

Conflict of Interest Resolution and Disclosure

**ISMA CME Training
July 28, 2017**

**Cheryl Stearley, CME Coordinator
Indiana State Medical Association**



Let's Hear What the ACCME Has to Say About Conflicts of Interest and Disclosure

<https://youtu.be/SnM3tD-5xds>

The Expectation

Disclosure is an expectation in [Criterion 7](#) for both [Standard 2](#) and [Standard 6](#) of the ACCME Standards for Commercial Support (SCS).

Criterion 7

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

- [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](#).

Disclosure – Standard 2 (cont.)

- **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 education activity being delivered to learners.

Disclosure – Standard 6

In **SCS 6**, disclosure is made by the accredited CME provider to learners prior to the beginning of an educational activity.

- **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.

Disclosure – Standard 6 (Cont.)

- **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.

Lets Examine What Is and Isn't

- A Commercial Interest
- A Financial Relationship
- A Conflict of Interest

Commercial Interest

Definition:

ACCME defines a commercial interest as

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.

NOTE: The correct/most current definition of a Commercial Interest must appear on your Disclosure of Financial Relationship Form.

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

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 (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 payment 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 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.

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.

Conflicts of Interest

When Do Relationships Create Conflicts 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.

Resolution of Personal Conflicts of Interest



**The ACCME has developed
a new tool
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



Let's take an in-depth look

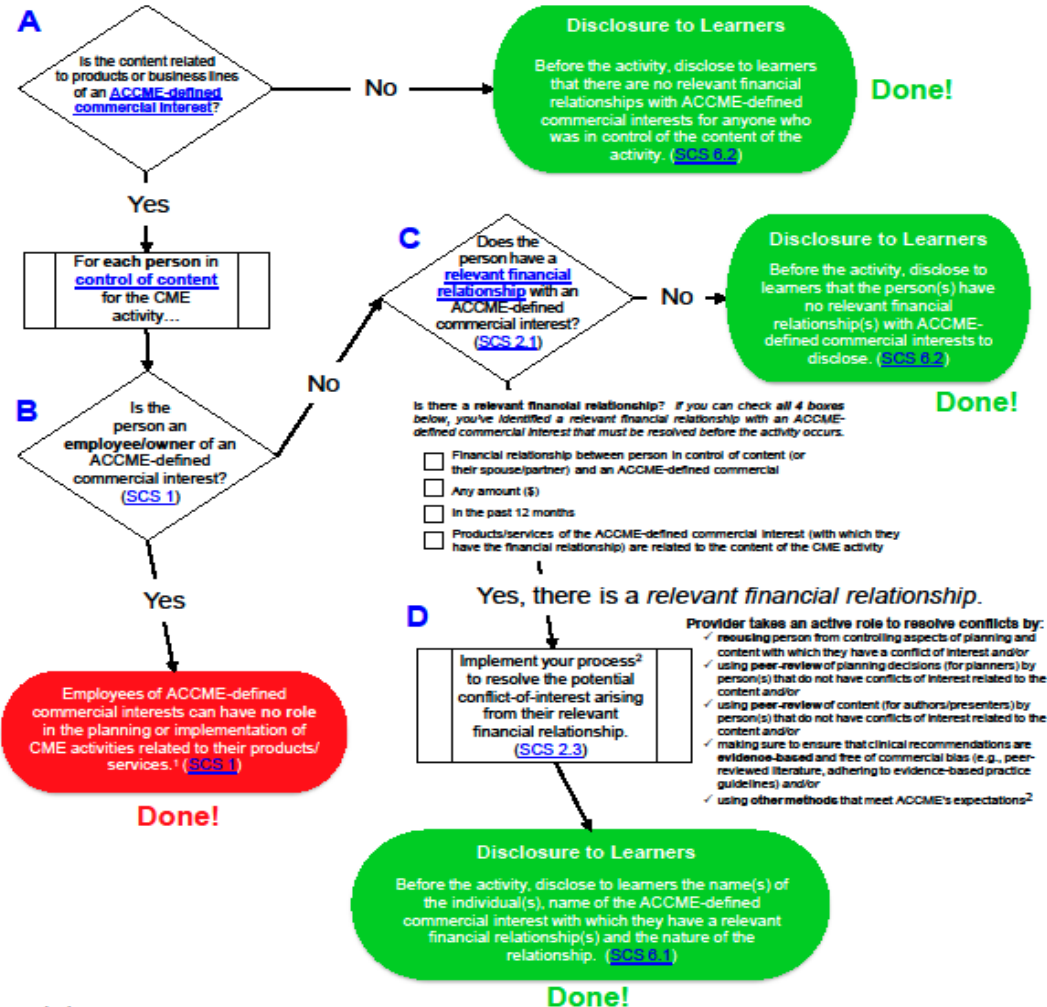




Flowchart for the Identification and Resolution of Personal Conflicts of Interest Meeting the Expectations of ACCME's Criterion 7

(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.

