

University of Maryland School of Medicine

Policies Concerning

Professionalism and Consulting and Other Interactions with Industry

These Policies set out the School of Medicine's requirements for faculty, exempt staff, student, and School of Medicine compliance with University System of Maryland and University of Maryland Baltimore policies concerning professional activities involving interactions with industry and with School of Medicine policies set out here that supplement and clarify other University policies as they relate to School of Medicine personnel.

These Policies address interactions of faculty and exempt staff with industry when those interactions are not pursuant to University agreements with industry.

In these Policies:

- The term "industry" includes pharmaceutical firms; medical device firms; medical or research equipment developers, manufacturers, or vendors; medical or research service providers; and any other for-profit business or nonprofit organization with an economic interest in advocating (or opposing) the use of specific drugs, devices, medical equipment, medical services, or methods of health care. The term "industry" also includes associations or affiliates of such firms and organizations.
- The term "staff" means regular exempt staff and contingent exempt staff, and includes pre- and post-doctoral research trainees.

Professional activities that relate to interactions with industry addressed by these Policies include, but are not limited to: consulting, membership on a scientific board or other advisory board, membership on a governing board, employment, participation in seminars or other educational engagements, and any commitment to perform compensated or uncompensated work initiated by, arranged with and/or reportable to industry.

A. Policy on Professional Consulting and Other External Professional Activity of Faculty and Exempt Staff

1. School of Medicine faculty and staff are required to obtain prior approval for consulting and other external professional activities that involve interaction with industry, whether or not compensation is involved. (USM Policy II-3.10, Policy on Professional Commitment of Faculty, is applicable to faculty.)
2. The School has high expectations of faculty and staff professional effort within the scope of employment. External professional activities on behalf of industry, whether paid or unpaid, may be approved under these Policies, and undertaken by faculty and

staff, when the activities are not expected to create a conflict of commitment or a conflict of interest.

- a. A conflict of commitment may result from external professional activities on behalf of industry if it cannot be assured that all responsibilities associated with the faculty or staff member's School/department position can be fully satisfied and will continue to be met, and that performance of the external activities will give promise of enhancing the professional standing of the individual or contributing to the fulfillment of the mission of the School and the University. In general it is the responsibility of a faculty or staff member's Department Chair (subject to approval of the Dean or designee) to determine whether specific external professional activities will be permitted or must be disallowed due to conflict of commitment.
 - b. A conflict of interest may result from external professional activities. Conflict of interest is defined and evaluated in the State Ethics Law and other policies of the University System of Maryland and the University. Generally the Department Chair evaluates potential and actual conflicts and makes recommendations to decision-makers as defined in the conflict of interest policies. Relevant policies include: USM Policy on Conflicts of Interest in Research and Development – III-1.11; the UMB Procedures implementing that USM Policy; UMB Policy on Procedures Implementing Board of Regents Policy on Conflicts of Interest in Research or Development – III 1.11(A); and Policies and Procedures on Financial Conflict of Interest to Promote Objectivity in PHS-Funded Research – III 1.11(B).
3. Requests of faculty and staff for approval of external professional activities on behalf of industry should be initially directed to the Department Chair (by Department faculty and staff), to the Dean or his/her designee (by Chairs and by those faculty and staff who work in the Dean's Office), or to the President or designee (by the Dean). Requests approved by a Chair should be directed to the Dean's designee for action on requests. The Dean's designee will evaluate and approve or disapprove for the School all proposals for external professional activities that involve interaction with industry. The Dean's designee's decisions generally will follow resolution of any conflict of interest issues.
4. Each School of Medicine faculty and staff member is required to report on an annual basis each approved external professional activity that the faculty or staff member has performed on behalf of industry and any income received from each activity. Reports should be made initially to the administrator who approved the external professional activity and then forwarded to the Associate Dean for Faculty Affairs, who will review all reports of approved activities annually to assure that reported activities are consistent with approvals given by the School and University. The Associate Dean for

Faculty Affairs will maintain approval requests and annual reports for at least four years.

