

# **COMMERCIAL INTERESTS AND CONFLICT OF INTEREST RESOLUTION: ENSURING INDEPENDENCE**

**(C7 - SCS 1, 2 & 6)**

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CME Accreditation & Recognition Administrator**

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Since several of you are new to your role in CME.....

its been a couple of years since we've focused on this topic, ..... and,

many providers still struggle with compliance in this particular criterion, we're going to examine it again.



# ACCREDITATION CRITERIA

## Criterion #7

The provider develops activities/  
educational interventions independent  
of commercial interests.

# What is a Commercial Interest (CI)?

## Definition:

**Any entity producing, marketing, re-selling or distributing health care goods or services consumed by, or used on, patients.**

The ACCME does not consider providers of clinical service directly to patients to be commercial interests - unless the provider of clinical service is owned, or controlled by, an ACCME-defined commercial interest.

# Organizations Not Considered A Commercial Interest

A commercial interest is not eligible for ACCME accreditation. Commercial interests cannot be accredited providers and cannot be joint providers. Within the context of this definition and limitation, **the ACCME considers the following types of organizations to be eligible for accreditation and free to control the content of CME:**

- Government organizations
- Non-health care related companies
- Liability insurance providers
- Health insurance providers
- Group medical practices
- For-profit hospitals
- For profit rehabilitation centers
- For-profit nursing homes
- Blood banks
- Diagnostic laboratories

# STANDARDS FOR COMMERCIAL SUPPORT TIED TO CRITERION 7

## STANDARD 1: INDEPENDENCE

- **SCS 1.1** A CME provider must ensure that the following decisions were made free of the control of a commercial interest:
  - 1) Identification of CME needs
  - 2) Determination of educational objectives
  - 3) Selection and presentation of content
  - 4) Selection of all persons and organizations that will be in a position to control the content of the CME
  - 5) Selection of educational methods
  - 6) Evaluation of the activity
- **SCS 1.2** A commercial interest cannot take the role of non-accredited partner in a joint-provider relationship.

# STANDARDS FOR COMMERCIAL SUPPORT TIED TO CRITERION 7

## STANDARD 2: RESOLUTION OF PERSONAL CONFLICTS OF INTEREST

- SCS 2.1 Requires that anyone who is in a position to control the content of an educational activity disclose information to the accredited CME provider about **relevant financial relationships** that the individual **and their spouse or partner** have with ACCME-defined commercial interests.

# WHAT IS A FINANCIAL RELATIONSHIP?

## Definition:

**Those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria for promotional speakers' bureau, ownership interest (i.e., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit.**

With respect to financial relationships with commercial interests, when a person divests themselves of a relationship it is immediately not relevant to conflicts of interest but it must be disclosed to the learners for 12 months.



# WHAT IS A RELEVANT FINANCIAL RELATIONSHIP?

## Definition:

Financial relationships in any amount, which occurred in the twelve-month period preceding the time that the individual was asked to assume a role controlling content of the CME activity, and which relate to the content of the educational activity, causing a **conflict of interest (COI)**.

# RELEVANT FINANCIAL RELATIONSHIPS OF SPOUSE OR PARTNER

Prior to 2016, if an individual in control of content disclosed that their **spouse/partner** had a relevant financial relationship with an ACCME-defined CI, providers were required to consider the individual as also having that relationship. In particular, in situations where a person in control of CME content disclosed that their **spouse/partner** was an **employee** of a CI, then that person would have also been considered a *CI employee*, and the relationship would have been unresolvable.

In July 2016, the ACCME Board modified the interpretation of the Standards for Commercial Support related to *relevant financial relationships*. And now, in situations where a person in control of CME content (faculty or planner) discloses that their **spouse/partner** is an **employee** of a commercial interest, and the content being controlled is related to the products/services of that CI, then that person is considered to have a resolvable *relevant financial relationship*.

And as with any relevant financial relationship, providers are required to implement mechanisms to resolve these COI.

# CONFLICTS OF INTEREST:

## WHEN DO RELATIONSHIPS CREATE A CONFLICT OF INTEREST?

The ACCME considers financial relationships to create actual conflicts of interest in CME when individuals have both a financial relationship with a commercial interest and the opportunity to affect the content of CME about the products or services of that commercial interest.

The potential for maintaining or increasing the value of the financial relationship with the commercial interest creates an incentive to influence the content of the CME – an incentive to insert commercial bias.

# If Content of a CME Activity is NOT Related to the Products or Services of a Commercial Interest, Do I Still Need to Obtain Information Regarding Financial Relationships?

The ACCME says “No.” Standard 2.1 requires the provider to identify relevant financial relationships of those who control CME content in order to identify conflicts of interest. **As just mentioned, TWO things must be present for there to be a Conflict of Interest.**

1. Financial Relationship(s) with an ACCME-defined commercial interest; and
2. The ability to control content *related* to products/services of the commercial interest.

**If no financial relationships exist, the content of the CME activity is not clinical in nature, and/or the content is not related to the products or services of a commercial interest, there are no *relevant financial relationships* to identify and no conflicts of interest to identify or resolve.**

## Back to Standard 2: RESOLUTION OF PERSONAL CONFLICTS OF INTEREST

- **SCS 2.2** An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, teacher or author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.
- **SCS 2.3** The provider must have implemented a mechanism to **identify and resolve** all conflicts of interest prior to the educational activity being delivered to learners.

# MECHANISM TO IDENTIFY FINANCIAL RELATIONSHIPS WHICH MAY PRODUCE POTENTIAL CONFLICTS OF INTEREST: **THE DISCLOSURE FORM**

You may be surprised to learn the ACCME **does not require** that providers use a **disclosure form** to gather information about relevant financial relationships. A disclosure form is one mechanism that providers may use to obtain (and show that they possess) this information.

