



Accreditation CouncilTM
for Continuing Medical Education

learn well

Call For Comment
Standards for Integrity and
Independence in Accredited
Continuing Education

Information Package

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Introduction

The Accreditation Council for Continuing Medical Education (ACCME®) is pleased to invite you to participate in a call for comment about the proposed revisions to the rules that protect the independence and integrity of accredited continuing education for healthcare professionals.

The proposed ACCME Standards for Integrity and Independence in Accredited Continuing Education are based on the feedback we received from the continuing education stakeholder community. Our goal is to streamline, clarify, and modernize the Standards, and to ensure their continued relevance and effectiveness in the changing healthcare environment. The initiative supports the ACCME's strategic goal to assure the quality of accreditation.

To support your participation in the call for comment, we have included in this information package the background and purpose of the proposed revisions, our approach to the revision process, an overview of the revisions, and the proposed Standards at a glance. We have also included the full text of the proposed Standards, the survey questions, and the current Standards and related policies. We suggest you review these materials before completing the online survey.

[The survey is available here.](#)

We will accept comments until February 21, 2020, at 5 PM Central.

Background and Purpose

Independence is the cornerstone of accredited continuing education: The purpose of accredited education is to assure clinicians and teams a protected space to learn, teach, and engage in scientific discourse free from commercial influence. The ACCME Standards for Integrity and Independence in Accredited Continuing Education (renamed in the proposal from the Standards Commercial Support: Standards to Ensure Independence in CME ActivitiesSM) are designed to create a clear, unbridgeable separation between accredited education and industry marketing and to ensure that accredited continuing Education serves the needs of patients and the public.

The ACCME acts as the steward of the Standards. First adopted in 1992, the Standards were last updated in 2004, following an intensive review and consensus-building process by multiple stakeholders. Over the past 15 years, the Standards have become a national and international model, adopted by accreditors across the health professions. Joint Accreditation for Interprofessional Continuing EducationTM adopted the Standards in its accreditation process for

multiple health professions. Data suggest that the Standards provide a stable and well-established framework that has been effective at ensuring independence and insulating clinicians from promotion and marketing. Further, there is considerable evidence demonstrating that accredited continuing education effectively improves the ability of clinicians and teams to deliver high-quality care based on evidence.

Review Process

To oversee the process of review, the ACCME convened the Task Force on Protecting the Integrity of Accredited Continuing Education, with members representing diverse perspectives, including accredited continuing education providers and the public. The Task Force and ACCME leadership engaged with stakeholders to identify new and existing challenges related to managing the complex issues of disclosure, conflicts of interest, and commercial support in a rapidly evolving healthcare environment. Engagement included the following:

- Call for feedback open to all
- Focus groups with accredited continuing education providers
- Discussion sessions with volunteers on the ACCME's Accreditation Review Committee and Committee for Review and Recognition
- Multiple webinars with the ACCME's Recognized Accreditors
- A day-long meeting with accreditor colleagues in the health professions
- A conference call with staff at the Food and Drug Administration (FDA)

We thank all of you who have participated in our dialogue so far and look forward to your responses to our proposed Standards.

Next Steps

The ACCME Board of Directors will review the responses to the call for comment at its March 2020 meeting. After the Board makes modifications and adopts the revised Standards, the ACCME will release a transition plan for the accredited continuing education community. This plan will include:

- Transition phase to give accreditors, accredited educational providers, faculty, volunteers, and other stakeholders time to prepare to meet the expectations of the revised Standards.
- Education and resources to support the continuing education community's successful adoption of the revised Standards.

The current Standards for Commercial Support remain in place and accredited continuing education providers should continue to comply with them, in addition to complying with other accreditation requirements.

Task Force on Protecting the Integrity of Accredited Continuing Education

We thank the members of the Task Force on Protecting the Integrity of Accredited Continuing Education for their work overseeing the review and revision process. The Task Force engaged in an inclusive process with stakeholders to obtain feedback; reviewed, analyzed, and discussed stakeholder feedback; and prepared the proposed revised Standards for review by the ACCME Board of Directors. We appreciate their diversity of perspectives, expertise, and commitment to advancing the quality and integrity of accredited education.

