

# Conflict of interest primer, UCDHS

Because of the potential for abuse, having a financial interest that conflicts with the role you have within UCDHS is considered inappropriate, even if you have good intentions, never exploit the conflict, and do not harm anyone.

UC Davis employees are government employees. California has special conflict of interest laws and regulations affecting government employees. These laws include the Fair Political Practices Act, also known as the Political Reform Act of 1974. In addition, Federal law has special sections relating to health care conflicts of interest that result in more stringent standards than for most other businesses. This all adds up to a set of strict standards every one of us must follow.

## Basic rules

Besides the conflict of interest rules described below, there are basic prohibitions against certain actions.

- You may not offer or receive any item or service of value that may be viewed as a bribe, kickback, or inducement for the referral of business or patients.
- You may not accept gratuities from sales representatives for personal enrichment.
- To avoid the appearance of favoritism, you may not accept a gift or gratuity when it appears that it was given to you because of your University position. Certain gifts are excepted (see "When is a gift *not* a gift?" below).

As a matter of policy, the UC Davis Health System discourages the existence of potential conflicts of interest. Such conflicts may make it difficult for an employee to discharge his or her work duties. In particular, receiving gifts exceeding the threshold of \$340 in a twelve-month period should occur only in extraordinary circumstances, and only after the review and approval by your department chair or supervisor.

## How do conflicts arise?

Three things are needed to produce a conflict of interest in a decision made by the University:

1. You have a significant financial interest;
2. A decision is going to be made that materially affects that interest (either positive or negative);
3. You participate in, influence, or make the decision.

## Making or participating in a decision

The usual ways by which you end up making decisions for the University are when you commit the University to a course of action (e.g., by choosing something to order), or when you enter into any contract on behalf of the University.

Even if you do not *make* a decision, you typically are **participating** in a decision when you negotiate regarding the decision or advise the decision-maker, directly or indirectly (e.g., by offering an opinion), or otherwise attempt to influence the decision.

## Resolving a conflict of interest

Once a potential conflict of interest is identified, the conflict may be avoided by doing one of the following:

1. Removing the financial interest before participating in a decision. For example, selling stock or promptly returning an unused gift.
2. Disqualifying yourself from the decision and avoiding making, participating in, or influencing the decision. For clinicians, this may be problematic. For example, you may be a surgeon who is using a particular implant. By selecting that specific implant you are causing the University to purchase it. It is then difficult to practice without being involved in a conflict of interest.

## Financial interests

According to law and University policy, there are several different types of significant financial interests. These include the following situations:

- You receive or have been promised income (e.g., salary, honorarium) of at least \$500 in the past 12 months.
- You receive gifts valued at more than \$340 in the past 12 months.
- You hold any position in a for-profit business.
- You or your immediate family invest in California real estate.
- You or your immediate family have an investment worth at least \$2000 in a for-profit business (excluding diversified mutual funds).

In addition, the *appearance* of a financial interest, even when the financial interest does not rise to the levels listed below, may be sufficient to cause problems.

Whether or not the effect of a decision is material depends upon the type of interest. For many of these types of interests (e.g., gifts), an effect of even 1¢ is considered material. Questions regarding this can be answered by calling any of the numbers listed at the end of this paper.

### ***When is a gift not a gift?***

The following are **not** considered gifts for this policy, and are not considered a financial interest.

