

## 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 education 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 cop-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 relationship 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.
- 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 are 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 purpose 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.

3.11 Social events or meals at continuing nursing education activities cannot compete with, or take precedence over, the educational events.

### **Expenditures for Learners**

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 4. Appropriate Management of Associated Commercial Promotion**

Commercial exhibits and advertisements are promotional activities and not continuing nursing education. Therefore, monies paid by commercial interests to providers for these promotional activities are not considered 'commercial support.' However,

accredited providers are expected to fulfill the requirements of Standard 4, and to use sound fiscal and business practices with respect to promotional activities.

4.1 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 continuing education activities.

4.2 Product-promotion material or product-specific advertisement of any type is prohibited in or during continuing nursing education 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 continuing nursing education.

- **Print**, advertisements and promotional materials shall not be interleaved within the pages of the continuing nursing education content. Advertisements and promotional materials may face the first or last pages of printed CNE content as long as these materials are not related to the continuing nursing education content they face and are not paid for by the entities with commercial interests in the continuing nursing education activity.
- **Computer-based**, advertisements and promotional materials shall not be visible on the screen at the same time as the continuing nursing education content and shall not be interleaved between computer 'windows' or screens of the continuing nursing education content.
- **Audio and video recording**, advertisements and promotional materials shall not be included within the continuing nursing education. There will be no 'commercial breaks.'
- **Live, fact-to-face continuing nursing education**, advertisements and promotional materials shall not be displayed or distributed in the educational space immediately before, during, or after a continuing nursing education activity. Providers shall not allow representatives of an entity with commercial interests to engage in sales or promotional activities while in the space or place of the continuing nursing education activity.

4.3 Educational materials that are part of a continuing nursing education activity, such as slides, abstracts, and handouts, shall not contain any advertising, trade name, or a product-group message.

4.4 Print or electronic information distributed about the non-continuing nursing education elements of a continuing nursing education 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.

4.5 A provider shall not use an entity with a commercial interest as the agent providing a continuing nursing education activity to learners, e.g., distribution of self-study

continuing nursing education activities or arranging for electronic access to continuing nursing education activities.

### **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 verifications 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.

### **Commercial Support for the Continuing Nursing Education Activity**

The provider's acknowledgement 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.

- 6.2 For an individual with not relevant financial relationship(s), the learners must be informed that not relevant financial relationship(s) exist.
- 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.

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