

MNA Accredited Approver Unit

APU New Standards for Integrity and Independence-Session 1

Kristi Anderson, MN, RN, NPD-BC, CNL

MNA Director of Professional Development; Accredited Approver Program Director

Montana Nurses Association



Activity Information (Not Disclosures)

Criteria for successful completion: active participation in the webinar

- Credit awarded separately for session 1 and session 2

Montana Nurses Association is accredited with distinction as a provider of nursing continuing professional development by the American Nurses Credentialing Center's Commission on Accreditation.

(Absence of COI/Relevant Financial Relationships Statement not included!)

Standards

Standard 1-Ensuring Valid Content—Unchanged

Standard 2-Prevent Commercial Bias & Marketing—Unchanged

Standard 3-Identify, Mitigate, & Disclose Relevant Financial Relationships—**New**

Standard 4-Manage Commercial Support—Unchanged

Standard 5-Manage Ancillary Activities—**Time New**

Updated resources and forms available now on MNA site— Provider Unit Resources—

New Password APUNCPD (Approved Provider Unit Nursing Continuing Professional Development)

Provider Unit Materials

[UPDATED APU Documents - Google Drive link](#)

[UPDATED APU Documents - Dropbox](#)

[Provider Unit Manual](#)

Other Resources

[Crosswalk - New Standards for Integrity & Independence](#)

[Determining Relevant Financial Relationships Guide](#)

[Provider FAQ page](#)

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New Password APUNCPD (Approved Provider Unit Nursing Continuing Professional Development)

Documentation Materials

1. *Activity Documentation Form*
2. *Financial Disclosure Form*
3. *Mitigation Worksheet*
4. *Commercial Support Agreement*

Self-Study Application Materials

1. *Eligibility Form*
2. *Self-Study Application-EDP 4 change*
3. *Tips for Completing Provider Application*

Standards for Integrity and Independence Resources

1. *Standards for Integrity & Independence (full standards)*
2. *Key Steps for the Identification, Mitigation, & Disclosure of Relevant Financial Relationships*
3. *ANCC Toolkit-Standard #3*

Other Resources

- Approved Provider Manual
- Key Changes Crosswalk
- Determining Relevant Financial Relationships Guide
- FAQ's

New Terms

Commercial Interest Entity

Company that makes, produces, markets, or resells products or services consumed by or used on patients or a company that is controlled by an entity that does these things



Ineligible Company

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

Resolution



Mitigation

Ineligible vs Eligible Company Examples

Ineligible Company

- Companies producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients
- Examples
 - Device manufacturers/distributors
 - Pharmaceutical companies/distributors
 - Manufacturers of health-related wearable products
 - Growers, distributors, manufacturers or sellers of dietary supplements
 - Pharmacy benefit managers

Eligible Company

- Companies providing clinical services directly to patients
- Education companies
- Examples
 - Hospitals/government agencies/universities
 - Electronic health records companies
 - Health profession membership organizations
 - Software/game developers
 - Insurance/managed care companies

Changes

Nurse Peer
Review Leader



Accredited Approver Program Director

Agenda



Required for activities longer than 3 hours

COI Form



Changed to *Financial Disclosure Form* and
Mitigation Worksheet

Activity Disclosure



Changed to activity information with “disclosure”
only referring to financial information

Standard 5

Manage Ancillary Activities—**Time New**

- **30-minute interval** must separate NCPD activities from those influenced by ineligible companies if in the same educational space
 - In-person
 - Virtual

Standard 3-Identify, Mitigate, & Disclose Relevant Financial Relationships-Clinical Content

Relevant Financial Relationships

All 3 conditions must be met:

- Financial relationship between the person in control of content and an ineligible company (any amount)
- Past 24 months (changed from 12)
- Content is related to the products

Spouse information not required!

Relevant Financial Relationship Determination

Do **NOT** identify, mitigate, or **disclose** relevant financial relationships if:

- Content is nonclinical only (not related to clinical care or knowledge)
 - Leadership, communication skills training, preceptor
- Other rare instances-contact MNA Director of Professional Development
- Do not **DISCLOSE**—not applicable

Standard 3-Identify, Mitigate, & Disclose Relevant Financial Relationships-Clinical Content

Financial Disclosure Form for each person-completed by those controlling content

1. Collect information about all financial relationships with ineligible companies within the prior 24 months

Mitigation Worksheet for activity-completed by Nurse Planner

2. Exclude owners or employees of ineligible companies
3. Identify relevant financial relationships
4. Mitigate relevant financial relationships

Financial Disclosure prior to the start of the activity

5. Disclose all relevant financial relationships

Review--***Key Steps for the Identification, Mitigation, and Disclosure of Relevant Financial Relationships***

Complete/Review *Financial Disclosure* forms for all involved

Do NOT identify, mitigate, or disclose relevant financial relationships if content is nonclinical only

If content is clinical:

1. Collect information about **ALL** financial relationships with **ineligible** companies within the prior **24 months**-*Financial Disclosure Form*

- Disclosure includes
 - Name of ineligible company with financial relationship
 - Nature of relationship
- Nurse planner signature not required

-If financial relationships are not entered on the Financial Disclosure Form, disclose absence of relevant financial relationships

-If financial relationships are entered on the Financial Disclosure Form, move on to step 2- Mitigation Worksheet

Mitigation Worksheet for Activity

-Complete if financial relationships are entered on the ***Financial Disclosure Form***

-Nurse Planner cannot mitigate their own financial relationships

2. Exclude owners or employees of ineligible companies

- Exceptions
 - Content not related
 - Content related to basic science, research and do not make care recommendations
 - Participating as technicians to teach safe/proper use of devices and do NOT recommend whether or when a device is used

