

Policy and Guidelines

Interactions between the University of Rochester Medical Center (URMC) and the Pharmaceutical, Biotech, Medical Device, and Hospital Equipment and Supplies Industries (“Industry”)

Purpose of Policy:

The purpose of this policy is to establish guidelines for interactions with Industry representatives for all Personnel of the University of Rochester Medical Center and its Affiliates (collectively URMC).

Interactions with Industry occur in a variety of contexts, including marketing of new pharmaceutical products, medical devices, equipment, and supplies on-site, on-site training for newly purchased devices, educational support of medical students and trainees, and continuing medical education. Faculty and trainees also participate in interactions with Industry off campus and in scholarly publications.

Many aspects of these interactions are positive and important for promoting the educational, clinical and research missions of the Medical Center. However, these interactions must be ethical and cannot create conflicts of interest or improper relationships that could endanger patient safety, data integrity, the integrity of our education and training programs, or the reputation of either the faculty member or the institution. In some situations, a conflict of interest or improper relationship could violate certain federal or state anti-kickback laws. These laws impose severe civil and criminal penalties upon institutions and individuals who request or receive anything of value (such as a gift, meal, trip or payment) in exchange for a clinical or business referral.

Statement of Policy:

It is the policy of URMC to adhere to the highest ethical standards and legal requirements, to avoid conflicts of interest, improper relationships and other interactions with Industry that may suggest the appearance of a conflict of interest or an improper relationship. Individuals must consciously and actively divorce clinical care decisions from any perceived or actual benefits expected from any company. It is unacceptable for patient care decisions to be influenced by the possibility of personal financial gain. When conflicts of interest do arise, they must be addressed appropriately.

Scope of Policy:

This policy applies to the University of Rochester Medical Center and to each of its Divisions and practice groups, including Strong Memorial Hospital, Golisano Children’s Hospital, Eastman Dental Center, the School of Medicine and Dentistry, the University of Rochester Medical Faculty Group, the Primary Care Network, and the School of Nursing. It also applies to the following URMC Affiliates: Highland Hospital, the Highlands at Brighton, the Highlands at Pittsford, the Highland Living Center, the

Visiting Nurse Service of Rochester and Monroe County and Visiting Nurse Signature Care. Collectively the URM C Divisions and URM C Affiliates will be referred to subsequently as URM C “Components”.

All URM C Personnel must follow this policy. This includes: (a) all faculty including employed medical staff and staff employed by the University of Rochester or by a URM C Affiliate; (b) all URM C students and post-graduate trainees, (c) all non-employed URM C clinical or administrative staff when on URM C premises, and (d) all members of the immediate family of URM C Personnel.

Industry representatives are also expected to be aware of this policy and to adhere to its principles. Violations of this policy by Industry representatives will be managed through progressive warnings and restrictions on access.

This policy incorporates the following types of interactions with Industry. It does not include faculty research and related activities.

- I. Gifts and compensation
- II. Site access by sales and marketing representatives
- III. Provision of scholarships and other educational funds to students and trainees
- IV. Support for educational and other professional activities
- V. Disclosure of relationships with Industry
- VI. Training of students, trainees, faculty, and staff regarding the potential for conflicts of interest in Industry interactions
- VII. Violations

Individuals who have questions about compliance with this policy should contact the URM C Compliance Office (275-1609) or the URM C Office of Counsel (758-7600) for assistance. Please direct questions about policy development, implementation, or clarifications to Robert Panzer, MD, Associate VP for Patient Care Quality & Safety (Robert_Panzer@urmc.rochester.edu).

I. Gifts, Compensation and Other Benefits

A. Scope of This Section. This Section contains the general rule for accepting benefits from Industry. It applies to most kinds of gifts, compensation and other benefits supplied by Industry including money, meals, equipment, trips, tickets, books, pens, and other items of value (Gifts). Sections III and IV of this Policy contain specific rules for certain types of benefits that Industry may supply, including scholarships and educational and professional support.

B. Gifts as Compensation for Referrals. Personnel may not accept Gifts from Industry in exchange for ordering a health care item or service. For example, individuals may not accept payment for prescribing a drug or changing a patient’s prescription. This conduct is potentially illegal and could result in serious criminal or civil consequences for URM C and for the Personnel who receive the compensation.

