

## UMass Memorial Medical Center Policy

<b>1143 Vendor Relationships</b>	
<b>Developed By:</b> Compliance Office	<b>Effective Date:</b> 12/3/2012 <b>Approved by:</b> Jennifer Daley, MD Chief Operating Officer
<b>Applicability:</b> All employees and contracted personnel and all Vendors of UMass Memorial Medical Center (“UMMMC”) and UMass Memorial Medical Group (“UMMMG”) and certain designated private practitioners, as defined below.	<b>Rescission: Supersedes policy dated:</b> 4/26/12
<b>Keywords:</b> Vendor Relationships	

### I. Policy:

The purpose of this policy is to establish oversight of financial and other relationships between employees and contracted personnel and Vendors. This policy is designed to supplement the UMass Memorial [Policy 1120 - Conflict of Interest](#) .

UMass Memorial seeks to ensure that *all* of our decisions – clinical and otherwise – are based on the integrity of our professional judgments, our research and our analyses, and not tainted in any way by the nature of our relationships with any outside parties. This policy does not seek to inhibit true scientific, independent and objective research or collaboration or to prohibit relationships with industry in support of these objectives. This policy establishes criteria to ensure the above objectives are met and that our decision making remains above reproach in fact and in appearance.

In general, no gifts, sponsorship or anything of value of any kind may be accepted from any Vendor by any employee or contracted personnel unless the gift or sponsorship meets a specific exception listed below.

#### A. Gifts, Meals and Entertainment

Employees are prohibited from accepting gifts of any kind from any Vendor.

The only **exceptions** include:

- Meals provided as part of UMass Memorial/UMass Medical School CME events sponsored by Vendors. Funds provided by Vendors for CME events, and processed through the UMass Memorial Foundation consistent with Section (B) below, may be used to support the reasonable and appropriate costs of the CME event, including food; and,
- Meals provided as part of national CME events and sanctioned by the hosting program, and
- Meals provided directly by a vendor during and outside of national CME event, but, consistent with Massachusetts Department of Public Health regulations, only if the meal is educational in nature with respect to a drug, medical device product, disease state, etc. .

**B. Support for Continuing Medical Education (“CME”), Graduate Medical Education (“GME”) or Continuing Education for Nursing and Pharmacy**

All CME and GME events hosted or sponsored by UMMMC or UMMMG must comply with the requirements below and the ACCME Standards for Commercial Support (Attachment B) whether or not CME credit is awarded:

- **UMass Memorial Foundation.** All funding from Vendors to support CME and GME programs must be directed to the UMass Memorial Foundation. Funding may be restricted to a clinical department and must be overseen by the Department Chair. Funding may not be restricted to a clinical division, a specific program or an individual physician. An oversight committee comprised of physician and other leaders will oversee Vendor sponsorship exceeding established thresholds (see below) to ensure potential conflicts of interest are appropriately managed.
- **ACCME Standards.** Funding associated with such meetings may be used to support CME programs, including speakers and reasonable and appropriate provisions of food and facilities consistent with ACCME standards. Payments to faculty associated with such meetings must fully comply with Section (E) – *Consulting or Service Agreements*, below.
- **Prohibition on Food.** Vendors are not permitted to bring food into any UMass Memorial facility or to any meeting sponsored by UMass Memorial on or off campus and are prohibited from paying for such food.
- **Allowance of Product Symposia.** Product Symposia organized by UMass Memorial exclusively for the education of Clinical Personnel, UMass Memorial patients or the broader community is permissible. Vendor products directly related to a UMass Memorial educational event may be displayed and discussed as part of the educational event. Vendor funding to support these activities is acceptable provided it is processed consistent with this section.
- **Prohibition on Vendor Product Fairs.** Vendor Product Fairs are prohibited. Vendors are never be permitted to display or market any products on any UMass Memorial premises, unless they are directly related to a UMass Memorial sponsored educational event, as noted above.
- **UMass Memorial and UMass Medical School Sponsored Meetings.** International, national and regional meetings co-sponsored by UMass Memorial or UMass Medical School are designed to benefit the broader community of physicians and are permissible. Industry funding to support such meetings is acceptable provided such funding is exclusively for support of such meetings and not to otherwise directly benefit UMass Memorial or UMass Medical School.
- **Oversight Committee.** An oversight committee of rotating UMass Memorial and UMass Medical School physician leaders will function in an advisory capacity regarding the implementation and oversight of this policy and, will review and oversee industry sponsorship to assess potential conflicts of interest and to propose approaches for management of such potential or actual conflicts of interest. The oversight committee will review any vendor contribution exceeding \$10,000 in support of CME, GME (fellowship or other support), or general research support in any one fiscal year. The committee shall also have the following responsibilities:

