

Applying the Standards for Integrity and Independence in Accredited Continuing Education

2023 Update

Series: PART B - Identifying, Mitigating, and
Disclosing Relevant Financial Relationships
(Standard 3)

November 3, 2023

Wisconsin Nurses Association

Location and Purpose of the Standards

<https://www.accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce>

<https://www.accme.org/faq/10236#collapse-592781>

Purpose:

Maintain ethical standards. Protect learning environment from industry (commercial) influence.

Standards for Integrity and Independence in Accredited Continuing Education

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The Standards for Integrity and Independence in Accredited Continuing Education are designed to ensure that accredited continuing education serves the needs of patients and the public, is based on valid content, and is free from commercial influence.

The Standards were [released in December 2020](#), replacing the Standards for Commercial Support: Standards to Ensure Independence in CME Activities.

Resources

[New and Current Approved Provider Information](#)

[Individual Educational Applicant Information](#)

The Standards for Integrity and Independence

[Standards Toolkit Introduction and Contents Overview -Toolkit p. 1 \(PDF\)](#)

[Disclosure Form \(to collect disclosure information from all in control of content\) * – Toolkit p. 2 \(Word Doc\)](#)

[Required Nurse Planner Mitigation Form * – Toolkit pp. 3-4 \(Word Doc\)](#)

[Disclosure to Learners Examples – Toolkit p. 5 \(PDF\)](#)

[Optional Speaker Letter on Why Disclosure Information Must Be Collected – Toolkit p. 6 \(Word Doc\)](#)

[Optional Speaker Letter about Content Validity – Toolkit p. 7 \(Word Doc\)](#)

[Optional Content Validity Review of Educational Content Documentation Form – Toolkit p. 8 \(Word Doc\)](#)

[Content Validity Summary of Important Points – Toolkit p. 9 \(PDF\)](#)

[Expanded List of Mitigation Strategies – Toolkit p. 10 \(PDF\)](#)

[WNA Crosswalk – Old Language to New Language used in The Standards \(PDF\)](#)

[Algorithm – Quick Reference for Identifying, Mitigating and Disclosing to Learners any Relevant Financial Relationships for All in Control of Content \(PDF\)](#)

[The ACCME Standards \(adopted by ANCC\) \(Link\)](#)

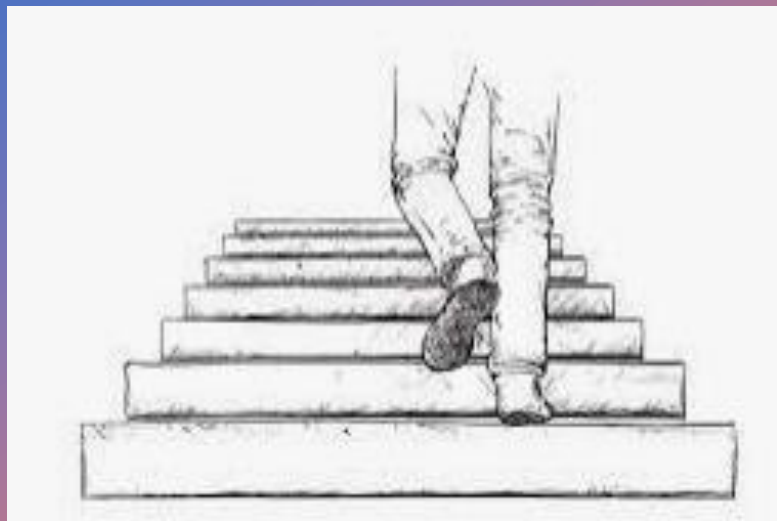
[ACCME Standards FAQ \(Link\)](#)

[ACCME Structured Self-Assessment \(Word Doc\)](#)

[2022 ANCC Guidance Related to Clinical Content \(PDF\)](#)



Break It Down & Take it in Steps



What is an “Ineligible Company?”

See “Series: PART A”
Video

Eligibility / Ineligibility

- New definitions and categories in 2022.
- Ineligible Company: ~~primary~~ Any part of business (or parent, sister company business) is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

Standard 3- Identify, Mitigate, Disclose Relevant Financial Relationships

Concepts:

- A person in control of content may have a relationship with an ineligible company.
- Company is Ineligible, not the person.
- A relationship can create commercial bias.
- Learning environment needs to be free of commercial bias.

When is a Financial Relationship Relevant?

- A financial relationship, in any amount, exists / has existed in past 24 months between the person in control of content and an ineligible company.
- The content of the education is related to the products or business lines of an ineligible company with whom the person has a financial relationship.

Implications:

- Know what an ineligible company is.
- Know the content being planned.
- Know types of relationships that are relevant.

What relationships?

Key step - Recognize relationships in healthcare that might result in financial benefit to an individual (see also WNA Disclosure Form).