Other examples could include:

- 1) Collecting the information verbally and recording it in a spreadsheet or table
- 2) Collecting disclosure information electronically (for example, via e-mail or a web-based form)

# THE DISCLOSURE FORM

- Providers may choose the mechanism to obtain this information that best suits their organizational needs and can be used to demonstrate compliance to the ISMA/ACCME.
- Utilizing a **Disclosure Form** for collection of relevant financial relationships is considered a *best practice* in the CME community.  
Providers report it simplifies things!
- Please note if using a **Disclosure Form**, you should include the most current definition of a Commercial Interest on it.

# **DID YOU BRING A COPY OF YOUR ORGANIZATION'S DISCLOSURE FORM?**

Please take a moment to look  
at what's on it.





## CONTINUING MEDICAL EDUCATION

## DISCLOSURE OF FINANCIAL RELATIONSHIP FORM

Name/Credential:	Click here to enter text.		
Telephone Number:	Click here to enter text.	E-Mail Address:	Click here to enter text.
Activity Name:	Click here to enter text.	Date:	Click here to enter text.
Please indicate your role in this CME activity: <input type="checkbox"/> Presenter/Faculty <input type="checkbox"/> Course Director <input type="checkbox"/> Moderator <input type="checkbox"/> Planning Committee (Please check all that apply)			

**Purpose:** It is the policy of the Indiana State Medical Association (ISMA) to ensure balance, independence, objectivity, and scientific rigor in all of its sponsored educational activities. All participating faculty, course directors, and planning committee members are required to disclose to the program audience any financial relationships related to the subject matter of continuing medical education (CME) activities/programs. Relationships of spouse/partner with proprietary entities producing health care goods or services should be disclosed if they are of a nature that may influence the objectivity of the individual in a position to control the content of the CME activity. Disclosure information is reviewed in advance in order to manage and resolve any possible conflicts of interest. This information is necessary in order for us to be able to move to the next steps in planning this CME activity.

**Persons who fail to provide this information in advance of the course (allowing for adequate time for review) are not eligible to be involved in this CME activity.**

**Participation:** We are pleased that you are willing and able to participate in this CME activity, which is accredited by the ISMA. The ISMA is accredited by the Accreditation Council for Continuing Medical Education (ACCME). As such, we are required to meet the ACCME's expectations for our practice of continuing medical education.

## Step 1: Disclosure of Relevant Financial Relationships

**Relevant financial relationships are those in which an individual (including their spouse/partner) in the last 12 months:**

- has had a personal financial relationship (any amount) with a commercial interest, which is defined as any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients; and who
- has control over educational content related to the products and/or services of the commercial interest(s).

Regarding your role in this CME activity (check one):

- ☐ No, I/we have no relevant personal financial relationship. (If you checked this box, skip to Step 2)
- ☐ Yes, I/we do have a personal financial relationship with a commercial interest and control over educational content related to the products and/or services of the commercial interest(s). (Provide information below)

Nature of Financial Relationship	Name of Commercial Interest(s) and Relationship	Self	Spouse/Partner
<input type="checkbox"/> Consultant	Click here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Speaker's Bureau	Click here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Grant/Research Support <input type="checkbox"/> Principal Investigator	Click here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Stock Shareholder (self-managed)	Click here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Honoraria	Click here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Full-time/part-time Employee/Owner*	Click here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Other (Describe):	Click here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>

\* The ISMA PROHIBITS employees and owners of Commercial interests from participating on any CME PLANNING COMMITTEE and serving as presenters.

Additional information may be requested to address any perceived conflict of interest. All identified conflicts of interest must be managed and resolved in advance of the activity and disclosure information will be shared with the activity participants.



## CONTINUING MEDICAL EDUCATION

## Step 2: Speaker Disclosure of Off-Label and/or Investigational Uses

If at any time during my educational activity, I discuss an off-label/investigative use of a commercial product/device, I understand that I must provide disclosure of that intent.

- ☐ No, I do not intend to discuss an off-label/investigative use of a commercial product/device.
- ☐ Yes, I do intend to discuss off-label/investigative use(s) of the following commercial product(s)/device(s).

Click here to enter text.

## Step 3: Statements &amp; Rules of ISMA/ACCME Accreditation / Content Validation

Please read the statements/rules of ISMA/ACCME accreditation below, sign, and return to the ISMA Continuing Medical Education Office. If you have any questions regarding your ability to comply, please contact Jessica Davis, CME Coordinator, at 317-261-2060, or by e-mail at [jessica.davis@isma.org](mailto:jessica.davis@isma.org).

- The content and/or presentation of the information with which I am involved will promote quality or improvements in healthcare and will not promote a specific business interest of a commercial interest. Content for this activity, including any presentation of therapeutic options, will be well-balanced, evidence-based, and unbiased, and has adequate justification for their indications and contraindications in the care of a patient.
- Recommendations involving diagnosis and treatment discussed in the presentation are based on evidence which is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of a patient.
- All scientific research referred to, reported or used in CME in support of justification of patient care recommendation will conform to the generally accepted standards of experimental design, data collection, and analysis. Citations of the work are recommended.
- The content will not promote recommendations, treatment, or manners of practicing medicine that are not within the definition of CME or known to have risks or dangers that outweigh the benefits or known to be ineffective in the treatment of patients. The content will not advocate for unscientific modalities of diagnosis or therapy.
- Objectives of my presentation are consistent with overall objectives of the course, and the content is relevant to participants' needs.
- I have disclosed (via Disclosure Form to ISMA) all relevant financial relationships. I understand these will be disclosed to the audience, if they are relevant/potentially relevant to the educational content.
- I have not and will not accept any honoraria, additional payment or reimbursement beyond that which has been agreed upon directly with the ISMA.
- I understand that ISMA CME staff will need to review my presentation and/or content prior to the activity, and I will provide educational content and resources in advance, as requested.
- I understand that commercial entity corporate names or logos should not appear on my slides or handouts.
- I understand that ISMA CME staff may be attending the event to ensure that my presentation is educational, and not promotional, in nature.
- If I am discussing specific health care products or services, I will use generic names to the extent possible. If I need to use trade names, I will use trade names from several companies when available, and not just trade names from any individual company.
- If I am discussing any product use that is off-label, I will disclose that the use or indication in question is not currently approved by the FDA for labeling or advertising.
- If I have been trained or utilized by a commercial entity or its agent as a speaker (e.g., speaker's bureau for any commercial interest), the promotional aspects of the presentation will not be included in any way with this activity.
- If I am a speaker for any commercial interest, the promotional aspects of this relationship will not be included in any way with this activity.
- If I am presenting research funded by a commercial company, the information presented will be based on generally accepted scientific principles and methods and will not promote the commercial interest of the funding company.
- If I am presenting research studies, I will include weaknesses and strengths of each study, in addition to harms and benefits of specific products. I will also discuss studies presenting different conclusions about the product, if available.

