

# COI: Highest Area of Non-Compliance in AAFP Audits—and, How Do We Fix It?

Jolene White

July 23, 2019

# Introductions



## **Jolene White (presenter)**

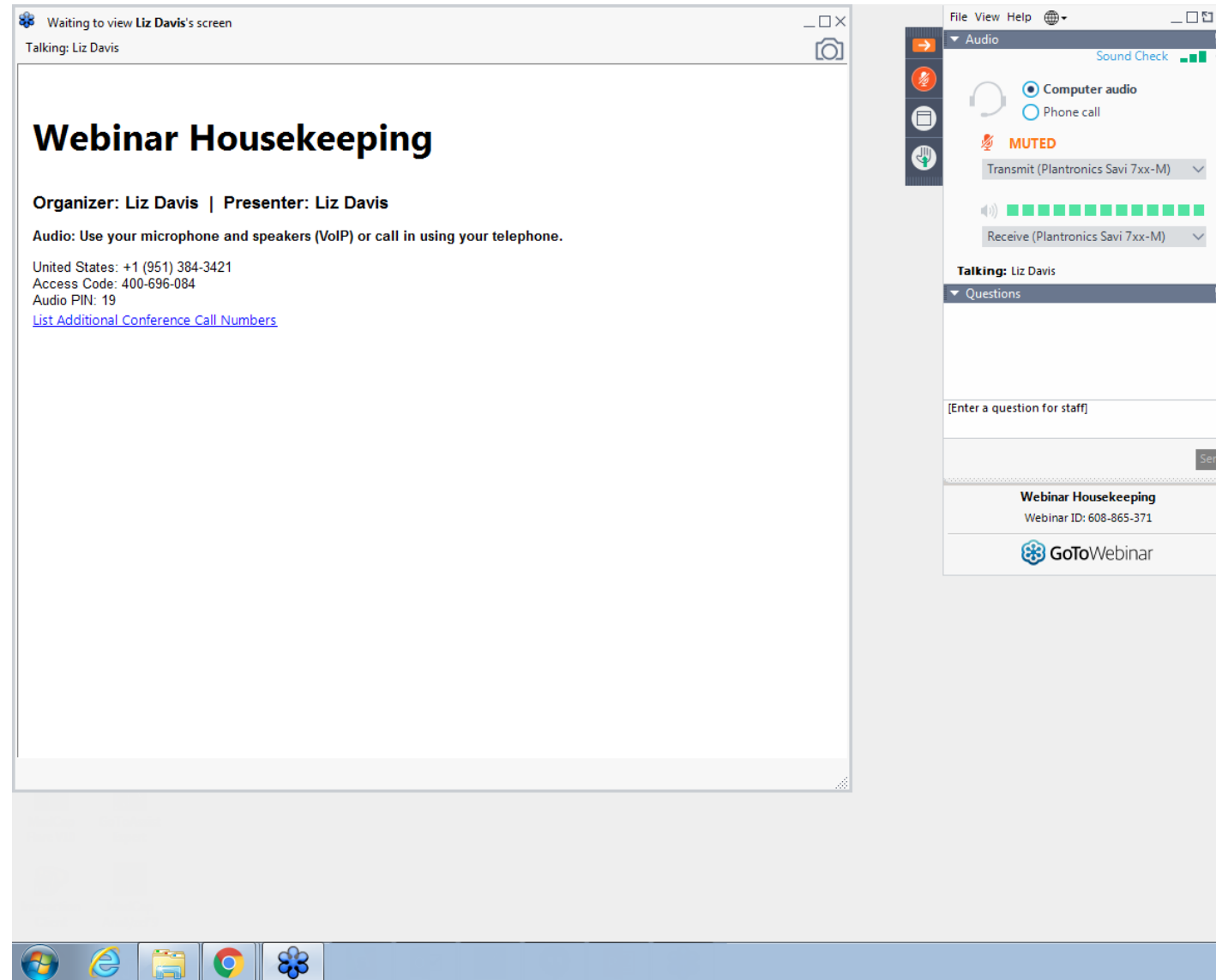
- AAFP, AAFP Credit System Specialist



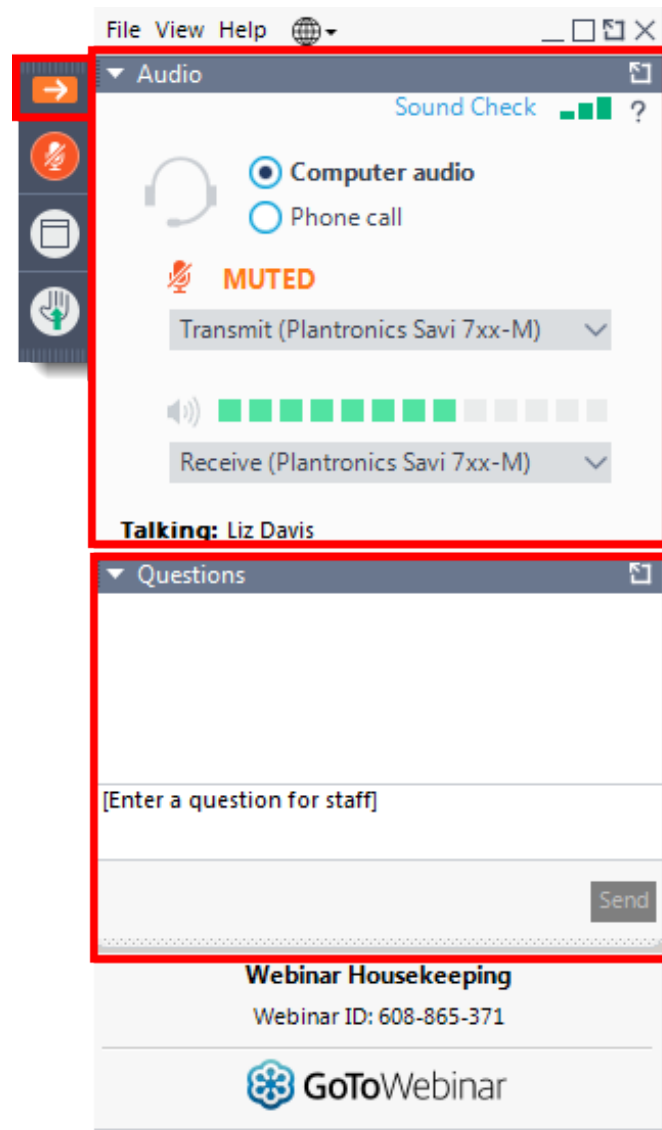
## **Morgan Hosler (moderator)**

- AAFP, AAFP Credit System & Compliance Senior Strategist

# GoToWebinar Housekeeping: What Attendees See



# GoToWebinar Housekeeping: Attendee Participation



## Participation

Open and close your control panel

Join audio:

- Choose **Mic & Speakers** to use VoIP
- Choose **Telephone** and dial using the information provided

Submit questions and comments via the Questions panel

**Note:** Today's presentation is being recorded and will be provided later this month.

# Learning Objectives

As a result of this live, interactive webinar, you will be able to:

- Recognize what encompasses Standards 2 and 6 of the ACCME Standards for Commercial Support and how to follow those standards with your CME activities.
- Recall what is considered “non-compliant” when handling conflict of interest situations and how to avoid non-compliance in these areas.
- Demonstrate more confidence in handling conflict of interest situations when creating CME activities.

# The AAFP Credit System Eligibility Requirements

**AAFP Credit System**

## AAFP Credit Eligibility Requirements

Credit System and Compliance staff review all applications submitted for AAFP CME credit in accordance with the AAFP Credit System's Eligibility Requirements outlined below.

View our [Decision Tree](#) (1 page PDF) document to understand how staff come to credit determination decisions. CME Provider Organizations are encouraged to use this tool if there is uncertainty about whether a topic is eligible for AAFP CME credit.

### Activity Level

The CME activity must be relevant to the scope of family medicine.

The CME activity must fully comply with the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support and the American Medical Association (AMA) Council on Ethical and Judicial Affairs (CEJA) *Gifts to Physicians from Industry Opinion 9.6.2*.

The AAFP is committed to assuring that appropriate quality CME is available to the nation's family physicians. As a national credit system, the AAFP must monitor and enforce compliance with current regulations governing CME, such as the ACCME *Standards for Commercial Support*, and the above referenced CEJA Opinion, both of which the AAFP has adopted as its own policies. The primary purpose of these standards is to ensure independence, balance, transparency, and absence of commercial bias in CME.

