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Policies for Interactions Among Clinicians at Boston Medical Center and Boston University School of Medicine and Representatives of the Healthcare Industry

Introduction

These policies are intended to apply to all BMC and BUSM employees and all trainees at BMC and BUSM who are directly engaged in the provision of clinical services (collectively referred to as "clinicians" below).

The leadership of the clinical departments of Boston Medical Center ("BMC") and Boston University School of Medicine ("BUSM") have developed the following policies for interactions among their clinicians and representatives of the pharmaceutical and device industries. The healthcare industries, particularly the pharmaceutical and device industries, play a vital role in drug discovery and in improving the public health. The clinicians at BMC and BUSM are eager to promote a mutually beneficial relationship with industry that facilitates discovery, dissemination of new information, evidence-based use of medications and devices, and that is characterized by the highest professional standards of rigor and integrity. These policies are intended to meet these goals by setting standards for the interactions between clinicians and representatives of the health care industries. We specifically seek to preserve and fortify the independence of our clinicians; ensure that we incorporate the most objective information in the care of our patients; slow the rising cost of healthcare; reduce the potential for real or perceived bias in our programs of clinical care and education; ensure compliance with the law, and develop a relationship with industry that promotes appropriate use of medications and devices. The complexities of relationships with industry preclude us from identifying all circumstances in which a financial conflict of interest may arise or in which an interaction may be inappropriate. We believe that the guiding principles in unclear situations should be to protect the interests of our patients and the independence of the faculty. **The overriding goal of these policies is to ensure as much as possible that the integrity of our educational programs and clinical decision-making are not compromised by financial or other personal relationships with industry.** Clinicians must consciously and actively divorce clinical care decisions (including referrals and diagnostic or therapeutic management) from any perceived or actual benefits accrued or expected from any company (including, but not limited, to personal gifts, research funding, scholarships for CME attendance, or consulting agreements).

Adherence to the policies is important to avoid actual or perceived conflict of interest in clinical practice and violation of the federal and state anti-kickback statutes and other laws. These policies will need to be revised in the future as the law and the expectations of the public and the medical profession evolve.

These policies augment BMC's and BUSM's policies on conflict of interest. In the case of clinicians, when these policies are more stringent than those policies on conflict of interest, these policies will apply. Since the BMC Conflict of Interest Policy and the BU Policy on Investigators' Conflicts of Interest, as administered by the BUMC Advisory Committee on Investigators' Conflicts of Interest, apply to all research activity, these policies are not intended to apply to conflicts of interest in research activity.

For purposes of this policy, “industry” refers to for-profit commercial entities that provide pharmaceuticals (including biologics), medical devices, clinical services or supplies, as well as intermediary organizations retained by industry... **1..Provision of Compensation or Gifts from Industry to Clinicians**

a. Gifts and Food:

1. **Clinicians may not accept any form of personal gift from industry or its representatives.**

2. Food, directly or indirectly funded by industry, may not be provided at BMC or on the BUSM campus. In addition, clinicians should use discretion in participating in industry-sponsored meals off campus. Specifically, FPP physicians should not facilitate the attendance of trainees at meals off campus sponsored by industry or at educational events off campus sponsored by industry which are not accredited by the Accreditation Council for Continuing Medical Education (“ACCME”) or the American Dental Association Continuing Education Dental Recognition Program (“ADA CERP”).

b. Honoraria and Consulting:

1. Clinicians may accept only fair market compensation for specific consulting or other services provided by him or her to industry. **Compensation from any commercial source to clinicians may not exceed \$500 per hour or \$5000 per day for any consulting service or honoraria. The terms of the arrangements, services provided, and compensation must be set forth in writing and must be approved prior to the consultation or service by the clinician’s Department Chair**

2. Clinicians may not accept compensation for listening to a sales presentation (e.g., detailing) by an industry representative.

3. Clinicians who are simply attending a Continuing Medical Education (“CME”) or other instructional activity, and are not speaking or otherwise actively participating or presenting at the meeting, may not accept compensation from companies either for attending or defraying costs related to attending the meeting.

c. Payment of Clinicians by Industry for Clinical Services

1. Clinicians may not receive any form of compensation for changing a patient’s prescription or using a specific device in a patient.

d. Vendor Access:

1. As a general rule, industry representatives may not interact with trainees at BMC or on the BUSM campus. Interactions are allowed in limited circumstances, however, when the expertise of representatives is required for instruction in the use of a device and a faculty member is present to supervise the interaction.

i. 2. Clinicians may only accept support from industry for travel and related expenses to review a vendor’s products under circumstances that do not create an actual or perceived conflict of interest and are compliant with BU policy (<http://www.bu.edu/policies/gift/policy.html>).