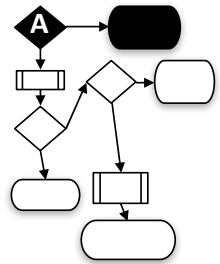
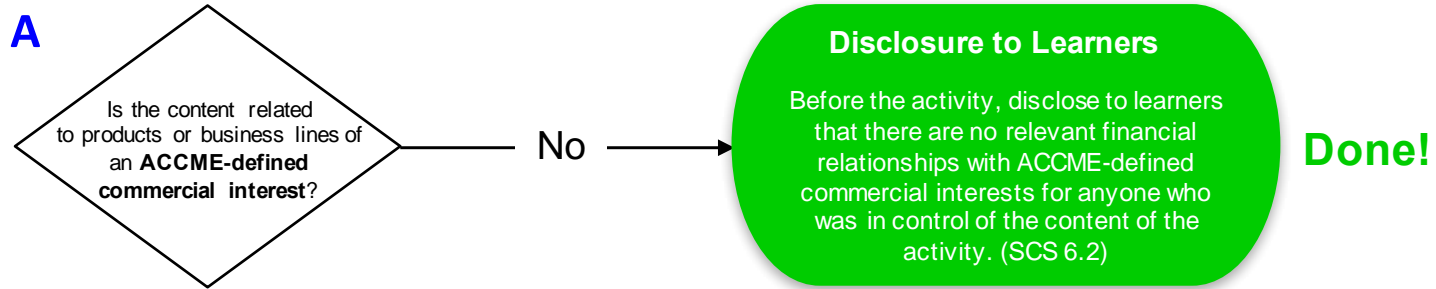


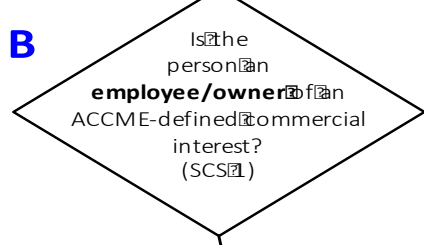
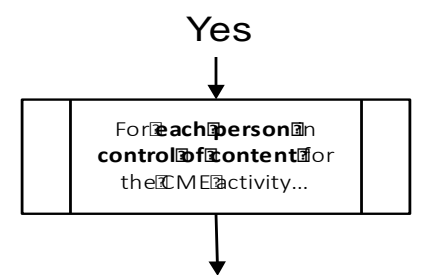
Footnotes

- 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 Ask ACCME frequently-asked-question](#) regarding commercial employees.
- 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](#) for Criterion 7 on www.accme.org.

THE DECISION TREE

Start at A





Yes

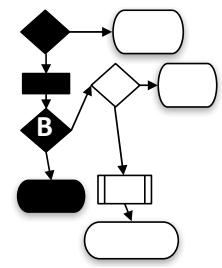
Employees of ACCME-defined commercial interests can have **no role** in the planning or implementation of CME activities related to their products/services.¹⁰ (SCS1)

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.

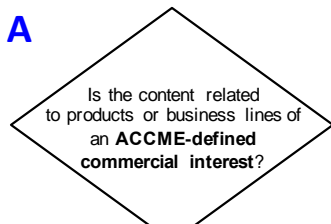
EXCEPTION #2

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.

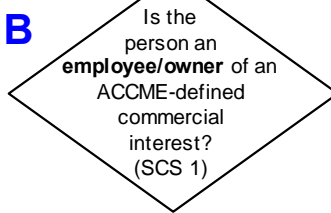
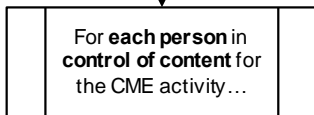
EXCEPTION #3

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). To meet ACCME expectations, this special-use case requires careful supervision by the accredited provider's faculty and staff and proper professional behavior by industry staff.



