DIVISION CHAIRS
Chair William “Bill” Drummond (B)                            Chair Thomas “Tom” Cogswell (R)
Chair Linda F. Bisson (D)                                             Chair James “Jim” W. Posakony (SD)
Chair Timothy “Tim” J. Bradley (I)                             Chair David Gardner (SF)
Chair Elizabeth Ligon Bjork (LA)                              Chair Joel Michaelsen (SB)
Chair Shawn Kantor (M)                                                Chair Quentin Williams (SC)

RE: Divisional Review of the Proposed Guidelines on Vendor Relations

Dear Division Chairs:

On behalf of Chair Michael T. Brown, the above revised proposed guidelines is being forwarded for your review and comments. As background information, in June 2007, the Academic Council discussed the outcome of the senate-wide review of this proposal and requested that the UCOP Office of Clinical Services withdraw the proposal and further requested that any revised proposal include a set of guidelines that would regulate policy at the broadest level and allow campuses flexibility at the campus level to act consistently with individual contexts and needs. Moreover, a revised proposal should offer a more comprehensive and forceful rationale than accompanied the original proposal. A revised proposal was submitted by the Office of Clinical Services for consideration by the Academic Council at its September 2007 meeting. At that meeting, the Academic Council determined that the proposal would be sent out to just the Divisions for review.

The revised proposal is attached both as a “clean” version and one with track changes. We would very much appreciate that responses be submitted by no later than November 26, 2007.

Cordially,

Maria Bertero-Barceló, Executive Director
Academic Senate

Encl: 1
Copy: Academic Council Chair Michael T. Brown
Divisional Senate Directors
Michael Brown  
President of the ACADEMIC SENATE  

Re: Academic Senate Review of the Draft Proposed Guidelines Regarding Vendor Relations  

Dear Michael,  

I want to thank the Academic Council for their review of the proposed Draft Guidelines Regarding Vendor Relations. I have been looking carefully at the Senate’s response. The attached revised policy has been significantly improved as a result of the Senate’s suggestions, and I request council’s reconsideration for endorsement.

The original proposal contained many elements, several of which were contained in my December 6, 2006 transmittal letter to Chair Oakley but not in the draft policy itself (“Three Additional Proposed Policies”). These three preliminary proposals were not fleshed out by me and elicited significant Council criticism—for vagueness, limited scope and for their effect on academic freedom. The Academic Council’s request to withdraw the entire policy and revise appeared to be based upon these features – features that now have been excised from the proposal.

As to the other comments, I have point-by-point responses in this letter. I appreciated the comments and changed the document in a number of places to address the Senate’s concerns.

Before presenting the point-by-point handling of Council concerns, I’d like to inform you of two items added to this version that did not appear in the policy that Academic Council reviewed previously. The policy now references existing University policy and federal law that would be relevant to the reader of this policy: APM 025 (lines 206-207) and the federal Anti-kickback Statute (lines 208-221). Neither addition represents a change to current University policy.

Let me add what I believe many, if not all, faculty know: there is a large and growing body of literature that shows the activities banned by this policy have an unwanted effect upon the University and our patients, which should be weighed against the benefits, such as free lunches and gifts, that would no longer be enjoyed under this policy. Research shows that these unwanted effects are the result of unconscious social effects of such relationships and are not caused by bad people intending to do bad things.

We have many units, large and small, that are grappling with this issue. The policy-writing effort was initiated at the request of leaders at many of these units. Some have implemented versions of this policy

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1 Line numbers refer to the revised “Health Care Vendor Relations Policy” Version date: 9/5/200710:20:00 AM, attached.
already. Others are waiting for systemwide guidance. It is important to have consistency and coherence across the system in how UC addresses this nationwide issue. The proposed policy is consistent with those being implemented at other health sciences institutions, such as Stanford and Yale, and is consistent with the approaches recommended by the scientific literature.

**Response to Academic Senate Review and letter of Academic Council Chair John Oakley, July 12, 2007**

Following is a list of the recommendations and other comments in Chair Oakley’s letter and my replies to each:

*Council Recommendation*: UC should establish comprehensive guidelines to cover interactions between all vendors and all UC faculty and staff (UCI, UCLA, UCR, UCORP, UCPT). Including volunteer faculty (UCSF); other specific UC locations, schools and units (see full UCFW letter); and relationships between vendors and administrators (UCFW).

