

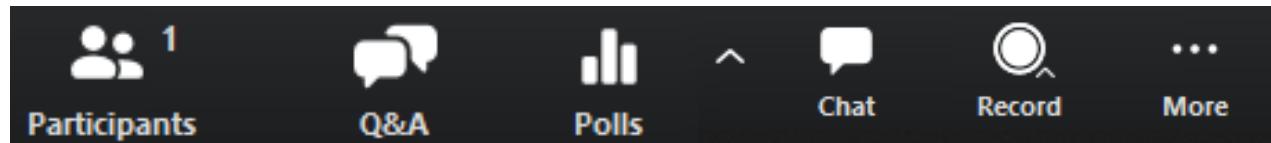
Proposed Changes ACCME Standards for Commercial Support



ACCME Standards for Integrity and
Independence in Accredited Continuing
Education
January 23, 2020

Webinar Instructions

- To join the webinar, click here: <https://zoom.us/j/611072335>
- To dial into the webinar via telephone:
 - Dial +1 646 558 8656 or +1 669 900 9128
 - Enter Webinar ID: 611 072 335
- Throughout the program, you may ask questions by clicking on the “Q&A” button on your screen.



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Disclaimer

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Jan is representing herself as a CPD professional and not the ACEHP, its Board of Directors, or any accrediting body in this webinar.



About the CME Coalition



CME's voice in Washington, DC



Founded in 2011



45+ members representing CME providers, Medical Societies,
Patient Organizations, HCPs, and Commercial Supporters

Background on CME Coalition



Advocacy with Policymakers

Congress
CMS
FDA



Cooperation with Key Stakeholder Groups (ACEHP, AMA, AAFP, etc.)



Policy Analysis



Compliance Support

Background on the ACCME Standards for Commercial Support

- First published in 1992; fully revised in 2004 with partial changes in 2008 and 2014
- Purpose is to separate medical product marketing from accredited education
- To ensure the integrity of the CME/CE enterprise
- Other accrediting organizations have adopted the SCS, either as written or with minor modifications; e.g. the ANCC (nursing), the ACPE (pharmacy) and Joint Accreditation (interprofessional CE)

Purpose of Webinar

Inform the Members of the CME Coalition and other interested parties

Solicit comments/concerns from Members and others

Call to action - Submit your own comments prior to 5 PM CST February 21, 2020



Overview of Revision

- New terminology
- Some new requirements
- More clarity for who can and cannot be accredited or control content of accredited continuing education activities
- Incorporation of policies into the standards, rather than separate documents
- 5 Standards instead of 6

Intent is to have everything in one document

Overview of ACCME Process

- ACCME process of revision began in 2019 with a Call for Comment on current SCS
- Next steps
 - CPD Community will submit comments by February 21st
 - The ACCME Board of Directors will review the responses to the call for comment at its March Meeting
 - After the Board makes modifications and adopts the revised Standards, the ACCME will release a transition plan for the accredited continuing education community
 - Meanwhile, the current SCS will remain in place, and providers should adhere to them

New Name

**Current
ACCME Standards
for Commercial
Support**

**Proposed
ACCME Standards
for Integrity and
Independence in
Accredited
Continuing
Education**

New Terminology

- **Eligible entities:** Organizations that are eligible for accreditation in the ACCME System
- **Ineligible entities:** Organizations that are not eligible for accreditation, formerly called *commercial interests*
 - Intended to clarify that eligibility for accreditation is not based on whether an organization is for-profit or nonprofit, but based on its primary mission and function
- **Mitigate:** replaces “resolve” with reference to actions taken related to handling conflicts of interest; no change in intent
- **Accredited Continuing Education:** replaces Continuing Medical Education; differentiates from *non-accredited education*



Deeper Dive

Types of Organizations That May Be Accredited in the ACCME System

Eligible Entities: Entities eligible to be accredited in the ACCME System are organizations whose primary mission and function are: (1) providing clinical services directly to patients; or (2) the education of healthcare professionals; or (3) serving as fiduciary to patients, the public or population health; and other organizations that are not otherwise ineligible. Examples of such organizations include:

- Ambulatory procedure centers
- Blood banks
- Diagnostic labs (that do not sell proprietary products)
- Electronic health records companies
- Government or military agencies
- Group medical practices
- Health law firms
- Health profession membership organizations
- Hospitals or healthcare delivery systems
- Infusion centers
- Insurance or managed care companies
- Nonprofit organizations
- Nursing homes
- Pharmacies
- Publishing or education companies
- Software or game developers
- Rehabilitation centers
- Schools of medicine or health science universities
- Technology or data management companies (non-health related)

Deeper Dive 2

Types of Organizations That *Cannot* Be Accredited in the ACCME System

Ineligible Entities: Entities that are ineligible to be accredited in the ACCME System are organizations whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. Examples of such organizations include:

- Advertising, marketing, or communication firms (whose clients are ineligible entities)
- Bio-medical startups (that have begun an approval process through the FDA)
- Compounding pharmacies (that manufacture proprietary compounds)
- Device manufacturers or distributors
- Diagnostic labs (that market or sell proprietary products)
- Growers, distributors, or sellers of medical foods and dietary supplements
- Pharmaceutical companies or distributors
- Pharmacy benefit managers
- Reagent manufacturers/sellers
- Manufacturers of health-related wearable products

The owners and employees of ineligible entities are considered to have unresolvable financial relationships and must be excluded from participating as planners or faculty and must not be allowed to influence or control any aspect of planning, delivery, or evaluation of an accredited activity.

