

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 Highlands Living Center, Visiting Nurse Service of Rochester and Monroe County, and Visiting Nurse Signature Care. Collectively the URMC Divisions and URMC Affiliates will be referred to subsequently as URMC “Components”.

All URMC Personnel must follow this policy. URMC Personnel includes: (a) all Faculty including employed medical staff, (b) all staff employed by the University of Rochester or by a URMC Affiliate; (c) all URMC students and post-graduate trainees, (d) all non-employed URMC clinical or administrative staff when on URMC premises or conducting activities on behalf of URMC, and (e) all members of the immediate family of URMC Personnel. Non-employed clinical and administrative staff who are affiliated with URMC are also encouraged to follow this policy at all of their practice locations.

When interacting with URMC 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 warnings and/or restrictions on access.

This policy incorporates the following types of interactions with Industry. It does not include Faculty research and related activities conducted within the scope of the Faculty appointment.

- 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. Other Situations; 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 URMC Compliance Office (275-1609) or the URMC 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 gifts, compensation and other benefits from Industry. Except as otherwise described in this Policy, it applies to all gifts, compensation and other benefits supplied by Industry including money, meals, equipment, trips, travel expenses, 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 URMC and for the Personnel who receive the compensation. See also Strong Memorial Hospital Policy 13.9, Gifts, Gratuities, and Improper Inducements.

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

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.

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 Opinion on Gifts to Physicians from Industry () and the Accrediting Council for Continuing Medical Education Standards for Commercial Support (<https://www.ama-assn.org/delivering-care/ethics/gifts-physicians-industry>), the Office of the Inspector General's Fraud Alert on Prescription Drug Marketing Practices (<http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html>), the Pharmaceutical Manufacturers Research Association's Code on Interactions with Health Care Professionals (<https://www.phrma.org/codes-and-guidelines/code-on-interactions-with-health-care-professionals>) and the Advanced Medical Technology Association (<http://advamed.org/res/112/advamed-code-of-ethics-on-interactions-with-health-care-professionals>).

F. Gifts Related to Sales Presentations. Personnel may not accept gifts or compensation in any form for listening to sales presentations by an Industry representative, whether in person, online, or on the telephone.

G. Gifts of Educational Materials (e.g. books) for Use by URMCM Personnel. Personnel may not directly accept gifts of educational materials. Such gifts may be accepted by a URMCM Component, center, department, or departmental division if they are deemed to have significant educational value and are de-identified as to their source before being provided to the recipient. This is not intended to preclude Faculty from accepting review copies of textbooks for evaluation purposes.

H. Samples. Medication samples should not be accepted, stored and/or dispensed within the Hospital inpatient setting or Hospital-based outpatient settings. In the rare event that it is necessary to do so for reasons of quality or safety, samples may only be stored and/or dispensed with the express written consent of senior leadership (i.e. Hospital Chief Executive Officer, Chief Operating Officer, Chief Medical Officer, or Chief Quality Officer) following submission of a written justification that includes a plan to ensure appropriate distribution and tracking of the samples. Samples may not be used to routinely provide a full course of treatment to patients. URMCM Personnel may not accept samples for personal use. Vouchers or non-medication teaching kits may be given to patients in place of samples. See also Strong Memorial Hospital Policy 7.20, Medication Samples.

I. Other Gifts Directed at Patients. Gifts to URMCM or URMCM Personnel that are directed at patients, including but not limited to anatomical models, are not permitted.

J. Printed Educational Materials. Educational materials for patients that are supplied by Industry are permitted only if the materials are of significant educational value to assist patients

in preventing, treating or managing illnesses or conditions, and appropriate materials are not available from a public source (e.g. government agency, foundation, or disease-related association). Such materials are not permitted if one of their primary purposes is to promote a particular drug or device or to otherwise promote the industry's proprietary interest, or to promote drugs that are not on the Hospital's formulary. They may not be provided directly to URM C Personnel and must be evaluated under these criteria and accepted by the Center Director or Department Chair in consultation with the Chief Quality Officer.

K. Prior Gifts. URM C personnel should remove prior gifts (e.g. pens and other paraphernalia) from URM C 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 URM C 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 or technical assistance 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. Technical assistance or in-service training of URM C 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 URM C 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.

F. See Strong Memorial Hospital Policy 12.1.1, Sales Representatives and Vendors, for additional requirements relating to sales representatives and vendors applicable at SMH.

