

UC “Health Care Vendor Relations Policy” (Policy)

<http://www.ucop.edu/ucophome/coordrev/policy>

Frequently Asked Questions (FAQs) – Industry Support

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Section A. General Implementation Questions

A-1. Why is there a new UC Policy on relationships between health sciences faculty, staff, and students and Health Care Vendors?

This Policy, while new, supplements the provisions of the Political Reform Act and University Business and Finance Bulletin G-39 (Conflict of Interest Policy) adding restrictions to Health Care Vendor relationships in those circumstances where the potential drawbacks of the relationship outweigh the anticipated benefit. This Policy will help assure the public that relationships between members of the UC health sciences schools’ communities and Health Care Vendors do not unduly influence the conduct or outcomes of the schools’ research, education or patient care programs.

A-2 Why am I told by my campus that I cannot do something that is allowed by the Systemwide Health Care Vendor Relations Policy?

This Policy provides a minimum set of standards. Local policy may be more restrictive. In addition, there may be other relevant laws and policies that apply. This policy does not supplant any of those.

A-3 Do the Political Reform Act’s provisions regarding gifts and honoraria still apply?

Yes. If you want to participate in a University decision (e.g., helping to select a vendor), there are limits on allowable financial interests, such as income from lectures and reimbursement of out-of-state travel. Because the rules are circumstance-specific, you should contact your conflict of interest coordinator for questions regarding these limits.¹

¹ See: Section K. California Political Reform Act for more information.

In addition, the University has designated positions that are required to file annual financial disclosures. Employees holding those positions are “designated officials” and must file Statements of Economic Interests (Form 700). Designated officials are subject to complex regulations concerning gifts limits and honoraria. Designated officials must consider the restrictions of the Act in addition to this Policy.

A-4. Why is training needed as a part of implementing this policy?

Relationships with Health Care Vendors, properly managed, can benefit the University and our patients. Training efforts will help members of the health sciences schools’ community better understand how to appropriately manage their interactions with Health Care Vendors.

A-5. What will the training cover?

The training will detail what is allowable and what is not in establishing relationships between members of the health sciences schools’ community and Health Care Vendors for the areas of research, education and patient care. The training will also discuss how marketing programs influence provider behavior.

A-6. Who will participate in training?

All members of the UC health sciences schools’ community including faculty, administrators, staff, students, residents, fellows and trainees will receive training.

A-7. How will training be conducted?

Each campus will determine the suitable and appropriate methods to provide training for the target audiences, which may include in-person or online presentations and printed educational materials.

Section B. Vendor Supported Educational Activities – Held On Campus (or Medical Center Facility)

B-1. May Health Care Vendors financially support educational activities, such as grand rounds seminars, lecture series or other educational programs?

Yes, if the funds are donated to the University. However, the funds must be managed in accordance with the conflict-of-interest standards established by the relevant national governing body, such as the:

- [Accreditation Council for Continuing Medical Education \(ACCME\) Standards for Commercial Support.](#)
- [American Dental Association Continuing Education Recognition Program \(CERP\) Standards and Criteria.](#)
- [Accreditation Council for Pharmacy Education \(ACPE\) Standards for Continuing Pharmacy Education.](#)

Under the Policy, the relevant standards will apply, whether or not continuing education credit is offered for the educational activity.

If the relevant national governing body has not established conflict-of-interest standards for commercial support, the [ACCME Standards for Commercial Support](#) will apply. For purposes of brevity, the FAQs below refer to the ACCME Standards only.

B-2. May Health Care Vendors supply refreshments or food for educational activities sponsored by our department, such as grand rounds seminars and lecture series?

No. However, a Health Care Vendor may donate funds to a department as a gift to the “The Regents of UC.” The terms, conditions and purposes of the commercial support must be documented in a written agreement.

The department may, in turn, use the funds to support meetings, including purchasing food for meetings. The funds must be managed in accordance with ACCME Standards, even when the educational activity is not an accredited continuing education program. In addition, the cost of meals provided must conform to University policy.

