



CE Pearls: ACPE Spring Education Conference
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Ensuring Independence in your CPE Program

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Disclosure

- ▶ The presenters have no relevant financial relationships to disclose.

Learning Objectives

- ▶ Identify common areas of provider noncompliance with the Standards for Commercial Support.
- ▶ Discuss processes to address areas of noncompliance in your accredited provider program.
- ▶ Apply aspects of the Standards for Commercial Support using case scenarios.
- ▶ Explore provider approaches to ensure independence and integrity of CPE activities.

Questions

Do you receive commercial support for CPE activities?

- A. Yes
- B. No

If No, do the Standards for Commercial Support apply to you?

- A. Yes
- B. No

Standards for Commercial Support (SCS)

- Commercial Interest Definition
 - Any entity producing, marketing, reselling, or distributing health care goods or services consumed by, or used on, patients.
 - Providers of clinical service directly to patients are not 'commercial interests'
- SCS Elements
 - Independence in accredited CE
 - Identification and resolution of conflicts of interest
 - Appropriate use of commercial support
 - Management of commercial promotion
 - Content without bias
 - Transparency and public disclosure

Gathering Disclosure of Relevant Financial Relationships

Who Must Disclose?

What Is Disclosed?

When Is Disclosure Obtained?

How Does Disclosure Occur?

What Defines a Relative Financial Relationship?

- ▶ Financial Relationship between person in control of content (or their spouse/partner) and a commercial interest
- ▶ Any amount (\$)
- ▶ In the past 12 months
- ▶ Products or services of the commercial interest (with which they have the financial relationship) are related to the CPE activity.

Question

We do not take commercial support so there is no chance for a conflict of interest with my speakers.

- A. True
- B. False

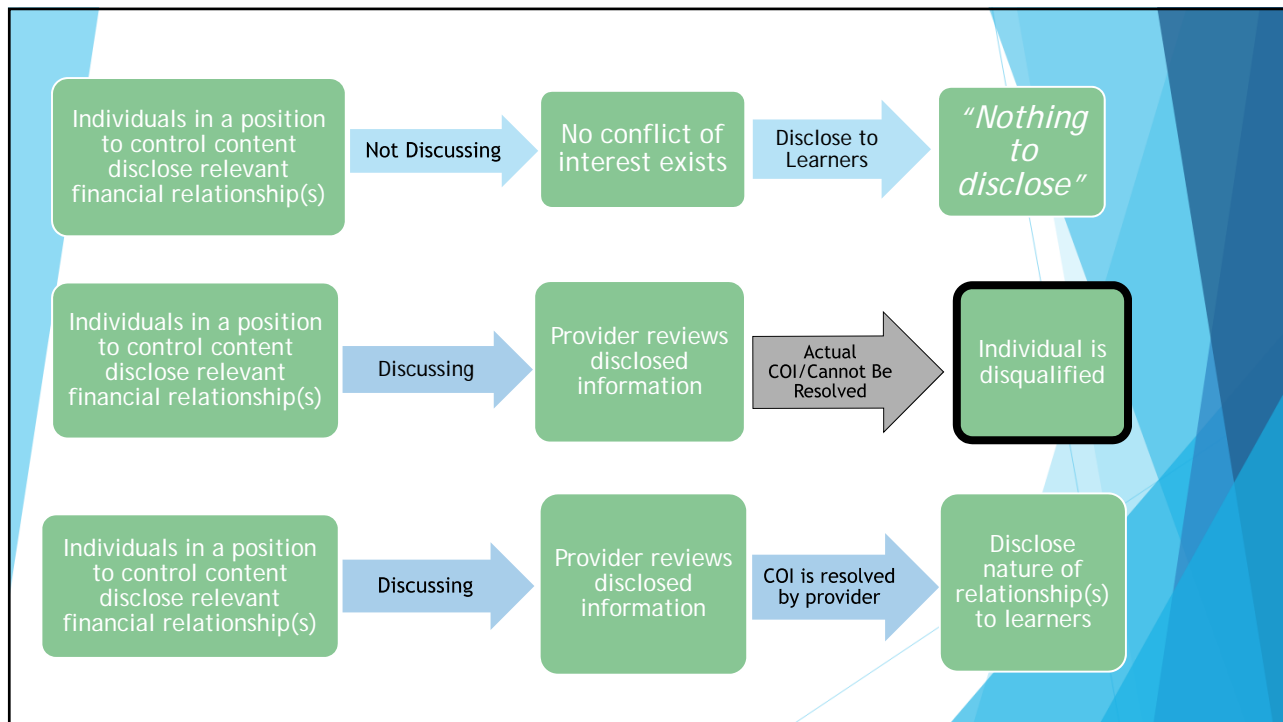
Case Scenarios - Identification of Conflicts of Interest

