIENTS AND FRIENDS OF BASS, BERRY & SIMS PLC

PhRMA Refinements: A Revised Code of Ethics

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Introduction

Pharmaceutical Researchers and Manufacturers of America ("PhRMA") has revised its code of ethics, which is entitled "Code on Interactions with Healthcare Professionals" ("Code"). The Code sets forth voluntary ethical standards for relationships between healthcare professionals and pharmaceutical and biotechnology companies. While the Code does not have the force of law, the Office of Inspector General of the Department of Health and Human Services (the "OIG") describes this ethics code as "useful and practical advice for reviewing and structuring these relationships."¹

Importantly, the Code is cited in the OIG's compliance program guidance for pharmaceutical manufacturers, in which the OIG states: "Although compliance with the PhRMA Code will not protect a manufacturer as a matter of law under the anti-kickback statute, it will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements."² Thus, pharmaceutical manufacturers and their business partners pay particular attention to the Code. The revised Code will take effect in January 2009.³

Major Changes to the PhRMA Code

The following summarizes the major changes to the PhRMA Code:

Distribution of Non-Educational Items Prohibited

The original Code allowed pharmaceutical manufacturers to distribute items of minimal value to

¹ 68 Fed. Reg. 23737 (May 5, 2003).

² *Id.*

³ See PhRMA's *Code on Interactions with Healthcare Professionals* (January 2009). To view the entire code, see <http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf>. Unless otherwise noted, all page references in this article refer to the above source.

healthcare professionals as long as the items were "associated with the professional's practice."⁴ The revised Code prohibits distribution of all minimal value items, such as pens, mugs, and note pads with the company logo, unless they advance disease or treatment education. Note that the revised Code continues the current prohibition on items intended for the benefit of the healthcare professional and on payments in cash or cash equivalents (e.g., gift certificates).

An Example from the Q&A Section of the revised Code:

Q: Under the Code, may items such as stethoscopes be offered to healthcare professionals?

A: No. Under the Code only items designed primarily for the education of patients or healthcare professionals may occasionally be offered to healthcare professionals, if the items are not of substantial value and do not have a value to healthcare professionals outside of their professional responsibilities.⁵

Meals Provided Outside of Healthcare Professionals' Office Prohibited

The original Code allowed sales representatives to provide meals to healthcare professionals during informational presentations. The revised Code prohibits sales representatives from providing restaurant meals to healthcare professionals, but allows for occasional in-office meals when accompanied by an informational presentation. The revised Code continues the prohibition on providing entertainment or recreation to healthcare professionals.

An Example from the Q&A Section of the revised Code:

Q: Can a field sales representative of Company B conduct an informational presentation accompanied by a meal for a healthcare professional in a restaurant down the street from a hospital?

A: No. An informational presentation or discussion conducted by a field sales representative or her immediate manager may only be accompanied occasionally by a meal if the presentation is held in the healthcare professional's office or hospital.⁶

Requisite Training of Pharmaceutical Representatives

The revised Code contains new provisions regarding the training and conduct of company representatives. These provisions require companies to ensure that their representatives receive adequate training about the applicable laws, regulations and industry codes, and the Code itself. The Code also stresses the importance of professionalism and integrity for company representatives. Companies are encouraged to periodically assess their representatives to ensure they are complying with all company policies and standards. If the company discovers noncompliance, it should take appropriate action to ensure compliance.

⁴ See PhRMA's *Code on Interactions with Healthcare Professionals* (July 1, 2002).

⁵ See *Code*, page 18.

⁶ See page 21.

Healthcare Professionals as Consultants

The revised Code contains new provisions (in addition to the restrictions from the original Code) regarding consulting arrangements between healthcare professionals and pharmaceutical companies. These provisions encourage companies to use defined criteria, such as medical expertise and knowledge in a particular therapeutic area, when selecting healthcare professionals for consulting positions. The revised Code also stipulates that, while modest meals or receptions may be appropriate during company-sponsored meetings with healthcare professional commercial consultants, companies should not provide recreational or entertainment events in conjunction with these meetings.

Pharmaceutical Companies' Adherence to the Code

The revised Code encourages all companies that interact with healthcare professionals to adopt policies to ensure adherence to the Code. PhRMA will identify companies on their website that publicly announce a commitment to the Code and go through an annual certification process. Certification must be signed by the company's Chief Executive Officer and Chief Compliance Officer. Companies are also encouraged to seek external verification, at least every three years, that the company has policies in place to ensure compliance with the Code.

Independence of Continuing Medical Education Programs

The revised Code contains more detailed instructions for making sure that Continuing Medical Education ("CME") is independent from any company's particular medicine or course of treatment. The Code suggests that a company's CME grant-making functions should be separated from its marketing division to ensure neutrality. Companies are encouraged to respect the judgment of the CME provider and should not provide any guidance regarding the faculty or content at the CME.

An Example from the Q&A Section of the revised Code:

- Q: May a company publicize its interest in a general topic for a CME program for which a grant would be provided?
- A: Yes, a company may communicate to multiple CME providers or the public a general topic for a CME program that might be of interest to physicians. For example, a company may publicize that it will consider funding the topics of new treatments or disease management techniques in a particular therapy area such as diabetes or hypertension.⁷

Proper Use of Non-Patient Identified Prescriber Data

The revised Code includes principles for the proper use of non-patient identified prescriber data. For example, companies should respect confidentiality of prescriber data, develop policies regarding use of the data, educate employees, and maintain an internal contact person to handle questions about use of the data. If any misuse of the data occurs, appropriate disciplinary actions

⁷ See page 21.

should be taken. Companies should respect the requests of healthcare professionals who do not want their prescriber data made available to the company's sales representatives.

Disclosure Required for Certain Relationships with Healthcare Professionals

The revised Code sets forth disclosure requirements for any healthcare professional who serves as a member of a committee that sets formularies or develops clinical guidelines while also serving as a speaker or consultant for the company. The nature of the relationship between the healthcare professional and the pharmaceutical company should be disclosed to the committee. Companies are encouraged to continue to disclose the nature of these relationships for at least two years after the relationship has ended.

An Example from the Q&A Section of the revised Code:

- Q: Does the Code address the issue of disclosure of company interactions with healthcare professionals who are members of committees that develop formularies or clinical practice guidelines?
- A: Yes. The Code states that, to avoid even the appearance of impropriety, companies that have retained a healthcare professional member of a formulary or clinical practice guidelines committee as commercial consultant or speaker should require the healthcare professional to disclose to the committee the existence and nature of his or her relationship with the company.⁸

Conclusion

The revised Code reemphasizes that interactions between healthcare professionals and company representatives should be focused on informing healthcare professionals about products, providing scientific and educational material, and supporting medical research.⁹ It also addresses new issues not previously discussed in the original Code, such as independence of CME programs, training of sales representatives, and responsible use of non-patient identified prescriber data. Overall, the revised Code encourages disclosure, transparency, and responsible relationships with healthcare professionals. If you have any questions about the revised PhRMA Code, please contact any of the attorneys in our Health Law Practice Area listed on the following page.

⁸ See page 31.

⁹ Press Release, Pharmaceutical Researchers and Manufacturers of America (July 10, 2008). To view the entire press release, see

http://www.phrma.org/news_room/press_releases/phrma_code_reinforces_commitment_to_responsible_interactions_with_healthcare_professionals/.

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