

ACCME Standards for Integrity and Independence in Accredited Continuing Education

Wisconsin Nurses Association
2022

ESSENTIAL CONCEPTS

STANDARD 3:

Identify, Mitigate, and Disclose Relevant Financial Relationships

"The Standards"

www.accme.org/standards

Integrity of content

Ethical, non-biased information

Protection of learning environment from commercial industry influence

Today's Focus is Standard #3:

Identify, Mitigate, and Disclose Relevant Financial Relationships

To maintain ethical standards; to protect learning environment from industry (commercial) influence.

Commercial Bias

"Attempts to sway participants' opinions in favor of a particular commercial product for the purpose of furthering the business of an ineligible company."

by

Speakers - Planners - Faculty - All Others in Control of Content

(Paraphrased, from Indiana State Medical Association, 2020.)

"And speaking of IVs, our new tubing is the greatest..."



Credit: Shutterstock

Eligible vs. Ineligible Companies

Eligible Company - okay

Ineligible Company - no way

www.accme.org/standards

Ineligible Company

those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

(Don't let the "primary" throw you off. Any entity whose business includes...)

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.


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

Which is not a relationship with an ineligible company?


0

 Zania, RN, MSN, is an employee of Eli Lilly

0

 Dr. M. is a researcher for the American Lung Association

0

 Dr. Tanya H. is on the speakers bureau for Abbott Nutrition

A key step to identify relevant financial relationships is knowing if the organization is an "ineligible company."

How do you find out?

- The Standards at www.accme.org/standards
- Research on products and business lines

processes

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.

When to start managing financial relationships?



Start the process for identifying and mitigation of relevant financial relationships (RFR) before each person assumes their role.

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)

Contact WNA if:

- You think your content is not clinical.
- You aren't sure if your content is clinical.

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Clinical vs. Non-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?
- Is the topic similar to communication skills or leadership concepts?

Step 1: Collect Disclosure Information from all in control of content.

Collect information - HOW?

- No prescribed or mandated form
- CME disclosure form from your institution
- Verbal or email w/ definition of Ineligible Company + Documentation of results for all in control of content (provide sample script or email in ARF)
- WNA Disclosure Form Tool kit p. 3

WNA Disclosure Information Collection Form

1. WNA DisclosureForm was updated in 2022.

IEA APPLICANTS: <https://www.wisconsinnurses.org/iea-forms/>

OR

APPROVED PROVIDERS:

<https://www.wisconsinnurses.org/current-wna-ceap-approved-providers/>

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 2: Exclude Owners and Employees of Ineligible Companies:

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

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).

Can you have a vendor rep come in and do a presentation on IV pumps and give contact hours for it?


0

 No.

0

 Yes, if the vendor is teaching safe use AND does not make use recommendations.

0

 Yes + you can give CE for exhibits and vendor halls now too, because they are vendors.

Step 3: 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.

The Nurse Planner needs to document if relationships are relevant.

- Review Disclosure information from all in control of content.
- Complete Nurse Planner Mitigation Worksheet for ALL disclosed relationships.
- Form can be found at several locations on WNA website:
<https://www.wisconsinnurses.org/education/ceap/> under IEA, Approved Provider, or Resources.

Review employer information - is company ineligible?



Source: Clipartix

Step 4: Mitigation

- Equates to "Resolution" of Relevant Financial Relationship.
- Mitigate if relationship is relevant and anytime in past 24 months.
- Document - WNA Nurse Planner Mitigation Worksheet, other

Mitigate relevant financial relationships.

Mitigations strategies must be discussed with the person to whom the strategies apply.

- See WNA website Resources page for "Expanded List of Mitigation Strategies"
- <https://www.wisconsinnurses.org/education/ceap/resources/>

Step 5: Disclosure to Learners: Financial Disclosure

- "Disclosure TO LEARNERS" prior to education
- Use visible, written method
- One new requirement: Statement of mitigation

No one in control of content has any relevant financial relationships with ineligible companies.*

*Ineligible companies are those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

See SAMPLES at: <https://www.wisconsinnurses.org/wp-content/uploads/2022/01/5.-Toolkit-Disclosure-to-Learners-Examples-page-5.pdf>.

Terms:

Commercial Entity -> Ineligible Company

Conflict of Interest -> Relevant Financial Relationship

Resolving -> Mitigating

Financial Disclosure:

Disclose to learners, prior to clinical content delivery, the presence or absence of relevant financial relationships for all in control of content:

- Name of person in control of content
- Ineligible Companies with which they are affiliated.
- Role / type of affiliation (e.g., researcher, stock holder, consultant, board member, etc.)
- Statement, "All relevant financial relationship have been mitigated."


