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	ORIGINATOR: Director, Pharmacy and Respiratory Care Services	
ORGANIZATIONAL POLICY Hospital Employee Relationships with Healthcare Vendors	CONCURRENCE: Chair, Corporate Compliance Committee	
	APPROVAL: CEO/PRESIDENT	

INTRODUCTION

Effective July 1, 2002, the Pharmaceutical Research and Manufacturers of America (PhRMA) adopted a voluntary code (Code) on their relationships with healthcare professionals. The Code addresses interactions with respect to marketed products and related marketing activities. A new compliance guideline was also issued September 30, 2002 by the Office of the Inspector General (OIG) of the Department of Health and Human Services (DHHS) regarding the relationship between pharmaceutical manufacturers and healthcare providers. The OIG Compliance Program Guidance for Pharmaceutical Manufacturers (Guideline) will serve as an interpretation of existing law and as a directive to the drug manufacturers and the healthcare industry on how the OIG will enforce the laws. The Guideline suggests that the PhRMA Code be used as a starting point in determining which practices are permitted or prohibited. Although the PhRMA Code is voluntary, the federal Guideline indicates that it will be given legal effect through consideration of whether a company adopted the standards. More importantly the government will also examine whether the acceptance by physicians and other healthcare professionals of free items may implicate federal laws, such as the anti-kickback statute.

PURPOSE OF POLICY

The purpose of this policy is to insure that clinical practitioners and employees in the organization have a mutually beneficial relationship with the healthcare industry which is in compliance with the OIG guidelines, PhRMA code and the organization's corporate compliance policy.

SCOPE

This organizational policy and procedure is intended to serve as an operational framework for all employees, departments, and units of Ellis Hospital and does not preclude the development of specific intradepartmental policies and procedures. Intradepartmental policies provide guidelines for functions that are applicable only within the specific department. The intradepartmental policy may not however conflict with this organizational policy and procedure.

PROCEDURES

1. BASIS OF INTERACTIONS

Our relationships with healthcare companies are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on being informed about products, obtaining scientific and educational information and receiving support for medical research and education.

2. INFORMATIONAL PRESENTATIONS BY OR ON BEHALF OF A HEALTHCARE COMPANY

Informational presentations and discussions by industry representatives and others speaking on behalf of a company provide valuable scientific and educational benefits, if they are unbiased. In connection with such presentations or discussions, occasional meals (but no entertainment/recreational events) may be offered and accepted as 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 non-professional guest is not appropriate. Offering or accepting "take-out" meals or meals to be eaten without a company representative being present is not appropriate.

3. THIRD-PARTY EDUCATIONAL OR PROFESSIONAL MEETINGS

- A. Continuing medical education (CME) or other accredited third-party scientific and educational conferences (including user meetings) or professional meetings can contribute to the improvement of patient care and therefore, financial support from companies restricted for education 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 (e.g., Medical Education department, Ellis Hospital Foundation), which in turn, can use the money to reduce the overall conference registration fees 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. Policy #9106 Grants – Federal, State and Corporate may be referred to for further information.
- B. Financial support from healthcare companies should not be offered or accepted for the costs of travel, lodging, or other personal expenses of non-faculty or non-organizer Hospital employees attending CME or other third-party scientific or educational conferences or professional meetings, either directly to the individuals attending the conferences or indirectly to the conference's sponsor (except as set out in section 4 below). Similarly, funding should not be offered or accepted to compensate for the time spent by Hospital employees attending the conference or meeting.
- C. Financial support for meals or faculty attended receptions may be provided to the CME or accredited program sponsors who, in turn, can provide meals or receptions directly as 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 conducive to the 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.
- D. A conference or meeting shall mean any activity, held in 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 presentation(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. 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 and accepted 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 defined as the major educational, scientific, or policy-making meetings of national, regional, or specialty healthcare organizations.

5. EDUCATIONAL AND PRACTICE-RELATED ITEMS

- A. Items primarily for the benefit of patients may be offered by healthcare companies and accepted by Hospital employees if they are not of substantial value (not to exceed \$100). For example, an anatomical model for use in an examination room primarily involves a patient benefit, whereas a CD player does not. More expensive items, cash or cash equivalents (exceeding \$100) must be donated to the Hospital Foundation. Items should not be offered or accepted on more than an occasional basis, even if each individual item is appropriate. Providing product samples for patient use only in accordance with the Prescription Drug Marketing Act and the hospitals sample policy and procedures is acceptable.
- B. Gifts from healthcare companies may be offered to and accepted by Hospital employees when they are of such limited value (less than \$100 per person per year) they could not be reasonably be perceived by anyone as an attempt to influence the judgment of the recipient.
- C. Items of nominal value may be offered and accepted if they are primarily associated with a Hospital employees practice (such as pens, notepads, and similar “reminder” items with company or product logos).
- D. Items intended for the personal benefit of Hospital employees (such as artwork, music CDs or tickets to a sporting or entertainment event) should not be offered or accepted.
- E. Payments in cash or cash equivalents (such as a gift certificate) should not be offered to or accepted by Hospital employees either directly or indirectly. Cash or equivalent payments of any kind create a potential appearance of impropriety or conflict of interest.

6. INDEPENDENCE OF DECISION MAKING

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

7. ADHERENCE TO POLICY/PROCEDURES

All organizational employees, including hospital paid practitioners, must adhere to this policy and the above procedures.

8. FREQUENTLY ASKED QUESTIONS

A. Question 1

Under the Policy, may items such as stethoscopes be offered to and accepted by Hospital

employees?

Answer 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.

B. Question 2

Under the Policy, may golf balls be provided to Hospital employees if they bear a company or product name?

Answer

No. Golf balls, 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.

C. Question 3

Under the Policy, may Hospital employees be provided with a take home meal or gasoline for their cars if they are provided with product information at the same time?

Answer

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

D. Question 4

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

Answer

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 the hospital.

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.

E. Question 5

A representative of Company X provides pizza for the staff of a hospital department. Is this consistent with the Policy?

Answer

This would be consistent with the Policy if the representative will provide an informational presentation to the staff in conjunction with a 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 Policy.

F. Question 6

A representative of Company X invites physicians and other healthcare professionals 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 Policy?

Answer

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.

G. Question 7

Company C invites 30 physicians and other healthcare professionals 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 Policy?

Answer

No. A modest buffet meal accompanying a scientific or educational 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 Policy.

H. Question 8

Under what circumstances would the Policy permit a company to provide entertainment or recreational activities directly to healthcare practitioners?

I. Answer

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 may also provide receptions at seminars and educational meetings in which the faculty is available to interact with the audience before or after the program.

Companies should generally not provide entertainment or recreational activities to healthcare practitioners. Thus, companies should not invite Hospital employees 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.

J. Question 9

A sales representative invites a physician or other healthcare professionals out for a round of golf and lunch following the golf. The healthcare professionals are very busy and are difficult to see in their office or place of work. The cost of the golf and the lunch combined are \$65 per person. Does this comply with the Policy?

Answer

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

EXHIBITS

REFERENCES

www.phrma.org - PhRMA Code on Interactions with Healthcare Professionals – July 1, 2002
Federal Register 62057 Vol. 67 No. 192 - OIG Compliance Program Guidance for Pharmaceutical Manufacturers – September 30, 2002

Anti-Kickback Guidelines for Payments, Discounts, Gifts and Meals - # 9309
OIG Reference

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