

P/RMA

CODE

ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS

PRMA

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Preamble

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents research-based pharmaceutical and biotechnology companies. Our members develop and market new medicines to enable patients to live longer and healthier lives.

Ethical relationships with healthcare professionals are critical to our mission of helping patients by developing and marketing new medicines. An important part of achieving this mission is ensuring that healthcare professionals have the latest, most accurate information available regarding prescription medicines, which play an ever-increasing role in patient healthcare. This document focuses on our interactions with healthcare professionals that relate to the marketing of our products.

Effective marketing of medicines ensures that patients have access to the products they need and that the products are used correctly for maximum patient benefit. Our relationships with healthcare professionals are critical to achieving these goals because they enable us to –

- ▶ inform healthcare professionals about the benefits and risks of our products,
- ▶ provide scientific and educational information,
- ▶ support medical research and education, and
- ▶ obtain feedback and advice about our products through consultation with medical experts.

In interacting with the medical community, we are committed to following the highest ethical standards as well as all legal requirements. We are also concerned that our interactions with healthcare professionals not be perceived as inappropriate by patients or the public at large. This Code is to reinforce our intention that our interactions with healthcare professionals are to benefit patients and to enhance the practice of medicine. The Code is based on the principle that a healthcare professional's care of patients should be based, and should be perceived as being based, solely on each patient's medical needs and the healthcare professional's medical knowledge and experience.

Therefore, PhRMA adopts, effective July 1, 2002, the following voluntary Code on relationships with healthcare professionals. This Code addresses interactions with respect to marketed products and related pre-launch activities. It does not address relationships with clinical investigators relating to pre-approval studies.

1

Basis of Interactions

Our relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical research and education.

2

**Informational Presentations by or
on Behalf of a Pharmaceutical Company**

Informational presentations and discussions by industry representatives and others speaking on behalf of a company provide valuable scientific and educational benefits. In connection with such presentations or discussions, occasional meals (but no entertainment/recreational events) may be offered so long as they: (a) are modest as judged by local standards; and (b) occur in a venue and manner conducive to informational communication and provide scientific or educational value. Inclusion of a healthcare professional's spouse or other guests is not appropriate. Offering "take-out" meals or meals to be eaten without a company representative being present (such as "dine & dash" programs) is not appropriate.

3

Third-Party Educational or Professional Meetings

- ▶ Continuing medical education (CME) or other third-party scientific and educational conferences or professional meetings can contribute to the improvement of patient care and therefore, financial support from companies is permissible. Since the giving of any subsidy directly to a healthcare professional by a company may be viewed as an inappropriate cash gift, any financial support should be given to the conference's sponsor which, in turn, can use the money to reduce the overall conference registration fee for all attendees. In addition, when companies underwrite medical conferences or meetings other than their own, responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conferences or meetings in accordance with their guidelines.
- ▶ Financial support should not be offered for the costs of travel, lodging, or other personal expenses of non-faculty healthcare professionals attending CME or other third-party scientific or educational conferences or professional meetings, either directly to the individuals attending the conference or indirectly to the conference's sponsor (except as set out in section 6 below). Similarly, funding should not be offered to compensate for the time spent by healthcare professionals attending the conference or meeting.
- ▶ Financial support for meals or receptions may be provided to the CME sponsors who in turn can provide meals or receptions for all attendees. A company also may provide meals or receptions directly at such events if it complies with the sponsoring organization's guidelines. In either of the above situations, the meals or receptions should be modest and be conducive to discussion among faculty and attendees, and the amount of time at the meals or receptions should be clearly subordinate to the amount of time spent at the educational activities of the meeting.
- ▶ A conference or meeting shall mean any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentations(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented.

4

Consultants

It is appropriate for consultants who provide services to be offered reasonable compensation for those services and to be offered reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services. Compensation and reimbursement that would be inappropriate in other contexts can be acceptable for bona fide consultants in connection with their consulting arrangements. Token consulting or advisory arrangements should not be used to justify compensating healthcare professionals for their time or their travel, lodging, and other out-of-pocket expenses. The following factors support the existence of a bona fide consulting arrangement (not all factors may be relevant to any particular arrangement):

- ▶ a written contract specifies the nature of the services to be provided and the basis for payment of those services;
- ▶ a legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants;
- ▶ the criteria for selecting consultants are directly related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria;
- ▶ the number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified purpose;
- ▶ the retaining company maintains records concerning and makes appropriate use of the services provided by consultants;
- ▶ the venue and circumstances of any meeting with consultants are conducive to the consulting services and activities related to the services are the primary focus of the meeting, and any social or entertainment events are clearly subordinate in terms of time and emphasis.