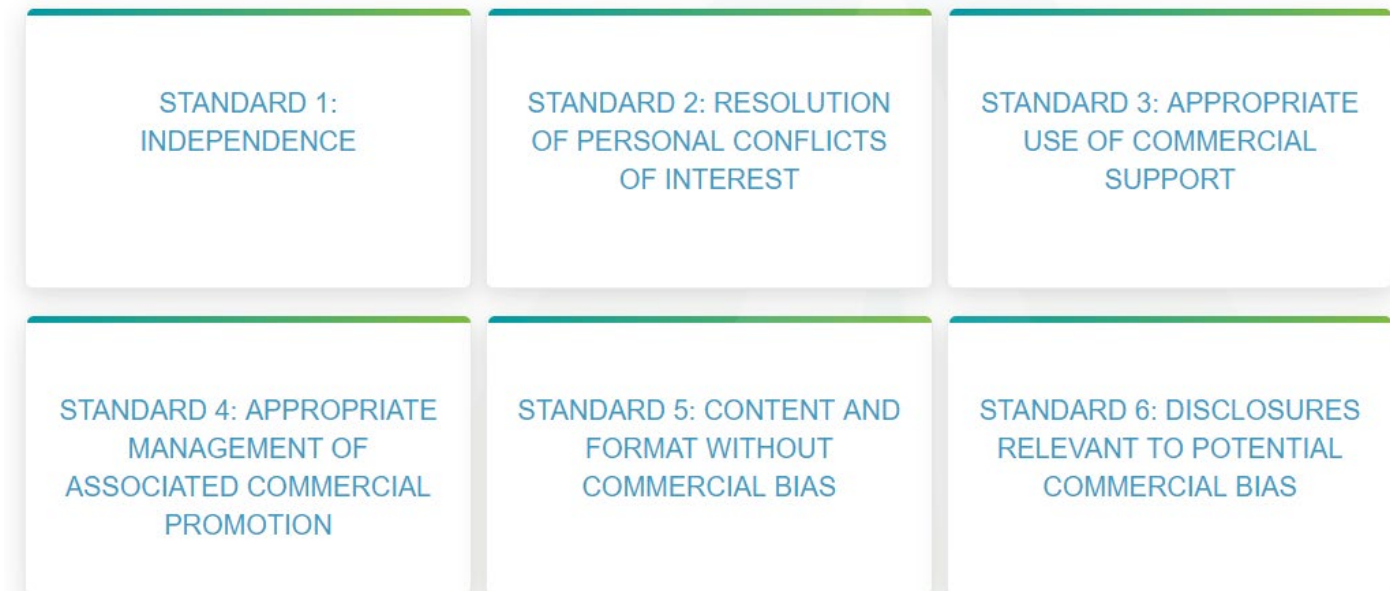
**PRESCRIBED:**  
The CME activity must be primarily designed for physicians and have an