All Required Disclosures to Learners Before the Activity

- Name of Provider organization awarding contact hours
- Statement: APU WNA Approval / IEA Submitted
- Criteria for awarding contact hours "Successful Completion Requirements"
- For "Clinical" Content: presence/absence of relevant financial relationships for all in control of clinical content
- Only if applicable - joint provider statement
- Only if applicable - commercial support information (company names - NO LOGOs)
- Enduring Materials Only: Date by which learner must COMPLETE activity for CHs.


Putting it all together

We are planning an activity on cardiac meds. Ms. R. reported a relationship with Sanofi (paid speaker) that ended in September, 2022. What do we do?


0

 It no longer exists so it's not a problem.

0

 Let Ms. R. know it's not possible to present on the topic.

0

 Mitigate and Disclose the relationship since Ms. R. is only an affiliate, not owner /...

Dr. S., a presenter for an activity on bi-polar disorder, discloses the following relationships. Which ones are relevant financial relationships? **

0

Rosemont Pharma, Inc. -
board member

0

Navitus Health Solutions
- stock holder

0

DBSA - advisor

Our NP needed to add Dr. S. to the Mitigation Worksheet for the activity:

Rosemont Pharma, Inc. - board member	Navitus Health Solutions - stock holder	DBSA - advisor
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WNA CEAP - Nurse Planner Mitigation Work Sheet - Part B: Documentation Identification & Mitigation of Relevant Financial Relationships

Activity Title: _____ Date(s): _____

The Nurse Planner (NP) uses this worksheet. Keep it in the Activity File. You will need to submit it as part of your application for approval or renewal.

- ✓ Follow the Process (Key Steps) listed in Part A of this form.
- ✓ Refer to the Standards as needed: www.accme.org/standards.
- ✓ Refer to the Standards FAQ for information about navigating rules on stocks and stock options: <https://accme.org/faq/10236>.
- ✓ The Nurse Planner does not analyze their own disclosure information. Someone else familiar with the Standards does this (e.g., a planner, PNP, APU staff.)
- ✓ For presenters with relevant financial relationships, WNA CEAP suggests a method other than, or in addition to, attestation only.

No one in control of content listed any relationships on their Disclosure Form. (If this box is unchecked, complete the table below.)

Name	Role(s) in Activity	Company Listed	Relationship Listed	Step(s) taken to mitigate relevant financial relationships or "Not Relevant [NR]"	Date Implemented or N/A
Example: Antoinette Zar, DNP	Presenter	DME Unlimited (Ineligible company)	Owner	Removed from any role in activity.	December 1, 2021
Example: Ava Zanaczek, MD	Presenter	American Cancer Society (eligible company)	Advisor	NR	N/A
Example: Andres Zavac PhD, RN	Planner	Pharma-Care (ineligible company)	Researcher	No planning of related content & no participation in faculty selection	November 9, 2021

Toolkit Page 3-4 - Mitigation Worksheet (this type of summary is required).

WNA CEAP - Nurse Planner Mitigation Work Sheet - Part B: Documentation Identification & Mitigation of Relevant Financial Relationships

Activity Title: <u>Living Bipolar</u>	Date(s): <u>3-14-2022</u>
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The Nurse Planner (NP) uses this worksheet. Keep it in the Activity File. You will need to submit it as part of your application for approval or renewal.

- ✓ Follow the Process (Key Steps) listed in Part A of this form.
- ✓ Refer to the Standards as needed: www.accme.org/standards.
- ✓ Refer to the Standards FAQ for information about navigating rules on stocks and stock options: <https://accme.org/faq/10236>.
- ✓ The Nurse Planner does not analyze their own disclosure information. Someone else familiar with the Standards does this (e.g., a planner, PNP, APU staff.)
- ✓ For presenters with relevant financial relationships, WNA CEAP suggests a method other than, or in addition to, attestation only.

No one in control of content listed any relationships on their Disclosure Form. (If this box is unchecked, complete the table below.)

Name	Role(s) in Activity	Company Listed	Relationship Listed	Step(s) taken to mitigate relevant financial relationships <u>or</u> "Not Relevant [NR]"	Date Implemented <u>or</u> N/A
Dr. S	Presenter	"Rosemont Pharma" (Rosemont Pharmaceuticals) <i>(Ineligible Company)</i>	Board Member	Review of presentation by content expert on planning committee.	1/19/22
Dr. S	Presenter	Navitus Health Solutions (Ineligible Company)	Stock ownership	Review of presentation by content expert on planning committee.	1/19/22
Dr. S	Presenter	"DBSA" (Depression and Bipolar Support Alliance) (Eligible Company)	Advisor	NR	N/A

Correct answer to Nurse Planner Mitigation Worksheet exercise

Thank you!

For general questions including documentation requirements and fee questions: megan@wisconsinnurses.org.

For questions on the ANCC/WNA criteria for educational planning and the Standards for Integrity & Independence:

WNAprl@wisconsinnurses.org.