



On September 28, 2004, ACCME announced its adoption of the "2004 Updated ACCME Standards for Commercial SupportSM," effective for all CME activities after May 2005.

Contemporaneous with the release of the Updated Standards for Commercial Support, the ACCME released information intended as resources for implementing the Updated Standards for Commercial Support. The resources included background rationale, answers to questions about compliance, and "Identifying and Resolving Conflicts of Interest in Continuing Medical Education." We have revised the document "Identifying and Resolving Conflicts of Interest in CME" to ensure that the information is presented in a constructive manner.

These resources have been prepared by the ACCME, but are not part of the Updated Standards for Commercial Support. The ACCME will base its accreditation decisions on substantial compliance with all ACCME accreditation standards in effect, including the Updated Standards for Commercial Support.

Identifying and Resolving Conflicts of Interest in Continuing Medical Education

An Educational Resource for Implementing the ACCME Standards for Commercial SupportSM

Background

Values Underlying the ACCME Standards for Commercial Support

1. Accredited CME providers must place a higher priority on the health and well being of the public than on individuals' personal economic interests.
2. 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.
3. 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.
4. 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.

The ACCME requires that accredited providers establish mechanisms to identify and resolve conflicts of interest (COI). ACCME expects that at initial accreditation and reaccreditation accredited providers will be engaged in a process that goes beyond simple disclosure, with necessary interventions to resolve conflict of interest implemented before the activity. The ACCME recognizes there are a variety of mechanisms and strategies for compliance. Accredited providers are allowed the flexibility of developing mechanisms that are appropriate for their organizations and activities. The following sections demonstrate **with examples** how providers can implement a mechanism to identify and resolve COI – as well as demonstrate compliance to the ACCME.



In many places throughout the document you will see this icon and font associated with ideas or examples. The reader should understand that these are not prescribed practices nor do they represent a list of options from which providers must choose. They are simply ideas or examples that ACCME believes represent practices in keeping with the spirit and word of the 2004 Standards for Commercial Support.

1 Relevant Financial Relationships (SCS 2.1, 2.2)

The ACCME has **adopted the following working definitions.**

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.

Relevant financial relationships are financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

ACCME **has not set a minimum dollar amount** for relationships to be significant. Inherent in any amount is the incentive to maintain or increase the value of the relationship.

Circumstances 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.

Accredited providers must engage in their mechanism(s) to identify and resolve conflicts of interests prior to the education activity being delivered to learners.

In order to begin the process of managing COI, the provider must know about relevant financial relationships prior to the activity being developed and delivered to the learners. CME providers must obtain from the planners, speakers or authors disclosures of their financial relationships that are relevant to the content being considered or planned for the activity (SCS 2.1). This disclosure information is so important to the CME process that individuals who refuse to disclose relevant financial relationships are disqualified from having a CME role that will give them the opportunity to affect the development, management, presentation or evaluation of that CME activity (SCS 2.2).



Two approaches that providers have offered to ACCME as their mechanisms for getting disclosure information -

Provider asks for...

1. ...disclosure of all financial relationships from planners, speakers or authors.
2. ...disclosure only of financial relationships from planners, speakers or authors where the relationship is associated with the content of the activity.

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2 Identifying Conflicts of Interest (SCS 2.3)

From the ACCME's perspective, a COI is present when a planner, speaker or author has **both** a current financial relationship with a commercial interest **and** the opportunity to affect content relevant to products or services of that commercial interest.

The CME provider must have a mechanism to determine if conflicts of interest are present for individuals who have control of CME content.

Conflicts of interest are identified through an analysis of the information disclosed and an understanding of the planned content of the CME. Circumstances create COI. Context counts. A passage from one ACCME accredited provider's institutional COI Policy may help put this issue in perspective.



"A conflict of interest occurs when there is a divergence between an individual's private interests and his or her professional obligations to [the institution] such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. A conflict of interest depends on the situation, and not on the character or actions of the individual."

When a person has divested themselves of a relationship any associated conflict of interest is resolved. However, the relationship must be disclosed to the learners for the next 12 months, as part of demonstrating compliance with SCS 6.

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3 Resolving conflict of interest in CME (SCS 2.3)

What can a provider do to manage COI? A provider's 'best' strategy depends, largely, on the facts and circumstances of the activity. So, any examples the ACCME offers are presented for clarification and explanation. Providers must develop solutions that best fit the facts and circumstances of their program of CME.

In CME there are two components to conflict of interest – a current financial relationship with a commercial interest **and** the opportunity to affect content relevant to products or services of that commercial interest. So, as long as the relationship is current, managing or resolving the COI must involve the content of the CME. This is where the provider and teacher/author need to identify safeguards that can be, or already are, incorporated into the process to prevent the insertion of commercial bias.

