

# UMass Memorial Medical Center

## Policy Manual

### # 1143 Policy on Vendor Relationships

Effective Date: 7/1/2008

#### I. PURPOSE AND POLICY STATEMENT

To establish policy regarding oversight of financial and other relationships between Clinical Personnel and Clinical Vendors.

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. Above all, we recognize that the high trust placed in all of us by our patients, our community, our house staff and our medical students is a cherished privilege and must continually be earned. 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 Clinical Vendor by any Clinical Personnel unless the gift or sponsorship meets a specific exception listed in section V below. Please see *Attachment A: Vendor Relationships Policy – Frequently Asked Questions* for further details and responses to common questions.

#### II. SCOPE:

This policy applies to all Clinical Personnel and Clinical Vendors of UMass Memorial Medical Center (“UMMMC”) and UMass Memorial Medical Group (“UMMMG”) and certain designated private practitioners, as defined below. This policy supplements the UMass Memorial Conflict of Interest policy.

#### III. RESPONSIBILITY:

- A. **All Clinical Personnel.** It is the responsibility of all Clinical Personnel to know, understand and comply with this policy with respect to their own behavior, including all of their interactions with Clinical Vendors.

**POLICY: #1143 Policy on Vendor Relationships**

**PAGE NO: 2 of 20**

**B. Department Chairs, Chiefs of Service and Management.** It is the responsibility of chairs, chiefs and all managers to ensure that they understand and comply with the policy. It is also their responsibility to ensure that all of their faculty or staff understand if and how this policy applies to their daily activities and responsibilities and, to the extent it does, the applicable requirements of the policy. It is the responsibility of Materials Management and the Compliance Office to ensure dissemination/communication of this policy to all affected vendors.

**C. Enforcement.** Pursuant to section K of this policy, it is the responsibility of department chairs and senior management to enforce this policy with the support of the Compliance Office, the Medical Staff Executive Committee and the Chief Medical Officer.

#### **IV. DEFINITIONS:**

**“Clinical Personnel”** is defined as 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 definition includes but is not limited to, 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.

**“Clinical Vendor”** is defined as 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 definition includes all representatives of such entities.

**“Gifts”** are defined as 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.

#### **V. REQUIREMENTS:**

##### **A. Gifts, Meals and Entertainment**

Clinical Personnel are prohibited from accepting gifts of any kind from any Clinical Vendor.

The only exceptions include:

- Meals provided as part of UMass Memorial/UMass Medical School CME events sponsored by Clinical Vendors. Funds provided by Clinical Vendors for CME events, and processed through the UMMM Foundation consistent with Section (B) below, may be used to support the reasonable and appropriate costs of the

**POLICY: #1143 Policy on Vendor Relationships**

**PAGE NO: 3 of 20**

CME event, including food; and,

- Meals provided as part of national CME events (which may be funded, provided directly or offered by Clinical Vendors).

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

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 Clinical 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 Clinical 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 (D) – *Consulting or Service Agreements*, below.
- **Prohibition on Food.** Clinical 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 are permissible. Clinical Vendor products directly related to a UMass Memorial educational event may be displayed and discussed as part of the educational event. Clinical Vendor funding to support these activities is acceptable provided it is processed consistent with this section.
- **Prohibition on Clinical Vendor Product Fairs.** Clinical Vendor Product Fairs are prohibited. Clinical 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

**POLICY: #1143 Policy on Vendor Relationships**

**PAGE NO: 4 of 20**

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, Fellowships or other Graduate Medical Education (GME)**

Clinical 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:

- Clinical Vendor support for scholarships and fellowships 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 or fellowships must be within the sole discretion of department chair or, in the case of graduate medical education, the associate dean for graduate medical education.
- Clinical 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 Clinical Vendor support is used should have legitimate educational merit and associated

expenses should be reasonable and consistent with UMass Memorial policies.