It is not appropriate to pay honoraria or travel or lodging expenses to non-faculty and non-consultant attendees at company-sponsored meetings including attendees who participate in interactive sessions.

5

Speaker Training Meetings

It is appropriate for healthcare professionals who participate in programs intended to recruit and train speakers for company sponsored speaker bureaus to be offered reasonable compensation for their time, considering the value of the type of services provided, and to be offered reimbursement for reasonable travel, lodging, and meal expenses, when (1) the participants receive extensive training on the company's drug products and on compliance with FDA regulatory requirements for communications about such products, (2) this training will result in the participants providing a valuable service to the company, and (3) the participants meet the criteria for consultants (as discussed in part 4.a. above).

6

Scholarships and Educational Funds

Financial assistance for scholarships or other educational funds to permit medical students, residents, fellows, and other healthcare professionals in training to attend carefully selected educational conferences may be offered so long as the selection of individuals who will receive the funds is made by the academic or training institution. "Carefully selected educational conferences" are generally defined as the major educational, scientific, or policy-making meetings of national, regional, or specialty medical associations.

7

Educational and Practice-Related Items

- ▶ Items primarily for the benefit of patients may be offered to healthcare professionals if they are not of substantial value (\$100 or less). For example, an anatomical model for use in an examination room primarily involves a patient benefit, whereas a VCR or CD player does not. Items should not be offered on more than an occasional basis, even if each individual item is appropriate. Providing product samples for patient use in accordance with the Prescription Drug Marketing Act is acceptable.
- ▶ Items of minimal value may be offered if they are primarily associated with a healthcare professional's practice (such as pens, notepads, and similar "reminder" items with company or product logos).
- ▶ Items intended for the personal benefit of healthcare professionals (such as floral arrangements, artwork, music CDs or tickets to a sporting event) should not be offered.
- ▶ Payments in cash or cash equivalents (such as gift certificates) should not be offered to healthcare professionals either directly or indirectly, except as compensation for bona fide services (as described in parts 4 and 5). Cash or equivalent payments of any kind create a potential appearance of impropriety or conflict of interest.



Independence and Decision Making

No grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items should be provided or offered to a healthcare professional in exchange for prescribing products or for a commitment to continue prescribing products. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional's prescribing practices.

9

Adherence to Code

Each member company is strongly encouraged to adopt procedures to assure adherence to this Code.

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Under the Code, may items such as stethoscopes be offered to health-care professionals?



Yes, because these items primarily benefit patients, so long as the items are not of substantial value and are only occasionally offered to the healthcare professional. Items that are of more than minimal value and do not primarily benefit patients are also not permitted even if they bear a company or product name.



Under the Code, may golf balls and sports bags be provided if they bear a company or product name?



No. Golf balls and sports bags, even if of minimal value, do not primarily entail a benefit to patients and are not primarily associated with the healthcare professional's practice, even if they bear the name of a company or product.

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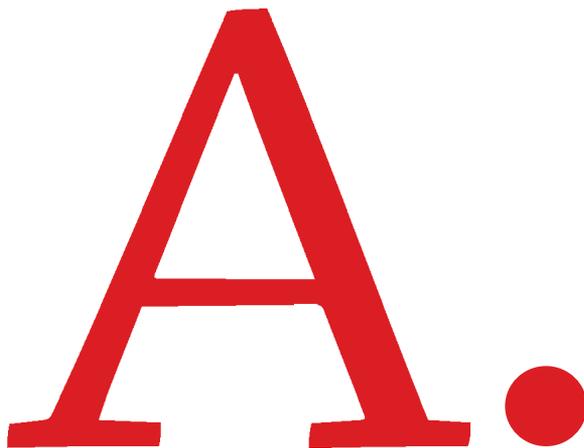
Under the Code, may healthcare professionals be provided with gasoline for their cars if they are provided with product information at the same time?

A.