The following approaches, which may be chosen by some providers, can be seen to resolve conflict of interest.

Sometimes the mechanism involves specifying, “Who does what?” within an activity:



“Because our medical staff only wanted to know about patho-physiology and to understand the mechanisms of disease we asked the person with the conflict of interest to limit their presentation to these areas, so that her financial relationships were not relevant to the educational event.”



“We managed the person’s COI and took steps to prevent commercial bias by asking someone else, without a COI, to evaluate and discuss the clinical implications of the primary speaker’s discovery for us – after the primary speaker reported on her scientific discovery.”



“When a proposed speaker has a conflict of interest related to the content, we choose someone else, who does not have a relationship to the commercial interests related to the content to resolve the conflict of interest.”



“When a proposed speaker has a conflict of interest related to content we sometimes will change the focus of the activity so that the content is not about products or services of the commercial interest that are the basis of the conflict of interest.”



“When an individual has been the principal investigator on a project funded by a commercial interest, we will choose to limit the individual’s presentation to the data and results of the research. Someone else could be assigned to address the broader implications and recommendations for clinical care.”

Sometimes the mechanism involves *content validation* --- Providers have offered the following as elements of their mechanisms to resolve COI when they chose not to alter the content of the activity or the role of the person with a conflict of interest.



"We notify potential teachers, in writing, that we follow the ACCME Standards for Commercial Support. We tell them that they have an important role in maintaining these standards. We require them to base their presentation and recommendations on the 'best available evidence.' Our audience judges if commercial bias is present. Our planning committee monitors the presentations."



"We limit or specify the sources for recommendations that the teacher or author can use - as per the American Academy of Family Physicians Evidence Based CME requirements. Rather than having a person with a conflict of interest present personal recommendations or personally select the evidence to be presented, we limit the role of the person to reporting recommendations based on formal structured reviews of the literature with the inclusion and exclusion criteria stated (known as 'Evidence-based education'). For example, the individual could present summaries from the systematic reviews of the Cochrane Collaboration."



"We have always asked our teachers/authors to submit their presentations for peer-review. In this way our planning committee identifies bias before publication on our website."



"Over the years, we have combined several tactics into a mechanism to resolve conflicts of interest that preserves participation of experts with financial relationships. First, presenters, authors, planners and reviewers are instructed to base recommendations for clinical care on the best available evidence. This is in addition to our peer review of content prior to presentation or publication that ensures the content is valid and aligned with the interest of the public. Then in addition, as a form of peer review, participants are asked to evaluate the objectivity of the presentation or publication, and to identify any perceived commercial bias. We intervene at the activity, or after the activity, to address any bias issues that have crept in."

Actions that do not, in themselves, demonstrate that the provider has engaged in a process to resolve conflicts of interest prior to the activity.

Formal CME activities are now being held to a higher standard than simple disclosure in assuring independence from commercial influences. ACCME will not accept simple disclosures (as specified in Standard 6) or disclaimers, on their own, as a mechanism to resolve conflict of interest.

Describing and Documenting a Mechanism to Identify and Resolve Conflict of Interest

