

Health Care Vendor Relations Policy

(See also Frequently Asked Questions)

I. Summary

All employees of the University of California are subject to the conflict-of-interest provisions of the Political Reform Act and to the University of California policies delineated in Business and Finance Bulletin G-39 (Conflict of Interest Policy). The Health Care Vendor Relations Policy is intended to supplement the aforementioned provisions as follows:¹

V.A. Gifts and Compensation Provided by Vendors: New requirement.

Prohibits gifts from health care vendors to individuals. Provides alternative methods for health care vendors to support educational programs, provide samples for evaluation, and provide samples for low income patients

V.B Interaction between Health Care Vendors and University personnel: New requirement. Implements patient confidentiality provisions and provides that Health Care Vendors may not make uninvited sales calls.

V.C. Responsibilities of committees that oversee purchasing decisions: This provision re-states current University of California policy without change.

V.D. Vendor preceptorships: New requirement that Health Care Vendor paid preceptorships (education programs) are to be conducted as either University courses or as Continuing Education courses.

V.E. Publicity of industry support: This provision re-states current University of California policy without change.

V.F. Anti-kickback law: This provision re-states current University of California policy without change.

V.G. Education: New requirement for training on Health Care Vendor interactions for all affected individuals.

This Policy establishes minimum standards for campus implementation of Health Care Vendor relationship policies. Campuses may implement stricter policies.

II. Purpose

The Political Reform Act, which governs University of California employees, aims to remove bias from their decisions. The University of California Policy and Guidelines Regarding Acceptance of Gifts and Gratuities by Employees under California's Political Reform Act (January 2001) adds the following statement:

¹ See Section V of this policy for a full explanation of the requirements.

In addition to compliance with the requirements of law, University officers and employees must avoid the appearance of favoritism in all of their dealings on behalf of the University. All University officers and employees are expected to act with integrity and good judgment and to recognize that the acceptance of personal gifts from those doing business or seeking to do business with the University, even when lawful, may give rise to legitimate concerns about favoritism depending on the circumstances.

Recent research shows that certain health care vendor activities allowed under the Political Reform Act, such as the provision of gifts of nominal value, may affect provider behavior and give the appearance of favoritism. This policy supplements the provisions of the Political Reform Act and University Business and Finance Bulletin G-39 (the Conflict of Interest Policy) in order to reduce the influence of health care vendors on the decisions made by University of California health care professionals.

Additionally, while offers of free or discounted goods, gifts, benefits, donations, honoraria, travel expenses or grants for teaching or research programs frequently serve an important and socially beneficial function, they may, in some circumstances, violate the federal Anti-Kickback Statute and similar California state law. Guidance on compliance with this law is provided hereinafter.

III. Applicability

This policy applies to those members of the UC community who work, train, or are students at health care locations or in health professional schools (e.g., medicine, dentistry, nursing, pharmacy, optometry, veterinary medicine).

Except as specifically noted, this policy applies both to on and off-campus activities.

IV. Definitions

The terms “Health Care Individual”, “Gift” and “Health Care Vendor” have special definitions for the purpose of this policy.

- A. **UC Community:** Regents, faculty and other academic personnel, staff, students, residents, volunteers, contractors, agents, and others associated with the University.
- B. **Health Care Individual:** A member of the UC Community who works, trains, or is a student at health care locations or in health professional schools.
- C. **Gift to a Health Care Individual:** Payment to a Health Care Individual or provision to of free or discounted items, medical samples for personal use, food, or travel when the Health Care Individual is not providing a service of similar or greater value to the Health Care Vendor. For example, pens, notepads, free textbooks, free meals, payment for attending a meeting, and samples are all considered Gifts. Honoraria for a specific service rendered (e.g., delivering a speech) are not considered Gifts.

