Policy Number: 05-ACC-001

Adoption Date: March 22, 2005

Editorial Revisions: May 24, 2009

Policy Revisions: June 12, 2012

July 24, 2016

**UCSF CME Disclosure and Resolution of Conflict of Interest Policy**

Policy

In accordance with the Accreditation Council for Continuing Medical Education’s (ACCME) Standards of Commercial Support, it is the policy of the UCSF CME program to ensure balance, independence, objectivity, and scientific rigor in all of its continuing medical education activities. UCSF CME ensures that all personnel involved in planning, production, and teaching of UCSF CME activities will disclose any and all potential conflicts of interest and resolve them prior to the CME activity. The 2004 ACCME Standards for Commercial Support: Standards to Ensure Independence in CME Activities call for accredited providers to produce accredited CME that is independent and free of the control of ACCME-defined commercial interests. Each UCSF CME activity is planned, presented, and evaluated in accordance with these national standards.

To ensure independence, UCSF CME requires that, for each activity:

1. Each individual in a position to influence or control CME content must disclose all financial relationships with any ACCME-defined commercial interests. (OBTAIN)
2. Any individual involved with planning or teaching in a CME activity who discloses a relationship with a commercial interest that creates a conflict of interest with the content of the activity must have that conflict of interest resolved prior to the start of the activity. (RESOLVE)
3. The relevant financial relationships with commercial interests of planners and speakers (or lack thereof) must be disclosed to learners prior to the learners’ participation in the continuing medical education activity. Information provided in this manner includes the name of the individual, the name of the commercial interest, and the nature of the relationship the person has with each commercial interest. (DISSEMINATE)

Definitions

**Planner:** Planner refers to the individual (or individuals) identifying needs and outcomes of a CME activity and selecting its topics and presenters. A planner may also be involved with other logistical aspects of the activity’s design and production. An activity chair or course director, as well as members of a planning committee, are considered planners.

**Faculty**: Faculty refers to an individual delivering, moderating or giving comment on content of the CME activity. This includes authors, activity chairs/course directors, presenters/speakers, moderators, panelists, instructors, and technical trainers.

**Commercial Interest**: As defined by the ACCME, a commercial interest is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The ACCME does not consider providers of clinical service directly to patients to be commercial interests except when the provider of clinical service is owned, or controlled by, an ACCME-defined commercial interest.

**Financial Relationships:** Financial relationships are those relationships in the past 12 months in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit in any amount. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received or expected. UCSF considers relationships of the person involved in the CME activity to include financial relationships of a spouse or partner.

**Relevant Financial Relationship with a Commercial Interest:** A financial relationship of an individual and/or his/her spouse or partner is considered relevant if it is with an entity that produces, markets, resells or distributes health care goods or services that is directly related to the content of a CME activity or to the presentation content or role of the individual in the CME activity.

**Conflict of Interest (COI):** The ACCME and UCSF consider circumstances to create a conflict of interest when an individual has an opportunity to affect CME content about products or services of a commercial interest with which he/she has a financial relationship.

Background

1. **Each individual in a position to influence or control CME content must disclose all financial relationships with any commercial interests (regardless of relevance to content)**. This includes, but is not limited to, Planners and Faculty (as defined above), editors, expert reviewers (including members of the CME Governing Board), and administrative staff.
   1. Planners of CME activities must disclose financial relationships prior to consideration by the Governing Board to allow the activity to offer CME credit.
   2. Faculty, editors, reviewers and staff must disclose financial relationships within a period that allows sufficient time for any identified conflicts of interest to be resolved prior to the start of the activity.
   3. Disclosure must be provided in writing on the standardized OCME *Faculty Disclosure* form or via the online disclosure form accessible from the UCSF CME website*.* In order to properly identify and resolve conflicts of interest, the instrument utilized to collect disclosure information must specify:
      1. the ACCME’s definition of a commercial interest,
      2. that relationships from the previous 12 months must be reported, and
      3. that the relationships of one’s spouse, partner or significant other must also be reported (and indicated as belonging to the spouse or partner).
   4. For Planners, disclosure must take place at the earliest stages of planning and submitted with the CME Credit Request application.
   5. For Faculty, editors, reviewers and staff, disclosure should be submitted no later than 4 weeks prior to the activity.

