

Content Integrity Standards for Industry Support in CNE Activitiesⁱ

A. INTRODUCTION

The American Nurses Credentialing Center's Content Integrity Standards for Industry Support in Continuing Nursing Educational Activities serves as a resource for Providers¹ to plan, implement and evaluate quality continuing nursing educational activities with integrity, free from the undue influence of commercial interest organizations. Federal law, core values for the Accreditation Program (2009 and 2013 Application Manuals, Accreditation Program) and the *Code of Ethics for Nurses with Interpretive Statements* (ANA, 2001) create the foundation for these standards, which are designed to help Providers comply with Food and Drug Administration Guidance on Industry-Supported Scientific and Educational Activities.

B. DEFINITION OF A COMMERCIAL INTEREST ORGANIZATION

The American Nurses Credentialing Center (ANCC) defines an organization as having a commercial interest ("Commercial Interest Organization")² if it:

- Produces, markets, sells or distributes health care goods or services consumed by or used on patients;
- Is owned or operated, in whole or in part, by an organization that produces, markets, sells or distributes health care goods or services consumed by or used on patients; or
- Advocates for use of the products or services of commercial interest organizations.

Commercial Interest Organizations are ineligible for accreditation.

An organization is NOT a Commercial Interest Organization² if it is:

- A government entity;
- A non-profit (503(c)) organization;
- A provider of clinical services directly to patients, including but not limited to hospitals, health care agencies and independent health care practitioners;
- An entity the sole purpose of which is to improve or support the delivery of health care to patients, including but not limited to providers or developers of electronic health information systems, database systems, and quality improvement systems;
- A non-healthcare related entity whose primary mission is not producing, marketing or selling or distributing health care goods or services consumed by or used on patients.
- Liability insurance providers
- Health insurance providers
- Group medical practices
- Acute care hospitals (for profit and not for profit)
- Rehabilitation centers (for profit and not for profit)

¹ Providers refers to an ANCC Accredited Provider or an organization approved by an ANCC Accredited Approver e.g. Approved Provider or an Individual Activity Applicant

² Reference: Accreditation Council for Continuing Medical Education (ACCME) Standards of Commercial Support, August 2007 (www.accme.org) - ANCC's definition is intended to ensure compliance with Food and Drug Administration Guidance on Industry-Supported Scientific and Educational Activities and consistency with the ACCME definition)

- Nursing homes (for profit and not for profit)
- Blood banks
- Diagnostic laboratories

C. RELATED ORGANIZATIONS

- Parent Organization – An organization that owns one or more subsidiary organizations. A parent organization that is a Commercial Interest Organization is **not eligible** for accreditation.
- Subsidiary Organization – An organization that is owned by a parent company. A subsidiary of a Commercial Interest Organization is **not eligible** for accreditation.
- Sister Organizations – Two organizations that share a common parent owner are “sister organizations.” An organization **may be eligible for accreditation** if it establishes and maintains an adequate corporate firewall to shield it from the influence of a sister organization that is a Commercial Interest Organization.

Adequacy of a corporate firewall will be evaluated by examining evidence demonstrating independence, based on the following factors:

1. The commercial interest organization and its non-commercial interest sister organization (the “educational organization”) have separate federal tax ID numbers;
2. The commercial interest organization and the educational organization are separate legal entities;
3. The operational structure of the commercial interest organization and the educational organization are separate and distinct, including but not limited to:
 - Phone, fax and email communication;
 - Web sites/links to web sites;
 - Electronic and hard copy documents;
 - Written policies and procedures that may impact the delivery of continuing education;
 - Separate governance structures and personnel; and
 - Independence in decision making;
4. Educational content for activities is planned, developed, implemented and controlled exclusively by the educational organization. The commercial interest organization shall have no influence over content of the educational activity.