Co-Chair: Norman Kahn, MD, serves as Convener, Conjoint Committee on Continuing Education. Dr. Kahn is the former CEO of the Council of Medical Specialty Societies (CMSS); he is a former member of the ACCME Board of Directors and served as chair of the task force that issued the 2004 Commercial Support: Standards to Ensure Independence in CME Activities.

Co-Chair: Susan Spaulding has served as public board member for healthcare organizations including the Federation of State Medical Boards of the United States and the National Board of Medical Examiners. She served as public member of the ACCME Board of Directors during the adoption of the 2004 Standards for Commercial Support: Standards to Ensure Independence in CME Activities.

Barb Anderson, MS, is Chair, Interprofessional Continuing Education Partnership; and Director, Office of CPD, University of Wisconsin, Madison. She serves as a volunteer surveyor for ACCME, and for Joint Accreditation for providers of interprofessional continuing education (IPCE).

Joni Fowler, PharmD, BCPP, is President/Owner, Creative Educational Concepts, Inc., a provider accredited by Joint Accreditation for Interprofessional Continuing Education™. Dr. Fowler serves on the Joint Accreditation Review Committee and as a volunteer surveyor for Joint Accreditation for providers of interprofessional continuing education (IPCE).

Linda Gage-White, MD, PhD, MBA, is board-certified in otolaryngology and holds joint appointments in Otolaryngology and Pediatrics at Louisiana State University School of Medicine in Shreveport. She currently serves on the ACCME Board of Directors and formerly served on the ACCME Accreditation Review Committee.

Stuart Gilman, MD, MPH, is Director of Advanced Fellowships in the Office of Academic Affiliations, Veterans Health Administration. Dr. Gilman currently is a Federal Government representative to the ACCME Board of Directors and formerly served on the ACCME Accreditation Review Committee.

Timothy Holder, MD, is Medical Director, Supportive Care and Survivorship, Cancer Treatment Centers of America, Tulsa. He is the immediate past chair, ACCME Accreditation Review Committee, and formerly served on the ACCME Board of Directors and Committee for Review and Recognition.

Wanda Johnson, CMP, CAE, is CEO, American Society for Parenteral and Enteral Nutrition. She formerly served for 25 years at the Endocrine Society, most recently as Chief Program Officer.

Jeffrey Mallin, MD, is a pediatrician with the Southern California Permanente Medical Group at the Kaiser Permanente Downey Medical Center, where he was Director of Medical Education for 10 years. Dr. Mallin currently serves on the ACCME Board of Directors and is Vice Chair, Committee for Review and Recognition; he is a former member of the ACCME Accreditation Review Committee.

Proposed Revisions to Standards: Approach and Overview

The proposed, revised Standards were developed in response to the feedback we received and the review and analysis conducted by the Task Force, ACCME executive staff, and the ACCME Board of Directors,

Approach to Revisions

In preparing the proposed revisions to the Standards, the ACCME and the Task Force agreed it was essential to:

- Consider the potential effect of revisions on stakeholders, including accredited education providers, colleague accreditors in the health professions, and international organizations.
- Minimize unintended consequences.

The revised Standards should:

- Modernize policy language and concepts.
- Express expectations clearly.
- Remain criterion-based, with objective rather than subjective statements, to allow for consistent accreditation decision making.

Overview of Revisions

Structure

- **New name** to reflect the scope and intent of the Standards.
- **New overview** to explain the principles and purpose of the Standards.
- **Re-organization** beginning with Standards applicable to all accredited continuing education, followed by the Standards applicable to education that is commercially supported and education that includes associated marketing by ineligible entities.
- **Policies and definitions** are integrated into the Standards to provide all relevant requirements in one document.
- **Brief introductions** to each Standard, describing its overall purpose and when it is applicable.

New terms

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*. The new term is 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: The term *mitigate* replaces *resolve*, in guidance related to relevant financial relationships to clarify that accredited providers are expected to mitigate the potential effect of these relationships on accredited continuing education. The expectation hasn't changed, only the term used to describe it.

Accredited continuing education: The term *accredited continuing education* replaces *continuing medical education* to be inclusive of all health professions. We include *accredited* to explicitly differentiate between accredited and nonaccredited education providers and education.

Proposed Standards at a Glance

Overview

- Purpose and principles of the Standards.
- Role of accredited continuing education providers in ensuring that accredited education serves the needs of patients.