C. Gifts Provided On-Site. Personnel may not accept Gifts from Industry anywhere at URMCM.

D. Gifts Provided Off-Site In addition, URMCM employed Personnel may not accept gifts at any non-URMCM-operated clinical facility such as other hospitals, outreach clinics and the like, nor at non-health care settings.

Non-employed medical staff are strongly discouraged from accepting gifts at non-URMCM-operated clinical facilities or non-health care settings but are not proscribed by this policy from doing so.

See Section IV F concerning participation of URMCM personnel in conferences or meetings where there is Industry Support of Non-URMCM Educational Events.

E. Other Gifts or Benefits. All Personnel are strongly advised not to accept any form of Gift from Industry under any circumstances. In addition to creating a potential conflict of interest, accepting Gifts creates a degree of risk under anti-kickback laws especially when the person making the gift benefits from URMCM orders, prescriptions or referrals. Individuals should be aware of other applicable policies, such as the AMA Statement on Gifts to Physicians from Industry (<http://www.ama-assn.org/ama/pub/category/4001.html>) and the Accrediting Council for Continuing Medical Education Standards for Commercial Support (www.accme.org), the Office of the Inspector General's Fraud Alert on Prescription Drug Marketing Practices (<http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html>), and the codes of ethics of the Pharmaceutical Manufacturers Research Association (http://www.phrma.org/code_on_interactions_with_healthcare_professionals/) and the Advanced Medical Technology Association (http://www.advamed.org/NR/rdonlyres/FA437A5F-4C75-43B2-A900-C9470BA8DFA7/0/coe_with_fags_41505.pdf).

F. Gifts Related to Sales Presentations. Personnel may not accept gifts or compensation for listening to a sales talk by an Industry representative.

G. Gifts of Educational Materials (e.g. books). Personnel may not directly accept such gifts but they may be directed to URMCM Personnel (including students and other trainees) through a URMCM Component, center, department, or departmental division if they are deemed to be of significant educational value and are de-identified as to their source before being provided to the recipient.

H. Samples, Patient Education Gifts. Certain gifts directed at patients are permitted. Medication samples for patients may be accepted as long as their use complies with URMCM policies for samples. Also, gifts of anatomical models directed at patients, such as those for use in examination rooms are permitted, but only if the cost of such items is modest (less than \$100) and if such items are only occasionally provided.

Gifts of educational materials directed at patients are permitted only if appropriate materials are not available from a public source (e.g. government agency, foundation, or disease-related association).

I. Prior Gifts. URMIC personnel should remove prior gifts (e.g. pens and other paraphernalia) from URMIC sites so that patients and their families, payers, purchasers, and the public will be assured that Industry gifts will not influence their care or decision making at any URMIC site.

II. Site Access by Sales and Marketing Representatives

A. Access to Patient Care Areas. Sales and marketing representatives are not permitted in any patient care areas except to provide in-service training on devices and other equipment and then only by appointment.

B. Access to Non-Patient Care Areas. Sales and marketing representatives are permitted in non-patient care areas by appointment only. Appointments will normally be made for such purposes as:

1. In-service training of URMIC Personnel for clinical equipment or devices already purchased.
2. Evaluation of new purchases of equipment, devices, or related items.
3. Provision of useful information about formulary medications or approved devices with the approval of the appointment by the participating clinician.

C. Appointments Related to Formulary Drugs. Appointments to provide information about new drugs that are in the formulary or are possible additions to the formulary will normally be with Pharmacy staff. Similarly, appointments to provide information about new devices will normally be arranged with the Purchasing Department or entities such as the SMH Value Analysis Committee.

D. Appointments with Clinical Personnel. Appointments may be made on a per visit basis or as a standing appointment for a specified period of time, at the discretion of the faculty member or other clinician, his or her department or departmental division, or designated hospital personnel issuing the invitation and with the approval of appropriate hospital management.

E. Distribution of Medication Information. Representatives may not directly distribute promotional materials or drug information via intramural mail of the medical center, nor may they have direct access to student, resident, or staff mailboxes. Representatives may initiate distribution of drug detail information, educational materials, or reprints of published articles to faculty, staff, fellows, residents or students at URMIC sites with the prior explicit approval of the Department of Pharmacy or the respective clinical department chairman, chief of service, practice director, residency program

director, or their specific designee, after they personally review the content of the material. Approved materials may be sent via US mail or delivered directly to an office for distribution at the discretion of the office's staff. Any material (printed, audio, video, computer software, or data) distributed to staff by representatives must clearly state the name and company affiliation of the sender.