No. Items intended for the personal benefit of a healthcare professional should not be offered.

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The Code says that informational presentations and discussions may be accompanied by occasional, modest meals. What types of presentations and meals would this include?



An informational presentation or discussion may be accompanied by a modest meal provided that the venue and manner of presentation/discussion is conducive to a scientific or educational interchange. For example, if a medical or scientific expert (who is a consultant to or employee of the company) is providing information about recently obtained study data to an audience of healthcare professionals, this could be done over lunch or dinner at a quiet restaurant providing the meal was of modest value as judged by local standards.

Following the same logic, if a sales representative is providing substantial scientific or educational information regarding a company's products to one or a few healthcare practitioners, this could also be done during a modest meal which could be at or outside of a physician's office.

However, if the nature or location of the meal would not facilitate communication of the information, then a meal would not be appropriate. Further, the use of modest meals on more than an occasional basis would not be appropriate.



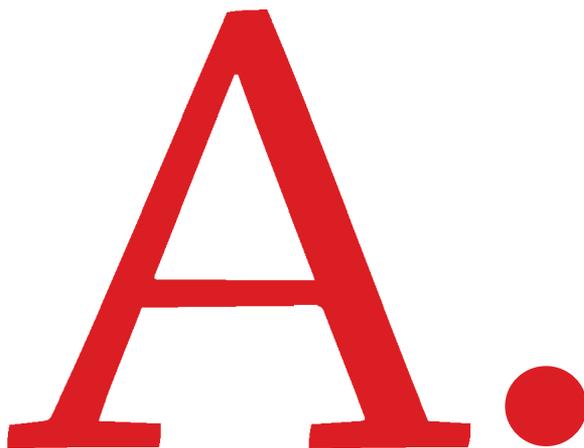
A representative of Company X provides pizza for the staff of a medical office. Is this consistent with the Code?



This would be consistent with the Code if the representative will provide an informational presentation to the medical staff in conjunction with the meal of modest value, so long as the location of the presentation is conducive to a scientific or educational communication. Merely dropping off food for the office staff, however, would not be consistent with the Code.

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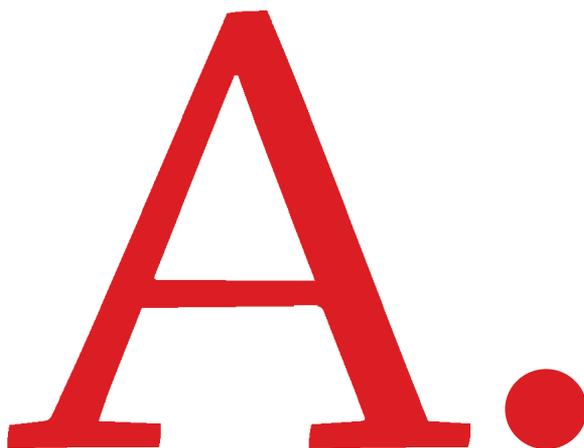
A representative of Company X invites physicians to meet to hear a scientific and educational presentation about a new drug at the café at a nearby bookstore. Coffee and cake are provided by the representative and, following the presentation (which is in small groups), each physician is given a gift certificate for books in the amount of \$30. Does this conform to the Code?



No. While the presentation may present scientific or educational information and the coffee and cake may appropriately be provided, an open-ended gift certificate is a cash equivalent. A medical textbook, a book on patient care, or a gift certificate redeemable solely for a medical textbook or book on patient care could be provided if it is not of substantial value.

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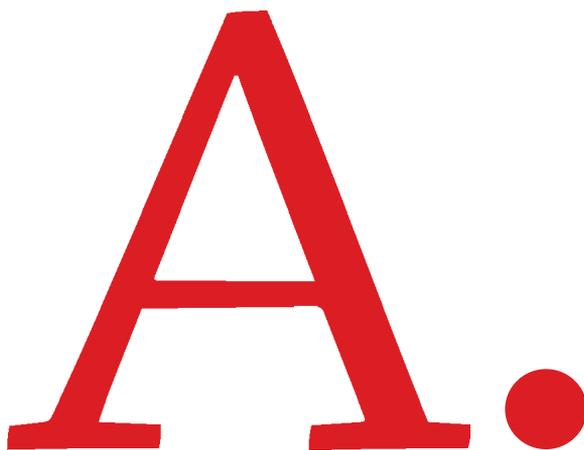
Company C invites 30 physicians to a corporate suite at a professional baseball game for a 45-minute scientific and educational presentation followed by a buffet and the three-hour game. Does this conform to the Code?