Eligibility Section

- Updated definitions of organizations that are eligible and ineligible for accreditation.
- Updated lists of organizations that are eligible and ineligible for accreditation.
- Clarification about how corporate structure (parent and subsidiary companies) affects eligibility.

Standard 1: Ensure Content Is Valid

- Incorporates the current CME Clinical Content Validation Policy.
- **New:** Clarifies that education may inform learners *about* approaches that are not generally accepted, but must not advocate for those approaches or teach *how or when* to use them. See Standard 1.4.

Standard 2: Prevent Marketing or Sales in Accredited Continuing Education

- Updates and simplifies the guidance for independence.
- **New:** Prohibits faculty from marketing or selling their products or services. See Standard 2.2.
- **New:** Accredited providers must receive consent from learners before sharing their names or contact information with ineligible entities. See Standard 2.3

Standard 3: Identify, Mitigate, and Disclose Relevant Financial Relationships with Ineligible Entities

- **New:** Accredited providers must collect disclosure information from those in control of content about **all** their financial relationships with ineligible entities. It is the accredited provider's responsibility to determine which relationships are relevant.
- Simplified definition of relevant financial relationships. See Standard introduction and Standard 3.1.
- Clarification that owners or employees of ineligible entities must be excluded from controlling content. Includes exceptions to this exclusion. See Standard 3.2.
- Simplified guidance on identifying, mitigating, and disclosing relevant financial relationships. See Standards 3.3–3.5.
- **New:** When disclosing relevant financial relationships to learners, accredited providers must include a statement that all relevant financial relationships have been mitigated. See Standard 3.5d.
- **New:** Exception for self-directed education, including the role of accredited providers.

Standard 4: Manage Commercial Support Appropriately

- Simplified guidance about decision making and disbursement, agreements, accountability, and disclosure to learners.
- **New:** Accredited providers must pay or reimburse expenses to individuals such as faculty; joint providers cannot make these payments. See Standard 4.1b.

Standard 5: Manage Ancillary Marketing around Accredited Continuing Education

- Simplified, updated guidance about the separation of accredited education and marketing by ineligible entities.
- Clarifies that learners must be able to easily distinguish between accredited education and other activities, such as nonaccredited continuing education and marketing. These other activities must not be interleaved within the accredited education. See Standard 5.2a.



ACCME Standards for Integrity and Independence in Accredited Continuing Education

Draft for Comment – January 2020

The profession of healthcare is not only defined by expertise, but also by a dedication to put service of others above self-interest. When individuals enter the healthcare profession, they commit to upholding professional and ethical standards including acting in a patient's best interests, protecting the patient from harm, respecting the patient, fostering informed choice, and promoting equity in healthcare.

While the interests of healthcare and business sometimes diverge, both are legitimate, and collaboration between healthcare professionals and industry can advance patient care. Since healthcare professionals serve as the legally mandated gatekeepers of medications and devices, and trusted authorities when advising patients, they must protect their own learning environment from industry influence to ensure they remain true to their ethical commitments.

As the stewards of the learning environment for healthcare professionals, the accredited continuing education community plays a critical role in navigating the complex interface between industry and the health professions. Organizations accredited to provide continuing education, known as accredited providers, are responsible for ensuring that healthcare professionals have access to learning and skill development activities that are trustworthy and are based on best practices and high-quality evidence. These activities must serve the needs of patients and not the interests of industry.

This independence is the cornerstone of accredited continuing education. Accredited continuing education must provide healthcare professionals, as individuals and teams, with a protected space to learn, teach, and engage in scientific discourse free from influence from entities that may have an incentive to insert commercial bias into education.

The Accreditation Council for Continuing Medical Education (ACCME®) acts as the steward of the Standards for Integrity and Independence in Accredited Continuing EducationSM, which have been drafted to be applicable to accredited continuing education across the health professions.

The Standards are designed to:

- ensure that accredited continuing education serves the needs of patients and the public;
- present learners with only accurate, balanced, scientifically justified recommendations;
- assure healthcare professionals and teams that they can trust accredited continuing education to help them deliver safe, effective, cost-effective, compassionate care that is based on best practice and evidence; and
- create a clear, unbridgeable separation between accredited continuing education and marketing and sales.

Terms used for the first time are written in *blue italics*, followed by the definition for the term.

