

UVM College of Medicine Pharmaceutical Policy Q&A

Does FAHC have a similar policy and will they be rolling theirs out in the near future? If so, do they align?

Yes, FAHC has had policies on vendor relations for many years. The FAHC policies have been recently updated, and the updates are entirely consistent with the UVM policies. FAHC will be rolling their policy changes out on the same, or a similar, timeline as UVM. Representatives of the two institutions have been and will continue to be in communication to ensure that the two policies continue to align with each other.

How did how this policy develop and come about? Why this, why now?

There has been growing recognition in many quarters over the past decade that relations between physicians and medical institutions on the one hand and industry on the other provide numerous opportunities for conflicts of interest. Protection of the interests of our patients and of our profession necessitate that we formulate policies and practices that recognize and minimize to the extent possible such conflicts and their consequences. Several medical schools have already instituted such policies, which have been called for by the AAMC, the AMA, and AMSA. Our proposed policy was drafted by a committee appointed by Interim Dean Fogarty in early 2007 to review the topic and the actions other medical schools have taken to this point, and recommend a policy for the UVM COM. That draft has already been approved by the COM department chairs and has been awaiting coordination with FAHC.

Understanding that industry has provided our residents and students with unrestricted grants to attend meetings in the past, what better use will these funds serve?

Such unrestricted educational grants would still be permissible under the policy provided that the following are met:

- The College department, division or program selects the students or trainees to receive such financial support;
- The funds are provided to the department, division or program and not directly to the student or trainee;
- The department, division or program has determined that the funded event has educational merit; and
- The recipient is not subject to any implicit or explicit expectation of a quid pro quo (see section III of the policy).

I believe that this is an example of the tail wagging the dog. Medical students are not the individuals who should have been the ones to have paramount say in this issue. Why?

Medical students are impressionable learners and emulate behaviors of their teachers. Some are more connected to the national trends and have pointed out their concerns about interactions between pharmaceutical companies and physicians. Students are not the ones to have paramount say and this policy was drafted by a committee that did not include any students. Many of them are, to their credit, educated and concerned about this matter of great importance to their future patients and profession.

If students are never exposed to a drug representative during medical school and residency, how will they learn to deal with them when meeting them for the first time when out in practice?

The underlying question here is whether physician and student exposure to drug company representatives is beneficial or harmful, and the data suggest the latter conclusion. As reviewed by Wazana (JAMA, 2000), such interactions were associated with inability to identify wrong claims about medication, non-rational prescribing behavior, and prescribing fewer generic drugs, preferring newer and more expensive medications without demonstrated advantages. Regarding students, recent evidence (Sanders et al, 2007) suggest that medical student exposure to pharmaceutical representatives is correlated negatively with skepticism about information supplied by industry and correlated positively with the view that receipt of gifts from industry is appropriate. Thus, there is little reason to believe that “dealing with” drug representatives is useful for students or physicians and good reason to believe that avoiding it serves the best interests of our patients and our profession. It is certainly worth asking the question: “If the drug companies did not believe that they could influence physician prescribing behavior, why would they be willing to spend billions on pharmaceutical marketing and detailing directly to physicians?”

Our residents have always been able (along with residents nationwide) to attend our specialty meeting with a grant from industry. Where else do I find funding for this?

See above regarding the conditions under which unrestricted educational grants would be permissible under the policy. If the conditions cannot be met, department, CME, or education funds would need to be used.

Are we prohibiting pharmaceutical supported meals as stated in the memo?

Yes – if accepted directly from industry, meals are gifts and would be prohibited at the College and in connection with any College activities or events, and would be strongly discouraged under all other circumstances.

What about the drug samples we use for our clinic patients?

Samples are not part of the UVM COM policy but may be part of the FAHC policy. We understand that the Faculty Practice Plan is carefully reviewing FAHC's current policies, which permit the distribution of drug samples in the outpatient clinics but not other areas of the hospital. The *JAMA* article, cited above, strongly recommends against this practice, stating:

The direct provision of pharmaceutical samples to physicians should be prohibited and replaced by a system of vouchers for low-income patients or other arrangements that distance the company and its products from the physician. The availability of free samples is a powerful inducement for physicians and patients to rely on medications that are expensive but not more effective. Samples also provide company representatives with access to physicians. The increasing reliance on direct-to-consumer advertising by drug companies only heightens the tension between current marketing practices and good patient care.