## Step 4: Declaration

I will uphold the ISMA CME standards to ensure balance, independence, objectivity, and scientific rigor in my role in the planning, development or presentation of this CME activity. I understand that CME accreditation guidelines prohibit me from accepting any reimbursement (financial, gifts, or in-kind exchange) for this presentation from any source other than the accredited CME provider or its educational partner (or fiscal agent).

Signature/Printed Name: Click here to enter text.

Date: Click here to enter text.

If sending this completed document electronically, please type your name above and check this box:

- ☐ By checking this box, I attest that the completed information is accurate. Please accept this as my signature.



**ISMA**  
INDIANA  
STATE  
MEDICAL  
ASSOCIATION



## CONTINUING MEDICAL EDUCATION

*Thank you for providing us with this information.*  
**RETURN TO:** Jessica Davis, CME Coordinator, at [jdavis@ismanet.org](mailto:jdavis@ismanet.org)

### Glossary of Terms as Defined by the American Council on Continuing Medical Education (ACCME)

#### **Commercial Interest**

The ACCME defines a "commercial interest" as any entity producing, marketing, re-selling, or distributing health care goods or services, used on, or consumed by, patients. The ACCME does not consider providers of clinical service directly to patients to be commercial interests. For more information, visit <http://www.accme.org/requirements/cme-requirements-cme-providers/standards-for-commercial-support>.

#### **Financial Relationships**

Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received, or expected. ACCME considers relationships of the person involved in the CME activity to include financial relationships of a spouse or partner.

#### **Relevant Financial Relationships**

ACCME focuses on financial relationships with commercial interests in the 12-month period preceding the time that the individual is being asked to assume a role controlling content of the CME activity. ACCME has not set a minimal dollar amount for relationships to be significant. Inherent in any amount is the incentive to maintain or increase the value of the relationship. The ACCME defines "relevant" financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

#### **Conflict of Interest**

Circumstances create a conflict of interest 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. The ACCME considers "content of CME about the products or services of that commercial interest" to include content about specific agents/devices, but not necessarily about the class of agents/devices, and not necessarily content about the whole disease class in which those agents/devices are used.

# MECHANISM TO IDENTIFY AND RESOLVE A CONFLICT OF INTEREST

The ACCME developed  
**a new tool**  
in 2017 to help you navigate  
the identification of relevant  
financial relationships  
and the resolution of conflicts  
of interest in CME activities.

**It's called.....**

## **Flowchart for the Identification and Resolution of Personal Conflicts of Interest**

If you use this flowchart early in your planning process, you can ensure you implement approaches to safeguard independence during the planning process and before the educational activity occurs.

The flowchart and a step-by-step tutorial are available on the ACCME website at

[www.accme.org/coiflowchart](http://www.accme.org/coiflowchart)