- Informational materials that will assist the recipient in the performance of his or her official duties. This includes books and free admission to seminars. Transportation to the seminar **is** a gift, unless transportation to that location is not commercially available.
- Gifts returned to the donor unused or donated to the University or another charity within 30 days and without being claimed as a charitable contribution for tax purposes. A fruit basket placed in a public area for the benefit and enjoyment of staff and public alike is not a gift. The same fruit basket, taken home, is a gift.
- Personalized plaques and trophies individually valued at less than \$250.
- Certain travel expenses in conjunction with a speech, panel discussion, or similar service:
  - Payments for lodging and subsistence directly in connection with the event and necessary to your presence for the speech, panel discussion, or similar service.
  - Free admission, refreshments, and other non-cash nominal benefits during the entire event.
  - Actual transportation costs incurred to travel to and from the site for an event within the State of California. Reimbursement for out-of-state travel usually is considered a gift. Reimbursement from a 501(c)(3) may be treated differently—consult one of the resources listed at the end of this document for more help.
- Home hospitality, including at a vacation home owned or leased by the host, when the host or a member of the host's family is present. However, hospitality at a condominium or hotel suite rented on a short-term basis is a gift. In addition, if the hospitality is paid for by the employer or claimed by the host as a business expense, it is a gift.
- Presents that are exchanged on special occasions and the presents exchanged are not substantially disproportionate in value. This applies to birthdays, holidays, and similar occasions.
- Prizes and awards from bona fide competitions not related to the person's status as a University employee.
- Tickets to political fundraising events or fundraising events for a charitable organization exempt from taxation under section 501(c)(3) of the Internal Revenue Code.
- Meals received in the course of an official fundraising activity.
- Other situations. Call one of the numbers at the end of this paper if you have questions.

## ***Exclusions from state conflict of interest regulations***

Certain decisions are excluded from State conflict of interest laws, including:

- Teaching decisions: such as selecting books or other educational materials for use within this institution.
- A personal decision to pursue a course of study or research, actions to fund such a project, and decisions on how to pursue the project. Note, however, that other rules apply to research conflicts and are addressed by the UC research conflict of interest policy (<http://www.ucop.edu/research/disclosure.html>).

## ***What is a kickback?***

In addition to the prohibition under California conflict of interest regulations, the Federal anti-kickback statute penalizes anyone who knowingly and willfully solicits, receives, offers or pays compensation in cash or in kind to induce, or in return for:

- Referring an individual to a person for the furnishing, or arranging for the furnishing, of any item or service payable under the Medicare or Medicaid program; or
- Purchasing, leasing or ordering, or arranging for or recommending purchasing, leasing or ordering, any goods, facility, service or item payable under the Medicare or Medicaid program.

This provision is extremely broad, so some exceptions have been set out, including certain discounts, compensation paid to a bona fide employee by an employer, certain types of compensation for capitated patients, some investments in ambulatory surgery centers, and others. Contact UC Davis Health System Legal Affairs for information about the exceptions.

Even though California conflict of interest law covers some of the same activities, this law is significant for its penalties: an offense is classified as a felony, and is punishable by exclusion from the Medicare program, fines of up to \$25,000 and imprisonment for up to 5 years. In contrast, a violation of the California conflict of interest law is classified as a misdemeanor and may result in disciplinary action or fines of up to three times the dollar amount involved or \$10,000 (whichever is more).

## ***What is a Stark violation?***

The Stark regulations are extremely complex. Stark is a prohibition against self-referrals for the following:

- Clinical laboratory services.
- Physical and occupational therapy and speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices and supplies.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

In general, these regulations only apply to referrals by physicians. However, if a referral made by a physician assistant or nurse practitioner (or other non-physician) is directed or controlled by a physician, it may be viewed as if the directing or controlling physician made it.

When you refer a patient for those services to yourself (outside of UC), an immediate family member (again, outside of UC), or a non-UC entity with which you have a financial relationship

(investment, ownership, or compensation), Stark is potentially violated. There are many exceptions to the regulation. Contact UC Davis Health System Legal Affairs for information about the exceptions.

## ***Example scenarios***

### **1.**

You are invited to an informational conference or seminar and provided free admission to attend (not to speak or participate in a panel). The free admission would not be a gift so long as the conference or seminar is provided to you to assist you in the performance of your official duties. Thus, a conference on new technologies in the field in which you practice and conduct research would fall within this exclusion. However, the exclusion applies only to free admission and nominal benefits during the event, such as a meal, coffee and donuts, etc. However, providing free lodging or transportation to the conference would constitute a gift.

