INTRODUCTION

Vendor Relations Policy – Key Points
All employees of the University of California are subject to the conflict-of-interest provisions of the Political Reform Act, as well as the UC policies concerning conflict of interest. One of the goals of the Political Reform Act is to remove bias from decisions made by UC employees.

This training provides an overview of the minimum standards for campus implementation of Health Care Vendor relationship policies. A brief excerpt of this policy is worth noting:
INTRODUCTION

Vendor Relations Policy – Key Points

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.
Impacted Individuals

The Vendor Relations policy applies to all University of California Health Sciences programs and campuses. At UC Riverside, this includes UCR School of Medicine, as well as UCR Health. The policy applies to all healthcare individuals who are defined as, “Members of the UC Community who work, train, or are students at healthcare locations or in health professional schools.” These include, but are not limited to:

- Regents
- Faculty and other academic personnel
- Physicians, nurses, and other care providers
- Residents and fellows
- Students
- Managers and staff
- Volunteers
SUMMARY OF POLICY

Recent research shows that certain healthcare 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.

Additionally, while offers of free or discounted goods, gifts, donations, etc. frequently serve an important beneficial function, they may sometimes violate the federal Anti-Kickback Statute. Therefore, guidance on compliance with this law is provided in this training.
SUMMARY OF POLICY

Gifts
• Briefly stated, gifts from a vendor to a healthcare individual are prohibited.

Sales Calls
• Sales calls from vendors must be made only at the invitation of appropriate university personnel and may take place only in non-patient care areas.
SUMMARY OF POLICY

Visitation

- Vendors may only enter patient care areas when providing healthcare support services at the request of the physician or other provider.
- A device manufacturer is allowed in the operating room only when requested by the physician to provide support and guidance during a procedure.
SUMMARY OF POLICY

Unrestricted Educational Funds

- Unrestricted educational funds are permitted when provided to the university or a component of the university, such as a department, in which the university determines how funds will be utilized.
- The donation must be in compliance with the Accreditation Council for Continuing Medical Education (ACCME) standards (national accrediting standards).
- The grant must be documented in a written agreement.
SUMMARY OF POLICY

Professional Conferences
• Materials, food, and refreshments that are received at national professional conferences and that are distributed to all attendees as part of the registration are permitted.

On- and Off Campus Enforcement
• The policy applies to all activities that are on-and-off campus.
REASON FOR POLICY

As referenced earlier, many studies have shown that the provision of gifts results in a bias in the person receiving the gift. The person receiving the gift is unconscious of the bias produced by the gift and does not intend to be influenced by the gift. Studies have also shown that prescription patterns are directly influenced by the gifts that individuals receive from pharmaceutical representatives, even small items, such as pens, mugs, etc.

This is not a small issue!

- Gifts are a form of pervasive marketing that works. Vendors would not do it if it was not effective.
- Pharmaceutical marketing is a $12 to $15 billion per year business. On average, $8,000 to $15,000 is spent per physician, per year.
REASON FOR POLICY

• Marketing accounts for 33% of pharmaceutical expenses.
• Congressional concern over this issue has resulted in enactment of the Physician Sunshine Act effective 2013!

IN RECENT HEADLINES:
Recent court cases and settlements highlight the seriousness of how pharmaceuticals (“pharma”) has used these types of strategies to increase sales of their product by providing payments to physicians, paying physicians to speak about their products and providing “free” items:
In July 2012, GlaxoSmithKline (GSK) pled guilty and agreed to pay $3 billion to the federal government to resolve multiple allegations. GSK had promoted one of their drugs, then approved only for major depression, for other off-label uses such as weight loss, treatment of substance addictions and attention deficit hyperactivity disorder among others. GSK paid millions of dollars to physicians to speak at and attend meetings, sometimes at lavish resorts, at which the off-label use was routinely promoted, and used sales reps, sham advisory boards, and supposedly independent CME programs to promote the drug for these unapproved uses.
The UCR School of Medicine/UCR Health Vendor Relations Policy is even more important in light of the required public reporting of these payments starting in 2013:

- Pharmaceutical, device, and medical supply companies will be required to notify Health and Human Services (HHS) of any payment to a physician or teaching hospital of $10.00 or more.
- If the value is less than $10.00, the manufacturer must report if the aggregate amount exceeds $100 in a calendar year.
PHYSICIAN SUNSHINE ACT

• Transparency for Providers and Teaching Hospitals: The payments will be posted and publicly available on a CMS website. Vendors must send information to HHS by 3/31/2014 for payments made to physicians and teaching hospitals beginning January 2013.
Manufacturers are required to report the following elements to HHS:

