



## Identifying and Resolving Conflicts of Interest in Continuing Medical Education

### *Implementing the 2004 Updated ACCME Standards for Commercial Support*

Standard 2 of the ACCME's *Updated Standards for Commercial Support* calls for "resolution of personal conflicts of interest." For everyone in a position to control the content of a CME activity, CME providers must:

1. Identify all relevant financial relationships with any commercial interest (SCS 2.1),
2. Have a mechanism to determine whether these relationships create a conflict of interest with the individual's control of content (SCS 2.3), and if so
3. Have a mechanism to resolve all conflicts of interest prior to the education activity being delivered (SCS 2.3).

### **Underlying Issues**

- Accredited CME providers must place a higher priority on the health and well being of the public than on individuals' personal economic interests.
- Some people in CME have personal economic interests derived from financial relationships with commercial interests that create a personal sense of duty or loyalty to the commercial interest.
- Some financial relationships with commercial interests are important enough to conflict with the person's responsibility to CME learners and to conflict with the public interest.
- If a person in CME has a conflict of interest, the CME provider must manage the conflict in a manner that is in the best interest of the public.

### **Mechanisms to Identify and Resolve Conflicts of Interest**

The ACCME requires that accredited providers establish mechanisms to identify and resolve conflicts of interest. The remaining sections of this document provide some ACCME definitions and expectations regarding these processes. The ACCME does not believe there is one compliance mechanism or strategy that must be used to be in compliance. Accredited providers are allowed the flexibility of developing mechanisms that are appropriate for their organizations and for the way in which the content for a CME activity will be developed. The CME provider meets ACCME's requirements by having a successful mechanism in place. Evidence of compliance is that the CME provider can describe the mechanism and can document its ability to identify and resolve conflicts of interest.

***As an example,** for many CME activities the mechanism will have sequential steps for planners and presenters. A CME provider begins the process by identifying a lead individual to form a planning committee for a CME activity and requests a disclosure of the individual's relevant financial relationships. The CME provider determines whether the individual has conflicts of interests and resolves them as necessary. Next, the individual identifies likely members of the planning committee and requests disclosures from them. The individual determines whether potential planning committee members have conflicts of interest and resolves them as necessary. When the planning committee is formed, the planning committee outlines the program content and identifies likely presenters and requests disclosures from them. The planning committee determines whether potential presenters have conflicts of interests and resolves them. The mechanism can be described and its functioning documented through the disclosures obtained and all individuals controlling content having no unresolved conflicts of interest.*

## 1. Identify Relevant Financial Relationships (SCS 2.1, 2.2)

ACCME focuses on individuals in a position to control the content of a CME activity. For these individuals relevant financial relationships are those in which the individual has both:

- A relationship with a commercial interest (a) that benefits the individual in any financial amount and (b) that has occurred within the past 12 months; and
- The opportunity to affect the content of CME about the products or services of the commercial interest

[Definitions of the terms “commercial interest” and “financial relationship” are provided at the conclusion of this document.]

When CME providers are considering placing individuals in roles that will control the content of a CME activity, CME providers must obtain from the individuals disclosures of their financial relationships likely to be relevant to the role being considered. Roles include CME planning, speaking, authoring, or other positions that control CME content. Individuals who refuse to disclose relevant financial relationships are disqualified from roles with the opportunity to affect the development, management, presentation or evaluation of the CME activity (SCS 2.2).

## 2. Identify Conflicts of Interest (SCS 2.3)

The CME provider must have a mechanism to determine whether individuals who have control of CME content have conflicts of interest. The primary source of information is likely to be the relevant financial relationships disclosed by individuals. The provider may need to clarify information that individuals disclose and individuals’ assumptions about their roles. A provider determines that a conflict of interest is present when the individual both has a financial relationship with a commercial interest within the past 12 months and has the opportunity to affect content relevant to products or services of the commercial interest.

## 3. Resolve Conflicts of Interest (SCS 2.3)

When an individual with control over CME content has a commercial conflict of interest, the CME provider must have a mechanism to resolve the conflict so as to assure that the best interest of the public is the priority. A conflict of interest can be resolved by sufficiently modifying either of the two factors that create the conflict:

- Alter the financial relationship with the commercial interest; **and/or**
- Alter the individual’s control over CME content about the products or services of the commercial interest

Presented below are some **examples** of strategies that will resolve conflict of interest, followed by some **examples** of strategies that do not adequately resolve conflict of interest.

**Alter financial relationships.** Individuals may change their relationships with commercial interests (e.g., discontinue contracted services). This way no duty, loyalty, or incentive remains to introduce bias into the CME content.

**Alter control over content.** An individual’s control CME content can be altered in several ways to remove the opportunity to affect content related to the products and services of a commercial interest.

Possible alternatives that “**alter control over content**” include the following:

- Choosing someone else to control that part of the content. If a proposed speaker has a conflict of interest related to the content, choose someone else who does not have a relationship to the commercial interests related to the content.

- Change the focus of the CME activity. The CME provider could change the focus of the activity so that the content is not about products or services of the commercial interest that is the basis of the conflict of interest.
- Change the content of the person's assignment. The role of a person with a conflict of interest can be changed within the activity so that it is no longer about products or services of the commercial interest. For example, an individual with a conflict of interest regarding products for treatment of a condition could address the pathophysiology or diagnosis of the condition, rather than 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 the Cochrane Collaboration.

The above list of mechanisms to alter control over content is not exhaustive. Providers should consider the objective of sufficiently modifying individuals' control over content so that a conflict of interest is no longer present.

**Actions that do not resolve conflicts of interest.** Listed below are examples of actions that do not resolve conflicts of interest.

- "Balance" by adding someone without a conflict. Conflicts of interest are not resolved by adding the views of someone without a conflict of interest to the views of someone with a conflict of interest, for example in a "point – counterpoint" presentation. ACCME uses the term "balance" to refer to a separate mechanism to prevent commercial bias. In a balanced presentation no single product or service should be represented when other equal but competing products are available. (SCS 5.2) More broadly, CME presentations should base recommendations on available evidence, e.g., "On balance the data support the following . . ." However, ACCME expects personal conflicts of interest to be resolved. All views concerning recommendations in CME content need not agree, but they should be offered by individuals who do not have personal conflicts of interest related to the content.
- Disclosures or disclaimers. ACCME does not accept disclosures or disclaimers as mechanisms that resolve conflicts of interest. Conflict of interest is not resolved by a person saying to learners, "*I know I have a conflict of interest that may or may not bias my views– but I believe my way is the right way to treat patients and here it is.*" Formal CME activities are now being held to a higher standard than simple disclosure in assuring independence from commercial influences.
- Quoting literature. If an individual with a conflict of interest can select the evidence to be presented, the conflict of interest is not resolved. While evidence-based presentations are important in CME activities, equally important is assuring independence in selecting the evidence to be presented. Basing a presentation entirely on scientific evidence that is derived from or is all in favor of the commercial interest that is the basis of the conflict of interest does not prevent commercial bias.

**Failure to resolve conflicts of interest.** If modifications cannot be made, the conflict of interest is not resolved. In order to preserve the independence of continuing medical education, an individual with an unresolved conflict of interest must not have responsibility for, or control of, the content, planning and implementation of continuing medical education related to the unresolved conflict of interest.

## **APPENDIX: Definitions of “Commercial Interest” and “Financial Relationships”**

**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.

**Financial relationships.** 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 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.