3. Industry representatives are not allowed in in-patient or out-patient care areas and must visit with clinicians by appointment only. Under limited circumstances, device industry representatives may be allowed in patient care areas at the request of a clinician to facilitate a clinical procedure involving a pertinent device. Under these circumstances, representatives must comply with all BMC patient care requirements and wear appropriate clothing and identification that distinguishes them from employed staff.

2. Provision of Scholarships and other Funds to BUMC Trainees

Clinicians should ensure that support of educational programs for trainees by the pharmaceutical or device industries is free of any actual or perceived conflict of interest. **Accordingly, direct support of trainee salaries, reimbursement for travel expenses or other non-research funding in support of scholarship or training by industry or its representatives is not allowed.**

Under some circumstances, industry support of trainee salaries or other non-research funding in support of scholarship or training is allowed through a national professional organization or other non-profit entity provided the following conditions are met:

- a. **The trainee recipient is selected through a peer-review process and both the trainee and the proposed training are endorsed by the department;**
- b. **The trainee and the supporting faculty member are not subject to any implicit or explicit *quid pro quo* (i.e., no strings attached). Specifically, there should be no actual or perceived conflict of interest related to the financial support of trainees.**

3. Provision of Free Drug Samples to Clinicians

- a. Free samples may be given to the pharmacy by industry representatives for distribution to patients only. Clinicians may not accept free drug samples from industry. Although distribution of free samples to patients is not encouraged, **all** distribution of free samples to patients must be administered by the BMC pharmacy.
- b. Free drug samples may never be sold.
- c. Free drug samples may not be used for personal use by any employees of BMC, BU or their respective family members.

4. Industry Support for Educational Events at BMC or BUSM

Industry support for educational events at BUMC is allowed under the following circumstances:

- a. All educational activities supported by industry must comply with the ACCME and ADA CERP standards (http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf.) regardless of whether or not formal CME credit is awarded. ;
- b. All industry funding for these activities must be channeled through the Office of Continuing Medical Education of BUMC.
- c. The Course Director is responsible for content, speaker, forum, and management of conflict of interest assisted by the Office of CME.

- d. Although the industry support can be acknowledged, no marketing, detailing, or other form of industry advertising should occur on campus in connection with the event;
- e. Attendee fees must be used to cover the costs of any food provided.

5. Guidelines for Delivering Industry-Supported Lectures or Participating in Legitimate Conferences and Meetings of Clinicians off the BMC or BUSM Campus

Clinical meetings and scientific meetings sponsored by professional societies frequently derive a portion of their support from industry. Such support may give rise to inappropriate industry influence on the content of the conference or its attendees. Grants for meetings and conferences that originate from the company's marketing division may be particularly problematic. Industry support generally takes one of two forms and different standards apply in each case.

- a. First, industry may partially support meetings run by professional societies. Clinicians are expected to participate in meetings of professional societies as part of their CME and professional obligations. Nonetheless, faculty should be aware of the potential influence of industry on these meetings and attentive to the guidelines set forth below in evaluating whether and how to attend or participate in these meetings.
- b. A second type of meeting or lecture is fully supported by industry directly or through intermedicate educational companies retained by industry. Clinicians may actively participate (*e.g.*, giving a lecture, organizing the meeting) in such meetings or lectures **only if**:
 - 1. Financial support by industry is fully disclosed at the meeting by the sponsor.
 - 2. **The meeting and lecture's content, including slides and written materials, must be determined by the clinician.** This provision precludes clinicians from serving in any other relationship with industry that does not allow clinicians to fully control the content of the lecture. Since providing lectures as a member of an industry-sponsored Speaker's Bureau usually precludes clinicians from controlling the content of lectures, clinicians may not serve on Speaker's Bureaus unless they retain full control of content of all industry-sponsored lectures.
 - 3. The clinician delivering a lecture is expected to provide a balanced assessment of therapeutic options, and should promote objective scientific and educational activities and discourse. Importantly, clinicians should clearly distinguish those uses of medications or devices that are approved by the FDA from those that are not FDA-approved in their lecture. The content of the lecture should be compliant with applicable FDA regulations.
 - 4. The clinician 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.
 - 5. The clinician receives compensation **only** for the services provided and the compensation is reasonable and reflects fair market rates.
 - 6. Time spent in preparing and delivering the lectures does not impair the clinician's ability to fulfill departmental responsibilities.
 - 7. The clinician delivering the lecture explicitly describes all his or her related financial interests (past, existing, or planned) to the audience.
 - 8. The clinician makes clear to the audience that the content of the lecture reflects the views of the clinician and not those of BMC or BUSM.

9. Clinicians should not facilitate the participation of trainees in industry-sponsored events that fail to comply with these standards.

