

# PhRMA Revises Code on Interactions with Healthcare Professionals

Reducing Industry Spending While Increasing Transparency Obligations

July 15, 2008

On July 10, 2008, the Board of Directors of the Pharmaceutical Research and Manufacturers Association of America (“PhRMA”) adopted revisions to the 2002 PhRMA Code on Interactions with Healthcare Professionals (the “2008 Code”). ([www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf](http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf)). These revisions take formal effect on January 1, 2009, but the changes inaugurated by the 2008 Code will likely be implemented as soon as practicable before then by the signatories and others who elect to follow the Code.

At an operational level, the 2008 Code revisions make changes to a number of the existing ground rules for interactions between industry representatives and health care professionals by refining the scope of these interactions, restricting certain relationships that were once permissible, and providing additional clarification to areas that were either vague or not previously addressed. At a conceptual level, the 2008 Code revisions reflect a renewed effort by PhRMA to initiate self-reform on behalf of its members that will stanch the tsunami of legislative, enforcement, litigation, and public policy pressures weighing on the industry’s current marketing paradigm.

## Summary of 2008 Code Revisions

The 2008 Code’s revisions to the existing 2002 Code can largely be divided into two categories: (1) further limits on relationships, primarily financial in nature, between industry and healthcare professionals; and (2) new forms of mandatory disclosure, transparency improvements and process monitoring. The Code also generally encourages companies to adopt policies and procedures to assure adherence with the 2008 Code provisions. 2008 Code, § 9.

## Narrowing the Scope of Permissible Financial Relationships with Healthcare Professionals

When compared to the 2002 Code, the terms of the 2008 Code further limit the scope of permissible industry relationships with healthcare professionals as follows:

2002 CODE	2008 CODE
<p>The 2002 Code permitted gifts to physicians primarily for the benefit of patients and nominal practice-related reminder items (<i>e.g.</i> pens, pads, mugs) in the amount of \$100 or less. 2002 Code, § 7(a).</p>	<p>The 2008 Code adds the following restrictions and limitations on the types of gifts that may be provided to physicians: (a) it forbids non-educational gifts (<i>e.g.</i> pens, pads, mugs) even if they are of minimal value; and (b) it allows only gifts that are designed primarily for the education of patients or healthcare professionals (<i>i.e.</i>, to communicate important information about the nature and characteristics of prescription medicines and the diagnosis and treatment of disease), but only if they are \$100 or less in value and they have no value to healthcare professionals outside their professional duties. 2008 Code, § 10, 11.</p>
<p>The 2002 Code permitted industry representatives to provide occasional and modest meals to healthcare professionals outside of a practice setting (<i>i.e.</i> office, hospital) even when not in connection with a speaker program. 2002 Code, § 2.</p>	<p>The 2008 Code now forbids any meals outside of the office or hospital setting other than in connection with speaker programs, and maintains the requirement that all meals within the practice setting be occasional and modest. 2008 Code, § 2.</p>
<p>The 2002 Code stated that the selection of consultants and speakers should be based on criteria directly related to the purpose of the event. 2002 Code, § 4(a).</p>	<p>The 2008 Code now requires industry to define specific criteria for the selection or retention of speakers and consultants. 2008 Code, § 6.</p>
<p>The 2002 Code permitted social or entertainment events at continuing medical education (CME) or other third-party scientific and educational conferences or professional meetings if clearly subordinate in terms of time and emphasis. 2002 Code, § 3(c).</p>	<p>The 2008 Code now prohibits entertainment at industry-sponsored meetings with healthcare professionals, including consultants, as well as any healthcare professional who is not a salaried employee. 2008 Code, §§ 3, 6.</p>
<p>The 2002 Code stated that the location of meetings for consultants and speakers should be conducive to the services provided. 2002 Code, § 3(c).</p>	<p>The 2008 Code now specifically forbids resorts as locations for any such meetings. 2008 Code, § 7.</p>
<p>The 2002 Code stated that industry sponsorship of CME through independent companies must allow the CME provider to have responsibility for control over selection of content, faculty, educational methods, materials and venue. 2002 Code, § 3(a).</p>	<p>The 2008 Code states that industry may no longer provide <i>any</i> advice or guidance regarding educational program content or faculty, even if asked by the CME provider, and further, should follow standards established by a CME accrediting body (<i>i.e.</i>, the Accreditation Council for Continuing Medical Education) regarding commercial support. 2008 Code, § 4.</p>
<p>The 2002 Code permitted industry to provide financial support for meals or receptions at CME events if compliant with the CME provider's policies. 2002 Code, § 3(c).</p>	<p>The 2008 Code now forbids the provision of meals or receptions at CME events, although it permits CME providers to apply general unrestricted financial support from industry to a CME event to meals for all participants. The 2008 Code states that financial support for CME should not be an inducement or reward for prescribing a particular course of treatment. 2008 Code, § 4.</p>

