

UNIVERSITY OF CALIFORNIA, ACADEMIC SENATE

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Assembly of the Academic Senate
Academic Council
1111 Franklin Street, 12th Floor
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October 1, 2007

DIVISION CHAIRS

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Chair Linda F. Bisson (D)
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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,

A handwritten signature in cursive script, appearing to read "María".

María Bertero-Barceló, Executive Director
Academic Senate

Encl: 1

Copy: Academic Council Chair Michael T. Brown
Divisional Senate Directors



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September 5, 2007

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 206-207¹) 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

¹ Line numbers refer to the revised "Health Care Vendor Relations Policy" Version date: 9/5/2007 10:20:00 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 duty² 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).

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 micro-management 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.”³

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.

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

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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.

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

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

Deleted: This policy establishes minimum standards for campus implementation of vendor relationship policies.¶

50 III. Applicability

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

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

55 IV. Definitions

56 The terms “individual”, “gift” and “vendor” have special definitions for the purpose of
57 this policy.

58 A. UC Community: Regents, faculty and other academic personnel, staff,
59 students, residents, volunteers, contractors, agents, and others associated with the
60 University.

61 B. Individual: A member of the UC Community who works, trains, or is a
62 student at human health care locations or in human health schools.

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Deleted: working or training

63 C. Gift to an individual: payment to an individual or provision to an individual
64 of free or discounted items, medical samples for personal use, food, or travel
65 when the individual is not providing a service of similar or greater value to the
66 vendor. For example: pens, notepads, free textbooks, free meals, payment for
67 attending a meeting, and samples are all considered gifts. Honoraria and travel,
68 food, and lodging expense reimbursement for speakers' training are considered
69 gifts. Honoraria for a specific service rendered (e.g., delivering a speech) are not
70 considered gifts.

Deleted: speaker's fees

71 1. A gift to the University is considered a gift to the individual under any
72 of the following circumstances:

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

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75 b) The vendor selected or participated in selecting the ultimate
76 recipient of the gift.

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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:

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(1) spouse, child, parent, grandparent, grandchild, brother, sister, parent-in-law, brother-in-law, sister-in-law, nephew, niece, aunt, uncle, or first cousin;

Deleted: or the spouse of any such person, unless the donor is acting as an agent or intermediary for a vendor;

(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.

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108 **V. Policy**

109 A. Gifts and Compensation Provided by Vendors

110 1. This section applies to University employees and students at all
111 locations, and to all other individuals when at University-owned or
112 operated locations.

Deleted: <#>Applicability of state law¶
<#>All employees of the University of California are subject to the conflict-of-interest provisions of the Political Reform Act. This policy supplements those provisions.¶

113 2. Gifts from vendors to an individual are prohibited.

114 3. In circumstances where the gifts were in part supporting the mission of
115 the University (e.g., food for conferences, payment for educational travel,
116 and samples for evaluation), there are appropriate alternatives that can
117 enable the vendors to continue to support the University’s mission. For
118 example, to replace the free food or payment for educational travel,
119 vendors may donate funds to a unit of the University (e.g., department or
120 division) to support meetings. These funds will be managed in accordance
121 with national continuing education accrediting body conflict of interest
122 standards even when the meetings are not accredited continuing education
123 programs. Donations or gifts will not have an effect on a vendor’s ability
124 to communicate with University employees or trainees.

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

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

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

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

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In addition to the limited sampling described above, the University may dispense sample supplies to patients when the supplies are either packaged or purchased by the University.

141 B. Interaction between vendors and University personnel

142 1. This section applies to University-owned or operated locations.

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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.

Deleted: Unsolicited visits made by vendors are not permitted.

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,

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177 calibration or adjustment of a medical device for that particular
178 patient.

179 c) A representative of a medical device manufacturer views health
180 information, such as films or patient records, to provide
181 consultation, advice or assistance where the provider, in her
182 professional judgment, believes that this will assist with a
183 particular patient's treatment.

184 C. Committees overseeing purchase decisions

- 185 1. This section applies to University-owned or operated locations.
- 186 2. Hospital and medical group formulary committees and other
187 committees overseeing purchases of drugs medical devices, nutritional
188 products, or other medical products or services, will follow the Political
189 Reform Act regulations, which include restrictions on the participation of
190 individuals who have financial relationships with vendors affected by the
191 purchase decisions.

