



DISCLOSING RELEVANT FINANCIAL RELATIONSHIPS TO LEARNERS

MAINE MEDICAL ASSOCIATION
MAINE MEDICAL EDUCATION TRUST

OBJECTIVE

Be able to write and present a disclosure to learners that is compliant with Standard 3: Identify, Mitigate, and Disclose Relevant Financial Relationships.



AGENDA



1. Practice Problems

2. Disclosure Rules for
Standard 3

3. Practice Problem Answers

TWO TYPES OF DISCLOSURE

FACULTY DISCLOSURE FORM

- Collecting information from individuals in control of content about their financial relationships with ineligible companies.

DISCLOSURE TO LEARNERS

- Informing learners about the relevant financial relationships individuals in control of content have with ineligible companies.

<u>Name of Ineligible Company</u>	<small>manages the funds.</small> <u>Nature of Financial Relationship</u>	<u>Has the Relationship Ended?</u>
Example: ABC Company	Consultant	X
		<input type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>
<input type="checkbox"/> In the past 24 months, I have not had any financial relationships with any ineligible companies. (If the statement above is true, check the box to the left.)		
By signing, I attest that the above information is correct		
as of this date of submission.		
Signature		Date

Dr. X has nothing to disclose.

EXERCISE: WOULD THIS DISCLOSURE BE COMPLIANT?

1. *Find a piece of paper and writing utensil (or open up a blank computer document).*
2. *Number your paper 1-5.*
3. *We will look at 5 examples of disclosures to learners.*
4. *Determine whether each disclosure would meet the requirements (be in compliance) or not (be in noncompliance) of Standard 3 (Identify, Mitigate and Disclose Relevant Financial Relationships).*
5. *Record your answers and jot down your reasoning.*

WOULD THIS DISCLOSURE BE COMPLIANT?

1. Daphne Blake, DO has no conflicts of interest.

WOULD THIS DISCLOSURE BE COMPLIANT?

2. Velma Dinkley, PhD is a consultant for Vanda Pharmaceuticals.

WOULD THIS DISCLOSURE BE COMPLIANT?

3. None of the speakers or planners for today's activity have received financial contributions that would conflict with providing the highest quality, evidenced based education possible.

WOULD THIS DISCLOSURE BE COMPLIANT?

4. Today's speakers have no relevant financial relationships with the manufacturer(s) of any commercial product(s) and/or provider of commercial services discussed in today's CME activity.

WOULD THIS DISCLOSURE BE COMPLIANT?

5. Fred Jones, MD, speaker for this event, has no relevant financial relationships with ineligible companies to disclose.

Shaggy Rogers, planner for this activity, discloses that he owns stock in Green Thumb Industries.



THE RULES

THE RULES

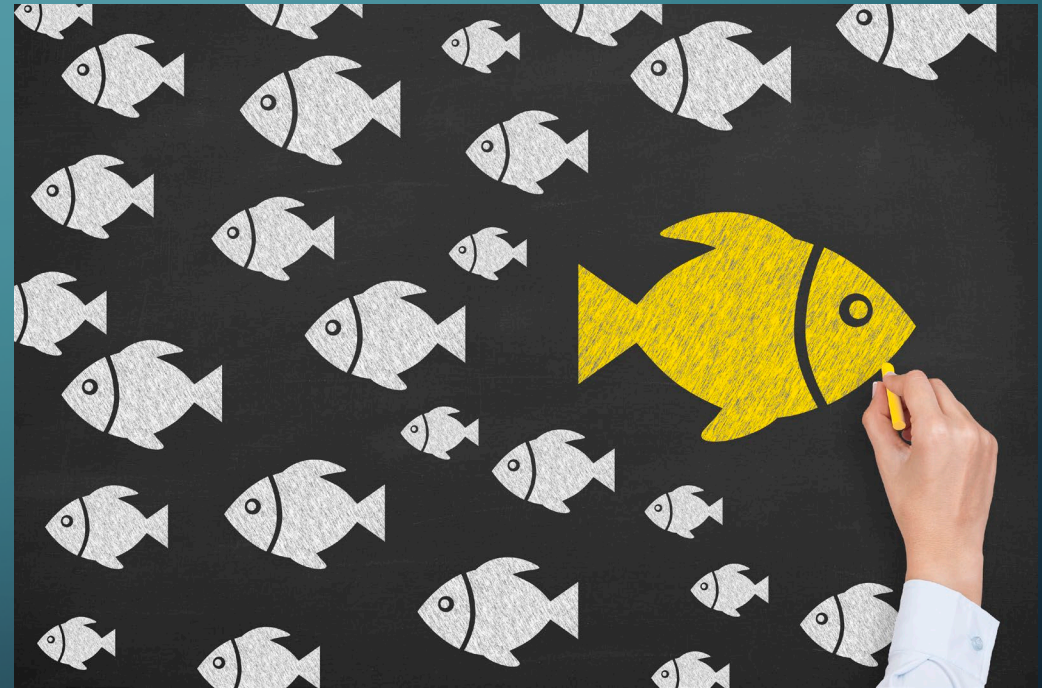
1. All individuals in control of content must be accounted for in the disclosure to learners