D. TYPES OF COMMERCIAL SUPPORT FOR CONTINUING NURSING EDUCATIONAL ACTIVITIES

Commercial Interest Organizations may provide monetary funding or other support (“Commercial Support”) for continuing nursing educational activities in accordance with the following fundamental principles:

1. Commercial Support must not influence the planning, development, content, implementation or evaluation of an educational activity; AND
2. Receipt of Commercial Support must be disclosed to learners.

Commercial Support may be used to pay for all or part of an educational activity and for expenses **directly related** to the educational activity, including but not limited to: travel, honoraria, food, support for learner attendance and location expenses. Commercial Support

may be used to support more than one educational activity at the same time or multiple activities over a period of time.

Commercial Support is:

1. Financial Support - money supplied by a Commercial Interest Organization to be used by a Provider for expenses related to the educational activity. Financial support may be provided as an unrestricted grant, educational grant, donation or scholarship.
2. "In-Kind" Support – materials, space or other non-monetary resources or services used by a Provider to conduct an educational activity; which may include and is not limited to human resources, marketing services, physical space, equipment such as audio-visual materials and teaching tools (for example, anatomic models). In-kind donations may not bear the trade names, logos or other identifying insignia of the Commercial Interest Organization. In-kind support may not include promotion of goods or services of the Commercial Interest Organization. In the event that the trade name, logo or other identifying insignia cannot be removed (i.e. embedded in the piece of equipment), the Provider must ensure that learners are aware of similar products produced by other companies. In addition, disclosure of the in-kind donation must be provided to learners.

E. ENSURING CONTENT INTEGRITY OF AN EDUCATIONAL ACTIVITY IN THE PRESENCE OF COMMERCIAL SUPPORT

Commercial Interest Organizations providing Commercial Support for continuing educational activities **may not** influence the planning, implementation or evaluation of an educational activity. The following requirements to ensure content integrity **must** be satisfied by the Provider when Commercial Support is accepted:

1. Written Agreement – There must be a written agreement between a Commercial Interest Organization providing Commercial Support and the Provider utilizing Commercial Support. The written agreement **must** include the following:
 - a. Name of the Commercial Interest Organization;
 - b. Name of the Provider;
 - c. Complete description of all Commercial Support provided, including both financial and in-kind support;
 - d. Statement that the Commercial Interest Organization will not participate in planning, developing, implementing or evaluating the educational activity;
 - e. Statement that the Commercial Interest Organization will not recruit learners from the educational activity for any purpose
 - f. Description of how Commercial Support must be used by the Provider
 - g. Signature of a duly authorized representative of the Commercial Interest Organization with authority to enter into binding contracts on behalf of the Commercial Interest Organization;
 - i. Unrestricted Use: Commercial Support given freely and without constraint by the Commercial Interest Organization and the Provider has sole discretion to administer Commercial Support as appropriate for planning, developing, implementing or evaluating the educational activity;
 - ii. Restricted Use: Commercial Support given to support a specific aspect of an educational activity such as meals, breakout sessions or speaker honoraria.

- h. Signature of a duly authorized representative of the Provider with authority to enter into binding contracts on behalf of the Provider; and
 - i. Date on which the written agreement was signed.
 2. Payments – All payments for expenses related to the educational activity must be made by the Provider. The Provider must keep a record of all payments made using Commercial Support funding. Commercial Support funds may only be used to support expenses directly related to the educational activity.
 3. Unused Funds – The Commercial Interest Organization may request the return of unused Commercial Support funds.
 4. Accounting of Expenses – The Commercial Interest Organization may request that the Provider submit a record of how Commercial Support funding was spent.
 5. Jointly Providing – In the event that more than two organizations will be providing an educational activity receiving Commercial Support (jointly providing), the organization identified as the “Provider” of the activity is responsible for managing Commercial Support funds in adherence with the ANCC Accreditation criteria. A Commercial Interest Organization may not jointly provide educational activities.

