

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

Policy Adopted June 25, 2008

Frequently Asked Questions (FAQ)

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Frequently Asked Questions (FAQ)

A. General Questions

Q-A1. Why does UPMC need a policy like this?

A. UPMC has numerous interactions with the various Industries and their representatives. These interactions are mostly positive and benefit UPMC and its patients, promoting in various ways all of our missions: patient care, education, research, and community health.

However, some of the interactions with Industry create conflicts of interest for UPMC Personnel (faculty, staff, fellows, residents, and students). Industry and their representatives promote their products to UPMC personnel, even when use of the particular product may not be in the best clinical or financial interest of UPMC and its patients.

Also, even if UPMC Personnel can largely avoid or manage conflicts of interest, the public (patients, insurers, employers, and others) perceive that these conflicts exist and could lead to care that is not in their best clinical or financial interest.

Q-A2. Does this policy provide rules for expected behavior or general guidelines?

A. Both. Where expectations are clear (at times guided by national or regulatory standards) the policy will identify expectations that must be followed by UPMC Personnel and by those entering UPMC facilities or programs. Where the issues are “gray”, the policy will provide guidelines for UPMC Personnel to help them achieve the intent of the relevant principles.

Q-A3. Why have a “Frequently Asked Questions” document in addition to the policy?

A. The FAQ can expand on and clarify the policy in anticipation of or in response to questions that arise. In particular, the FAQ can provide guidance in “gray areas” where the policy is not explicit. However, the authoritative source of guidance is the approved policy itself.

Q-A4. Is every aspect of the policy effective June 25, 2008?

A. No, though most aspects of the policy can and must be followed as of that date, some will take time for implementation.

For example, it may take up to a year to fully achieve certain goals, such as replacing promotional patient education material from Industry whenever possible with publicly available material such as from foundations, professionally societies, and government agencies. It will also take time to remove past Industry promotional materials and paraphernalia (e.g. pens, bags, etc) from our clinical settings so that we can reduce the perception that Industry is biasing our clinical and administrative decisions.

B. Scope

Q-B1. Where does this policy apply?

A. 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 URMCAffiliates: 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

Q-B2. To whom does this policy apply?

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

C. Gifts, Meals, and Products

Q-C1. Are gifts from anyone to URMCAffiliates Personnel prohibited?

A. No. The policy applies to interactions including gifts from the Pharmaceutical, Biotech, Medical Device, and Hospital Equipment and Supplies Industries. URMCAffiliates Personnel may accept minor non-monetary gifts from patients. They may also accept meals and minor gifts from organizations that do not have a role as an actual or potential vendor to URMCAffiliates or a role in promoting their medication or devices for patient care treatment (e.g. professionally societies).

Q-C2. Why preclude gifts of meals and minor items like pens? Do they really affect patient care decisions?

A. Research has shown that even *de minimus* gifts, such as pens, engender a sense of obligation on the part of the recipient. Moreover, research has shown that in cases where a doctor has a pen or pad advertising a particular product, that product gets prescribed more often. Such gifts, including meals provided by pharmaceutical and device companies, can influence the decision-making process. Our goal is to provide our patients with the best, most objective care, and to show our patients that we do so without bias. This is why we have chosen to eliminate such incentives.

Q-C3. In the past, one of our pharmaceutical reps provided lunch for our noon conference attended mainly by residents and students. Is this still allowed under the new policy? If they can't bring lunch, can they simply give us the money? If not, how can we finance our lunches?

A. As discussed previously, the main thrust of our policy is to eliminate incentives that create bias or perception of bias such as meals, and consequently no meals may be provided or donated directly by the pharmaceutical and device industry anywhere at the University of Rochester Medical Center facilities listed or at URMIC internal events even if offsite.

Under the policy, Industry may provide funds to pools within URMIC components for such internal private seminars and conferences, and those components (e.g. SMH, HH, SMD, etc.) will aggregate such donations and allocate them completely to fund meals at appropriate educational events, removing a direct link from the donation to the receipt of the meal by attendees.

Of note, several departments and residency programs have already eliminated pharmaceutical representative supplied or funded lunches, as did the entire Primary Care Network in 2007

Q-C4. Can a sales rep take a doctor or administrator out to lunch or dinner for a business purpose?

A. While our policy does not explicitly prohibit restaurants as the setting for meetings of industry reps with clinical or administrative leaders, we strongly discourage them because of the implied *quid pro quo* that is present in such situations. If Industry representatives and URMIC Personnel meet in a restaurant,

they should each pay their own meal expenses, unless URMC is already essentially paying for such expenses, for example through a contract including such costs in the fees paid by URMC.

