

## APPENDIX B

# Standards For Disclosure And Commercial Support

These Standards have been adapted from the Accreditation Council for Continuing Medical Education (ACCME), which articulates its policies for disclosure and commercial support in:

- (1) *The Standards For Commercial Support: Standards to Ensure Independence in CME Activities*, as adopted by ACCME in September 2004; and
- (2) ACCME policies applicable to commercial support and disclosure.

### STANDARD 1: INDEPENDENCE

1.1 An entity has a commercial interest if it is:

1. An entity that produces, markets, sells or distributes health care goods or services consumed by or used on patients; OR
2. An entity that is owned or operated, in whole or in part, by any entity that produces, markets, sells or distributes health care goods or services consumed by or used on patients.

An entity is NOT a commercial interest if it is:

1. A government entity;
2. A non-profit (503(c)) organization; or
3. A non-healthcare related entity.

This definition permits an accredited provider to be owned by an entity that is not a commercial interest. It also allows a provider to have a 'sister company' or parent company that is a commercial interest, as long as the accredited provider has and maintains adequate corporate firewalls to prohibit any influence or control by the sister or parent company over the continuing education program of the accredited provider. In this case, ANCC would expect that the accredited provider would have an adequate corporate firewall in place to prohibit any influence or control by the 'sister company' over the continuing education program.

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

- 1.2 A continuing nursing education provider must ensure that the following decisions were made free from the control of a commercial interest:
- (a) identification of continuing nursing education needs,

- (b) determination of educational objectives,
- (c) selection and presentation of content,
- (d) selection of all persons and organizations that will be in a position to control the content of the continuing nursing education,
- (e) selection of educational methods, and
- (f) evaluation of the activity.

1.3 An entity with a commercial interest cannot take the role of non-accredited partner in a co-provider relationship.

## STANDARD 2: RESOLUTION OF PERSONAL CONFLICTS OF INTEREST

2.1 An individual must disclose any financial relationships with an entity with a commercial interest (see STANDARD 1).

2.2 The provider must be able to show that each individual who is in a position to control the content of an education activity has disclosed all financial relationships with any entity with a commercial interest in the provider. ANCC defines “financial relationships” as 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 relationships can also include ‘contracted research’ where the institution gets the grant and manages the funds and the individual is the principal or named investigator on the grant. 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. ANCC considers relationships of the person involved in the continuing nursing education activity to include financial relationships of a spouse/partner. Financial relationships must be disclosed to the learners during the time when the relationship is in effect and for 12 months afterward.

*With respect to personal financial relationships, ‘contracted research’ includes research funding where the institution gets the grant and manages the funds and the person is the principal or named investigator on the grant.*

ANCC considers financial relationships in any amount occurring within the past 12 months as “relevant” in terms of creating a conflict of interest.

2.3 An individual who refuses to disclose financial relationships will be disqualified from being a planning committee member, a teacher, or an author of continuing nursing education and cannot have control of, or responsibility for, the development, management, presentation, or evaluation of the CNE activity.

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

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<sup>1</sup> These materials can be found at [www.accme.org](http://www.accme.org) under Accreditation Requirements – ACCME Essential Areas & Elements (Element 3.3). ACCME provides additional information about commercial support and disclosure in the form of frequently asked questions under the “Ask ACCME” tab on its web site.

**2.5** ANCC considers a “conflict of interest” to exist when an individual has an opportunity to affect continuing nursing education content in relation to a commercial interest with which he/she has a financial relationship.

ANCC considers “opportunity to affect continuing nursing education content” to include content about specific agents/devices, but not necessarily about the class of agents/devices, and not necessarily content about the whole disease class in which those agents/devices are used.

*With respect to financial relationships* with commercial interests, when a person divests himself/herself of a relationship, it is immediately not relevant to conflicts of interest but it must be disclosed to the learners for 12 months.

### **STANDARD 3: APPROPRIATE USE OF COMMERCIAL SUPPORT**

**3.1** The provider must make all decisions regarding the disposition and disbursement of commercial support.

ANCC defines “commercial support” as financial, or in-kind, contributions given by a commercial interest, which is used to pay all or part of the costs of a continuing nursing education activity.