III. Provision of Scholarships and Other Educational Funds to URM C Trainees and Students

A. Industry support of URM C trainees and students, including provision of scholarships, educational grants, or funds to support travel to meetings shall be free of any actual or perceived conflict of interest, must be specifically for the purpose of education and must comply with all of the following provisions:

1. The URM C school, center, department, departmental division, or program selects the recipient.
2. The funds are provided to the URM C school, center, department, departmental division, or program and not directly to the trainee or student.
3. The URM C school, center, department, departmental division, or program has determined that the funded fellowship, conference, program, or meeting has educational merit.
4. The trainee or student is not subject to any implicit or explicit expectation of providing something in return for the support, i.e., a "quid pro quo." If at all possible, the identity of the donor(s) shall not be disclosed to trainees or students.

B. This provision may not apply to national or regional merit-based awards which have their own processes for selection and administration of awards to trainees or students. Application for such an award by trainees or students should be with the knowledge of their school, department, division, or program.

IV. Support for Educational and Other Professional Activities

A. ACCME or Equivalent Standards. Personnel should be aware of the ACCME Standards for Commercial Support or equivalent standards such as those of the American Nurses Credentialing Center's (ANCC) Commission on Accreditation. They provide useful guidelines for evaluating all forms of Industry interaction, both on and off campus and including both URM C-sponsored and other events. The ACCME Standards may be found at www.accme.org

B. ACCME or Equivalent Standards at URM C Sponsored Events. All educational events sponsored by URM C and its schools, centers, departments, or departmental divisions must be compliant with ACCME Standards for Commercial Support or equivalent standards *whether or not CME or equivalent credits are awarded*. Meetings

governed by ACCME or equivalent standards and the individuals who actively participate in meetings and conferences supported in part or in whole by Industry should follow these guidelines:

1. Financial support by Industry is fully disclosed by the meeting sponsor and conference speakers.
2. The meeting or lecture content is determined by the speaker and not the Industry supporter.
3. The lecturer is expected to provide a fair and balanced assessment of therapeutic options and to promote objective scientific and educational activities and discourse.
4. The URMC center, department, or participant is not required by an Industry supporter to accept advice or services concerning speakers, content, etc., as a condition of the supporter's contribution of funds or services.
5. The lecturer makes clear that content reflects individual views and not the views of URMC or any of its Components.
6. The use of the URMC name in non-URMC event is limited to the identification of a URMC individual by his or her title and affiliation.

C. Industry Support of URMC Sponsored Events. Educational grants that are compliant with the ACCME Standards may be received from Industry for public conferences and programs and administered by centers, departments, departmental divisions, or the URMC Office of Continuing Professional Education (CPE) under the following circumstances:

1. Public conferences held onsite or offsite with registration fees and providing Continuing Education credits (e.g. CME) typically organized through the URMC Office of CPE, may receive support from Industry which may be used to offset any conference expenses, such as speaker fees, speaker travel costs, reasonable meals, preparation of materials, and room rental fees. Individuals attending the conference typically pay a registration fee that at least covers any meals or incidental expenses.
2. Public programs (e.g. Grand Rounds or regional specialty events) onsite or offsite that are free and typically organized by centers, departments, or departmental divisions may receive support from Industry to offset speaker honoraria or travel expenses (as such expenses would not normally be perceived by attendees as a gift).

3. Centers, departments, or departmental divisions not using the coordination of the Office of CPE must maintain records of compliance with the ACCME Standards.

D. Industry Provided Meals Prohibited. Meals or other types of food directly provided or funded by Industry are prohibited at all URMCM-sponsored educational events and conferences, whether onsite or offsite.

E. Industry Support of Private URMCM Educational Activities. Grants or gifts to fund meals at private educational activities, whether onsite or offsite, such as noon conferences and journal clubs may be received by URMCM Components but not by individual centers, departments, or departmental divisions. These funds will be pooled centrally within URMCM Components and distributed proportionally among eligible activities within that URMCM Component, using procedures established and overseen by its leadership. This will ensure that any grants or gifts will be dissociated from the receiving center, department, or departmental division and thereby avoid conflict of interest or the perception of conflict of interest by the public or purchasers.

