

# THE STANDARDS UNVEILED:

## YOUR GUIDE TO EXCELLING IN CME WITH STANDARDS 1, 2 AND 3



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# FOR THOSE WHO ARE NEWBIES ..... WHAT ARE “THE STANDARDS?”

## Standards for Integrity and Independence in Accredited Continuing Education

### Designed to:

- Ensure accredited **continuing medical education** serves the needs of patients and the public
- Present learners with only accurate, balanced, scientifically justified recommendations
- Assure learners they can trust your accredited **continuing medical education** to help them deliver, safe, effective, cost-effective, and compassionate care that is based on best practice and evidence
- Create a clear separation between accredited **continuing medical education** and marketing and sales.

# HOW IS “CONTINUING MEDICAL EDUCATION” DEFINED?

## What does it consist of?



Let's take a look at the handout I've provided in your packets.

# CME CONTENT: DEFINITION AND EXAMPLES

## About the Rule

### The Policy

Continuing medical education consists of educational activities that serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, the public, or the profession.

The content of CME is that body of knowledge and skills generally recognized and accepted by the profession as within the basic medical sciences, the discipline of clinical medicine, and the provision of health care to the public.

### ACCME Note

The ACCME definition of CME is broad, to encompass continuing educational activities that assist physicians in carrying out their professional responsibilities more effectively and efficiently.

#### Examples of topics that are included in the ACCME definition of CME content include

- **Management** - for physicians responsible for managing a health care facility
- **Educational methodology** - for physicians teaching in a medical school
- **Practice management** - for physicians interested in providing better service to patients
- **Coding and reimbursement** in a medical practice

**When physicians participate in continuing education activities that are not directly related to their professional work, these do not fall within the ACCME definition of CME content.** Although they may be worthwhile for physicians, continuing education activities related to a physician's nonprofessional educational needs or interests, such as personal financial planning or appreciation of literature or music, are not considered CME content by the ACCME.

# NOW BACK TO “THE STANDARDS”



# SOME STANDARDS APPLY TO ALL ACCREDITED CONTINUING EDUCATION

- **Standard 1: Ensure Content is Valid**
- **Standard 2: Prevent Commercial Bias and Marketing in Accredited CE**
- **Standard 3: Identify, Mitigate, and Disclose Relevant Financial Relationships**
- Standard 4: Manage Commercial Support Appropriately  
**(Applies only to CE that receives financial/in-kind support from ineligible companies)**
- Standard 5: Manage Ancillary Activities Offered in Conjunction with Accredited CE  
**(Applies only when there is marketing by ineligible companies or non-accredited education associated with the accredited CE)**

# STANDARD 1: ENSURE CONTENT IS VALID

Accredited providers are responsible for ensuring that their education is **fair and balanced** and that any clinical content presented **supports safe, effective patient care.**

# There are 4 Elements in Standard 1

## Element 1:

All recommendations for patient care in accredited continuing education must be **based on current science, evidence, and clinical reasoning**, while giving a **fair and balanced view** of diagnostic and therapeutic options.

## Element 2:

**All scientific research** referred to, reported, or used in accredited education in support or justification of a patient care recommendation **must conform to the generally accepted standards of experimental design, data collection, analysis, and interpretation.**

## Element 3:

Although accredited CE is an appropriate place to discuss, debate, and explore **new and evolving topics**, these areas need to be **clearly identified as such** within the program and individual presentations.

It is the responsibility of accredited providers to facilitate engagement with these topics **without advocating for, or promoting, practices that are not, or not yet, adequately based on current science, evidence, and clinical reasoning.**

## Element 4:

Organizations **cannot** be accredited if they **advocate for unscientific approaches** to diagnosis or therapy, or if their education **promotes recommendations, treatment, or manners of practicing healthcare that are determined to have risks or dangers that outweigh the benefits** or are known to be ineffective in the treatment of patients.