We suggest, instead, that industry reps be invited to meet with URMC clinicians or administrators in their offices by appointment in accordance with the site access provisions of the policy.

Q-C5. Does the policy affect free medication samples for needy patients?

A. No. Free medication samples are sometimes a source of pharmaceuticals for needy patients or short trials for other patients, and they may be accepted by URMC sites if processed in accordance with the Samples Policy (for example SMH policy 7.1E) which requires appropriate documentation and tracking. However, URMC sites are not required to accept samples.

Q-C6. Does the policy permit URMC personnel to accept medication samples for themselves?

A. Free drug samples given directly to individual faculty, staff, fellows, residents, or students at URMC are considered personal gifts under this policy and may not be accepted.

Q-C7. Can industry buy books directly for faculty, staff, fellows, residents, or students?

A. No, such gifts are intended to create gratitude and potential bias in the future decision making by staff and trainees. Industry can donate money or books to a component of the medical center (e.g. SMD, SON), center, department, or division for the same purpose as long as the use and distribution is guided by bona fide educational needs and the books are de-identified as to the source of the gift so as to not create bias.

Q-C8. I have various materials (e.g. pens, bags) with pharmaceutical or device company logos that I picked up at non-URMC sites or out-of-town meetings. May I keep them, including those I received in the past?

A. Given the importance of avoiding bias or the perception of such bias by our patients or public organizations, all URMC staff and trainees should discard such gifts and in particular avoid carrying such materials in patient care settings. We

expect full implementation of this expectation to occur progressively during the first year of implementation.

Q-C9. Are all gifts from industry prohibited?

A. No, while gifts to faculty and staff are prohibited, 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.

D. Site Access by Sales and Marketing Representatives

Q-D1. Under the policy are sales and marketing reps allowed on the URM campus?

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

For patient care areas, directors, managers, or supervisors may arrange in-service training by industry reps by appointment only on devices and other equipment.

Similarly, industry reps may be permitted in non-patient care areas by appointment only for such purposes as:

1. In-service training of URM personnel for equipment or devices already purchased.
2. Evaluation of new purchases of equipment, devices, or related items.
3. Educational discussion of formulary medications with faculty physicians though normally such information can better be provided to the Pharmacy for review and sharing in context as appropriate.
4. Discussion of potential new additions to the formulary with expert faculty physicians, though again such information can be better provided to the Pharmacy for review and consideration by the Therapeutics Committee. Representatives may not actively promote inpatient use of any medication that has been reviewed and deemed non-formulary by the Therapeutics Committee

Q-D2. Is it true that sales and marketing representatives may no longer directly distribute any written materials to faculty, staff, fellows, residents, or students?

A. Yes. Sales and marketing materials (including reprints of published articles) from pharmaceutical and medical device companies may no longer be left for direct distribution such as to internal mail boxes. Materials may be sent to chairs or division leaders, program directors, or their designee for personal review. If on review the materials are felt to be of educational value and meeting a need not handled by publicly available materials, the department may accept copies of the paper materials or media and share with faculty, staff, fellows, residents, or students. Only the department or program may distribute the materials and they should indicate the approval to the recipients in some way so they know the materials are approved.

Q-D3. Can an industry representative provide support in the operating room or procedure areas?

A. While industry reps with appropriate knowledge of a device being used may be useful in the operating room or procedural area, in order to provide technical support or advice, a company must first comply fully with the procedures described in policy 14.10 “Credentialing and Privileging Health Care Workers Not Employed by SMH” and clinicians using such technical support must comply with other requirements such as patient notification and consent.

E. Industry Funding for Education

Q-E1. I have been invited by a pharmaceutical company to give a talk to community physicians at a non-URMC site. Am I allowed to do this and receive an honorarium?

A. University policy allows faculty to consult and such talks would be considered consulting activities. As with any consulting agreement, any honorarium or payment received should be consistent with fair market value for the services being provided and should not be payment in whole or in part for prescribing drugs, ordering devices or equipment or making referrals. Participation in speaker bureaus is also permitted.

