



Disclosure and Resolution of Conflict of Interest Policy

Policy

In accordance with the Accreditation Council Continuing Medical Education's (ACCME) Standards of Commercial Support, revised September 28, 2004, it is the policy of the University of North Texas Health Science Center Office of Professional and Continuing Education (PACE) to ensure balance, independence, objectivity, and scientific rigor in all of its continuing medical education activities. PACE ensures that all personnel involved in planning and production of UNTHSC-sponsored activities will disclose any and all potential conflicts of interest and resolve them prior to the CME activity. Each activity is planned, presented, and evaluation in accordance with the national standards developed by the ACCME

Background: Overview of ACCME Standards for Commercial Support

In September 2004, the ACCME adopted updated Standards for Commercial Support (SCS) with the intent of further limiting the potential for commercial bias in CME activities. The new standards (available at www.accme.org) promote the development of effective strategies for ensuring full disclosure of faculty relationships with commercial interests, the resolution of potential conflict of interest, and the presentation of impartial and balanced information to learners.

Relevant Sections of ACCME SCS

STANDARD 2: Resolution of Personal Conflicts of Interest

- **2.1**
The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed to the provider all relevant financial relationships with any commercial interest. The ACCME defines "relevant" financial relationships" as financial relationships in any amount occurring within the past 12 months that creates a conflict of interest.
- **2.2**
An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.
- **2.3**
The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.

Standard 2 contains three requirements not present in earlier versions: 1) the ACCME SCS regarding disclosure have been expanded to apply not only to

speakers at CME activities but also to content planners for the CME activities and others who are in a position to influence the content of a CME activity; 2) if a speaker or planner refuses or otherwise fails to disclose conflicts of interest, he or she MUST be recused from the activity; and 3) disclosed conflicts of interest must be "resolved" prior to participation in the planning or presentation of a CME activity.

Following is an abbreviated list of terms provided by the ACCME relevant to this policy.

Commercial Interest: The ACCME defines a "commercial interest" as any proprietary entity producing health care goods or services, with the exemption of non-profit or government organizations and non-health care related companies.

Relevant 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. ACCME considers relationships of the person involved in the CME activity to include financial relationships of a spouse or partner.

Conflict of Interest (COI): The ACCME considers 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.

Procedure

The process for ensuring compliance with this policy applies a multi-step approach including prevention, surveillance, and monitoring/evaluation. The steps for each area are described below.

Identification

All individuals who are involved with planning CME activities must sign conflict of interest disclosure forms prior to planning the CME activity. All relevant financial relationships with any commercial interest must be disclosed. Individuals subject to this requirement include, but are not limited to, activity course directors and program chairs, planning committee members, faculty/speakers/presenters, authors and editors, expert reviewers, moderators, panel members, PACE staff in position to control content and joint sponsor staff in position to control content. This disclosure must be provided in writing on the standardized PACE *Faculty Disclosure* form or in another pre-approved format.

Relevant financial relationships must be disclosed to learners prior to 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. Information that an individual has no relevant financial relationship must also be disclosed in advance to the learning audience.

Resolution

All faculty and non-faculty involved with planning or instructing an activity who disclose a conflict of interest must resolve that conflict prior to the CME activity. Appropriate

mechanisms for resolution will be identified by the planning committee and can include the following:

Non-Faculty Resolution

A non-faculty member, e.g. staff, who has an identified conflict of interest will be asked to recuse themselves from any discussion/decision making process where the conflict of interest would come into play.

Faculty Resolution

Peer Review: A faculty member with a conflict of interest must submit his/her work to a panel for peer review. Recommendations of the panel, as it relates to the conflict, must be taken. If the faculty member refuses the recommendation they will be asked to resign and a new faculty member will be appointed.

or

Evidence-Based: Material to be presented must be the best available evidence in the literature, supported by the grade or level of that evidence and by identifying the conclusions that the evidence supports.

or

Other methods deemed appropriate by UNTHSC.

Refusal to Disclose

Non-Faculty

If a non-faculty member refuses to disclose conflicts of interest then that person will be asked to step down from the position requiring disclosure of conflicts of interest.

Faculty Member

If a faculty member refuses to disclose they will be replaced and not considered to present until such disclosure is made.

Contingency

Because it is sometimes necessary to appoint a speaker at the last minute, most activities with multiple presenters will have at least one back-up presentation by a presenter for which conflict has already been identified and resolved.

Additional Information

Additional information may be requested of faculty/non-faculty to assist in resolution of conflict of interest. Resolution of the conflict of interest must also be disclosed to the audience in advance, stating: "All identified conflicts of interest have been resolved in accordance with the ACCME's Standards for Commercial Support" or similar approved language.

Off-Label Disclosure

In addition, all faculty are required to disclose to learners off-label and/or investigational use of a product and any limitations on the information presented, including preliminary data, anecdotal evidence or unsupported opinion.

Surveillance Onsite Review/Audit

As part of the activity review and approval process, the PACE advisory committee and/or leadership will make recommendations as to the need for an onsite review/audit of a given activity. Factors for making such a determination may include: jointly sponsored

activity, a history of perceived bias if the activity is a repeat activity, high percent of faculty with identified COI that has been resolved, high levels of commercial support, single source commercial support, and/or international destinations. Once a determination has been made that PACE should provide onsite review, staff are assigned to attend selected conferences and will document compliance with the ACCME's SCS.

Evaluation/Monitoring for Bias

CME activity participants may be surveyed about perceived commercial bias as part of the post-activity evaluation.

Additional Strategies and Resources

PACE leadership serve as ongoing resources to provide training and answer questions from CME coordinators, course directors, presenting faculty, educational partners/joint sponsors and potential grantors (commercial interests) related to standards of practice in CME, ACCME Standards for Commercial Support, this and all other PACE CME policies.