

To: CME Providers of AAFP Credit

From: AAFP CME Accreditation Department

Subject: Policy and Procedures for Full Disclosure and Identification and Resolution of Conflicts of Interest

The following three pages are a sample template for CME providers to use when creating their CME policy and procedures for full disclosure and identification and resolution of conflicts of interest. A policy and procedure will be required by May 2005 to meet ACCME Standards for Commercial Support requirements. This template is based on the AAFP's policy and procedure.

This template should be edited to meet the CME provider's own policy and procedures. AAFP encourages CME providers to meet with their own education committee and/or advisory board when creating their policy and procedures. If the CME provider is audited by AAFP for a CME activity that takes place after May 2005, the CME provider will be required to submit their policy and procedures for full disclosure and identification and resolution of conflicts of interest to AAFP to be found compliant.

ACCME's Standards for Commercial Support do not require faculty disclosure of unlabeled/investigational uses of products to the learners (Page 1, #2). AAFP requires faculty to disclose this information for all AAFP-produced CME activities. CME providers may or may not require their faculty to disclose this information. AAFP believes that disclosing this reinforces the content validity of the CME activity.

CME Provider

CME Policy and Procedures for Full Disclosure and Identification and Resolution of Conflicts of Interest

The following policy governs all **CME Provider** produced CME activities:

1. Disclosure of Financial Relationships

The existence of any financial relationship or interest an individual in a position to influence/control content currently has, or has had, within the last year must be disclosed in writing to learners prior to presentation. Disclosure information must be received and reviewed by **CME Provider** prior to confirmation of the individual's participation. Any conflicts of interest must be identified and resolved prior to the individual's confirmation as an activity faculty or other content-influencing/controlling role.

The intent of this policy is not to prevent individuals from participating, but rather is to identify and resolve any conflict of interest. Should resolution be impossible, a replacement for the individual must be chosen.

Because the review, identification, and resolution process must take place prior to the activity, all individuals in a position to influence/control content must return the disclosure information by the due date. Additional clarification is asked of those who participate in Speakers' Bureaus to assist **CME Provider** reviewers in understanding the nature of your Speakers' Bureau relationship (a list of recommended speakers acting independently of any guidance or direction from a commercial entity versus a list of speakers who are acting as agents, or who are contractually bound as agents of the commercial entity) in order to assure that your participation will not be in conflict with previous commitments. The disclosure will be reviewed and, should a conflict be identified, additional information or dialogue may be required. Failure to disclose within the necessary timeframe will result in withdrawal of the invitation to participate.

Acknowledgement of all disclosures—i.e., nothing to disclose or existence of affiliation(s), and/or financial relationship(s) or interest(s)—for every individual who serves in a position to influence/control content of the educational activity must be presented in writing to the learners.

2. Disclosure of Unlabeled/Investigational Uses of Products

Faculty must disclose to **CME Provider** and the learners when an unlabeled use of a commercial product, or an investigational use not yet approved for any purpose, is discussed during an educational activity. Faculty must disclose that the product is not labeled for the use under discussion or that the product is still investigational.

The intent of this policy is not to prohibit or limit the exchange of views in scientific and educational discussions, including discussions of unapproved uses, but to ensure that faculty discloses to learners that such discussion will take place.

Should an unplanned discussion of unlabeled or investigational uses of a product occur (usually in the course of a question and answer session), it is the responsibility of the faculty member to inform the learners that the use under question/discussion is unlabeled or investigational prior to answering the question or responding to the discussion point.

Acknowledgement of planned discussion of unapproved or investigational uses of products must be presented in writing to the learners prior to the start of the activity, or (for enduring materials) at the point that first mention is made of the unapproved/investigational use in the activity.

3. Failure or Refusal to Disclose/False Disclosure

Failure or refusal to disclose, false disclosure, or inability to work with the **CME Provider** to resolve an identified conflict of interest will result in withdrawal of the invitation to participate and replacement of the faculty/planner.