How Do You Resolve Conflicts of Interest?

What happens when there is a relevant financial relationship?

Provider takes an active role to resolve conflicts by:

- ▶ Recusing individual from controlling aspects of planning and content with which they have a conflict *and/or*
- ▶ Using peer-review of planning decisions (for planners) by individual(s) that do not have a conflict of interest related to the content *and/or*
- ▶ Using peer-review of content (for authors/presenters) by individual(s) that do not have conflicts of interest related to the content *and/or*
- ▶ Ensuring that clinical recommendations are evidence-based and free of commercial bias *and/or*



Documentation of Resolution of COI Example

Clinical Pathways in Diabetes Care Activity Support - AstraZeneca

Name of Person/Role	Relevant Financial Relationship Reported	COI Identified	Method of Resolution	Effectiveness of Resolution
Speaker/Chair Tom Apothecary, PharmD	Stock AZ-Lilly, Amgen Speaker-AZ Research-BI	Stock-AZ, Lilly Speaker-AZ Research - BI	Internal Peer Review External Peer Review Evidence Based On site monitoring	Bias not found 98%
Speaker Andy Healer, MD	Stock - Millennium, Abbott Research - BI, BD	None-products and services of commercial interests will not be discussed in the activity	N/A	
Planning Committee Janet Pills, RPh	Nothing to Disclose	N/A	N/A	
Planning Committee Amy Aorta, PharmD	Nothing to Disclose	N/A	N/A	
Reviewer Terry Treatment, PharmD	Nothing to Disclose	N/A	N/A	

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Case Scenarios - Resolution of Conflicts of Interest

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What is disclosed to learners?
How does it occur?



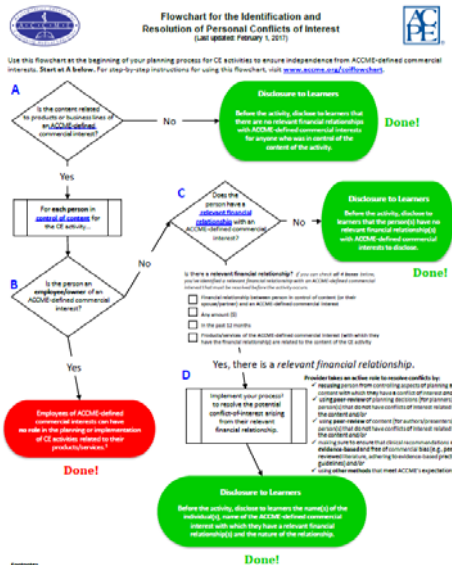
Case Scenarios - Disclosure to Learners



What should a provider do if learners report commercial bias in the activity?

As noted from activity evaluation or other means

SCS: Conflict of Interest Flowchart*



*Adopted from Accreditation Council for Continuing Medical Education (ACCME)

Managing Relationships with Commercial Interests

Provider and Commercial Interest Relationships in Independent CPE

- ▶ Role of commercial interest employees
- ▶ Nature of support
 - Unrestricted educational grant
 - In-kind support
 - Promotional opportunities
 - “Sponsorship”

Provider and Commercial Supporter Challenges in Independent CPE

- ▶ Overall, most grantors are well trained the Standards for Commercial Support
- ▶ Struggles with involvement
 - Faculty suggestion
 - Changing the grant submitted learning objectives
 - Content review before the activity
- ▶ Fear of losing an opportunity now and in the future
- ▶ Opportunity for reinforcement of the guidelines



What do I need to look for when I accept commercial support?