# **During Reaccreditation time – within the Self Study Report**

**Providers are asked to describe what they do to ensure the content of their CME activities meets all 4 Elements of Content Validity, in both the planning & monitoring stages**



# LET'S GIVE THIS SOME THOUGHT

## Planning:

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Convey expectations to speakers up front

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Review all content within a presentation before it is given



# LET'S GIVE THIS SOME THOUGHT

## Monitoring:

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Attend CME activity in person to ensure:

- Fair Balance/Relevance
  - Free from commercial bias
- 



# **STANDARD 2: PREVENT COMMERCIAL BIAS AND MARKETING IN ACCREDITED CE**

Accredited continuing education must protect learners from commercial bias and marketing.

# There are 3 Elements in Standard 2

## Element 1:

The accredited provider must ensure that all decisions related to the planning, faculty selection, delivery, and evaluation of accredited education are made **without any influence or involvement from the owners and employees of an ineligible company.**

# Owners and Employees of Ineligible Companies

- Owners and employees of ineligible companies (AKA commercial interests) are considered to have **unresolvable financial relationships** and must be excluded from participating as planners or faculty.
- Ineligible companies are prohibited from engaging in Joint Providership with accredited providers.

## Definition of Ineligible Companies:

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

# What are Examples of Ineligible Companies

- **Pharmaceutical companies or distributors**
- **Bio-medical startups that have begun gov't regulatory approval process**
- **Device manufacturers or distributors**
- **Compounding pharmacies that manufacture proprietary compounds**
- **Diagnostic labs that sell proprietary products**
- **Growers/distributors/manufacturers/sellers of medical foods and dietary supplements**
- **Manufacturers of health-related wearable products**

## Element 2:

Accredited education must be **free of marketing or sales of products or services.**

Faculty must not actively promote or sell products or services that serve their professional or financial interests during accredited education.

# WHAT IS MEANT BY FACULTY NOT ACTIVELY PROMOTING OR SELLING PRODUCTS THAT SERVE THEIR INTEREST?

## Examples:

1. Referral of patients
2. Book promotion
  - **A faculty member can reference a book they've written, but can have no overt promotion**
  - **Book sales would be allowed outside of the educational space; provider may also raffle off a book**

## Element 3:

The accredited provider **must not share the names or contact information of learners** with any ineligible company or its agents **without the explicit consent** of the individual learner.

# WHAT IS MEANT BY EXPLICIT CONSENT?

- An accredited provider is expected to explain to learners that you intend to share their information with an ineligible company.
- You can do that at registration; however, the learner must have the ability to opt out and still register for an activity.

# **During Reaccreditation time – within the Self Study Report**

**Providers are asked to describe how they ensure that the content of their CME activities meets all 3 Elements of Standard 2 – Preventing Commercial Bias**



# LET'S GIVE THIS SOME THOUGHT

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Careful selection of planning committee members and faculty chosen to deliver CME

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Collecting disclosure and avoiding use of employees/owners of ineligible companies



# LET'S GIVE THIS SOME THOUGHT

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Carefully review all presentations to ensure they include no marketing/ sale of products or services

(this includes logos/product images, etc.)

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Collect disclosure and avoid use of employees/ owners of ineligible companies



# LET'S GIVE THIS SOME THOUGHT

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Simply avoid sharing names or contact information of learners with ineligible companies

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Or give learners the option to “opt out”



# STANDARD 3:

## IDENTIFY, MITIGATE, AND DISCLOSE RELEVANT FINANCIAL RELATIONSHIPS

### About the Rule

Many healthcare professionals have financial relationships with ineligible companies. These relationships must not be allowed to influence accredited continuing education.

**The accredited provider is responsible for identifying relevant financial relationships** between individuals in control of educational content and ineligible companies and managing these to ensure they do not introduce commercial bias into the education.

**Financial relationships of any dollar amount are defined as relevant if the educational content is related to the business lines or products of the ineligible company.**

# STANDARD 3 IS MULTI-FACETED



We're going to address each element separately.

