

VENDOR RELATIONS POLICY TRAINING



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 judgement 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.

INTRODUCTION

Impacted Individuals

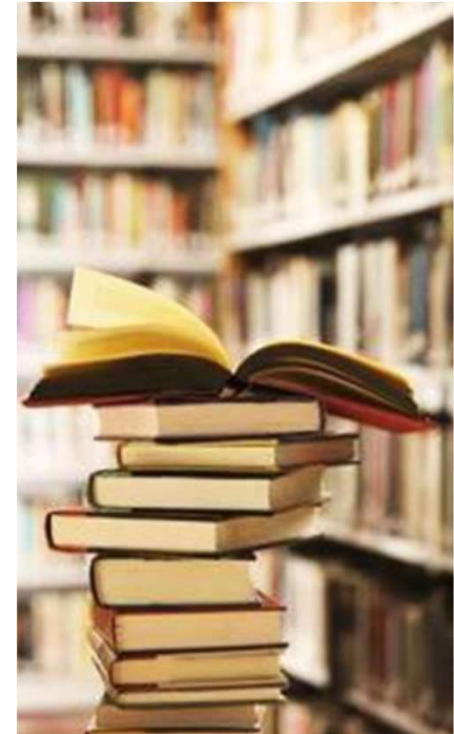
The Vendor Relations policy applies to all University of California Health Sciences programs and campuses. At UC Riverside, this includes UCR School of Medicine, as well as UCR Health. The policy applies to all healthcare individuals who are defined as, “Members of the UC Community who work, train, or 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
- Researchers

SUMMARY OF POLICY

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 procedure 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 may be unaware 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.
- In the 3-year period from 2017 through 2019, pharmaceutical and medical device manufacturers reported paying close to \$2 billion in speakers' (and related) fees to health care professionals.*

**U.S. Department of Health and Human Services OIG Special Fraud Alert: Speaker Programs
Nov. 16, 2020.*

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:

REASON FOR POLICY

In January, 2020 electronic medical record (EMR) provider, Practice Fusion, executed a deferred prosecution agreement with the U.S. Attorney's Office and agreed to pay \$145 million to resolve criminal and civil investigations conducted by the U.S. Department of Justice. Practice Fusion provided free web-based EMR Services to physicians and is alleged to have accepted kickbacks from Pharmaceutical companies to suggest that the physicians using their EMR prescribe opiates to their patients.

OPEN PAYMENTS

Under the Physician Payment Sunshine Act, pharmaceutical and medical device and supply manufacturers are required to report payments made to physicians to the U.S. Department of Health and Human Services (HHS). These payments are made viewable to the public at

www.CMS.gov/OpenPayments.

Beginning January, 2021 payments made to the following non-physician practitioners are also reportable, with public reporting to take place in 2022: Physicians' Assistants, Nurse Practitioners, Clinical Nurse Specialists, CRNA's, and Certified Nurse Midwives



OPEN PAYMENTS

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



OPEN PAYMENTS

Reportable payments or transfers:

- Consulting fees
- Compensation for services other than consulting
- Honoraria
- Gifts
- Entertainment
- Food
- Travel (including specific destinations)
- Education
- Grants



OPEN PAYMENTS

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 or contributions
- Royalties or licenses

OPEN PAYMENTS

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



GIFTS

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.



GIFTS

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 speaking)
- 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

GIFTS

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



GIFTS

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 not required to change how we interact with vendors.

VENDORS: EDUCATIONAL SCENARIOS



VENDORS: EDUCATIONAL SCENARIOS

Lunches & 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 purpose 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: EDUCATIONAL SCENARIOS

Vendor Presence

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



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

VENDORS: EDUCATIONAL SCENARIOS



Acknowledgement of Support

Q: Can we acknowledge that the vendor donated funds to support the activity?

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.

VENDORS: 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: 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. 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: EDUCATIONAL SCENARIOS

Off-Campus Meetings

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?



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.

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

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

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.



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.

VENDORS: MEETINGS, TRAINING, AND FUNDRAISING EVENTS

Training at a Vendor Facility

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?



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.

VENDORS: MEETINGS, TRAINING, AND FUNDRAISING EVENTS

Fundraising Event Support

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



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.

VENDORS: MEETINGS, TRAINING, AND FUNDRAISING EVENTS

Research Meeting

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?

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.

VENDORS: PRODUCTS, MATERIALS, AND SUPPLIES



VENDORS: PRODUCTS, MATERIALS, AND SUPPLIES

Vendor Selection – New Products

Q: How does this new policy affect my involvement in selecting a vendor or recommending a drug for the hospital's formulary?



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.

VENDORS: PRODUCTS, MATERIALS, AND SUPPLIES

Vendor Marketing Materials

Q: Is it true that vendors and marketing reps may not leave any written materials with employees?

A: Yes. Vendor-branded sales and marketing materials from pharmaceutical and medical device companies can not 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.

VENDORS: PRODUCTS, MATERIALS, AND SUPPLIES

Samples at Conferences

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?



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.

VENDORS: 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



VENDORS: PRODUCTS, MATERIALS, AND SUPPLIES

Vendor Supplies

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?



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.

VENDORS: PRODUCTS, MATERIALS, AND SUPPLIES

Presence in Healthcare Settings: Responding to Gifts

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.

VENDORS: 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.



VENDORS: 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 record keeping and labeling requirements. The Purchasing Department 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.
- 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.

VENDORS: PRODUCTS, MATERIALS, AND SUPPLIES

Research Support

Q: Can I receive an unrestricted gift for research support from a vendor?



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.

VENDORS: PRODUCTS, MATERIALS, AND SUPPLIES

Off-Label Use

Q: Are healthcare providers permitted to promote products for off-label uses?

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.

VENDOR RELATIONS POLICY

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.

RESOURCES

Healthcare Vendor Relationship Policy (incl. FAQs)

<http://www.ucop.edu/ucophome/coordrev/policy/PPO31208Policy.pdf>

ACCME Policy on Commercial Support

http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c-uploaddocument.pdf

Council on Pharmacy Education (CPE) Standards

http://www.acpe-accredit.org/pdf/CPE_Standards_Final.pdf

CONTACTS

Compliance & Privacy Office

951.827.4672

Information Security Officer

951.827.4680

Health Sciences Counsel

951.827.5171

Risk Management Director

951.827.8224

Locally Designated Official

951.827.1128

Whistleblower Hot Line

800.403.4744