F. Industry Support of Non-URMCM Educational Events. URMCM Personnel may attend non-URMCM off-site or out-of-town conferences with meals provided by Industry as long as the talk or conference adheres to ACCME or equivalent requirements, as evidenced by the availability of CME or equivalent Continuing Education credits, and the presenter being a bona fide faculty member or expert clinician. However, they may not directly accept compensation, including consultancy payments or the defraying of costs, for simply attending a CME or other activity or conference (that is, if the individual is not presenting).

All Personnel should evaluate very carefully their own participation in non-URMCM meetings and conferences that are fully or partially supported or run by Industry because of the high potential for perceived or real conflict of interest.

G. Meetings of Professional Societies. This Section does not apply to meetings of professional societies governed by ACCME or equivalent Standards and hosted at URMCM facilities that may receive partial Industry support.

V. Disclosure of Relationships with Industry

A. Articles. Individuals are prohibited from publishing articles under their own names that are written in whole or material part by Industry employees or other writers paid for by Industry.

B. Scholarly Publications. In scholarly publications, individuals must disclose their related financial interests in accordance with the International Committee of Medical Journal Editors (www.icmje.org).

C. Teaching. Faculty with supervisory responsibilities for students, residents, trainees or staff should ensure that the faculty's conflict or potential conflict of interest does not affect or appear to affect his or her supervision of the student, resident, trainee, or staff member.

D. Purchasing and Procurement. Individuals having a direct individual or committee role in making institutional decisions on equipment or drug procurement must disclose to the purchasing unit, prior to their making any such decision, any financial interest they or their immediate family have in companies that might substantially benefit from the decision.

Such financial interests could include equity ownership, compensated positions on advisory boards, a paid consultancy, participation in a speakers bureau or other forms of compensated relationship. They must also disclose any research or educational interest they or their department have that might substantially benefit from the decision. The purchasing unit will decide whether the individual must recuse him/herself from the purchasing decision, seeking guidance from URMCC Conflict of Interest leaders as appropriate. For more information about conflicts of interest in institutional decisions, see the University of Rochester's Code of Conduct for Business Activities (<http://www.rochester.edu/working/codeofconduct/>)

1. This provision does not apply to indirect ownership such as stock held through mutual funds.
2. The term "immediate family" includes the individual's spouse or domestic partner and dependent children.

E. Therapeutics and New Technology. Individuals recommending institutional decisions on equipment or drug procurement (e.g. through recommendations to the Therapeutics Committee or New Technology Committee) must disclose any conflicts of interests as listed above. Such committees will decide whether the individual must recuse him/herself from making the recommendation to the committee and also may seek guidance regarding Conflict of Interest issues.

F. Educational Presentations. For disclosure requirements related to educational activities, see the ACCME Standards for Commercial Support (www.accme.org) and Section IV of this policy.

VI. Training of Students, Trainees, Faculty, and Staff Regarding Potential Conflict of Interest in Interactions with Industry

All students and other trainees (e.g. residents and fellows), faculty, and staff within URMCC Components shall receive appropriate initial and subsequent training regarding potential conflicts of interest in interactions with Industry. URMCC will develop appropriate education materials and methods, and each URMCC Component will oversee such training and its quality.

VII. Violations.

A. Violations. Punishment for violations of these policies by Personnel will be imposed consistent with applicable URM and University policies, including but not limited to the University of Rochester Code of Conduct.

Violations of these policies by Industry representatives will be managed through progressive warnings and restrictions on access.

B. Reporting Violations. Personnel witnessing violations of these policies shall report the violations to the appropriate supervisor or department, to the Medical Center Compliance Office at (585) 275-1609, to the Office of Counsel, or to Senior Leadership. Alternatively, they may make an anonymous report to the URM Integrity Hotline at (585) 756-8888.

**Adopted June 25, 2008
Joel Seligman
President, University of Rochester**

URM thanks the Stanford School of Medicine for publicly posting its policy on these issues and giving URM permission to directly use or adapt parts of its policy statement and FAQ language.