

Approved by: UMMG Executive Committee**Date Approved: *July 8, 2009***

It is the policy of the University to conduct business with full transparency, disclosing all conflicts of interests and acknowledging activities or relationships that could be perceived to be conflictive in nature. All Healthcare Professionals should abide by all University of Miami Conflict of Interest policies. In addition, the University of Miami Medical Group has adopted the following policy that shall apply to all HealthCare Professionals and pharmaceutical/medical device industry representatives.

1. **BASIS OF PRACTITIONER/VENDOR INTERACTIONS**

Relationships between Healthcare Professionals and Industry Representatives are intended to benefit patients and to enhance the practice of medicine. Interactions between industry representatives and practitioners and staff should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical research and education. These interactions usually occur to obtain information about new drugs in the formulary or for training and evaluation of equipment/devices. Industry representatives may interact with professionals in non-patient care areas, by appointment only. Representatives are not allowed in patient care areas, may not see patients or medical records, and may not attend rounds or surgery. One exception is that industry representatives may be allowed in patient care areas to provide training on devices or equipment, if appropriate patient authorization is obtained prior to the interaction, where applicable. They are prohibited from using clinical areas and the University of Miami email system and addresses to inform practitioners/staff of industry sponsored events. The University will establish a procedure for registration of Industry Representatives (as stated in March 2004 policy).

2. **INFORMATIONAL PRESENTATIONS BY OR ON BEHALF OF A PHARMACEUTICAL COMPANY**

Informational presentations and discussions by Industry Representatives speaking on behalf of a company, whether on UM premises or not, must provide valuable scientific and educational benefits. Inclusion of a Healthcare Professional's spouse or other non-healthcare professional guests is not permitted.

3. **MEALS**

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; (b) occur in a venue and manner conducive to informational communication; and (c) provide scientific or educational value. 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. Offering "take-out" meals or meals to be eaten

without a company representative being present (such as "dine & dash" programs) is not permitted.

4. EDUCATIONAL OR PROFESSIONAL MEETINGS

- a. Continuing medical education (CME) or other 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 only to the department, division or similar administrative unit, and not directly to the conference sponsor, facilitator, or individual practitioners. 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.
- b. Financial support should not be offered for the costs of travel, lodging, or other personal expenses of non-faculty healthcare professionals ("non-faculty" refers to those not speaking or teaching at the event) attending CME or other third-party scientific or educational conference 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).
- c. Meeting Attendance: Funding is not permitted to compensate for the time spent by Healthcare Professionals attending the conference or meeting. Honoraria are only for educational presentations.
- d. 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.
- e. 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.

5. CONSULTANTS

- a. Physicians who provide consulting services, the scope of which is defined in advance in a written and signed contract, are permitted 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, as approved by the Chair, or by the Dean, in the case of a Chair, and in

accordance with University policy. Compensation and reimbursement that would not be permitted 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 written contract must specify the nature of the services to be provided, the amount of compensation and the basis for payment of those services. The following additional factors support the existence of a bona fide consulting arrangement (not all factors may be relevant to any particular arrangement):

- i. a legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants;
 - ii. 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;
 - iii. the number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified purpose;
 - iv. the retaining company maintains records concerning, and makes appropriate use of, the services provided by consultants;
 - v. 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.
- b. Non-faculty and non-consultant attendees may not accept honoraria, travel or lodging expenses to attend company-sponsored meetings. Participation in interactive sessions is not considered consulting.
- c. The UMMG consulting policy should be reviewed to be certain that professional income is properly designated. UMMG policy states:
- i. Consulting agreement income is defined as income received for providing advice or services to a company, agency or individual for the benefit of that company, agency or individual. Consulting generally consists of providing a service or advice rather than giving a prepared talk or presentation;
 - ii. Honorarium is defined as payment for presentation of an educational talk, speech, academic presentation or panel discussion only. The honorarium may include travel expenses and is generally given on a per speech or event basis. Payment for giving advice to a particular individual, agency or company in response to a specific question or questions is generally not considered an honorarium. Payment for the presentation or dissemination of knowledge and information to an audience comprised of various individuals and companies can be considered an honorarium.

6. SPEAKER TRAINING MEETINGS

It is permitted for healthcare professionals who participate in Speakers Bureaus or Consulting Programs funded by industry 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. (This provision does not apply to meetings of professional societies

that may receive partial industry support, meetings governed by ACCME Standards, and the like.)