- Assess potential conflicts of interest associated with other financial relationships involving the sponsoring vendor and targeted department or division, such as CME/GME support, clinical research funding and vendor purchases;
- Develop corrective action plans, if necessary, with department chairs to manage potential conflicts within their departments;
- Review uses of funds for consistency with this policy;
- Review aggregate vendor contributions and associated expenditures semiannually;
- Advise Chairs, Executive Management and the Executive Management Compliance Committee regarding potential and actual conflicts of interest, or suggested changes to policy or procedure.

### **C. Support for Scholarships and other Trainee Activities**

Vendor support for scholarships or discretionary funds to support trainee or resident travel or non-research funding support may be accepted provided that all of the following conditions are met:

- Vendor support for scholarships must comply with UMMMC and UMMMG policy requirements for such funds, including the execution of an approved budget and written gift agreement through the UMass Memorial Foundation, and maintenance of the funds in an appropriate restricted account, overseen by the department chair. Selection of recipients of scholarships must be within the sole discretion of department chair or, in the case of graduate medical education, the associate dean for graduate medical education.
- Vendor support for other trainee activities, including travel expenses or attendance fees at conferences, must be accompanied by a written gift agreement through the UMass Memorial Foundation, maintained in an appropriate account overseen by the respective department chair. Selection of recipients and specific expenses to be supported must be within the sole discretion of the clinical department. All activities for which Vendor support is used should have legitimate educational merit and associated expenses should be reasonable and consistent with UMass Memorial policies.

### **D. Support for Fellowships**

The UMass Memorial/UMass Medical School Graduate Medical Education Committee (GMEC) must approve all fellowships. UMass Memorial Clinical Departments may not accept industry funding for fellowship programs except as approved by GMEC.

- As part of GMEC's approval process, the following will be assessed:
  - The need and appropriateness of the fellowship;
  - The funding of the fellowship:
    - Industry is not permitted to direct funding to a fellowship program. Industry is permitted to restrict contributions to GME, however, these restricted funds must be contributed to the UMass Memorial Foundation restricted only to GME and deposited in a centralized/pooled GME fund. These funds may not be restricted to a department, division, faculty member, program or in any other way;

- Funding may include any combination of departmental funds (revenue from billable services (non-accredited fellowships only) generated by the fellow or funds requested from the centralized GME funding pool), and will be determined by a sub-committee of GMEC as discussed below.
- In no case will GMEC permit funds contributed by an Industry sponsor to pass directly through the centralized GME pool to a “related” clinical department;
- In assessing the proposed funding sources for a fellowship, GMEC will review the financial relationships of the clinical department, key individuals involved with the fellowship and the external funding sources.
- No fellow may be designated as an industry-sponsored trainee, nor may the trainee be informed directly or indirectly that funding to support their respective fellowship program is in part provided by an industry-sponsor. Sponsors may not be provided with names or other information identifying recipients of the sponsor’s funding.
- GMEC will establish a sub-committee responsible for oversight of Industry donations of funds restricted to GME and, for the allocation of these funds to clinical departments applying for such funds. The sub-committee:
  - Will be comprised of the chair and vice-chair of GMEC, three program directors, one of whom will serve as sub-committee Chair, and the Vice President and Chief Compliance Office who will serve in an advisory, non-voting role;
  - Administrate the application process, which will include:
    - A clinical department application form;
    - Disclosure form for clinical department faculty member applicants, detailing all financial relationships with Industry; and
    - Interview of appropriate faculty members
  - Will propose equitable distribution of funds based upon the number of approved applications and funds available in the above GME fund pool;
  - Provides an annual accounting for the GME fund pool:
    - Amounts received
    - Amounts disbursed
    - Balance
    - List of companies contributing to the fund over the year
- Selection of fellows – selection of recipients of fellowships must be within the sole discretion of the department chair and program director.

