

## PhRMA Adopts Revised Marketing Code

On July 10, 2008, the Board of Directors of the Pharmaceutical Research and Manufacturers of America (PhRMA) unanimously adopted an updated and revised marketing code to govern the pharmaceutical industry's relationships with physicians and other healthcare professionals. The voluntary code revises the original code that was introduced in 2002 and will take effect in January 2009. The revisions to the prior code are limited and in many circumstances supplement the original code with current industry practice as it has evolved since 2002. Nevertheless, the **new code** includes a number of changes that will impact the way in which many pharmaceutical companies interact with healthcare professionals.

The original Code on Interactions with Healthcare Professionals (the "Code") set forth guidelines on how pharmaceutical companies and their representatives should appropriately interact with members of the medical community. It made it explicitly clear that all interactions are to benefit the patients and enhance the practice of medicine, and should focus on informing healthcare professionals about products, providing scientific and educational information, and supporting medical research and education. Business practices covered by the Code included consulting agreements, speaker training, gifts, and continuing medical education activities.

While the new Code does not make radical changes to the original Code, it does incorporate a number of modifications that will likely require review of and revisions to the compliance policies of most pharmaceutical companies. Several of the most significant changes to the Code are described below.

1. **Gifts.** The original Code permitted pharmaceutical companies and their representatives to offer gifts of minimal value to healthcare professionals, so long as those gifts were associated with the healthcare professional's practice (e.g., pens, notepads, etc.). Under the new Code, giving these types of "non-educational" items to healthcare professionals is no longer appropriate, even if those items are given to healthcare professionals for patient use. The new Code does not, however, directly address the industry practice of providing non-educational items directly to patients.
2. **Modest Meals.** The original Code stated that company representatives could provide occasional, modest meals in connection with informational presentations. The new Code would limit meals provided by field representatives and their immediate managers to in-office or in-hospital settings. Modest, occasional, out-of-office meals at restaurants or other locations remain permissible for speaker programs and substantive interactions with headquarters personnel.
3. **Consultant and Speaker Arrangements.** The original Code included basic standards for consulting and speaker arrangements, including various factors supporting the existence of a bona fide consulting or speaker arrangement. The original Code also allowed for entertainment and social events during consultant meetings and speaker training, so long as such events were clearly subordinate to the services being provided by the consultants or speakers in terms of time and emphasis. The new Code reemphasizes the current criteria for the establishment of a consultant relationship or speaker program, but expressly prohibits the industry from offering any recreational or entertainment activities in conjunction with consultant engagements or speaker training.

4. **Speaker Compensation Cap.** While the original Code did not provide specific guidance on this topic, the new Code provides that each company should cap the total amount of annual compensation it will pay to an individual healthcare professional in connection with all speaking arrangements (although consulting arrangements are not subject to the cap). While the new Code does not suggest a specific dollar amount for the cap, it requires that all compensation and reimbursement be reasonable and based on fair market value.
5. **Disclosure of Consultant Relationships.** In the case of consultants or speakers who also sit on committees that set formularies or develop practice guidelines, the new Code states that companies should require those speakers and consultants to disclose to the committees the nature and existence of their relationships with the company. The new Code also advises that speakers or consultants may be required by committees on which they serve to recuse themselves from decisions with respect to the product about which they speak or consult (although not to all matters relating to the company).

These revisions, along with new Code provisions addressing the use of prescriber data, training of sales representatives, and external verification of compliance, are likely to significantly affect the compliance and marketing policies and procedures of a majority of pharmaceutical companies. Other changes generally codify industry practices that have evolved since 2002, largely in response to the OIG Compliance Program Guidance for Pharmaceutical Manufacturers and to provisions in industry Corporate Integrity Agreements.

In order to ensure compliance with the new Code, it will be critical for companies to review all of the changes made to the Code as well as their internal policies and procedures in these areas. In addition, although compliance with the Code is voluntary, the emphatic endorsement of the original Code by the OIG suggests that the new Code will continue to substantially influence interactions between the industry and physicians and impact the industry's relationship with both state and federal entities.

## Contact Information

If you have any questions about the new Code and its effect on your business activities, please do not hesitate to contact one of our attorneys below or your regular Ropes & Gray contact.

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