*Reply*: Council is correct to suggest that there are broader concerns with vendor-UC relations than those being addressed under the present policy and I am willing to work with the Academic Council if you wish to consider extending this to the University as a whole. Yet, it appears worthwhile to proceed first with clinical administrators, staff, and faculty. One reason is simply an administrative one — the issues are best delineated there. A second and more substantive reason is that there is a difference between clinicians and others, related to the fiduciary duty that clinicians have to their patients. Many (but perhaps not all) other faculty and administrators do not have quite the intensity of duty that clinicians do. Moreover, the accumulating corpus of research on clinicians and the effects of vendor relationships is impressive, consistent in its findings, and growing to the extent that it has become a policy matter.

A clinician-patient relationship is a fiduciary relationship, and carries with it elevated standards of behavior. The duty of loyalty requires subordination of the clinician’s other interests to those of the patient. Research on the effects of vendor relationships on clinicians consistently shows an improper subconscious effect on the loyalty a clinician owes to the patient.

*Council Recommendation*: In Section III, Applicability, remove the word “human” from both lines 26 and 27, and add the word “veterinary” to the listing of health schools; in the interests of clarity, “residents” should be added to those to whom this policy applies, so that line 26 would read, “…all University employees, residents, and students….”.

*Reply*: Agree with and have implemented the recommendation (lines 51-53).

*Council Recommendation*: Policy should be broadened to include vendors of most, if not all, areas regulated by the FDA, and similar products related to animal health (e.g., artificial joints, CT scanners, IV lines, animal drugs, human blood and tissues, etc.) (UCFW).

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2 The following features are consistent with a fiduciary relationship, and are prominent in health care:

- Fiduciaries provide services to the entrustors
- Fiduciaries must have power over the entrustor to be effective
- The sole purpose of the relationship is to serve the entrustor
- An entrustor finds it difficult to assess the quality of the fiduciary’s performance as fiduciary has expertise the entrustor lacks
- Cost of monitoring use of power high
- Alternative controls on fiduciary are too weak
Reply: Agree with and have implemented the recommendation. The definition of vendor (lines 105-107) now includes all the categories in the recommendation.

Council Request for Clarification: Travel/Lodging: For demonstrations or training sessions which do not require substantial travel, and hence are not covered in the proposal, clarify the limits for free admission, refreshments, and similar non-cash benefits to be provided by the vendor for the training session (UCSF).

Reply: The section on training sessions (lines 95-100) does apply even when there is no substantial travel. The term “nominal” as used in this section is identical to that used in the state conflict of interest rules, and is intended to allow some common-sense flexibility. We will be providing FAQs and examples to help individuals navigate these gray areas.

Council Request for Clarification: Boundaries: The proposal does not define the physical boundaries of where the policy would be in effect, nor adequately clarify affected populations (UCPB).

Reply: Agree with and have implemented the recommendation. The policy now distinctly indicates the affected populations and the physical boundaries See lines 54, 110-112, 142, 185, and 193.

Council Request for Clarification: The policy should clarify that vendors cannot legally provide health care – i.e., different terminology should be used in Part V.C.3.a [Part V.B.3.a. in the current draft] (UCPT).

Reply: I agree that the terminology was confusing and have corrected that by changing the term from “providing health care” to “providing health care support services” (e.g., line 154). Technically, the vendors are providing “health care” as defined by the federal government (lines 262-269) but that term could be misinterpreted in the current context.

Council Request for Clarification: The policy (paragraph IV.B.2 (c)) should be amended to exclude gifts from domestic partners and relatives of domestic partners to the same extent that gifts from spouses and relatives of spouses are excluded. See California Family Code § § 297.5 (a) and (g). (UCFW)

Reply: Agree with and have implemented the recommendation. See lines 82-89.

Council Concern for Unintended Consequences: In particular, gifts addressed to The Regents that are intended to be given to an individual’s various donor’s accounts should not be prohibited (UCI).

Reply: The proposed prohibition on unrestricted gifts will not be incorporated into the policy. See my reply to “Three Additional Proposed Policies”, below.