**CME PROVIDER LOGIN**  
View your CME Provider Dashboard  
[Dashboard Login](#)

**BEGIN YOUR APPLICATION**  
Create a CME Provider Account  
[Create an Account](#)

**Questions?**  
Contact the AAFP Credit System  
(800) 274-2237  
[cmecredit@aafp.org](mailto:cmecredit@aafp.org)

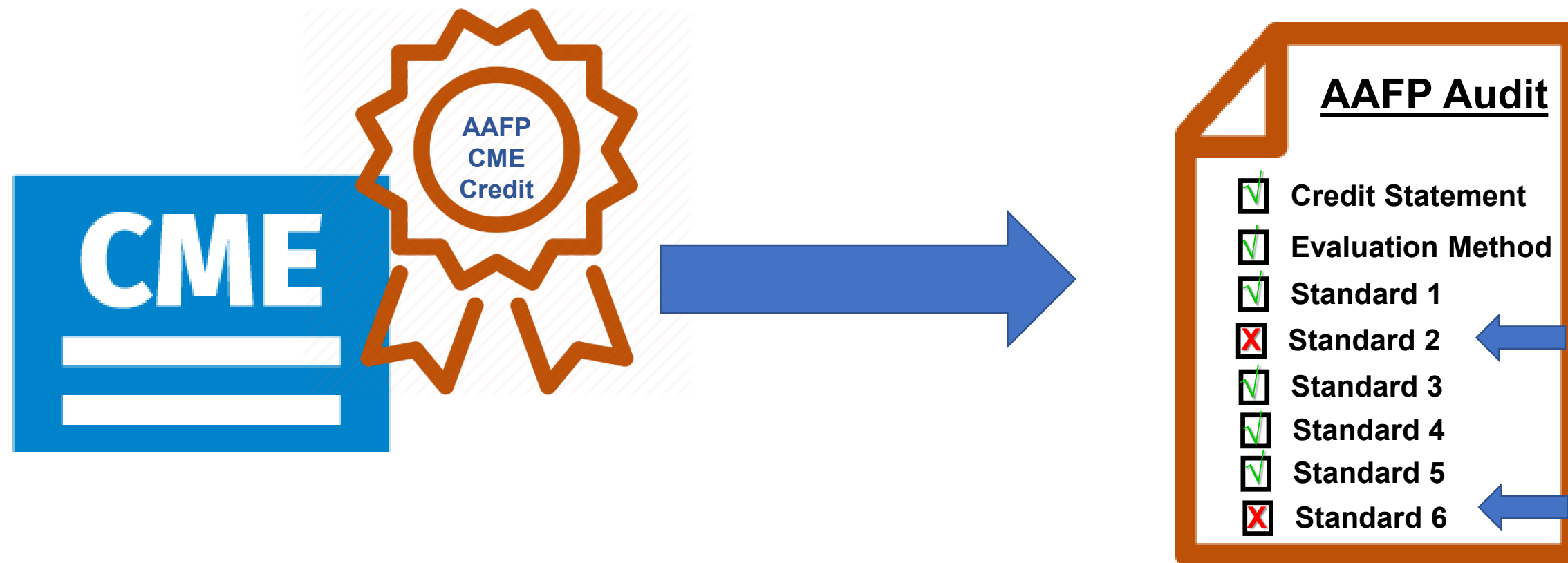
## Standards for Commercial Support



<http://www.accme.org/accreditation-rules/standards-for-commercial-support>

<https://www.aafp.org/cme/creditsys/about/eligibility.html>

# AAFP Credit System Audits





# What is a Commercial Interest?

**A *commercial interest*** is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

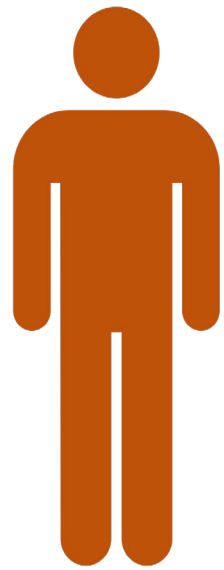


Medical Device and/or  
Pharmaceutical Company

<http://www.accme.org/accreditation-rules/policies/definition-commercial-interest>



# What is a Content Controller?



Individual/Content  
Controller

- ☐ Presenter/Faculty
- ☐ Educational Staff
- ☐ Planners/Planning Committee Members
- ☐ Content Reviewers/Editors
- ☐ Anyone else that has influence over the educational content
- ☐ AAFP active/life member involved for Prescribed credit

# What is a Conflict of Interest (COI)?

When an individual has an opportunity to affect CME content about products or services of a commercial interest with which he/she has a financial relationship.



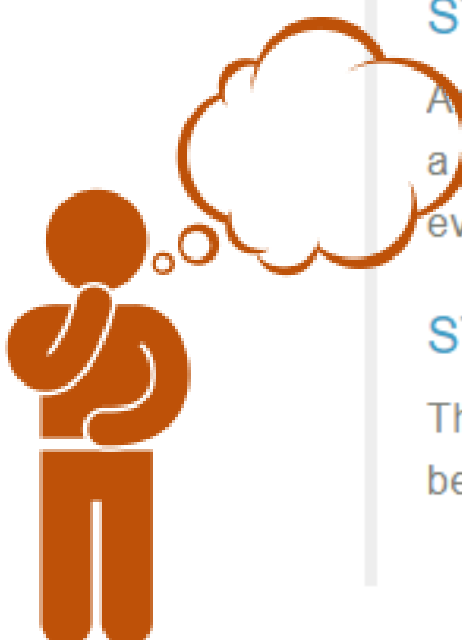
# Standard 2: Resolution of Personal Conflicts of Interest



## STANDARD 2.1

The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. The ACCME defines "relevant" financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

## STANDARD 2.2



An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

## STANDARD 2.3

The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.

CME Conflicts of Interest Form for CME Activities

Please check where applicable and sign below. Provide additional pages as necessary.

Date \_\_\_\_\_  
Name: **Dr. John Doe**  
Address, City, State, and Zip Code: \_\_\_\_\_  
Phone Number: \_\_\_\_\_  
E-mail: \_\_\_\_\_  
Name of CME Activity: \_\_\_\_\_  
Date(s) and Location of CME Activity: \_\_\_\_\_  
Topic: \_\_\_\_\_  
Role you hold specific to this CME activity: \_\_\_\_\_

DISCLOSURE OF FINANCIAL RELATIONSHIPS WITHIN 12 MONTHS OF DATE OF THIS FORM

A commercial interest is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

☐ A. Neither I nor an immediate family member (spouse or partner) has a financial relationship with or interest in a commercial interest.

☒ B. I have or an immediate family member (spouse or partner) has a financial relationship with or interest in a commercial interest. Please check the relationship(s). (Check all that apply):

- ☐ Research Grants  
☐ Speakers' Bureaus\*  
☐ Ownership  
☐ Receipt of Equipment or Supplies  
☐ Consultant or Advisory Board  
☐ Manuscript Preparation\*\*
- ☒ Stock/Bond Holdings (excluding mutual funds)  
☐ Employment  
☐ Partnership  
☐ Honorarium  
☐ Other (please list) \_\_\_\_\_

Please indicate the names of the organization(s) with which you have a financial relationship or interest and the topic areas that correspond to the relationship. If more than four relationships, please list on separate piece of paper:

Organization with which Relationship Exists	Type of Relationship	Topic Area(s) Involved
1. <b>Pfizer</b>	1. <b>Stock</b>	1. <b>Diabetes</b>
2.	2.	2.
3.	3.	3.
4.	4.	4.