5. For faculty and staff involved in human subjects research, evaluation of conflict of interest also is a responsibility of the Institutional Review Board. For faculty in a position to control content in certified Continuing Medical Education activities, evaluation of potential conflict of interest is a responsibility of the School and the CME Program.
6. A faculty or staff member may use the physical resources of the School in connection with external professional activities beyond routine use of the office, computer, library, and telephone only if the University is reimbursed for use of the resources in accordance with an approved sponsored work agreement between the University and the industry entity that is routed to the Office of Research and Development through COEUS. A faculty or staff member shall not state or imply that the School or the University recommends or endorses the results of external professional activity on behalf of industry. In reports, publications, and presentations resulting from such activity on behalf of industry, a faculty or staff member shall make clear that opinions, recommendations or findings provided in external professional work are those of the faculty or staff member and are not the opinions, recommendations, or findings of the School or University.
7. In general, approved external professional activity should be performed during periods of annual, personal or holiday leave, or, for part-time faculty and staff, during periods of time when there is no scheduled School work. Due to conflict of commitment concerns, use of leave time may be a condition of approval of external professional activity, whether paid or unpaid.

B. Policy on Limitations of Gifts and Interactions with Industry

1. a. Interactions of School faculty, staff and students with representatives of industry associated with health care or medical education must consistently reflect the principles of professional accountability and professionalism in all medical education settings.
- b. Interactions with industry that are prohibited or restricted at the School are also prohibited or restricted at affiliate sites and other off-campus locations.
- c. This Policy is distinct from State of Maryland and federal law and regulations, and existing policies of the University System of Maryland and the University of Maryland Baltimore applicable to conflict of interest in the course of School employment; such other policies apply to conduct of research, procurement, and other aspects of the work of faculty and staff. To the extent that this Policy may be

more restrictive than other applicable legal requirements and policies, this Policy shall take precedence.

2. Gifts to Individuals

School faculty, staff and students may not accept any gift from industry, including food, whether given at the School or at another location.

Industry representatives may not bring or serve food for medical education conferences or pay directly for physician meals at medical education conferences. This is considered a personal gift and is not permitted at the School, at affiliated sites (e.g. clinical practice offices, hospitals where the faculty or staff teach or work), or at any other locations on or off campus. Industry representatives may provide a grant or funds to the School or the University of Maryland Baltimore Foundation to be used for catering at an accredited CME activity or other School-sponsored activity. Off-campus, faculty may accept meals or other catered food and beverage services supported by contributions from industry only when the contributions were made to support an accredited CME activity.

Faculty, staff and students must not accept free or discounted travel (including transportation, lodging, meals, and all other costs) or gifts of travel funds from industry.

3. Pharmaceutical Samples

Faculty and students should comply with any site-specific policies governing central management of pharmaceutical samples at practice, research or education sites.

4. Site Access by Pharmaceutical Representatives and Device Manufacturer Representatives

Faculty are encouraged to interact with representatives from industry according to standards that promote balanced education and critical evaluation.

To protect patients, patient care areas, and work schedules, access by qualified pharmaceutical representatives to individual faculty or groups of faculty should be restricted to areas that are not used for patient care and are not open to the public. In addition, interaction should take place only by appointment or by invitation of a faculty physician.

Faculty may involve students and trainees in such meetings only where appropriate for educational purposes and only under the direct supervision of a faculty member.

Access by device manufacturers to patient care areas should be permitted only when the representatives have been appropriately credentialed by the clinical site and at the invitation of a School faculty member.

Representatives from industry may not be present in any patient care interaction unless there has been prior disclosure to and consent by the patient (or, if the patient is not competent to consent, a person authorized by HIPAA or by the patient's power of attorney to consent to disclosure of medical information on behalf of the patient), and then only to provide in-service training or assistance on devices and equipment. Representatives given the opportunity for patient care interaction must certify in writing that they have completed HIPAA training and that they will maintain the confidentiality of patient information.