Council Concern for Unintended Consequences: UCSF supports the use of drugs and devices for evaluation and education, as stated in proposed policy, but recommends setting a three-month limit to the evaluation/education period (UCSF).

Reply: The proposed policy allows local flexibility on setting limits (lines 23-24). Different schools have differing needs for evaluation and education, and some may find the three-month limit too restrictive.

Council Concern for Unintended Consequences: The guidelines as written would prohibit most casual interactions between clinicians and vendors and impose an unnecessary layer of bureaucracy and micromanagement onto those interactions and the acceptance of even small gifts (UCAF).

Reply: Research shows that these casual interactions and acceptance of small gifts significantly change provider behavior. That is why industry spends so much money on these efforts. Yet neither the University nor our patients benefit in any significant way in this regard.

“A research-informed understanding of conflict of interest has important implications for policy. Specifically, the interventions mentioned earlier—limiting gift size, educational initiatives, and
mandatory disclosure—are unlikely to eliminate bias because they rest on a faulty model of human behavior. The finding that individuals are not aware of their bias, even when taught about it, suggests that the problem cannot be dealt with effectively through training.

“The finding that the bias is strong, even in studies with small stakes, suggests that a policy of limiting gift size is unlikely to eliminate bias. Because even small gifts can subtly bias how arguments are evaluated, they can be surprisingly influential. The sheer ubiquity of trinkets given by pharmaceutical companies is evidence of their effectiveness; why else would profit-minded companies continue to provide them? Thus, policies against gifts should not be limited to large gifts.”

_Council Concern for Unintended Consequences:_ The proposal stigmatizes the acceptance of any gift from vendors, including bags containing conference materials at professional meetings and the like. Although aware of the research that suggests that even minor gifts can influence behavior, some felt that the regulations placed an unfair burden of guilt or refusal on the recipients of such gifts regardless of the context or the gift’s triviality (UCPB).

_Reply:_ We should avoid the stigmatization that comes from the assumption that the effects of gifts upon clinicians are a matter of deliberate choice. Rather, the research indicates that clinicians’ resultant biases are unintentional. Moreover, the matter of unconscious bias should be part of the training clinicians receive on clinician-industry interactions (lines 223-224).

_Council Concern for Unintended Consequences:_ There are certain situations in which the provision of pharmaceutical or device samples (i.e., glucose meter, medical or dental implants) may be of enormous benefit to indigent patients (UCLA, UCSD – see recommended language for V.B.3 [now V.A.4] in appended letter).

_Reply:_ Agree with and have implemented the recommendation. See lines 133-138.

_Council Concern for Unintended Consequences:_ Policy does not mention gifts (samples) from a vendor to a clinic or unit that has one person sign for them, and be responsible for their receipt (UCFW).

_Reply:_ Local implementation procedures will specify how samples are received. See lines 139-140.

_Council Concern that Implementation/Enforcement Mechanisms are Unclear:_ Proposal is unclear as to how it will be implemented and how faculty would be held accountable for violations. The proposal appears redundant with the Faculty Code of Conduct (UCI, UCSC, UCSF, UCFW). If implemented, the policy should be revisited and assessed in a few years (UCSD).

_Reply:_ University policies largely rely on trusting individuals to do the right thing once they are informed about what the right thing is. For example, policies such as APM 025 “Conflict of Commitment and Outside Activities of Faculty Members” and APM 028 “Disclosure of Financial Interest in Private Sponsors of Research” primarily rely on voluntary reporting.

This present policy, while consistent with the Faculty Code of Conduct, is not redundant, as it addresses, specifically, the relationship between members of the UC committee and vendors.

I agree that this policy should be revisited and reassessed and commit to doing so two years after implementation.

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3 Dana J, Loewenstein G. A social science perspective on gifts to physicians from industry. _JAMA_. 2003; 290:252-255.
Council Concern that Policy Intrudes on Local Authority: The system-wide proposal is an unjustifiable intrusion by central administrative authorities into decision-making that should best be left in the hands of individuals, or their departments, under the guidance of local leadership (UCLA, UCPB).

Reply: This policy addresses an issue that affects many units, large and small, within the entire University of California system. As with other system wide policies, this one defers specific implementation details to the campuses. It also allows local units to adopt more restrictive policies.