Deleted: that are provided upon prescription or suggestion of a health care professional,

192 D. Vendor preceptorships

- 193 1. This section applies to University-owned or operated locations.
- 194 2. Vendor preceptorships are educational programs for vendor
195 representatives. Vendors have the same access to the official educational
196 offerings of the University as other members of the general public.
197 Generally, these are official courses of the University or continuing
198 education programs under the auspices of the University's continuing
199 education departments and in accordance with national continuing
200 education accrediting body guidelines. Departments may not produce
201 vendor preceptorships without oversight by the continuing education
202 department

203 E. Publicity of industry support

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

Deleted: (Government Code sections 6250 et seq.)

208 F. Anti-kickback law

- 209 1. The federal Anti-Kickback Statute prohibits the knowing and willful
210 solicitation or receipt, offer or payment, overtly or covertly, directly or
211 indirectly, of any remuneration (anything of value) in return for patient,
212 product, or service referrals, or to induce such referrals. This prohibition

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213 extends to arranging for, recommending, or approving any purchase, lease
214 or order of any goods and services that could potentially be reimbursed by
215 Medicare or any state health care program.

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

221 3. See appendix C for more information.

222 G. Education

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

225 **VI. Appendix**

226 A. References

227 1. University of California Policy and Guidelines Regarding Acceptance
228 of Gifts and Gratuities by Employees under California's Political Reform
229 Act (January 2001) [http://www.ucop.edu/ucophome/coordrev/policy/1-24-](http://www.ucop.edu/ucophome/coordrev/policy/1-24-01att.pdf)
230 [01att.pdf](http://www.ucop.edu/ucophome/coordrev/policy/1-24-01att.pdf)

231 2. [APM 025-Conflict of Commitment and Outside Activities of Faculty](http://www.ucop.edu/ucophome/coordrev/policy/1-24-01att.pdf)
232 [Members](http://www.ucop.edu/ucophome/coordrev/policy/1-24-01att.pdf) <http://www.ucop.edu/acadadv/acadpers/apm/apm-025-07-01.pdf>

233 3. [BFB-39 Conflict of Interest Policy and Compendium of Specialized](http://www.ucop.edu/ucophome/coordrev/policy/1-24-01att.pdf)
234 [University Policies, Guidelines, and Regulations Related to Conflict of](http://www.ucop.edu/ucophome/coordrev/policy/1-24-01att.pdf)
235 [Interest](http://www.ucop.edu/ucophome/coordrev/policy/1-24-01att.pdf) <http://www.ucop.edu/ucophome/policies/bfb/g39.pdf>

236 4. [California Public Records Act \(Government Code section 6250 et seq\)](http://www.ucop.edu/ucophome/coordrev/policy/1-24-01att.pdf)

237 5. [Conflict of interest provisions of the California](http://www.ucop.edu/ucophome/coordrev/policy/1-24-01att.pdf) Political Reform Act
238 [\(Government Code section 87100 et seq\)](http://www.ucop.edu/ucophome/coordrev/policy/1-24-01att.pdf) and the regulations of the Fair
239 Political Practices Commission [\(California Code of Regulations title 2](http://www.ucop.edu/ucophome/coordrev/policy/1-24-01att.pdf)
240 [section 87100 et seq\).](http://www.ucop.edu/ucophome/coordrev/policy/1-24-01att.pdf)

241 6. Privacy provisions of the Health Insurance Portability and
242 Accountability Act (HIPAA)

243 7. Blumenthal D. "Doctors and drug companies." N Engl J Med. 2004
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261 B. Other definitions

262 1. Health care (45CFR160.103) means care, services, or supplies related
263 to the health of an individual. Health care includes, but is not limited to,
264 the following: (1) Preventive, diagnostic, therapeutic, rehabilitative,
265 maintenance, or palliative care, and counseling, service, assessment, or
266 procedure with respect to the physical or mental condition, or functional
267 status, of an individual or that affects the structure or function of the body;
268 and (2) Sale or dispensing of a drug, device, equipment, or other item in
269 accordance with a prescription.