1. A Gift to the University is considered a Gift to the Health Care Individual under either of the following circumstances:
 - a) The Gift is conveyed by the Health Care Vendor directly to the Health Care Individual (or group of Health Care Individuals) -- e.g., the Health Care Vendor brings food to a meeting.
 - b) The Health Care Vendor selected or participated in selecting the ultimate recipient of the Gift.
2. Exclusions from the definition of a Gift:
 - a) Items provided at a discount or free as part of a University contract;
 - b) Items provided at a discount or free as part of a research project;
 - c) Prizes or awards from bona fide competitions;
 - d) A Gift from one of the following relatives or domestic partners, unless the donor is acting as an agent or intermediary for a Health Care Vendor:
 - (1) spouse, child, parent, grandparent, grandchild, brother, sister, parent-in-law, brother-in-law, sister-in-law, nephew, niece, aunt, uncle, or first cousin;
 - (2) registered domestic partner, or the registered partner's child, grandchild, parent, brother, or sister; or
 - (3) the spouse or registered domestic partner of any person listed above.
 - e) Free admission and refreshments and similar non-cash nominal benefits provided to a Health Care Individual during the entire event at which the Health Care Individual gives a speech, participates in a panel or seminar, or provides a similar service;
 - f) Free admission and refreshments and similar non-cash nominal benefits provided to a Health Care Individual during a training session provided by the Health Care Vendor for the purpose of training the Health Care Individual in the use of the Health Care Vendor's product. Note that free (i.e., Health Care Vendor paid or sponsored) travel or lodging would be a Gift. If free training of UC employees or associates is anticipated, the training activity should be referenced in the purchase contract for the Health Care Vendor's product. Additional

free training may be provided if the selection of attendees is not made by the Health Care Vendor and the reimbursement is made through the University, not directly to the individual;

- g) A rebate or discount that is made in the regular course of business to members of the public without regard to their status as a Health Care Individual (e.g., a coupon in the newspaper for a discount on a pain reliever); and
- h) Materials provided by the organizers of a professional meeting that are available to all attendees when the meeting is conducted under national continuing education accreditation body guidelines (e.g., a tote bag with a Health Care Vendor's name on it).

D. **Health Care Vendor:** a company or its representative or the agent of a company that either produces or markets drugs, devices, nutritional products, or other medical products or services.

V. Policy

A. Gifts and Compensation Provided by Vendors

1. This section applies to University employees and students at all locations, and to all other Health Care Individuals when at University-owned or operated locations.
2. Gifts from Health Care Vendors to a Health Care Individual are prohibited.
3. In circumstances where Health Care Vendors wish to provide a Gift in support of the mission of the University (e.g., food for conferences or payment for educational travel), appropriate alternatives may be available. For example, in lieu of providing free food or payment for educational travel, Health Care Vendors may donate funds to a University unit (e.g., department or division) to support meetings. Such funds will be managed in accordance with national continuing education accrediting body conflict of interest standards even when the meetings are not accredited continuing education programs. Donations or Gifts will not have an effect on the Health Care Vendor's ability to communicate with University employees or trainees.
4. Free samples, vouchers, supplies, or equipment designated for a Health Care Individual are considered Gifts and are prohibited. Vendors may donate their product to a unit of the University if the administrative head of the unit approves the donation and the donation is:
 - a) limited to the amount necessary for evaluation or education, and not intended to stock the University for patient care purposes on an

ongoing basis,

- b) limited to the amount necessary for trial fitting of a device when the trial device is disposable and trial fitting is the standard of care, or
- c) restricted to use in University-sanctioned free clinics, or to regular clinics for low income and indigent patients. The quantity provided to the patient must be sufficient for either the complete course of treatment or, if continuing therapy is indicated, a substantial amount so that other sources of treatment can be sought.

Sample donations are also subject to all other policies of the University, including those addressing drugs, devices, and investigational items.

B. Interaction between Health Care Vendors and University personnel

1. This section applies to University-owned or operated locations.
2. Financial relationships between the Health Care Vendor and the University or Health Care Individuals at the University shall not affect the ability of the Health Care Vendor to make sales calls.
3. Vendors may make in-person sales calls only at the invitation of appropriate University personnel. Such sales calls may take place only in non-patient-care areas. Exceptions can occur by local policy when it is determined that there is a compelling need for the call to occur in a patient care area. For sales calls that take place in a patient care area, patient privacy laws (including HIPAA) will be followed. The Health Care Vendor may not access patient information during a sales call unless the patient has given written authorization regarding such access.
4. Vendors may also enter patient care areas when:
 - a) Providing health care support services, such as:
 - (1) An orthopedic device manufacturer or its representative determines and delivers the appropriate range of sizes of a prosthesis for the surgeon to use during a particular patient's surgery.
 - (2) The device manufacturer or its representative is present in the operating room, as requested by the surgeon, to provide support and guidance regarding the appropriate use, implantation, calibration or adjustment of a medical device for that particular patient.