Individuals who actively participate in those activities should follow these guidelines:

- a. the participants receive extensive training on the company's drug products or mechanical devices and on compliance with FDA regulatory requirements for communications about such products;
- b. this training will result in the participants providing a valuable service to the company;
- c. The contracts for these services are reviewed and endorsed by the appropriate clinical department chair and/or division chief;
- d. Financial support by industry is fully disclosed at the meeting by the sponsor;
- e. The meeting or lecture content is determined by the speaker and not the industrial sponsor;
- f. The lecturer is expected to provide a balanced assessment of therapeutic options and should promote objective scientific and educational activities and discourse;
- g. UM physician is not required by the company sponsor to accept advice or services concerning teachers, authors, or other educational matters including content as a condition of the sponsor's contribution of funds or services;
- h. Gifts of any type should not be accepted.
- i. Time spent in preparing and delivering the lectures does not impair the UM physician's ability to fulfill Departmental responsibilities;
- j. The lecturer explicitly describes all his or her related financial interests (past, existing, or planned) to the audience;
- k. The lecturer makes clear to the audience that the content of the lecture reflects the views of the lecturer and not UMMG or UM;
- l. Physicians should not facilitate the participation of UM trainees in industry-sponsored events that fail to comply with these standards;
- m. The use of UMMG or UM name in non-UM events is limited to the identification of the individual by his or her title and affiliation.
- n. UM physicians' names and likenesses are not allowed to appear in marketing materials for the sponsor or the sponsor's products, or to participate in activities intended for the sole purpose of their promotion.
- o. This policy governs all UM practitioners, clinical and administrative staff, and all those participating in UM medical education programs.

7. 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 or to sponsor any part of their training may be offered, so long as the selection of individuals who will receive the funds is made by the academic or training institution and the funding is provided to the department or division, with no direct support to the trainee(s). "Carefully selected educational conferences" are generally defined as the major educational, scientific, or policy-making meetings of national, regional, or specialty medical associations.

8. GIFTS, 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.

- a. Items should not be offered on more than an occasional basis, even if each individual item is appropriate.
- b. Items intended for the *personal benefit* of Healthcare Professionals may not be offered or accepted.
- c. Payments in cash or cash equivalents (such as gift certificates) shall not be offered to Healthcare Professionals either directly or indirectly, except as compensation for bona fide services (as described in parts 4 and 5).
- d. **Research Grants:** All grants should be made in accordance with institutional guidelines and only through clearly defined agreements.

9. PRODUCT SAMPLES

No Samples of drugs, medical devices, or any other products may be accepted by UM Miller School of Medicine faculty, staff or students under any circumstances and will not be permitted in any School of Medicine facilities.

10. INDEPENDENCE OF DECISION MAKING

No grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items can 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.

- a. **Purchasing/Formulary Decision-Making:** If an employee is involved with making a purchasing or formulary decision, and if either the employee, his or her family, partners, or other individuals with whom they have a personal relationship have received a gift or compensation from or have any other financial interest in the business being considered, the employee is required to disclose the conflict. The employee may then provide evidence and their insight regarding the product or service, but have no vote in the purchasing or formulary decision.
- b. **Family and Personal Relationships – Interaction with Industry:** Faculty/staff must not use their official University position(s) or influence for further gain or advancement for themselves, their families, partners, or other individuals with whom they have a personal relationship.
- c. **Ghost Writing:** Practitioners shall only use information from industry with review and modification, as required.

11. VISITOR REGISTRATION FOR INDUSTRY REPRESENTATIVES

The University will establish a procedure for registration of Industry Representatives.

12. ENFORCEMENT FOR INDUSTRY REPRESENTATIVES

Industry Representatives who do not adhere to this Policy may lose their privileges to visit the University facilities.

13. ENFORCEMENT FOR UM PRACTITIONERS AND STAFF

Deviation by UM Practitioners and Staff from this policy will be addressed in the following manner:

1. Unintentional and minor deviation from policy
Action: Verbal reprimand from department chair or delegated supervisor
2. Subsequent unintentional deviation from policy
Action: Written reprimand from department chair and warning that any further infractions would result in a fine.
3. Intentional or flagrant or repeated offenses
Action: Minimum fine of 5% of monthly salary, based on previous 12-month average. Higher amounts may be imposed if deemed appropriate by the nature of the infraction.
4. Additional intentional or flagrant or repeated offenses; or significantly egregious offense
Action: Termination from medical staff, including relinquishment of clinical privileges or termination from employment, as deemed appropriate

The department chair will be accountable for enforcing the policy when violations occur within the department. The department chair may request recommendations from the UMMG on which sanctions may be most appropriate as individual issues arise. The Dean is ultimately responsible for ensuring that the chairs enforce the policy.