- The name of the teaching hospital or physician including first, middle initial, and last name
- Business address
- Specialty (provider taxonomy) and National Provider Identification (NPI)
- Date of payment
- Associated covered drug, device, biological, or medical supply
- Form of payment
- Nature of payment
PHYSICIAN SUNSHINE ACT

Reportable payments or transfers:
• Consulting fees
• Compensation for services other than consulting
• Honoraria
• Gifts
• Entertainment
• Food
• Travel (including specific destinations)
• Education
• Grants
PHYSICIAN SUNSHINE ACT

Reportable payments or transfers (continued):

• Research (bona fide research activities, including clinical investigations that are subject to both a written agreement or contract between the applicable manufacturer and the organization conducting the research)

• Charitable contributions

• Royalties or licenses
PHYSICIAN SUNSHINE ACT

Reportable payments or transfers (continued):

• Current or prospective ownership or investment interests
• Direct compensation for serving as faculty or as a speaker for a medical education program
• Any other payments or other transfers
What is a Gift?
A gift is:
• any item of value where services of equal or lesser value are not provided by the healthcare individual receiving the item, and/or
• any item that is directed by the vendor to the healthcare individual, and the vendor has selected the recipient of the gift
What are not gifts?

- Items provided at a discount or free as part of a university contract (must be included in the purchase agreement)
- Items provided at a discount or free as part of a research project
- Prizes or awards from bona fide competitions
- Honoraria for a specific service rendered (such as a speech)
- Free admission, refreshments, and similar non-cash nominal benefits provided to an individual during the entire event at which he or she gives a speech, participates in a panel or seminar, or provides a similar service
What are not gifts?

- A rebate or discount that is made in the regular course of business to a member of the public without regard to his or her status as a healthcare individual (i.e., discount coupon in the newspaper for a pain reliever)
- Materials provided by the organizers of a professional meeting that are available to all attendees when the meeting is conducted under national continuing education guidelines
What are not gifts?

- Free admission, refreshments, and similar non-cash nominal benefits provided by the vendor during a session to train the individual in the use of the vendor’s product. However, free travel and lodging would be considered a gift. If free training is anticipated, the training activity should be referenced in the purchase contract for the product.
COMMON SITUATIONS

The following slides present common situations that are impacted by these policies. After a review of these situations, you will gain a deeper understanding of why we are now required to change how we interact with vendors.
Vendors: Educational Scenarios
Vendors in Educational Scenarios

Lunches and Refreshments

Q. May healthcare vendors supply refreshments or food for educational activities sponsored by our department, such as grand rounds and lecture series?

A. No, but a vendor may donate funds to an unrestricted educational fund for the department as a gift to the UC Regents. However, these conditions must be met:

- The terms, conditions and purposes of the commercial support must be documented in a written agreement.
- The vendor may also not impose any restrictions on how the department uses the donation.
- The funds must be managed by the university in accordance with national accrediting organizations' standards, such as the ACCME Standards for Commercial Support.
Vendors in Educational Scenarios

Vendor Presence

Q: When a vendor’s donation is used to support a seminar as part of an unrestricted educational fund, may a vendor representative be present at the seminar?

A: No, unless the seminar is open to the public at large.

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Vendors in Educational Scenarios

Acknowledgement of Support

A. Yes, sponsors of the event are required to acknowledge the support provided to the learners. Informed learners are final safeguards in assuring that an instructional activity is independent from commercial influence. You may state “This activity is supported, in part, by a donation from ______.” It is not appropriate to say that the activity is “sponsored by” the company.

Q: Can we acknowledge that the vendor donated funds to support the activity?
Vendors in Educational Scenarios

Unrestricted Educational Funds

Q: If a vendor is allowed to donate funds to a department, isn’t that the same as the vendor directly supplying food for the activity?

A. No. There is a significant difference. Under the policy, it is the department that decides how the funds are used and supplies the food, not the vendor. This distances the vendor from the event and reduces the subconscious effect of gift-giving on behavior.
Vendors in Educational Scenarios

Off-Campus Meetings

Q: Our department hosts educational meetings (i.e., Journal Club) at local restaurants and sometimes at faculty members’ homes. Vendor reps attended and financially supported these meetings in the past. Since the meetings are offsite, can we continue this practice to defray expenses?

A. No. The Journal Club is an educational activity organized by the university so the funds must be managed in accordance with the ACCME standards and university rules regarding business meetings and entertainment events. In addition, unless the Journal Club event is open to the public, the industry rep can no longer attend.
A. If the invitee is not providing a service to the vendor of a similar or greater value than the dinner (such as giving a lecture or participating in a panel or seminar), he or she cannot accept the free dinner. However, the individual could attend the event and pay for his or her own dinner.