Following this recommendation, many academic medical centers (Stanford, Yale, Harvard, Penn, Dartmouth, University of California) now prohibit the receipt or distribution of free drug samples

Has anyone informed and educated the industry and pharmaceutical representatives about this policy?

Not yet, though if approved it will need to be publicized among those who need to know about it. FAHC is sending a notice to all of its vendors of the changes in its vendor relations policies. Vendors at FAHC are aware of existing policies from prior communications. The State of Vermont already has a fairly strict disclosure law for pharmaceutical companies to disclose the gifts and support to physicians and hospitals throughout the state.

Does this policy apply to FAHC or just COM? If it applies to both, then do FAHC executives have a similar policy in place regarding industry?

This policy would apply to the UVM COM. FAHC already has vendor relations policies and has made changes to these policies that conform to the COM policies. The changes have been reviewed and approved by the Board of the Faculty Practice Plan. FAHC vendor relations policies apply to all employees, officers, directors and trustees, in addition to physicians. Even the existing policies prohibit vendor gifts, food and entertainment to executives. All such gifts were strictly prohibited in connection with the EMR selection process. FAHC new policies will add further restrictions, and as with the current policies, these will apply equally to administrators and physicians.

Do FAHC executives who make purchasing decisions have similar disclosure requirements?

Yes, FAHC has had a disclosure process under its Conflict of Interest Policy for over a decade. Conflicts of interest, once disclosed, are managed by the FAHC Board Audit Committee and its General Counsel. This policy has also been updated recently and will require more detailed, web-based disclosure of vendor ownership interests and compensation arrangements or financial interests at the time of appointment, upon privilege renewal, and prior to the initiation of any vendor-sponsored research project.

Why can't educational materials be accepted from pharmaceutical companies? What is the definition of educational material for patients, for MD's textbooks, instructional videos, etc.?

Gifts are not only *intended* to affect the behavior of those who receive them, they are *known* to affect the behavior of those who receive them. Thus, gifts whose acceptance may affect clinical decisions need to be avoided. Industry financial support of education, if it comports with Section III of the policy, is not prohibited.

(The policy would not prohibit educational gifts to departments or programs, as opposed to individuals.)

What is the definition of patient care area?

A patient care area is any area that relates to direct patient care and in which a patient is likely to be found. That would include clinics, the OR, ER, hospital wards etc.

“Interactions must be ethical and cannot create conflicts of interest that could endanger the integrity of our education and training programs, data integrity, patient safety, or the reputations of faculty members, staff members, students, trainees or the institution.” Though true, in my opinion should be the responsibility of the physician and not written into some sort of list/law of ethical/unethical practice. If the consensus is that this policy is to be imposed onto the physicians, then the same ethical standards/laws need to be imposed on every level of this organization (FAHC specifically, and not just the COM).

As with any law or regulation, it would not be necessary if everyone already complied with it. Policies and procedures are in place for most of the issues mentioned above. This policy relates strictly to the relationships with pharmaceutical and industry representatives and would appear to be the area most commonly treated as a routine part of our business.

There are times when we are in the market for large equipment (radio-surgery systems, robotic surgery equipment, stereotactic equipment) which cannot be easily transported or demonstrated locally. Under this policy, a trip sponsored by a manufacturer to a user site would have to be paid for by us and not by the company. Does this make sense for FAHC?

FAHC vendor relations policies permit vendors to pay for travel for training, after a product has been selected. During the selection process, FAHC prohibits vendor payment of travel and requires that travel expenses be handled like any other reasonable business expense.

Define the College--does this include FAHC property? I don't have time to meet with them any other place except in clinic

FAHC has similar policies that strictly regulate vendor activities on its campus. The UVM COM policy would govern activities at the College, as well as elsewhere if in connection with activities of the College (e.g., teaching, research).

We (infrequently) have representatives come to our post-clinic conference and they bring food. Is this now prohibited?

Yes. Such gifts would be prohibited by this policy.