- Planners
- Presenters
- Panel Members
- Moderators/Facilitators
- Content Reviewers
- Authors of Enduring Content



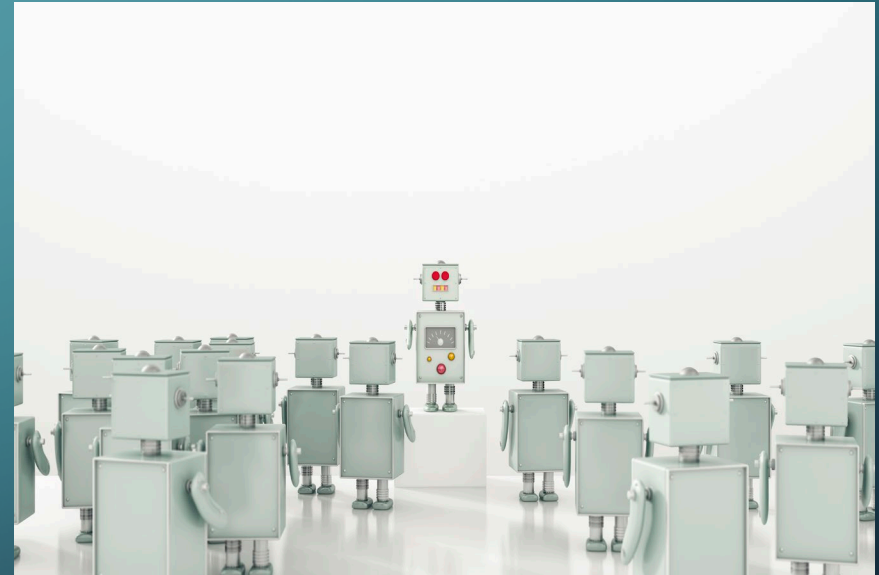
THE RULES

2. A disclosure must be made to learners even if no one has any relevant financial relationships.



THE RULES

3. A disclosure must be made to learners for every activity, including each session within a series.



THE RULES

4. For an individual with relevant financial relationships, the disclosure must include:

- The individual's name
- The nature of the relationship(s)
- The name(s) of the ineligible company(ies) with which they have a relationship

The full name of the ineligible company must be used.



THE RULES

5. If there are individuals with relevant financial relationships, the following statement **must** be included:

All relevant financial relationships have been mitigated.



THE RULES

6. No ineligible company logos, trade names, or product group messages can be included in the disclosure to learners.



THE RULES

7. The disclosure to learners must be given prior to the learners engaging with the educational content.



THE RULES

8. The disclosure must be given in a verifiable format.

- The disclosure must be able to be submitted as evidence during reaccreditation.
- In writing is best!
 - In writing is required for activities approved through the Maine Medical Education Trust.