Eligibility

The ACCME is committed to ensuring that accredited continuing education (1) presents learners with only accurate, balanced, scientifically justified recommendations, and (2) protects learners from promotion, marketing, and commercial bias. To that end, the ACCME has established the following guidance on the types of entities that may be eligible to be accredited in the ACCME System. The ACCME, in its sole discretion, determines which entities are awarded ACCME accreditation.

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)

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 the planning, delivery, or evaluation of accredited continuing education, except in the limited circumstances outlined in Standard 3.2. Ineligible entities are also prohibited from engaging in *joint providership* with accredited providers. Joint providership enables accredited providers to work with some types of nonaccredited organizations to deliver accredited education.

The ACCME determines eligibility for accreditation based on the characteristics of the entity seeking accreditation and, if applicable, any parent company. Subsidiaries of an ineligible parent company cannot be accredited. If an eligible parent company has an ineligible subsidiary, the owners and employees of the ineligible subsidiary must be excluded from accredited continuing education except in the limited circumstances outlined in Standard 3.2.

Standard 1: Ensure Content is Valid

Standard 1 applies to all accredited continuing education.

Accredited providers are responsible for ensuring that their education supports safe, effective patient care. Recommendations made in accredited continuing education must be accurate, balanced, and scientifically justified.

1. All recommendations involving clinical medicine in accredited education must be scientifically justified and generally accepted within the profession of medicine as appropriate for the care of patients.
2. Accredited education must give a fair and balanced view of diagnostic and therapeutic options.
3. 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, and analysis.
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.
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

Standard 2 applies to all accredited continuing education.

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

1. The accredited provider must ensure that all decisions related to the planning, delivery, and evaluation of accredited education are made without any influence or involvement from the owners and employees of an ineligible entity.
2. Accredited education must be free of marketing or sales of products or services. Faculty must not promote or sell products or services that serve their professional or financial interests during accredited education.
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: Identify, Mitigate, and Disclose Relevant Financial Relationships with Ineligible Entities

Standard 3 applies to all accredited continuing education.

Many healthcare professionals have financial relationships with ineligible entities. 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 entities, 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 entity.

Accredited providers must take the following steps:

- 1. Collect information:** 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. There is no minimum financial threshold; individuals must disclose all financial relationships, regardless of the amount, with ineligible entities. Individuals must disclose regardless of their view of the relevance of the relationship to the education. Individuals must include the known financial relationships of their spouse or partner. Disclosure information must include:
 - a. The name of the ineligible entity with which the person has a financial relationship.
 - b. The nature of the financial relationship. Examples of financial relationships include employee, researcher, consultant, speaker, independent contractor (including contracted research), royalties or patent beneficiary, executive role, and ownership interest. Individual stocks and stock options should be disclosed; diversified mutual funds do not need to be disclosed.
- 2. Exclude owners or employees of ineligible entities:** Review the information about financial relationships to identify individuals who are owners or employees of ineligible entities. These individuals must be excluded from controlling content or participating as planners or faculty in accredited education. There are three exceptions to this exclusion—employees of ineligible entities can participate as planners or faculty in these specific situations:
 - a. when the content of 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.
- 3. 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.

4. **Mitigate relevant financial relationships:** Take steps to prevent all those with relevant financial relationships from inserting commercial bias into content.
 - a. Mitigate relationships prior to the individual assuming their role. Take steps appropriate to the role of the individual. For example, steps for planners will likely be different than for faculty and would occur before planning begins.
 - b. Document the steps taken to mitigate relevant financial relationships.
5. **Disclose all relevant financial relationships to learners:** Disclosure to learners must include each of the following:
 - a. The names of the individuals with relevant financial relationships
 - b. The names of the ineligible entities with which they have relationships
 - c. The nature of the relationships
 - d. A statement that all relevant financial relationships have been mitigatedLearners must receive this information before engaging with the accredited education.

Identify ineligible entities by their name only. Disclosure to learners must not include ineligible entities' corporate or product logos, trade names, or product group messages.

Disclose absence of relevant financial relationships. Inform learners about planners, faculty, and others in control of content (either individually or as a group) with no relevant financial relationships with ineligible entities. Learners must receive this information before engaging with the accredited education.

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

Standard 4 applies only to accredited continuing education that receives financial or in-kind support from ineligible entities.

