

## **MAINE MEDICAL CENTER Institutional Policy Manual**

**Policy Title:** Promoting Ethical Partnerships with Health Care Vendors

**Policy Summary:** It is the policy of Maine Medical Center to protect the integrity of clinical decisions, healthcare education, research activities and the purchasing or prescribing of medical devices and pharmaceuticals from real or perceived conflicts of interest created by gifts, payments, or other remuneration from those who sell health care goods and services.

**Policy:** It is the policy of Maine Medical Center to promote ethical relationships with its vendors such that patients at Maine Medical Center receive pharmaceuticals and medical devices which are unsurpassed in quality and which are obtained at the lowest cost consistent with this level of quality. In order to achieve this goal, it is the policy of Maine Medical Center to eliminate or minimize conflicts of interest in its relationships with pharmaceutical, medical device and other health care industries. A conflict of interest is a real or perceived divergence between a health care professional's personal interest in a matter and that individual's professional responsibility to another person, colleague, learner or organization. Conflicts of interest are created when those who sell goods and services within the health care system provide gifts, payments, or other remuneration to health care professionals who are in a position to influence the purchase or use of the goods and services.

1. *Applicability:* This policy and its associated procedures apply to all employees, faculty and learners at Maine Medical Center. Non-employed clinical staff who are privileged at MMC (for example, physicians in private practice) are expected to abide by these policies when they are present at MMC, engaged in teaching MMC learners, or are representing MMC in leadership positions or programs.
2. *Scope:* The policy governs the relationship of MMC employees, faculty and learners to health care vendors, defined as any commercial company that provides goods and services that are used in patient care or in clinical settings. Examples include pharmaceutical companies, medical device companies, suppliers of goods used in the hospital for patient care, companies providing diagnostic services, and companies providing residential or home care for patients after discharge from the hospital.
3. *Interpretation:* The Department of Corporate Compliance has designated the Conflict of Interest Compliance Committee (COICC) to determine, on request, whether a particular practice or relationship is compliant with the policy and how best to manage the conflict. A member of the COICC committee who is also a member of the Research Conflict of Interest committee will act as liaison between committees ensuring oversight is consistent among all MMC departments. The COICC will summarize and report all identified conflicts, management plans and reporting compliance to the Executive Compliance Committee quarterly.

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## Procedures:

1. **Conflicts of Interest:** A conflict of interest is a divergence between a health care professional's personal or financial interest in a matter and that individual's professional responsibility to another person, colleague, learner or organization. An employee's outside personal or financial interests have the potential to cause conflicts of interest. For example, when health care professionals who are in a position to influence the purchase of medical products receive gifts, payments, or other remuneration from the manufactures of such products, a bias may be created in favor of the manufacture's products.

1.1. *Annual Disclosure Form:* The following groups must complete a Conflict of Interest Disclosure form annually in order to report potential sources of conflicts of interest.

1. MMC employees and non-employed contracted physicians in leadership positions, defined as anyone with the job title of, director, medical director, chief, vice president, senior vice president, chief operating officer or chief executive officer;
2. Physicians employed and contracted by Maine Medical Center or Maine Medical Partners;
3. Other MMC employed practitioners with prescribing rights (e.g., NP, PA);
4. Pharmacists;
5. Dieticians;
6. Current faculty in MMC educational programs (Occasional presenters at MMC conferences are not required to fill out the annual MMC disclosure form, although they may be required to complete a form specific to the conference at which they are speaking);
7. Members of MMC committees or workgroups which make recommendations about the use or purchase of drugs, biologicals or medical technologies, including but not limited to, members of the Pharmacy and Therapeutics committee, the Technology Assessment Committee and Value Analysis Committees.

1.2. *Unanticipated conflicts:* Members of the above groups must report to their supervisor any new or unanticipated conflicts of interest when they occur.