F. CONFLICT OF INTEREST EVALUATION AND RESOLUTION

The potential for conflicts of interest exists when an individual has the ability to control or influence the content of an educational activity **and** has a financial relationship with a commercial interest³, the products or services of which are pertinent to the content of the educational activity. The Nurse Planner is responsible for evaluating the presence or absence of conflicts of interest and resolving any identified actual or potential conflicts of interest during the planning and implementation phases of an educational activity. If the Nurse Planner has an actual or potential conflict of interest, he or she should recuse himself or herself from the role as Nurse Planner for the educational activity.

- Employees of commercial interest organizations **are not permitted** to serve as planners, speakers, presenters, authors and/or content reviewers if the content of the educational activity is related to the products or services of the commercial interest organization.
- Employees of commercial interest organizations **are permitted** to serve as planners, speakers, presenters, authors and/or content reviewers if the content of the educational activity is NOT related to the products of the commercial interest organization.
- Individuals who have non-employee relationships with commercial interest organizations (see bullet 2 below) **are permitted** to serve as planners, speakers, presenters, authors and/or content reviewers as long as the Provider has implemented a mechanism to identify, resolve and disclose the relationship as outlined in these standards.

The Nurse Planner is responsible for ensuring that all individuals who have the ability to control or influence the content of an educational activity disclose all relationships with any commercial interest, including but not limited to members of the Planning Committee,

³ *Commercial interest, as defined by ANCC, is any entity producing, marketing, reselling, or distributing healthcare goods or services consumed by or used on patients, or an entity that is owned or controlled by an entity that produces, markets, resells, or distributes healthcare goods or services consumed by or used on patients. Nonprofit or government organizations, non-healthcare-related companies, and healthcare facilities are not considered commercial interests.*

speakers, presenters, authors, and/or content reviewers. Relevant relationships⁴ must be disclosed to the learners during the time when the relationship is in effect and for 12 months afterward. All information disclosed must be shared with the participants/learners prior to the start of the educational activity.

- Relationships with any commercial interest of the individual's spouse/partner may be relevant relationships and must be reported, evaluated, and resolved.
- Evidence of a relevant relationship with a commercial interest may include but is not limited to receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (stock and stock options, excluding diversified mutual funds), grants, contracts, or other financial benefit directly or indirectly from the commercial interest.
- Financial benefits may be associated with employment, management positions, independent contractor relationships, other contractual relationships, consulting, speaking, teaching, membership on an advisory committee or review panel, board membership, and other activities from which remuneration is received or expected from the commercial interest.

Evaluation

The Nurse Planner is responsible for evaluating whether any relationship with a commercial interest is considered relevant to the content of the educational activity. Disclosures may be categorized in the following ways:

- No relationship with a commercial interest exists. No resolution required.
- Relationship with a commercial interest exists. The relationship with the commercial interest is evaluated by the Nurse Planner and determined not to be relevant to the content of the educational activity. No resolution required.
- Relevant relationship with a commercial interest exists. The relevant relationship is evaluated by the Nurse Planner and determined to be pertinent to the content of the educational activity. Resolution is required.

Resolution and Activity Assessment

Actions taken to resolve conflicts of interest must demonstrate resolution of the identified conflicts of interest prior to presenting/providing the educational activity to learners. Such actions must be documented and the documentation must demonstrate (1) the identified conflict, and (2) how the conflict was resolved. Actions may include but are not limited to the following:

- Removing the individual with conflicts of interest from participating in all parts of the educational activity.
- Revising the role of the individual with conflicts of interest so that the relationship is no longer relevant to the educational activity.
- Not awarding continuing education contact hours for a portion or all of the educational activity.

⁴ *Relevant relationships, as defined by ANCC, are relationships with a commercial interest if the products or services of the commercial interest are related to the content of the educational activity.*

- Undertaking review of the educational activity by a content reviewer to evaluate for potential bias, balance in presentation, evidence-based content or other indicator of integrity, and absence of bias; and,
- Monitoring the educational activity to evaluate for commercial bias in the presentation.

