



Understanding When Conflict of Interest (COI) Exists

When you need COI Forms and when you don't!

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Understand Conflict of Interest

The Confusing 4 C's

- Content Integrity
- Conflict of Interest (COI)
- Commercial Interest
- Commercial Support

ANCC Content Integrity Standards

<http://www.nursecredentialing.org/Accreditation-CEContentIntegrity.pdf>



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**American Nurses Credentialing Center's
Content Integrity Standards
for Industry Support in Continuing Nursing Educational Activities
(Effective date: 1/1/2013)
(Updated: 5/1/2013)
(Updated: 8/8/2014)**

- A. Introduction
- B. Definition of a Commercial Interest Organization
- C. Related Organizations
 - 1. Separate federal tax ID number
 - 2. Separate legal entity
 - 3. Operational structure separation
 - a. Phone, fax line, email
 - b. Web sites/links to web sites;
 - c. Electronic databases and hard copy documents;
 - d. Written policies and procedures
 - e. Governance structure and personnel;
 - f. Independent decision making
 - 4. Control of educational content
- D. Types of Commercial Support for Continuing Nursing Educational Activities
 - 1. Financial Support
 - 2. "In-Kind" Support
- E. Ensuring Content Integrity of an Educational Activity in the Presence of Commercial Support
 - 1. Written agreement between Commercial Interest and Provider
 - 2. Payments
 - 3. Unused Funds
 - 4. Accounting of Expenses
 - 5. Joint Providership
- F. Conflict of Interest Evaluation and Resolution
- G. Additional Criteria for Ensuring Content Integrity
 - 1. Promotion
 - 2. Advertisements
 - 3. Recruitment
 - 4. Confidentiality
 - 5. Advertising an Educational Activity

GOAL: Quality Education -- Free of Bias

Content Integrity

- Actual or potential conflicts of interest are resolved
- Content is based on best available evidence
- Independence from commercial interest organization funding for the activity (commercial support)
- Free from promotional activity

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Conflict of Interest

A conflict of interest (COI) exists when three conditions are present:

1. An individual is in a position to control content of the educational activity, and
2. The individual has a financial relationship with a commercial interest* organization, and
3. The products and/or services of the commercial interest* organization are relevant to the content of the educational activity

Commercial Interest Organization

The American Nurses Credentialing Center (ANCC) defines an organization as having a commercial interest (“Commercial Interest Organization”)* 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.

Relevant relationships in COI

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.

- Relationships with any commercial interest of the individual's spouse/partner may be relevant relationships and must be reported, evaluated, and resolved.
- Relationships are considered relevant if they have occurred within the past 12 months

Eligibility to participate in planning/presenting

- *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 **are permitted** to serve as planners, speakers, presenters, authors and/or content reviewers as long as the nurse planner has implemented a mechanism to identify, resolve and disclose the relationship according to ANCC standards.

Nurse Planner Decision Matrix

1. Are the products or services of any commercial interest relevant to the content of educational activity?
2. Identify who has the opportunity to influence the content of the educational activity.
3. For all individuals who have the opportunity to influence content: document relationships the individual (including spouse/significant other) has with commercial interest organizations within the past 12 months that are relevant to the content.
4. If the relationship is relevant, COI form with resolution is required.

Documenting COI

H. Nurse Planner Assessment of Content for Commercial Interest* Relevance

**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. (i.e. pharmaceuticals, supplements, botanicals, medical devices, and medical equipment products.)*
<http://www.nursecredentialing.org/Accreditation-CEContentIntegrity.pdf>

Yes, COI Forms Required

This educational activity includes content related to the products and/or services of a commercial interest entity by ANCC definition. A conflict of interest (COI) form is included in [Attachment 2] for each individual listed in Table I who has a financial relationship with a commercial interest entity relevant to this activity's content.

No, COI Forms Required

This educational activity does not include any content related to the products and/or services of a commercial interest entity so does not require COI forms for the planners or presenters. Explain below why content is considered exempt for COI:

Examples: Non clinical content i.e. Staff Development Methods; Outcome Measures; Leadership Skills;
Clinical content without product related treatments discussions i.e. Understanding Hemodynamic Mechanisms; EKG Interpretation; Stages of Breast Cancer.

