Gifts and Meals

16. May I accept gifts, meals or handouts when I am attending a national professional meeting?

Yes. According to the policy, you may accept gifts, meals or items bearing industry logos provided as part of an off-site meeting of a professional society, where the items are incidental to attendance.

Examples:
- Permitted: At a professional association meeting off-site, the honors dinner is incidental to your attendance. The cost of the dinner has been underwritten by industry. You are permitted under the policy to accept the meal.
- Permitted: At a professional association meeting off-site, you are given a tote bag with paper, pens, and meeting program. The bag and items are incidental to your attendance. The paper, pens and bag have industry logos. You are permitted under the policy to accept these items.
- May I attend an industry-sponsored dinner, assuming that the invited speaker is nationally known and an expert in his or her field?
  No, unless it is a part of a professional conference or a program for CE credit.

17. May I accept meals while on a training rotation at a private provider's office?

Yes. Students and residents who are assigned to off-site private medical, dental or other provider offices are not prohibited from accepting meals and hospitality provided by industry.

This exception does not apply to The Children’s Hospital Colorado, Denver Health Medical Center, National Jewish Medical and Research Center, University of Colorado Hospital, the Veterans Affairs Medical Center or other affiliated hospital, which are not considered “off-site.”

18. May I accept meals when I am acting as a provider for a clinical or other educational program?

Yes. The policy permits acceptance of a scientific, clinical or other achievement awards, even if funded or named by industry.

19. Can my department accept a gift from industry?

Yes. The policy permits a school, department, division or center (“academic unit”) to 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.

Additionally, an academic unit may create a conflict-free, central fund to support tuition, travel or participation in educational activities by faculty or trainees.

Academic units may acknowledge receipt of gifts or unrestricted grants.

Publications

21. May I use slides or materials prepared by industry in presentations that I present or papers that I author?

Yes, but with limitations. If you have determined the content to be appropriate and worth including in your presentation or paper and the slide is complex and difficult to otherwise reproduce, then you may include the slides/materials (including logos) with the proper citation in your publications or presentation. However, as noted above (question 11), faculty members may not participate in a publication or presentation where they are required to use a slide, figure, table, text or other materials prepared by industry, or where any of these materials are subject to review or approval by industry.

19. May I be listed as an author or co-author on industry sponsored papers, monographs or other publications?

No. CU ANSCHUTZ students, residents and faculty may not be listed as authors or co-authors on papers, monographs or other publications that are ghost-written1 by industry representatives.

Examples:
- Not permitted – industry representative has prepared draft publication.
- Not permitted – industry representative has prepared bibliography.
- Not permitted – Industry representative has selected the results to be included.

At all times, any industry support received must be disclosed in the publication.

Samples for Patients

23. Does the policy preclude accepting drug samples for distribution to patients?

No. Free or discounted drug samples or drug purchase vouchers may be distributed to clinical care units in accordance with specified hospital policies. However, individual CU ANSCHUTZ students, residents and faculty members may not accept free or discounted drug samples, medical devices or other supplies from industry or industry representatives.

24. May faculty members utilize industry-prepared dosing charts, clinical guidelines or patient-education handouts that are supplied by industry?

Yes, the policy 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.

1CU ANSCHUTZ defines “ghostwriting” as the provision of written material that is officially credited to someone other than the writer(s) of the material. Transparent writing collaboration with attribution between academic and industry investigators, medical writers, and/or technical experts is not ghostwriting.
General Issues

1. Where can I find a copy of the policy?

http://www.ucdenver.edu/academics/colleges/medicalschool/facultyAffairs/RulesPolicy s/Pages/RulesPolicies.aspx

2. What is the principal objective of the policy?

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.

3. To whom does the policy apply?

This policy applies to all University of Colorado Anschutz Medical Campus (CU Anschutz) students, residents and other trainees, and to all regular faculty members >0.5 FTE at the Schools of Dental Medicine, Medicine, Public Health and Pharmacy and the College of Nursing, Health Sciences Library faculty are also covered by this policy. The term “CU Anschutz students, residents and faculty” is used to describe all these parties in an inclusive manner.

Faculty members and residents are covered under this policy, even if they are employed by, or based at, Children’s Hospital of Colorado, Denver Health Medical Center, National Jewish Medical and Research Center, University of Colorado Hospital, the Veterans Affairs Medical Center or another affiliated hospital or institution. Affiliated hospitals and institutions may also have additional or more restrictive policies governing interactions and relationships with industry representatives.

