

BUSM Policy for Interactions with Industry by Faculty/Clinicians

Approved by: BUSM Executive Committee

Approved: Aug. 20, 2014

PURPOSE

To establish Boston University School of Medicine (“BUSM”) standards governing the relationship between BUSM faculty/clinicians and for-profit commercial providers of services or supplies that support patient care, including entities that provide pharmaceuticals (including biologics), medical devices, clinical services or supplies, as well as intermediary organizations retained by such entities (hereinafter “industry” or “vendors”).

POLICY STATEMENT:

This policy, together with Boston University’s Conflict of Interest Policy and other related policies, provides the standards by which all BUSM faculty/clinicians are expected to conduct themselves when dealing with industry. Although relationships between faculty/clinicians and vendors can facilitate a mutually beneficial exchange of information about products or services relevant to patient care, these relationships can also create the potential for conflicts of interest and abuse. These standards are designed to protect the integrity of clinical decision making and to ensure that faculty/clinicians comply with all relevant federal and state laws and regulations including, but not limited to, the anti-kickback and self-referral laws, Prescription Drug Marketing Act, Massachusetts Pharmaceutical and Medical Device Manufacturers Conduct Law and the laws governing tax-exempt organizations. This policy draws upon the guidance issued by the Office of Inspector General, the American Medical Association, the Accreditation Council for Continuing Medical Education (“ACCME”), the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Advanced Medical Technology Association (AdvaMed).

This policy does not apply to dealings between industry and BUSM with respect to funding for research. Such relationships are covered by the BU Policy on Investigators’ Conflicts of Interest, as administered by the BUMC Advisory Committee on Investigators’ Conflicts of Interest.

For activities where continuing medical education (“CME”) credit is sought, the organizer should also consult the Boston University School of Medicine CME Office for guidance with respect to policies and procedures addressing vendor sponsorship.

These policies augment Boston University’s general policies on conflict of interest. In the case of faculty/clinicians, when these policies are more stringent than University-wide policies on conflict of interest, these policies will apply.

APPLICATION

This policy applies to (a) all BUSM faculty; and (b) other BUSM employees and trainees who are directly engaged in the provision of clinical services. These groups will be collectively referred to as “faculty/clinicians.”

EXCEPTIONS

As approved by Department Chairs.

PROCEDURE

1. Receipt Of Gifts, Gratuities or Other Business Courtesies

- a. Faculty/clinicians may not accept any form of personal gift from industry or industry representatives.
- b. Food, directly or indirectly funded by industry, may not be provided at BMC or on the BUMC campus. In addition, faculty/clinicians should use discretion in participating in industry-sponsored meals off-campus. Specifically, faculty/clinicians 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 ACCME or the American Dental Association Continuing Education Dental Recognition program (“ADA CERP”).

2. Consulting

- a. Consulting arrangements must be reduced to writing and clearly describe the nature of the consulting services and compensation. Compensation must be reasonable, at fair market value and only for specific bona fide services. Reimbursement for reasonable expenses as part of such arrangements is permissible. Such arrangements must comply with any applicable institutional employment contracts, conflict of commitment and conflict of interest policies.
- b. Faculty/clinicians may not accept more than \$500 per hour or \$5000 per day from vendors for any consulting service or in the form of honoraria. The terms of the arrangements, services provided, and compensation must be submitted in writing and approved prior to the consultation or service by the faculty/clinician’s Department Chair.
- c. Faculty/clinicians who are simply attending a continuing education program or other instructional activity and who are not speaking or otherwise actively participating or presenting at the meeting, may not accept compensation from vendors either for attending or defraying costs related to attending the meeting.
- d. Faculty/clinicians may not accept compensation for listening to any sales presentation by an industry representative.
- e. Faculty/clinicians may not receive any form of compensation for changing a patient’s prescription or using a specific device in a patient or for recommending the use of any product or service to a patient.
- f. Faculty/clinicians may not be paid for attaching their signature to a professional paper, article, or speech unless they have had meaningful input.

3. Vendor Access and Vendor Product Support

- a. As a general rule, industry representatives may not interact with trainees at BMC or on the BUMC 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 teaching physician or in the case of non-physician trainee, instructor, is present to supervise the interaction.

- b. Industry representatives are not allowed in in-patient or out-patient care areas and must visit with faculty/clinicians by appointment only. Under limited circumstances, device vendor representatives may be allowed in patient care areas at the request of a faculty/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.
- c. Generally, faculty/clinicians may not accept support from industry for travel and related expenses to review a vendor's products except under limited circumstances. Please consult the Compliance Office in advance of planning such a review.
- d. Free drug samples may not be accepted by any faculty/clinicians.

