



SANFORD SCHOOL OF MEDICINE
The University of South Dakota
CONTINUING MEDICAL EDUCATION

ENTITY Sanford School of Medicine of The University of South Dakota	NUMBER
SUBJECT Identification and Resolution of Conflicts of Interest-- policy	REVISED June 6, 2007 July 21, 2008

I. PURPOSE

The ACCME updated their *Standards for Commercial Support (Standards to Ensure Independence in CME Activities)* on September 27, 2004 with revisions in August 2007. In accordance with these new *Standards*, this Policy on Identification and Resolution of Conflict of Interest exists to provide guidance for all staff, instructors, planners and managers of CME activities sponsored by the Office of Continuing Medical Education Sanford School of Medicine of The University of South Dakota.

III. DEFINITIONS

A. Commercial Interest

The ACCME has revised its definition of a commercial interest as of August 2007. A **commercial interest** is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

The ACCME does not consider providers of clinical service directly to patients to be commercial interests.

A commercial interest is not eligible for ACCME accreditation. Within the context of this definition and limitation, the ACCME considers the following types of organizations to be eligible for accreditation and free to control the content of CME:

- 501-C Non-profit organizations (*Note: ACCME screens 501c organizations for eligibility. Those that advocate for 'commercial interests' as a 501c organization are not eligible for accreditation in the ACCME system. They cannot serve in the role of joint sponsor, but they can be a commercial supporter.*)
- Government organizations
- Non-health care related companies
- Liability insurance providers
- Health insurance providers

- Group medical practices
- For-profit hospitals
- For profit rehabilitation centers
- For-profit nursing homes

B. Commercial Support

The ACCME defines commercial support as financial or in-kind contributions given by a commercial interest, which are used to pay all or part of the costs of a CME activity.

C. 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. Contracted research includes research funding where the institution gets the grant and also manages the funds. Importantly, ACCME considers relationships of the person involved in the CME activity to include financial relationships of a spouse or partner.

D. Conflict of Interest

The ACCME considers financial relationships to create actual conflicts of interest in CME when individuals have both a financial relationship with a commercial interest and the opportunity to affect the content of CME about the products or services of that commercial interest. The ACCME considers “content of CME about the products or services of that commercial interest” to include content about specific agents and/or devices, but not necessarily about the class of agents and/or devices, and not necessarily content about the whole disease class in which those agents and/or devices are used.

When do relationships create ‘conflicts of interest?’ (SCS 2.1)

The ACCME considers financial relationships to create actual conflicts of interest in CME when individuals have both a financial relationship with a commercial interest **and** the opportunity to affect the content of CME about the products or services of that commercial interest.

Where is the “conflict”? SCS 2.1

When the provider’s interests are aligned with those of a commercial interest the interests of the provider are in ‘conflict’ with the interests of the public. The interests of the people controlling CME must always be aligned with what is in the best interests of the public.

How do these circumstances create “conflict”? SCS 2.1

The potential for increasing the value of the financial relationship with the commercial interest creates an incentive to influence the content of the CME – an incentive to insert commercial bias. Commercial bias is prohibited in CME.

IV. Intent of Conflict of Interest resolution principles

The OCME of SSOM maintains the assertion that the control of CME activities must exist free of biased or commercial interests. Only with this separation and independence can the learner be assured that the activity will represent high quality education presented with integrity, objectivity and validity. Given this intent, the OCME functions in all sponsored or jointly sponsored activities to evaluate and control the process, content, and deliverance of all programs to maintain these high standards and in the event that COI may be possible or exist, guarantee that the public and the learner be protected or that a method to resolve the conflict be implemented.

- A.** To insure independence, the establishment exists of a multi-level monitoring at all levels of the activity.
 - 1. Course Director, planning committee members, staff member or anyone who may be in a position to control planning, development process or content will receive information defining COI. Each member will be asked to review COI Disclosure guidelines and complete a formal disclosure statement and return in a timely manner prior to planning activities.
 - 2. The activity presenter, case presenters, panelists, moderators or anyone else involved with control of content will receive information defining COI and complete a formal disclosure statement and return in a timely manner that allows for adequate review.