Just a few examples:

- Speakers' Bureau
- Paid advisor / consultant
- Stock holder
- Board member
- Researcher
- Employee / Owner



Those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest, or other financial benefit.

Relevant financial relationships: when do we care?

Three times you don't need to use this process to identify, mitigate and disclose RFRs:

- "Non-clinical" content (e.g., leadership, communication skills)
- Spontaneous learning (RARE)
- Self-directed Improvement Planning (RARE)

Implications:

- Know what “clinical” content is.
- Know that most content IS clinical.

What is “Clinical” content?

- Is ANY chance of any mention of an ineligible company's products or business lines in the delivery of the education?
- Is there any discussion of, or recommendations being made for, anything related to caring for a patient or management of their health in any setting?
- Are there scenarios used in the educational content that are based in a setting where health care is provided?

ANCC Guidance

- [2022 ANCC Guidance Related to Clinical Content](#)
- In order for an activity to be considered non-clinical, the content of the education would need to afford no opportunities for individuals in control of content to insert commercial bias related to the products or services of ineligible companies.

WNA Guidance: Most content is clinical

Implications:

- Make the correct assessment early.
- Contact WNA if any question on “clinical” vs. “non-clinical.”



Identify, Mitigate, Disclose



Step-by-Step Nurse Planner PROCESS SUMMARY:

- Collect and Review disclosure information. Document.
- Exclude owners and employees of ineligible companies unless one of three exceptions is met.
- Determine which financial relationships w/ ineligible companies are relevant to the activity content.
- Use accepted strategies to mitigate the relationship.
- Disclose the relationship to learners prior to educational content.

Step 1 – Collect disclosure Information from all in control of content on ALL financial relationships

Collect information - WHAT?

When content is "clinical" - nearly always!

- ALL financial relationships with ineligible companies
- Any time in the past 24 months
- Must provide definition of "ineligible company."
- No longer concerned about spouse/partner.
- There is still no minimum financial threshold.

Step 1- Collect disclosure Information from all in control of content on ALL financial relationships

How?

- WNA Disclosure Form
- CME Disclosure Form used by your organization
- Other methods:
 - Include definition of ineligible company.
 - Helpful to include examples of relationships.

Type of Relationship & Who Has It Matters!

Owners/Employees vs. Affiliates



- Ineligible Company OWNERS/EMPLOYEES may NOT control content of for-credit education except under very specific circumstances.
- Ineligible Company AFFILIATES (non-owner/non-employee) may control content if their relevant financial relationships are mitigated (resolved).

Nurse Planner Relationships

NEW 2022 per
ANCC

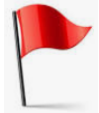
The nurse planner for the activity can **not** have any relevant financial relationships.



Implications:

- STOP!
- Contact WNA for guidance early!

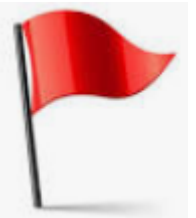
Step 2 – **Exclude** Employees and Owners of Ineligible Companies from All Educational Roles



It doesn't matter:

- If they are “just going to address the topic generally.”
- If they are “not going to talk about their specific company's products.”
- If you looked at the presentation and there is no evidence of bias.

You **MUST** exclude employees / owners of ineligible companies unless one of the following three exceptions applies.



Step 2 – **Exclude** Employees and Owners of Ineligible Companies from All Educational Roles

Except when...

- When content of the activity is not related to the business lines or products of the employers' company.
- When the content of the approved activity is limited to basic research AND no care recommendations are made.
- When they are participating as technicians to teach safe and proper use of medical devices AND do not recommend whether or when a device is used.

If one of these three exceptions is not met, EXCLUDE THE EMPLOYEE/OWNER of an INELIGIBLE COMPANY FROM ALL EDUCATIONAL ROLES (planner, reviewer, presenter, content developer, other faculty).

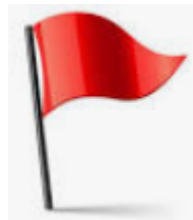
How do I know if the content is related to the products or business lines of ineligible companies?

- Know what the ineligible company's business lines are.
- Know what the person is planning, reviewing, or presenting.
- Look at examples:
- <https://www.accme.org/faq/10236> (fifth question in list):

[STANDARD 3.2: WHAT ARE SOME EXAMPLES OF CONTENT THAT IS OR IS NOT RELATED TO THE BUSINESS LINES OF THE INELIGIBLE COMPANY?](#)

Implications:

-Contact WNA for guidance.



Step 3 – YOU Determine Which Relationships Are Relevant

A financial relationship is relevant when:

- A financial relationship, in any amount, exists / has existed in past 24 months between the person in control of content and an ineligible company.
- The content of the education is related to the products or business lines of an ineligible company with whom the person has a financial relationship.