**Lets take an in-depth look  
at this Flowchart**

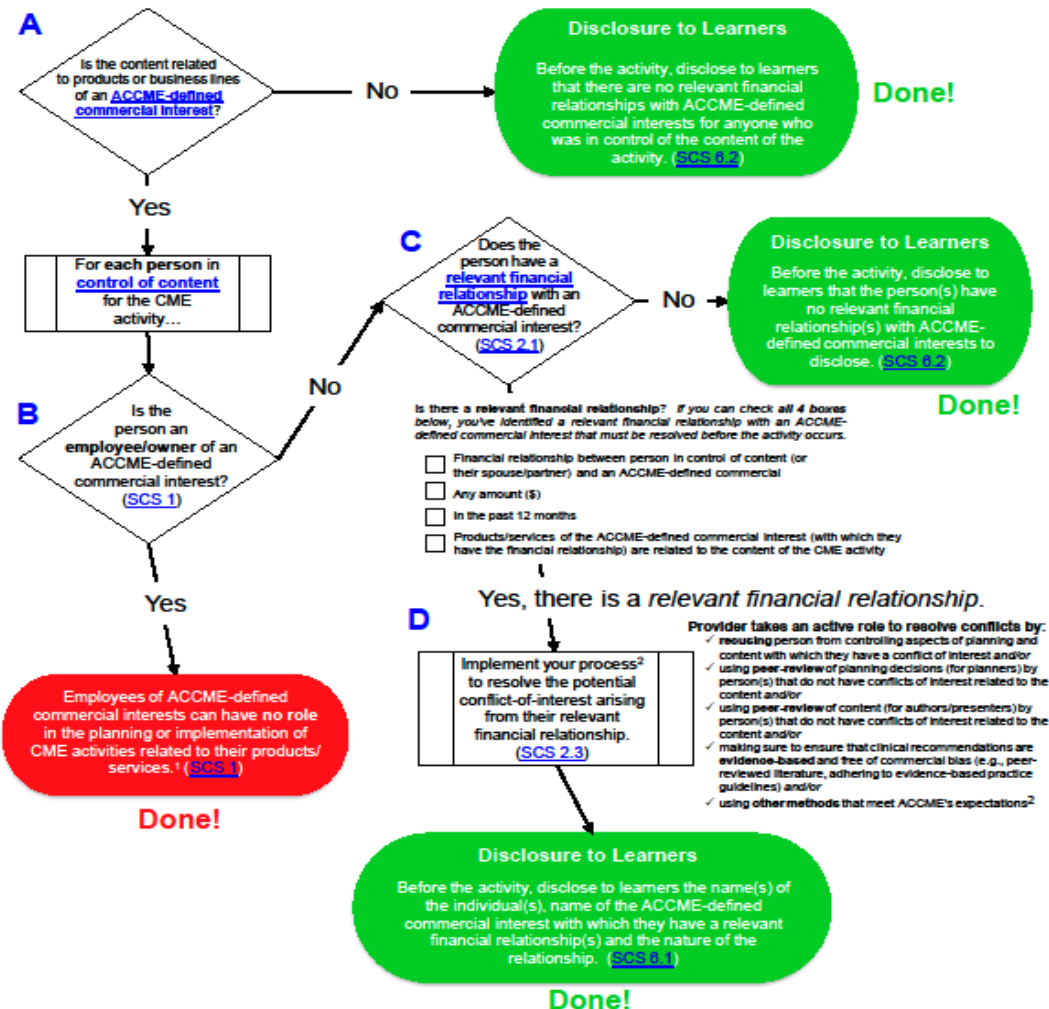




## Flowchart for the Identification and Resolution of Personal Conflicts of Interest Meeting the Expectations of ACCME's Criterion 7

(Last updated : February 1, 2017)

Use this flowchart at the beginning of your planning process for CME activities to ensure independence from ACCME-defined commercial interests. **Start at A below.** For step-by-step instructions for using this flowchart, visit [www.accme.org/coiflowchart](http://www.accme.org/coiflowchart).



### Footnotes

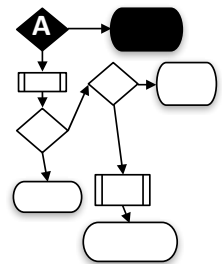
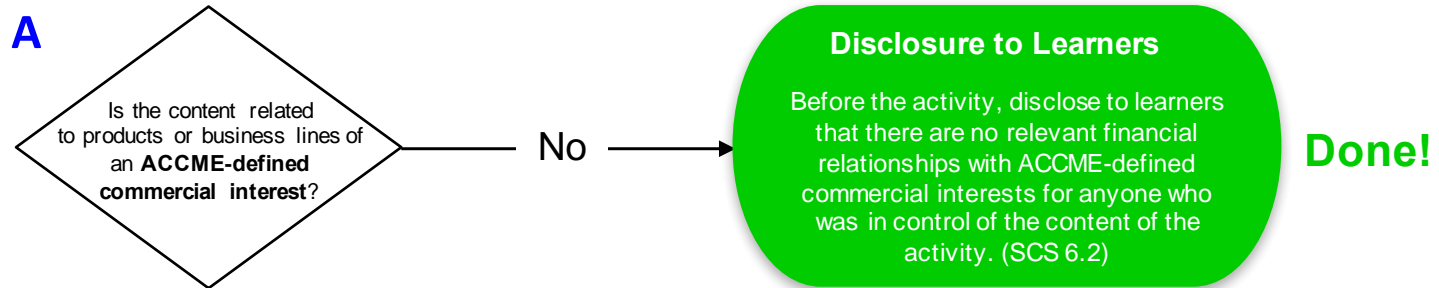
1. The use of employees of ACCME-defined commercial interests as faculty and planners or in other roles where they are in a position to control the content of accredited CME is prohibited, except in specific situations. For more information, visit [this.AskACCME.frequently-asked-question](http://this.AskACCME.frequently-asked-question) regarding commercial employees.
2. There are a range of approaches providers can use to resolve potential conflicts of interests. For more information, visit ACCME's [Provider.Examples.of.Compliance.and.Noncompliance](http://Provider.Examples.of.Compliance.and.Noncompliance) for Criterion 7 on [www.accme.org](http://www.accme.org).



**ISMA**  
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MEDICAL  
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# THE DECISION TREE

## Start at A



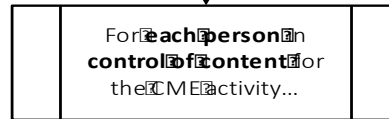


**A**

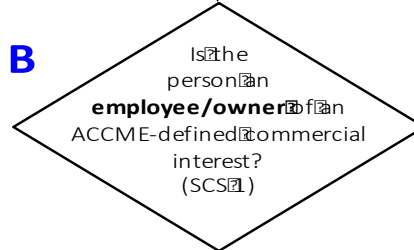


Is the content related to products or business lines of an **ACCME-defined commercial interest**?

Yes



**B**



Is the person an **employee/owner** of an ACCME-defined commercial interest? (SCS1)

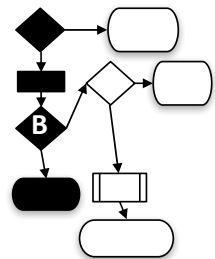
Yes

Employees of ACCME-defined commercial interests can have **no role** in the planning or implementation of CME activities related to their products/services.<sup>10</sup> (SCS1)

**Done!**

**IMPORTANT**

**WHAT ARE THE 3 EXCEPTIONS ?**





# LETS REFRESH.....

## Exceptions for Use of Employees of ACCME-Defined Commercial Interest

### **EXCEPTION #1**

Employees of ACCME-defined commercial interests can control the content of accredited CME activities when the content of the CME activity is not related to the business lines or products of their employer.