1.3. *Enforcement:* It is the responsibility of an individual's Department Director or Clinical Chief to review Conflict of Interest forms annually to determine whether reported relationships are compliant with this policy. Department Directors and Clinical Chiefs are responsible for developing corrective action plans. Conflicts of interest may be eliminated by ending the relationship that gives rise to the conflict, or by removing individuals from situations in which they have the ability to influence the purchase, use or prescribing of a medical product or service.

## 2. Gifts

2.1. *Prohibition on gifts:* MMC employees, faculty, and learners may not accept gifts or hospitality from representatives of the health care vendors regardless of the value of the gift.

2.2. *Business meetings:* Health care vendor support may not be accepted for department meetings or retreats (either on or off-campus).

2.3. *Social gatherings:* Health care vendor support may not be accepted for purely social gatherings.

2.4 *Gifts and bequests to MMC:* The Development Office may accept philanthropic donations from a health care vendor to support the mission of MMC, but such donations may not be directed by the vendor so as to benefit one or a small group of staff members, nor may such donations be accepted with the explicit purpose of supporting educational events for health care professionals (see section 3.1).

2.5 *Donations to non-MMC charitable organizations:* MMC staff may accept donations from vendors on behalf of a charitable organization as long as the staff do not directly benefit from the gift.

### 3. **Education**

3.1 *MMC educational events (on or off campus):* Health care vendor sponsorship for Maine Medical Center educational conferences is prohibited.

3.1.1 *Co-sponsorship with entities which are not Health Care Vendors:* Health care vendor refers to any commercial company that provides goods and services that are used in patient care or in clinical settings. This policy does not prohibit Maine Medical Center from co-sponsoring educational events with organizations that do not provide goods and services that are used in patient care settings, as long as the co-sponsorship does not constitute a conflict of interest that threatens the integrity of clinical decisions, medical education, research activities or the purchase of medical devices and pharmaceuticals.

3.1.2 *Co-sponsorship with professional and not-for-profit organizations:* Maine Medical Center may co-sponsor educational events with professional organizations (for example, the American Medical Association, the American Nurses Association, the Maine Medical Association), regardless of whether that such organizations in their ancillary activities also produce goods and services that are used in patient care or in clinical settings, and as long as the co-sponsorship does not constitute a conflict of interest that threatens the integrity of clinical decisions, medical education, research activities or the purchase of medical devices and pharmaceuticals. Likewise, Maine Medical Center may co-sponsor educational events with not-for-profit organizations (for example, the American Cancer Society, the American Heart Association), regardless of whether that such organizations in their ancillary activities also produce goods and services that are used in patient care or in clinical settings, and as long as the co-sponsorship does not constitute a conflict of interest that threatens the integrity of clinical decisions, medical education, research activities or the purchase of medical devices and pharmaceuticals.

3.1.3 *Co-sponsorship with educational institutions:* Maine Medical Center may co-sponsor educational events with educational institutions, (for example, a college or university), regardless of whether that institution also produces goods and services that are used in patient care or in clinical settings, as long as the co-sponsorship does not constitute a conflict of interest that threatens the integrity of clinical decisions, medical education, research activities or the purchase of medical devices and pharmaceuticals.

3.1.4 *Co-sponsorship with direct care providers in Maine:* Maine Medical Center may co-sponsor educational events with organizations whose primary focus is delivering direct patient care in Maine (e.g., other Maine Hospitals, private physician practices), as long as the co-sponsorship does not constitute a conflict of interest that threatens the integrity of clinical decisions, medical education, research activities or the purchase of medical devices and pharmaceuticals.

3.1.5 *Reporting of sponsorships:* The division or department organizing a co-sponsored educational event or an event that receives support from outside Maine Medical Center is responsible for reporting on an annual basis all sources of outside support for educational events to the Office of Medical Education or, for nursing programs, to the Center for Clinical and Professional Development. Reports will include (1) name of entity providing support, (2) the amount and/or nature of the donation, (3) members of program committee organizing the event, and (4) an accounting of major expenses associated with the event.