6. Written scholarship in collaboration with Industry

Faculty are specifically not allowed to assert authorship on any publication written by the marketing arm of industry or its representatives (e.g., ghostwriting) in which the faculty member has not had meaningful input

7. Disclosure of Relationships with Industry

- a. Clinicians must fully disclose all relationships with industry to their respective Chair on an annual basis through the reporting mechanisms of Boston University School of Medicine and Boston Medical Center. As noted in 1.b.(1) above, speaking or consulting that is compensated by industry must be approved by the clinician's chair prior to providing the service. If the Department Chair has personal financial interest in the same entity as that proposed for the faculty member, the Chair should recuse themselves and the approval should be granted by the Dean, BUSM.
- b. Clinicians must disclose all of their related financial interests, including past, existing or expected interests (e.g., grants and sponsored research, compensation from consulting, speaker's bureaus, advisory boards; investments and ownership interests) to journal editors in manuscripts submitted for publication, and audiences at lectures or presentations.
- c. Clinicians must disclose their actual and potential conflicts of interest related to any institutional deliberations and generally may not participate in deliberations in which he or she has an actual or potential conflict of interest. See Boston Medical Center Vendor Relations Policy (No. 9.16); Boston Medical Center Conflict of Interest Policy (No. 9.4); Boston University Conflict of Interest Policy (<http://www.bu.edu/ethics/conflict.pdf>).
- d. Clinicians with supervisory responsibilities for trainees or staff must ensure that the faculty's conflict or potential conflict of interest does not affect or appear to affect his or her supervision of the activities or responsibilities of the trainee or staff member.
- e. The financial relationships of faculty will be publicly disclosed on the BUMC internet site. Compensation in the form of honoraria or equity from the pharmaceutical (including biologics) and device industries will be included in the disclosure. The list will include all companies with whom the faculty member has received compensation or royalty income during the past 12 months, the receipt of \$10,000 or more from a single entity will be denoted with an asterisk, and the total dollar amount received from all commercial entities will be displayed.

8. Enforcement

Department Chairs will be responsible for reporting violations of the policies to the Chief Medical Officer of Boston Medical Center and the Provost of BUMC. Clinicians who violate the aforementioned policies will be subject to sanctions in accordance with their Physician Practice Agreement and the Boston University Faculty Handbook. These sanctions may include disciplinary actions, financial penalties, and possibly termination for repeat violations of the policy described herein. Enforcement of these provisions and sanctions against

individual faculty members will be overseen by a standing committee appointed by the President and CEO of Boston Medical Center and Provost of BUMC,, and comprised of representatives from Boston Medical Center and Boston University.

In addition, companies whose representatives violate the aforementioned policies will also be subject to sanctions. Companies or their vendors who violate two of these policies within a one year period will be denied access to clinical staff at Boston University School of Medicine and Boston Medical Center for a six month period. Companies with three violations within two years will be denied access for a two year period.

The following references were utilized in the compilation of these Guidelines:

1. American Medical Association. Opinion of the Council on Ethical and Judicial Affairs, E-8.061 <<http://www.ama-assn.org/ama/pub/category/4001.html>> Accessed January 20, 2005.
2. Department of Health and Human Services, Office of Inspector General. OIG Compliance Program Guidance for Pharmaceutical Manufacturers. Fed Regist 2003;68:23731-43.
3. Pharmaceutical Research and Manufacturers of America. PhRMA Code on Interactions with Healthcare Professionals. Wash D.C., PhRMA, 2002.
4. Accreditation Council for Continuing Medical Education Report on Standards for Commercial Support accessed March 12, 2005 at http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf
5. Moses, H, et.al. *Collaborating with Industry-Choices for the Academic Medical Center*. N Engl J Med 347:1371-5, 2002.
6. Boston Medical Center Vendor (Pharmaceutical) Representatives BMC Policy and Procedure #18.30
7. Boston Medical Center Vendor Relations Policy (No. 9.16)
8. Boston Medical Center Conflict of Interest Policy (No. 9.4)
9. Brennan, TA, et al. Health Industry practices that create conflicts of interest. A policy proposal for academic medical centers. JAMA 295:429-433, 2006.
10. Coleman DL, et al. Guidelines for interactions between clinical faculty and the pharmaceutical industry: one medical school's approach. Acad Med 81:154-160, 2006.
11. Chimonas, S, Brennan, TA, Rothman, DJ. Physicians and Drug Representatives: Exploring the dynamics of the relationship. Society of GIM 22:184-190, 2007.
12. Guidelines for Interactions Among Yale Medical Group Physicians and the Pharmaceutical Industry
13. Coleman, DL. Establishing policies for the relationship between industry and clinicians: Lessons learned from two academic health centers. Academic Medicine 83:882-7, 2008.