However, we recommend that faculty and staff evaluate very carefully their participation in meetings and conferences that are fully or partially supported or run by industry because of the high potential for such talks functioning as a promotional or marketing activity. In instances in which URM C faculty and staff do participate in such talks, we encourage them to follow to the extent possible the policy guidelines set forth below that apply to URM C-sponsored events, whether or not CME or equivalent credits are provided. Following all the guidelines may not be possible if URM C faculty are participating as part of a speakers bureau or as a promotional speaker using Industry supplied presentation materials.

- Financial support by industry is fully disclosed by the meeting sponsor.
- The meeting or lecture content is determined by the faculty organizers and speakers - not the industrial sponsor.
- Any lecturer is expected to provide a fair and balanced assessment of therapeutic options and to promote objective scientific and educational activities and discourse.
- The organizer is not required by an industry supporter to accept advice concerning speakers or content as a condition of the sponsor's contribution of funds or services.
- Any lecturer makes it clear that content reflects individual views and not the views of URM C or any of its components.
- The use of the URM C name in a non-URM C event is limited to the identification of the individual by his or her title and affiliation.
- The URM C participant is aware of and fully complies with UR Conflict of Interest policies.

Q-E2. Is it still allowable for our department to receive grants from industry for fellowships, scholarships, or other educational funds for fellows, residents, or students?

A. Yes, so long as it is compliant with URM C policy. Such support must be specifically for the purpose of education, and should be free of any actual or perceived conflict of interest. In order to be compliant with the policy it must meet the following conditions:

- The URM C center, department, division, or program selects the student or trainee.

- The funds are provided to the center, department, division, or program and not directly to student or trainee.
- The center, department, division, or program has determined that the funded conference or program has educational merit.
- The trainee is not subject to any implicit or explicit expectation of providing something in return for the support, i.e., a "quid pro quo."

Q-E3. Are all gifts from industry for education prohibited?

A. No, while meals, books, and patient materials with company identifiers are prohibited, gifts of anatomical models 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. In addition, books that are de-identified as to source and deemed of educational value by the receiving URM center, department, division, or program may be received and then distributed.

Q-E4. I understand that we no longer allow pharmaceutical sponsors to purchase meals on the URM campus and offsite locations, but what about using funds for meals at internal private seminars and conferences (e.g. noon conferences) that are derived from unrestricted gifts for education?

A. Good question. We do not allow Industry to directly deliver, buy, or fund meals for URM events.

Industry may give unrestricted grants to fund internal educational, private seminars and conferences to URM components (e.g. SMH, HH, SMD, SON). Such funds will be aggregated by each organization's leadership and distributed proportionately to its areas. For example, grants to SMH might in part be distributed among residency programs for noon conferences with an even amount per resident per time period, and in part be distributed among hospital areas for sessions targeting education on devices.

Q-E5. Pharmaceutical or device industry support of our major educational conferences, open to the public, is important since we recruit major national speakers who require both an honorarium and travel expenses. Also these conferences are long enough that food is needed to have an appropriate experience for the attendees who do pay a modest registration fee. Is industry support of these expenses permitted?

A. Yes, Industry may give grants to a URM Center, department, or division for a specific public conference or program typically but not always coordinated by the Office of Continuing Professional Education (CPE). Such funds may be used to offset conference expenses such as speakers, materials, and meals if such a conference has a registration fee proportional to the group value of any meals, such that attendees generally would not perceive any meals or materials as gifts.

Q-E6. Can Industry pay for an outside speaker's honorarium or travel costs to present at a URM Center public event that has no registration fee, such as a Grand Rounds or a community-wide specialty conference?

A. Yes, Industry support of public Grand Rounds or specialty conferences without a registration fee organized by centers, departments, or divisions is permitted but limited to coverage of outside speaker honoraria and travel expenses. This way the attendee of the conference is less likely to perceive or to be perceived as having received a direct "gift" from the industry supporter.

Q-E7. Which educational events may industry representatives attend? Can they "market" their products to conference attendees?

A. Pharmaceutical sales and marketing representatives may, of course, attend public conferences, just like anyone else. However, they should not abuse that privilege to promote their products to attendees, in essence avoiding the requirement that they only meet with URM Center faculty or staff with an advance appointment.

Q-E8. Isn't there a big loophole in the policy if a company can make an education gift to a URM Center component (e.g. SMH) and then the URM Center component can turn around and use that pooled money for the same purpose of providing meals for a noon or other private conference?