3.1.6 *Vendor displays at conferences:* The MMC sponsor of a conference may invite vendors to have displays in areas adjacent to, but not inside, meeting rooms at conferences. The MMC sponsor may not charge for such displays. Vendors may not distribute gifts from such displays. The MMC sponsor must display a sign in the display area that says that MMC does not endorse the products or services on display, does not collect fees for the displays, and that vendors may not distribute gifts.

3.1.7 *Training on equipment and devices:* Health care vendors may provide routine training on equipment and devices purchased from the company as part of the purchase agreement for the equipment or device. (Access to MMC clinical sites and employees requires a business associate contract and/or vendor conduct agreement. See the Access Policy and the Vendor Activities policy.)

3.2 *Non-MMC educational events:* MMC employees, faculty and learners must take reasonable steps to insure that the non-MMC sponsored event that they attend conforms to the following guidelines:

- Payment for attendance at industry-sponsored events is prohibited;
- Financial support by the health care vendor must be fully disclosed by the sponsor to the participants before beginning the activity;
- The program content, including slides and written material, must be determined by the faculty planners and presenters and may not be produced by the health care vendor sponsor;
- Industry funding should be used to improve the quality of the education provided and not to support hospitality, such as meals, social activities, etc., except for meals at a modest level;
- The program delivers a balanced assessment of diagnostic and therapeutic options and promotes objective scientific discourse;
- All planners and presenters must fully disclose to the audience all related financial interests;
- The programs must be available on equal terms to all interested practitioners, and may not be limited to attendees selected by the industry sponsor(s).

3.2.1 *Industry support for attending educational events:* MMC employees, faculty and learners may not accept support for attending an educational event from a health care vendor sponsor, including support for travel, lodging, meals, or entertainment. Nor may the spouses of employees, faculty and learners accept support from industry for travel, lodging, meals, or entertainment when accompanying an MMC employee, faculty or learner to an educational event.

3.2.2. *Scholarships:* MMC learners may accept scholarships for travel, lodging, meals and registration fees from non-industry sources for attendance at educational events.

#### 4. **Pharmaceutical Samples**

Drug samples may not be accepted by MMC employees, faculty or learners or in any MMC or MMP clinical setting. This policy does not apply to non-employed clinical staff who are privileged at MMC (i.e., health care professionals in private practice) at the health care professional's private practice setting. MMC learners in placed in private practice settings should not participate in accepting or dispensing samples. (See also the MMC Institutional Policy Dispensing Out-Patient Prescriptions and Sample Medications.)

#### 5. **Purchasing and Formulary Decisions**

*5.1 Approval of drugs, biologicals and products:* All new drugs, biologicals and products must be approved prior to use at MMC by the appropriate governing committee including, but not limited to Value Analysis Committees (VAC's), Technology Assessment Committee (TAC), Pharmacy and Therapeutics Committee (P & T Committee) and the Ergonomics Committee. . (See also the MMC Institutional Policy Pharmacy and Therapeutics Committee.)

*5.2 Conflict of interest reporting:* Members of MMC committees or workgroups which make recommendations about the use or purchase of drugs, biologicals, medical technologies or clinical services including but not limited to members of the Pharmacy and Therapeutics committee, the Technology Assessment Committee and Value Analysis Committees, must complete a conflict of interest form annually. The chairs of such committees and workgroups will review the forms of all committee members. Members of the above groups must report to the chairperson any new or unanticipated conflicts of interest when they occur.

*5.3 Recusal from committee deliberations:* Members of MMC committees or workgroups which make recommendations about the use or purchase of drugs, biologicals, medical technologies or clinical services must recuse themselves from committee deliberations when they have a financial relationship or have received remuneration in the last three years from the company that produces or distributes the item under discussion. The minutes of the committee meeting will reflect the recusal.