\*If you checked "Speakers' Bureaus" in item B, please continue:

- Did you participate in company-provided speaker training?
- Did you travel to participate in this training?
- Did the company provide you with slides of a presentation in which you were trained as a speaker?
- Did the company pay the travel/lodging/other expenses?
- Did you receive an honorarium or consulting fee for participating in this training?
- Have you received any other type of compensation from the company?

<input type="checkbox"/> Yes	<input type="checkbox"/> No
<input type="checkbox"/> Yes	<input type="checkbox"/> No
<input type="checkbox"/> Yes	<input type="checkbox"/> No
<input type="checkbox"/> Yes	<input type="checkbox"/> No
<input type="checkbox"/> Yes	<input type="checkbox"/> No
<input type="checkbox"/> Yes	<input type="checkbox"/> No

\*If you checked "Manuscript Preparation" in item B, please continue:

- Was any assistance provided by a commercial interest, medical communications company or professional writer?

☐ Yes ☐ No

If yes, please describe who provided the assistance. \_\_\_\_\_

- Was the topic suggested by an advisory panel that receives support (ex: educational grant) from a commercial interest?

☐ Yes ☐ No

I have read the [CME Provider] Policy and Procedures for Managing Conflicts of Interest. If I have indicated a financial relationship or interest, I understand that this information will be reviewed to determine whether this relationship precludes my participation, and I may be asked to provide additional information. I understand that failure or refusal to disclose, false disclosure, or inability to resolve conflicts of interest will disqualify me from participating in this activity.

Signature \_\_\_\_\_

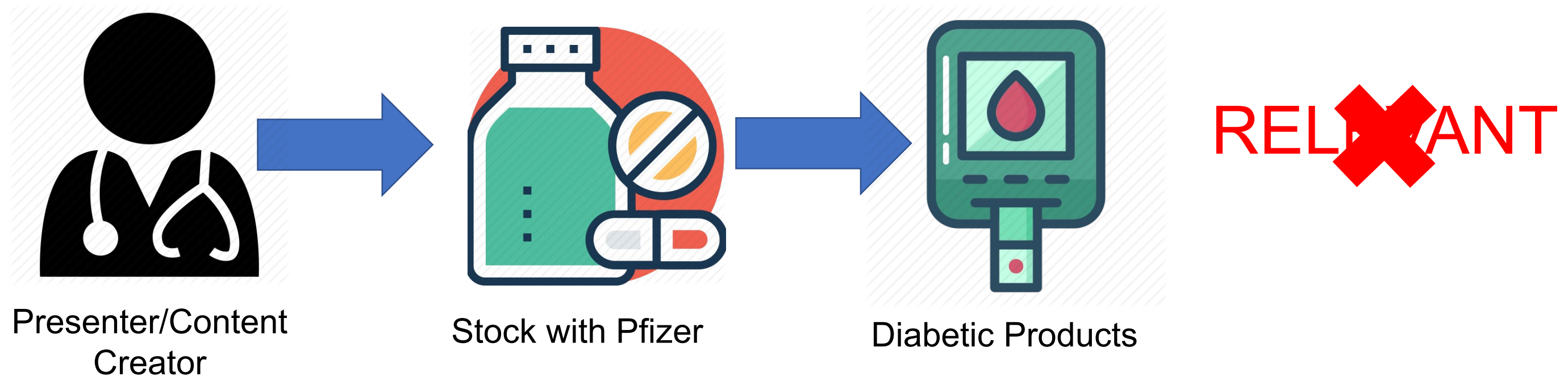
Date: \_\_\_\_\_

RETURN BY: \_\_\_\_\_ TO: [CME Provider, contact person, address, phone number, etc.]

Tips for Success:

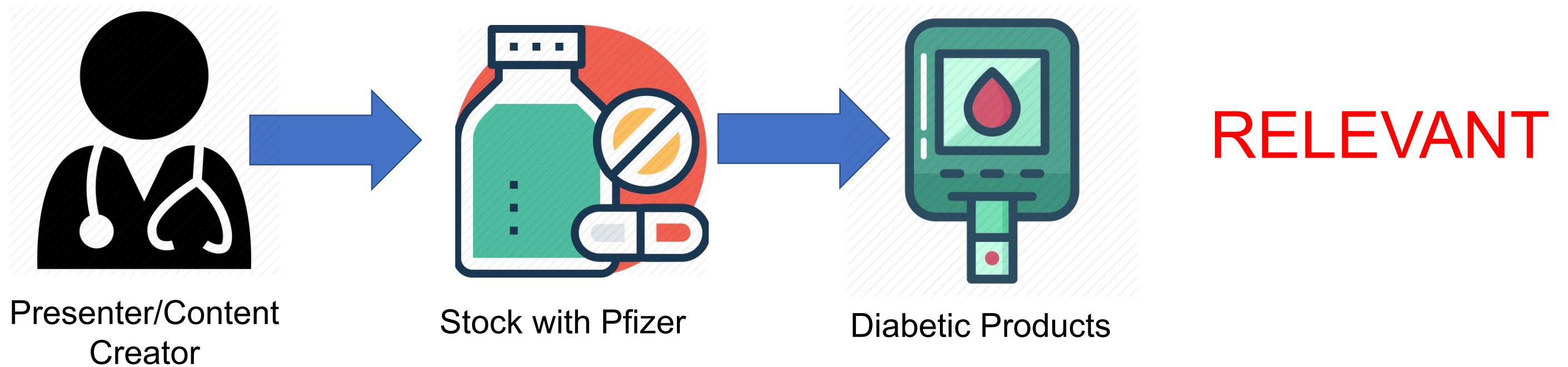
- ☐ Fill out & review COI forms before CME activity
- ☐ Make sure staff complete a COI form
- ☐ Use correct ACCME commercial interest definition
- ☐ Save the forms for at least one year