Sponsors of the event are required to acknowledge the support to the learners. Informed learners are the final safeguards in assuring that an instructional activity is independent from commercial influence. You may state, for example, “This activity is supported in part by a donation from [name of Health Care Vendor].” It is not appropriate to say that the activity is “sponsored” by the company.

B-3. When a Health Care Vendor’s donation is used to support a seminar, may a Health Care Vendor representative be present at the seminar?

Usually not. The Health Care Vendor representative may attend only if the seminar is open to the public at large.

B-4. If a Health Care Vendor is allowed to donate funds to a department, which the department then uses to purchase food for grand rounds, lecture series or other educational activities, isn’t that the same as a Health Care Vendor directly supplying food for the activity?

No. There is a significant difference. Under the Policy, it is the department that decides how the funds will be used and supplies the food, not the Health Care Vendor. Health Care Vendors can attend educational events only if the event is open to the public and only as a member of the general public. This puts the Health Care Vendor at arm’s length distance from the event, and reduces the subconscious effect of gift-giving on behavior.

Section C. Education Activities – Held at an Off-Campus Site

C-1. Our department is organizing a continuing education activity at a hotel conference center. We are considering asking a Health Care Vendor to support the event, including the costs of a dinner event. Since this event is off-campus, does the Policy apply?

Yes. Policy provisions relating to gifts from Health Care Vendors govern both on-campus and off-campus activities. As with on-campus educational activities, Health Care Vendors may donate funds to your department, which may then be used to support the educational activity, including purchasing food for the off-campus educational activity. Since the continuing education activity is organized by the University, the funds must be managed in accordance with ACCME Standards as well as University rules regarding business meetings and entertainment events.

C-2. Can a faculty member within our department attend an educational conference that is organized by a professional society and sponsored by Health Care Vendors? The

conference registration includes breakfast, lunch and refreshments. Can the faculty member accept the meals and refreshments?

Yes. When an activity complies with ACCME Standards, the meals and refreshments from a Health Care Vendor would be allowable, because the Health Care Vendors are not directly paying for the meals and refreshments.

However, for meals and refreshments not included in the registration fee but paid for directly by the Health Care Vendor, the faculty member who attends must either decline the meals and refreshments or pay for his/her own share of the cost.

C-3. Our department often receives invitations to dinner lectures sponsored by Health Care Vendors, held at restaurants downtown. Could an individual covered by the Policy attend the event and accept the free dinner? Faculty attend the dinners on their own time.

If the invitee is not providing a service to the Health Care Vendor of similar or greater value than the dinner (e.g. giving a lecture, or participating in a panel or seminar), he or she could not accept the free dinner. However, the individual could attend the event and pay for his or her own dinner.

C-4. A Health Care Vendor representative has invited some of our faculty members and trainees to meet at the café of a nearby bookstore to listen to a scientific and educational presentation about a new drug. The representative provides coffee and cake. Does this conform to the Policy?

This is similar to the situation described in question C-3, above. The Policy allows attendance. However, the faculty and trainees who attend must either decline the refreshments or pay for their own share of the cost.

C-5. Our department hosts education meetings (e.g., Journal Club) at a local restaurant and sometimes at the home of faculty members. In the past, Health Care Vendor representatives attended and financially supported those meetings. Since the meetings are off-site, can we continue this practice to defray expenses?

No. Because the Journal Club is an educational activity organized by the University, the funds must be managed in accordance with ACCME Standards as well as University rules regarding business meetings and entertainment events. In addition, unless the Journal Club is a public event, the industry representatives can no longer attend the event.

C-6. Commonly, the sponsor of an off-site CME conference invites book publishers and industry company representatives to set up exhibit tables that attendees may visit during the conference. Sponsors usually charge the Health Care Vendor representatives an exhibit registration fee to offset the associated expenses for exhibit space (e.g., set-up, after hour security). Is this practice permitted under the University policy?

Yes. The course sponsor may charge Health Care Vendors a reasonable exhibit fee in accordance with ACCME rules and University policies for continuing medical education.