*5.4 Input from clinical staff:* All MMC employees, faculty and learners, as well as non-employed clinical staff who are privileged at MMC, may provide opinions about the merit of drugs, biological, medical technology or clinical services to the appropriate MMC committee by submitting a statement in writing to the appropriate committee which discusses the merits of the product in question and which discloses any relationships the authors of the statement or their immediate family members have with the manufacture of the product and any other relationships which might be perceived as a conflict of interest in the purchasing or formulary decision.

*5.5 Product evaluation:* Items being brought into the organization for evaluation must be approved prior to use at MMC by the appropriate governing committee. Evaluation may include trialing a product to determine whether to use, order, purchase or recommend the product. The evaluation process, trial criteria, and time frame must be specified in advance in coordination with the Purchasing Department, which has oversight of all new product introductions at MMC.

*5.5.1 Product samples for evaluation:* Products may be provided by the health care vendor at no charge to MMC to allow for their evaluation (under the conditions stated in 5.5). The number of products provided by the company must be reasonable given the duration and other features of the evaluation process.

*5.5.2 Travel for product evaluation:* A health care vendor may underwrite the costs of transportation, lodging and meals to evaluate medical technology that it is not feasible to demonstrate on-campus. Such travel must be approved and organized by the Purchasing Department. (See also the MMC Institutional Policy Travel and Travel Reimbursement.)

## **6. Academic Integrity**

*6.1 Authorship:* MMC employees, faculty and learners who are listed as authors on a publication must be fully involved in the research and writing of a manuscript, as specified in the guidelines for authorship of the International Committee of Medical Journal Editors. MMC faculty must be willing to take full responsibility for the intellectual content of their presentations and writings.

*6.2 Speaker's Bureaus:* MMC employees, faculty and learners are not permitted to discuss a specific drug, biological, medical product or medical service when they are being compensated by the maker of the product for the presentation, except in the rare circumstance in which the faculty member invented or was a central figure in the development of the product. Written approval from one's supervisor for such exceptions is required.

*6.3 Compensation for scholarly presentations:* MMC employees, faculty and learners may accept reasonable compensation in the form of support for transportation, lodging, meals and honoraria for academic or scholarly presentations, (except under the restrictions given in 6.2). Such compensation must be disclosed on the annual conflict of interest form. The program content, including slides and written material, must be determined by the faculty member and may not be produced by a health care vendor. The program must deliver a balanced assessment of diagnostic and therapeutic options and promote objective scientific discourse.

*6.4 Research Grants:* Research grants may be accepted to support independent medical research with scientific merit, well defined objectives and milestones, with no direct or indirect link to purchases. There are specific Conflict of Interest (COI) disclosure and management requirements for all research investigators. These requirements also apply to those receiving funding through a federal Sponsored Program grant. Please see the institutional policy Financial Conflict of Interest in Research and Sponsored Programs for these requirements.

## **7. Consulting for the Health Care Vendor**

*7.1 Requirement for contract:* MMC employees, physicians and students who provide consulting services for the health care vendor must do so under a contract that identifies tasks, deliverables and fair market value payment. Such contracts must be defined in advance of providing such services.

*7.2 Requirement for disclosure and approval:* A disclosure of the relationship and compensation must occur in writing to one's supervisor in MMC prior to entering into the contractual relationship and must also be disclosed on the annual conflict of interest form. The supervisor must approval the relationship.

*7.3 Clinical Decisions:* The provision of consultative services to a company by a clinician does not preclude the clinician from using, prescribing, ordering or recommending that company's drugs, biologicals, technologies or services during routine clinical care.

## **8. Royalties:**

*8.1 Requirement for significant contribution to development:* MMC employees, physicians and learners may enter into agreements to receive royalties only where the individual is expected to make, or has made a novel, significant contribution to the development of a product, technology, process or method.