For Regularly scheduled activities, commercial relationship disclosure guidelines shall include:

1. Requirement of anyone in a position to control content to be disclosed.
2. The course director in corroboration with the course/activity coordinator should make the determination if an individual may be in a position to influence control of content and should be disclosed.
3. Disclosure forms will be completed before each activity by all such designated individuals
4. Course director and course coordinator shall review the completed disclosure forms. If any type of relationship is noted to exist, the course director will decide if a Conflict of Interest exists.
5. In the event of a COI, the course director must resolve the conflict of interest prior to educational activity.
6. Documentation of the type of COI and the process of resolution of the COI will be recorded and retained in the activity files.
7. Transmission of relevant information from the disclosure forms will be presented to the activity participants by one or more of the following disclosure forms:
 - a. Copies of the completed disclosure forms adjacent to sign-in sheets
 - b. Disclosure information may be placed on a poster and displayed at the activity
 - c. Disclosure information may be included in the activity handouts
 - d. Disclosure announcements may be made with speaker introductions
 - e. Disclosure slide may be acknowledged at the beginning of speakers slide presentation
8. The manner and the information disclosed to the audience must accompany the activity file

Techniques for identification of COI

- i. Pre-activity interventions
 1. Course director (or designated physician) reviews all disclosure forms to assess for COI.
 2. Course director (or designated physician) reviews slides and presentation materials potential bias or COI before presentation.
- ii. Activity interventions
 1. Course director or physician appointed by the director evaluates the activity content for commercial bias
- iii. Post-activity assessment

1. Audience evaluation for perceived commercial bias

Resolution of Conflict of Interest

Establishment of COI requires that resolution must be completed prior to the activity and may take many forms that upon review meet the approval of the course director or the Medical Director of CME. These may include one or several of the following methods but are not limited to:

1. Written or oral request by course director for change of content.
2. Course director asks for evidence based peer review that leads to altering the content of educational material to become compliant for content that previously had been judged to have commercial bias.
3. Limiting or changing the role of any individual who may have a relationship or conflict of interest in a manner such that they no longer have relevant control of content.
4. If unable to resolve COI, deny the individual a role in content creation or delivery
5. Withdraw or deny CME certification for any or all educational activities in which other forms of resolution of conflict failed.
6. During activity course director or appointed physician perceives COI and through directed questions and comments counters commercial bias.
7. Post activity course director may formally discuss with the speaker the perceived bias and how to avoid in the future.
8. Option to not invite the presenter to speak in the future.

Documentation

Each of the above steps will be documented on a resolution of Conflict of Interest form that will be completed by the course director or the designated physician surrogate and placed in the permanent activity file.

V. ACKNOWLEDGEMENT OF COMMERCIAL SUPPORT TO LEARNERS

The source of all support from commercial interests must be disclosed to learners. When commercial support is “in-kind”, the nature of the support must be disclosed to the learners. Importantly, the disclosure of support from a commercial interest must never include the use of a trade name or a product-group message. However, acknowledgement of commercial support may state the name, mission, and areas of clinical involvement of the company or institution and may include corporate logos and slogans, as long as they are not product promotional in nature.



Disclosure of Commercial Relationships

Activity Title: _____ Activity Date: _____

Name: _____

Check one: Speaker Course Director Author Reviewer Moderator Planning Committee

Topic: _____

As a provider accredited by the Accreditation Council for Continuing Medical Education (ACCME), Sanford School of Medicine of The University of South Dakota Office of Continuing Medical Education must ensure balance, independence, objectivity, and scientific rigor in all its individually sponsored or jointly sponsored educational activities. Any individual being considered to participate in a sponsored activity who is in a position to control the content is required to disclose any financial relationships* with commercial interests**. The intent of this disclosure is to aid the Office of Continuing Medical Education in determining: 1) if a conflict of interest exists; and, if so, 2) if that conflict can be resolved. All such information disclosed by everyone appointed to participate in the CME activity will be disclosed to the CME activity participants. Refusal to disclose prohibits participation.

PLEASE REVIEW CAREFULLY and COMPLETE EACH SECTION

I. Do you, your spouse or legally recognized domestic partner, or dependent children currently (within the past 12 months) have a financial interest* with any commercial interests**? YES NO

Should your status change, you are responsible for notifying the Office of CME as soon as possible.

II. I have the following relevant*** financial interests*, arrangements, or affiliations with the following commercial interests** (if additional space is needed, please attach):

Affiliation/Financial Interest	Name of Organization(s)
Grant/Research Support	
Consultant	
Speakers' Bureau	
Stock Shareholder	
Other Financial or Material Support	

III. If you have relevant relationships***, do you feel you are able to participate in and/or present the CME activity in a fair and unbiased manner? YES NO

IV. I attest that I am **not** receiving direct payments from a commercial entity with respect to this activity.

Initials

VII. Commercial Bias (speaker/author only)

The Standards for Commercial Support require that your presentation be free of commercial bias and that any information regarding commercial products/services be based on scientific methods generally accepted by the medical community. Presentations must give a balanced view of therapeutic options. When discussing therapeutic options, it is our preference that you use only generic names. If it is necessary to use a trade name, then those of several companies where available must be used.