**A *relevant relationship*** is a financial relationship, in any amount, occurring within the past 12 months that creates a conflict of interest.





# Scenario #1-Dr. Doe



# Standard 2: Resolution of Personal Conflicts of Interest

## STANDARD 2.1

The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. The ACCME defines "relevant" financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

## STANDARD 2.2

An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

## STANDARD 2.3

The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.

<http://www.accme.org/faq/are-there-any-circumstances-when-employees-accme-defined-commercial-interests-can-be-position>



# COI Mitigation Options

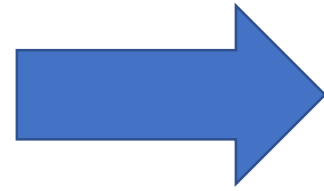


- ☐ Peer review of the content prior to the activity occurring
- ☐ Assign a different topic for the individual/content controller
- ☐ Limit the scope of the topic that the content controller may control
- ☐ Cancellation of the content controller's involvement

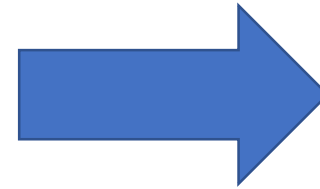
# Peer Review Mitigation Strategy



Dr. Doe's Educational  
Content



Peer Reviews Educational  
Content for bias



Peer Reviewer Documents  
Review

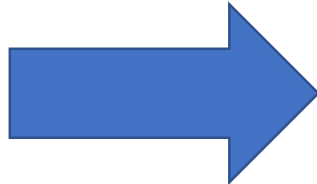
## Tips for Success:

- ☐ Peer reviewer documents their determination
- ☐ Resolve any bias that's found
- ☐ Save all documentation!!

# Scenario #2-Dr. Quinn



Presenter/Content  
Creator



## CME Conflicts of Interest Form for CME Activities

Please check where applicable and sign below. Provide additional pages as necessary.

Date: \_\_\_\_\_  
Name: **Dr. Michaela “Mike” Quinn**  
Address, City, State, and Zip Code: \_\_\_\_\_  
Phone Number: \_\_\_\_\_  
E-mail: \_\_\_\_\_  
Name of CME Activity: \_\_\_\_\_  
Date(s) and Location of CME Activity: \_\_\_\_\_  
Topic: \_\_\_\_\_  
Role you hold specific to this CME activity: \_\_\_\_\_