4. Identification and Resolution of Conflicts of Interest

- A. The **CME Provider** will inform all individuals who are invited to serve in roles that may impact the content of an educational activity (faculty, planners, authors, editors, reviewers, staff, etc.) of the **CME Provider** Policy on Full Disclosure. Disclosure forms and due dates will be distributed with the invitation to serve. Confirmation of service is contingent upon return and review of disclosure information and resolution of any conflicts of interest.
- B. Each individual faculty/planner/author/editor/reviewer/staff must complete and return his/her disclosure paperwork. The **CME Provider** will proceed through a review of the submitted information and, should any of the disclosed information trigger a concern regarding a possible conflict of interest, reviewers may seek input from the candidate and/or other individuals prior to confirming the candidate's service.
- C. Should no conflict of interest be identified, the individual may be confirmed in their role in the activity.
- D. Should a conflict of interest be identified, the individual will be contacted and asked for clarification or additional information. Upon receipt and review of this additional information, methods of resolution will be identified and discussed with the individual. Resolution methods may include, but not be limited to, one or more of the following:
 - Assuring valid content through:
 - Evidence-based content using best available, highest strength of evidence
 - Peer review of content prior to the activity; activity faculty must be responsive to revision requirements*
 - Assigning a different topic for the individual
 - Assigning a different faculty for a topic
 - Cancellation of the faculty
- E. The resolution process and outcomes will be documented in the CME activity file.

* The **CME Provider** considers independent peer review for evidence-based content appropriate action to resolve conflict of interest on the part of speakers and authors.

CME Provider Full Disclosure for CME Activities

Please check where applicable and sign below. Provide additional pages as necessary.

Date _____

Name of CME Activity: _____

Date(s) and Location of CME Activity: _____

Topic: _____

Name of Faculty/Planner/Author/Editor/Reviewer: _____

Address, City, State, and Zip Code: _____

Phone Number: _____ E-mail: _____

DISCLOSURE OF FINANCIAL RELATIONSHIPS WITHIN 12 MONTHS OF DATE OF THIS FORM

- A.** Neither I nor any member of my immediate family has a financial relationship or interest with any proprietary entity producing health care goods or services.
- B.** I have or an immediate family member has a financial relationship or interest with a proprietary entity producing health care goods or services. Please check the relationship(s). (Check all that apply):
- | | |
|---|---|
| <input type="checkbox"/> Research Grants | <input type="checkbox"/> Stock/Bond Holdings (excluding mutual funds) |
| <input type="checkbox"/> Speakers' Bureaus* | <input type="checkbox"/> Employment |
| <input type="checkbox"/> Ownership | <input type="checkbox"/> Partnership |
| <input type="checkbox"/> Consultant for Fee | <input type="checkbox"/> Others (please list) _____ |

Please indicate the names of the organizations with which you have a financial relationship or interest, and the specific clinical areas that correspond to the relationship. If more than four relationships, please list on separate piece of paper:

Organization with Which Relationship Exists	Clinical Area Involved
1.	1.
2.	2.
3.	3.
4.	4.

*If you checked "Speakers' Bureaus" in item B, please continue:

- Did you participate in company-provided speaker training related to your proposed topic? Yes No
 - Did you travel to participate in this training? Yes No
 - Did the company provide you with slides of the presentation in which you were trained as a speaker? Yes No
 - Did the company pay the travel/lodging/other expenses? Yes No
 - Did you receive an honorarium or consulting fee for participating in this training? Yes No
 - Have you received any other type of compensation from the company? Please specify: Yes No
- _____
- When serving as faculty for the CME Provider, will you use slides provided by a proprietary entity for your presentation/handout materials? Yes No
 - Will your topic involve information or data obtained from commercial speaker training? Yes No

DISCLOSURE OF UNLABELED/INVESTIGATIONAL USES OF PRODUCTS

- A.** The content of my material(s)/presentation(s) in this CME activity will not include discussion of unapproved or investigational uses of products or devices.
- B.** The content of my material(s)/presentation(s) in this CME activity will include discussion of unapproved or investigational uses of products or devices as indicated:
- _____

I have read the CME Provider policy on full disclosure. If I have indicated a financial relationship or interest, I understand that this information will be reviewed to determine whether a conflict of interest may exist, and I may be asked to provide additional information. I understand that failure or refusal to disclose, false disclosure, or inability to resolve conflicts of interest will require the CME Provider to identify a replacement.

Signature _____ Date: _____

RETURN BY _____ TO: CME Provider, contact person, address, phone number, etc.