Section D. Educational Travel

D-1. A faculty member attends an annual educational conference that is sponsored by a professional society, and has been invited to give a lecture at the conference this year. Can

a Health Care Vendor pay for the faculty member's travel and hotel costs? What about an honorarium for the speech, or the faculty member's registration / admission fee?

No. In this example, the lecture would be considered service provided to the event organizer – the professional society - and not to the Health Care Vendor. Since the faculty member is not providing a service of similar or greater value to the Health Care Vendor, payment by the Health Care Vendor to the faculty member would be a gift, and not allowed.

D-2. Can a faculty member on a Health Care Vendor's Speakers Bureau accept free travel and an honorarium to attend a meeting whose purpose is to educate the faculty member about the studies related to the product about which they are to speak?

No. The expense reimbursement and honorarium are considered gifts and not allowable under the Policy since the faculty member's role is more analogous to that of an attendee than a participant.

D-3. If a company invites a faculty member to visit its facilities for a tour or to become educated about one of its products, may the company pay the faculty member for travel expenses and honoraria?

In general, when the faculty member is not providing a service of equal or greater value to the Health Care Vendor, the Health Care Vendor cannot reimburse travel expenses or pay an honorarium. In cases where training is required for proper equipment usage, the training should be written into the UC purchase contract for the Health Care Vendor's product. Otherwise, free training may be provided if the Health Care Vendor does not select the trainees and the individual receives expense reimbursement from the University. The Health Care Vendor may reimburse the University for its expenses.

As in the other examples, the University's conflict of interest rules also apply. So, if the Health Care Vendor were to directly reimburse a faculty member for travel costs (as in this example), the individual may be temporarily prohibited from participating in purchase decisions related to the Health Care Vendor, as the reimbursement may exceed the 12-month limits under conflict of interest rules.

D-4. If a Health Care Vendor invites a faculty member to visit its facilities to review and comment on a product, to discuss his or her independent research projects or to explore the potential for collaborative research, may the Health Care Vendor pay travel expenses and an honorarium?

Yes. If the faculty member is providing genuine services, the faculty member may accept from the Health Care Vendor reasonable compensation for time and travel expenses. Token advisory or consulting arrangements cannot be used to justify accepting compensation.

D-5. If a Health Care Vendor convenes a group of physicians or other health care providers or faculty to recruit clinical investigators or convenes a group of clinical investigators to discuss their results, may the Health Care Vendor pay their travel expenses?

Yes. Expenses may be paid if the meetings serve a genuine research purpose. One guide to their propriety would be whether the NIH conducts similar meetings when it sponsors multi-center clinical trials. When travel subsidies are acceptable, the guidelines emphasize that they be used to pay only for "reasonable" expenses. The reasonableness of expenses would depend on a

number of considerations. For example, reimbursement for meetings is likely to be problematic if overseas locations are used for exclusively domestic investigators. It would be inappropriate to pay for recreation or entertainment beyond the kind of modest hospitality described in the Policy.

The AMA Opinion 8.061 provides the following guidance about “genuine research purposes”: A number of factors can be considered. Signs that a genuine research purpose exists include the facts that there are (1) a valid study protocol, (2) recruitment of physicians with appropriate qualifications or expertise, and (3) recruitment of an appropriate number of physicians in light of the number of study participants needed for statistical evaluation.

D-6. May a Health Care Vendor compensate a faculty member for time and travel expenses for participating in focus groups?

Yes. As long as the focus groups serve a genuine purpose and are not used for promotional purposes, a faculty member may be compensated for time and travel expenses. The number of people used in a particular focus group or in multiple focus groups should be an appropriate size to accomplish the purpose, but no larger. If the faculty member is providing genuine services, reasonable compensation for time and travel expenses can be given.

D-7. If a faculty member attending a conference engages in interactive exchange, may his or her travel expenses be paid by a Health Care Vendor?

No. Mere interactive exchange would not constitute genuine consulting services.