Key questions to ask yourself when a financial relationship is reported to you by an individual in control of content upon disclosure collection

In this order:

- Is their relationship with an ineligible company?
- Are they an employee/ owner or not?
 - If an employee / owner, is one of the three exceptions met?
- What content are they presenting?
- Is the content related to the products or business lines of the company they have the relationship with?

Step 4: Mitigation

- Equates to "Resolution" of Relevant Financial Relationship.
- Mitigate if relationship is relevant and anytime in past 24 months.
- Educational provider is responsible for the mitigation strategy.
- Use accepted mitigation strategies.
- Different strategies depending on role.
- See resource for [mitigation strategies](#).
- Document relevance of relationship and mitigation strategies
- Dual roles (planner / presenter) may require different strategies.

Step 5 - Disclose

No one in control of content has a relevant financial relationship with an ineligible company.

(Ineligible companies are those that produce, market, sell, resell or distribute products used by or on patients.)

OR

No one in control of content has a relevant financial relationship with an ineligible company except for:

Name, Relationship, Ineligible Company Name

This relevant financial relationship has been mitigated.

(Ineligible companies are those that produce, market, sell, resell or distribute products used by or on patients.)

What disclosures-to-learners are required for NCPD?

Always:

- Approval Statement
- How learners earn contact hours –
be sure disclosure to learners matches your documentation (IEA Application or APU P&D Template)

When clinical content (almost always):

- Disclosure of relevant financial relationship or lack of

As applicable:

- Commercial support – No logos.
- Enduring Material expiration date – Date by which learner must complete the education.
- Joint Providership – Name of jointly providing organizations and clarity on who is providing contact hours.

Disclosure to Learners

- Disclosures must be provided to the learners **prior to the beginning** of the educational activity.
- Disclosures may be provided in several ways, including but not limited to the marketing material, agenda, opening PowerPoint slide, or verbally in the opening remarks of an activity.

The activity file documentation must provide evidence that these disclosures were provided to learners.

- Evidence of required information provided to learners prior to start of the educational activity: Include relevant slide(s), screen shot(s), script(s), or other evidence showing what the learners will receive.

Disclosure to Learners - TIPS

- Successful completion requirements (how learners earn contact hours) and disclosure-to-learners info must match.
- “Non-endorsement of products” is **old** terminology / no longer disclosed for nursing.
- “Off label use” is old terminology but if there is discussion of a product that is not based on current accepted evidence, this should be clear to participants, and it may still be used for CME.
- The expiration date for EM must still be clearly stated even for a closed audience.
- Use the correct approval statement. Down. To. The. Punctuation.
- Per ANCC: Don’t say “CEU.” Use “contact hours.”

REFLECTION: Is this financial relationship relevant?

- A potential speaker is a stockholder in a pharmaceutical company that makes chemotherapy, and they are talking about combination cancer treatments (e.g., chemo + radiation).
- A potential planner is an employee of a durable medical equipment company, and the content is about assisting older adults with ambulation.
- A content reviewer (external to the planning committee) is a consultant for a healthcare management company that owns a pharmacy that produces its own brand of medication for nearly all cardiovascular diseases. The content is about management of CHF.
- A potential speaker is the author of a book on nutrition and the topic is healthy eating.
- A potential planner is a consultant for a firm that educates about preventing childhood diseases and the content is asthma.
- More importantly – do you know the steps and key questions to figure this out?

REFLECTION: Answers to Is this financial relationship relevant?

- A potential speaker is a stockholder in a pharmaceutical company that makes chemotherapy, and they are talking about combination cancer treatments (e.g., chemo + radiation). **RELEVANT because the content is related to the products or business lines of the company with whom there is a relationship. Can be mitigated, since it is a non-employee/owner relationship.**
- A potential planner is an employee of a durable medical equipment company, and the content is about assisting older adults with ambulation. **RELEVANT because the content is related to the products or business lines of the company with whom there is a relationship. Cannot be mitigated. Does not meet any of the three exceptions.**
- A content reviewer (external to the planning committee) is a consultant for a healthcare management company that owns a pharmacy that produces its own brand of medication for nearly all cardiovascular diseases. The content is about management of CHF. **RELEVANT because the content is related to the products or business lines of the company with whom there is a relationship. Can be mitigated, since it is a non-employee/owner relationship.**
- A potential speaker is the author of a book on nutrition and the topic is healthy eating. **Not a relevant financial relationship. There is not involvement of an ineligible company. However, there is concern for bias. Be sure the author knows not to promote their book.**
- A potential planner is a consultant for a firm that educates about preventing childhood diseases and the content is asthma. **Not a relevant financial relationship. There is not involvement of an ineligible company. However, there may be a concern for bias. Be sure the consultant knows not to promote their company.**

Most importantly: **Do you know the steps and key questions to figure these scenarios out?**



Any Questions on:

Standard 3

- Identifying, mitigating, and disclosing relevant financial relationships?
- Please re-review the video content and contact WNA for questions if needed.