**D. Consulting or Service Agreements**

Consulting arrangements that simply pay Clinical Personnel 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:

- **Contract.** Consulting should be supported by a written contract with specific deliverables, which must be restricted to scientific issues - not marketing and which require Clinical Personnel technical and professional judgment or assessment.
- **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 UMMMMG; 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 UMass Memorial Clinical Personnel is leading or presenting at a conference.

**E. 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

**POLICY: #1143 Policy on Vendor Relationships**

**PAGE NO: 6 of 20**

professional knowledge and should incorporate materials developed exclusively by the faculty member with no Clinical 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.

**F. Ghostwriting**

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

**G. Drug (P&T) and Device Procurement Committees:**

Clinical Personnel with any financial relationship with a Clinical Vendor may not be a member of the Pharmacy and Therapeutics Committee or any subcommittees or any clinical device 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
- Any outside business arrangements with any clinical vendor, 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.

**H. Drug Samples:**

Drug samples may be accepted from Clinical Vendors under the following conditions:

- Drug samples must be received by and placed under the administration of the Pharmacy Department.
- Drug samples may not be accepted in any area of the Medical Center or by any Clinical

Personnel without specific approval from the Pharmacy Department.

- The Pharmacy and Therapeutics Committee must approve those sample drugs to be accepted as part of the samples formulary. Drug samples not approved by the Pharmacy and Therapeutics Committee must not be accepted.
- The Pharmacy Department must approve any location where drug samples will be stored and is responsible for monitoring appropriate administration of drug samples.
- The UMMC Policy on Drug Samples should be referenced and complied with in all respects.
- The above requirements apply only to the three campuses of the Medical Center and specifically do not apply to other entities, individuals or locations, including: UMMMG - 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 Clinical Personnel.

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

UMass Memorial does not support the use of our facilities by Clinical Vendors for marketing purposes. Therefore, Clinical Vendors presenting to UMMC or UMMMG 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 UMMC Policy #1413: Observers of Patient Care Activities
- Representatives are permitted in non-patient care areas by scheduled appointment only. Therefore, representatives should not be in any UMass Memorial facility without a scheduled appointment with a faculty member or other authorized Clinical Personnel;
- All representatives must be registered in the Vendormate system and must receive, wear and visibly display the appropriate one-day vendor badge at all times while on

**POLICY: #1143 Policy on Vendor Relationships**

**PAGE NO: 8 of 20**

UMMMC premises:

- All Clinical Vendors must register in Vendor Mate (the UMMMC 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 Vendormate site. (<https://umassmemorial.vendormate.com/vm/login.do>);
- If specifically approved by a senior vice president, a Clinical Vendor may be given a UMMMC “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 Clinical Vendor has received and formally acknowledged an understanding and agreement to comply with UMMMC policies;

**J. Reporting**

“Clinical Personnel” are required to disclose all of their outside relationships with “Clinical Vendors” in their annual Conflicts of Interest Disclosure Form.

**K. 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.

Clinical Vendors who violate this policy will be subject to disciplinary action.

**VI. RESCISSION**

This policy rescinds policy #1143 Vendor Gifts, Entertainment and Sponsored Meetings and Training Policy, dated 11/3/05 and becomes effective upon issuance.

**VII. MONITORING:**

Department Chairs, Division Chiefs, Senior Management, Chief Medical Officer, and the Compliance Office are responsible for monitoring compliance with this policy.

**POLICY: #1143 Policy on Vendor Relationships**

**PAGE NO: 9 of 20**

**Developed By:** Compliance Office X4-0008  
Individual/Committee Ext.

**Approved By:** Walter Ettinger, MD President 7/22/08  
Authorized Signature Title Date

**POLICY: #1143 Policy on Vendor Relationships**

**PAGE NO: 10 of 20**

Attachment A

**Vendor Relations Policy  
Frequently Asked Questions (FAQs)**

**Gifts & Meals**

*Q. In the past a vendor would provide subscriptions to certain medical journals and, copies of certain medical textbooks to the department. Is this still permissible under the Policy's ban on gifts?*

**A.** No. The new policy bans all gifts from industry, including pens, pads, hats, candy, medical journals, textbooks and other such items provided free of charge which is not part of a contracted purchase.