I. Individuals in a Position to Control Content

Complete the table below listing each person in a position to control content of the educational activity. Include name, credentials, educational degrees(s), role in the activity, and any financial relationships with a commercial interest entity (*define above in Item I*) that is relevant to the content.

There must be at least two people –one Nurse Planner and one other planner to plan each educational activity. The **Nurse Planner** is knowledgeable of the CNE process and is responsible for adherence to the ANCC criteria **AND** hold a baccalaureate degree or higher in nursing (or international equivalent) **AND** be actively involved in planning, implementing and evaluating this continuing education activity. One planner needs to have appropriate subject matter expertise for the educational activity being offered (**Content Expert**) and can also be the Nurse Planner or a Presenter who is on the Planning Committee. **The individuals who fill the roles of Nurse Planner and Content Expert must be identified.**

Columns D, E, and F relate to the nurse planner's assessment of **Conflict of Interest** for the individuals in column A. "**Conflict of Interest** exists when an individual is in a position to control or influence the content of an education activity and has a financial relationship with a commercial interest organization, the products or services of which are pertinent to the content of the educational activity."

For questions when assessing conflict of interest for columns D, E, and F review the ANCC Standards:

<http://www.nursecredentialing.org/Accreditation-CEContentIntegrity.pdf>

A	B	C	D	E	F
Name of individual and credentials	Role(s) in activity <ul style="list-style-type: none"> • Nurse Planner (only one) • Content Expert • Other Planner • Presenter/Author 	Planning committee member? (Yes/No)	Commercial interest relationship relevant to the content? (Yes/No)	If yes in D Name of Commercial Interest and nature of relationship	If yes in D COI Form attached (Yes or n/a)
<i>Example: Jane Smith, BSN, RN</i>	<i>Nurse Planner</i>	<i>Yes</i>	<i>No</i>	<i>n/a</i>	<i>n/a</i>
<i>Example: Sue Brown, PhD, RN</i>	<i>Content Expert</i>	<i>Yes</i>	<i>No</i>	<i>n/a</i>	<i>n/a</i>
<i>Example: Ida Row, MSN, RN</i>	<i>Other Planner</i>	<i>Yes</i>	<i>No</i>	<i>n/a</i>	<i>n/a</i>
<i>Example: John Doe, MD</i>	<i>Presenter</i>	<i>No</i>	<i>Yes</i>	<i>Pfizer Speakers Bureau</i>	<i>Yes</i>
<i>Add rows as needed</i>					
Qualifications for the Nurse Planner: Provide information about expertise/education in adult education or adult learning and ANCC credentialing criteria.					
Qualifications for the Planning Committee Content Expert(s): Describe professional experience or areas of expertise, which contribute to content expertise for this activity. May include educational background, professional/practice experience, and publications.					

Documenting Control of Content

A	B	C	D	E	F
Name of individual and credentials	Role(s) in activity <ul style="list-style-type: none"> • Nurse Planner (only one) • Content Expert • Other Planner • Presenter/Author 	Planning committee member? (Yes/No)	Commercial interest relationship relevant to the content? (Yes/No)	If yes in D Name of Commercial Interest and nature of relationship	If yes in D CDI Form attached (Yes or n/a)
<i>Example: Jane Smith, BSN, RN</i>	<i>Nurse Planner</i>	<i>Yes</i>	<i>No</i>	<i>n/a</i>	<i>n/a</i>
<i>Example: Sue Brown, PhD, RN</i>	<i>Content Expert</i>	<i>Yes</i>	<i>No</i>	<i>n/a</i>	<i>n/a</i>
<i>Example: Ida Row, MSN, RN</i>	<i>Other Planner</i>	<i>Yes</i>	<i>No</i>	<i>n/a</i>	<i>n/a</i>
<i>Example: John Doe, MD</i>	<i>Presenter</i>	<i>No</i>	<i>Yes</i>	<i>Pfizer Speakers Bureau</i>	<i>Yes</i>
<i>Add rows as needed</i>					

2016 WMSD COI Form

Conflict of Interest Form
2015 ANCC Criteria

Title of Educational Activity:

Educational Activity Date:

Role(s) in Educational Activity: (Check all that apply)

Nurse Planner Content Expert Faculty/Presenter/Author

Other Planner Other, Describe

Section 1: Demographic Data

Name with Credentials/Degrees:

If RN, check all Nursing Degree(s) held: AD Diploma BSN Masters Doctorate

Current Employer	<input type="text"/>
Position/Title	<input type="text"/>
Phone number:	<input type="text"/>
Email Address:	<input type="text"/>
Mailing Address	<input type="text"/>
City, State and Zip Code	<input type="text"/>

Section 2: Conflict of Interest

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 interest,* 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.