4. Department/Corporate Educational Grants or Scholarships

- a. Direct support, including support provided to BUSM or a Faculty Practice Plan corporation, of trainee or faculty/clinician salaries, reimbursement for travel expenses or other non-research funding in support of scholarship or training by industry or industry representatives is not allowed.
- b. Under some circumstances, vendor support of trainee or faculty/clinician 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:
 - 1. The trainee recipient is selected through a peer-review process and both the trainee and the proposed training are endorsed by the department;
 - 2. The trainee and the supporting member or faculty/clinician is 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. The fellowship or scholarship program must be reviewed and approved by the Department Chair or Vice President; and
 - 4. The funds for the training or scholarship must be paid to a corporation.

5. Educational Events at BMC or BUSM

Vendor support for educational events at BMC or BUSM 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 medical educational activities must be channeled through the Office of Continuing Medical Education of BUSM;
- 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 vendors advertising should occur on campus in connection with the event; and
- e. Attendee fees must be used to cover the costs of any food provided.

6. LECTURES or PARTICIPATION in LEGITIMATE CONFERENCES and MEETINGS OFF the BMC or BUMC Campus

Clinical meetings and scientific meetings sponsored by professional societies frequently derive a portion

of their support from vendors. Such support may give rise to inappropriate vendor 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. Vendor support generally takes one of two forms and different standards apply in each case.

- a. First, vendors may partially support meetings run by professional societies. Faculty/clinicians are expected to participate in meetings of professional societies as part of their continuing professional education and professional obligations. Nonetheless, faculty/clinicians should be aware of the potential influence of vendors 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 vendors directly or through intermediate educational companies retained by vendors. Faculty/clinicians may actively participate (e.g., giving a lecture, organizing the meeting) in such meetings or lectures **only if**:
 1. Financial support by the vendor 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 faculty/clinician. This provision precludes faculty/clinicians from serving in any other relationship with industry that does not allow the faculty/clinician to fully control the content of the lecture. Since providing lectures as a member of a vendor-sponsored Speaker's Bureau usually precludes faculty/clinicians from controlling the content of lectures, faculty/clinicians may not serve on Speaker's Bureaus unless they retain full control of content of all vendors-sponsored lectures.
 3. The faculty/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, faculty/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 faculty/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 faculty/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 faculty/clinician's ability to fulfill departmental responsibilities.
 7. The faculty/clinician delivering the lecture explicitly describes all his or her related financial interests (past, existing, or planned) to the audience.
 8. The faculty/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. Faculty/clinicians should not facilitate the participation of trainees in vendor-sponsored events that fail to comply with these standards.

7. DISCLOSURE of RELATIONSHIPS with VENDORS

- a. Faculty/clinicians must fully disclose all relationships with vendors on an annual basis through the reporting mechanisms of Boston University School of Medicine and Boston Medical Center.
- b. Faculty/clinicians engaged in speaking or consulting that is compensated by vendors must have approval from the Department Chair prior to providing the service. If the Department Chair has personal financial interest in the same entity as that proposed

for the member, the Department Chair should recuse himself or herself and the approval should be granted by the Dean of BUSM.

- c. Faculty/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.
- d. Faculty/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 University Conflict of Interest Policy (<http://www.bu.edu/ethics/conflict.pdf>) and Boston Medical Center Conflict of Interest Policy (No. 9.4).
- e. Faculty/clinicians with supervisory responsibilities for trainees must ensure that the instructor'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.

8. ENFORCEMENT

In the case of members of the BMC Medical Dental Staff, Department Chairs will be responsible for reporting violations of the policies to the Chief Compliance Officer of Boston Medical Center, Chief Medical Officer of BMC, and to the Provost of BUMC. Members who violate the aforementioned policies will be subject to sanctions in accordance with their Faculty Practice Plan 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 referred to the Chief Compliance Officer and may be subject to sanctions by BMC and/or BU. For example, companies or their vendors who violate two of these policies within a one year period may be denied access to clinical staff at Boston University School of Medicine and faculty/clinicians and members at Boston Medical Center for a six month period.

Companies with three violations within two years may be denied access for a two year period.

This policy is not intended to address all possible situations involving financial relationships between BUSM faculty/clinicians and vendors. If anyone has a *question concerning the interpretation or applicability* to a particular circumstance of any of the laws, regulations or standards referred to in this policy, he or she **should** contact the Department Chair, Vice President or Chief Compliance Officer. Anyone who is *in doubt as to the propriety or legality* of any course of action **must** consult with the Chief Compliance Officer prior to taking action. If anyone is *aware of any actual or threatened violation of this policy, or suspects* a violation of this policy has occurred, he or she **must** report the situation to the Chief Compliance Officer.

Responsibility: Department Chairs, Provost of BUMC, BMC Chief Compliance Officer, BMC Chief Medical Officer.