

HIGHLAND HOSPITAL OF ROCHESTER	HIGHLAND HOSPITAL POLICY	APPROVED BY: Clinical Council
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Policy:

The purpose of this policy is to establish guidelines for interactions with industry representatives for all Personnel of Highland Hospital, including non-employed practitioners. It is based on a policy of the University of Rochester Medical Center.

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. Practitioners 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 Hospital’s mission. 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 Highland Hospital 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.

Description:

This policy applies to Highland Hospital and each of its ambulatory sites. It is based on a policy adopted by the University of Rochester Medical Center for 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. Similar policies apply to the UPMC 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.

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

When interacting with Hospital personnel, industry representatives are also expected to be aware of this policy and to adhere to its principles. Violations of this policy by representatives will be managed through warnings and/or restrictions on access.

This policy incorporates the following types of interactions with industry

- A. Gifts and compensation
- B. Site access by sales and marketing representatives
- C. Provision of scholarships and other educational funds to students and trainees
- D. Support for educational and other professional activities
- E. Other Situations; Disclosure of relationships with industry
- F. Training of students, trainees, practitioners, and staff regarding potential conflict of interest in industry interactions
- G. Conflict of Interest in Research

Individuals who have questions about this policy should contact the URMC Compliance Office (275-1609) or the URMC Office of Counsel (758-7600) for assistance.

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 most kinds of 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 the Hospital and for the Personnel who receive the compensation.

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

D. Gifts Provided Off-Site. In addition, Hospital-employed Personnel may not accept gifts at any other clinical facility such as other hospitals, outreach clinics and the like.

Non-employed medical staff are strongly discouraged from accepting gifts at other clinical facilities but are not proscribed by this policy from doing so.

See Section IV F concerning participation of Hospital personnel in conferences or meetings where there is Industry Support of Non-Hospital 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 Hospital 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_faqs_41505.pdf).

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

G. Gifts of Educational Materials (e.g. books) for use by Hospital Personnel. Personnel may not directly accept gifts of educational materials. Such gifts may be accepted by a Hospital 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.

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,

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Chief Operating Officer, Chief Medical Officer, or Associate Chief Medical 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. Hospital 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 Highland Hospital Policy 2.47-3, Medication Use: Procurement, Preparation, Dispensing.

I. 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 Hospital Personnel and must be evaluated under these criteria and accepted by the Department Chair in consultation with the Associate Chief Medical Officer.

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

I. Prior Gifts. Hospital personnel should remove prior gifts (e.g. pens and other paraphernalia) from Hospital 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 Hospital 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 Hospital 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

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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 Hospital’s 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. Violations. Violations of this policy by representatives will be managed through warnings and/or restrictions on access.

F. See Highland Hospital Policy 4.25, Sales Representatives and Vendors, for additional requirements relating to sales representatives and vendors applicable at Highland Hospital.

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

A. Industry support of students and trainees 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 Hospital, or for URMC students or trainees, the URMC school, center, department, departmental division, or program, selects the student or trainee.
2. The funds are provided to the Hospital and not directly to student or trainee.
3. The Hospital, or for URMC students or trainees, the URMC school, center, department, departmental division, or program has determined that the funded fellowship, conference, or program has educational merit.
4. 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.” If at all possible, the identity of the donor(s) shall not be disclosed to students or trainees.

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 selectees. Application for such an award by the student or trainee should be with the knowledge of their school or program.

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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 URMC-sponsored and other events. The ACCME Standards may be found at www.accme.org

B. ACCME or Equivalent Standards at Hospital-Sponsored Events. All educational events sponsored by the Hospital 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 Hospital 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 the Hospital, URMC or any of its affiliates.

C. Industry Support of Hospital-Sponsored Events. Educational grants that are compliant with the ACCME Standards may be received from Industry for public conferences and programs and administered by the Hospital under the following circumstances:

1. Public conferences 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

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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 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 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 Hospital-sponsored educational events and conferences, whether onsite or offsite.