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

A. Industry support of URMC 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 URMC school, center, department, departmental division, or program selects the recipient.
2. The funds are provided to the URMC school, center, department, departmental division, or program and not directly to the trainee or student.
3. The URMC 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 SupportSM 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 URMC-sponsored and other events. The ACCME Standards may be found at www.accme.org. (<http://www.accme.org/requirements/accreditation-requirements-cme-providers/standards-for-commercial-support>)

B. ACCME or Equivalent Standards at URMC Sponsored Events. All educational events sponsored by URMC and its schools, centers, departments, or departmental divisions must be compliant with ACCME Standards for Commercial SupportSM 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 meeting topic, content and speakers are determined at the sole discretion of the the URMC center, department or division. 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 it clear that content reflects individual views and not the views of URMC or any of its Components.

C. Industry Support of URMC Sponsored Events. Educational grants may be received from Industry for public conferences and programs and administered by centers, departments, departmental divisions, or the URMC Center for Experiential Learning (CEL) only if they are in strict compliance with the ACCME Standards, and 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 CEL, may receive support from Industry which may be used to offset conference expenses. Individuals attending the conference typically pay a registration fee that covers at least part of the conference expenses.
2. Public programs (e.g. Grand Rounds or regional specialty events) onsite or offsite that are free to attendees 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 CEL 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 URMC-sponsored educational events and conferences, whether onsite or offsite.

E. Industry Support of Private URMC 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 URMC Components but not by individual centers, departments, or departmental divisions. These funds will be pooled centrally within URMC Components and distributed proportionally among eligible activities within that URMC 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-URMC Educational Events. URMC Personnel may attend non-URMC off-site or out-of-town conferences. They may accept meals provided in conjunction with such activities, but may not directly or indirectly accept compensation from Industry, including gifts, consultancy payments, payment or reimbursement for travel or accommodations, or the defraying of other costs, for simply attending a CME or other activity or conference (that is, if the individual is not presenting).

G. Speaking Engagements:

URMC Faculty and Personnel may participate in industry-funded speaking engagements only if the Faculty or Personnel retain full control and authority over the material presented, except as otherwise provided below.

Prohibited arrangements specifically include any of the following:

- i) speaking engagements that result from arrangements where the URMC Faculty or Personnel's name appears on a publicly available list of potential speakers maintained by industry or another commercial entity; or
- ii) any presentation where the commercial entity or other outside entity (a) prepares the slide set, (b) controls the content of the presentation, (c) controls what the speaker says, or (d) has final right of approval of content (other than a review to confirm that the content does not promote off-label use); or
- iii) speaking at promotional events or at educational events that are designed solely or predominantly for sales, marketing or promotional purposes; or
- iv) speaking at events where industry sponsors provide gifts or honoraria to individuals solely for attending.

Speaking engagements funded by commercial entities are permitted only where the presentations would otherwise meet standards for continuing medical education (whether or not formal CME credits are offered), including that the presentations: have an educational value; provide a fair and balanced assessment of therapeutic options; refer to commercial products primarily by generic names; provide the presenter's perspectives on best practices; and promote improvements or quality in health care rather than a specific proprietary business interest. The presenter must maintain full control and rights of final approval of all content.

Notwithstanding the above, speaking engagements resulting from being listed on a speakers list, or that use an industry-prepared slide set, may be permissible when the talk is solely for educational or training purposes, addressing matters such as safety and quality, do not promote the industry sponsor's product or otherwise encourage its use over other alternative treatments, and otherwise meet the criteria listed in the previous paragraph. This exception also includes situations where a portion of the content is mandated by the FDA, e.g. information about proper use of a drug or device required for training on its use. The audience invitation, any

advertisements, and the slide set or other mandated content (as applicable) must be submitted to the Senior Associate Dean for Academic Affairs or their designee for confirmation that the arrangement meets this exception prior to the engagement.

The permitted use of URMC's name when participating in speaking engagements is limited to identifying the speaker's title and affiliation. In particular, URMC's name shall not be used in any way that may appear to be an endorsement of the commercial entity or its products. At any presentation for which the faculty member has received industry payment or support, the speaker must disclose the name of the company, and the nature of the industry support.

Participation in speaking engagements is also subject to Section H (Consulting) below.

H. Consulting:

All consulting arrangements between URMC Personnel and Industry must be subject to a written contract or memorandum of understanding that outlines the terms of the arrangement, including but not limited to a full description of the scope of work to be performed, and the compensation. Payments made under such arrangements must be fair market value and commensurate to the tasks performed. URMC Personnel providing consulting services should maintain documentation of the services provided, including reasonable estimates of the time and effort devoted and of compensation received.