- (3) A representative of a medical device manufacturer views health information, such as films or patient records, to provide consultation, advice or assistance where the provider, in her professional judgment, believes that this will assist with a particular patient's treatment.
 - b) Servicing equipment, including installation and removal;
 - c) Invited for specific vendor service at the request of a representative of the University for its health care operations; or
 - d) Acting as a member of the general public (e.g., as a patient).
5. Unless acting as a member of the general public, the Health Care Vendor will agree to a confidentiality agreement to protect the health information of University of California patients. The following are acceptable in lieu of a confidentiality agreement:
 - a) a HIPAA business associate agreement,
 - b) a determination that the Health Care Vendor is acting as a member of a covered entity (as defined by HIPAA), or
 - c) provisions to ensure that the Health Care Vendor does not have access to protected health information.

C. Responsibilities of committees that oversee purchasing decisions

1. This section applies to University-owned or operated locations.
2. Hospital and medical group formulary committees and other committees overseeing purchases of drugs medical devices, nutritional products, or other medical products or services will follow the Political Reform Act regulations, which include restrictions on the participation of Health Care Individuals who have financial relationships with Health Care Vendors affected by the purchase decisions.

D. Vendor preceptorships

1. This section applies to University-owned or operated locations.
2. Vendor preceptorships are educational programs for Health Care Vendor representatives. Vendors have the same access to the official educational offerings of the University as other members of the general public. Generally, these are official courses of the University or continuing education programs under the auspices of the University's continuing education departments and

in accordance with national continuing education accrediting body guidelines. Departments may not produce Health Care Vendor preceptorships without oversight by the continuing education department.

3. Informal training, conducted at no charge to the Health Care Vendor, is excepted from this restriction.

E. Publicity of industry support

1. California's Public Records Act provides that information about industry support of the University is a public record.
2. APM 025 requires that faculty report annually any paid consulting arrangements. These reports are public records.

F. Anti-kickback law

1. The federal Anti-Kickback Statute prohibits the knowing and willful solicitation or receipt, offer or payment, overtly or covertly, directly or indirectly, of any remuneration (anything of value) in return for patient, product, or service referrals, or to induce such referrals. This prohibition extends to arranging for, recommending, or approving any purchase, lease or order of any goods and services that could potentially be reimbursed by Medicare or any state health care program.
2. Gifts or responses to solicitation for donations must not be allowed to factor into Health Care Vendor selection. Dealing with a Health Care Vendor who implies any link between Gifts or donations and Health Care Vendor selection must be discontinued. Legal guidance should be sought if there is any uncertainty about the propriety of a particular situation.
3. See appendix C for more information.

G. Education

All Health Care Individuals to whom this policy applies shall receive training regarding interactions with Health Care Vendors.

VI. Appendices

A. References

1. University of California Policy and Guidelines Regarding Acceptance of Gifts and Gratuities by Employees under California's Political Reform Act (January 2001) <http://www.ucop.edu/ucophome/coordrev/policy/1-24-01att.pdf>

2. APM 025-Conflict of Commitment and Outside Activities of Faculty Members <http://www.ucop.edu/acadadv/acadpers/apm/apm-025-07-01.pdf>
3. Business and Finance Bulletin-G39 Conflict of Interest Policy and Compendium of Specialized University Policies, Guidelines, and Regulations Related to Conflict of Interest
<http://www.ucop.edu/ucophome/policies/bfb/g39.pdf>
4. California Public Records Act (Government Code section 6250 et seq)
5. Conflict of interest provisions of the California Political Reform Act (Government Code section 87100 et seq) and the regulations of the Fair Political Practices Commission (California Code of Regulations title 2 section 87100 et seq)
6. Privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA)