3. Identify relevant financial relationships

- Financial relationship with ineligible company in the past 24 months and content relates to products
 - Choose Y/N

4. Mitigate relevant financial relationships

- Choose strategies for planners and speakers/faculty

Mitigation Strategies

Mitigation steps for planners

(choose at least one)

- ✓ Divest the financial relationship
- ✓ Recusal from controlling aspects of planning and content with which there is a financial relationship (Remove/revise the role of the individual so that the relationship is no longer relevant)
- ✓ Peer review of planning decisions by persons without relevant financial relationships
- ✓ Use other methods –describe

Mitigation steps for faculty and others

(choose at least one)

- ✓ Divest the financial relationship
- ✓ Peer review of content by persons without relevant financial relationships (nurse planner, planning committee member, content reviewer, etc.)
- ✓ Attest that clinical recommendations are evidence-based and free of commercial bias (e.g., peer-reviewed literature, adhering to evidence-based practice guidelines)
- ✓ Use other methods –describe the method

Disclose Relevant Financial Relationships

Do NOT disclose absence of relevant financial relationships if content is nonclinical only (not related to clinical care/knowledge)

NO relevant financial relationships (clinical content)

None of the planners or presenters for this educational activity have relevant financial relationships to disclose with ineligible companies.

If there ARE relevant financial relationships (clinical content)

None of the planners or presenters for this educational activity have relevant financial relationships to disclose with ineligible companies **except for speaker Nicolas Garcia, who is on the speakers' bureau for XYZ Device Company.**

All of the relevant financial relationships listed for this individual have been mitigated.

Relevant Financial Relationship Determination

Do NOT identify, mitigate, or disclose relevant financial relationships if:

- **Content is nonclinical only** (not related to clinical care or knowledge)*

If the above exception does not apply:

1. Does the person have the ability to control the content of the activity?

- If yes, complete ***Financial Disclosure Form***

2. Does the person have a non-employee financial relationship with an ineligible company in the past 24 months? (see employee/owner exceptions)

- If no, disclose absence of relevant financial relationships
- If yes, complete ***Mitigation Worksheet***

3. Are the products of the ineligible company related to the topic?

- If no, document on ***Mitigation Worksheet*** and disclose absence of relevant financial relationships
- If yes, document on ***Mitigation Worksheet*** and disclose presence of relevant financial relationships

*Other rare instances--contact MNA Director of Professional Development

Scenario

You are planning an activity on nurse resiliency.

- Do you need to complete a ***Financial Disclosure Form?***
- How would you disclose this to learners?

Scenario

You are planning an activity on cardiac rhythm analysis.

- Do those involved need to complete a ***Financial Disclosure Form?***

From the ***Financial Disclosure Forms***, you determine that no one reports a financial relationship with an ineligible company.

- Do you need to complete the ***Mitigation Worksheet?***

How would you disclose this to learners?

Scenario

You are planning an activity related to treatment of diabetes.

- Do you need to complete a ***Financial Disclosure Form?***

From the ***Financial Disclosure Form***, you see that one of your speakers was a consultant with XYZ Diabetes Pharmaceuticals 6 months ago.

- Do you need to complete the ***Mitigation Worksheet?***

How would you disclose this to learners?

Activity: Care of the Heart Failure Patient

What are the relevant financial determination steps?

How would you disclose financial relationship(s)?

Planners and Speakers:

1. Brock Anderson, DNP, APN, FNP-BC
 - Planning committee member/speaker
 - Speakers' bureau with ABC Cardiac Meds
2. Braelynn Anderson, PhD, APN, Professor
 - Nurse planner
 - No relevant financial relationships
3. Kylie Anderson, DNP, FACNM, Assistant Professor
 - Planning committee member/speaker
 - No relevant financial relationships

Timelines

Now—

- Updates available on MNA site-Provider Unit Resources

Start implementing changes now to accommodate your planning timelines

- Use updated forms for activities being planned 12/1/21 or later

By 3/15/22—

- PNP-submit completed ***Financial Disclosure Form*** or template & ***Activity Information*** templates (1 for nonclinical activity and 1 for clinical activity requiring mitigation)

APUs submitting applications for March cycle 2022 or later—

- Use updated self study template-change to EDP 4
- Can submit activities planned prior to these changes

By 3/15/22-PNP Template Submission

1. Completed Financial Disclosure Form (or template)
2. Completed Activity Information (or templates)-evidence of required info provided to learners prior to activity
 - Activity information-nonclinical topic
3. Completed Activity Information (or templates)-evidence of required info provided to learners prior to activity
 - Activity information-clinical topic requiring mitigation

Activity information includes:

- Approved provider statement (always required)
- Criteria for successful completion (always required)
- Financial disclosure (if topic is clinical only-**do not include if content is nonclinical**)
- If applicable-commercial support, joint providership, expiration date (enduring materials)

What are the relevant financial determination steps?

What is our activity information provided to learners?

Activity: Emotional Intelligence

- Live activity
- No commercial support
- Not jointly provided
- Attend 90% and complete an evaluation

What are the relevant financial determination steps?

What is our activity information provided to learners?

Activity: Treatment of HTN

- Enduring material-expiration date 7/1/22
- No commercial support
- Not jointly provided
- Watch full recording and achieve at least 80% on post test
- Speaker was the primary investigator for research study for Pfizer 12 months ago
- No financial relationships for others

Questions/Comments

Eval access



References

- ANCC Primary Accreditation Application Manual for Accredited Approvers, 2015.
- Accreditation Council for Continuing Medical Education. Standards for Integrity and Independence in Accredited Continuing Education. Published 2020.
- Toolkit for the Standards for Integrity and Independence in Accredited Continuing Education © 2020 by the Accreditation Council for Continuing Medical Education (ACCME®)