Risk Stratification

- ▶ Helps providers determine characteristics associated with an increased chance of commercial bias
- ▶ Helps providers identify activities that may need to be more closely monitored for potential commercial influence
- ▶ Allows providers to determine appropriate strategies to assure compliance
- ▶ Helps providers stay aware of factors that place activities at risk for non-compliance with standards

Risk Stratification Tool

Issue		Weight	Score
1. Joint provider			
No joint providership	No	0	
Joint provider is non-profit organization	Yes	1	
Joint provider is for-profit organization	Yes	2	
2. Experience with joint provider			
Not applicable		0	
Positive experience (all activities conducted in compliance with CME provider policies and Standards for Commercial Support)		-1	
No experience		1	
Negative experience (all activities not conducted in compliance with CME provider policies and SCS)		3	
3. Same live activity repeated on multiple occasions in commercially-supported activity (includes live and internet live activities)			
	No	0	
12. Presence of a financial relationship between one or more of the speakers and/or planners and the commercial supporter.			
	Yes	2	
	No	0	
TOTAL RISK SCORE			
Low Risk	<2		
Medium Risk	3 to 11		
High Risk	12 to 19		
Very High Risk	> 20		

How do I determine if an entity is/has a commercial interest?

- ▶ Identify business lines - products, services provided
- ▶ Consider organizational structure, including parent/sister companies
- ▶ Refer to guiding principles
 - ACPE: <https://www.acpe-accredit.org/pdf/FAQSCSAugust2014022317.pdf>
 - ACCME: <http://www.accme.org/faq/how-can-i-determine-if-my-organization-commercial-interest>
- ▶ Consult with ACPE staff

Case Scenarios - Managing Relationships with Commercial Interests

Standards for Commercial Support - Evidence

SCS 5.1 - Independence

- ▶ Evidence demonstrating independence, e.g. activity announcements, grant agreements, joint providership agreements, planning documents

SCS 5.2 - Resolution of Personal Conflicts of Interest

- ▶ Evidence of disclosure of relevant financial relationships for everyone in a position to control content (e.g. completed disclosure forms)
- ▶ Evidence of identification and resolution of all conflicts of interest prior to the education activity being delivered to learners

SCS 5.3 - Appropriate Use of Commercial Support

- ▶ Grant agreements, if applicable
- ▶ Evidence of receipt and expenditure of commercial support, e.g., income and expense statements
- ▶ Activity announcements for selected CPE activities

Standards for Commercial Support - Evidence

SCS 5.4 - Appropriate Management of Commercial Promotion

- ▶ Evidence of separation of promotion/advertising from continuing education, e.g., activity announcements, agreements, educational materials, reviewer/learner comments

SCS 5.5 - Content and Format without Commercial Bias

- ▶ Educational materials for selected CPE activities

SCS 5.6 - Disclosures Relevant to Potential Commercial Bias

- ▶ Evidence of disclosure to learners of relevant financial relationships and sources of all commercial support

Monitoring

- ▶ Activity evaluation forms for selected CPE activities
- ▶ Summary of activity evaluation feedback pertaining to bias, including free text comments, and evidence of provider follow-up on comments of bias, if identified

Key Takeaways

Takeaway #1:

Provider must obtain disclosure of relevant financial relationships from everyone in a position to control content.

Key Takeaways

Takeaway #2:

Ensure your method for collecting disclosure information contains the definition of a commercial interest and relevant financial relationship.

Key Takeaways

Takeaway #3:

Even if there are no relevant financial relationships related to the activity, *"NOTHING TO DISCLOSE"* must be disclosed to the learners.

Key Takeaways

Takeaway #4:

The provider determines if there is a conflict of interest after reviewing the disclosed information. The provider should have a procedure in place for resolving conflicts of interest.

Thank You!

Questions?