Section E. Educational Materials (Materials Provided to All Attendees)

E-1. I attended a continuing education event and received a tote bag with a Health Care Vendor logo on arrival. Can I accept it?

Yes, you may, as long as it was available to all attendees and the event was conducted in accordance with ACCME Standards.

Section F. Health Care Vendor Preceptorships (Education)

F-1. May a Health Care Vendor representative “shadow” a physician or other health care provider or faculty while seeing patients, as part of a Health Care Vendor preceptorship?

If local policy permits, a Health Care Vendor representative may shadow a physician or other health care provider or faculty. However, the Health Care Vendor representative may see a patient in this setting only after the provider obtains the patient’s prior written authorization. Also, the Health Care Vendor representative must agree to patient confidentiality either by being subject to the HIPAA Business Associate Agreement (BAA) or by signing a confidentiality agreement.

F-2. Paragraph V.D.3. of the Policy refers to “Informal Training.” What is an example of “informal training”?

An example would be when a Health Care Vendor representative and a physician have a phone conversation in which the physician answers questions about the use of the Health Care Vendor’s product.

F-3. May a Health Care Vendor representative attend grand rounds or lectures as part of a Health Care Vendor preceptorship?

Yes, but if patient-identifiable information will be discussed, the patient must have first authorized the disclosure and the Health Care Vendor must agree to patient confidentiality either by being subject to the HIPAA Business Associate Agreement (BAA) or by signing a confidentiality agreement.

However, if the meeting is open to the general public, the only rules applying to attendance are those that apply to other members of the public.

Section G. Grants, Fellowships & Scholarships

G-1. Can trainees and students within our department receive scholarships from Health Care Vendors to attend educational conferences or to participate in other educational activities?

A Health Care Vendor cannot award a scholarship directly to a student or trainee. As an alternative, a Health Care Vendor may support the educational mission of the University by donating funds to the department (not to an individual), and the department may, in turn, apply the funds towards a student or trainee scholarship. The department, not the Health Care Vendor, must select the student or trainee for participation and determine whether the educational activity has merit. There must be no expectation that the student or trainee will provide something to the Health Care Vendor in return for participation in the educational activity. Individual campuses are encouraged to develop more specific guidance on this subject.

Section H. Research

H-1. My research activities include the use of Health Care Vendor donated supplies. How can I continue to advance my research effort with limited or no replacement funding for these supplies?

Research supply donations are not affected by this Policy.

H-2. Can I receive an unrestricted gift for research support from a Health Care Vendor?

Yes. Monetary gifts to the University for research are considered gifts to the University, even when there is a designated recipient. Existing University policies governing gifts and grants still apply.

Section I. Gifts & Samples, Products for Evaluation, Donations for the Free Clinic

I-1. When attending conventions or other professional meetings either on campus (such as vendor days) or away from campus, can I accept Health Care Vendor gifts or samples for evaluation or personal use?

No. You may not accept samples. Other items directly provided by Health Care Vendors (e.g., at their booths) also could not be accepted. However, if you paid a registration fee that included refreshments or give-aways (e.g., a tote bag), you would not be receiving a “gift” under the Policy and could attend the event and accept food and other items provided to all attendees.

I-2. I have always received samples of medical and dental devices for evaluation and for resident and student training labs. How can I continue to explore advances in technology for these items?

Departments, not individuals, can accept donated samples for evaluation and trial. The samples are not to be used after evaluation and trial is concluded, except for those patients otherwise unable to afford care.

I-3. In the past, Health Care Vendors have provided equipment and medications that have helped the University provide inexpensive or free health care in clinical settings that routinely serve disadvantaged patients. How can I continue to run my clinic and provide these services at affordable rates?

Equipment and medications donated by a Health Care Vendor may be used for all patients at University-sanctioned free clinics. They may also be used in regular clinics, but only for low income and disadvantaged patients. The quantity provided needs to be enough for either complete courses of treatment or, if continuing therapy is indicated, a substantial amount so that other sources of treatment can be sought. Providing less than that creates a significant risk that the patient will be unable to complete an appropriate course of therapy.