***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. (Please reference content integrity document for further clarity <http://www.nursecredentialing.org/Accreditation-CE-ContentIntegrity.pdf>)

All individuals who have the ability to control or influence the content of an educational activity must disclose all **relevant relationships**** with any commercial interest, including but not limited to members of the Planning Committee, speakers, presenters, authors, and/or content reviewers. Relevant relationships 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.

****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.

- 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.

Is there an actual, potential or perceived conflict of interest for yourself or spouse/partner?

Yes No

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If yes, please complete the table below for all actual, potential or perceived conflicts of interest** Check all that apply:

Category	Description
Salary	<input type="text"/>
Royalty	<input type="text"/>
Stock	<input type="text"/>
Speakers Bureau	<input type="text"/>
Consultant	<input type="text"/>
Other	<input type="text"/>

** All conflicts of interest, including potential ones, must be resolved with the nurse planner prior to the planning, implementation, or evaluation of the continuing nursing education activity.

Section 3: Statement of Understanding

Completion of the line below serves as the electronic signature of the individual completing this Conflict of Interest Form and attests to the accuracy of the information given above.

 Typed or Electronic Signature: Name and Credentials (Required) Date

Section 4: Conflict Resolution (to be completed by Nurse Planner)

Or document separately

Procedures used to resolve conflict of interest or potential bias if applicable for this activity:

1. Not applicable since no conflict of interest.
2. Removed individual with conflict of interest from participating in all parts of the educational activity.
3. Revised the role of the individual with conflict of interest so that the relationship is no longer relevant to the educational activity.
4. Not awarding contact hours for a portion or all of the educational activity.
5. Undertaking review of the educational activity by the Nurse Planner and/or member of the planning committee 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 presentation.
6. Undertaking review of the educational activity by the Nurse Planner and/or member of the planning committee 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 presentation.
7. Undertaking review of the educational activity by a content reviewer to evaluate for potential bias, balance in presentation, evidence-based content or other indicators of integrity, and absence of bias, AND monitoring the educational activity to evaluate for commercial bias in the presentation.
8. Undertaking review of the educational activity by a content reviewer to evaluate for potential bias, balance in presentation, evidence-based content or other indicators of integrity, and absence of bias, AND reviewing participant feedback to evaluate for commercial bias in the presentation.
9. Other - Describe:

Nurse Planner Signature
 (**If this form is for the activity Nurse Planner, an individual other than the Nurse Planner must review and sign.)
 Completion of the line below serves as the electronic signature of the Nurse Planner reviewing the content of this Conflict of Interest Form.

 Typed or Electronic Signature: Name and Credentials (Required) Date

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COI Resolution Process

- Removing the individual with conflict of interest from participating in all parts of the educational activity.
- Revising the role of the individual with conflict 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.
- Undertaking review of the educational activity by the Nurse Planner 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 the Nurse Planner 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
- 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

Key Takeaways

- It's all about preventing commercial influence in CNE.
- No COI for anyone if the content does not involve clinical treatment or management of patients with discussion of products or services used on patients.
- Not a commercial interest company by ANCC definition if the company's products and services are not used on patients.
- No COI if the planner/presenter has no commercial relationships relevant to content that does discuss products and services used on patients.
- Actual COI often can be resolved, always is disclosed.

WMSD Resources

- WMSD Website
 - <http://www.westernmsd.org/MainMenu/CE>
- WMSD Resources – Individual Activity Applications or Approved Providers
 - ANCC Content Integrity Standards
 - <http://www.nursecredentialing.org/Accreditation-CEContentIntegrity.pdf>
 - Evaluating Conflict of Interest Flowchart 2015
- WMSD Website FAQs
 - <http://westernmsd.org/MainMenu/CE/Frequently-Asked-CNE-Questions>