*8.2 Requirement for contract:* MMC employees, physicians and learners who enter into arrangements to receive royalties must do so under a contract that identifies tasks, deliverables and fair market value payment.

*8.3 Requirement for disclosure and approval:* A disclosure of the relationship and compensation must occur in writing to one's supervisor in MMC prior to entering into the contractual relationship and must also be disclosed on the annual conflict of interest form. The supervisor must approve the relationship.

*8.4 Clinical objectivity:* Royalty arrangements must be consistent with preserving the objectivity of medical decision making and avoiding of improper influence, for example, royalties should not be conditioned on a requirement that the product be purchased or recommended for use at MMC, nor a requirement to market the product upon commercialization.

## **Definitions**

*Conflict of interest:* A conflict of interest is a real or perceived divergence between a health care professional's personal interest in a matter and that individual's professional responsibility to another person, colleague, learner or organization.

*Drugs, dietary supplements, and biologicals:* Drugs, dietary supplements, and biologicals are health related products that achieve their principal intended action by pharmacological, immunological, or metabolic means.

*Education:* Education is the direct communication of information concerning health care, patient risks and benefits, disease states and the use of medical technologies, drugs, dietary supplements, and biologicals.

*Faculty:* Maine Medical Center staff or providers privileged at MMC who have a formal role in providing education, training or oversight to persons enrolled in an educational program in which MMC participates. Occasional presenters at MMC conferences are not required to fill out the annual MMC disclosure form, although they may be required to complete a form specific to the conference at which they are speaking.

*Health care vendor:* Health care vendor refers to any commercial company that provides goods and services that are used in patient care or in clinical settings and to health care institutions or residential facilities to which MMC may refer patients. Examples include pharmaceutical companies, medical device companies, suppliers of goods used in the hospital for patient care, companies providing diagnostic services, companies providing residential or home care for patients after discharge from the hospital.



*Health care professional:* Health care professional refers to individuals or entities involved in the provision of health care services and/or items to patients, as well as those who are involved in the decision to purchase, lease, recommend, use or arrange for the use of medical technology or drugs.

*Leadership position:* A leadership position is defined as a position with the job title of manager, director, medical director, chief, associate vice president, vice president, chief operating officer or chief executive officer.

*Medical Technology:* Medical technologies are products and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities and which are dependent upon hands on health care professional interaction.

*Outside Financial Interests:* The following partial list can serve as a guide for the types of activities by staff, or household members of such staff, which may cause conflicts of interest because they are an outside financial interest:

- Investments or employment with any outside concern that does business with MMC, except for less than 5 percent ownership of stock held in publicly traded corporations;
- Participating in any transaction for personal gain in which MMC is a party;
- Disclosure or use of confidential or "insider" information about MMC, particularly for personal profit or advantage;
- Competition with MMC directly or indirectly, in the purchase, sale or ownership of property or business interests; and
- Participating in any business or employment that may conflict with the proper performance of one's duties at MMC.

## **References:**

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### **Related MMC Institutional Policies**

Access  
Conflict of Interest  
Contracts with Business Associates  
Financial Conflict of Interest in Research and Sponsored Programs  
Dispensing Out-Patient Prescriptions and Sample Medications  
Medical Education  
Organization Ethics  
Pharmacy and Therapeutics Committee  
Travel and Travel Reimbursement  
Vendor Activities

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### **Related Documents**

Executive Compliance Committee Charter  
Conflict of Interest Compliance Committee Charter

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**Original Date:** *August 3, 2009 (Approved) January 1, 2010 (Effective)*

**Review Date(s):**

**Approval Committee(s) and Dates:**

President's Council: 6/16/ 2009  
Institutional Policy Review Committee: 10/8/2012  
Executive Compliance Committee: April 16, 2019

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*Director, Clinical Ethics*

**President's Approval:** \_\_\_\_\_ **Date:** \_\_\_\_\_  
*SVP Medical and Academic Affairs*