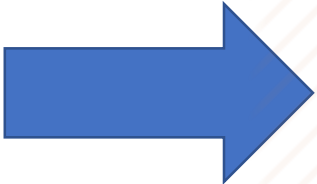
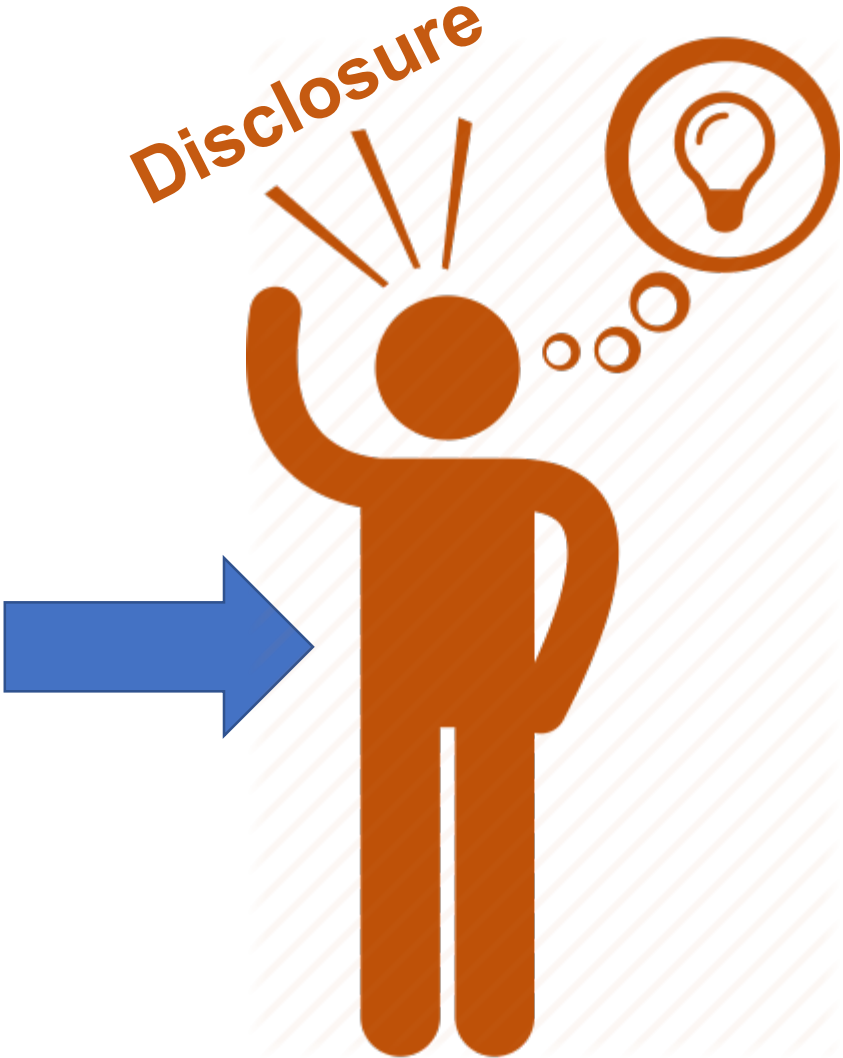
### DISCLOSURE OF FINANCIAL RELATIONSHIPS WITHIN 12 MONTHS OF DATE OF THIS FORM

A commercial interest is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

- ☒ **A.** Neither I nor an immediate family member (spouse or partner) has a financial relationship with or interest in a commercial interest.
- ☐ **B.** I have or an immediate family member (spouse or partner) has a financial relationship with or interest in a commercial interest. Please check the relationship(s). (Check all that apply):
- |   |   |
|---|---|
| <input type="checkbox"/> Research Grants                  | <input type="checkbox"/> Stock/Bond Holdings (excluding mutual funds) |
| <input type="checkbox"/> Speakers’ Bureaus*               | <input type="checkbox"/> Employment                                   |
| <input type="checkbox"/> Ownership                        | <input type="checkbox"/> Partnership                                  |
| <input type="checkbox"/> Receipt of Equipment or Supplies | <input type="checkbox"/> Honorarium                                   |
| <input type="checkbox"/> Consultant or Advisory Board     | <input type="checkbox"/> Other (please list) _____                    |
| <input type="checkbox"/> Manuscript Preparation**         |   |

Please indicate the names of the organization(s) with which you have a financial relationship or interest, and the topic areas that correspond to the relationship. If more than four relationships, please list on separate piece of paper:

Organization with which Relationship Exists	Type of Relationship	Topic Area(s) Involved
1.	1.	1.
2.	2.	2.
3.	3.	3.
4.	4.	4.



# Standard 6: Disclosures Relevant to Potential Commercial Bias

## STANDARD 6.1

An individual must disclose to learners any relevant financial relationship(s), to include the following information: The name of the individual; The name of the commercial interest(s); The nature of the relationship the person has with each commercial interest.

## STANDARD 6.2

For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

## STANDARD 6.3

The source of all support from commercial interests must be disclosed to learners. When commercial support is "in-kind" the nature of the support must be disclosed to learners.

## STANDARD 6.4

Disclosure must never include the use of a corporate logo, trade name or a product-group message of an ACCME-defined commercial interest.

## STANDARD 6.5

A provider must disclose the above information to learners prior to the beginning of the educational activity.

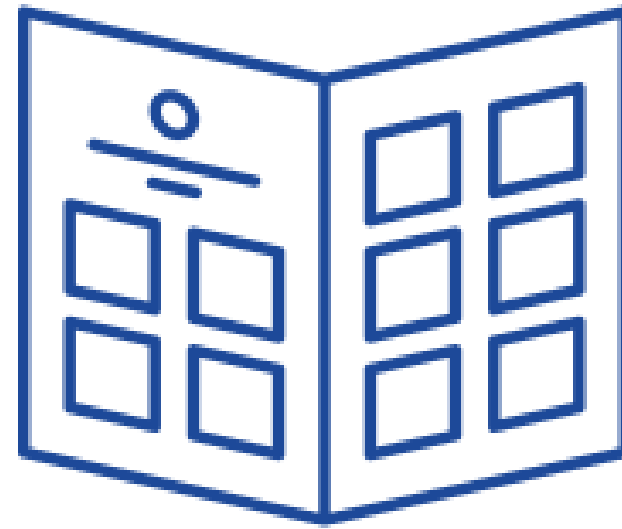
## Tips for Success:

- ❑ Document and save disclosures!