### **2.**

Assume the same facts as above, but you are presenting a poster or abstract at the conference.

Presenting a poster or abstract is not considered a significant service to the sponsor. The same rules apply as in example 1.

### **3.**

You are invited to speak at a symposium being sponsored by a drug company. The speech will be on a topic of state or national public policy and will occur in Palm Springs on a Tuesday morning from 9:00 a.m. to 10:00 a.m. The earliest flight into Palm Springs from Sacramento arrives at 10:20 a.m. Thus, it is necessary for you to travel the night before, receive lodging and dinner that night, and breakfast the next morning. A luncheon is scheduled for noon on Tuesday, to which you are also invited. You will not give a speech at the luncheon. There is a return flight out of Palm Springs that afternoon leaving at 4:30 p.m. You take that flight home. What things are gifts?

None of the payments are gifts. The travel is in California. The lodging and meals are necessary to you being there for the speaking event at 9:00 a.m. They are also directly in connection with your speech at the event. The luncheon is also exempted because it is a meal at the event on the same day you speak. Thus, even if you could have caught a 1:00 p.m. flight home, staying for the meal would not cause the luncheon to be considered a gift.

However, if you stayed over Tuesday night before flying home on Wednesday, the second night's lodging and the second morning's breakfast would be considered gifts

### **4.**

Assume the same facts, but instead the event will be held out of state. Under these facts, the lodging and meals would be treated the same as the in-state speech but the travel payment would be a gift.

### **5.**

A drug company sponsors a lecture series for the residents. Other than providing the food, the company has no control over the event. The department determines the topics. There are no speaker expenses, as all the speakers are member of the faculty. The total cost of the food over the year is \$2250, and there are 15 residents in the department.

The food is a gift. The total gift amount per person is \$150 per year. This gift is below the 12-month \$340 limit, so does not represent a significant financial interest.

## **6.**

Assume the same facts, but instead the drug company pays \$750 to each guest lecturer. The drug company directly pays the guest for the lecture.

The payment for guest lecturers does not represent a gift to the participants and is not counted towards the 12-month \$340 limit. If you are one of the guest lecturers, the payment to you represents a significant financial interest (income more than \$500 in 12 months).

## **7.**

Assume the same facts as in the previous example, but the drug company gives the department money to hire guest lecturers. The department selects the lecturers without either consulting the drug company or using a list provided by the company.

In this example, the department is acting independently of the drug company, and the recipient of the honorarium is considered to have received the money from the department, not the drug company. The less autonomy the department has in making its decision, the more likely the drug company will be seen as the payer and the more likely the speaker's fee creates a significant financial interest in the drug company.

## **8.**

You are being trained as a speaker for educational conferences and meetings. May you accept expense reimbursement from the sponsoring company?

In general, that would constitute a gift. Both the training and its reimbursement raise questions about independence. In addition, the training is a gift because your role is generally more analogous to that of an attendee than a participant. Any fee paid to you is also treated as a gift.

Speaker training sessions can be distinguished from meetings with leading researchers, sponsored by a company, designed primarily for an exchange of information about important developments or treatments, including the sponsor's own research, for which reimbursement for certain travel expenses may be appropriate. Even then, transportation cost reimbursement for out-of-state travel is considered a gift, and an honorarium would be counted as income.

## **9.**

If a company invites you to visit its facilities for a tour or to become educated about one of its products, may the company pay expenses and honoraria?

In general, expenses should not be reimbursed, nor should honoraria be paid for your time since the presentations are analogous to a pharmaceutical company's educational or promotional meetings. Those payments would be gifts.

Medical devices, equipment and other technologies may require, in some circumstances, special evaluation or training in proper usage, which cannot practicably be provided except on site. In cases where the company insists on such visits as a means of protection from liability for improper usage, you may ask your departmental chair or supervisor to approve the activity. In no case would honoraria be appropriate and any expense reimbursement should be only for those strictly necessary. Transportation expenses may be paid only if within California, otherwise it would be a gift.

