

**POLICY TO LIMIT CONFLICTS OF INTEREST BETWEEN
HEALTH CARE PROFESSIONALS AND
INDUSTRY REPRESENTATIVES**

The University of Colorado Denver Schools of Dental Medicine, Medicine,
Nursing, Public Health and Pharmacy and the Health Sciences Library

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Background

Productive partnerships between academic health care professionals and industry representatives serve a vital purpose, facilitating drug discovery, technology transfer and the evidence-based use of drugs and medical devices for the benefit of patients. Indeed, the University of Colorado “encourages and supports outside interactions of its faculty and student employees with federal, state and local governments and with business and industry, as important parts of their research, education and public service activities.”¹

At the same time, relationships between industry representatives and health care providers raise the possibility of conflicts of interest. Drug and medical device manufacturers and their representatives frequently provide gifts, meals, honoraria, drug samples and travel stipends to health care providers and trainees in order to increase the sale of their products.^{2 3 4 5 6 7 8 9 10} The promotional information provided by industry representatives may be biased or incomplete, leading to prescribing decisions that are not evidence-based, cost-effective or in the best interests of patients.^{3 5 9 11 12 13 14 15 16 17 18 19 20 21} Gifts, meals and dissemination of biased information may also compromise the scientific integrity and independence of a school’s educational programs.^{4 10 22 23} Finally, gifts, meals, drug samples and paid travel add to the cost of medications for all patients.^{2 5 6 9 10 11 19}

Development of this Policy

The Association of American Medical Colleges (AAMC), the Prescription Project, the American Medical Student Association (AMSA) and various policy leaders have urged all academic medical centers to “accelerate their adoption of policies that better manage, and when necessary, prohibit, academic-industry interactions that can inherently create conflicts-of-interest and undermine standards of professionalism.”¹⁰ Importantly, according to the AAMC, it is the obligation of students, residents and faculty in the health professions “to manage all conflicts of interest, real and perceived, through effective self-regulation.”¹⁰

Therefore, the students, residents and faculty of the University of Colorado Denver Schools of Dental Medicine, Medicine, Nursing, Public Health and Pharmacy and the Health Sciences Library have adopted the following policies to govern and guide their interactions with pharmaceutical and medical device company representatives. The overriding objective is to maintain a critical, reflective and unbiased clinical care and learning environment for faculty and trainees alike.^{4 24 25}

Scope of Policy and Definitions

This policy applies to all health sciences students, residents and other trainees, and to all regular faculty members, at the University of Colorado Denver Schools of Dental Medicine, Medicine, Nursing, Public Health and Pharmacy. Health Sciences Library faculty are also covered by this policy. The term “Health Sciences Center (HSC) students, residents and faculty” is used to describe all these parties in an inclusive manner.

The restrictions and prohibitions contained in this policy apply to all HSC students, residents and faculty who are engaged in learning, teaching or patient care at any of the affiliated hospitals and outpatient clinics, excluding private offices. Faculty members and residents are covered under this policy, even if they are employed by, or based at, an affiliated hospital or institution.

The terms “industry” and “industry representatives” refer to all sales, marketing and other product-oriented personnel, even if they are not classified by the sponsoring company as participating in sales or marketing. All companies manufacturing drugs, medical devices, diagnostic testing equipment or supplies, nutritional supplements and other health-related products are included. However, the term “industry representatives” does not include personnel from drugstores, supermarkets or pharmacies who visit schools or departments to recruit trainees as future employees.

Exclusions

This policy complements, but does not replace, other university, hospital and practice plan policies that govern conflicts of interest. In the event of any inconsistencies between this policy and other applicable policies, to the extent that this policy is more restrictive the provisions of this policy shall apply.

- Part-time (< 0.5 FTE) and volunteer faculty members are excluded. However, part-time and volunteer faculty members may be subject to specific disclosure requirements under the University of Colorado Conflict of Interest Policy. ¹
- The policies and prohibitions set forth below do not address research conflicts of interest, consulting activities, enrollment of patients in clinical trials or participation on hospital pharmacy or formulary committees. These activities are governed by other hospital, University or practice plan policies.
- Similarly, while this policy prohibits receipt of free or discounted drug samples by individual students, residents and faculty, it does not prohibit or restrict distribution of drug samples to hospital practice sites or practices, which are governed by hospital-specific regulations.
- This policy does not prohibit receipt of equipment or supplies by students, faculty or other investigators, when such equipment and supplies are necessary for the conduct of university-approved scientific research.

Relationships with industry representatives are common and often complex. Not every interaction, stipend or gift can be anticipated. When deciding whether a specific situation is covered under this policy, it should be remembered that the principal objective of this policy is to ensure that gifts and payments to students, residents and faculty members do not inappropriately or adversely influence either: a) prescribing or clinical decision-making; or b) the independence and scientific content of the University’s educational programs.