Council Recommendation: Amend Section V.G to call on all schools and units to develop a comprehensive curriculum to instruct faculty, staff, and trainees on relations with industry (UCLA, UCSD).

Reply: The policy calls for training (lines 223-224). It was specifically left vague to allow schools and units to make independent curriculum decisions. However, if the Academic Senate wishes to mandate a comprehensive curriculum on this, I will change this section accordingly.

Council Identification of Issues Not Covered by Policy: Patient information documents: providing patient information documents to patients in the clinics is acceptable as long as such documents are judged to be free of bias by the clinic chief or his/her designee. These documents should be accompanied by a disclaimer from the relevant department or school indicating that the information was not an endorsement of either the vendor or the specific products described in the document (UCSF).

Reply: Local units can decide upon the approval process for patient information documents.

Council Concern about Three Additional Proposed Policies: Summary of Responses * * *

Reply: These proposed policies were not intended to be included in the draft policy. They were forwarded to the Academic Senate for discussion, because, unlike the items in the proposed policy, they dealt directly with academic activities: publication and funding. After review of the comments, I have decided not to include any of these three proposals in the draft policy. However, the Senate’s discussion of the proposed policies was informative and appreciated.

Again I thank you and I thank the Academic Council for its comments. Attached is the revised policy for your reconsideration for endorsement.

Sincerely,

Rory Jaffe
Proposed 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 University Business and Finance Bulletin G-39 (Conflict of Interest Policy). This policy supplements those provisions as follows (full text is in section V “Policy”):

A. Gifts and Compensation Provided by Vendors: New policy. Prohibits gifts from vendors to individuals. Provides alternative methods for vendors to support educational programs, provide samples for evaluation, and provide samples for low income patients.

V.B. Interaction between vendors and University personnel: New policy. Implements patient confidentiality provisions and provides that vendors may not make uninvited sales calls.

V.C. Committees overseeing purchase decisions: States current policy without change.

V.D. Vendor preceptorships: New policy. Requires that vendor preceptorships (education programs) are to be conducted as either University courses or as Continuing Education courses.

V.E. Publicity of industry support: States current policy without change.

V.F. Anti-kickback law: States current policy without change.

V.G. Education: New Policy. Asks for training on vendor interactions for all affected individuals.

This policy establishes minimum standards for campus implementation of 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:

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 (Conflict of Interest Policy) in order to reduce the influence of 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 schools (e.g., medicine, dentistry, nursing, pharmacy, optometry, veterinary medicine). Except as specifically noted, this policy applies both on and off-campus.

IV. Definitions

The terms “individual”, “gift” and “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. **Individual**: A member of the UC Community who works, trains, or is a student at human health care locations or in human health schools.

C. **Gift to an individual**: Payment to an individual or provision to an individual of free or discounted items, medical samples for personal use, food, or travel when the individual is not providing a service of similar or greater value to the vendor. For example: pens, notepads, free textbooks, free meals, payment for attending a meeting, and samples are all considered gifts. Honoraria and travel, food, and lodging expense reimbursement for speakers’ training are 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 individual under any of the following circumstances:

      a) The gift is conveyed by the vendor directly to the individual (or group of individuals) -- e.g., the vendor brings food to a meeting.

      b) The vendor selected or participated in selecting the ultimate recipient of the gift.
2. Exclusions from the definition of a gift:

   a) Items provided for a discount or free as part of a University contract;

   b) Prizes or awards from bona fide competitions (e.g., a competitive grant);

   c) A gift from one of the following relatives or domestic partners, unless the donor is acting as an agent or intermediary for a 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.

   d) Free admission, and refreshments and similar non-cash nominal benefits provided to an individual during the entire event at which the individual gives a speech, participates in a panel or seminar, or provides a similar service;

   e) Free admission, and refreshments and similar non-cash nominal benefits provided to an individual during a training session provided by the vendor for the purpose of training the individual in the use of the vendor’s product. Note that free travel or lodging would be a gift. If free training is anticipated, it shall be referenced in the purchase contract for the vendor’s product;

   f) 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 worker (e.g., a coupon in the newspaper for a discount on a pain reliever).