Supplies may be donated to departments or units, but not to individuals. Health Care Vendor donations must be acknowledged and no Health Care Vendor representatives are permitted in patient care settings. Follow Campus / Medical Center Purchasing policies and procedures concerning acceptance of products and samples.

I-4. I fit soft contact lenses and the various manufacturers provide diagnostic lenses for our use. Is this permitted under the Policy? Also, what about vendor-donated contact lens solutions used in the fitting process?

Yes, you are permitted under this Policy to accept and use vendor-supplied free samples of disposable trial devices, such as diagnostic lenses, when trial fitting is the standard of care. Solution necessary for the trial fitting also is allowed.

However, you should use diagnostic lenses and solutions from all appropriate suppliers. Supplying free solutions beyond that used for the initial trial would not be allowed, unless the patient cannot afford to purchase the solutions (see I-3 for more detail).

Section J. Miscellaneous Questions

J-1. Under the Policy, are sales or marketing representatives for a Health Care Vendor allowed to visit a UC Medical Center facilities or UC clinic?

Industry representatives are permitted to visit facilities only by appointment and only under very specific circumstances. Each campus has local policies and procedures governing pharmaceutical and sales representatives, such as pre-registration requirements, a vendor code of conduct, identification badges and procedures to protect patient confidentiality, including patient consent procedures. Industry representatives with appropriate knowledge of medical devices whose assistance may be needed in the operating room (OR) in order to provide technical support or advice, must pre-register with the locally-designated office (such as materials management) and adhere to patient confidentiality procedures as described in the Policy.

J-2. Is it true that Health Care Vendor sales and marketing representatives may no longer leave any written materials with employees?

Yes. Health Care Vendor branded sales and marketing materials from pharmaceutical and medical device companies can no longer be left in the clinics or with staff. The reason for this is

to avoid any expectation of future purchases on the part of the company, and to ensure that we do not promote a Health Care Vendor or its products to our patients.

J-3. In the past, our nursing group received industry support for our fund-raising event. Is this still allowable under the Policy?

Yes. The group may solicit corporate sponsorship for the University event, but University personnel must ensure that: (1) no company promotional materials are available at the event; (2) all event-associated fund-raising efforts are coordinated with the University Institutional Development / Philanthropy Office or the Gift Office to properly document gift acceptance and acknowledgment procedures; and (3) no donations are provided directly to any individual.

J-4. Are health care providers permitted to promote products for off-label uses?

Based on professional judgment and personal experience, physicians (and other health care providers who may legally prescribe drugs) may talk about products for off-label uses.

However, if the health care provider is receiving funding support from a company for studies of the company's products involving off-label uses, the activity may be viewed as "illegal marketing." To avoid the risk of bias, the health care provider should make sure that any such discussion is independent, based on facts and unbiased, and disclose financial relationships to the CME event sponsors and to the learners in accordance with ACCME Standards.

Section K. California Political Reform Act

The Political Reform Act prohibits a public official from making, participating in the making or in any way attempting to use his or her official position to influence a governmental decision in which he or she has a financial interest. All University employees are public officials as are members of University decision-making bodies.

K-1. What does it mean to participate in a decision?

You are making, participating in making, or influencing a governmental decision if you exercise discretion or judgment with regard to the decision, for example, if you advise or make recommendations to the decision-maker or prepare or present any report, analysis, or opinion which requires the exercise of judgment and the purpose is to influence the decision.

K-2. What does it mean to have a financial interest in a governmental decision?

The Political Reform Act sets out an eight-step process for determining whether you have a financial interest in a governmental decision that would require you to refrain from participating in any way in the decision. The pamphlet "Can I Vote?" provides an overview of your obligation under the Act and will assist you in determining whether you have a disqualifying financial interest. (<http://www.fppc.ca.gov/library/CanIVote7-05.pdf>)

Section L. Anti-Kickback Statute

L-1. What are the key points of the federal Anti-kickback laws?