# IDENTIFICATION

## INVOLVES COLLECTING INFORMATION

### From all in control of content

- **Planners:**
  - ✓ CME Staff, Course Director, CME Committee
- **Faculty Presenters:**
  - ✓ Speakers, Panelists, Moderators
- **Reviewers:**
  - ✓ Peer Reviewers, CME Staff



# WHAT SPECIFICS ARE TO BE COLLECTED ?

**All** financial relationships with ineligible companies (commercial interests).

- Regardless of the amount
- Regardless of their view of the relevance of the relationship to the education
- Within the past 24 months

**NOTE:** Individuals no longer need to disclose the financial relationships of their spouse/partner.

# FOR EACH FINANCIAL RELATIONSHIP, DISCLOSURE INFORMATION MUST INCLUDE:

- Name of ineligible company
- Nature of the relationship
  - Consultant
  - Speakers Bureau
  - Grant/Research Support
  - Principal Investigator
  - Board Member
  - Stock Ownership\*
  - Other

# LET'S LOOK AT STOCK OWNERSHIP – WHEN DOES IT CREATE AN EMPLOYEE/OWNER RELATIONSHIP?

## PRIVATELY HELD:

If an individual is an owner of stock in a company that is **privately held**, that individual would be considered to be an owner of the company. **This relationship is not mitigatable.**

## PUBLICLY TRADED:

If stock/stock options are in **publicly traded companies**, and the financial relationships are relevant to the CME content, **those relationships are mitigatable** and should be disclosed to learners.

# HOW DO THESE FORMS OF STOCK OWNERSHIP DIFFER?

## Publicly Traded Company

A company that has sold all or a portion of itself to the public via an initial public offering, meaning shareholders have a claim to part of the company's assets and profits.

They can tap the financial markets by selling stock to raise capital.

## Privately Held Company

The company is owned by its founders, management, or a group of private investors.

A private company cannot dip into the public capital markets and must rely on private funding.

### **NOTE:**

**ACCME does not require individuals who control CME content to disclose diversified mutual funds, but any other stocks or stock options should be disclosed to the provider.**

# **During Reaccreditation time – within the Self Study Report**

**Providers are asked to describe the process(es) they have in place to collect disclosure information.**

**How do YOU collect disclosure?**

**Put on your “surveyor” hat and tell me what you would look for if reviewing a Self-Study.**



# Did you know you are not REQUIRED to use a disclosure form?

**That is correct!**

ACCME does not require the use of a specific disclosure form.

However, they do require providers to collect and disclose financial relationships for all individuals in control of content to their learners.

**Using a disclosure form is the most common method utilized.**

# Identification Involves Determining Relevancy

Financial relationships are relevant if the educational content an individual can control is related to the business lines or products of the ineligible company.

**ACCME says providers sometimes believe that CME content is not relevant to a financial relationship if there are no products directly mentioned. However, this is not true.**

## NOTE:

If faculty advise they will not be discussing a company's products, but they will be talking about a therapeutic area of interest for said company, providers must still disclose the relationships – they are considered relevant.

**Of importance, no CME Provider should be allowing faculty/speakers to self-determine relevancy.**



**This is no longer acceptable, with the implementation of the new Standards.**

# **During Reaccreditation time – within the Self Study Report**

**Providers are asked to describe the process they use to determine which financial relationships are relevant to the educational content.**

**How do YOU collect disclosure?**

**Put on your “surveyor” hat and tell me what you would look for if reviewing a Self-Study.**



# **Also During Reaccreditation time – within the Self Study Report**

**Providers are asked if their organization utilizes employees/owners of ineligible companies for reasons listed within the  
“three exceptions to the exclusion”**

**If yes, the provider is asked to describe their processes for meeting regulations around the exceptions.**

**Do you know what these exceptions are?**

# 3 Exceptions from Excluding Employees/Owners

1. Content of the CE is not related to the business lines/products of their employer/company.
2. Content of the CE is limited to basic science research (i.e., pre-clinical research and drug discovery) and they do not make care recommendations.
3. When participating as technicians to teach the safe and proper use of medical devices and do not recommend whether or when a device is used.

# MITIGATION

Mitigation involves taking steps to prevent those with relevant financial relationships from inserting commercial bias into content.

## Actions Involved:

- Mitigate relationships prior to individuals assuming their roles.... and take mitigation steps appropriate to the role of an individual (planners vs. speakers)
- Document the steps taken to mitigate relevant financial relationships.

# **During Reaccreditation time – within the Self Study Report**

**Providers are asked to describe the  
methods & steps they use to mitigate  
for both Planners and Speakers**

**(noting the steps used for both can and will likely differ)**



# How do YOU mitigate conflicts of interest for Planners/Reviewers?

Put on your “surveyor” hat and tell me what you would look for if reviewing a Self-Study.