ANCC does not consider providers of clinical service directly to patients to be commercial interests. For the purposes of eligibility, ANCC considers the following types of organizations eligible for accreditation and free to control the content of continuing nursing education (Standard 1):

- Liability insurance providers
- Health insurance providers
- Group medical practices
- Acute care hospitals (for-profit and not-for-profit)
- For-profit rehabilitation centers
- For-profit nursing homes
- Universities with nursing development and continuing nursing education programs
- Specialty Nursing Organizations
- Constituent Member Associations
- Federal Nursing Services
- National nurses organizations based outside the United States
- A single-focused organization<sup>1</sup> devoted to offering continuing nursing education

<sup>1</sup>The single-focused organization exists for the single purpose of providing education.

**3.2** A provider cannot be required by an entity with a commercial interest to accept advice or services concerning teachers, authors, or other education matters, including content, from the entity as conditions of contributing funds or services.

**3.3** All commercial support associated with a continuing nursing education activity must be given with the full knowledge and approval of the provider.

### **Written Agreement Documenting Terms of Support**

- 3.4 The terms, conditions, and purposes of the commercial support must be documented in a written agreement with the entity 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 a co-provider.
- 3.5 The written agreement must specify the entity that is the source of commercial support.
- 3.6 Both the entity and the provider must sign the written agreement regarding the support to be provided/accepted.

### **Expenditures for an individual providing continuing nursing education**

- 3.7 The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers, and authors.
- 3.8 The provider, the co-provider, or designated educational partner must directly pay any teacher or author honoraria or reimbursement of out-of-pocket expenses in compliance with the provider's written policies and procedures.
- 3.9 No other payment shall be given to the director of the activity, planning committee members, teachers or authors, co-provider, or any others involved with the supported activity.
- 3.10 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**

- 3.11 Social events or meals at continuing nursing education activities cannot compete with, or take precedence over, the educational events.
- 3.12 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 continuing nursing education 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, co-provider, or educational partner. This element applies only to nurses whose official residence is in the United States.

### **Accountability**

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



## **STANDARD 5. CONTENT AND FORMAT WITHOUT COMMERCIAL BIAS**

- 5.1 The content or format of a continuing nursing education activity or its related materials must promote improvements or quality in health care and not a specific proprietary business interest of an entity with a commercial interest.
- 5.2 Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the continuing nursing education educational material or content includes trade names, when available, trade names from several companies should be used, not just trade names from a single company.

## **STANDARD 6. DISCLOSURES RELEVANT TO POTENTIAL COMMERCIAL BIAS**

Relevant financial relationships of those with control over continuing nursing education content.

Disclosure of information about provider and faculty relationships may be disclosed verbally to participants at a continuing nursing education activity. When such information is disclosed verbally at a continuing nursing education activity, providers must be able to supply ANCC with written verification that appropriate verbal disclosure occurred at the activity. With respect to this written verification:

- A. A representative of the provider who was in attendance at the time of the verbal disclosure must attest, in writing:
- that verbal disclosure did occur; and
  - itemize the content of the disclosed information (Standard 6.1) or that there was nothing to disclose (Standard 6.2).
- B. The documentation that verifies that adequate verbal disclosure did occur must be completed within one month of the activity.
- 6.1 The accredited provider is responsible for ensuring that learners are aware of any relevant financial relationship(s), to include the following information:
- The name of the individual,
  - The name of the commercial interest(s), and
  - The nature of the relationship the person has with each commercial interest.
- 6.2 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 Continuing Nursing Education Activity**

The provider's acknowledgment of commercial support as required by Standard 6.3 and 6.4 may state the name, mission, and areas of clinical involvement of the company or institution and may include corporate logos and slogans, if they are not product-promotional in nature.

6.3 The source of all support from entities with commercial interests must be disclosed to learners. When commercial support is other than monetary support, the nature of the support must be disclosed to learners.

6.4 'Disclosure' must never include the use of a trade name or a product-group message.

**Timing of Disclosure**

6.5 A provider must disclose the above information to learners prior to or at the time of the beginning of the educational activity.