B. Other definitions

1. **Health care** (45CFR160.103) means care, services, or supplies related to the health of an individual. Health care includes, but is not limited to, the following: (1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body; and (2) Sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.
2. **Registered Domestic Partner** (California Family Code Section 297):
 - a) Domestic partners are two adults who have chosen to share one another's lives in an intimate and committed relationship of mutual caring.
 - b) A domestic partnership shall be established in California when both persons file a Declaration of Domestic Partnership with the Secretary of State pursuant to this division, and, at the time of filing, all of the following requirements are met:
 - (1) Both persons have a common residence.
 - (2) Neither person is married to someone else or is a member of another domestic partnership with someone else that has not been terminated, dissolved, or adjudged a nullity.

(3) The two persons are not related by blood in a way that would prevent them from being married to each other in this state.

(4) Both persons are at least 18 years of age.

(5) Either of the following:

(a) Both persons are members of the same sex.

(b) One or both of the persons meet the eligibility criteria under Title II of the Social Security Act as defined in 42 U.S.C. Section 402(a) for old-age insurance benefits or Title XVI of the Social Security Act as defined in 42 U.S.C. Section 1381 for aged individuals. Notwithstanding any other provision of this section, persons of opposite sexes may not constitute a domestic partnership unless one or both of the persons are over the age of 62.

(6) Both persons are capable of consenting to the domestic partnership.

c) "Have a common residence" means that both domestic partners share the same residence. It is not necessary that the legal right to possess the common residence be in both of their names. Two people have a common residence even if one or both have additional residences. Domestic partners do not cease to have a common residence if one leaves the common residence but intends to return.

C. Other relevant guidance

1. The Federal Department of Health Services Office of Inspector General has published compliance guidance, including the following (Federal Register, Vol. 68, No. 86 pp 23731- 23743):

... the anti-kickback statute prohibits in the health care industry some practices that are common in other business sectors. In short, practices that may be common or longstanding in other businesses are not necessarily acceptable or lawful when soliciting federal health care program business.

The anti-kickback statute is a criminal prohibition against payments (in any form, whether the payments are direct or indirect) made purposefully to induce or reward the referral or generation of federal health care business. The anti-kickback statute addresses not only the offer or payment of anything of value for patient referrals, but also

the offer or payment of anything of value in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or ordering of any item or service reimbursable in whole or part by a federal health care program. The statute extends equally to the solicitation or acceptance of remuneration for referrals.

* * *

While educational funding can provide valuable information to the medical and health care industry, manufacturer grants to purchasers, GPOs², PBMs³ and similar entities raise concerns under the anti-kickback statute. Funding that is conditioned, in whole or in part, on the purchase of product implicates the statute, even if the educational or research purpose is legitimate. Furthermore, to the extent the manufacturer has any influence over the substance of an educational program or the presenter, there is a risk that the educational program may be used for inappropriate marketing purposes.

To reduce the risks that a grant program is used improperly to induce or reward product purchases or to market product inappropriately, manufacturers should separate their grant making functions from their sales and marketing functions. Effective separation of these functions will help insure that grant funding is not inappropriately influenced by sales or marketing motivations and that the educational purposes of the grant are legitimate. Manufacturers should establish objective criteria for making grants that do not take into account the volume or value of purchases made by, or anticipated from, the grant recipient and that serve to ensure that the funded activities are bona fide. The manufacturer should have no control over the speaker or content of the educational presentation. Compliance with such procedures should be documented and regularly monitored.

* * *

Manufacturers, providers, and suppliers of health care products and services frequently cultivate relationships with physicians in a position to generate business for them through a variety of practices, including gifts, entertainment, and personal services compensation arrangements. These activities have a high potential for fraud and abuse and, historically, have generated a substantial number of anti-kickback convictions.

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² Group purchasing organizations

³ Pharmacy benefit managers

Absent unusual circumstances, grants or support for educational activities sponsored and organized by medical professional organizations raise little risk of fraud or abuse, provided that the grant or support is not restricted or conditioned with respect to content or faculty.

UC “Health Care Vendor Relations Policy” (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