Title: Personal Gifts, Entertainment, and Company Support for Activities

Policy #: ADM-17

Purpose: The purpose of this policy is to set forth the standards for Beth Israel Deaconess Medical Center and its Affiliates (collectively, "BIDMC") relating to (1) the transfer of gifts between members of our Workforce and those in a current or potential business relationship with BIDMC, (2) the acceptance of Company (defined below) payments or support for speaking, travel, meals, events, programs, fellowships, and awards, and (3) maintaining objectivity in activities and avoiding commercial co-promotion. This policy applies to employees, members of the Medical and Professional Staff, consultants, agents, volunteers, trainees, and members of the Board of Directors.

Policy Statement: BIDMC is committed to preventing undue influence by vendors or biomedical companies on how it carries out its missions in healthcare, education, and research. Free or discounted goods, whether received or given, if tied to the generation of federal healthcare program business, may violate the Anti-Kickback Law and other regulatory prohibitions.[1] In addition, the Massachusetts Pharmaceutical / Medical Device Manufacturer Code of Conduct[2] prohibits gifts from biomedical manufacturers to health care practitioners licensed in Massachusetts. In harmony with the purposes of these rules, BIDMC prohibits all members of the Workforce from accepting personal gifts, travel, meals, speaking fees, or scholarships from Companies, except as allowed below.

When situations are not specifically addressed in this policy, decisions should be guided by the BIDMC Code of Conduct, always keeping in mind that our patients and their welfare come first, and that we are committed to ethical and compliant conduct. When in doubt, please ask for advice from your supervisor, from the Office of Compliance and Business Conduct, or from the Office of the General Counsel.

This policy does not cover:

- Charitable gifts from Companies to BIDMC, which are governed by the Development Department Gift Policy Memorandum (available through the Development Office);
- Free or discounted goods offered or provided to patients from BIDMC, which are restricted by ADM-31, Restrictions on Free or Discounted Goods and Services;
- Gifts of data, reagents, equipment, or other laboratory materials provided by Companies to lab personnel for use in the scope of research at BIDMC, which are governed by RS-23, Classification and Administration of Research Gifts;
- Gifts of product samples or prescription drug samples solely and exclusively for use by patients, which are governed by BIDMC Policy CP-11, Drug Sample Management; or
- Demonstration or evaluation units accepted for a limited period, which are governed by

[1] HHS OIG Compliance Program Guidance for Pharmaceutical Manufacturers, April 2003.
[2] Massachusetts Pharmaceutical and Medical Device Manufacturer Code of Conduct (Mass.Gen.L. c. 111N).

ADM-15, Supplier Contact and Negotiation.

Members of the Workforce who interact with any Company representatives are expected to be familiar with BIDMC Policies ADM-02, Vendor Access, and ADM-15, Supplier Contact and Negotiation.

A. Introduction:

While gifts may be a way to promote goodwill and understanding in a business arrangement, or may be a way to say thank you to a care provider, they often create a complex set of expectations between giver and recipient. Either or both parties may regard the gift -- even a small, inexpensive gift -- as a vehicle for indebting the recipient to the giver, and making the recipient feel obligated to reciprocate in some manner.[3]

While we acknowledge that gifts may be a normal courtesy, they also may compromise – or appear to compromise – our ability to make objective decisions on behalf of our patients or our organization. Gifts can exert an unconscious influence over purchasing decisions, patient referrals, or other decisions related to patient care.

B. Definitions:

1. "Company" means any pharmaceutical company, medical device company, biotechnology manufacturing/supply company, hospital equipment or service provider, (or its representatives) or any other person or entity that provides or is seeking to provide goods or services to BIDMC, or that otherwise does business with or is seeking to do business with BIDMC.
2. "Gift" means anything of any value that is received by an individual for which the recipient has not paid fair market value.
3. "Workforce" means persons working for the benefit of BIDMC, whether or not they are paid by BIDMC. This includes employees, members of the Medical and Professional Staff, consultants, agents, volunteers, trainees, and Board members.

C. Gifts:

BIDMC prohibits any member of its Workforce from soliciting any personal Gift of any value from a Company (defined above) or from a patient, except as authorized by this policy.

BIDMC prohibits any member of its Workforce from accepting any personal Gift of any value from a Company, whether on-site or off-site. By way of example, this includes token items such as pens, pads of paper, mugs, calendars, entertainment or recreational items of any value, meals in conjunction with entertainment or recreation, tickets to concerts or events, vacation trips, and payments of any kind, including cash and cash equivalents, gift certificates, equity, royalties, tangible items, or rebates that are prohibited under applicable federal or state fraud and abuse laws or regulations.