270 2. Registered Domestic Partner (California Family Code Section 297):
271 (a) Domestic partners are two adults who have chosen to share one
272 another's lives in an intimate and committed relationship of mutual
273 caring.
274 (b) A domestic partnership shall be established in California when
275 both persons file a Declaration of Domestic Partnership with the
276 Secretary of State pursuant to this division, and, at the time of
277 filing, all of the following requirements are met:
278 (1) Both persons have a common residence.
279 (2) Neither person is married to someone else or is a
280 member of another domestic partnership with someone else
281 that has not been terminated, dissolved, or adjudged a
282 nullity.
283 (3) The two persons are not related by blood in a way that
284 would prevent them from being married to each other in
285 this state.
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(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.

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(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.

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C. Other relevant guidance

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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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330 While educational funding can provide valuable
331 information to the medical and health care industry,
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334 statute. Funding that is conditioned, in whole or in part, on
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336 educational or research purpose is legitimate. Furthermore,
337 to the extent the manufacturer has any influence over the
338 substance of an educational program or the presenter, there
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340 inappropriate marketing purposes.

341 To reduce the risks that a grant program is used improperly
342 to induce or reward product purchases or to market product
343 inappropriately, manufacturers should separate their grant
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357 * * *

358 Manufacturers, providers, and suppliers of health care
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367 Absent unusual circumstances, grants or support for
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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”):

V.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.

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

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

50 **III. Applicability**

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

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

55 **IV. Definitions**

56 The terms “individual”, “gift” and “vendor” have special definitions for the purpose of
57 this policy.

58 **A. UC Community:** Regents, faculty and other academic personnel, staff,
59 students, residents, volunteers, contractors, agents, and others associated with the
60 University.

61 **B. Individual:** A member of the UC Community who works, trains, or is a
62 student at human health care locations or in human health schools.

63 **C. Gift to an individual:** payment to an individual or provision to an individual
64 of free or discounted items, medical samples for personal use, food, or travel
65 when the individual is not providing a service of similar or greater value to the
66 vendor. For example: pens, notepads, free textbooks, free meals, payment for
67 attending a meeting, and samples are all considered gifts. Honoraria and travel,
68 food, and lodging expense reimbursement for speakers’ training are considered
69 gifts. Honoraria for a specific service rendered (e.g., delivering a speech) are not
70 considered gifts.

71 1. A gift to the University is considered a gift to the individual under any
72 of the following circumstances:

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

75 b) The vendor selected or participated in selecting the ultimate
76 recipient of the gift.

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2. Exclusions from the definition of a gift:

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

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

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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:

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(1) spouse, child, parent, grandparent, grandchild, brother, sister, parent-in-law, brother-in-law, sister-in-law, nephew, niece, aunt, uncle, or first cousin;

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(2) registered domestic partner, or the registered partner's child, grandchild, parent, brother, or sister; or

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(3) the spouse or registered domestic partner of any person listed above.

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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;

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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;

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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).

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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.

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107

108 **V. Policy**

109 A. Gifts and Compensation Provided by Vendors

110 1. This section applies to University employees and students at all
111 locations, and to all other individuals when at University-owned or
112 operated locations.

113 2. Gifts from vendors to an individual are prohibited.

114 3. In circumstances where the gifts were in part supporting the mission of
115 the University (e.g., food for conferences, payment for educational travel,
116 and samples for evaluation), there are appropriate alternatives that can
117 enable the vendors to continue to support the University's mission. For
118 example, to replace the free food or payment for educational travel,
119 vendors may donate funds to a unit of the University (e.g., department or
120 division) to support meetings. These funds will be managed in accordance
121 with national continuing education accrediting body conflict of interest
122 standards even when the meetings are not accredited continuing education
123 programs. Donations or gifts will not have an effect on a vendor's ability
124 to communicate with University employees or trainees.

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

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

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

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

141 B. Interaction between vendors and University personnel

142 1. This section applies to University-owned or operated locations.