POLICY

A. Gifts and Meals

1. HSC students, residents and faculty may not accept any personal gift from industry or its representatives, even if the gift is of nominal monetary value (*zero dollar limit*). Pens, notepads, mugs, penlights, calipers, textbooks and free or discounted tickets to sporting events are examples of prohibited items.
2. HSC students, residents and faculty may not accept or distribute promotional materials that bear the logo or name of the company.
3. Meals, beverages, snacks or other hospitality paid for by industry or industry representatives shall not be provided to, or accepted by, HSC students, residents or faculty.
4. These prohibitions include all gifts, meals and other hospitality, even if offered after hours or at off-campus venues.

Exceptions to Policies A.1 - A.4

- A school, department, division or center (“academic unit”) may receive unrestricted grants from industry to support teaching conferences, visiting professorships, grand rounds or other educational programs. Such funds from industry must be deposited in a central, conflict-free account that is managed at the level of the academic unit. The academic unit must retain sole discretion for distributing the funds in support of unbiased educational programming or scholarship; there can be no quid pro quo of any kind. Industry representatives may not select speakers or topics and may not pre-approve the content of educational programs, slides or educational handouts. Industry representatives also may not earmark contributions for specific recipients.
- The prohibition against accepting meals and hospitality provided by industry (A.3) does not apply to students or residents who are assigned to off-site private medical, dental or other provider offices.
- The gift restrictions (A.1) do not include receipt of scientific, clinical or other achievement awards, even if funded or named by industry.
- Donations or loans of medical devices, equipment or supplies to academic units, if solely for use in the educational activities of these units, are not prohibited under this policy.
- Policies A.1 - A.4 do not prohibit acceptance of gifts, meals or items bearing industry logos provided as part of an off-site meeting of a professional society, where the items provided are incidental to attendance.
- Policy A.2 does not prohibit distribution of industry-branded educational guides or pamphlets to patients or health care providers, so long as the purpose is education, not marketing or promotion. A responsible faculty member must review the content of the guides to ensure that they provide balanced, evidence-based and objective information.

B. Drug and Medical Device Samples

Individual HSC students, residents and faculty members may not accept free or discounted drug samples, medical devices or other supplies from industry or industry representatives.

Exceptions to Policy B

- Free or discounted drug samples or drug purchase vouchers may be distributed to clinical care units in accordance with specified hospital policies.
- This policy does not prohibit industry representatives from meeting with faculty members, residents or other trainees to demonstrate use of a medical or surgical device, so long as a faculty member has pre-approved, and is present to supervise, the interaction.

C. Travel and Paid Attendance at Meetings

HSC students, residents and faculty may not accept gifts, monetary stipends, paid travel or honoraria solely for attendance at industry-sponsored dinners, lectures or sales presentations.

Exceptions to Policy C

- This policy does not prohibit participation by students, residents or faculty at professional development courses, fellowships or other educational programs, such as continuing education courses or professional meetings, held at other institutions or organizations, even if the educational program receives industry support. Students or residents who attend educational courses or programs must be selected by an academic unit (school, department, division or center) and must receive prior approval by the dean, department chair or division or section head, who must determine that the conference or training program has educational merit.
- This policy does not prohibit participation by students, residents or faculty at on- or off-site educational programs that are designed to demonstrate the proper use of medical or surgical devices or techniques, even if the programs receive industry support.
- This policy does not prohibit an academic unit from creating a conflict-free, central fund to support tuition, travel or participation in educational activities by faculty or trainees.
- This policy does not prohibit travel related to development or conduct of a grant or contract that is related to research or technology transfer.

D. “No Strings Attached” Grants

Individual HSC students, residents and faculty may not accept “no strings attached” grants or gifts from industry or industry representatives; in the absence of work products or other defined deliverables, set forth in a written contract, these are equivalent to gifts and are prohibited.

Exception to Policy D

- This prohibition does not preclude receipt of fair market compensation for specific services provided by a faculty member to a pharmaceutical corporation or medical device manufacturer, where compensation reflects time and effort and where expected work products are defined in advance in a written contract. Thus, contracts for consulting or participation on advisory boards are not prohibited by this policy

E. Participation on Speakers' Bureaus

Speakers' bureaus, which are often "little more than extensions of [a company's] marketing department," may pose real or perceived conflicts of interest.²⁶; In June, 2011 the SOM Speakers' Bureau Policy was modified to **prohibit most speakers' bureau activity by School of Medicine Faculty**. "Speakers' bureau activity" is defined as: *compensation by any pharmaceutical company, medical device manufacturer or manufacturer of other health- or nutrition-related products or their subsidiaries, for speaking engagements whether on a one-time or recurring basis*. This definition does not include compensation for research consulting.