#### **E. Consulting or Service Agreements**

Consulting arrangements that simply pay Employees a guaranteed amount with minimal or no associated duties or deliverables (such as participation on scientific advisory boards that do not regularly meet and provide scientific advice) or excessive compensation for the services provided shall be considered gifts and are consequently prohibited. All consulting agreements must meet the following requirements to be acceptable:

- **Nature of Services Provided.** The only services Employees may provide to corporate entities are those of a scientific or clinical nature, such as those directly involved in the development, testing, safety assessment, or application of a product. Activities serving commercial purposes are not allowable. Such activities include:

- Marketing- all aspects, including analysis, strategy, and recruitment;
- Sales- any aspect;
- Advertising- all aspects, including serving as an expert speaker (see also Speakers' Bureaus);
- Investor relations- all aspects, including providing information on products to potential investors.
- **Contract.** Consulting must be supported by a written contract with which clearly describes responsibilities and specific deliverables, which must be restricted to scientific issues - not marketing and which require Employees technical and professional judgment or assessment. The contract must also specify compensation to be paid to Employees. All consulting agreements are required to be uploaded by Employees into their UMass Medical School/UMass Memorial Conflict of Interest Disclosure Statement.
- **Scientific Issues.** The specific and substantive deliverables in the written agreement must be restricted to scientific issues such as:
  - design of a new clinical trial or conduct of an existing clinical trial with which UMass Memorial is involved;
  - development of a new diagnostic, therapeutic or technical product; or
  - development of an educational product
- **Compensation and Reimbursement.**
  - The compensation paid must be reasonable and reflect fair market value for the services and time provided;
  - The compensation paid must not be considered excessive when looked at overall for all time expended for consulting or honoraria;
  - All services must be performed on personal time unless the consulting income is paid to the UMMM; and
  - Travel and expense reimbursement must be reasonable and necessary for the provision of the above services
- **Research Grants and Honoraria.**
  - Grants for general support of research are acceptable if not directed to or designated for use by specific individuals. Research grants should not be accepted or utilized to support research unless it is carried out independently and objectively for purposes of the advancement of scientific knowledge or clinical efficacy. Research funding should never be accepted or used to support marketing research. Honoraria should not be accepted unless the Employee is leading or presenting at a conference.

#### **F. Speaking Arrangements/Speakers Bureaus**

UMass Memorial endorses the use of lectures to disseminate knowledge evolving from clinical or research developments.

- **General:** These lectures should be based upon Clinical Personnel research or scientific or professional knowledge and should incorporate materials developed exclusively by the faculty member with no Vendor input or requirement for approval. Clinical Personnel should not participate in or accept compensation for any lecture not meeting these requirements.
- **Speakers Bureaus:** UMass Memorial views speakers bureaus sponsored by Clinical Vendors as an extension of the marketing process. Consistent with this policy, UMass Memorial prohibits Clinical Personnel from participating in, or

receiving compensation for, talks given through a speakers bureau. Private non-employed members of the medical staff may not use, refer to or allow use of their UMass Memorial medical staff appointments in promotions or presentations related to any speakers bureau or other speaking engagement where a company has the contractual right to control/approve the content of materials or what is said.

**G. Ghostwriting:** Employees writing on behalf of UMass Memorial, or using its name, are prohibited from publishing articles or editorials written by Vendor employees. Employees should always be responsible for the content of any papers or talks that they give, including the content of slides.

**H. Drug (P&T), Device and Service Procurement Committees:**

Employees with any financial relationship with a pharmaceutical, biotechnology or medical device company may not be a member of the Pharmacy and Therapeutics Committee or any subcommittees or any clinical device or service procurement committee of UMMMC or UMMMG. Financial relationships include:

- Consulting or other contractual arrangements
- Clinical research sponsorship – where the faculty member is the Principal or Co-principal Investigator
- Outside business arrangements including:
  - Direct business arrangements (joint venture or other support not described above)
  - Loans, leases/rental arrangements
  - Investment relationships (unless held in mutual, pension or other similar investment fund over which the individual exercises no asset management control)

Individuals with the above financial relationships may continue to serve in an ad-hoc, advisory capacity (without vote) for content expertise at the request of such committees. Individuals requested to present to the P&T Committee in an ad-hoc capacity must complete a Conflict of Interest disclosure, which must be reviewed in advance by the Chief Compliance Officer, the Chief Pharmacist and Chair of the P&T Committee. No individual may present in an ad-hoc capacity if they hold equity in the company whose drug is under consideration.

To ensure potential conflicts of interest involving the procurement of significant supplies, devices or services are identified in a timely manner and are appropriately managed, any individuals who may influence or authorize significant purchases are required to complete the [New Product/Service Selection Conflict of Interest Attestation Form](#) as indicated below:

- **Value Analysis Teams (VAT):**
  - VAT administrative personnel (standing taskforce or group members) will complete the New Product Attestation form annually;
  - Employees who become involved in a VAT or Major Medical/Moveable Equipment purchasing processes where the potential purchase expected to exceed \$50,000 and who are perceived to influence the purchasing process (the products under consideration or vendors to be included in the RFP process) are required to complete the New Product/Service Attestation Form (the “Attestation Form”).