PRESENTING THE DISCLOSURE

In-Person Events

- Sign-in Sheets
- Slide Shows
- Housekeeping slides
- Agenda

Virtual Events

- Slide Shows
- Housekeeping Slides
- Email invitation/announcement

Enduring Content

- Landing Page
- Slide shows

THE RULES

9. If the activity is non-clinical, not addressing any clinical content, then a disclosure to learners does not need to be made. This could include:

- Leadership Training
- Communication Training
- Legal Updates or Procedures



THE RULES -SUMMARY

1. All individuals in control of content must be accounted for in the disclosure to learners
2. A disclosure must be made to learners even if no one has any relevant financial relationships.
3. A disclosure must be made to learners for every activity, including each session within a series.
4. For an individual with relevant financial relationships, the disclosure must include the individual's name, the nature of the relationship(s), and the name(s) of the ineligible company(ies) with which they have a relationship.
5. If there are individuals with relevant financial relationships, the statement "All relevant financial relationships have been mitigated" **must** be included.
6. No ineligible company logos, trade names, or product group messages can be included in the disclosure to learners.
7. The disclosure to learners must be given prior to the learners engaging with the educational content.
8. The disclosure must be given in a verifiable format.
9. If the activity is non-clinical, then a disclosure to learners does not need to be made.



THE ANSWERS

WOULD THIS DISCLOSURE BE COMPLIANT?

1. Daphne Blake, DO has no conflicts of interest.

- Meets the requirements for an individual disclosure.
- Does not include anyone else in control of content
 - Would only be compliant if Daphne Blake, DO were the only planner and speaker for the activity.

WOULD THIS DISCLOSURE BE COMPLIANT?

1. Daphne Blake, DO has no conflicts of interest.

Questions:

Q. Do we need to state her role in the activity?

A. No, this is not a requirement.

Q. Is it okay to use the phrase “conflicts of interest?”

A. Yes, although this is not the language used in the Standards for Integrity and Independence, it would be considered compliant.

REVISE THE DISCLOSURE

HOW COULD YOU REVISE THIS DISCLOSURE TO BE COMPLIANT IF DAPHNE BLAKE, DO IS A SPEAKER AND OTHERS WERE INVOLVED IN PLANNING?

1. *Daphne Blake, DO has no conflicts of interest.*

*Daphne Blake, DO has no conflicts of interest.
None of the planners have conflicts of interest.*

Neither the speaker for today nor any of the planners for this activity have conflicts of interest.

WOULD THIS DISCLOSURE BE COMPLIANT?

2. Velma Dinkley, PhD is a consultant for Vanda Pharmaceuticals.



- Not Compliant
 - Does not account for anyone else in control of content.
 - Velma Dinkley, PhD would have to be the only planner and speaker for the activity.
 - Does not include the phrase “All relevant financial relationships have been mitigated.”

REVISE THE DISCLOSURE

HOW COULD YOU MAKE THIS COMPLIANT?

2. Velma Dinkley, PhD is a consultant for Vanda Pharmaceuticals.

Velma Dinkley, PhD is a consultant for Vanda Pharmaceuticals.

*All relevant financial relationships have been mitigated.
None of the planners for today's activity have relevant financial relationships to disclose.*

WOULD THIS DISCLOSURE BE COMPLIANT?

3. None of the speakers or planners for today's activity have received financial contributions that would conflict with providing the highest quality, evidenced based education possible.

Compliant

- Accounts for all individuals in control of content.
- The phrasing says they have no financial conflicts of interest.

WOULD THIS DISCLOSURE BE COMPLIANT?

3. None of the speakers or planners for today's activity have received financial contributions that would conflict with providing the highest quality, evidenced based education possible.

Q. Is there one correct way to phrase the lack of relevant financial relationships?

A. No. There are no rules regarding how the disclosure is phrased when there are no relevant financial relationships. But be careful that the phrasing does not restrict the disclosure.

WOULD THIS DISCLOSURE BE COMPLIANT?

Be careful that the phrasing does not restrict the disclosure.

Ex. None of the speakers or planners for today's activity have received financial contributions from companies that market healthcare products.

This includes only part of the definition of 'ineligible company' and therefore restricts what might be disclosed.

WOULD THIS DISCLOSURE BE COMPLIANT?

3. None of the speakers or planners for today's activity have received financial contributions that would conflict with providing the highest quality, evidenced based education possible.

Q. Do you have to name everyone in the disclosure? Does everyone in control of content need their own disclosure?

A. No. Those who do not have relevant financial relationships can be grouped together.

WOULD THIS DISCLOSURE BE COMPLIANT?

4. Today's speakers have no relevant financial relationships with the manufacturer(s) of any commercial product(s) and/or provider of commercial services discussed in today's CME activity.