D. 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 individuals when at University-owned or operated locations.

2. Gifts from vendors to an individual are prohibited.

3. In circumstances where the gifts were in part supporting the mission of the University (e.g., food for conferences, payment for educational travel, and samples for evaluation), there are appropriate alternatives that can enable the vendors to continue to support the University’s mission. For example, to replace the free food or payment for educational travel, vendors may donate funds to a unit of the University (e.g., department or division) to support meetings. These 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 a vendor’s ability to communicate with University employees or trainees.

4. Free samples, supplies, or equipment designated for an individual are considered a gift and are prohibited. Vendors may donate their product for evaluation or educational purposes to a unit of the University if the administrative head of the unit approves the donation. Sample donations are restricted to the following two situations:

   a) The samples are in an amount necessary for evaluation or education, and are not intended to stock the University for patient care purposes on an ongoing basis. or

   b) The samples are for University-sanctioned free clinics, and for the short-term use in regular clinics for low income and indigent patients awaiting eligibility for other means of obtaining low cost or free medications, provided that there is institutional oversight and no direct involvement of pharmaceutical representatives in patient care settings.

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

B. Interaction between vendors and University personnel

1. This section applies to University-owned or operated locations.
2. Financial relationships between the vendor and the University or individuals at the University shall not affect the ability of the vendor to make sales calls.

3. Vendors may make sales calls only at the invitation of appropriate University personnel. Such sales calls may only occur 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 in a patient care area, patient privacy laws (including HIPAA) will be followed. The vendor may not access patient information during a sales call unless the patient has given written authorization to do so.

4. Vendors may also enter patient care areas when:
   a) Providing health care support services (see examples below);
   or
   b) Servicing equipment, including installation and removal; or
   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 vendor will agree to a confidentiality agreement to protect the health information of our patients. The following are acceptable in lieu of a confidentiality agreement:
   a) a HIPAA business associate agreement,
   b) a determination that the vendor is acting as a member of a covered entity (as defined by HIPAA), or
   c) provisions to ensure that the vendor does not have access to protected health information.

6. Examples of a vendor providing health care support services:
   a) 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.
   b) 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.

c) 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.

C. Committees overseeing purchase 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 individuals who have financial relationships with 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 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 vendor preceptorships without oversight by the continuing education department.

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

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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. When soliciting or accepting gifts and donations, do not allow an
affirmative or negative response to factor into vendor selection and do not
imply or continue to deal with a vendor who implies any link between
gifts or donations and vendor selection. Promptly seek legal guidance if
uncertain about the propriety of a particular situation.

3. See appendix C for more information.

G. Education

1. All individuals to whom this policy applies shall receive training
regarding interactions with vendors.

VI. Appendix

A. References

1. University of California Policy and Guidelines Regarding Acceptance
   of Gifts and Gratuities by Employees under California’s Political Reform

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. BFB-39 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)

   Oct 28;351(18):1885-90.

8. Brennan TA, Rothman DJ, Blank L, Blumenthal D, Chimonas SC,
   Cohen JJ, Goldman J, Kassirer JP, Kimball H, Naughton J, Smelser N.


B. Other definitions

1. **Health care** (45CFR 160.103) 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. 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.

* * *

Version date: 9/5/2007 10:26:00 AM
While educational funding can provide valuable information to the medical and health care industry, manufacturer grants to purchasers, GPOs, PBMs 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.

* * *

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.
Proposed Health Care Vendor Relations Policy

I. Summary

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V.E. Publicity of industry support: States current policy without change.

V.F. Anti-kickback law: States current policy without change.

V.G. Education: New Policy. Asks for training on vendor interactions for all affected individuals.

This policy establishes minimum standards for campus implementation of 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:

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 (Conflict of Interest Policy) in order to reduce the influence of 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 schools (e.g., medicine, dentistry, nursing, pharmacy, optometry, veterinary medicine).

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

IV. Definitions

The terms “individual”, “gift” and “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. Individual: A member of the UC Community who works, trains, or is a student at human health care locations or in human health schools.