A. It may seem that way, but no, there is no loophole. Let's look at the difference. Prior to implementing this policy industry reps provided or paid for meals for talks and were at the event with promotional materials. They may have discussed their products with participants. Now when private educational events take place they are free of company intervention or direction. If food is provided it is provided by the center, department, or division offering the event. And while the department may have received funds through a URM Center component that in turn received funds from Industry, these funds are mixed with all other support and allocated to

various departments fairly. Most importantly, no one should feel any obligation to any company.

Q-E9. In the past our student group has received Industry support for our fund-raising event. Is this still allowable under the URM Policy?

A. It is fine for to solicit corporate sponsorships for your event. We would just ask two things:

- Please do not have Industry promotional materials at your event.
- Please touch base with the URM Advancement office first so that they can help you comply with policies.

Q-E10. A URM employee attends a yearly CME educational conference. Can their travel and hotel costs be paid for by Industry?

A. No. Industry paying for an individual to simply attend a conference represents a gift. Section IV-F of the URM policy notes that URM Personnel “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).”

Q-E11. A URM employee is planning to attend an Industry organized non-CME conference focused on optimal use of a device or technology. Can his/her travel and hotel costs be paid for by Industry?

A. It depends. Consider this answer as describing guidelines consistent with the policy but not explicitly addressed in it.

Normally in-services and training for a new or existing device will be onsite at URM. If some or all of such training needs to be out of town, travel costs would normally be built into the URM implementation plans and covered by URM. Alternatively, if the device company has resources to defray unbudgeted travel costs, the price of the overall contract to URM could be adjusted appropriately and URM could still cover URM Personnel travel costs as usual.

However, if the vendor can only offer to defray travel costs by direct payments (e.g. to the airline or hotel) or by reimbursement to the individual after the travel, the answer depends on the situation.

The defraying of costs would generally not be problematic when: 1) URMC has an actual interest in using, purchasing the device or technology or learning about its safe and effective use, 2) the URMC faculty or staff member is going out of town at the direction of a senior or departmental leader, 3) the training on the device is necessary to ensure its safe and effective use, 4) the training is by recognized experts, 5) the location is at a central site appropriate for the experts and attendees and conducive to learning rather than entertainment, 6) the training agenda is substantial and comprises the majority of the time away, 7) the industry sponsor does not provide entertainment or other benefits that could be perceived to be a gift, and 8) the individual attending completes a UR Travel & Conference expense report (noting any items directly paid by the vendor) which is reviewed and approved by the senior or departmental leader directing the travel, even if all of the expenses are directly billed to the device manufacturer and submission to UR Finance is unnecessary.

At the other extreme, where the defraying of costs would not be permitted, is an invitation from the Industry device manufacturer to an individual to come to a periodic, non-CME get-together, with no substantial new knowledge or expert speakers, and where the relevant URMC management has no clinical or business reason to need the individual to attend. Such a non-CME (and not CME eligible) conference has a substantial risk of being primarily a promotional event, intended to both promote the company's product and create a personal relationship or gratitude that could potentially bias future clinical or administrative decisions or recommendations by the URMC faculty or staff member. Additionally, if entertainment or other non-educational benefits are provided, or if the location of the program is in a setting that is more conducive to recreation or sightseeing than education, it could be prohibited by the policy on gifts, compensation and other benefits.

Q-E12. In the past, our pharmaceutical reps paid for and attended our Journal Club meetings, which are held at a restaurant in downtown Rochester. Since these are off-site, can this practice continue?

A. No, the practice cannot continue. This is because the Journal Club is a URMC-sponsored event and so must abide by this policy. The past practice of having pharmaceutical reps pay directly for these private URMC events is no longer allowable. Furthermore, unless it is a public event, and the industry rep comes as a member of the public, they are no longer allowed to attend.

Q-E13. There is a dinner talk focusing on a newly released drug, given by a pharmaceutical representative at a nice restaurant in the Rochester area. There is no expert speaker and no CME credits. The main value is the opportunity to have an excellent meal with my friends and colleagues. May I attend?

A. Under this policy, URMC faculty, staff, fellows, residents, and students may not accept such meals as gifts. Bona-fide educational events will have expert speakers from URMC or elsewhere and will generally obtain CME or other Continuing Education status with appropriate requirements for lack of bias and disclosure of conflicts of interest. Technically, you could attend the talk without the dinner but the value and objectivity of the educational content should be considered before doing so.

Q-E14. Can you provide more guidance on attending non-URMC events whether in Rochester or out-of-town where meals are provided?