Yes



No



No

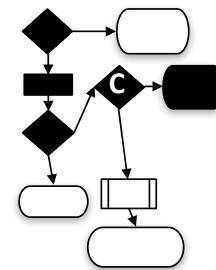
Disclosure to Learners

Before the activity, disclose to learners that the person(s) have no relevant financial relationship(s) with ACCME-defined commercial interests to disclose. (SCS 6.2)

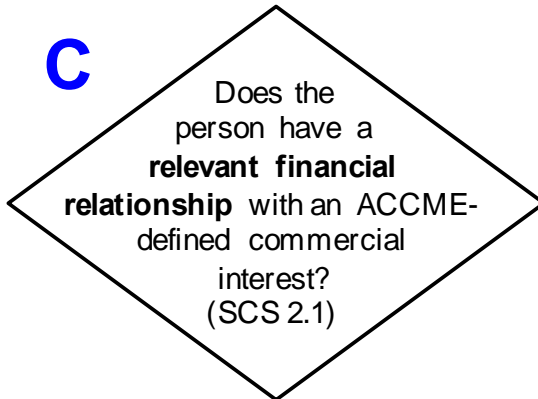
Done!

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

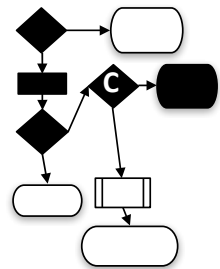


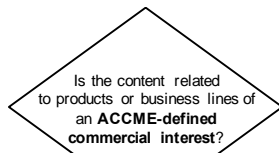
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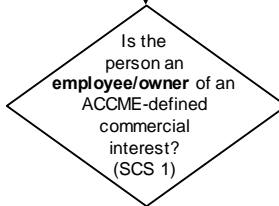
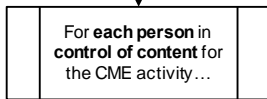
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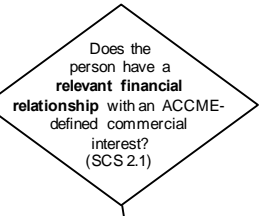




Yes



No

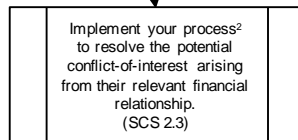


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Yes, there is a relevant financial relationship.

D

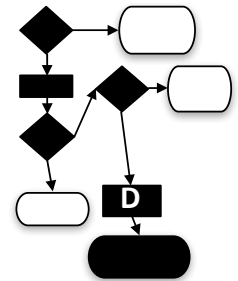


- Provider takes an active role to resolve conflicts by:**
- ✓ **recusing** person from controlling aspects of planning and content with which they have a conflict of interest *and/or*
 - ✓ using **peer-review** of planning decisions (for planners) by person(s) that do not have conflicts of interest 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 ² to resolve the potential conflict-of-interest arising from their relevant financial relationship. (SCS 2.3)	
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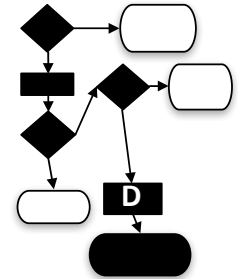
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- ✓ using **other methods** that meet ACCME's expectations²

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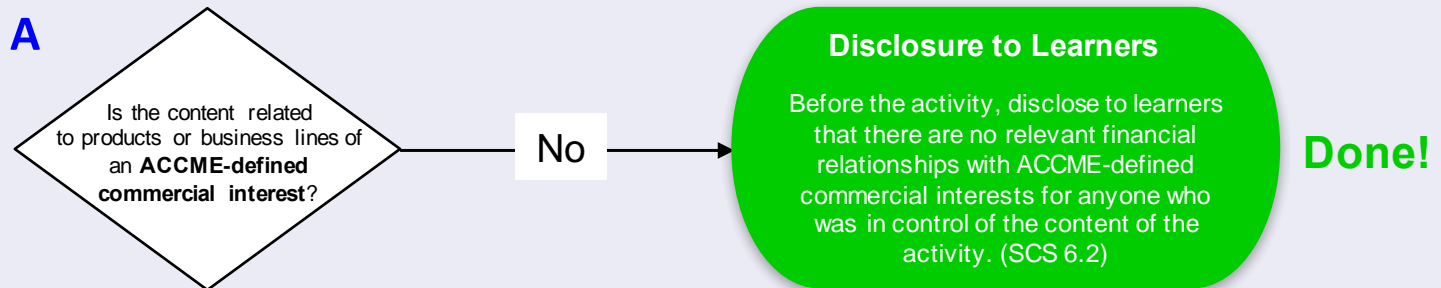
Done!



