

## **POLICY FOR DISCLOSURE OF FINANCIAL RELATIONSHIPS AND RESOLUTION OF CONFLICTS OF INTEREST**

### **Policy**

It is the policy of the University of Arkansas for Medical Sciences (UAMS) College of Medicine to ensure balance, independence, objectivity, and scientific rigor in all sponsored or jointly sponsored educational activities. All individuals who are in a position to control the content of the educational activity (course/activity directors, planning committee members, staff, teachers, or authors of CME) must disclose all relevant financial relationships they have with any commercial interest(s) as well as the nature of the relationship. Financial relationships of the individual's spouse or partner must also be disclosed, if the nature of the relationship could influence the objectivity of the individual in a position to control the content of the CME. The ACCME describes relevant financial relationships as those in any amount occurring within the past 12 months that create a conflict of interest. *Individuals who refuse to disclose will be disqualified from participation in the development, management, presentation, or evaluation of the CME activity.*

**Definition of Conflict of Interest:** A conflict of interest (COI) is considered to exist when an individual has a financial relationship with a commercial interest and the opportunity to influence the CME content relevant to products or services of that commercial interest.

**Definition of Financial Relationships with Commercial Interest(s):** Financial relationships are those relationships 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. 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 for 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.

**ACCME Standards for Commercial Support (SCS) require its accredited providers to have a mechanism in place to:**

1. Identify any relevant financial relationships that individuals who develop and participate in CME activities have with commercial interest(s) that produce healthcare goods or services,
2. Review the information to determine if relationship(s) exist that could create a conflict of interest (COI) with regard to the individual's control of CME content, and to
3. Resolve the conflict of interest prior to the CME activity.

### **Procedures**

1. **Complete a Disclosure and Attestation Statement Form** All individuals involved in planning, content development, and implementation of a CME activity **MUST** complete, sign, and submit the UAMS Office of Continuing Medical Education's (OCME) Disclosure and Attestation Statement form to identify any relevant financial relationships with commercial interest(s) that produce healthcare goods or services, consumed by patients, or used in patient care.

2. **Refusal or Failure to Disclose:** Individuals refusing to disclose or to sign the attestation statement will be disqualified from participating in the CME activity in any capacity. Failure to complete and return a disclosure form is the same as refusing to disclose and requires disqualification from participation.
3. **Review of Disclosure Forms:** The disclosure forms must be reviewed for identification of relevant financial relationships with commercial interest(s).
4. **Resolve All Conflicts of Interest:** The CME Course Director is responsible for resolving conflicts of interest. The following mechanisms for resolving conflicts of interest may be used to bring a successful resolution to the conflict:
  - A. *Altering financial relationships:* An individual may change his/her relationships with commercial interest(s), e.g. discontinue contracted services. In doing so, no duty, loyalty, or incentive remains to introduce bias into the CME content. When an individual divests himself/herself of the relationship, it is immediately no longer relevant and resolves the previous conflict of interest. However, the ACCME requires that the existence of the former relationship be disclosed to the learners during any CME activity in which that individual influences CME content during the 12 months following the divestiture.
  - B. *Altering control over content:* An individual's control of CME content can be altered in several ways to remove the opportunity to affect content related to the products/services of a commercial interest. These include:
    - *Choosing someone else to control that part of the content* – If a proposed teacher/author has a conflict of interest related to the content, choose someone else who does not have a relationship to the commercial interest(s) related to the content.
    - *Change the focus of the CME activity* – The CME provider can change the focus of the activity so that the content is not relevant to the products/services of the commercial interest that is the basis of the conflict.
    - *Change the content of the person's assignment* – The role of a person with a conflict of interest can be changed within the CME activity so that he/she is no longer teaching about issues relevant to the products/services of the commercial interest. For example, an individual with a conflict of interest regarding products for treatment of a disease state could address the pathophysiology or diagnosis of the disease rather than the therapeutics.
    - *Limit the content to a report without recommendations* – If an individual has been funded by a commercial company to perform research, the individual's presentation may be limited to the data and results of the research. Someone else can be assigned to address broader implications and recommendations.
    - *Limit the sources for recommendations* – Rather than having a person with a conflict of interest present personal recommendations or personally select the evidence to be presented, limit the role of the person to reporting recommendations based on formal structured reviews of the literature with the inclusion and exclusion criteria stated (evidence-based). For example, the individual could present summaries from the systematic reviews of a peer-reviewed source.

- C. *Peer Review*: The conflict can be resolved by an effective peer review of content prior to presentation or publication to ensure the content is valid and aligned with the interest of the public. One way to resolve the conflict of interest is to have slide presentations, scientific abstracts or free-standing papers or articles, peer reviewed (evaluated for evidence of commercial bias) by commercially disinterested peers before they are accepted for presentation or publication.
- D. *Attestation*: Persons who indicate the existence of such relationships (potential or actual conflicts of interest) will be asked to agree in writing that said conflicts or relationships will not bias or otherwise influence their involvement in the CME activity. Furthermore, teachers/authors will be required to limit practice recommendations to those based on the best available evidence (or absence of evidence) and that such recommendations be consistent with generally accepted medical practice. *Attestation alone is not an adequate means of conflict resolution.*
- E. *Evaluation*: Attendees will be queried regarding their impressions concerning bias (or the absence of bias) and scientific integrity within the activity. CME Associates, Course Directors, and OCME Staff share the responsibility to evaluate the perception of bias by the learners in any CME activity. They further share responsibility to communicate any evidence of bias to those who created the impression of bias. Documentation of the evidence, and any actions taken based on the evidence, must be communicated to the OCME.
- F. *Elimination*: Activity Directors, activity planning committee members and/or teachers/authors who are perceived as either manifesting conflicts of interest or being biased may be eliminated from consideration as resources (committee members, teachers, authors, etc.) in subsequent certified CME activities.
5. **Disclosure to Participants**: All relevant financial relationships, and/or the lack of relevant financial relationships, must be disclosed to CME activity participants prior to the start of the activity. It is encouraged to use a written method of disclosure, although verbal disclosure is acceptable.

