



ACCREDITATION COUNCIL FOR PHARMACY EDUCATION

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TO: ACPE-accredited Continuing Pharmacy Education (CPE) Providers

FROM: Dimitra V. Travlos, PharmD, BCPS
Assistant Executive Director and Director, CE Provider Accreditation Program
Accreditation Council for Pharmacy Education (ACPE)

RE: Updated ACPE Standards for Commercial Support

At its October 2006 meeting, the ACPE Board of Directors approved an update to ACPE's *Criteria for Quality and Interpretive Guidelines* Criterion 17 Non-commercialism. The update includes the adoption of the Accreditation Council for Continuing Medical Education (ACCME) Updated Standards for Commercial Support, October 2004.

Implementation Timeline:

A transition period is in effect from today to December 31, 2007. Providers will be first evaluated by these guidelines beginning January 1, 2008.

Background:

In the last few years, many guidance documents have been developed regarding commercialism in continuing education for healthcare professionals:

- AMA Gifts to Physicians from Industry (1990)
- PhRMA Code of Interactions with Healthcare Professionals (2002)
- OIG Compliance Program Guidance for Pharmaceutical Manufacturers (2003)
- AdvaMed Code of Ethics (2004)

These guidance documents contributed to ACPE's decision to discontinue the eligibility of drug and device manufacturers to be accredited providers of continuing pharmacy education. The announcement of this decision ("Drug and Device Manufacturers No Longer Recognized as ACPE-Accredited Providers of Continuing Pharmacy Education") was distributed via email to the ACPE list serve on February 11, 2005.

During our collaborative meetings with ACCME and the American Nurses Credentialing Center (ANCC), representatives of ACCME stated that these standards are meant to be the health professions' standards for commercial support and, as such, asked if ANCC and ACPE would consider adopting them as well. ANCC did adopt these standards during their standards revision process in 2005.

ACPE staff receives many questions in the area of commercialism in relation to continuing pharmacy education activities. We are able to answer many of these questions; however, many times, the answer is not clearly documented in our current documents. ACPE staff has explored the applicability of these standards with ACPE providers and the ACPE CE Provider Advisory Committee in 2004 and 2006. The committee and the majority of providers have advised that ACPE should adopt these standards.

If you have any questions regarding the content of the documents, please contact the ACPE staff.

Attached:

1. Updated Criterion 17. Non-commercialism
2. Frequently Asked Questions: Guidelines for Standards for Commercial Support



Standard 5: Standards for Commercial Support (SCS)

All continuing pharmacy education (CPE) programs should provide for an in-depth presentation with fair and full disclosure and equitable balance. Appropriate topics and learning activities shall be distinguished from topics and learning activities which are promotional or appear to be intended for the purpose of endorsing either a specific commercial drug or other commercial product (as contrasted with the generic product/drug entity and its contents or the general therapeutic area it addresses), or a specific commercial service (as contrasted with the general service area and/or the aspects or problems of professional practice it addresses).

Guideline 5.1: Independence

- a. A CPE provider must ensure that the following decisions were made free of the control of a commercial interest. A ‘commercial interest’ is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. Providers of clinical service directly to patients are not ‘commercial interests.’
 - 1) Identification of CPE needs;
 - 2) Determination of educational objectives;
 - 3) Selection and presentation of content;
 - 4) Selection of all persons and organizations that will be in a position to control the content of the CPE;
 - 5) Selection of educational methods;
 - 6) Evaluation of the activity.
- b. A commercial interest cannot take the role of non-accredited partner in a cosponsorship relationship.

Guideline 5.2: Resolution of Personal Conflicts of Interest

- a. The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed to the provider all relevant financial relationships with any commercial interest. The ACPE defines “relevant financial relationships” as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.
- b. An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an

author of CPE, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CPE activity.

- c. The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.

Guideline 5.3: Appropriate Use of Commercial Support

- a. The provider must make all decisions regarding the disposition and disbursement of commercial support.
- b. A provider cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as conditions of contributing funds or services.
- c. All commercial support associated with a CPE activity must be given with the full knowledge and approval of the provider.

Written agreement documenting terms of support

- d. The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the provider and its educational partner(s). The agreement must include the provider, even if the support is given directly to the provider's educational partner or cosponsor.
- e. The written agreement must specify the commercial interest that is the source of commercial support.
- f. Both the commercial supporter and the provider must sign the written agreement between the commercial supporter and the provider.

Expenditures for an individual providing CPE

- g. The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.
- h. The provider, the cosponsor, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of-pocket expenses in compliance with the provider's written policies and procedures.

- i. No other payment shall be given to the director of the activity, planning committee members, teachers or authors, cosponsor, or any others involved with the supported activity.
- j. If teachers or authors are listed on the agenda as facilitating or conducting a presentation or session, but participate in the remainder of an educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their teacher or author role only.

Expenditures for learners

- k. Social events or meals at CPE activities cannot compete with or take precedence over the educational events.
- l. The provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CPE activity. The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, cosponsor or educational partner.

Accountability

- m. The provider must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support.

Guideline 5.4: Appropriate Management of Associated Commercial Promotion

- a. Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CPE activities.
- b. Product-promotion material or product-specific advertisement of any type is prohibited in or during CPE activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CPE.
 - For **print**, advertisements and promotional materials will not be interleaved within the pages of the CPE content. Advertisements and promotional materials may face the first or last pages of printed CPE content as long as these materials are not related to the CPE content they face **and** are not paid for by the commercial supporters of the CPE activity
 - For **computer based**, advertisements and promotional materials will not be visible on the screen at the same time as the CPE

content and not interleaved between computer ‘windows’ or screens of the CPE content

- For **audio and video recording**, advertisements and promotional materials will not be included within the CPE. There will be no ‘commercial breaks.’
 - For **live, face-to-face CPE**, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CPE activity. Providers cannot allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CPE activity.
- c. Educational materials that are part of a CPE activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or a product-group message.
- d. Print or electronic information distributed about the non-CPE elements of a CPE activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions, may include product promotion material or product-specific advertisement.
- e. A provider cannot use a commercial interest as the agent providing a CPE activity to learners, e.g., distribution of self-study CPE activities or arranging for electronic access to CPE activities.

Guideline 5.5: Content and Format without Commercial Bias

- a. The content or format of a CPE activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.
- b. Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CPE educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company.

Guideline 5.6: Disclosures Relevant to Potential Commercial Bias

Relevant financial relationships of those with control over CPE content

- a. An individual must disclose to learners any relevant financial relationship(s), to include the following information:
- The name of the individual;
 - The name of the commercial interest(s);

- The nature of the relationship the person has with each commercial interest.
- b. For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

Commercial support for the CPE activity

- c. 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 learners.
- d. ‘Disclosure’ must never include the use of a trade name or a product-group message.

Timing of disclosure

- e. A provider must disclose the above information to learners prior to the beginning of the educational activity.

NOTE: The Standards for Commercial Support and accompanying guidelines were adopted by ACPE (October 2006) with permission from the Accreditation Council for Continuing Medical Education. The updated definition of a commercial interest was approved by the ACPE Board of Directors in January 2008.