### **EXCEPTION #2**

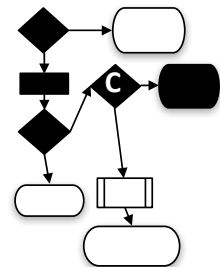
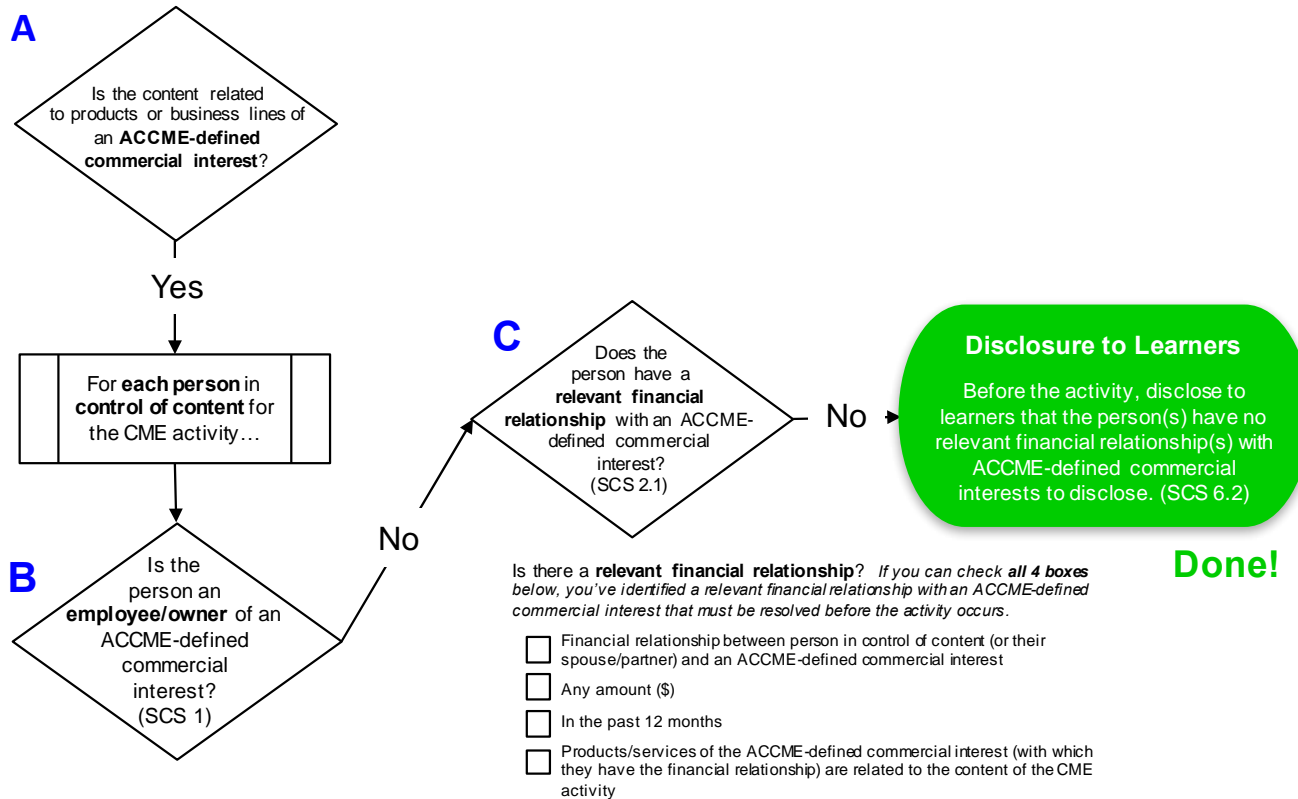
Employees of ACCME-defined commercial interests can control the content of accredited CME activities when the content of the accredited CME activity is limited to basic science research (ie, pre-clinical research, drug discovery) or the *processes/ methodologies* of research, themselves unrelated to a specific disease or compound/drug.

### **EXCEPTION #3**

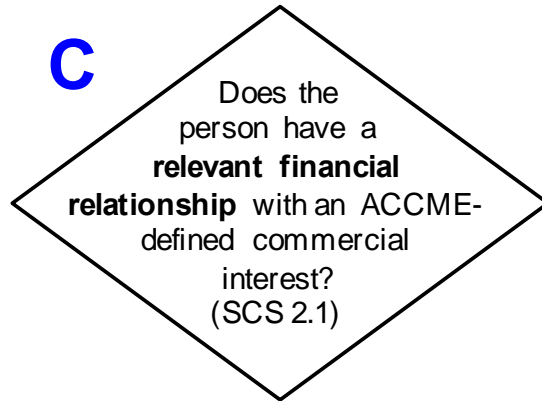
Employees of ACCME-defined commercial interests can participate as technicians in accredited CME activities that teach the safe and proper use of medical devices.

**It is critical that accredited providers ensure that commercial employees never expand their role into areas of clinical medicine (ie, never talk about indications for use, comparisons between competing products or comparisons between the device and/or invasive surgery and/or medical treatment).**

**The ACCME considers these high risk exceptions and advises they should only be invoked with caution, as the provider remains ultimately responsible for what the individual actually presents in the CME activity.**

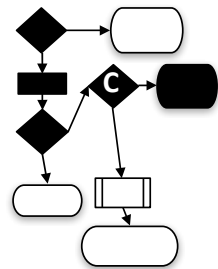


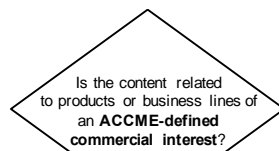
**C**



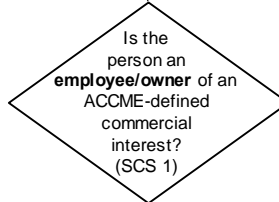
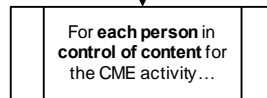
Is there a **relevant financial relationship**? *If you can check **all 4 boxes** below, you've identified a relevant financial relationship with an ACCME-defined commercial interest that must be resolved before the activity occurs.*

- ☐ Financial relationship between person in control of content (or their spouse/partner) and an ACCME-defined commercial interest
- ☐ Any amount (\$)
- ☐ In the past 12 months
- ☐ Products/services of the ACCME-defined commercial interest (with which they have the financial relationship) are related to the content of the CME activity

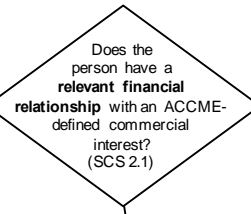




Yes



No

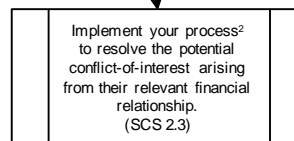


Is there a **relevant financial relationship**? If you can check **all 4 boxes** below, you've identified a relevant financial relationship with an ACCME-defined commercial interest that must be resolved before the activity occurs.