CME Participation Exclusions:

1. An individual who does not disclose financial relationships, whether by refusal or neglect to complete the UCSF disclosure process, may not participate in a UCSF CME activity.
2. Per ACCME policy, the use of employees of ACCME-defined commercial interests as Faculty and Planners or in other roles where they are in a position to control the content of accredited CME is prohibited, except in the specific situations identified by the ACCME that maintain independence and serve the public interest.
3. Planners and Faculty who are on industry-funded speakers’ bureaus may not participate in UCSF continuing medical education. This includes planning, chairing, moderating, and teaching CME. A speaking engagement for which honorarium is received is not considered part of a speakers’ bureau, unless it contains one or more of these characteristics:
   1. the company has the contractual right to dictate or control the content of the individual’s presentation or talk, and/or
   2. the company creates the slides or presentation material and has final approval of the content and edits, and/or
   3. the individual is expected to act as a company’s agent or spokesperson for the purpose of disseminating company or product information.
4. The CME administrator should confirm with the individual in writing whether or not the relationship is truly a speakers’ bureau or simply an honorarium using the criteria above.
5. **Any individual involved with planning a CME activity who discloses a relationship with a commercial interest that creates a conflict of interest with the content of the activity must have that conflict of interest resolved prior to the certification of the CME activity. Any individual involved with instructing or moderating in a CME activity who discloses a relationship with a commercial interest that creates a conflict of interest must have that conflict of interest resolved prior to teaching in the activity.**
   1. The UCSF CME Governing Board has adopted formal peer review of content as the primary method for resolution of conflicts of interest in UCSF CME programming. Both the activity curriculum and each presentation of faculty with conflicts of interest is formally peer reviewed. Additional information, and changes in content, may be requested of faculty to assist in the resolution of conflicts of interest.
   2. Resolution of conflict of interest must also be disclosed to the audience in advance, stating: “All conflicts of interest have been resolved in accordance with the ACCME’s Standards for Commercial Support.”
6. **The relevant financial relationships with commercial interests, of planners and speakers (or lack thereof) must be disclosed to learners prior to the learners’ participation in the continuing medical education activity.**
   1. Information provided in this manner includes the name of the individual, the name of the commercial interest, and the nature of the relationship the person has with each commercial interest. Information that an individual has no relevant financial relationships must also be disclosed in advance to the learning audience.
   2. All CME presenters and instructors are required to disclose to learners any off-label and/or investigational use of a product and any limitations on the information presented, including preliminary data, anecdotal evidence or unsupported opinion. Individuals must attest that they will make this disclosure and/or not discuss off-label and/or investigational use of products.

The UCSF CME Governing Board requires that at least one member of an activity planning committee, preferably the activity chair, is “non-conflicted” to ensure a fair and balanced selection of content and to perform peer review of presenter content if necessary. “Non-conflicted” refers to an individual who has disclosed she or he has no financial relationships with ACCME-defined commercial interests, or a CME Governing Board member determined that the financial relationships disclosed were irrelevant to the activity content and pre-empted any potential conflict of interest.

Activity content is reviewed for validity by the CME Governing Board, regardless of the nature of commercial relationships among the members of the planning committee.

Procedure

All faculty and staff engaged in the development, teaching, or peer review (or control of content in any other manner) of UCSF continuing medical education activities complete full disclosure of personal financial relationships with ACCME-defined commercial interests. OCME reviews the disclosed relationships and determines if they are relevant to the activity content and if a potential conflict of interest exists. Members of the CME Governing Board or another subject matter expert may be called upon to verify relevancy.

For each Planner or Faculty member that discloses financial relationships, OCME will review disclosed information to determine if such financial relationships are (1) with ACCME-defined commercial interests, (2) relevant to the content of the activity in which the individual is participating, (3) acceptable for participation within the guidelines and polices of UCSF CME. Financial relationships disclosed that are not relevant to the content of the activity do not represent a conflict of interest and are considered resolved.