I attest that my presentation will be free of commercial bias:

Initials

V. Content Validation (speaker/author only)

Sanford School of Medicine, in accordance with the ACCME and the American Medical Association (AMA) policies on assuring the independence of CME activities require all CME faculty to attest that:

- 1) 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 (ACCME July 2002);
- 2) All scientific research referred to, reported or used in a CME activity in support or justification of a patient care recommendation conforms to the generally accepted standards of experimental design, data collection and analysis (ACCME July 2002); and
- 3) Research findings and therapeutic recommendations are based on scientifically accurate, up-to-date information and are presented in a balanced, objective manner (AMA 2002).

Please acknowledge that you agree to follow the standards outlined above:

Initials

VIII. Unlabeled/Investigational Uses (speaker/author only)

Should your presentation include discussion of any unlabeled/investigational use of a commercial product, you are required to disclose this to the participants. **Please indicate below whether you intend to discuss** unlabeled/investigational uses of a commercial product.

Please initial (choose one):

_____ I plan on discussing unlabeled/investigational uses of a commercial product and will disclose this to the audience.

_____ I do not plan on discussing unlabeled/investigational uses of a commercial product.

Signature

Date

To be completed by Department

Action taken:	<input type="checkbox"/> No relationships exist.
	<input type="checkbox"/> Relationships exist, reviewed by Course Director, No conflict of interest exists
	<input type="checkbox"/> Relationships exist, reviewed by Course Director, a conflict of interest exists. (If this option is checked, please complete and submit the Conflict of Interest Resolution Form.)

* A **Financial Relationship** 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.

** A **Commercial Interest** is any proprietary entity producing health care goods and services with the exception of non-profit or government organizations and non-health care related companies.

*** **Relevant Financial Relationships** ACCME focuses on financial relationships with commercial interests in the 12-month period preceding the time that the individual is being asked to assume a role controlling content of the CME activity. ACCME has not set a minimal dollar amount for relationships to be significant. Inherent in any amount is the incentive to maintain or increase the value of the relationship. The ACCME defines “**relevant** financial relationships” as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.



Resolution of Conflict of Interest Form

Title of Program:

Date of Program:

Speaker Disclosure:

Other Disclosures:

Resolving Conflicts of Interest

<p>Before Activity: (Check all that apply)</p>	<p>At least one intervention <i>must</i> happen BEFORE the activity.</p> <p>Option #1:</p> <p><input type="checkbox"/> Course Director* reviewed slides of presentation before the activity. Outcome:</p> <ul style="list-style-type: none"> <input type="checkbox"/> No commercial bias was perceived. <input type="checkbox"/> Commercial bias was perceived and the presentation was revised. <input type="checkbox"/> Other (please describe): <p>Option #2:</p> <p><input type="checkbox"/> Course Director* asked the person with the conflict to:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Refrain from making recommendations on topics in which the conflict exists <input type="checkbox"/> Base all recommendations on peer reviewed data <input type="checkbox"/> Other (please describe): <p>Option #3:</p> <p><input type="checkbox"/> Other (please describe):</p>
<p>During Activity: (Check all that apply)</p>	<p><input type="checkbox"/> Course Director* moderated the meeting:</p> <ul style="list-style-type: none"> <input type="checkbox"/> No commercial bias was perceived. <input type="checkbox"/> Commercial bias was perceived and Course Director or appointed moderator asked questions or made comments to counter the commercial bias.
<p>During Activity:</p>	<p>Option #1:</p> <p><input type="checkbox"/> CME Activity Coordinator monitored this activity and verifies compliance with the ACCME standards.</p> <p>Option #2:</p> <p><input type="checkbox"/> Other (please describe):</p>
<p>Post-Activity: (Check all that apply)</p>	<p><input type="checkbox"/> Under 5% of the audience perceived commercial bias. No action needed.</p> <p><input type="checkbox"/> Over 5% of the audience perceived commercial bias. Resolved by one of the following:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Course Director* spoke with person with conflict about the bias that was perceived and discussed how to avoid commercial bias in the future. <input type="checkbox"/> Course Director* will not invite person to participate in subsequent meetings. <input type="checkbox"/> Other (please describe):

*or designated physician

Course Director Signature

Date

Program Activity Coordinator Signature

Date

Nurse Planner Signature (if appropriate)

Date

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The potential for increasing the value of the financial relationship with the commercial interest creates an incentive to influence the content of the CME – an incentive to insert commercial bias. Commercial bias is prohibited in CME.