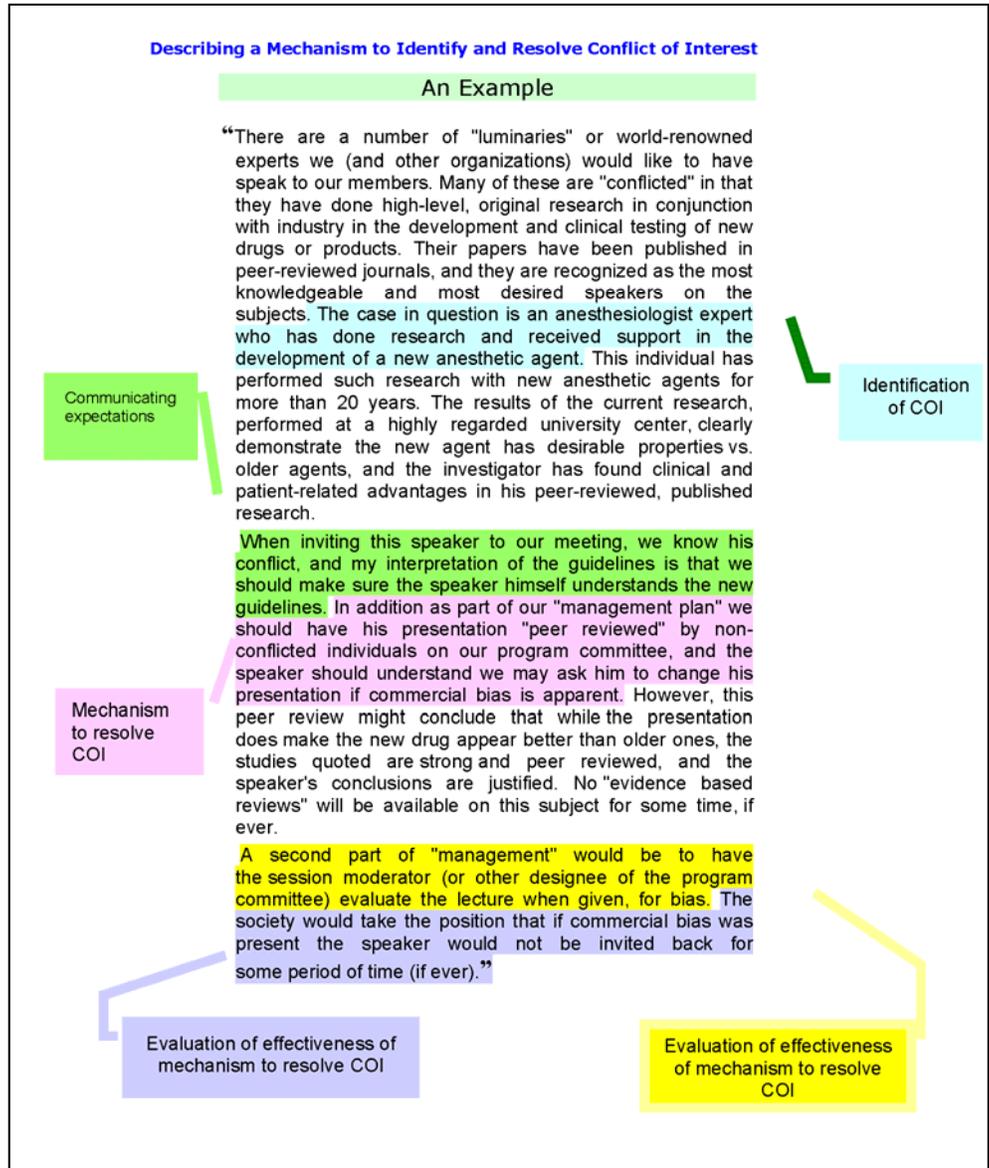
The provider needs to document the implementation of the safeguards they have chosen so that ACCME can verify the provider has a mechanism to identify and resolve COI. As has always been the case, providers will be asked to **1)** describe their practices in the Self-Study Report prepared for the initial accreditation and reaccreditation process and **2)** provide examples and documentation of how the process was actually used for their CME activities.

Here is an actual example of a mechanism that was shared with the ACCME by a provider.

The colored highlights in this example demonstrate how much information about compliance this provider has in this brief description-that could very well be included in the provider's self-study report.

The ACCME expects that accredited providers will demonstrate compliance with this accreditation requirement in the same ways that they currently demonstrate compliance. That is, performance-in-practice will serve to verify compliance. Accredited providers will be able to use the documentation produced during normal planning and implementation of CME to verify:

- That all who are in a position to control content have disclosed relevant financial relationships. (SCS2.1)
- That individuals who refuse to disclose are disqualified from any role involved in planning, management, presentation, or evaluation. (SCS 2.2) (**When applicable**)
- The implementation of a mechanism to identify and resolve conflicts of interest prior to the start of an activity. (SCS 2.3)
- That disclosure of relevant (or no) financial relationships of those with control of content was made to learners prior to the beginning of activity. (SCS 6.1, 6.2)
- That honoraria and expense reimbursement were paid in compliance with the provider's policies and procedures. (SCS 3.8)
- That signed written agreements documenting terms of commercial support exist. (SCS 3.4-3.6) (**When applicable**)
- That disclosure of source of commercial support was made to learners prior to the activity. (SCS 6.3) (**When applicable**)



Next Steps

The ACCME has already started sharing examples of mechanisms for resolving COI through these resources and at its accreditation workshops. Accredited providers have come forward to offer their strategies to their colleagues.

The ACCME bases its accreditation process on an 'Improvement' model. Accredited providers found *Not in Compliance* or in *Partial Compliance* with any accreditation requirement are **1)** Informed of the difference between what they are doing and what ACCME expects and **2)** Given time (usually one year) to modify their practices and then asked to demonstrate compliance. The ACCME has found that in almost all cases this mechanism results in accredited providers coming into *Compliance* with ACCME requirements.