*Q. Why prohibit meals? Do they really affect patient care decisions?*

**A.** Research has shown that even small or *di minimus* gifts, such as pens, engender a sense of obligation on the part of the recipient. Moreover, research has shown that in cases where a doctor has a pen or pad advertising a particular product, that product gets prescribed more often (AMA Guidelines Regarding Industry Interactions; *Drug Makers Pay for Lunch as They Pitch*, New York Times, July 28, 2006). Thus it has been shown that such gifts, including meals provided by "pharma" or device companies, can influence the decision-making process. UMass Memorial's goal is to provide our patients with the best, most objective care. This is why we have chosen to eliminate such incentives.

*Q. In the past, one of our pharma or device reps provided lunch for our meetings. Is this still allowed under the new policy? If not, how can we finance our lunches?*

**A.** No. As discussed above our policy intends to eliminate the incentives such as meals. No meals may be provided nor directly paid for by industry anywhere on or off of a UMass Memorial campus.

Under the new policy, Industry may provide funds to the UMass Memorial Foundation to support continuing medical education at UMass Memorial. (The funds may not be provided to a clinical department or an individual). These funds may be used by clinical departments to support legitimate continuing education which may include provision of appropriate meals in an appropriate setting consistent with UMM policy.

**POLICY: #1143 Policy on Vendor Relationships**

**PAGE NO: 11 of 20**

*Q. Can a sales rep take a doctor out to lunch or dinner for a business purpose?*

A. No. Industry reps should be invited to meet with UMass Memorial employed physicians by appointment in campus facilities. Because of the implied *quid pro quo* that such activities present, the new policy prohibits such restaurant meals with industry reps.

*Q. A vendor sponsor of a national/international meeting invites me and other clinicians/physician meeting attendees to dinner following the meeting. May I accept?*

A. While our policy does not explicitly prohibit such a meal we do not encourage these activities for the reasons stated above.

### **Industry Funding for Education**

*Q. I have been invited by a pharmaceutical (or device) company to give a talk to community physicians. Am I allowed to do this?*

A. UMass Memorial policy allows employed physicians to consult if appropriate criteria is met, including but not limited to a contract for deliverables, restriction to scientific issues versus marketing and compliance with Medical School consulting limitations. Such talks would be considered consulting. Physicians and staff should carefully evaluate their participation in meetings and conferences that are fully or partially sponsored or run by industry because of the high potential for promotional or marketing activities such 'talks' may portray. In instances in which employed physicians and staff do participate in such talks, they should follow the guidelines below, which are included in the policy:

- Financial support by industry is fully disclosed by the meeting sponsor.
- The meeting or lecture content is determined by the speaker and not the industry sponsor.
- The lecturer is expected to provide a fair and balanced assessment of therapeutic options and to promote objective scientific and educational activities and discourse.
- The lecturer is not required by an industry sponsor to accept advice or services concerning speakers, content, etc., as a condition of the sponsor's contribution of funds or services.
- The lecturer makes clear that content reflects individual views and not the views of UMass Memorial.

**POLICY: #1143 Policy on Vendor Relationships**

**PAGE NO: 12 of 20**

- The use of the UMass Memorial or UMass Medical School name in a non-UMass Memorial/UMass Medical School event is limited to the identification of the individual by his or her title and affiliation.

*Q. May I participate on an industry speakers bureau if I am comfortable with the objectivity of lecture content?*

**A.** No. Our new policy prohibits participation in any industry sponsored speakers bureau due to concerns with the potential for and the appearance of compromised objectivity and, the potential for implied *quid pro quo*.