The Attestation Form should be completed at that point in the process where potential vendors are being determined.

- **Facilities:**
  - Facilities administrative personnel will complete the Attestation Form annually;
  - Major Medical/Moveable Equipment purchased as part of Capital Improvements: follow similar requirements as VAT's above.
- **Information Systems:**
  - Major System projects – taskforce members will complete the Attestation Form for each project;
  - Other IT equipment where the potential purchase is expected to exceed \$50,000 (servers, disks, pc's, etc): prior to the purchase order (PO) being processed Materials Management will require the ordering IT manager to complete the Attestation Form.
- **New Product/Service Attestation Form processing:**
  - The Sr. Director of Materials Management, Senior Vice President of Facilities and Senior Vice President and CIO are responsible to ensure Attestation Forms are completed as required above;
  - All Attestation Forms must be returned to the Purchasing Department;
  - If Attestation Forms are returned/received which indicate a potential conflict of interests due to financial or other relationships, this should be promptly communicated to and discussed with the Chief Compliance Officer to determine the appropriate course of action, including assessment of the nature and extent of continued involvement by the individual making the disclosure in the purchasing process.
- **(Legal Office) Contract Intakes Form:** The Project Manager must sign/attest indicating for above purchases exceeding \$50,000 all stakeholders in the purchasing decision have completed New Product Attestation Forms and that potential Conflicts of Interest were communicated to the Compliance Office.

**I. Drug Samples:**

UMMMC Policy #2005, Drug Samples, should be referenced and complied with in all respects. Drug samples may be accepted only if they meet the criteria set forth within UMMC policy #2005.

- These requirements apply only to the three campuses of the Medical Center and specifically do not apply to other entities, individuals or locations, including: UMMC - Community Medical Group office locations operating outside of the three UMMC campuses noted above, Barre, Tri-River or Plumley Village Health Centers or to private members of the Medical Staff, unless they fall within the definition of Employees.

**J. Site Access by Sales and Marketing Representatives**

UMass Memorial does not support the use of our facilities by Vendors for marketing purposes. Vendors presenting to UMMC or UMMC facilities or to meet with UMass Memorial personnel must comply with the following requirements:

- Representatives should not be permitted in any patient care area unless *each* of the following exceptions are met:
  - The representative is present to provide in-service training on devices and other equipment, including provision of essential guidance on the use of such

- equipment,
- The presence of the representative is expressly requested and approved in advance by a faculty member, and
- The device representative is certified by their employer to provide the requested device training.
- Representatives should never scrub or provide direct patient care services at UMass Memorial and, cannot be “Observers” under UMMMM Policy #1413: Observers of Patient Care Activities
- Representatives are permitted in non-patient care areas by scheduled appointment only. Representatives should not be in any UMass Memorial facility without a scheduled appointment with a faculty member or other authorized Employee;
- All representatives must be registered in the Vendor Mate system and must receive, wear and visibly display the appropriate one-day vendor badge at all times while on UMMMM premises:
  - All Vendors must register in Vendor Mate (the UMMMM on-line web-based tool), and when presenting onsite must sign in and generate a one-day badge to be worn visibly while onsite. Please see the link below to get to the Vendor Mate site. (<https://umassmemorial.vendormate.com/vm/login.do>);
  - If specifically approved by a senior vice president, a Vendor may be given a UMMMM “hard” badge. If a senior vice president authorizes a “hard” badge, they are responsible to ensure all appropriate vendor registration information is obtained (consistent with the Vendor Mate on-line tool) and that the Vendor has received and formally acknowledged an understanding and agreement to comply with UMMMM policies;
  - Clinical Vendors providing products or services for which UMMMM is acting as a reference site (including any potential customer of such vendor) are subject to all of the above requirements of this Section. In addition, there must be a written agreement between UMMMM and the vendor that includes the terms and conditions of UMMMM acting as a reference site, and the agreement must comply with all UMMMM policies applicable to the purchase of goods and services.

#### **K. Fundraising – Solicitations from Vendors**

- a. **Faculty Involvement:** Fundraising solicitations made by UMass Memorial to our vendors is acceptable. However, faculty should have no active role in contacting vendors or soliciting funds from UMass Memorial vendors. These efforts should be coordinated and managed by the UMass Memorial Foundation. If as part of such efforts the need for faculty presence, or presentations on UMass Memorial clinical programs are determined necessary or appropriate, either is acceptable.