- 143 2. Financial relationships between the vendor and the University or
144 individuals at the University shall not affect the ability of the vendor to
145 make sales calls.
- 146 3. Vendors may make sales calls only at the invitation of appropriate
147 University personnel. Such sales calls may only occur in non-patient-care
148 areas. Exceptions can occur by local policy when it is determined that
149 there is a compelling need for the call to occur in a patient care area. For
150 sales calls in a patient care area, patient privacy laws (including HIPAA)
151 will be followed. The vendor may not access patient information during a
152 sales call unless the patient has given written authorization to do so.
- 153 4. Vendors may also enter patient care areas when:
- 154 a) Providing health care support services (see examples below);
155 or
 - 156 b) Servicing equipment, including installation and removal; or
 - 157 c) Invited for specific vendor service at the request of a
158 representative of the University for its health care operations; or
 - 159 d) Acting as a member of the general public (e.g., as a patient).
- 160 5. Unless acting as a member of the general public, the vendor will agree
161 to a confidentiality agreement to protect the health information of our
162 patients. The following are acceptable in lieu of a confidentiality
163 agreement:
- 164 a) a HIPAA business associate agreement,
 - 165 b) a determination that the vendor is acting as a member of a
166 covered entity (as defined by HIPAA), or
 - 167 c) provisions to ensure that the vendor does not have access to
168 protected health information.
- 169 6. Examples of a vendor providing health care support services:
- 170 a) An orthopedic device manufacturer or its representative
171 determines and delivers the appropriate range of sizes of a
172 prosthesis for the surgeon to use during a particular patient's
173 surgery.
 - 174 b) The device manufacturer or its representative is present in the
175 operating room, as requested by the surgeon, to provide support
176 and guidance regarding the appropriate use, implantation,

177 calibration or adjustment of a medical device for that particular
178 patient.

179 c) A representative of a medical device manufacturer views health
180 information, such as films or patient records, to provide
181 consultation, advice or assistance where the provider, in her
182 professional judgment, believes that this will assist with a
183 particular patient's treatment.

184 C. Committees overseeing purchase decisions

185 1. This section applies to University-owned or operated locations.

186 2. Hospital and medical group formulary committees and other
187 committees overseeing purchases of drugs medical devices, nutritional
188 products, or other medical products or services will follow the Political
189 Reform Act regulations, which include restrictions on the participation of
190 individuals who have financial relationships with vendors affected by the
191 purchase decisions.

192 D. Vendor preceptorships

193 1. This section applies to University-owned or operated locations.

194 2. Vendor preceptorships are educational programs for vendor
195 representatives. Vendors have the same access to the official educational
196 offerings of the University as other members of the general public.
197 Generally, these are official courses of the University or continuing
198 education programs under the auspices of the University's continuing
199 education departments and in accordance with national continuing
200 education accrediting body guidelines. Departments may not produce
201 vendor preceptorships without oversight by the continuing education
202 department

203 E. Publicity of industry support

204 1. California's Public Records Act provides that information about
205 industry support of the University is a public record.

206 2. APM 025 requires that faculty report annually any paid consulting
207 arrangements. These reports are public records.

208 F. Anti-kickback law

209 1. The federal Anti-Kickback Statute prohibits the knowing and willful
210 solicitation or receipt, offer or payment, overtly or covertly, directly or
211 indirectly, of any remuneration (anything of value) in return for patient,
212 product, or service referrals, or to induce such referrals. This prohibition

213 extends to arranging for, recommending, or approving any purchase, lease
214 or order of any goods and services that could potentially be reimbursed by
215 Medicare or any state health care program.

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

221 3. See appendix C for more information.

222 G. Education

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

225 VI. Appendix

226 A. References

227 1. University of California Policy and Guidelines Regarding Acceptance
228 of Gifts and Gratuities by Employees under California's Political Reform
229 Act (January 2001) <http://www.ucop.edu/ucophome/coordrev/policy/1-24-01att.pdf>
230

231 2. APM 025-Conflict of Commitment and Outside Activities of Faculty
232 Members <http://www.ucop.edu/acadadv/acadpers/apm/apm-025-07-01.pdf>

233 3. BFB-39 Conflict of Interest Policy and Compendium of Specialized
234 University Policies, Guidelines, and Regulations Related to Conflict of
235 Interest <http://www.ucop.edu/ucophome/policies/bfb/g39.pdf>

236 4. California Public Records Act (Government Code section 6250 et seq)

237 5. Conflict of interest provisions of the California Political Reform Act
238 (Government Code section 87100 et seq) and the regulations of the Fair
239 Political Practices Commission (California Code of Regulations title 2
240 section 87100 et seq).

241 6. Privacy provisions of the Health Insurance Portability and
242 Accountability Act (HIPAA)

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