## New Provisions Mandating Increased Disclosure, Transparency and Accountability

The 2008 Code also includes the following new mandates for industry disclosure, transparency and accountability:

1. Each industry company must individually and independently determine a cap on annual spending for speaker and consultant fees. 2008 Code, § 7.
2. Industry should require all healthcare professional speakers and consultants that help determine formularies or develop practice guidelines to disclose to the formulary or practice development committee the existence and nature of their relationships with the company, for a period of two years following termination of the speaking or consulting arrangement. 2008 Code, § 8, Question 25.
3. Industry and CME faculty should clearly distinguish between promotional speaker programs and independent CME, and industry should periodically monitor speaker programs for compliance with regulatory requirements. 2008 Code, § 7.
4. Industry financial support for CME should be intended to support education on a full range of treatment options, not the promotion of a particular medicine. 2008 Code, § 4.
5. Each industry company should develop and enforce policies for use of non-patient identified prescriber data and permit physicians to opt out of disclosing such data to company sales agents. 2008 Code, § 12.
6. Promotional materials should be accurate and not misleading, make only supported claims, reflect the balance between risks and benefits, and should be consistent with regulatory requirements. 2008 Code, § 1.
7. Each industry company should ensure that all its sales representatives are trained, assessed periodically regarding compliance, and be subject to appropriate disciplinary action if non-compliant. 2008 Code, § 14.
8. The 2008 Code calls on industry to publicly commit to abide by the 2008 Code. It specifically recommends formal, self-certification of compliance by both the chief executive officer and chief compliance officer and authorizes PhRMA to post names and contact information for company compliance officers. Moreover, PhRMA has stated that it will post on its website the names of companies that publicly make a commitment to adhere to the 2008 Code, the status of annual certifications, and indicate when a company has obtained external verification of compliance with the 2008 Code. 2008 Code, § 15.

## The Perfect Storm of Reform Initiatives

The 2008 Code has been introduced into a perfect storm of closely related regulatory, legislative and enforcement reform initiatives that have been well under way over the last year:

