

STANDARDS FOR DISCLOSURE AND COMMERCIAL SUPPORT

These Standards have been adapted from the Accreditation Council for Continuing Medical Education (ACCME), which articulates its policies¹ 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](#).
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STANDARD 1: Independence

ANCC defines an entity that has a “commercial interest” as any entity either producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients or an entity that is owned or controlled by an entity that produces, markets, re-sells, or distributes health care goods or services consumed by, or used on, patients. Exceptions are made for non-profit or government organizations and non-health care related companies. The definition allows an accredited provider to be owned by a firm that is *not* a commercial interest. It also allows a provider to have a ‘sister company’ that is a commercial interest, as long as the accredited provider had and maintained adequate corporate firewalls to prohibit any influence or control by the ‘sister company’ over the CE 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 CE program.

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

1.2 A CNE provider must ensure that the following decisions were made free from the control of a commercial interest:

- (a) identification of CNE 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 CNE,
- (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

¹ These materials can be found at 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.

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 CNE 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 CNE 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 CNE content in relation to a commercial interest with which he/she has a financial relationship.

ANCC considers "opportunity to affect CNE 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 or 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 CNE 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 CNE (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 devoted to offering CNE

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 CNE 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 CNE

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 pay directly 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 CNE 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 CNE 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 CNE activities.

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

- **Print**, advertisements and promotional materials shall not be interleaved within the pages of the CNE 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 CNE content they face **and** are not paid for by the entities with commercial interests in the CNE activity.
- **Computer-based**, advertisements and promotional materials shall not be visible on the screen at the same time as the CNE content and shall not be interleaved between computer 'windows' or screens of the CNE content
- **Audio and video recording**, advertisements and promotional materials shall not be included within the CNE. There will be no 'commercial breaks.'
- **Live, face-to-face CNE**, advertisements and promotional materials shall not be displayed or distributed in the educational space immediately before, during, or after a CNE 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 CNE activity.

- 4.3 Educational materials that are part of a CNE 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-CNE elements of a CNE 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 CNE activity to learners, e.g., distribution of self-study CNE activities or arranging for electronic access to CNE activities.

STANDARD 5. Content and Format Without Commercial Bias

- 5.1 The content or format of a CNE 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 CNE 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 CNE content

Disclosure of information about provider and faculty relationships may be disclosed verbally to participants at a CNE activity. When such information is disclosed verbally at a CNE 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:
 - a) that verbal disclosure did occur; and
 - b) 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 CNE 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.