- End the financial relationship
- Recuse individual from planning (at least from aspects with which there is a financial conflict)
- Partner with non-conflicted planner

# How do YOU mitigate conflicts of interest for Faculty/Speakers?

Put on your “surveyor” hat and tell me what you would look for if reviewing a Self-Study.



- End the financial relationship
- Recuse individual; replace with another speaker
- Review of content/presentation
- Remind speaker of expectations/guidelines and have them attest that clinical recommendations are/will be EB and free of commercial bias

# EXCEPTIONS TO MITIGATION

Accredited providers do not need to identify, mitigate, or disclose relevant financial relationships for education that is:

- **Non-clinical in nature**
- **Spontaneous case conversation among peers**
- **Self-directed**
  - where learner controls educational goals/reports on changes that resulted (i.e., personal development plan)

**How many of you are giving credit to these types of education?**

# WHAT CONSTITUTES A NON-CLINICAL TOPIC?

Education is considered **non-clinical in nature** when it is not providing any type of clinical recommendations in caring for patients, but is directly related to their professional work.

**Remember:** When a topic is not directly related to a physician's professional work, it does not fall within ACCME's definition of CME content.

# EXAMPLES OF NON-CLINICAL TOPICS

- Advocacy and Legislation
- Billing, Coding and Reimbursement
- Telehealth Fraud
- Electronic Medical Records (EMR)
- Improving Physician Communication with Patients
- Practice Management
- Starting Your Own Medical Practice
- Physician Burnout and Well-Being
- Physician Leadership

# WHAT CONSTITUTES SPONTANEOUS CASE CONVERSATIONS?

The exception is meant to apply to **spontaneous learning opportunities** that previously might not have been considered CME, like **team huddles and impromptu leadership discussions.**

In these cases, with the guidance of the CME Department, learners can describe the learning opportunity (problem-in-practice and change that resulted)

# WHAT SPONTANEOUS CASE CONVERSATIONS ARE NOT!

- Regularly scheduled series
- Case conferences
- Tumor boards

These are not considered “spontaneous case conversations among peers.”

The exception does not apply to conferences or grand rounds that have set times/dates and have traditionally been planned as accredited CME.

# Did you know about the QUICK TOOL?

## Released as part of ACCME's Toolkit for the Standards for Integrity and Independence in Accredited CE

(This can be found on  
ACCME's website and  
is included in your packet)



**Quick Tool for Planning Accredited  
Continuing Education**

For more information, visit  
[accme.org/standards](http://accme.org/standards)

<b>What is your name and email?</b>	Name: <input type="text"/> Email: <input type="text"/>
<b>When will the education take place?</b>	Date: <input type="text"/>
<b>Do you have a title or brief description for the education? If yes, please note it to the right; if no, leave blank.</b>  <small>Examples: Emergency Department team huddle; Leadership in a time of crisis; Well-being check-in</small>	Title/Brief Description: <input style="width: 100%; height: 40px;" type="text"/>
<b>What practice-based problem (gap) will this education address?</b>  <small>Examples: Improve care coordination; Better communication with patients and families; Want to give better feedback to students</small>	Practice-based problem (gap): <input style="width: 100%; height: 40px;" type="text"/>
<b>What is/are the reason(s) for the gap? How are your learners involved?</b>  <small>Examples: We need strategies to discuss difficult topics with family members; Don't know best ways to improve team collaboration</small>	Reason(s) for the gap: <input style="width: 100%; height: 40px;" type="text"/>
<b>Review the three statements to the right.</b>  <small>If you can check <u>any</u> of these boxes, you do not need to identify, mitigate, and disclose relevant financial relationships. If you are unable to check any boxes, please contact your CE program administrator to implement processes for ensuring the integrity and independence of this education.</small>	The education will... (check all that apply) <input type="checkbox"/> only address a non-clinical topic (e.g., leadership or communication skills training). <input type="checkbox"/> be for a learner group that is in control of the content (e.g., spontaneous case conversation among peers). <input type="checkbox"/> be a self-directed educational activity where the learner will control their educational goals and report on changes that resulted (e.g., learning from teaching, remediation, or a personal development plan).
<b>What change(s) in strategy, performance, or patient care would you like this education to help learners accomplish?</b>  <small>Examples: Eliminate stigmatizing language from communications with patients; Improve my management skills</small>	Desired change(s) in strategy, performance, or patient care: <input style="width: 100%; height: 40px;" type="text"/>
<b>In order to award CME/CE credit, please indicate the duration of the education.</b>	Education duration: _____ hours and _____ minutes <i>Please report time in 15-minute increments.</i>
<b>Discuss with learners the changes they intend to make to their strategies, performance, or patient care that will result from this activity and list that information to the right.</b>  <small>Example: I will use the evidence-based checklist we discussed to improve screening my patients for past military service.</small>	Changes learners intend to make to strategies, performance, or patient care: <input style="width: 100%; height: 40px;" type="text"/>
<b>After the activity, please collect attendance and learner change information for the activity and send it to the continuing education department in order for credit to be awarded. You can also list the attendees on the back of this form.</b>	
 <b>Note for Continuing Education Staff</b>	
<small>This completed form provides the necessary information to demonstrate the professional practice gap and underlying needs, expected results, appropriate format, changes in learners, independence, and administrative information needed to award credit to learners. Please enter this activity in ACCME PARS following your usual process, and provide to learners your accreditation statement, the credit designation statement, and any applicable MOC statements. If you have awarded MOC credit, please report learners in PARS within 30 days of the education. For questions or assistance, contact ACCME at <a href="mailto:info@accme.org">info@accme.org</a>.</small>	