Payments made as compensation for bone fide services, bona fide royalties, or licensing fees are not Gifts, and are allowable if the arrangement is formalized in a written agreement

[3]Katz D, Caplan A, Merz J. All gifts large and small: Toward an understanding of the ethics of pharmaceutical industry gift giving, The American Journal of Bioethics, 2003;3:39-46. See also Friedman, H. and Herskovitz, P. The effect of a gift-upon-entry on sales: reciprocity in a retailing context, Mid-American Journal of Business, 5;49.

specifying the services to be provided, does not violate the Conflicts of Interest Policy or other applicable BIDMC policy, or any law or regulation, and payment does not exceed the fair market value of the services.[4]

This policy does not prohibit patients or their families from giving non-monetary personal Gifts their care providers, provided that the Gift meets all of these requirements:

1. the Gift is meant as a token of gratitude,
2. it is not meant to influence the care given,
3. it has not been solicited,
4. it is not cash or a cash equivalent, and
5. it is valued at less than $50.

In rare instances where a Gift of value in excess of $50 is offered to an entire unit, the appropriate VP should be consulted for guidance. Members of the Workforce may not accept cash or cash equivalents. Cash equivalents include gift cards, gift certificates, checks, money orders, negotiable instruments, traveler's checks, and other similar items. Persons wishing to give Gifts of cash or cash equivalents should be referred to the BIDMC Development Office.

Donations to BIDMC departments are considered institutional gifts for the purpose of this policy, and are not prohibited.

This policy does not prohibit token Gifts donated by a Company (such as key chains, T-shirts, pens, gift cards of $50 value or less, etc.) to be used as part of a BIDMC-sponsored public awareness campaign or event (such as "Healthy Home/Healthy Work," or the AIDS Ride, or other such event), as they are designed to increase awareness of a community need and fit within the mission of the organization, and are solicited by bona-fide representatives of BIDMC in the Development Office. Such support should never be solicited from suppliers involved in active or pending negotiations.[5]

D. Company-Sponsored Travel for Meetings:

BIDMC prohibits any member of the Workforce from accepting payment or reimbursement directly from a Company for expenses to attend any professional, scientific, or trade meeting or conference, unless the attendee is a speaker, panelist, or organizer at the meeting.

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[4] 105CMR 970.004: "Bona fide services," an arrangement for consulting services, including, but not limited to, research, participation on advisory boards, collaboration with 501(c)(3) organizations dedicated to the promotion of health and the prevention of disease, and presentations at company-sponsored training including U.S. Food and Drug Administration ("FDA") required education and training involved in producing safe and effective medical devices, provided such an arrangement is formalized in a written agreement specifying the services to be provided, based on the fair market value of the consulting services and characterized by the following factors:

- a legitimate need for the consulting services clearly identified in advance;
- a connection between the competence and expertise of the consultant and the purpose of the arrangement;
- the number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified purpose;
- the retaining company maintains records concerning the arrangement and makes appropriate use of the services provided by consultants; and
- the venue and circumstances of any meeting with consultants is conducive to the consulting services and activities related to the services are the primary focus of the meeting.

[5] ADM-15, Supplier Contact and Negotiation.

A member of the Workforce who is a speaker, panelist, or organizer at a professional, scientific, or trade meeting or conference, may accept payment or reimbursement from third-party organizers of reasonable expenses and a modest honorarium related to attending, provided that the third-parties remain responsible for the content, selection of speakers, and distribution of monies.[6]

A member of the Workforce who is not a speaker, panelist, or organizer may accept payment or reimbursement from a Company for reasonable expenses related to attending technical training on the use of a product only if

1. the commitment to provide such expenses was described in the agreement with the Company for the purchase or lease of the product,
2. the primary purpose of the meeting is training or education related to the product and its upgrades and/or enhancements, and
3. the payment is only for reasonable travel, meals, and lodging expenses and fair market value for the person's time (if compensation is indicated).

BIDMC does not allow members of its Workforce to accept or give travel, lodging, or other Gifts for family members (including, but not limited to, children, spouse, significant other, parents, brothers, or sisters) or guests of the invitee to attend conferences or meetings described in the section above. Attendees whose attendance is supported under this policy may pay personally and bear all the additional costs of bringing a guest.