When the disclosure information is made verbally, the Course Director must supply the OCME with written verification that appropriate verbal disclosure occurred before the activity. With respect to this written verification:

- A representative of the provider, who was in attendance at the time of the verbal disclosure, must attest, in writing:
  - that verbal disclosure did occur; and
  - itemize the content of the disclosed information (SCS 6.1)
    - The name of the individual;
    - The name of the commercial interest(s);
    - The nature of the relationship the individual had with each commercial interest.
  - For individuals with no relevant financial relationship(s), the learner must be informed that no relevant financial relationship(s) exist. (SCS 6.2).
- The documentation that verifies that adequate written or verbal disclosure did occur must be completed and sent to the OCME within one month of the activity.

6. **Content Validation:** The content or format of a CME activity and its related materials must promote improvements or quality in healthcare and not proprietary business interest/commercial interest. All CME activities must also be compliant with the ACCME Content Validation Statements which state:
  - All the recommendations involving clinical medicine in a CME activity are based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients.
  - All scientific research referred to, reported, or used in CME in support or justification of a patient care recommendation conforms to the generally accepted standards of experimental design, data collection and analysis.
  - Providers are not eligible for accreditation if they present activities that promote recommendations, treatment, or manners of practicing medicine that are not within the definition of CME; are known to have risks or dangers that outweigh the benefits; or are known to be ineffective in the treatment of patients.
  
7. **Avoid Commercial Bias:**
  - a. **Educational Materials:** Educational materials such as slides, abstracts and handouts may not contain any advertising, trade names or product-group messages.
  - b. **Presentations:** Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, trade names from several companies should be used, not just trade names from a single company.

## **Process**

### **A. CME Activity Planners, Speakers, and Others Who May Influence Content**

1. **Obtain and Review of Disclosure Information** Disclosure of financial relationships with commercial interest(s) must be obtained from all individuals who are in a position to influence the content of a CME activity. This will be accomplished through the order below:
  - a. The Course Director is responsible for communicating, with all individuals in a position to influence the content for the CME activity, information about:
    - i. the need to disclose financial relationships with commercial interest(s),
    - ii. content validation
    - iii. presentation of balanced, unbiased content.
  - b. The CME Associate is responsible for obtaining the existence of, or lack, of financial relationships with commercial interest(s) from all individuals involved in the planning and implementation of the CME activity. A disclosure form is used for this purpose.

- c. The CME Associate is responsible for reviewing the disclosure information and for informing the Course Director of all reported relevant financial relationships.
  - d. The CME Associate sends all disclosure forms (or copies of same) to the OCME.
  - e. The OCME Staff Member reviews and confirms disclosure information was obtained for all individuals in a position to influence the CME content, that all relevant financial relationships were identified by the CME Associate, and that this information was communicated to the Course Director.
2. **Resolution of Conflict of Interests** When relevant financial relationships are identified they must be explored to determine whether a conflict of interest exists. If a conflict of interest does exist, it must be resolved prior to the CME activity.
- a. The CME Associate informs the Course Director of the relevant financial relationship(s).
  - b. The Course Director must explore with the individual(s) who reported the relationship(s)
    - i. whether or not conflict(s) of interest exists and
    - ii. resolve any conflicts through a conflict resolution process.
  - c. After the process, conflicts are considered resolved if:
    - i. No conflict exists;
    - ii. No material conflict exists;
    - iii. Material conflict exists but public good outweighs conflict
  - d. The Course Director submits to the OCME a written document that describes the resolution process, the decisions made, and the actions taken.
  - e. The OCME Staff Member reviews and confirms the resolution process, decisions, and actions. If the review reveals that a satisfactory resolution of the conflict has not been achieved, the Course Director is consulted to continue to resolve the conflict.
  - f. If this does not result in satisfactory resolution of all conflicts of interest, the resolution process will move through the following levels:
    - i. Assistant Director of CME
    - ii. Director of CME
    - iii. Associate Dean of CME
    - iv. CME Advisory Committee
    - v. Other resources with appropriate expertise
  - g. The conflict will be satisfactorily resolved or the involved individual will not be permitted to be involved in the CME activity. Documentation will be provided to the OCME outlining the resolution method and the result.

## **B. CME Advisory Committee Members**

1. Disclosure of financial relationships with commercial interest(s) must be obtained from all potential CME Advisory Committee Members.

2. The Assistant Director reviews the disclosure statements to identify and resolve conflicts of interest.
3. If this does not result in satisfactory resolution of all conflicts of interest, the process will continue through the following levels:
  - a. Director of CME
  - b. Associate Dean of CME
  - c. CME Advisory Committee
  - d. Other resources with appropriate expertise
4. After the process, conflicts are considered resolved if it is determined:
  - a. No conflict exists;
  - b. No material conflict exists;
  - c. Material conflict exists but public good outweighs conflict
5. If the conflict cannot be satisfactorily resolved, the Dean will request and accept the resignation of the involved CME Advisory Committee member.

Revised and approved March 16, 2009