Excerpted from the Toolkit for the Standards for Integrity and Independence in Accredited Continuing Education  
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# Documentation of the Steps Taken to Mitigate Relevant Financial Relationships is Key!



You will be asked about this at reaccreditation time during PIP activity review.



# COI Mitigation (Resolution) Form

This is another mechanism providers might use at an individual level.



CONTINUING MEDICAL EDUCATION

FOR CME OFFICE USE ONLY	
<b>MITIGATION OF CONFLICTS OF INTEREST</b>	
<b>Step 1</b>	<b>Owners/Employees of Ineligible Company (IC)</b>
<input type="checkbox"/>	Not an employee/owner of IC (go to Step 2)
<input type="checkbox"/>	Planning Committee employee/owner of IC (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 IC (choose from below):
	<input type="checkbox"/> Faculty/speaker is not allowed to present
	<input type="checkbox"/> Activity will not be accredited
<b>Step 2</b>	<b>Conflict of Interest (COI)</b>
<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"/> Discontinue contracted services that create financial relationship – must disclose such relationship to audience for <b>24</b> 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

Reviewed/Signed by: \_\_\_\_\_ Date: \_\_\_\_\_ Updated: Jan 2021

# It's Story TIME

**Terri Landel, SHO CME Program Administrator,  
will be sharing a challenging case with us**



## CASE EXAMPLE:

Cardiology Speaker with  
over 30 relationships

# DISCLOSURE

## The Final Element of Standard 3



Learners must receive disclosure information before engaging with an accredited educational activity.

# What Do We Include?

When there are relationships, disclosure to learners must include each of the following:

- a. Names of the individuals with relevant financial relationships
- b. Names of the ineligible companies with which they have relationships
- c. Nature of the relationship(s)
- d. **A statement that "all relevant financial relationships have been mitigated." (NEW)**

Or the opposite:

Providers must disclose the absence of relevant financial relationships ..... informing learners that planners, faculty, and others in control of content have no relevant financial relationships with ineligible companies.

# Methods of Disclosure

You may use a variety of these:

- Disclosure Grid
- Disclosure Slide at beginning of presentation
- Disclosure Statement on flyer and/or other promotional materials
- Verbal Disclosure to audience during presentation
  - You must be able to supply ISMA with written verification that appropriate verbal disclosure occurred (especially if this is the only method you use).

# TO CLOSE OUT....

## I'd like to refer you to ACCME's Planning Guide for Independence in Accredited CE

You will find this document available on the ACCME website at

<https://accme.org/resource/planning-guide-for-independence-accredited-continuing-education-pdf/>

It leads you through the process to ensure independence from commercial influence in your CME activities.

# FINAL QUESTIONS?