*Q. Is it still allowable for our department to receive grants from industry for scholarships or other educational funds for students and trainees?*

**A.** Yes, and in fact departments are encouraged to seek such funding, so long as the funding is donated to and administrated by the UMass Memorial Foundation, is specifically for the purpose of education and, is free of any actual or perceived conflict of interest. It must also meet the following conditions:

- UMass Memorial, the Foundation or the clinical department selects the student or trainee;
- The department, program or division has determined that the funded conference or program has educational merit.
- The recipient is not subject to any implicit or explicit expectation of providing something in return for the support, i.e., a "quid pro quo."

*Q. A device company sponsors an educational event. There is no registration fee. The device company has also booked and paid for rooms at a local hotel and, (maybe) agreed to or has paid for airfare. Is this acceptable?*

**A.** Provided that the clinical department makes the determination that this is an appropriate and substantive educational event, it is acceptable for the department to allow faculty or housestaff to attend. To differentiate, it would not be permissible to have or allow the vendor to pay a faculty/housestaff member's registration fee were there one. It is not permissible to have the vendor pay for our faculty/housestaff members' hotel or airfare - UMM should assume those costs, as these are out of pocket costs which the vendor would be paying on UMM's behalf.

*Q. While it is no longer permissible for pharmaceutical or device sponsors to purchase meals on or off campus, may we use unrestricted gift funds provided to support research and education?*

**POLICY: #1143 Policy on Vendor Relationships**

**PAGE NO: 13 of 20**

A. Correct. Our new policy does not allow Industry to buy meals for UMass Memorial events on or off campus. However, the policy does allow pharmaceutical, device, and biotech companies to make gifts to the UMass Memorial Foundation to support continuing education activities and programs (funds may not be contributed directly to departments or faculty members). Programs and activities (for which food may be purchased) must comply with policy requirements which are generally aligned with the Accrediting Council on Continuing Medical Education's Standards for Commercial Support (ACCME). This will mean, among other things, that the faculty will determine the topics and the choice of speakers for the events funded by industry support. Pharmaceutical vendor representatives should not be permitted to speak or disseminate promotional materials at any educational forum. Device vendor representatives should only speak at those educational forums where they are invited to speak as expert on the use of specific products. Device vendor representatives are permitted to distribute only those materials which serve predominantly educational purposes and not promotional purposes.

*Q. Is it acceptable for us to request industry sponsors to provide funding for grand rounds we are holding quarterly. These are CME events, and may be held off campus. No sales reps will be present and no promotional materials of any kind will be distributed.*

A. Yes. Requesting such funding from industry sponsors is completely appropriate as is the above use of the funds. As discussed above, the funds must be contributed to UMass Memorial through the UMass Memorial Foundation and not the clinical department.

*Q. In the past our clinical department has received Industry support for our fund-raising event. Is this still allowable under the new Policy? Is it acceptable to solicit such funds from industry.*

A. Yes. It is fine for to solicit and accept corporate sponsorships for your event. There are two requirements:

- There should be no vendor promotional materials at your event.
- Vendors are not permitted to purchase tickets to fund raising events and gift tickets to faculty members or clinical staff. If vendors wish to purchase tickets which they do not intend to use, these tickets may be gifted to the department which, in turn should raffle the tickets or provide them to non-faculty, non-management personnel who are not involved in purchasing or other decisions which could involve or affect the vendor.

*Q. A UMass Memorial employee attends an annual educational conference. Can the employee's travel and hotel costs be paid for by Industry?*

**POLICY: #1143 Policy on Vendor Relationships**

**PAGE NO: 14 of 20**

A. The policy allows an industry conference sponsor to cover reasonable travel and lodging costs, as well as payment of a reasonable honorarium only if the employee is leading or presenting at a conference. No honoraria, travel or lodging costs may be covered if the employee is simply attending the conference.