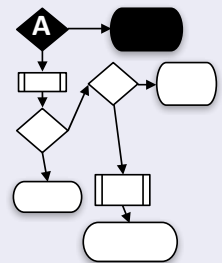
LET'S CONDUCT A FEW CASE REVIEWS

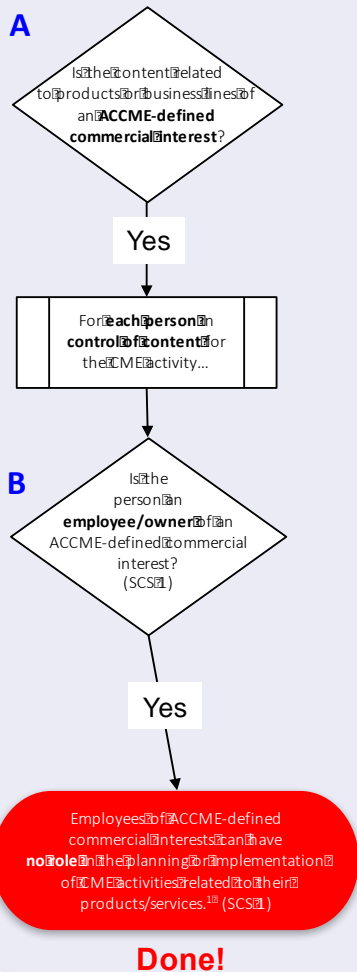


Start at A

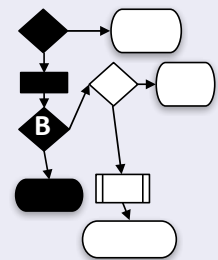


CASE #1: Dr. Jones is a speaker for a CME activity focused on improving team communication and coordination for chronic diseases.

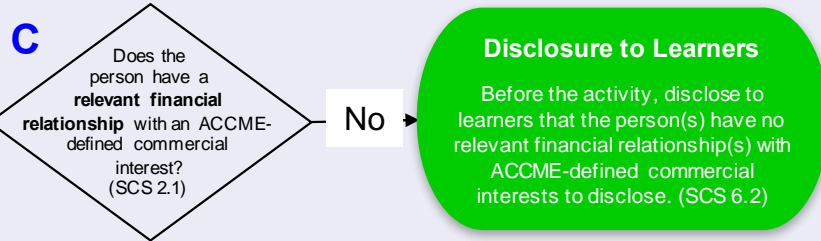
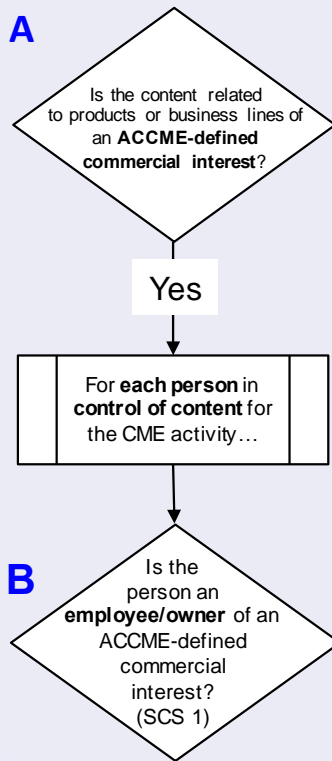




CASE #2: An employee of ABC Heart Medicine Company is a member of the planning committee for a CME activity about medications for heart disease.



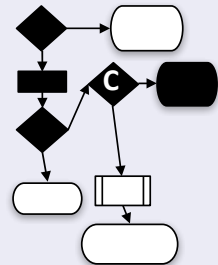
CASE #3: CME Coordinator, Joe, sends an email to everyone who is planning, authoring, or presenting in next year's *Tumor Board Case Conferences* asking, "What significant financial relationships (e.g. >\$5,000) have you had over the past year with an ACCME defined commercial interest?"