Under this policy, some industry-sponsored speaking engagements are permitted. The policy provides that a committee shall be established by the Dean and Faculty Officers to review requests for approval of non-marketing speaking engagements. Approval will be considered for faculty presentations that represent a genuine service to the community and that are solely for educational purposes. However, approval will not be granted if the talk focuses on specific products, if the speaker is required to use any slides or other materials provided by industry, or if the slides or other content are subject to any oversight or review by industry. In all cases, the faculty member must ensure that the content of all lectures, slides, references and educational handouts represents a balanced and objective assessment of treatment options, and that it is based on the best scientific evidence. In addition, faculty members may not present industry-sponsored talks if the company provides honoraria or gifts to the attendees.

All speaking relationships and contracts are subject to review and approval by the University, in accordance with University and practice plan policies, and must be disclosed annually in accordance with the University's Conflict of Interest Policy. In all cases, a student, resident or faculty member may only receive fair compensation for the services provided and must disclose his or her financial interests at the time of the lecture.

Exception to Policy E

This policy does not seek to limit or discourage participation on speakers' bureaus that is related directly to an active grant or contract and that is organized for the purpose of disseminating scientific data.

E. Ghostwriting

HSC students, residents and faculty may not be listed as authors or co-authors on papers, monographs or other publications that are ghost-written by industry representatives.

F. Continuing Medical Education (CME)

Continuing Medical Education (CME) activities are conducted in accordance with the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support and Accreditation Criteria.²⁶ These standards require disclosure of all financial ties and resolution of potential conflicts, including confirmation that supporting companies have no influence over the content of any CME program or the selection of speakers.

In order to ensure strict compliance with these standards, the Office of Continuing Medical Education and Professional Development (OCME &PD) utilizes a policy and process for resolving any real or potential conflict-of-interest (COI). If a disclosure by a CME program director reveals a financial relationship, then the COI is resolved by one of the following mechanisms, as approved by the OCME&PD Advisory Committee and Associate Dean for OCME&PD:

- *Alter the financial relationship* – Individuals may choose to discontinue or alter their relationship with a commercial entity and eliminate any bias associated with the proposed CME content.
- *Alter control over content* – The individual with the COI is removed from the CME activity.
- *Peer Review* – The course director or Associate Dean for OCME&PD reviews and validates all CME activity content to ensure it is evidence-based and at arms length from any sponsoring companies.
- *Withhold CME credit* - In the rare event that the conflict is unresolved, *AMA PRA Category 1 Credit* will not be provided.

G. Disclosure of Conflicts of Interest and Financial Ties

1. All medical students, residents and other trainees shall submit the same annual disclosure of potential conflicts-of-interest currently required of faculty and staff.
2. During lectures involving medical students, faculty members should declare, verbally or on a slide or lecture handout, the existence of financial ties as disclosed on the University of Colorado Conflict of Interest and Commitment Disclosure form by stating either: “I have financial ties that relate to the content of this presentation that are disclosed to the University [and list relevant ties];” or “I have no financial ties to report.”
3. A disclosure statement shall also be encouraged during small group seminars, clinical experiences and mentored research activities, if the subject matter discussed by the faculty member is directly related to a financial tie disclosed on the University Conflict of Interest and Commitment Disclosure form.

H. Educational Programs

1. “Shielding students and residents from all marketing activity will not prepare them for coping with the barrage of marketing they will face . . . when they complete training and enter practice.”¹⁰ Therefore, the five health sciences schools and the health sciences library faculty will develop inter-disciplinary instructional programs that will help learners understand the conflicts that may arise between industry representatives and health care professionals and how to develop and sustain productive and ethical relationships.^{9 11 20} Educational programs should also include evidence-based medicine, literature search strategies, critical appraisal of the health care literature and academic “counter-detailing” exercises.²⁷
2. The health sciences schools should develop programs to educate students, residents and faculty members about the processes of drug discovery and development, clinical testing, marketing, regulation and adverse event reporting.¹⁰
3. The health sciences schools and library faculties should explore opportunities to develop, in partnership with industry, new portals for disseminating objective and unbiased information about drugs and products that will “optimize the potential of modern information technology.”¹⁰

I. Implementation

The five health professional schools and the library faculty agree to form an inter-disciplinary committee to assist in implementation of this policy, address questions regarding interpretation of the restrictions and recommend changes to the policy as needed.

J. Enforcement

It is the responsibility of all students, residents and faculty members to understand their obligations under this policy.

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