Standard 1: Ensure Content is Valid

1.4 Accredited education may inform learners about approaches to diagnosis or treatment that are controversial or not generally accepted **but must not include advocacy for these approaches or teach healthcare professionals how or when to use them.**

1.5 Organizations cannot be accredited if they advocate for unscientific modalities of 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.

Standard 2: Prevent Marketing or Sales in Accredited Continuing Education

2.2 Faculty must not promote or sell products or services that serve their professional or financial interests during an accredited activity.

2.3 The accredited provider must not share the names and contact information of learners with any ineligible entities or their agents without the explicit consent of the individual learners each time the data is to be shared. This consent must include the name of the ineligible entity receiving the learner information and describe how the entity intends to use the information.

Standard 3.1: Identify, Mitigate, and Disclose Relevant Financial Relationships with Ineligible Entities

- **Collect information** from all planners, faculty, and others in control of educational content **about all their financial relationships with ineligible entities** within the prior 12 months.
- Mitigate relationships prior to the individual assuming their role. Take steps appropriate to role of the individual. **For example, steps for planners will likely be different than for faculty and would occur before planning begins.**

Standard 3.2: Ownership/Employee

- There are three exceptions to this exclusion - employees of ineligible entities can participate as planners or faculty in these specific situations:
 - a. If the activity is not related to the business lines or products of their employer/company;
 - b. When the content of the accredited activity is limited to basic science research, such as pre-clinical research and drug discovery, or the methodologies of research, and they do not make care recommendations; or
 - c. When they are participating as technicians to teach the safe and proper use of medical devices, and do not recommend whether or when a device is used.

Standard 3.3: Identify Relevant Financial Relationships

- **Identify relevant financial relationships:** Review the information about financial relationships to determine which relationships are relevant. Financial relationships are relevant if the educational content is related to the business lines or products of the ineligible entity.

Standard 3.5: Disclosure

Disclose all relevant financial relationships to learners:

5.d A statement that all relevant financial relationships have been mitigated; learners must receive this information before engaging with the accredited education.

Standard 3 – Self Directed Learning

Exception for self-directed continuing education: In self-directed accredited continuing education, where the learner is in control of content and there are no planners or faculty (such as a bedside, case conversation among peers), there is less opportunity for commercial bias.

In these cases, accredited providers do not need to identify, mitigate, or disclose relevant financial relationships.

However, when accredited providers serve as a source of information for the self-directed learner, they should direct learners only to resources and methods for learning **that are not controlled by ineligible entities.**

Standard 4: Manage Commercial Support Appropriately

Applies only to accredited continuing education that receives financial or in-kind support from ineligible entities.

Decision making and disbursement: The accredited provider must make all decisions regarding the receipt and disbursement of the commercial support.

- a) **The accredited provider is responsible for dispersing the commercial support.** Ineligible entities must not pay directly for any of the expenses related to the education or the learners.
- b) The accredited provider may use commercial support to fund honoraria or travel expenses of planners, faculty, and others in control of content for those roles only. **These expenses must be paid or reimbursed to the individuals directly by the accredited provider and not by the ineligible entity or by a joint provider.**

Standard 5: Manage Ancillary Marketing around Accredited Continuing Education

Arrangements to allow ineligible entities to market or exhibit in association with accredited education must not:

- a. Influence any decisions related to the planning, delivery, and evaluation of the education
- b. Interfere with the presentation of the education
- c. Be a condition of the provision of financial or in-kind support from ineligible entities for the education

Standard 5

- The accredited provider must ensure that learners can easily distinguish between accredited education and other activities, such as nonaccredited education and marketing.
 - a. Live continuing education activities: Marketing, exhibits, and **non-accredited education must not occur in the physical space immediately before or after an accredited education activity, and must not be interleaved within the accredited education.**
 - b. Print, online, or digital continuing education activities: Learners must not be presented with marketing while engaged in the accredited education activity. Learners must be able to engage with the accredited education **without having to click through**, watch, listen to, or be presented with product promotion or product-specific advertisement.

Standard 5 (2.d, 3)

- **Information distributed about accredited education that does not include educational content, such as schedules and logistical information, may include marketing by or for an ineligible entity.**
- **Ineligible entities may not provide preferential access to or distribute accredited education to learners.**

Questions and Answers



Summary

Read the whole document - you may see areas that concern you that have not been mentioned in this session.

Proposed Standards

www.accme.org/publications/call-for-comment-information-package-standards-for-integrity-and-independence

CME Coalition sample comments (available February 10th)

Webinar will be archived on www.cmecoalition.org

Provide your own comments to ACCME by 5PM CST February 21, 2020

Give practical examples and proposed solutions

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