- ☐ Financial relationship between person in control of content (or their spouse/partner) and an ACCME-defined commercial interest
- ☐ Any amount (\$)
- ☐ In the past 12 months
- ☐ Products/services of the ACCME-defined commercial interest (with which they have the financial relationship) are related to the content of the CME activity

Yes, there is a **relevant financial relationship**.

**D**



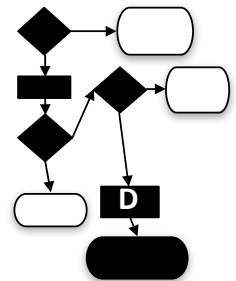
**Provider takes an active role to resolve conflicts by:**

- ✓ **recusing** person from controlling aspects of planning and content with which they have a conflict of interest *and/or*
- ✓ using **peer-review** of planning decisions (for planners) by person(s) that do not have conflicts of interest related to the content *and/or*
- ✓ using **peer-review** of content (for authors/presenters) by person(s) that do not have conflicts of interest related to the content *and/or*
- ✓ making sure to ensure that clinical recommendations are **evidence-based** and free of commercial bias (e.g., peer-reviewed literature, adhering to evidence-based practice guidelines) *and/or*
- ✓ using **other methods** that meet ACCME's expectations?

### Disclosure to Learners

Before the activity, disclose to learners the name(s) of the individual(s), name of the ACCME-defined commercial interest with which they have a relevant financial relationship(s) and the nature of the relationship. (SCS 6.1)

**Done!**



Yes, there is a relevant financial relationship

**D**

	Implement your process <sup>2</sup> to resolve the potential conflict-of-interest arising from their relevant financial relationship. (SCS 2.3)	
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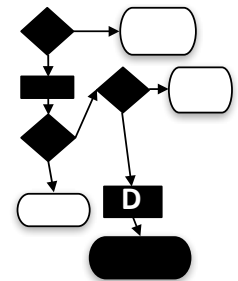
**Provider takes an active role to resolve conflicts by:**

- ✓ **recusing** person from controlling aspects of planning and content with which they have a conflict of interest *and/or*
- ✓ using **peer-review** of planning decisions (for planners) by person(s) that do not have conflicts of interest related to the content *and/or*
- ✓ using **peer-review** of content (for authors/presenters) by person(s) that do not have conflicts of interest related to the content *and/or*
- ✓ making sure to ensure that clinical recommendations are **evidence-based** and free of commercial bias (e.g., peer-reviewed literature, adhering to evidence-based practice guidelines) *and/or*
- ✓ using **other methods** that meet ACCME's expectations<sup>2</sup>

### Disclosure to Learners

Before the activity, disclose to learners the name(s) of the individual(s), name of the ACCME-defined commercial interest with which they have a relevant financial relationship(s) and the nature of the relationship. (SCS 6.1)

**Done!**



# LET'S CONDUCT A FEW CASE STUDIES



## **CASE #1**

Prior to the planning of a CME activity, the provider obtains disclosure of relevant financial relationships for the members of its CME committee who will be involved in the selection of the topics, content and presenters. If a committee member discloses a financial relationship with a commercial interest whose products are related to the therapeutic areas that may be addressed in the activity, the provider sends an email to each of those planners instructing them to ensure that their recommendations and decisions about the activity are based on the best available evidence and that they keep in mind the need for a balanced approach to the planning of the activity. The planners are asked to confirm their acceptance of this instruction via email, and these emails are retained by the provider.

## **COMPLIANT OR NON-COMPLIANT?**

**NO**

**WHY?** Asking an individual with a relevant financial relationship to attest to meeting the expectations of the ACCME prior to their involvement would not be acceptable for a planner, as there would not be an opportunity for the provider to review or make changes to the planning decisions, if this was the only mechanism implemented to resolve the conflict of interest.



## **CASE #2**

The provider plans an intensive hands-on course to train physicians to perform vascular interventions using new FDA-approved medical devices and equipment. The course director asks device manufacturers to provide equipment and medical devices for use in the CME activity and also to provide technicians to operate the equipment during the CME activity. The accredited provider tracks the loaned equipment as in-kind commercial support. The course director plans the CME activity independent of the device manufacturers; she determines what procedures will be taught, instructs the technicians on their limited roles, and is present to oversee and participate in the instruction. The course director monitors the CME activity to ensure that demonstration and comments provided by the device technicians are technical only (i.e., about the safe and proper use of the equipment) and do not include clinical recommendations about the medical devices/equipment of the manufacturer(s).

### **COMPLIANT OR NON-COMPLIANT?**

YES

**WHY?** This is allowable Exception #3 - Employees of ACCME-defined CI can participate as technicians in accredited CME activities that teach the safe and proper use of medical devices.





### **CASE #3**

The provider has all speakers/planners/staff sign an attestation form at the time of the disclosure stating "I will ensure that any financial relationship that I have with a commercial interest will not affect the recommendations I make about clinical care."

### **COMPLIANT OR NON-COMPLIANT?**

**NO**

**WHY?** The provider did not have evidence of consistently implementing a mechanism to resolve conflicts of interest when persons in control of content reported relevant financial relationships. The ACCME expects that providers will take action prior to planning or delivery of educational content to resolve conflicts of interest. Individuals with the conflict of interest may be involved in the resolution, but cannot be solely responsible.



#### CASE #4

A joint-provider works in collaboration with an accredited CME provider to plan a CME session on “Public Safety Collaboration as a Response to the Heroin/Opioid Epidemic.” The session will address varying roles associated with public safety engagement, focusing on a new Quick Response Team (QRT) model, its feasibility, usefulness, and implementation. The QRT response model consists of an interdisciplinary team led by Public Safety (law enforcement & EMS first responders) in collaboration with local behavioral health professionals to offer care coordination from treatment professionals and other community stakeholders to employ a systematic response following successful OD reversal.