E. Company-Sponsored Marketing Activities:

BIDMC is committed to protecting the reputation of the institution and its faculty for world-class clinical expertise and objective scientific discovery. To preserve its reputation for objectivity, and to avoid participation in federally-regulated labeling, advertising, and endorsement activities,[7] members of the Workforce may not engage in Company-sponsored marketing activities. Marketing activities include advertising, promotion, or other activity that is intended to be used by a Company to influence sales or the market share of a prescription drug, biologic or medical device; to influence a health care practitioner to prescribe a prescription drug, biologic, or medical device; to market a prescription drug, biologic, or medical device; or to evaluate the effectiveness of a Company detailing sales force.[8]

Members of the Workforce must maintain intellectual independence over the content of any material they present or publish, and may not participate in a Company's speakers bureau.[9] Attendance as a speaker is not allowed if a Company has developed or controlled the content of the presentation, if a Company has coached the speaker on what to say, or if the presentation is or can be considered marketing for the Company.[10] This policy is not intended to prohibit presentations by academic investigators of the results of their own

[6] 105 CMR 970.007(4)(b).
[7] E.g., FDA regulations on off-label marketing, 21 C.F.R. §§ 201.128 and 801.4; FTC Guidelines on Endorsements and Testimonials, 15 U.S.C. 45, 16 CFR 255.1 et seq.
[8] 105 CMR 970.009
[9] Compare Harvard Medical School Interim Policy Statement on Conflicts of Interest and Commitment (2011).
[10] FDA Guidance for Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64093 (1997).

industry-sponsored studies to peers, where there is an opportunity for critical evaluation and exchange of ideas.[11]

When a member of the Workforce will be compensated for providing a service as a speaker, panelist, or organizer, the arrangement should be documented in writing prior to the event, making clear that the presentation will be independent, objective, and non-promotional. The documentation must be kept by the person's manager or Chief in an appropriate location so that it can be reviewed or audited if needed.

The conference or meeting must be a "legitimate" conference, which means that: (a) it is primarily dedicated, in time and effort, to promoting objective scientific and educational activities and discourse; (b) the main incentive for the gathering is to further the participants' knowledge; and (c) there is disclosure of financial support or any potential for a conflict of interest by the Company sponsor if appropriate.[12]

Any member of the Workforce who is a member of a BIDMC committee that sets formularies or develops clinical guidelines, and who also serves as a speaker or commercial consultant for a Company, must disclose to the committee the nature and existence of his or her relationship with the Company. This disclosure requirement must extend for at least two years beyond the termination of any speaker or consultant arrangement.[13]

F. Company-Sponsored Meals:

With the exception of approved Company-sponsored educational events (below), or food provided in connection with ACCME-accredited programming, BIDMC considers Company-supplied food and meals to be prohibited personal gifts that may not be accepted by members of the Workforce, either on-site or off-site. "On-site" includes all clinical, administrative, educational, or research locations, whether owned or leased.

The prohibition of meals does not include meals that may be provided to an individual

1. who is a salaried employee of the Company;
2. while attending meetings as a member of a scientific advisory board or board of directors of a Company;
3. while attending a meeting required as a part of a bona fide consulting agreement, if the arrangement is formalized in a written agreement specifying the services to be provided, and such meals are modest in nature; or
4. in connection with receiving approved training at a specialized pharmaceutical or medical device training facility.

BIDMC may use general funds from Companies to support meals for educational events, as set forth in section G, below, Company Support for Educational Events and Programs at BIDMC.

G. Company Support for Educational Events and Programs at BIDMC:

BIDMC is committed to permitting only objective, evidence-based education for all members

[11] Association of American Medical Colleges. *Industry Funding of Medical Education*. Task Force Report at 20; (2008).
[12] AMA Code of Ethics, Opinion 8.061 "Gifts to Physicians from Industry."
[13] 105 CMR 970.005(3)

of the Workforce. To that end, Company support for lectures, symposia, or other educational events on the premises of BIDMC is permissible only if:

1. Support is received from a non-sales or non-marketing division of the Company, if one exists (e.g. a philanthropic foundation or arm of the Company);
2. Support is paid to the sponsoring department or to the Development Office of BIDMC and not to any individual member of our workforce;
3. Decisions regarding the nature of the educational program, its content, speakers, etc., rest solely with the BIDMC and its faculty, with no control or input by the Company;
4. The support is not provided in exchange for prescribing, disbursing, or using products, drugs, biologics or medical devices, or for a commitment to continue such;
5. There is full disclosure, in advance and at the meeting, of the nature and extent of the Company's involvement in the event;
6. All participants as faculty disclose the nature and extent of their involvement with the Company(s), if any;
7. Company sales and marketing personnel may never serve as faculty at any educational event.
8. If otherwise compliant with BIDMC policies, a portion of the general budget may be used to provide refreshments for attendees, provided that no food or drink is paid for, delivered by, or otherwise directly furnished by a sponsoring Company. Any refreshments should be incidental to the primary educational purpose of the event.
9. If the event is CME accredited, sponsorship by a single Company is prohibited, as set forth in the HMS Policy on Conflicts of Interest and Commitment (2011).
10. Any non-accredited Company-sponsored event must occur at a distinct time and location from any CME-accredited program.