*Q. In the past, our pharma reps paid for and attended our Journal Club meetings, which are held at a local restaurant. Since these are off-site, can this practice continue?*

A. No. The practice of industry reps paying for such meals is not compliant with our new Policy. If vendors wish to continue sponsoring Journal Club meetings they should contribute such funding to the UMass Memorial Foundation in support of continuing education. Your department would then have access to these funds provided your programs and activities were consistent with policy criteria – including having a substantive educational purpose; appropriate and reasonable location; reasonable food/refreshments, etc.

*Q. Can Industry pay for educational brochures to be provided to patients?*

A. No. Industry brochures may serve an educational purpose for either or both patients and caregivers. But they could also be perceived as promotional, or create a sense of obligation for the department. Consequently, this would not be allowed. A company could make an educational gift to development of such materials through the UMass Memorial Foundation. Alternatively, many existing foundations provide educational materials at little or no cost.

*Q. Are Industry Product Displays/Product Fairs permissible?*

A. Product Symposia or displays specifically requested or organized by UMass Memorial exclusively for the education of “Clinical Personnel”, the UMass Memorial patient or broader community are permissible if they meet the following requirements:

- A clinical department must invite the vendor(s) to conduct the product fair strictly for educational purposes of it's “Clinical Personnel” or patient community;
- Products displayed must be directly related to the educational event or, those specific products requested by the clinical department. The event must not be used in any way as a vendor product "promotional" event.
- There should be absolutely no gifts (bags, pens, mugs, hats, etc.) of any kind provided or distributed, nor should there be any promotional materials available or distributed. Only those materials directly related to the educational purpose of the event for which the vendor was invited are permitted to be distributed. All other materials including promotional brochures, etc are prohibited.

**POLICY: #1143 Policy on Vendor Relationships**

**PAGE NO: 15 of 20**

- All meals should be funded by the clinical department (through operating budget or appropriate use of funds donated to the UMass Memorial Foundation to support CME or educational events)
- The product fair should preferably be conducted in an area of the clinical department, not the "main lobby" to preserve the educational purpose of the event.

**Samples and Products**

*Q. Does the policy affect free samples for needy patients?*

A. Yes and no. UMass Memorial supports the provision of free samples for intended use including needy and indigent patients. To provide more effective oversight, any drug samples delivered to the three UMMMC campuses must be received and administrated by the UMMMC Pharmacy Department. Drug samples delivered directly to physicians are recognized as personal gifts and are not permitted under this policy.

*Q. Are we allowed to accept free materials from an outside supplier for resident and student training?*

A. No, because there is an implicit expectation that UMass Memorial would purchase these materials. Such purchasing decisions should be evaluated using objective criteria and must be free of any implied obligation.

**Site Access by Sales and Marketing Representatives**

*Q. Under the policy are sales and marketing reps allowed on UMass Memorial campuses?*

A. Industry reps are permitted in both patient-care and non-patient care areas only under very specific circumstances.

- *Patient care areas:* Industry reps may be requested by medical staff, faculty or other designated clinical staff to provide in-service training on devices and other equipment – by appointment only;
- *Non-patient care areas:* industry reps may be permitted in non-patient care areas by appointment only.

*Q. Is it true that sales and marketing representatives may no longer leave any written materials with employees?*

A. This is correct. Sales and marketing materials from pharma or device companies may not be left with departments, medical staff, faculty, housestaff or other staff or in any area of UMass

**POLICY: #1143 Policy on Vendor Relationships**

**PAGE NO: 16 of 20**

Memorial. This is to ensure that we do not promote a company or its products within UMass Memorial or, to our patients.

**POLICY: #1143 Policy on Vendor Relationships**

**PAGE NO: 17 of 20**

Attachment B

## **The ACCME Standards for Commercial Support<sup>SM</sup>**

*Standards to Ensure Independence in CME Activities*

### **STANDARD 1: Independence**

**1.1** A CME provider must ensure that the following decisions were made free of the control of a commercial interest. (See [www.accme.org](http://www.accme.org) for a definition of a ‘commercial interest’ and some exemptions.)