Two speakers are involved in this event:

**1)** a Retired Chief of Police and former Director of Public Safety; creator of the QRT Response Model and Founder of QRT National, a non-profit public safety education agency, focused on educating and preparing community leaders on proactive community engagement to the opioid epidemic. **2)** a patient whose sole intent is to provide personal testimony about his journey - living a life of public service as a firefighter/EMT, until the day he was hurt in the line of duty and became addicted to opioids. The patient is currently employed as COO of a pharma company and also serves as a board member for QRT National. Both are being allowed to speak, as the 2<sup>nd</sup> presenter is only giving personal testimony and does not intend to address treatment or make any clinical recommendations.

## CASE #4

### COMPLIANT OR NON-COMPLIANT?

NO

### WHY?

The “patient” is a direct employee of an ACCME-defined commercial interest and thus is prohibited by SCS-1 from controlling CME content.

While it is possible that the use of this individual might fit within the 1st of the 3 exceptions – *Employees of ACCME-defined commercial interests can control the content of accredited CME activities when the content of the CME activity is not related to the business lines or products of their employer*, this is again considered a high risk exception and should only be invoked with caution.

The CME provider, if audited, would be asked to supply proof of content for the personal testimony.

The ACCME notes the content of a CME activity can be “related to the products or business lines of a commercial interest” without specifically endorsing the commercial interest or its products.



# Documenting Conflict of Interest (COI) Resolution

The ACCME and ISMA look for **PROOF of HOW** you are resolving conflicts of interest/potential COI.

Providers should keep records to show that they have consistently **identified**, **resolved** and **disclosed** relevant financial relationships for all planners and speakers.

# Consider Keeping the Following:

## 1) Resolution Checklist

The ISMA utilizes a COI Resolution Checklist which is included on the last page of our Disclosure of Financial Relationship Form

*(for CME Office Use Only)*

Step 1	Owners/Employees of Commercial Interest (CI)
<input type="checkbox"/>	Not an employee/owner of CI (go to Step 2)
<input type="checkbox"/>	Planning Committee employee/owner of CI (choose from below):
	<input type="checkbox"/> No planning has occurred – individual is fully recused from committee
	<input type="checkbox"/> Planning has occurred – activity will not be accredited
<input type="checkbox"/>	Faculty/speaker employee/owner of CI (choose from below):
	<input type="checkbox"/> Faculty/speaker is not allowed to present
	<input type="checkbox"/> Activity will not be accredited
Step 2	Conflict of Interest (COI)
<input type="checkbox"/>	No relevant financial relationship (no COI)
<input type="checkbox"/>	Potential COI – presenter (choose from below):
	<input type="checkbox"/> Presentation materials reviewed to ensure fair balance, scientific objectivity and no commercial bias
	<input type="checkbox"/> Presenter will refrain from making recommendations on topics of COI
	<input type="checkbox"/> All recommendations for patient care are based on peer review data
	<input type="checkbox"/> Role is limited so financial relationship no longer relevant
	<input type="checkbox"/> Discontinue contracted services that create financial relationship – must disclose such relationship to audience for 12 months
	<input type="checkbox"/> Individual excluded from content creation and delivery; was replaced with another presenter
	<input type="checkbox"/> Activity will not be accredited
<input type="checkbox"/>	Potential COI - planner
	<input type="checkbox"/> Planner recused from planning content relevant to reported COI
	<input type="checkbox"/> Another non-conflicted planner will participate in planning to ensure fair balance; non-conflicted planner will review proposed content to ensure it is free from potential bias; non-conflicted planner will oversee selection of faculty



## 2) Copies of Email Communication in the activity file



Thu 2/23/2017 12:02 AM

Ladd, Lauren Michelle <lmladd@iupui.edu>

Re: Indiana Radiologic Society - Spring Meeting..... Planning Committee Disclosure

To Cheryl Stearley

Cc Kay Williams

Dr. Ladd,

Good afternoon. We have received your signed Disclosure Form as part of the Planning Committee for the Indiana Radiologic Society's Spring Meeting – April 22, 2017.

After reviewing your form, we noticed that you included disclosure of receiving a research grant from Horizon Pharma. Since both of the committee's proposed topics are related to evolving payment models and productivity measures and have nothing to do with Horizon Pharma, there is no conflict of interest to resolve. However, as you design further program content, the ISMA asks that you keep in mind continued independence is essential during all phases of the planning process and fair balance and integrity of the program must be retained. Therefore, no discussion of commercial products or services can be allowed within the design of the educational activity, and consequently, you may not suggest any topics or subject matter related to Horizon Pharma.

Thank you for your strict oversight and if you have any questions, please don't hesitate to contact me.

Sincerely,

**Cheryl Stearley**  
CME Coordinator

### 3) Content Review Form

When utilizing **Content Review** as a method for potential COI resolution, it would be wise to include a *Content Review Form* in the activity file.

This may be completed by CME Staff or a Peer Reviewer.





## CONTENT REVIEW FORM

### **INSTRUCTIONS TO CONTENT/PEER REVIEWER:** To add data to this form:

- 1) simply hover your cursor over the check box ☐ and click to select either yes or no;
- 2) to type in a comment or directions for changes to the content click on the words "click here to enter text"; the box will turn grey and you can begin typing.

**REMINDER:** Your primary concern will be to identify commercial bias and any concerns for fairness and balance in the presentation. We understand that in a slide review you will not have access to the accompanying narrative, so make your responses based solely on the data contained in the slides. Please reference slide number(s) where changes are to be addressed. In reviewing narrative material please make comments with reference to the page number.