Ineligible Companies

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

Noncompliant

- Does not account for all individuals in control of content.
- The definition of 'ineligible companies' is incomplete.

REVISE THE DISCLOSURE

HOW COULD THIS BE REVISED TO BE COMPLIANT?

4. Today's speakers have no relevant financial relationships with the manufacturer(s) of any commercial product(s) and/or provider of commercial services discussed in today's CME activity.

Today's speakers and planners for this activity have no relevant financial relationships with ineligible companies.

WOULD THIS DISCLOSURE BE COMPLIANT?

5. Fred Jones, MD, speaker for this event, has no relevant financial relationships with ineligible companies to disclose.

Shaggy Rogers, planner for this activity, discloses that he owns stock in Green Thumb Industries.



Noncompliant

- Does not contain the phrase “All relevant financial relationships have been mitigated.”
- Brings up the question: Have all relevant financial relationships been mitigated?

CHALLENGE: HOW WOULD YOU WRITE THIS DISCLOSURE TO LEARNERS?

ACTIVITY: PSYCHIATRY IN 2023

Name	Role	Presentation Title	Ineligible Company	Nature of Relationship	Relevance?
Charlie Brown, MD	Speaker	Treatment-Resistant Depression	None	N/A	N/A
Linus van Pelt, MD,	Speaker	Assessment and Treatment of Insomnia	Idorsia Pharmaceuticals US Inc.	Consultant	Manufacture Quvivivic, a prescription medicine for insomnia
Lucy van Pelt, MD, PhD	Speaker	Borderline Personality Disorder	Pfizer, Inc.	Speaker	Manufacture Navine, an antipsychotic
Sally Brown	Planner	N/A	None	N/A	N/A

CHALLENGE: HOW WOULD YOU WRITE THIS DISCLOSURE TO LEARNERS?

ACTIVITY: PSYCHIATRY IN 2023

*Linus van Pelt, MD is a consultant for Idorsia Pharmaceuticals US Inc.
Lucy van Pelt, PhD is a speaker for Pfizer, Inc.
All relevant financial relationships have been mitigated.
None of the other speakers or planners for this activity have relevant financial relationships to disclose with ineligible companies.*

COMPLIANT PHRASES

For disclosing the absence of relevant financial relationships:

- Nothing to disclose
- No conflicts of interest
- No relevant financial relationships
 - (with ineligible companies)

DISCLOSURE EXAMPLES

- Available on the [MMET Activity Downloads Webpage](#):

During the Activity

1. **Attendance.** Collect the **names** and **credentials** of participants. This [Sign-In Sheet Template](#) may be used or adapted. Collecting credentials on attendance sheets will help to determine the number of physicians and other learners in attendance that will need to be reported post-activity. If requesting MOC, also collect and submit the date of birth for each attendee requesting MOC and their Board ID Number.
2. **Disclosure to Learners** - Present the presence and/or absence of relevant financial relationships for all planners, presenters, and others in control of content to learners prior to their engagement with the educational content. See the [Template and Examples for Financial Relationships Disclosures](#).

- Available on the [Downloads for Accredited Providers Webpage](#):

CME Provider Materials

- [Accreditation Requirements](#) includes the Core Criteria, Menu of Commendation Criteria, and the Standards for Integrity and Independence
- [Standards for Integrity and Independence Toolkit](#) for use in mitigating relevant financial relationships (Standard 3)
- [Flowchart for Identifying, Mitigating, and Disclosing Relevant Financial Relationships](#) (Standard 3)
- [Template and Examples for Financial Relationship Disclosures](#)
- [Provider Dues and Accreditation Fees \(2022\)](#)
- [Provider Statements](#) to be used on CME activity literature intended for learners
- [List of Desirable Physician Attributes \(Competencies\)](#)

TIPS

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

Keep the disclosure to learners clear and simple. Use broad phrases such as “relevant financial relationships” and “ineligible companies” for the clearest compliant language.

Present the absence of relevant financial relationships.

Be sure to include ALL individuals in control of content.

Remember to include “All relevant financial relationships have been mitigated” if any individuals have relevant financial relationships.



QUESTIONS?

Office Hours: Mondays 9-10am



Contact: Elizabeth Ciccarelli at eciccarelli@mainemed.com