No. A modest buffet meal accompanying a scientific or educational presentation would be acceptable. However, the provision of entertainment and/or recreational activities, including entertainment at sporting events in connection with an educational or scientific presentation or discussion, is inconsistent with the Code.

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Under what circumstances would the Code permit a company to provide entertainment or recreational activities directly to health-care practitioners?



Companies may provide modest entertainment or recreational activities to healthcare practitioners in a context where those practitioners are providing a legitimate service to the companies, such as when they act as bona fide consultants on an advisory board or are trained at a speaker-training meeting.

Companies should generally not provide entertainment or recreational activities to healthcare practitioners. Thus, companies should not invite healthcare professionals to sporting events, concerts, or shows, or provide them with recreational activities such as hunting, fishing, boating, ski trips, or golf outings, even if those entertainment events or recreational activities are used to facilitate informational interchanges between the company representative and the healthcare professional. Similarly, it would be inappropriate to provide these types of entertainment and recreational events in conjunction with promotional scientific presentations by medical experts.

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Company A retains a small group of 15 nationally known physicians regarding a therapeutic area relevant to company A's products to advise on general medical and business issues and provide guidance on product development and research programs for those products. These physicians are paid significant fees, but those fees are typical of the fees paid to thought leaders in this therapeutic area. They normally meet once or twice a year at resort locations to discuss the latest product data, research programs and Company plans for the product(s). Does this comply with the Code? If it does, is it appropriate to pay for the spouse of the healthcare professional to attend, as well?

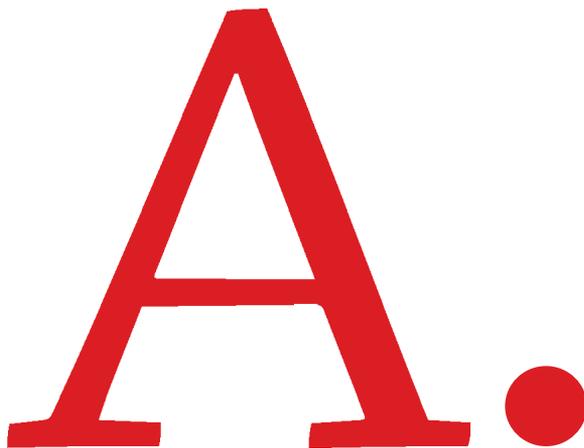


This arrangement appears to comply with the Code. The number of advisors seems reasonably small. The advisors seem to have been selected based on their expertise in the areas where advice is needed. While the consultants are paid significant fees, these appear to be reasonable under the circumstances. Finally, while holding consultant meetings at resort locations is not prohibited, the facilities chosen should be conducive to the services provided as well as reasonable and appropriate to the conduct of the meeting.

It would not be appropriate to pay for the cost of the spouse of the advisor. If the spouse attends, it should be at the cost of the advisor.

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Company A invites 300 physicians/consultants to a two-day and one-night speaker-training program at a regional golf resort. All attendees are compensated for their participation and their expenses are reimbursed. Prospective speakers are selected based on recommendations of the Company's district managers and an assessment of their qualifications by the Company's medical or scientific personnel. Each of the attendees is required to sign an agreement in advance covering the services they will provide. They are educated by a faculty on the full range of data surrounding the disease state and the Company's drug product, on presentation skills, and on FDA regulatory requirements. The Company plans to use at least 280 participants as speakers over the coming year, and it needs to train 300 speakers in order to ensure that 280 will actually be available when needed. Training sessions take both days, and the Company provides for a few hours of golf and meals. Does this program conform to the Code? If so, is it appropriate to pay for a spouse of the healthcare professional, as well?