Name of CME Program/Activity: [Click here to enter text.](#)

Title of presentation: [Click here to enter text.](#)

Date of presentation: [Click here to enter text.](#)

Presenter's name: [Click here to enter text.](#)

1. Is this presentation/material free of commercial bias?  
☐ Yes ☐ No - If not, please comment, providing specifics, below:

[Click here to enter text.](#)

2. Are the slides/narrative for this presentation fair and balanced?  
☐ Yes ☐ No If not, please explain:

[Click here to enter text.](#)

3. Do any slides or narrative materials need to be revised or deleted? ☐ Yes ☐ No  
If yes, please be specific – indicate slide number or description:

[Click here to enter text.](#)

4. Are the patient treatment recommendations included in this CME presentation evidence-based?  
☐ Yes ☐ No ☐ N/A If not, please comment below:

[Click here to enter text.](#)

Reviewer - Full Name: [Click here to enter text.](#)  
Title/Affiliation: [Click here to enter text.](#)  
Date of this review: [Click here to enter text.](#)

**When you have completed this content review, temporarily save the file, attach it to an email and return it the ISMA CME Coordinator, Cheryl Stearley, at [cstearlev@ismanet.org](mailto:cstearlev@ismanet.org). Please use one form for each presentation/speaker/author.**



# STANDARDS FOR COMMERCIAL SUPPORT TIED TO CRITERION 7

## STANDARD 6: DISCLOSURES RELEVANT TO POTENTIAL COMMERCIAL BIAS

- **SCS 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), and the nature of the relationship the person has with each commercial interest.
- **SCS 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 (Disclosures Continued)

- **SCS 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.
- **SCS 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.
- **SCS 6.5** A provider must disclose the above information to learners prior to the beginning of the educational activity.

# Disclosure to Learners

A variety of methods can be utilized:

- Flyer/Brochure
- Verbal Disclosure
- Powerpoint Presentation Slide
- Disclosure Grid
- Disclosure Script  
(i.e., for Recorded CME or Joint Providership)

# Disclosure in Flyer/Brochure

**Accreditation Statement:** (YOUR ORGANIZATION NAME) is accredited by the Indiana State Medical Association to provide continuing medical education for physicians.

**Designation Statement:** (YOUR ORGANIZATION NAME) designates this (ACTIVITY TYPE) for a maximum of (# OF CREDITS) AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

**Disclosure:** Dr. (NAME) and all planners associated with this activity do not have any relevant financial relationships or potential conflicts of interest.

**Disclosure Statement:** In accordance with the ACCME Standards for Commercial Support, and as a provider accredited by the Indiana State Medical Association, (YOUR ORGANIZATION NAME) must ensure balance, independence, objectivity and scientific rigor. Prior to an activity, all faculty, authors, editors and planning committee members participating in a (YOUR ORGANIZATION NAME)-sponsored activity are required to disclose to attendees any relevant financial interest or other relationship with the manufacturer(s) of any commercial product(s) and/or provider(s) of commercial services that are discussed in an educational activity.

**Commercial Support:** No commercial support was accepted in the planning and implementation of this CME activity. OR.....

This activity is supported by an unrestricted educational grant from (NAME OR ORGANIZATION).

# Verbal Disclosure

Providers must be able to supply the ISMA/ACCME with **written verification** that appropriate verbal disclosure occurred at the activity.

With respect to this written verification:

- A representative of the provider who was in attendance at the time of the verbal disclosure must attest, in writing:
  - that verbal disclosure did occur; and
  - itemize the content of the disclosed information (SCS 6.1); or that there was nothing to disclose (SCS 6.2).

(ie, you may wish to add a verbal attestation signature line to your Disclosure Form for completion post-conference)

- This documentation must occur within one month of the activity.

# Disclosure in Presentation Slide

Display disclosure of financial interests/relationships, or lack thereof, in slide format prior to the start of the educational activity.

## Disclosure of Financial Interest

I, (name), MD, have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation, they are:

### Affiliation/Financial Interest

- Grant/research support
- Consultant
- Stock/shareholder
- Advisory board

### Name of Organization(s)

# Disclosure Grid

## FINANCIAL DISCLOSURE CONFLICT OF INTEREST GRID

### Women in Medicine Retreat

*"Being a Woman of Influence: Mastering Negotiations through Clarity and Confidence"*

West Baden Hotel, French Lick, IN • February 2, 2019



The Indiana State Medical Association (ISMA) has implemented a process where everyone who is in a position to control the content of an educational activity has disclosed to us all relevant financial relationships with any commercial interest. In addition, should it be determined that a conflict of interest exists as a result of a financial relationship this will need to be resolved prior to the activity.

+

Name	Speaker	Planner	Commercial Interest/ Content Validity	Role/Nature of Financial Relationship	What I Received	Conflict/Resolved
Kathleen McAllen, MHA IU Executive Education School of Public & Environmental Affairs	X		No relevant financial relationships with any commercial interests	N/A	N/A	None
Ranae Obregon Director of Education Indiana State Medical Association		X	No relevant financial relationships with any commercial interests	N/A	N/A	None
Cheryl Stearley CME Accreditation & Recognition Administrator Indiana State Medical Association		X	No relevant financial relationships with any commercial interests	N/A	N/A	None





# Disclosure Script

## CME SCRIPT

This script must be read PRIOR TO the start of the activity.

(PROGRAM TITLE)

(DATE)

(LOCATION)

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### CME ANNOUNCEMENTS & DISCLOSURES:

Please refer to the *Financial Disclosure & Conflict of Interest Grid* in your handout. None of the speakers or CME planning committee members for today's program have any relevant financial relationships with a commercial interest.

The Indiana State Medical Association reviews and resolves all possible conflicts of interest, and maintains copies of signed financial disclosure and content validity forms in their CME activity files.

Please also refer to the *Grantor List* denoting companies who have provided unrestricted educational grants in support of today's program.

The Indiana State Medical Association (ISMA) designates this program for a maximum of \_\_\_\_ (# of assigned credit hours) *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

We request that you complete the *Program Evaluation Form* at the conclusion of today's program.

# Let's Wrap-up with Important Take-Aways

- Obtain information about relevant financial relationships **sufficiently in advance of an activity** so that you have time to engage with the person and resolve any conflicts before the activity. Disclosure to learners, by itself, or actions taken only after the activity, are not acceptable mechanisms.
- Keep records to show that you have consistently **identified, resolved and disclosed** relevant financial relationships for **all planners and speakers**.
- Permitting employees/owners of a Commercial Interest to be involved in CME, in any fashion, opens you up to extreme scrutiny by the ACCME.