

## Policy on Disclosure of Relationships with Commercial Interests

### Mechanism(s) to ensure disclosure (SCS 2.1, 2.2)

#### Identification of disclosure

All individuals who are involved with planning CME activities must sign (or complete online) conflict of interest disclosure forms prior to providing input about a 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, UNTHSC 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 UNTHSC PACE Faculty Disclosure form or in another pre-approved format, such as a partner's form, once it has been approved by UNTHSC PACE.

In addition to annual disclosure forms, UNTHSC PACE staff are required to complete UNTHSC's annual ethics and compliance training, which reinforces and educates about topics relevant to CME activities, including identifying personal conflicts of interests and State of Texas and internal rules for reporting.

Financial relationships include, but are not limited to, the following:

- Consultant/Advisor
- Grant/Research Funding
- Patent Royalty/Intellectual property rights
- Ownership Interest (equity, stock options or Directly purchased stock excluding mutual Funds)
- Honorarium (except funds received for faculty participation in accredited activities)
- Speakers' Bureau
- Paid member of committees, panels or boards
- Employment

#### 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 carrying out their designated role(s) relative 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/Disqualification**

### ***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. The fact that conflict is resolved will also be disclosed.

## **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 UNTHSC 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 UNTHSC 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 are surveyed about perceived commercial bias as part of the post-activity evaluation. Participants feedback has been found to be relatively reliable, especially in rare cases where bias is interjected in the presentation. In addition, other faculty/planning committee members are responsible for monitoring for bias, as are UNTHSC PACE staff who monitor the activity. A PACE staff member is in the room each time a presentation is made in order to monitor for bias. If bias is detected,

the issue is addressed with the presenter, reported to the most senior UNTHSC staff on file for additional action and documented in the activity file.

### **Additional Strategies and Resources**

UNTHSC 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 UNTHSC PACE CME policies.

### **Mechanism(s) to identify conflicts of interest prior to an activity (SCS 2.3)**

As described above, all individuals who are involved with planning CME activities must sign (or complete online) conflict of interest disclosure forms prior to providing input about a 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, UNTHSC 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 UNTHSC PACE Faculty Disclosure form or in another pre-approved format, such as a partner's form, once it has been approved by UNTHSC PACE.

Once the forms are returned to UNTHSC PACE, they are presented at a weekly (if needed) department meeting. UNTHSC PACE staff (typically coordinators, managers, executive director and/or associate VP) review each submitted disclosure form and makes an initial determination if potential conflict of interest exists. If potential conflict is initially identified, the form is forwarded to the program chair or other non-conflicted faculty member to determine if the initial determination was correct or, if in fact, conflict does not exist. This process occurs well before the activity is conducted.

### **Mechanism(s) to resolve conflicts of interest prior to an activity (SCS 2.3)**

UNTHSC uses several methods to resolve COI prior to an activity. The information below, restated from above, details the most frequently-used methods.

#### ***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, including participating in the National Faculty Education Initiative (NFEI), as deemed appropriate by UNTHSC.

## Process(es) and mechanism(s) for disclosure to the learners prior to the activity (SCS 6.1-6.5)

All conflicts of interests, resolution strategies and source(s) of support from commercial interests are disclosed IN WRITING to each participant in an activity. Participants are directed to the document containing the information prior to each presentation.

UNTHSC does not accept in-kind support from commercial interests in support of its CME activities.

## Definitions

- **“Financial relationships”** are defined as receipt of funds or “gifts-in-kind” by the individual (and his/her spouse/partner or immediate family) in any amount over the past 12 months or in the upcoming months, or for a Principal Investigator or an individual named in grant/research funding to that individual or his/her institution, employer or hospital directly from industry.
- **“Industry”** is defined as any proprietary, for-profit commercial entity producing, marketing or distributing health care goods or services consumed by or used on patients. Non-profit or government organization or non-healthcare related companies are not considered industry.
- **“Individuals”** are defined as persons (and their spouse/partner or immediate family members) who are in a position to control the content of the educational activity. Such individuals include, but are not limited to: activity directors, editorial positions for CME activities, planning committee member, speaker, freelance writer, author, UNTHSC employee, contributor, joint sponsor personnel, and/or vendor.
- **“Grant/Research Funding”** is defined as funds that are received from industry for research or clinical trials and/or educational purposes. The Principal Investigator or any names individual in a grant is considered to have a conflict of interest that requires disclosure and management whether the funds were received directly by that individual or by his/her institution, employer or hospital. Funds from a grant turned in to pay individuals for research or clinical trials that are part of the individual’s employment with the institution or university/school and they were NOT a named individual in the grant will not be considered a conflict of interest and will not need to be disclosed by the individual or to the activity participants.
- Activities with any of the following characteristics are considered participation in a **Speakers’ Bureau** whether or not it is labeled as such:
  - a) A company has the contractual right to dictate what you say
  - b) A company (not you) creates the slide set (or other presentation materials) and has the final approval for all content and edits
  - c) You receive compensation directly from the company and act as the company’s employee or spokesperson for the purposes of dissemination of company-generated presentation materials