Q: Our department receives invitations to dinner lectures at restaurants that are sponsored by vendors. Could an individual attend the event and accept the free dinner? What if he or she is on their own time?
Vendors: Conferences
Vendors: Conferences

Materials Part of Registration

Q: I attended a continuing education event and upon arrival, I received a tote bag with a vendor’s logo. Can I accept it?

A: Yes. You may accept it, as long as it was available to all attendees and the event was conducted in accordance with ACCME standards or other applicable national organizational standards.
Vendors: Conferences

Bringing Materials to Work

Q: Can I bring materials I received as part of registering for a conference to work?

A: Generally, no. Although the items were obtained as part of a conference and given to everyone attending the conference as part of the registration fee, the item still has marketing value and adds to a pervasive atmosphere of vendor advertising. The materials should be kept at home.
Vendors: Conferences

CME Provided by Professional Society

Q: Can a faculty member in our department attend an educational conference that is organized by a professional society and sponsored by vendors? The conference registration includes breakfast, lunch and refreshments. Can the faculty member accept the meals and refreshments?

A. Yes. When an activity complies with ACCME standards, the meals and refreshments are allowable because the vendors are not directly paying for the meals and refreshments.

However, meals and refreshments not included in the registration fee, but that are paid for by the vendor, are not allowed. The faculty member must either decline the meals and refreshments, or pay for his or her own share of the cost.
Vendors: Conferences

Speaking at a Professional Society Conference

Q: A faculty member attends an annual educational conference sponsored by a professional society and has been invited to give a lecture at the conference. Can a vendor pay for the faculty member’s travel and hotel costs? What about an honorarium for the speech, or the faculty member’s registration/admission fee?

A: No. In this example, the lecture is considered a service provided to the event organizer which is the professional society, not the vendor. Since the faculty member is not providing a service of similar or equal value to the vendor, payment by the vendor to the faculty member would be a gift, and not allowed.
Vendors: Meetings, Training, and Fundraising Events
Vendors: Meetings, Training, and Fundraising Events

Traveling to a Meeting

A: No, the expense reimbursement and honorarium are considered gifts and not allowable under the policy since the individual’s role is more similar to that of an attendee than a participant.

Q: Can an individual on a vendor’s speaker’s bureau accept free travel and an honorarium to attend an educational meeting? The meeting will educate the individual about studies related to the product they will speak about in the future.
Vendors: Meetings, Training, and Fundraising Events

Training at a Vendor Facility

A: Yes, if the individual is providing genuine services, the individual may accept from the vendor reasonable compensation for time and travel expenses. Token advisory or consulting arrangements cannot be used to justify accepting compensation.

Q: If a vendor invites an individual to visit its facilities to review and comment on a product, to discuss his or her independent research product or to explore the potential for collaborative research, may the vendor pay travel expenses and an honorarium?
Vendors: Meetings, Training, and Fundraising Events

Fundraising Event Support

A: Yes. The group may solicit corporate sponsorship for the university event, but university personnel must ensure that:

• No company promotional materials are available at the event.
• All event-associated fundraising efforts are coordinated with the university Advancement Office to properly document gift acceptance and acknowledgement procedures.
• No donations are provided directly to any individual.

Q: In the past, our nursing group received industry support for our fundraising event. Is this still available under the new policy?
Vendors: Meetings, Training, and Fundraising Events

Research Meeting

A: Yes. Expenses can be paid if the meetings serve a genuine research purpose. Signs that a genuine research purpose exists include a valid study protocol and the recruitment of an appropriate number of qualified physicians, in light of the number of participants needed for statistical evaluation.

When travel subsidies are acceptable, the guidelines emphasize that they be used to pay only for “reasonable” expenses. The reasonableness of expenses depends on a number of factors. For example, reimbursement for meetings is likely to be problematic for overseas locations visited by domestic investigators. It would be inappropriate to pay for recreation or entertainment beyond the kind of modest hospitality described in the policy.

Q: If a vendor convenes a group of physicians or other providers to recruit clinical investigators or convenes a group of clinical investigators to discuss their results, may the vendor pay the travel expenses?
Vendors: Products, Materials, and Supplies
Vendor Products, Materials, and Supplies

Vendor Selection – New Products

A. University policies relating to vendor selection still apply. There are still limits on income from lectures that must be disclosed and limits on the amount that you must excuse yourself from decision making.

Q: How does this new policy affect my involvement in selecting a vendor or recommending a drug for the hospital’s formulary?
Vendor Products, Materials, and Supplies

Vendor Marketing Materials

Q: Is it true that vendors and marketing reps may no longer leave any written materials with employees?