C. Gift to an individual: payment to an individual or provision to an individual of free or discounted items, medical samples for personal use, food, or travel when the individual is not providing a service of similar or greater value to the vendor. For example: pens, notepads, free textbooks, free meals, payment for attending a meeting, and samples are all considered gifts. Honoraria and travel, food, and lodging expense reimbursement for speakers’ training are 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 individual under any of the following circumstances:

   a) The gift is conveyed by the vendor directly to the individual (or group of individuals) -- e.g., the vendor brings food to a meeting.

   b) The vendor selected or participated in selecting the ultimate recipient of the gift.
2. Exclusions from the definition of a gift:

a) Items provided for a discount or free as part of a University contract;

b) Prizes or awards from bona fide competitions (e.g., a competitive grant);

c) A gift from one of the following relatives or domestic partners, unless the donor is acting as an agent or intermediary for a 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.

d) Free admission, and refreshments and similar non-cash nominal benefits provided to an individual during the entire event at which the individual gives a speech, participates in a panel or seminar, or provides a similar service;

e) Free admission, and refreshments and similar non-cash nominal benefits provided to an individual during a training session provided by the vendor for the purpose of training the individual in the use of the vendor’s product. Note that free travel or lodging would be a gift. If free training is anticipated, it shall be referenced in the purchase contract for the vendor’s product;

f) 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 worker (e.g., a coupon in the newspaper for a discount on a pain reliever).

D. 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 individuals when at University-owned or operated locations.

2. Gifts from vendors to an individual are prohibited.

3. In circumstances where the gifts were in part supporting the mission of the University (e.g., food for conferences, payment for educational travel, and samples for evaluation), there are appropriate alternatives that can enable the vendors to continue to support the University’s mission. For example, to replace the free food or payment for educational travel, vendors may donate funds to a unit of the University (e.g., department or division) to support meetings. These 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 a vendor’s ability to communicate with University employees or trainees.

4. Free samples, supplies, or equipment designated for an individual are considered a gift and are prohibited. Vendors may donate their product for evaluation or educational purposes to a unit of the University if the administrative head of the unit approves the donation. Sample donations are restricted to the following two situations:

   a) The samples are in an amount necessary for evaluation or education, and are not intended to stock the University for patient care purposes on an ongoing basis.

   b) The samples are for University-sanctioned free clinics, and for the short-term use in regular clinics for low income and indigent patients awaiting eligibility for other means of obtaining low cost or free medications, provided that there is institutional oversight and no direct involvement of pharmaceutical representatives in patient care settings.

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

B. Interaction between vendors and University personnel

1. This section applies to University-owned or operated locations.
2. Financial relationships between the vendor and the University or individuals at the University shall not affect the ability of the vendor to make sales calls.

3. Vendors may make sales calls only at the invitation of appropriate University personnel. Such sales calls may only occur 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 in a patient care area, patient privacy laws (including HIPAA) will be followed. The vendor may not access patient information during a sales call unless the patient has given written authorization to do so.

4. Vendors may also enter patient care areas when:

   a) Providing health care support services (see examples below); or

   b) Servicing equipment, including installation and removal; or

   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 vendor will agree to a confidentiality agreement to protect the health information of our patients. The following are acceptable in lieu of a confidentiality agreement:

   a) a HIPAA business associate agreement,

   b) a determination that the vendor is acting as a member of a covered entity (as defined by HIPAA), or

   c) provisions to ensure that the vendor does not have access to protected health information.

6. Examples of a vendor providing health care support services:

   a) 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.

   b) 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.

c) 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.

C. Committees overseeing purchase 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 individuals who have financial relationships with 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 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 vendor preceptorships without oversight by the continuing education department.

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. When soliciting or accepting gifts and donations, do not allow an  
affirmative or negative response to factor into vendor selection and do not  
imply or continue to deal with a vendor who implies any link between  
gifts or donations and vendor selection. Promptly seek legal guidance if  
uncertain about the propriety of a particular situation.

3. See appendix C for more information.

G. Education

1. All individuals to whom this policy applies shall receive training  
regarding interactions with vendors.

VI. Appendix

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. BFB-39 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)

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8. Brennan TA, Rothman DJ, Blank L, Blumenthal D, Chimonas SC,  
Cohen JJ, Goldman J, Kassirer JP, Kimball H, Naughton J, Smelser N.


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, GPOs, PBMs 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 ensure 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.

* * *

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.