A. Yes. Consider the following criteria to determine the likelihood an event is a bona fide educational activity free of bias and to determine whether the meal is incidental to a valuable educational activity or is a gift to be concerned about. These should serve as guidelines, as the policy itself is not as specific as the following:

- Is there a registration fee and is it at least roughly proportional to the value of the meal?

If so, then the meal would not be perceived by a reasonable person to be a gift and so this policy would not be an obstacle to attending and having the meal.

If there is no such registration fee, consider the following 3 criteria:

- Is the primary purpose and focus of the gathering to hear a presentation by an expert speaker (e.g. faculty from URMC or other academic center)?
- Are there CME or equivalent education credits which helps ensure compliance with standards like those of the ACCME intended to minimize bias?
- Is the event hosted by an educational or clinical institution (e.g. other academic center, hospital, or professional organization) – not directly by an Industry pharmaceutical or device company representative?

If the non-URMC event meets all 3 of these criteria, accepting a meal is incidental to a valuable educational activity and is permissible according to our current interpretation of the URMC policy.

However, if the non-URMC event meets none or only 1 of these criteria, a reasonable person would probably perceive the meal to be a gift. It would not be appropriate to accept a meal and questionable whether URMC Personnel should attend at all as the event has features more of a promotional than educational event.

If the non-URMC event meets two of these criteria, use discretion in deciding whether to attend and whether to accept a meal, considering the details of the event and how it meets these criteria, as well as your own perspective on these issues. The key consideration in all circumstances should be whether the meal could be perceived by a reasonable person to be a gift rather than a meal that is incidental to a bona fide educational presentation.

Q-E15. Can Industry pay for educational brochures to be provided to patients?

A. Understandably such materials may be valuable to patients, but they could also be perceived as promotional, or create a sense of obligation for the department, so, no, it would not be allowed unless materials of equivalent value were not available. However many government agencies, professional societies, or non-profit foundations provide educational materials at no cost so these could replace industry brochures.

Alternatively, a company could make an educational gift for such a purpose to a department, which the department then may decide to use to cover the printing costs of such non-industry materials.

Exceptions may be made if appropriate non-industry educational materials are not available, are not of sufficient quality, or require additional time to evaluate and acquire.

F. Industry Funding for Research

Q-F1. Does the policy affect grants or any other activities directly relating to UPMC research?

A. No. Research funding complies with extensive rules and regulations that govern funding to individuals, departments, centers, and UPMC components, including conflict of interest policies.

G. Training

Q-G1. How will each component of UPMC manage to create training for the diverse faculty, staff, fellows, residents, students, and managers that need to know about these policies? How will Industry representatives learn about the policy?

A. UPMC leadership will work with both UPMC Organizational Development staff and educators in the schools (SMD and SON) to develop effective educational materials. Such education and training will address not just the specifics of these policies, but also the broader issues related to Conflict of Interest.

In addition, to assist training of current and future Personnel, UPMC will post the policy, FAQ, and summary materials (e.g. a PowerPoint presentation) on the UPMC Intranet and Public Web Site.

H. Violations

Q-H1. How will this policy be enforced for UPMC Personnel?

A. As with all policies, faculty, staff, fellows, residents, and students are expected to comply and report any violations (even unintentional) by themselves or others to appropriate supervisors or departments, or through UPMC routes such as the Compliance Office or Integrity Hotline. Such violations and their context will be taken into consideration during performance evaluation processes, consistent with the UR Code of Conduct.

Some of the provisions of the policy will require time to allow transition to better practices and we do not plan for strict enforcement of such provisions during the first year after adoption of this policy. For example, it may take time to find public domain or non-profit domain educational materials for patients to replace industry supplied promotional. Also, eliminating Industry paraphernalia from the medical center such as pens, bags, and other gifts will take time.

For “gray areas” defined in the policy or FAQ, we expect URMIC Personnel to use discretion.

Q-H2. How will this policy be enforced for pharmaceutical or device sales representatives who by their nature are not subject to employee evaluations at URMIC?

A. Violations of this policy will result in progressive communications and discipline. For example, the SMH Pharmaceutical Representative policy describes “3 strikes” where a first violation results in a verbal warning, a second violation in a written warning copied to the regional manager, and a third violation in prohibition of the representative and possibly the company from accessing URMIC for a specified period of time. Flagrant violations can and have resulted in immediate site prohibition for the rep and/or the company.

I. Questions

Q-I1. *How can I get further clarifications on this policy?*

A. Individuals who have questions about compliance with this policy should contact the URMIC Compliance Office (275-1609) or the URMIC 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).

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