It is acceptable for faculty to approach non-vendors, including foundations regarding fundraising.

- b. **Fundraising Solicitations During Contracting Processes:** It is imperative that there be no “quid pro quo” between fundraising efforts involving our vendors and our purchasing decisions. Fundraising solicitations involving vendors should be entirely separated from and not contemporaneous with vendor contracting processes. It is the responsibility of the UMass Memorial Foundation and Materials Management to ensure effective communication regarding the timing of

fundraising and contracting processes and related vendors to ensure appropriate separation of these activities both in fact and appearance. The UMass Memorial Foundation and Materials Management should ensure vendors are clearly apprised that charitable gifts to UMass Memorial do not in any way implicate UMass Memorial purchasing decisions.

**L. Reporting:** “Employees” that are required to disclose all of their outside relationships with “Vendors” in their annual Conflicts of Interest Disclosure Form.

**M. Enforcement:** Department chairs and senior managers are expected to enforce this policy with the support of the Compliance Office and Medical Staff Executive Committee. Alleged violations of this policy should be communicated to the respective department chair or senior manager or to the Compliance Office. The Compliance Office will work with the respective department chair or senior manager to determine appropriate follow up. It is the intent of the organization, when practical and feasible, to emphasize education and assistance to facilitate compliance and clarification of expectations. However, the organization reserves the right to impose appropriate discipline when warranted under the circumstances particularly in cases of intentional, egregious or repetitive non-compliance. Appropriate corrective action will be determined by the department chair or senior manager in concert with the Chief Medical Officer and Chief Compliance Officer. Vendors who violate this policy will be subject to disciplinary action.

## II. Definitions:

**Employees:** All employees (including faculty members) and contracted personnel of UMass Memorial Medical Center (“UMMMC”) or UMass Memorial Medical Group (“UMMMG”) regardless of their responsibilities (i.e., administrative, patient care or clinical research) or their location (i.e., Medical School, Medical Center, campus or community office). This definition includes but is not limited to, administrative staff, physicians, housestaff, nurses and technicians. This definition also includes certain private practitioners, but only those who serve as members of any UMass Memorial Health Care (“UMMHC”), UMMMC or UMMMG committee.

**Contracted Personnel:** All individuals who provide personal services to, or act as agents for, UMMMC or UMMMG pursuant to a contract or other written agreement.

**Clinical Personnel:** All employees or contracted personnel of UMass Memorial Medical Center (“UMMMC”) or UMass Memorial Medical Group (“UMMMG”) who are directly or indirectly involved in the provision of patient care, regardless of the capacity in which the care is delivered (i.e., clinical or clinical research) or the location in which the care is delivered (i.e., Medical School, Medical Center, campus or community office). This includes but is not limited to, physicians, house staff, nurses and technicians. This definition also includes certain private practitioners, but only those serving as members of any UMass Memorial Health Care (“UMMHC”), UMMMC or UMMMG committee.

**Vendor:** Any vendor providing services or supplies to UMMMC or UMMMG. This includes, but is not limited to, pharmaceutical manufacturers; biotechnology, medical device, and hospital equipment supply companies; ambulance companies, nursing homes and accounting/consulting firms. This includes all representatives of such entities.

**Clinical Vendor:** Any vendor providing clinical services or supplies to UMMMC or UMMMG. This definition includes, but is not limited to pharmaceutical manufacturers;

biotechnology, medical device, and hospital equipment supply companies; ambulance companies and nursing homes. This includes all representatives of such entities.

**Industry:** Any outside for profit organization. This definition includes, but is not limited to pharmaceutical manufacturers; biotechnology, medical device, and hospital equipment supply companies; ambulance companies, nursing homes and accounting/consulting firms. This definition includes all representatives of such entities.

**Gifts:** Anything of value - regardless of amount or value – and includes, but is not limited to pens, pads, stethoscopes, journals, textbooks, meals or other hospitality provided at any time or location (including individual or group meals and meals at local restaurants sponsored by Clinical Vendors) and tickets to sporting or other events.

**III. General Procedure:** N/A

**IV. Clinical/Departmental Procedure:** N/A

**V. Supplemental Materials:**

The Vendor Relationships Policy website contains Frequently Asked Questions, ACCME Standards for Commercial Support, forms and other guidance associated with this policy. The website can be accessed at:

<http://www.umassmemorial.org/for-patients-and-visitors/vendor-information/vendor-relationship-policy>

**VI. References:** N/A