

Answers to Case Studies

#1: Yes, because these items primarily benefit patients, so as long as the items are not of substantial value and are only occasionally offered to the healthcare professional. Items that are more than minimal value and are not primarily benefiting the patient are not permitted even if they bear a company or product logo. Other examples: anatomical models, medical textbooks, books on patient care. Etc.

#2: No. Golf balls, even if nominal 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 logo.

#3: No. An informational presentation to the medical staff in conjunction with the meal of modest value must be provided. Merely dropping off food for the office staff with brochures (dine and dash) is not allowed. Pizza for staff & providers is o.k. if the rep provides informal presentation to the staff.

#4: Part one – Yes. An informal presentation accompanied by a modest meal provided that is in a venue and manner that is conducive to scientific or educational interchange is allowed. The meal must be of modest value to by local standards. Part two – No. It is not appropriate to include a spouse or guest at a meal in connection with a presentation regardless of who pays.

#5: AMA suggests – ensuring there are no actual or perceived conflicts of interest if a particular offer is accepted, you could accept the training only AFTER the supplier has been chosen. Then clarify that the training schedule and agenda are appropriate for your objectives and arrange transportation, lodging and meals at your own expense.

#6: No. This would be of personal benefit to the physician and not primarily to benefit patients. There would also be not educational value.

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

PhRMA COMPLIANCE PROVIDER TIPS

Lavish gifts, expensive trips, discounts, promotional products, and free samples are only a few of the incentives the pharmaceutical industry's drug representatives currently use or have used to promote their products, and "sway" provider prescribing decisions. Some of these marketing techniques could violate current fraud and abuse laws.

On April 23 2003 the HHS Office of Inspector General (OIG) published the final compliance program guidance for pharmaceutical manufacturers. Provider relationships with drug representatives are being closely scrutinized.

As a provider, you may want to ask yourself the following questions when offered an "incentive" to help determine whether it may have legal and/or ethical repercussions:

- *Is the incentive of nominal value?*
Individual gifts of minimal value –approximately \$100.00 or less on the open market are permissible as long as the gift is related to the providers work – i.e. pens, pads etc.
- *Is the incentive of value to patients or related to practice?*
i.e. glucose-monitoring home-test kit for patient use, stethoscope, medical textbooks, patient education books, etc.
- *Is the incentive offered with "no strings attached?"*
A provider should not accept a gift if they are given in relation to the provider's prescribing practices.
- *Does the incentive fall into what is allowable under "the code?"*
- *Does the incentive fall into what is allowable under internal policies and procedures?*
- *Would your patient's be pleased if they knew about the incentive?*

If the answer to any of the above questions is "no", providers should think carefully about accepting the gift or else consult legal counsel to help determine if the activity would violate any fraud and abuse laws.

Informational websites:

www.phrma.org/code_on_interactions_with_healthcare_professionals/

www.advamed.org/publicdocs/coe.html

www.oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf

www.ama/pub/category/5689.htm

www.ama-assn.org/ama/pub/category/4001.html

www.ama-assn.org/ama/pub/category/8943.html

www.jama.ama-assn.org/cgi/content/abstract/283/3/373

Pharma Audit Survey (Draft Example)

Issues	Comments
How often does a pharmaceutical company provide meals (Obtain schedule for luncheons)	
When meals are provided, do the pharma representatives provide education and stay for the entire meal? (observe in person or have someone to observe first hand for you)	
Do the department and/or individuals interact with the pharma company's reps other than for educational meals?	
Do the department and/or individuals receive any subsidies for CME, conferences or meetings? (check if these fall within guidelines)	
Do individuals consult with pharmaceutical companies?	
Does the clinic/entity receive drug samples?	
How are these samples distributed?	
Do the pharma reps offer any types of gifts/incentives to providers/clinics and/or staff? (check if these fall within guidelines)	
Does the entity have a policy on interactions with pharmaceutical representatives?	
Are staff/providers aware of the policy and are they following policy?	

Sample Draft Policy

Policy: Interactions with Pharmaceutical Representatives

Purpose: Pharmaceutical interactions with healthcare professionals are intended to benefit patients and to enhance the practice of medicine. Interactions should focus on informing healthcare professionals about products, providing scientific and educational information, and supporting medical research and education.

Procedure:

Informational Presentations and Meals:

- Occasional meals offered by pharmaceutical companies are appropriate if they are modest in cost and occur in a venue and manner conducive to informational communication and provide scientific or educational value.
- Inclusion of a spouse or other guest is not appropriate.
- Take-out meals or meals to be eaten without a company representative present are not appropriate.
- Entertainment/recreational events offered are not appropriate.

Third-Party Educational or Professional Meetings:

- Giving of any subsidy for continuing medical education, or other third-party scientific and educational conferences or professional meetings directly to a healthcare professional is not appropriate.
- Non-faculty healthcare professionals attending CME or other conferences should not accept support for the costs of travel, lodging, or other personal expenses.
- Funding should not be accepted to compensate for the time spent attending the conference or meeting.