## 10.

If the company invites you to visit its facilities for review and comment on a product, to discuss their independent research projects or to explore the potential for collaborative research, may the company pay travel expenses and an honorarium?

If you are providing genuine services, reasonable compensation for time and travel expenses (including transportation within California) can be given. Transportation outside California is a gift. The honorarium represents income and counts towards the \$500 12-month limit. However, token advisory or consulting arrangements cannot be used to justify compensation, in which case all compensation constitutes a gift.

To avoid receiving a gift, you or your department could pay for transportation expenses. To avoid receiving income, you could decline the honorarium or have the honorarium paid to your department as an unrestricted gift. To ensure that it is unrestricted, you cannot have control over use of the money and you cannot expect to benefit by it more than anyone else in your department.

## 11.

If a company convenes a group to recruit clinical investigators or convenes a group of clinical investigators for a meeting to discuss their results, may the company pay for their travel, food, and lodging expenses?

Food and lodging expenses may be paid if the meetings serve a genuine research purpose. One guide to their propriety would be whether the NIH conducts similar meetings when it sponsors multi-center clinical trials. When subsidies are acceptable, they may be used to pay only for "reasonable" expenses. The reasonableness of expenses would depend on a number of considerations. For example, meetings are likely to be problematic if overseas locations are used for exclusively domestic investigators. It would be inappropriate to pay for recreation or entertainment beyond modest hospitality.

Signs that a genuine research purpose exists include the facts that there are (1) a valid study protocol, (2) recruitment of investigators with appropriate qualifications or expertise, and (3) recruitment of an appropriate number of investigators in light of the number of study participants needed for statistical evaluation.

Even when the meeting serves a genuine research purpose, payment for travel outside California would be considered a gift. Also, any honorarium paid would count towards the \$500 12-month income limit.

## 12.

A company promises an unrestricted grant or gift if the contract is awarded to them.

This could be construed to be a kickback under the Social Security anti-kickback law. You should report this to the UC Davis Health System Legal Affairs department.

## 13.

You or your spouse is a part owner of a clinical laboratory and you write an order for a patient to receive a test there.

This act probably would violate the Stark self-referral prohibition. Clinical laboratory services are one type of services for which self-referral is prohibited. Your relationship probably does not fall within one of the exceptions. Contact the UC Davis Health System Legal Affairs department for assistance.

## ***Designated officials***

“Designated officials” are employees with special reporting requirements and further restrictions on receipt of gifts and honoraria. The list is updated yearly, and is at <http://www.ucop.edu/ogc/coi/ucda.html>. Currently, the following UCDHS positions are designated:

- Architects/Engineers/Project Managers
- Assistant Chief Pharmacists
- Associate Chief Pharmacist
- Associate Director Clinical Operations
- Associate Director Financial Services
- Associate Director Planning, Design & Construction
- Business Contracts Officer
- Buyers
- Chief Health System Counsel
- Dean
- Director
- Executive Associate Dean
- Materiel Manager
- Medical Stores Manager
- Senior Associate Director Admin & Prof Services
- Senior Associate Director Patient Care Services

## ***Getting help***

This is only the briefest of introductions to conflict of interest issues. In particular, the Stark self-referral prohibitions and Social Security anti-kickback laws are not detailed here. For more information, the following resources may be helpful:

UC Davis Conflict of Interest Coordinator: Lynette Temple 530-752-3949

UC Davis Health System Compliance Office: 916-734-8808

UC Davis Health System Legal Affairs: 916-734-2288

Fair Political Practices Commission (FPPC) hotline will answer anonymous hypothetical questions over the telephone: 1-866-ASK-FPPC (1-866-275-3772)

A more complete listing of the financial interest and gift rules can be obtained from the compliance office or at <http://web.ucdmc.ucdavis.edu/compliance/guidance/conflict/>.

Very detailed information on the conflict of interest regulations can be found at <http://www.fppc.ca.gov/index.html?id=52>.