The UCSF CME Governing Board requires that a non-conflicted subject matter expert peer review all content of presenters with disclosed relevant financial relationships prior to presentation or publication, as the primary method for mitigation of a potential conflict of interest in UCSF CME programming. Content validation includes review of patient treatment recommendations, preferred standards of care and the use of best evidence from the medical literature, inclusion of a disclosure slide, and confirmation of the absence of product promotion or corporate messaging, logos and trademarks.

The CME activity administrator (also known as “coordinator” or “conference manager”) is responsible for obtaining content in the form of slides or handouts from each individual with a conflict of interest in order to conduct peer review of the material. Two to six (2-6) weeks prior to the activity date, the CME administrator sends a final request to speakers for submission of all outstanding speaker slides and/or a substantial draft of proposed slides. Unanswered requests for disclosure or content for peer review are escalated to the Manager of Accreditation and Educational Development, and then to the Director of Innovations and Outcomes or Director of Administration, and finally the Associate Dean for CME.

Content validation forms, used to document peer review of presentation slides, should be pre-populated with presenter, activity and disclosure information and sent with presenter slides or other content materials to the appropriate peer reviewer with a clearly identified completion date. The reviewer is responsible for reviewing all materials submitted to ensure a fair and balanced presentation, free of promotion, and representing the best evidence for the subject matter. The reviewer must indicate any changes needed in the presentation to meet these criteria or indicate that the presentation is approved. Slides in UCSF CME activities must not contain logos of commercial interests, and should use generic names over trade names when referring to pharmaceutical or medical device products. The content validation process thus includes review of the following:

1. Referenced studies are cited to assure that they are scientifically objective and methodologically sound;
2. Inclusion and/or omission of important clinical information is appropriate to the subject matter;
3. Content is evidence-based, balanced and non-promotional in nature.

After confirming the nature of the disclosed relationships, the activity coordinator manages peer review of material as follows:

1. Given a non-conflicted Activity Chair: Assignment to the Activity Chair to review presentation slides and complete a content validation form.
2. Given a conflicted Activity Chair: Assignment to a non-conflicted planning committee member, a UCSF subject matter expert, the Associate Dean for CME or an alternate member of the CME Governing Board. If appropriate, the Manager of Accreditation and Educational Development will work with the Activity Chair to identify and assign a non-conflicted, non-course affiliated individual with expertise in the content area to conduct peer review.
3. The reviewer must indicate his/her opinion on content validity in writing prior to the activity start date to the CME administrator. The reviewer is expected to clarify with the conflicted individual any questions or concerns with the presentation or with the individual’s role in the activity before signing the content validation form. Content validation may be indicated on the appropriate peer review form, by email or written notation. Verbal validation is insufficient.
4. If revision to the presenter’s materials is required, the CME administrator or peer reviewer communicates with the presenter to make the necessary revisions and ensures that final materials reflect the changes noted by the reviewer. This process must be repeated until no other revisions are required and the conflict of interest is deemed resolved. In addition, the presenter should be reminder that they are to speak about the evidence base when making clinical recommendations with balanced presentation of various treatment options which are non-promotional in nature.
5. When revision to the presenter’s materials is not necessary, the conflict is considered resolved, and this is recorded in the activity file.
6. The content validation document, original materials, and finalized materials should be saved to the activity file.

In the circumstance where a presenter or instructor participating in CME will not be presenting content such as slides, handouts, or electronic media (e.g., panelists, case presenters, moderators or hands-on instructors):

1. The individual must be instructed to limit his/her role in the activity to specific actions that prevent addressing any of the following:
   1. The implications, or lack of, for the use of any product;
   2. Recommendations for the use of any product or patient treatment option;
   3. Recommendations on any topics in which the conflict exists.
2. The individual must respond with his or her understanding of the restrictions to his/her role in writing.
3. Documentation of this exchange between the CME administrator or an OCME staff or faculty member and the individual is saved to the activity file.

**Additional Strategies and Resources**

The Associate Dean for CME and the Manager of Accreditation and Educational Development serve as ongoing resources to provide training and answer questions from CME administrators, Planners, Faculty, educational partners/joint providers and potential commercial supporters related to the standards of practice in CME, the ACCME Standards for Commercial Support, and all associated UCSF CME policies.