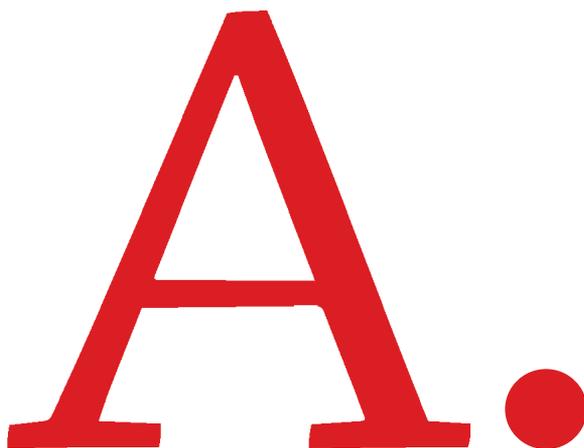
This arrangement appears to comply with the Code. Speaker training is an essential activity because FDA holds companies accountable for the presentations of their speakers. In this case, the participants undergo extensive training that will result in a valuable service being provided to the company, and the arrangement meets reasonable indicia of a bona fide consulting relationship. While resort locations are not prohibited, the Company may want to consider whether it would be more appropriate to hold the training session at a non-resort location. In this case, the number of speakers being trained is important; if significantly more participants were trained than were to be used as speakers, this arrangement would not comply with the Code.

The amount of time spent training speakers should be reasonable in relation to the material that has to be covered. The compensation offered to prospective speakers, including the value of any entertainment, should be evaluated to assure that it is reasonable compensation for that time.

It would not be appropriate to pay for the cost of the spouse of the healthcare professional. If the spouse attends, it should be at the cost of the healthcare professional.

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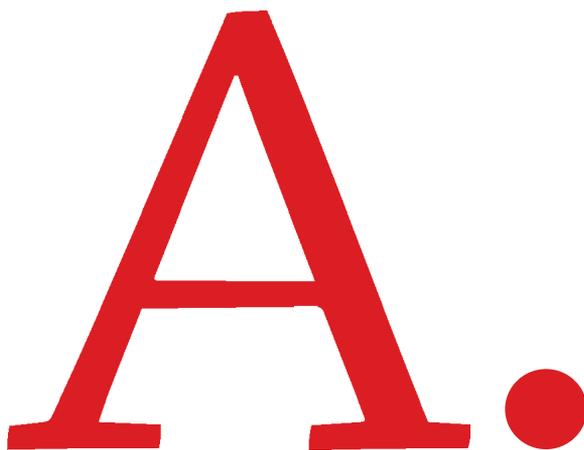
A sales representative invites a physician out for a round of golf and lunch following the golf. The physician is very busy and is difficult to see in her office. The cost of the golf and the lunch combined are \$65. Does this comply with the code?

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No. It is inconsistent with the Code to provide entertainment or recreational activities such as golf.

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Under the Code, may a healthcare professional's spouse or other guest be included in a meal with a pharmaceutical company representative that is provided in connection with an informational presentation by or on behalf of the company, if the healthcare professional pays for the spouse or guest?



No. The Code provides that 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 qualify as a healthcare professional for whom the informational presentation is appropriate.

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Under the Code, what guidelines apply to financial support for meals and receptions in connection with the meeting of a major medical society or other third-party scientific and educational conferences and professional meetings?

A.

Guideline 3 of the Code addresses financial support for meals or receptions provided in connection with continuing medical education meetings. The same provisions apply to other third-party scientific and educational conferences and professional meetings.

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Under the Code, may a company make a charitable contribution such as purchasing a table at a fundraising dinner or a foursome slot at a fundraising golf tournament?



Yes, but the company may not invite healthcare professionals to attend the event at its expense. The company may use some or all of its allotment for its own employees, and return any unused portion to the sponsoring organization to use as it wishes.

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Under the Code, may a company compensate a consultant for bona fide services by providing an item with a legitimate patient benefit in lieu of paying an honorarium or fee?



If the consulting arrangement otherwise complies with the Code, and the fair market value of the item represents reasonable compensation for the services provided, this may be permissible. However, it would be important to comply with all applicable recordkeeping and reporting requirements, just as with cash compensation. The written agreement for the consulting services should set forth the compensation and its fair market value, and disclose that this is taxable income.

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Does the Code apply to interactions with physician office managers, receptionists, and similar personnel who may not be healthcare professionals?



Although the Code does not directly apply to persons who are not healthcare professionals, it would be difficult to separate a company's interactions with any of a physician's employees from those directly with the physician. Therefore, the Code should be followed under these circumstances.

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