The Anti-Kickback Statute provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration in order to induce or reward the referral of business reimbursable under any of the Federal health care programs.

L-2. What is a kickback?

Prohibited kickbacks include not only remuneration intended to induce or reward referrals of patients, but also remuneration intended to induce or reward the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service or item reimbursable by any Federal health care program. If either party has this intent, the remuneration may constitute a prohibited kickback. "Remuneration" is defined very broadly, and includes anything that benefits the recipient, either directly or indirectly.

If you are concerned that a vendor may be trying to induce or reward you, promptly discuss the issue with University counsel. While the arrangement may be legitimate, given the severe penalties, it is best to be sure.

L-3. What penalties does the Anti-Kickback law impose?

An Anti-Kickback offense is classified as a felony and is punishable by fines of up to \$25,000 and imprisonment for up to five years. Violations of the Anti-Kickback Statute may also result in the imposition of civil money penalties.

L-4. Does the law have any exceptions?

Yes. Safe harbor provisions—that is, provisions which set forth which practices will not be treated as criminal offenses—have been developed "to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial or innocuous arrangements." Congress intended the safe harbor regulations to be evolving rules that would be updated periodically to reflect changing business practices and technologies in the health care industry.

L-5. What are the Anti-Kickback safe harbor provisions?

The Anti-Kickback safe harbor provisions are complex, and you should consult University counsel if your contemplated arrangement is intended to comply with any safe harbor provision. Safe harbors address the following types of payment practices:

- Investment interests
- Space rental
- Equipment rental
- Personal service and management contracts
- Sale of practice
- Referral services
- Warranties
- Discounts
- Employee compensation
- Group purchasing organizations
- Waiver of beneficiary coinsurance and deductible amounts
- Increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans
- Price reductions offered to health plans
- Practitioner recruitment
- Obstetrical malpractice insurance subsidies
- Investments in group practices
- Cooperative hospital service organizations

- Ambulatory surgical centers
- Referral arrangements for specialty services
- Price reductions offered to eligible managed care organizations
- Price reductions offered by contractors with substantial financial risk to managed care organizations
- Ambulance replenishing

L-6. What are some examples of kick-backs?

Example of Anti-kickback Violation for Marketing or Consulting Service: A vendor agrees to pay a physician in private practice \$1,000 per month, for “education/services.” However, there is no documentation of any marketing services performed by the physician on behalf of the vendor, and their conversations link the payment to the physician’s use of the vendor’s products.

Example of Anti-kickback Violation for an Indirect Payment: A hospital leases space to a pharmaceutical company for storage of certain drugs. The rent paid to the hospital is very expensive compared to the market value of the leased space. A portion of the lease amount is intended to be an indirect payment to the hospital in return for recommending the pharmaceutical company’s products.

Section M. Additional Resources

- Policy and Guidelines Regarding Acceptance of Gifts and Gratuities by Employees Under California’s Political Reform Act <http://www.ucop.edu/ucophome/coordrev/policy/1-24-01att.pdf>
- Limitations and Restrictions on Gifts, Honoraria, Travel and Loans <http://www.fppc.ca.gov/factsheets/giftstate.pdf>
- Travel Guide for California Officials and Candidates <http://www.fppc.ca.gov/index.html?id=32>
- AMA Ethical Opinion, E-9.011, “Continuing Medical Education”, http://www.ama-assn.org/apps/pf_new/pf_online?f_n=browse&doc=policyfiles/HnE/E-9.011.HTM&&s_t=&st_p=&nth=1&prev_pol=policyfiles/HnE/E-8.21.HTM&nxt_pol=policyfiles/HnE/E-9.01.HTM&
- ACCME Standards for Commercial Support: http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf
- American Dental Association Continuing Education Recognition Program Standards and Procedures: <http://adamailer.org/prof/ed/ce/cerp/standards.pdf>
- Accreditation Council for Continuing Pharmacy Education Accreditation Standards for Continuing Pharmacy Education: http://www.acpe-accredit.org/pdf/CPE_Standards_Final_092107.pdf