



Operating Policy and Procedure

SOM OP: 60.04 Identify, Mitigate and Disclose Relevant Financial Relationships

PURPOSE: The purpose of this policy is to provide guidance to course directors, planning committee members, and presenters regarding the collection of information, identification and mitigation of relevant financial relationships in an accredited continuing education activity.

REVIEW: This policy will be reviewed on September 1st of each odd-numbered year by the Managing Director for Continuing Medical Education. If a revision to the policy is recommended, the CME Committee will review and approve changes.

POLICY/PROCEDURE:

Policy

It is the policy of Texas Tech University Health Sciences Center Office of Continuing Medical Education to abide by the ACCME Standards for Integrity and Independence in Accredited Continuing Education. It is the policy of TTUHSC to collect information from all planners, faculty, and others in control of educational content about all their financial relationships with ineligible companies within the past 24 months and mitigate relationships prior to the individuals assuming their roles.

Ineligible companies are those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. Governmental agencies and providers of direct patient care services are not considered to be ineligible companies.

Procedures

1. Everyone in a position to control the content of an accredited continuing education activity will disclose all financial relationships with any ineligible companies (including name of the ineligible companies and nature of the relationship) using the Disclosure Statement form provided by the Office of CME.
 - a. The Office of CME maintains disclosures on a fiscal year basis. Those who control content (planners/presenters) should disclose any relationships that have occurred within the past 24 months that may be applicable from September 1 through August 31. In the event of a change in relationship status, those who control content must notify the TTUHSC Office of CME for his/her activity and complete an updated disclosure statement.
 - b. Any individual who refuses to disclose all financial relationships will be disqualified from being a planning committee member, teacher, or an author, and cannot have control of or responsibility for the development, management, presentation or evaluation of the accredited continuing education activity.
2. The Office of CME will review the disclosed relationships and exclude owners and employees of ineligible companies from participating as planners, faculty, or other roles unless the educational activity meets one of the expectations that ACCME has listed. Please reference ACCME Standards for Integrity and Independence in Accredited Continuing Education standard 3.2.
3. The Office of CME will determine which financial relationships are relevant to the content of the continuing educational activity, mitigate those relevant financial relationships to prevent commercial bias, and disclose the presence or absence of all relevant financial relationships to learners prior to the activity.

Financial relationships are relevant if the educational content an individual can control is related to the business lines or products of the ineligible company.

Any relevant financial relationships that are disclosed will be mitigated prior to the individuals assuming their roles. The mitigation process consist of using a single or combination of methods appropriate for the situation and activity. Possible methods to employ are:

For presenters with a conflict of interest:

- a. Presenters will attest that clinical recommendations are evidence –based and free of commercial bias.
- b. Presenters will refrain from making recommendations regarding products and services, e.g., limit talk to pathophysiology diagnosis and/or research findings
- c. Presenters will submit their talk/slides in advance to allow adequate time for peer review by non-conflicted person selected by the planning committee.
- d. Presenters may divest themselves of this financial relationship.

For planning committee members:

- a. A conflicted planner will recuse from controlling aspects of planning and content with which there is a financial relationship.
- b. Non-conflicted members of the planning committee may suggest speakers, areas of content, objectives, etc.

Other methods:

- a. Planners/presenters will recommend an alternative speaker for the topic for the planning committees consideration.
- b. The institutional CME Committee may be engaged to review the planners' choices of selection of presenters, content, topics, etc.

4. The ACCME “Worksheet for the identification and Mitigation of Relevant Financial Relationships of Planners, Faculty, and others” will also be utilized to document the mitigation strategies. Letters to planning committee members and presenters will reflect TTUHSC's commitment to compliance with the ACCME Standards for Integrity and Independence in Accredited Continuing Education. Letters to planning committee members and presenters will also set forth the strategies which will be employed to mitigate those relevant financial relationships to prevent commercial bias.
5. The Office of CME will disclose affiliations and non-affiliations of all those who control content to the learners in writing prior to the start of the educational activity via one or more of the following methods:
 - a. Disclosure flyer in packet/syllabus materials
 - b. Documented disclosure announcement in introductory remarks
 - c. Printed disclosure statement on evaluation

The ACCME worksheet “Examples of Communicating Disclosure to learners” will be utilized to effectively provide disclosure to learners in a format that can be verified at the time of accreditation.

6. Participants will evaluate CME activities regarding their perceptions of bias or promotion in the education content. If the participants perceive the presence of bias, the course director shall discuss with the presenter. Utilization of the presenter in the future shall be strongly discouraged by the Office of CME.

Exceptions:

TTUHSC will not identify, mitigate, or disclose relevant financial relationships for any of the following activities:

1. Accredited education that is non-clinical, such as leadership or communication skills training.
2. Accredited education where the learner group is in control of content, such as a spontaneous case conversation among peers.
3. Accredited self-directed education where the learner controls their educational goals and reports on changes that resulted, such as learning teaching, remediation, or a personal development plan.

When TTUHSC serves as a source of information for the self-directed learner, learners will be directed to resources and methods for learning that are not controlled by ineligible companies.