E. Industry Support of Private Hospital 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 the Hospital but not by individual departments, or departmental divisions. These funds will be pooled centrally within the Hospital and distributed proportionally among eligible activities within the Hospital, using procedures established and overseen by the Chief Operating Officer and Chief Medical Officer or Associate Chief Medical Officer. This will ensure that any grants or gifts will be dissociated from the receiving 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-Hospital Educational Events. Hospital Personnel may attend non-Hospital 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. Speakers Bureaus: Hospital Personnel may participate in speaker's bureaus and other speaking engagements that are funded by industry, subject to the following requirements and limitations. Such presentations must have an educational value, provide a fair and balanced assessment of therapeutic options, and include the presenter's perspectives on best clinical practice. Content and format must promote improvements or quality in health care, and may not promote a specific proprietary business interest. If the presentation pertains to medications or devices, it must give a balanced view of therapeutic options, and

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where possible, must refer to them by generic names. Hospital Personnel may not speak at marketing or training programs that are designed solely or predominantly for sales, marketing or promotional purposes, nor may they speak at events where industry sponsors provide gifts or honoraria to attendees. Participation in speakers' bureaus is also subject to Section H (Consulting) below. The permitted use of the Hospital's name with respect to speaking engagements is limited to identifying the speaker's title and affiliation, and the Hospital's name shall not be used in any way that may appear to be an endorsement.

H. Consulting. All consulting arrangements between Hospital 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. Hospital Personnel providing consulting services should maintain documentation of the services provided, including reasonable estimates of the time and effort devoted and of compensation received.

I. Meetings of Professional Societies. This Section does not apply to meetings of professional societies that are hosted at URMC or Hospital 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. Hospital Personnel are prohibited from publishing books, articles, reports or other materials under their own names that are written in whole or material part by Industry employees or other writers paid for by Industry, and from being listed as co-authors of such articles or publications.

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, Hospital Personnel should disclose all relevant personal financial interests when appropriate.

C. Teaching. Hospital Personnel with supervisory responsibilities for students, residents, trainees or staff should ensure that their conflict or potential conflict of interest does not affect or appear to affect their 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 disclose to the purchasing unit or committee any financial interest they or their immediate family members

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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. They must also disclose any research or educational interest they or their department have that might substantially benefit from the decision. The individual 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 [Hospital's Conflict of Interest Policy, HR # 345](#). http://intranet.urmc-sh.rochester.edu/highland/depts/hr/documents/HR345-CONFLICTOFINTEREST_004.pdf

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 (www.accme.org) and Section IV of this policy.

G. Disclosure of External Financial Relationships. The following individuals are required to annually report their external financial and fiduciary relationships to the Hospital, and provide updated ad hoc reports from time to time as appropriate. Financial and fiduciary relationships that must be reported include but are not limited to consulting, speaking engagements, continuing medical education presentations, advisory board service, or service on a board of directors or an ownership interest in a company in the pharmaceutical, biotech, medical device, or hospital equipment or supplies industry.

1. All physicians and dentists who are employed by the Hospital;
2. All employees of the Hospital who are actively involved in the negotiation of

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- sponsored clinical research that will be conducted at Highland Hospital, an offsite Hospital location, or otherwise in the name of Highland Hospital;
3. All individuals who are actively involved in the conduct of clinical research within the Hospital, at any offsite Hospital location, or otherwise in the name of Highland Hospital.

This disclosure requirement does not apply to physicians and dentists who are faculty of the University of Rochester School of Medicine and Dentistry, Eastman Institute of Oral Health, or School of Nursing. Such faculty are required to comply with the University's COI reporting and management processes.

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 the Hospital shall receive appropriate initial and subsequent training regarding potential conflicts of interest in interactions with Industry. UPMC will develop appropriate education materials and methods, and the Hospital will, where appropriate, oversee such training and its quality.

VII. Conflict of Interest in Research

A. A conflict of interest in research occurs when there is a divergence between an individual's private interests and his or her professional obligations to the Hospital, its patients, its Medical Staff, and/or its employees. The conflict may be either actual or apparent. An apparent conflict of interest may exist in circumstances in which an independent observer might reasonably question whether the individual's professional actions or decisions might be affected by considerations of financial gain. It is important to avoid or manage situations that may call into question the credibility and objectivity of research conducted at the Hospital by employees and others, or by Hospital employees regardless of location.

B. Certain individuals, as described in Section V.G above, are required to report external financial or fiduciary interests. If the report indicates an actual or apparent conflict of interest relating to research conducted at the Hospital or in the Hospital's name, whether on-site or off-site, the report will be forwarded to the Associate Medical Director. The Associate Medical Director shall be responsible for eliminating or managing the conflict of interest, and shall communicate that decision to the affected individual and their Department Chief.

VIII. Violations.

A. Violations. Punishment for violations of these policies by Personnel will be imposed consistent with applicable Hospital policy.

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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 the Chief Operating Officer or Associate Chief Medical Officer. Alternatively, they may make an anonymous report to the URMC Integrity Hotline at (585) 756-8888. Failure to report known or suspected violations is itself a breach of the Hospital's ethical standards and can lead to discipline, up to and including separation from the Hospital or the University.

Policy Number History:

Approved:

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