

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 the Independence in CME Activities, as adopted by ACCME in September 2004; and
- (2) ACCME policies applicable to commercial support and disclosure.

(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.)

STANDARD 1: Independence

- 1.1 ANCC defines an entity that has a “commercial interest” as any proprietary entity producing health care goods or services, with the exception of non-profit or government organizations.
- 1.2 A continuing nursing education provider must ensure that the following decisions were made free from 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 Interests

- 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 relevant 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 family member. Financial relationships must be disclosed to the learners for 12 months following initiation of the relationship.

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 relevant 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 continuing nursing 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 defines a “conflict of interest” as when an individual has an opportunity to affect continuing nursing education content with products or services from a commercial interest with which she/he has a financial relationship.**

ANCC considers “opportunity to affect continuing nursing education” 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.

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 activity.

- 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 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 commercial interest 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 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 continuing 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 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 to be “commercial support.” However, approved 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 nursing activities.
- 4.2 Product-promotion material or product-specific advertisement of any type is prohibited in or during 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 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 continuing nursing education 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 and not interleaved between computer “windows” or screens of the education content.
 - **Audio and video recording**, advertisements and promotional materials shall not be included within the continuing nursing education. There will not be “commercial breaks.”
 - **Live, face-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 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.
- 4.3 Educational materials that are part of 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 an 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 cannot use an entity with a commercial interest as the agent providing a continuing nursing activity to learners, e.g., distribution of self-study activities or arranging for electronic access for continuing nursing 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 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.

Disclosure of information about provider and faculty relationships may be disclosed verbally to participants of an activity. When such information is disclosed verbally at an activity, providers must be able to supply CNE-Net with written verification that appropriate verbal disclosure occurred at that 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:
- 1.) that verbal disclosure did occur; and
 - 2.) 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 approved 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

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.

- 6.3 **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 the beginning of the educational activity.**

COMMERCIAL SUPPORT AGREEMENT

Date:

Parties Involved in Agreement:

Provider and representative's name:

Entity providing commercial support:

The CE activity entitled _____ will be presented by (Provider organization) on _____ at _____.

(Commercial Support Entity's name) will provide (list what providing – e.g., funding for keynote speaker, canvas bags for participants, etc.). The (Entity) will be recognized as providing commercial support in the advertising.

The commercial support and/or entity will in no way influence or bias the content of the CE presentation. According to the ACCME commercial support standards the following must be met:

A. Appropriate Use of Commercial Support

- 3.14 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.
- 3.15 All commercial support associated with a continuing nursing activity must be given with the full knowledge and approval of the provider.
- 3.16 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.
- 3.17 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.

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 to be “commercial support.” However, approved providers are expected to fulfill the requirements of Standard 4 and to use sound fiscal and business practices with respect to promotional activities.

- 4.6 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 nursing activities.
- 4.7 Product-promotion material or product-specific advertisement of any type is prohibited in or during 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 nursing education.
 - **Print**, advertisements and promotional materials shall not be interleaved within the pages of the continuing nursing content. Advertisements and promotional materials may face the first or last pages of printed continuing nursing education content as long as these materials are not related to the nursing education content they face **and** are not paid for by the entities with commercial interests in the continuing nursing education.
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 - **Audio and video recording**, advertisements and promotional materials shall not be included within the continuing nursing education. There will not be “commercial breaks.”

- ***Live, face-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 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 activity.
- 4.8 Educational materials that are part of a continuing nursing activity, such as slides, abstracts, and handouts, shall not contain any advertising, trade name, or a product-group message.
- 4.9 Print or electronic information distributed about the non-continuing nursing education of a 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.
- 4.10 A provider cannot use an entity with a commercial interest as the agent providing a continuing nursing activity to learners, e.g., distribution of self-study activities or arranging for electronic access to continuing nursing activities.

Content and Format without Commercial Bias

- 5.3 The content or format of a continuing nursing 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.
- 5.4 Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the continuing nursing 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.

The signatures below by representatives from each organization listed above indicate agreement with the above statements.

Provider representative _____ Date _____

Commercial Support Entity _____ Date _____

CNE-Net™

DOCUMENTATION FORM FOR DISCLOSURE (This is done after the activity and inserted into the Applicant CE file).

Title of Activity: _____

Date of Activity: _____

Name of Presenter(s): _____

Names of Planning Committee: _____
(Can list all presenters and planning committee if no commercial support was disclosed)

Check appropriate box(es):

- Information that the presenter had no significant financial relationship with a commercial entity was disclosed to participants
- Information that the presenter had a significant financial relationship with a commercial entity was disclosed to participants
- Information that the presenter's presentation:
 - ___ Did refer to off-label or investigative usage was disclosed to participants
 - ___ Did not refer to off-label or investigative usage was disclosed to participants

Disclosure Occurred:

- Verbally, prior to the start of the conference (attach written disclosure)
- On the evaluation form, given to learners/participants prior to the CE activity
- Marketing materials (attach and highlight disclosure)
- Other _____

Signature of Applicant Nurse Planner:

Date form completed:

Date form filed in CE folder:

NOTE: The provider may choose to complete this form for each person on the planning committee and the faculty. Another option could be to document something like "The planners stated they had no conflict of interest; speaker Dr. Jones declared conflict of interest because he has done research with XYZ Company. He has stated that his presentation will reflect state-of-the science-data and not relate only to his own research findings."