- Senator Charles Grassley’s Physician Payments Sunshine Act of 2007, S. 2029, which PhRMA itself supports, may, if enacted, effectively de-legitimize financial relationships with healthcare professionals. Industry and healthcare professionals may fear that the public will misunderstand the significance of such disclosure and become reluctant to enter into such arrangements in the first instance.
- At least one major pharmaceutical company has announced that it will no longer provide direct financial support for continuing medical education provided by commercial medical education communication companies even though such direct funding likewise remains “appropriate” under the 2008 Code. (Pfizer Press Release, “Pfizer Changes Its Funding of Continuing Medical Education in the U.S.,” at [www.pfizer.com/news](http://www.pfizer.com/news) [July 2, 2008].)
- The Accreditation Council for Continuing Medical Education (ACCME) has issued an information and call-for-comment package that might culminate in a quasi-regulatory ban on all commercial support of continuing medical education programs whatsoever, even though 2008 Code says that such commercial support remains “appropriate.” (ACCME Policy Announcements and Calls for Comment, at [www.accme.org](http://www.accme.org); 2008 Code, § 4.)
- These CME funding measures were immediately preceded by a similar call for prophylactic reform by the report of the American Medical Association (AMA) Council on Ethical and Judicial Affairs (CEJA) (“Industry Support of Professional Education in Medicine” CEJA Report 1-A-08, available at [www.ama-assn.org/ama1/pub/upload/mm/471/ceja1.doc](http://www.ama-assn.org/ama1/pub/upload/mm/471/ceja1.doc)) and the Association of American Medical Colleges (AAMC) Report of the AAMC Task Force on Industry Funding of Medical Education to the AAMC Executive Council” (April 27, 2008) (available at [www.aamc.org/research/coi/industryfunding.pdf](http://www.aamc.org/research/coi/industryfunding.pdf)), which called on industry to “voluntarily discontinue CME funding practices that compromise professionalism as well as public trust.
- In late February of this year, a Joint Advisory Committee of the Association of American Medical Colleges (AAMC) and the Association of American Universities (AAU) issued its comprehensive report on identifying, assessing and managing individual and institutional financial conflicts of interest in research involving human subjects arising from financial relationships between researchers and industry entities. (See McDermott, Will & Emery “On the Subject: AAMC/AAU Joint Advisory Committee Issues New Guidelines on Managing Conflicts of Interest” (February 28, 2008, available at [www.mwe.com/index.cfm/fuseaction/publications.nldetail/object\\_id/7a0c63ef-8eab-43a0-9c36-39c2a61d4773.cfm](http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object_id/7a0c63ef-8eab-43a0-9c36-39c2a61d4773.cfm)).
- State attorneys general have been particularly aggressive in challenging pharmaceutical company behavior and have extracted significant monetary settlements. The most significant such action and settlement to date is the settlement between Merck and a working group of attorneys general from 29 states and the District of Columbia. (available at [www.merck.com/newsroom/vioxx/pdf/ag\\_document.pdf](http://www.merck.com/newsroom/vioxx/pdf/ag_document.pdf), and See McDermott Will & Emery White Paper: “Merck Settles Vioxx Litigation with State Attorneys General: an Analysis,” at [www.mwe.com/info/news/wp0508a.pdf](http://www.mwe.com/info/news/wp0508a.pdf) [May 29, 2008].) In addition to the \$58 million civil monetary settlement, the agreement includes remedial provisions regarding a broad range of practices including CME funding.
- While the 2008 Code calls for industry companies to establish policies for the disclosure of prescriber identifiable data to sales agents and to permit physicians to opt out of such disclosure, several states continue to pursue legislation or regulations effectively prohibiting such use despite federal district court decisions overturning such bans on First Amendment free speech grounds.
- Finally, the American Medical Association remains under extreme pressure from Congress to enhance its prescriber opt-out program in ways that might ultimately limit the value of the data by removing significant numbers of physicians from the data base.

## Weathering The Storm: Observations and Conclusions

Formal legislative or regulatory reform may emerge from this perfect storm prior to the effective date of the revised PhRMA Code and thereby trump key provisions of the Code. In such case, the 2008 Code may prove to be primarily a catalyst for industry to engage in self-reform in the interim. The PhRMA website listing of those who voluntarily elect to follow the Code may become an important yardstick by which companies are measured by external constituencies such as Congress and government regulators and enforcers. Such transparency in itself may thus be sufficient to spur rapid implementation of the 2008 Code by some companies in the effort to keep pace with rapid reform initiatives at the state and federal level. Accordingly, a carefully prioritized re-evaluation and revision of current internal policies and procedures to achieve conformity with the 2008 Code is a prudent step for pharmaceutical and biotechnology companies to consider taking now, and prompt and effective training of all affected employees will be an essential ingredient in any implementation of revised policies and procedures.

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