The host Department should exercise discretion as to when it would be appropriate to invite Company representatives to attend educational seminars on the premises of BIDMC. For example, it might be appropriate for a product expert to be available to answer specific questions about new medical technologies or procedures. In contrast, attendance is not appropriate if the representative's presence would serve no purpose other than to highlight the company's sponsorship of the educational event or market the Company's product.

Company representatives may not attend any conference, rounds, or discussions (formal or informal), where individual patients or any collective patient care matters are discussed. Please refer to BIDMC Policy #ADM-02, "Vendor Access."

H. Company Support for Trainee Fellowships and Travel:

BIDMC is committed to maintaining integrity and objectivity in medical education. Company financial support for (1) training fellowships or scholarships, or (2) travel by trainees (medical students, residents, fellows, and other medical professionals in training) to attend selected educational conferences is acceptable, provided that:

1. Support is received from a non-sales or non-marketing division of the Company, if one exists (e.g. a philanthropic foundation or arm of the Company);

2. Support is paid to the sponsoring department or to the Development Office of BIDMC, and not to any individual member of our Workforce;
3. Decisions regarding the nature of the travel or fellowship, the learning objectives and curriculum, the selection of the individuals who will benefit from the funds, and how the funds are administered, rest solely with the Department Chair, the Program Director, or their designee(s), with no control or input by the Company;
4. The support is not provided in exchange for prescribing, disbursing, or using products, drugs, biologics or medical devices, or for a commitment to continue such;
5. There is full disclosure to the trainee, in advance, of the nature and extent of the Company's support;
6. The program terms are in writing, and comply with the guidelines of the Graduate Medical Education office, as they may be promulgated from time to time; and
7. Travel is provided only to substantive educational, scientific, or policy-making meetings of national, regional, or specialty medical associations, or other meetings deemed of educational or training value by the Department Chairperson or the Program Director.

Company representatives may not directly contact or work with trainees without prior knowledge, consent, and approval of the Department Chair, the Program Director, or their designee(s). Trainees who are approached directly by a Company representative should report the contact to the Program Director.

The Department Chair, the Program Director, or their designee(s) is responsible to assure that any remuneration or financial support is accepted in a manner consistent with BIDMC Policy ADM-15, Supplier Contact and Negotiation.

I. Company Representative Preceptorships:

Companies sometimes ask members of the hospital staff to arrange for a "preceptorship" or "shadowing" experience for their representatives. "Preceptorships" or "shadowing experiences" introduce third parties into the patient-physician relationship who are not health professionals, and who typically have goals other than patient care. Industry representatives are engaged, directly or indirectly, in promoting products, and through their observation of patient-physician interactions, seek to understand and influence the physician's decision-making process.[14, 15] For this reason, preceptorships are not allowed at BIDMC.[16]

[14] *Patient Privacy and Outside Observers to the Clinical Encounter*, AMA Council of Ethical and Judicial Affairs, at page 2, lines 41-45.

[15] "We conclude that the practice of providing clinical "preceptorships" to pharmaceutical sales representatives is unjustifiable, is unethical, and should not be permitted." Wall LL, Brown D, Pharmaceutical Sales Representatives and the Doctor/Patient Relationship, Obstet Gynecol 2002;100:594–9, at page 594.

[16] "Preceptorships" for pharmaceutical sales representatives should not be confused with the common medical meaning of the term, i.e. "a tutorial taken by medical students who receive practical training at the bedside, in an office, or in the clinical setting under the supervision of preceptors." Ibid. at pages 595-596. For further guidance, please refer to BIDMC Policy GME-09, "Observation Experience."

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Approved By:

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Eliminated:

Related Policies:

ADM-02 Vendor Access Policy
ADM-15 Supplier Contact and Negotiation
ADM-19 Conflicts of Interest Policy for BIDMC and its Affiliates
ADM-31 Restrictions on Free or Discounted Goods and Services
CP-11 Drug Sample Management
RS-23 Classification and Administration of Research Gifts