

Health Care Vendor Relations Policy

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.

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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.

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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.