- (a) Identification of CME needs;
- (b) Determination of educational objectives;
- (c) Selection and presentation of content;
- (d) Selection of all persons and organizations that will be in a position to control the content of the CME;
- (e) Selection of educational methods;
- (f) Evaluation of the activity.

**1.2** A commercial interest cannot take the role of non-accredited partner in a joint sponsorship relationship.

### **STANDARD 2: Resolution of Personal Conflicts of Interest**

**2.1** The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. The ACCME defines “relevant” financial relationships” as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

**2.2** An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

**2.3** The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.

### **STANDARD 3: Appropriate Use of Commercial Support**

**3.1** The provider must make all decisions regarding the disposition and disbursement of commercial support.

**POLICY: #1143 Policy on Vendor Relationships**

**PAGE NO: 18 of 20**

**3.2** A provider cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as conditions of contributing funds or services.

**3.3** All commercial support associated with a CME activity must be given with the full knowledge and approval of the provider.

#### **Written agreement documenting terms of support**

**3.4** The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the provider and its educational partner(s). The agreement must include the provider, even if the support is given directly to the provider's educational partner or a joint sponsor.

**3.5** The written agreement must specify the commercial interest that is the source of commercial support.

**3.6** Both the commercial supporter and the provider must sign the written agreement between the commercial supporter and the provider.

#### **Expenditures for an individual providing CME**

**3.7** The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.

**3.8** The provider, the joint sponsor, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of-pocket expenses in compliance with the provider's written policies and procedures.

**3.9** No other payment shall be given to the director of the activity, planning committee members, teachers or authors, joint sponsor, or any others involved with the supported activity.

**3.10** If teachers or authors are listed on the agenda as facilitating or conducting a presentation or session, but participate in the remainder of an educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their teacher or author role only.

#### **Expenditures for learners**

**POLICY: #1143 Policy on Vendor Relationships**

**PAGE NO: 19 of 20**

**3.11** Social events or meals at CME activities cannot compete with or take precedence over the educational events.

**3.12** The provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or nonauthor participants of a CME activity. The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, joint sponsor or educational partner.

### **Accountability**

**3.13** The provider must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support.

## **STANDARD 4. Appropriate Management of Associated Commercial Promotion**

**4.1** Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.

**4.2** Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME.

- For **print**, advertisements and promotional materials will not be interleaved within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as these materials are not related to the CME content they face **and** are not paid for by the commercial supporters of the CME activity.
- For **computer based**, advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleaved between computer 'windows' or screens of the CME content
- For **audio and video recording**, advertisements and promotional materials will not be included within the CME. There will be no 'commercial breaks.'
- For **live, face-to-face CME**, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Providers cannot allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CME activity.

**4.3** Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or a product-group message.

**POLICY: #1143 Policy on Vendor Relationships**

**PAGE NO: 20 of 20**

**4.4** Print or electronic information distributed about the non-CME elements of a CME activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions, may include product promotion material or product-specific advertisement.

**4.5** A provider cannot use a commercial interest as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities.

#### **STANDARD 5. Content and Format without Commercial Bias**

**5.1** The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.

**5.2** Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company.

#### **STANDARD 6. Disclosures Relevant to Potential Commercial Bias**

##### **Relevant financial relationships of those with control over CME content**

**6.1** An individual must disclose to learners any relevant financial relationship(s), to include the following information:

- The name of the individual;
- The name of the commercial interest(s);
- The nature of the relationship the person has with each commercial interest.

**6.2** For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

##### **Commercial support for the CME activity.**

**6.3** The source of all support from commercial interests must be disclosed to learners. When commercial support is 'in-kind' the nature of the support must be disclosed to learners.

**6.4** 'Disclosure' must never include the use of a trade name or a product-group message.

##### **Timing of disclosure**

**6.5** A provider must disclose the above information to learners prior to the beginning of the educational activity.