Industry representatives generally should not be sponsored by faculty or staff for affiliate identification cards that would allow the industry representatives unaccompanied access to School buildings or affiliates' buildings.

5. Continuing Medical Education (CME)

Continuing medical education activities developed and offered by faculty on the UMB campus (including UMMC), or at affiliated sites (e.g. clinical practice offices, hospitals), should be sponsored by the School of Medicine, which is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The School, with support from the University of Maryland Baltimore Foundation, Inc., and the UMB Office of Research and Development, oversees the request, grant management, and reconciliation process for any commercial support of CME activities sponsored by the School in accordance with ACCME policy.

6. Participation in Industry-Sponsored Education Programs

School faculty and students may not participate in non-ACCME-accredited industry-sponsored events, as attendees or as speakers, if industry designs or plans or otherwise controls the content of the event.

Rationale: If industry controls the design and content of the program it will be difficult for faculty and attendees to verify that commercial bias is absent or that balanced education and critical evaluation are present.

Examples of prohibited "educational" activities include: "drug company dinners" at restaurants, promotional speaking for industry through industry-sponsored "speakers' bureaus," and social or business meetings planned by industry to discuss industry products with other health care professionals.

Exceptions to this Policy might include participation in industry-sponsored, FDA-regulated educational activities where planners and speakers are careful to design balanced activities with opportunities for critical discussion and to disclose the relationships of planners and speakers to the audience. The evaluation of the suitability of the activity must follow the process described below.

Under certain circumstances, School faculty may participate in some industry-sponsored FDA-regulated educational programs **in order to teach or present their scholarly work**. The proposed activity's design and implementation must be discussed by the faculty member and his or her Chair and prior approval for the activity must be obtained. Each of the following conditions must be met:

- The Chair or the Dean's designee must approve the faculty member's participation prior to the event.
- The Chair or Dean's designee must assure that the activity has been planned and will be implemented in a manner which safeguards the academic integrity of the faculty member and the School.
- Faculty must disclose their relevant relationships with industry when presenting at such programs.
- Honoraria paid to faculty must not exceed "fair market value." Proposed honoraria must be reviewed with and approved by the faculty member's Chair or the Dean's designee prior to the faculty member entering into a binding commitment to participate in the activity. Receipt of honoraria must not violate the State Ethics Law, federal research policy, or other legal restrictions.

7. Industry-Sponsored Scholarships and Other Educational Funds for Trainees

All scholarships or other educational funds from industry must be received by the University of Maryland Baltimore Foundation, Inc. Funds received from the Foundation are disbursed at the direction of the School.

The evaluation and selection of trainees receiving scholarships or educational funds must be the sole responsibility of School faculty and must be overseen by the Chair with no involvement by the industry donor. The Chair will report allocations of funds annually to the Dean or Dean's designee.

8. Ghostwriting

School faculty and students may not allow their professional scholarly papers or presentations of any kind, oral or written, to be ghostwritten by any person from industry, a medical education company, or another individual or organization with an

economic interest in the subject matter of the presentation. "Ghostwriting" refers to claiming authorship of a paper or presentation that was written or prepared in whole or in part by another person.

Discipline for Policy Violations

Failure to comply with this Policy is considered professional misconduct. Faculty will be subject to discipline as provided in Article V of the By-Laws of the School of Medicine Judicial Board, and as provided in the Board of Regents faculty policies, in cases of admitted or established violation of this Policy, such as: failure to request approvals as required; false reporting; undertaking outside activities that are not approved; or engaging in specific activities prohibited by this Policy. Disciplinary actions may include reprimand, probation, disapproval of external professional activities, and suspension or dismissal from the faculty. Staff and students subject to this Policy may be disciplined for violations of this Policy in accordance with policies applicable to them.