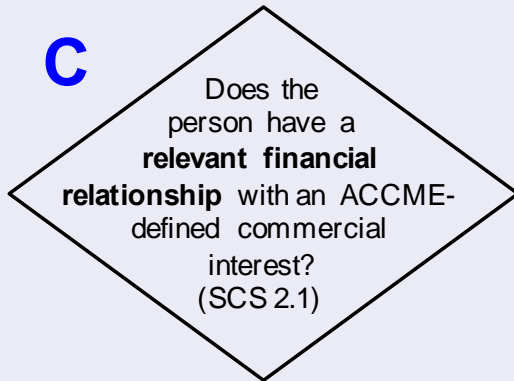
Is there a **relevant financial relationship**? If you can check all 4 boxes below, you've identified a relevant financial relationship with an ACCME-defined commercial interest that must be resolved before the activity occurs.

- 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

Done!



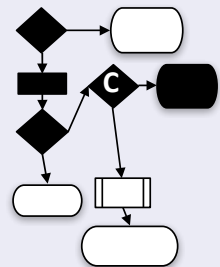
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- Any amount (\$)
- In the past 12 months
- Products/services of the ACCME-defined commercial interest (with which they have the financial relationship) are related to the content of the CME activity



CASE #4: Dr. Smith is the Chairperson of the CME Planning Committee for the Annual Conference on Spinal Surgery. Her husband is a shareholder for Spine Surgery Devices, Inc.

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

Yes

For each person in control of content for the CME activity...

Is the person an employee/owner of an ACCME-defined commercial interest? (SCS 1)

No

Does the person have a relevant financial relationship with an ACCME-defined commercial interest? (SCS 2.1)

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.

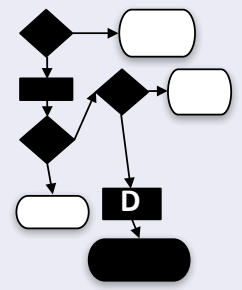
D

Implement your process² to resolve the potential conflict-of-interest arising from their relevant financial relationship. (SCS 2.3)

- 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!



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
- 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

CASE #4: Dr. Smith is the Chairperson of the CME Planning Committee for the Annual Conference on Spinal Surgery. Her husband is a shareholder for Spine Surgery Devices, Inc.

Yes, there is a *relevant financial relationship*.

D

Implement your process² to resolve the potential conflict-of-interest arising from their relevant financial relationship. (SCS 2.3)

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*
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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!

Documenting Conflict of Interest Resolution

The ACCME looks for PROOF of **HOW** you are resolving conflict of interest/potential COI.

They ask that providers keep records to show that they consistently **identified**, **resolved** and **disclosed** relevant financial relationships.

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:

Title of presentation:

Date of presentation:

Presenter's name:

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

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

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:

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

Reviewer - Full Name:

Title/Affiliation:

Date of this review:

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



Disclosure to Learners

A variety of methods can be utilized:

- Flyer/Brochure
- Verbal Disclosure
- Powerpoint Presentation Slide
- Disclosure Grid
- Disclosure Script
(ie, 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 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

Name of Organization(s)

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

Disclosure Grid



FINANCIAL DISCLOSURE CONFLICT OF INTEREST GRID

Indiana Academy of Dermatology - Fall Meeting

The Marriott Downtown • Indianapolis, IN • November 3, 2017

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 is resolved prior to the activity.



Name	Speaker	Planner	Commercial Interest/ Content Validity	Role/Nature of Financial Relationship	What I Received	Conflict/Resolved
Drew Anderson, MD		X	I do not have any relevant financial relationships with any commercial interests, and have read the Content Validity Standards.	N/A	N/A	None
Carrie Davis, MD		X	Celgene	Speakers Bureau	Honorarium	None/Not Relevant
Thomas Stasko, MD	X		I do not have any relevant financial relationships with any commercial interests, and have read the Content Validity Standards.	N/A	N/A	None
Cheryl Stearley, CME Coordinator Indiana State Medical Association		X	I do not have any relevant financial relationships with any commercial interests, and have read the Content Validity Standards.	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)

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.

Challenges/Dilemmas

Permitting employees/owners of a Commercial Interest to be involved in CME, in any fashion, opens you up to scrutiny by the ACCME.

Though the ACCME identifies 3 written exceptions to the rule for their inclusion in planning and presenting, the ACCME's V.P. of Accreditation & Recognition has verbally expressed **"there is no resolving such COI for planners."**

Conclusion

- 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 consistently identified, resolved and disclosed relevant financial relationships.