However, volunteer faculty members are excluded from this policy.

Hospitals or other organizational units may identify other individuals, such as staff, who must also adhere to this policy.

4. To whom do the terms “industry” and “industry representatives” refer?

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.

5. Does the policy apply at night or off-campus?

Yes. The exceptions are listed in FAQ #16.

6. Are industry representatives permitted to demonstrate a device?

Yes. The policy provides that industry representatives can meet 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 presentation.

7. Am I permitted to meet with industry representatives?

Yes. The policy provides that you can meet with industry representatives in accordance with this policy and other institutional policies. You may not accept gifts or meals as part of these meetings.

8. Can we accept equipment as a loan or as part of a research project?

Yes. 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.

9. Does this policy replace the other COI (conflict of interest) policies?

No. This policy complements, but does not replace other university, hospital and practice plan policies that govern conflicts of interest. The Office of Regulatory Compliance can assist you with interpretations and advise you on applicability of COI policies.

10. Who will answer my specific questions about a program, gift or other interaction with industry?

Please address all questions about this policy to the Office of Regulatory Compliance at 303-724-0034 or CO@ucdenver.edu.

Compensation

11. May CU ANSCHUTZ students, residents or faculty members serve on a speaker's bureau that is sponsored or supported by industry?

No, except in limited circumstances. CU ANSCHUTZ students, residents, and faculty may not participate in, or receive compensation for, talks or presentations if:

a) The faculty member is required to use any slides or other instructional materials provided by industry; or
b) The content of the lectures, slides, references or educational handouts is subject to oversight or approval by industry representatives; or
c) The presentation focuses on specific drugs or other products; or
d) The content of the lectures, slides, references or educational handouts does not represent a balanced and objective assessment of treatment options, or is not based on the best scientific evidence (as determined by the faculty member); or
e) The faculty member is offered compensation that is above fair market value; or
f) The company provides honoraria or gifts to the attendees; or
g) The overall purpose of the lecture or course is marketing.

These restrictions do not apply to presentations if approved CE credit is awarded to attendees or if the presentation is sponsored by an academic institution (for example, a visiting professorship or grand rounds presentation).

For SOM faculty members, speakers' bureau contracts and presentations must be reviewed by CU MEDICINE and also by the faculty COI committee established by the Faculty Senate, to ensure that the requirements listed above are met. For more information, see:


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.

Compensation for research consulting is permitted, subject to approval by, and assignment of income to, CU MEDICINE, where applicable. “Research consulting” is not expressly defined by the SOM but generally includes activities that focus on planning, conduct or analysis of a clinical or scientific investigation or dissemination of the results of an investigation performed or coordinated by the faculty member.

12. May faculty consult with industry or serve on advisory boards and receive compensation?

Yes. The policy 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. Faculty members must adhere to other institutional policies regarding outside activities.

13. May a faculty member endorse a product or combination of products or be part of a video to promote an industry product?

No. The University of Colorado Regent policy expressly prohibits explicit product endorsement and requires approval for other uses. Regent Policy 14-B (Use of University’s Name in Advertising) provides:

Consenting to the use of the University’s name in advertising involving explicit product endorsement is prohibited, and the use of the University’s name in advertising not involving product endorsement is permitted only with the express written approval of the President or his designated representative.

Education and Training

14. May I attend an educational conference at another university if it has industry sponsorship?

Yes. CU ANSCHUTZ students, residents and faculty are permitted to participate in professional development courses, fellowships and 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. Gifts or other compensation paid for educational courses or programs must be selected by an academic unit (school, department, division or center) and must receive prior approval from the dean, department chair or division or section head, who must determine that the conference or training program has educational merit.

15. May Continuing Education activities on-campus utilize industry support?

Yes, provided the educational activity is accredited and the industry support is in accordance with the separate University and national guidelines that govern the program and with The Accreditation Council for Continuing Medical Education’s Standards for Commercial Support. “Continuing Education” refers to courses, workshops and symposia that are accredited, that may include participants and speakers from outside the University and that award continuing education credits. Continuing Education activities must be coordinated with the appropriate Continuing Education Office.

However, “recurring structured conferences,” such as tumor board meetings, grand rounds and morbidity and mortality conferences, are covered under this policy, even if continuing education credits are offered.