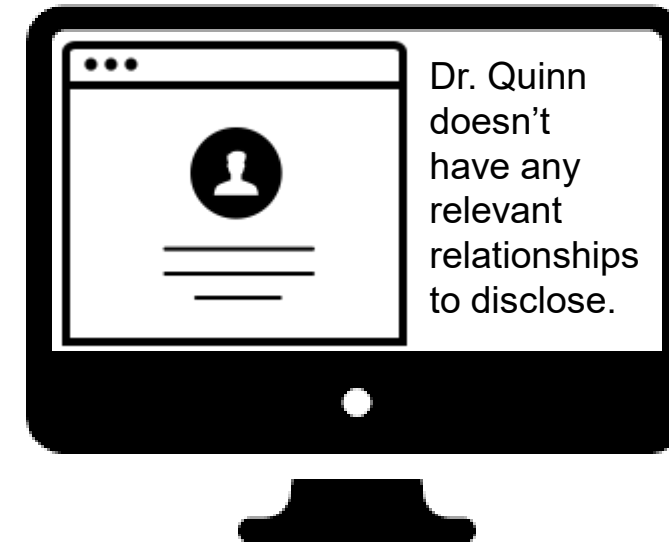
# COI Disclosure Options



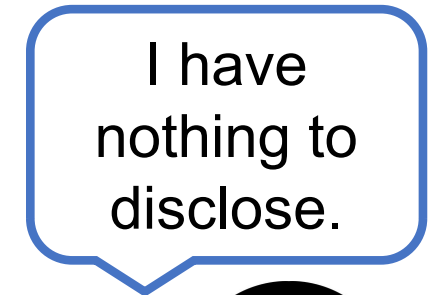
1<sup>st</sup> page or slide in the educational content



In the program brochure or a handout



On CME activity website



\*Verbally

<http://www.accme.org/accreditation-rules/policies/verbal-disclosure-learners>

# Standard 6: Disclosures Relevant to Potential Commercial Bias



## STANDARD 6.1

An individual must disclose to learners any relevant financial relationship(s), to include the following information: The name of the individual; The name of the commercial interest(s); The nature of the relationship the person has with each commercial interest.

## STANDARD 6.2

For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

## STANDARD 6.3

The source of all support from commercial interests must be disclosed to learners. When commercial support is "in-kind" the nature of the support must be disclosed to learners.

## STANDARD 6.4

Disclosure must never include the use of a corporate logo, trade name or a product-group message of an ACCME-defined commercial interest.

## STANDARD 6.5

A provider must disclose the above information to learners prior to the beginning of the educational activity.

# Disclosing for Relevant Relationships



- ☐ Individual's Name
- ☐ Name of the Commercial Interest
- ☐ Nature of the Relationship
- ☐ Optional: Topic Area Related to the Relationship

*“Dr. John Doe has disclosed that he holds stocks with Pfizer.”*

*“Dr. John Doe has disclosed that he holds stocks with Pfizer **on the topic of diabetes.**”*



# In Conclusion...

## Tips for Success:

### Standard 2.1

- ☐ Fill out & review COI forms before CME activity
- ☐ Make sure staff complete a COI form
- ☐ Use correct ACCME commercial interest definition
- ☐ Save the forms for at least one year

### Standard 2.3-Peer Review Process

- ☐ Peer reviewer documents their determination
- ☐ Resolve any bias that's found
- ☐ Save all documentation!!

### Standard 6

- ☐ Document and save disclosures!



# Contact Info & Resources

## **Resources:**

- ACCME Standards for Commercial Support  
<http://www.accme.org/accreditation-rules/standards-for-commercial-support>
- COI Policy and COI Form Template:  
<https://www.aafp.org/dam/AAFP/documents/cme/accreditation/cmea-disclosure-conflicts-policy.pdf>
- Audit Documentation Checklist:  
<https://www.aafp.org/cme/creditsys/about/audits.html#checklist>
- Coming Soon—Webcast version of today's webinar:  
<https://www.aafp.org/cme/creditsys/about/tutorials.html>

**Contact Us** | [cmecredit@aafp.org](mailto:cmecredit@aafp.org) | 800-274-2237





THANK  
YOU

<https://www.aafp.org/cme/creditsys/about/tutorials.html>

**© 2018 American Academy of Family Physicians. All rights reserved.**

All materials/content herein are protected by copyright and are for the sole, personal use of the user.

No part of the materials/content may be copied, duplicated, distributed or retransmitted  
in any form or medium without the prior permission of the applicable copyright owner.





AMERICAN ACADEMY OF FAMILY PHYSICIANS

**STRONG MEDICINE FOR AMERICA**