A: Yes. Vendor-branded sales and marketing materials from pharmaceutical and medical device companies can no longer be left in the clinics or with staff members. The reason is to avoid any expectation of future purchases on the part of the company, and to ensure that we do not promote a vendor or its products to our patients.
Vendor Products, Materials, and Supplies

Samples at Conferences

A: No. You may not accept samples. Other items directly provided by vendors (i.e., at their booths) also can’t be accepted. However, if you paid a registration fee that included refreshments or giveaways (i.e., tote bags), you would not be receiving a “gift” under the policy and could attend the event and accept food and other items provided to all attendees.

Q: Can I accept vendor gifts or samples for evaluation or for personal use, when attending conventions or other professional meetings, either on-campus or off-campus?
Vendor Products, Materials, and Supplies

Exhibit Halls & Vendor Fairs

Q: Commonly, sponsors of an offsite CME conference invite book publishers and industry company representatives to set up exhibit tables that attendees may visit during the conference. Sponsors usually charge the vendor reps an exhibit hall registration fee to offset the associated expenses for exhibit space (such as set up, after hours security). Is this practice permitted under university policy?

A: Yes, the course sponsor may charge vendors a reasonable exhibit fee in accordance with ACCME rules and university policy for continuing education.
Vendor Products, Materials, and Supplies

Vendor Supplies

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

Q: I have always received samples of medical and dental devices for evaluations and for resident and student training labs. How can I continue to explore advances in technology for these items?
Vendor Products, Materials, and Supplies

Presence in Healthcare Settings: Responding to Gifts

A: It is your responsibility to refuse any gifts from vendors. You can respond by saying, “We appreciate your generosity; however, University of California policy prevents us from accepting any gifts, including food items.” The vendor should also be referred to the Purchasing or Pharmacy Department for participation in the vendor registration process and to receive a copy of the university’s guidelines.

Q: How do we respond to a vendor who brings donuts for the department, and not seem rude?

A: It is your responsibility to refuse any gifts from vendors. You can respond by saying, “We appreciate your generosity; however, University of California policy prevents us from accepting any gifts, including food items.” The vendor should also be referred to the Purchasing or Pharmacy Department for participation in the vendor registration process and to receive a copy of the university’s guidelines.
Vendor Products, Materials, and Supplies

Clinic Staff: Pharma Reps Without an Appointment

Q: A pharmaceutical representative has shown up in the clinic and is asking to speak to the physician. How do we handle these situations?

A: Unless the representative has scheduled an appointment with the physician, he or she must be asked to leave. The representative may not remain in patient care areas in order to communicate with a physician.
Vendor Products, Materials, and Supplies

Supplies and Samples: Patient Use

Q: In the past, vendors have provided equipment and medications that have helped the university provide inexpensive or free healthcare in clinical settings that routinely serve disadvantaged patients. How can I continue to run my clinic and provide these services at affordable rates?

A. Supplies can be donated to departments, but not to individuals. Drug samples, by federal law, cannot be left or given to a department, but must be transferred to a licensed prescriber who is responsible for full accounting and compliance with recordkeeping and labeling requirements. The Purchasing and Pharmacy Departments can provide direction on accepting products for trial and sample medications for patient care use.

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

Research Support

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

Q: Can I receive an unrestricted gift for research support from a vendor?
A. Yes. Physicians and other healthcare providers who may legally prescribe drugs may talk about products for off-label uses based on their professional judgment and personal experience.

However, if the provider is receiving funding support from a company for studies of the company’s products involving off-label uses, the activity may be viewed as “illegal marketing.” To avoid the risk of bias, the provider should make sure that any such discussion is independent, based on facts and is unbiased. He or she will need to disclose financial relationships to the CME event sponsors and to the learners, in accordance with ACCME standards.
This concludes the short discussion on Common Situations that are impacted by the UC Vendor Relations Policy. Should you have questions regarding the interpretation or application of the policies discussed in this training, or if you have specific questions regarding your particular work experiences, please refer to the Resources and Contacts for resolution.
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<th>RESOURCE</th>
<th>WEBSITE ADDRESS</th>
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<td>Healthcare Vendor Relationship Policy (incl. FAQs)</td>
<td><a href="http://www.ucop.edu/ucophome/coordrev/policy/PPO31208Policy.pdf">http://www.ucop.edu/ucophome/coordrev/policy/PPO31208Policy.pdf</a></td>
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For a PDF version of Resources and active links, click here.
# CONTACTS

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<th>AREA</th>
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<tr>
<td>Compliance</td>
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CONCLUSION

Thank you for reviewing this material. Please feel free to visit this website at any time to review the various Compliance reference files.

The online training for this course is located in the UC Learning Center and is required to be reviewed annually both as a refresher course, and to be informed of any new changes in the policy and/or laws. The online training must be taken as part of the curriculum that includes Compliance-Code of Conduct and HIPAA Privacy and Security trainings.