Consultants:

- Consulting healthcare professionals who provide services can accept reasonable compensation for those services and reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing the services.
- Bona fide consulting arrangements are evidenced by:
 - A written contract that specifies the nature of the services to be provided and the basis for payment of those services;
 - A legitimate need for the services is identified in advance of the request for services;
 - The criteria for selection of the consultants are directly related to the identified purpose, and the

persons making the selections have the expertise to evaluate whether the consultant meets the criteria;

- The number of consultants is reasonable;**
- The retaining company maintains records concerning and makes appropriate use of the services;**
- 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.**

Speaker Training Meetings:

- Healthcare professionals who participate in programs intended to recruit and train speakers for company sponsored speaker bureaus can accept reasonable compensation 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) participants will provide a valuable service to the company, and (3) the participant meets the criteria as a consultant.**

Educational and Practice-Related Items:

- Items that primarily benefit the patient may be accepted (\$100 or less). For example, product samples, stethoscopes, patient education books, etc.**
- Items of minimal value may be accepted is associated with the healthcare professional's practice. For example, notepads, pens, etc.**
- Items for the personal benefit of the healthcare professional should not be accepted. For example, floral arrangements, artwork, music CDs, etc.**
- Payment in cash or cash equivalent (such as gift certificates) should not be accepted.**

PHARMA COMPLIANCE – What’s allowable and what’s not under the Code

<p>ALLOWED UNDER THE CODE</p> <p>Informational presentation accompanied by occasional meals</p> <p>Financial support given directly to sponsors of CME or third party conferences</p> <p>Occasional gifts if they primarily benefit patients and are valued under \$100 /includes practice related gifts of pens and notepads</p> <p>Funding to allow healthcare professional in training to attend major educational, scientific or policy making meetings (selection by institution)</p>	<p>NOT ALLOWED UNDER THE CODE</p> <p>ANYTHING provided or offered to a healthcare professional in exchange for prescribing or for a commitment to continue prescribing products</p> <p>Entertainment and recreational events – golf, spa, etc.</p> <p>“Dine and Dash” programs</p> <p>Inclusion of spouse or guest in sponsored meals/receptions</p> <p>Individual financial support for third party conference attendees</p> <p>Cash, except as compensation for bona fide consulting</p> <p>Honoraria, travel or lodging expense to non-faculty and non-consulting meeting attendees</p> <p>Gifts that are not practice related or benefit patients</p> <p>Items intended for personal benefit</p> <p>Cash equivalents – gift certificates</p>
<p>EXAMPLES</p> <p>Informational presentations by industry reps and others speaking on behalf of a company provide valuable scientific and educational benefits. Occasional meals may be offered as long as they are modest as judged by local standards and occur in a venue and manner conducive to informational communication and provide scientific or educational value</p> <p>Continuing medical education or third party scientific/ educational conferences or professional meetings can contribute to the improvement of patient care and therefore financial support from companies is permissible. Any subsidy must be given to the conference sponsor which can be used to reduce the overall conference registration fee for all attendees. Giving the subsidy to a healthcare individual directly may be viewed as an inappropriate cash gift.</p> <p>Items of minimal value may be offered such as notepads, pens and similar reminder items w/company or product logos</p> <p>Consultants who provide services can be offered reasonable compensation for those services, and reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing consulting. The arrangement must be a bona fide consulting arrangement. A written contract must be in place that outlines the services and basis for payment, a legitimate need for services must be identified in advance, selection criteria must be directly related to the identified purpose, number of retainees must be reasonable, the retaining company maintains records, and the venue and circumstances must be conducive to consulting services</p> <p>Financial assistance for scholarships or other educational funds to permit healthcare professionals in training to attend carefully selected educational conferences may be offered. The selection of those to receive the funds must be made by the academic or training institution</p>	<p>EXAMPLES</p> <p>No inducements. Anything that makes the healthcare professional feel obligated</p> <p>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</p> <p>Offering take out meals or meals to be eaten without a company representative being present is not appropriate</p> <p>Inclusion of a healthcare professional’s spouse or guest is not appropriate</p> <p>Any subsidy should be given to the conference sponsor to reduce fees for all attendees. No individual support</p> <p>Cash should never be offered except in bona fide consulting arrangements</p> <p>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 professional meetings, either directly or through the conference sponsor</p> <p>No gifts should be offered that are not practice related or to benefit the patient. All gifts should be minimal</p> <p>Items intended for the personal benefit of healthcare professionals should not be offered. Such as floral arrangements, artwork, music CDs, or tickets to a sporting event</p> <p>Payment in cash or cash equivalents (such as gift certificates) should not be offered either directly or indirectly except in bona fide consulting arrangements</p> <p>If it makes you pause to consider if it is right, it probably isn’t!!</p>