Consulting by Faculty should not exceed one day per week on average, annually. The scope of the consulting and time commitments should be discussed with the Faculty's Department Chair.

All consulting arrangements involving Faculty must also comply with the standards and requirements contained in the Faculty Handbook; Regulations of the Faculty of the School of Medicine and Dentistry, Consulting Policy and Outside Activities; Faculty Policy on Conflict of Interest and Commitment; University Policy on Intellectual Property and Technology Transfer; and Code of Conduct. See also the University's Guidance and Advice for Faculty Who Engage in Consulting. (These policies and guidelines are available on the University's website.) Faculty are encouraged to submit consulting agreements to the Office of Counsel for review prior to signature for advice about changes that may be required to ensure compliance with these policies.

I. Meetings of Professional Societies. This Section does not apply to meetings of professional societies that are hosted at URMC or other facilities that may receive partial Industry support, if they are governed by ACCME or equivalent Standards.

V. Other Situations; Disclosure of Relationships with Industry

A. Ghostwriting and Honorary Authorship. URMC Personnel are prohibited from publishing books, articles, reports or other materials under their own names that were written in whole or material part by Industry employees or other writers paid for by Industry, from being listed as co-authors of such articles or publications, and from being named as an honorary author in publications or presentations.

B. Scholarly Publications and Presentations. In scholarly publications, individuals must disclose their related financial interests in accordance with the standards of the International

Committee of Medical Journal Editors (www.icmje.org) or such other standards imposed by the journal or publication in question, whichever requires broader disclosure. In scholarly and public presentations Faculty should disclose all relevant personal financial interests when appropriate.

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, drug or medical device procurement must initially and periodically disclose to the purchasing unit or committee any financial interest they or members of their immediate family have in companies that might substantially benefit from the decision. Such financial interests could include but are not limited to equity ownership, compensated positions on advisory boards, paid consultancy, participation in a speakers bureau or other forms of compensated relationship. Such individuals must also disclose any research or educational interest they or their department have that might substantially benefit from the decision. An individual with such financial relationships may not serve on the Pharmacy and Therapeutics Committee except in extraordinary circumstances as approved by the Hospital Chief Operating Officer and the Chief Quality Officer. In any event, and for all procurement committees, an individual with such financial interests must recuse him/herself from participating in the purchasing decision, but may provide information to the committee or other entity evaluating the potential purchase. If the conflicted individual provides information, the purchasing unit or committee should, if feasible, seek the advice and opinion of another expert on the subject matter of the proposed purchase who does not have an external financial relationship with a company that may benefit or be harmed by the decision. 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/) (<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, drug or medical device procurement (e.g. through recommendations to the Therapeutics Committee or New Technology Committee) must disclose any financial interests, and recuse themselves from participating in the purchasing decision, as described above in Section D.

F. Educational Presentations. For disclosure requirements related to educational activities, see the ACCME Standards for Commercial Support (<http://www.accme.org/resources/standards-for-commercial-support-resources>) and Section IV of this policy.

G. Disclosure of External Financial Relationships to URMC. All URM Faculty members with paid academic, clinical or research appointments are required to annually report their external financial relationships to URM through the web-based Conflict of Interest reporting system, and provide updated reports as appropriate. Financial relationships that must be reported include but are not limited to consulting, speaking engagements, continuing medical

education presentations, and advisory board service. Study coordinators and other employees actively involved in conduct or negotiation of sponsored clinical research and who have a financial relationship with a study sponsor are also required to complete the web-based report. Other URMIC Personnel are required to disclose their external financial relationships pursuant to the Code of Conduct, for example, if they are involved in a transaction where they or a family member have a relationship with an external organization that seeks to do business with the University.

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

All students, residents, Faculty, and staff within URMIC Components shall receive appropriate initial and subsequent training regarding potential conflicts of interest. The education will include understanding potential conflicts of interest with industry (including pharmaceutical and device companies) and with personal work and financial interests outside of the medical center and university. Each URMIC Component will oversee the training of its constituents. Integral to the training of everyone is a clear understanding of current URMIC policies regarding industry interactions as well as the importance and process for disclosing potential conflicts of interest.

VII. Violations.

A. Violations. Punishment for violations of these policies by Personnel will be imposed consistent with applicable URMIC 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 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 URMIC Integrity Hotline at (585) 756-8888. The Compliance Office, in consultation with the Associate VP for Patient Care Quality & Safety, is responsible for general oversight to ensure compliance with this policy.

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Last Amended and Approved by Richard Feldman,
President, University of Rochester: April 1, 2019