Undertaking review of the educational activity by a content reviewer to evaluate for potential bias, balance in presentation, evidence-based content or other indicator of integrity, and absence of bias, AND reviewing participant feedback to evaluate for commercial bias in the activity.

Disclosure

Individuals refusing to disclose relationships with Commercial Interest Organizations may not participate in any part of the educational activity.

G. ADDITIONAL CRITERIA FOR ENSURING CONTENT INTEGRITY

1. Promotion. A Commercial Interest Organization may not promote its goods or services in relation to the content of an educational activity at any time during which the educational activity takes place including the introduction and conclusion of the activity, regardless of the format of the educational activity.
2. Advertisements for the Commercial Interest Organization. Advertisements promoting the products or services of a Commercial Interest Organization in relation to the content of an educational activity must be physically separated from the educational activity, regardless of the format of the educational activity.
3. Recruitment. A Commercial Interest Organization may not recruit learners from an audience for any reason.
4. Confidentiality. Providers may not share contact information related to learners without written permission from the learner.
5. Advertising an Educational Activity. A Commercial Interest Organization may advertise an educational activity for which it has given Commercial Support. Examples of advertising may include but are not limited to: Save the Date cards, flyers and emails.
6. Acknowledgement of Commercial Support. Providers may acknowledge Commercial Support provided by a Commercial Interest Organization on marketing materials for the educational activity.
7. Distribution of the Educational Activity. A Commercial Interest Organization may not distribute educational activities directly to learners.
8. Content of the Educational Activity. Content is the responsibility of the Provider of the educational activity. All materials used for the educational activity must be free from commercial bias. To guard against the presence of commercial bias, the Provider is responsible for ensuring the following:
 - a. Slides, handouts or other materials presented to the learner related to the educational activity do not display any logos or other trademarks of a Commercial Interest Organization
 - b. Live (in-person) educational activities are presented without reference to a Commercial Interest Organization; acknowledgement of commercial support is limited to the name of the entity providing support

- c. Enduring materials do not include logos, trademarks or other insignia of, or references to, a Commercial Interest Organization; acknowledgement of commercial support is limited to the name of the entity providing support
- d. Web-based materials do not include logos, other trademarks or other insignia of, or reference to, a Commercial Interest Organization; acknowledgement of commercial support is limited to the name of the entity providing support
- e. Evaluations of the educational activity make no reference to a Commercial Interest Organization or its products or services; and
- f. Learners are not recruited for any purpose during the activity or evaluation.

H. EXHIBITS, PROMOTIONS AND SALES

Commercial Interest Organizations may not exhibit, promote or sell products or services during the introduction of an educational activity, while the educational activity takes place or at the conclusion of an educational activity, regardless of the format of the educational activity. Exhibits, promotion and sales must be separated from the educational activity. The following standards apply to exhibiting, promoting and selling products or services:

- Exhibiting, promoting and selling products may not take place during an educational activity;
- Marketing or advertisement for exhibits, promotions or sales may not be included within educational activity content (e.g., slides, handouts, enduring materials);
- Marketing or advertisement for exhibits, promotions or sales must take place in a location that is physically separated from the area where educational content is delivered.

I. GIVEAWAYS

Commercial Interest Organizations may provide giveaways for learners, as long as there is physical separation between accessing the giveaway and learner engagement in the educational activity. Educational materials for an activity may not be packaged in items bearing logos, trademarks of a Commercial Interest Organization.

J. FAILURE TO COMPLY

Failure to comply with the American Nurses Credentialing Center's Content Integrity Standards for Industry Support in Continuing Nursing Educational Activities may result in suspension or revocation of accreditation or approval.

K. COMPLAINTS

All complaints related to a Provider's compliance with the American Nurses Credentialing Center's Content Integrity Standards for Industry Support in Continuing Nursing Educational Activities will be investigated by the ANCC Accreditation Program Office.

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