Accredited providers that choose to accept **commercial support** (defined as financial or in-kind support from ineligible entities) are responsible for ensuring that the education remains independent of the ineligible entity and that the support does not result in commercial bias or commercial influence in the education. The support does not establish a financial relationship between the ineligible entity and planners, faculty, and others in control of content of the education.

1. **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.
 - c. The accredited provider must not use commercial support to pay for travel, lodging,

honoraria, or personal expenses for individuals or groups of learners in accredited education.

- d. The accredited provider may use commercial support to defray or eliminate the cost of the education for *all* learners.
2. **Agreement:** The terms, conditions, and purposes of the commercial support must be documented in an agreement between the ineligible entity and the accredited provider. The agreement must be executed prior to the start of the accredited education.
3. **Accountability:** The accredited provider must keep a record of the amount or kind of commercial support received and how it was used, and must produce that accounting, upon request, for the accrediting body and for the ineligible entity that provided the commercial support.
4. **Disclosure to learners:** The accredited provider must disclose to the learners the name of the ineligible entities that gave the commercial support, and the nature of the support if it was in-kind, prior to the learners engaging in the education. Disclosure must not include the ineligible entities' corporate or product logos, trade names, or product group messages.

Standard 5: Manage Ancillary Marketing around Accredited Continuing Education

Standard 5 applies only when there is marketing by ineligible entities associated with the accredited continuing education.

Accredited providers are responsible for ensuring that education is completely separate from marketing by ineligible entities, including advertising, sales, exhibits, or promotion.

1. 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
2. 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 nonaccredited 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. Learners must not be presented with product promotion or product-specific advertisement while engaged in accredited education and must not be required to interact with representatives of ineligible entities.
 - 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.
 - c. Educational materials that are part of accredited education (such as slides, abstracts, handouts, evaluation mechanisms, or disclosure information) must not contain any marketing produced by or for an ineligible entity, including corporate or product logos, trade names, or product group messages.

- d. 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.
3. Ineligible entities may not provide preferential access to or distribute accredited education to learners.



Proposed Standards for Integrity and Independence in Accredited Continuing Education

Call for Comment

The Accreditation Council for Continuing Medical Education (ACCME®) is pleased to invite you to participate in a call for comment about the proposed revisions to the rules that protect the independence and integrity of accredited continuing education for healthcare professionals.

The proposed **ACCME Standards for Integrity and Independence in Accredited Continuing Education** are based on the feedback we received from the continuing education stakeholder community. Our goal is to streamline, clarify, and modernize the Standards, and to ensure their continued relevance and effectiveness in the changing healthcare environment.

You can review the proposed Standards here, as well as background information, the current Standards and related policies, and the survey questions.

We invite feedback from all stakeholders. All viewpoints are welcome, but please make your comments constructive.

Please complete this survey by February 21, 2020, at 5 PM Central.

Only the items with a star are required. We do not accept anonymous responses; to submit the survey, you will need to provide your contact information at the end.

If you have questions, please contact us at info@accme.org or visit www.accme.org.

Thank you for your participation.

Next



Proposed Standards for Integrity and Independence in Accredited Continuing Education

Eligibility

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate?

- Yes
- No

What modifications do you suggest?

1,500 character limit; about 250 words

Standard 1: Ensure Content is Valid

Is Standard 1 clear as written?

- Yes
- No

What modifications do you suggest?

1,500 character limit; about 250 words

Do you foresee challenges or unintended consequences implementing Standard 1?

- Yes
- No

Please explain.

1,500 character limit; about 250 words

What comments or questions do you have about Standard 1?

1,500 character limit; about 250 words

Standard 2: Prevent Marketing or Sales in Accredited Continuing Education

Is Standard 2 clear as written?

- Yes
- No

What modifications do you suggest?

1,500 character limit; about 250 words

Do you foresee challenges or unintended consequences implementing Standard 2?

- Yes
- No

Please explain.

1,500 character limit; about 250 words

What comments or questions do you have about Standard 2?

1,500 character limit; about 250 words

Standard 3: Identify, Mitigate, and Disclose Relevant Financial Relationships with Ineligible Entities

Is Standard 3 clear as written?

- Yes
- No

What modifications do you suggest?

1,500 character limit; about 250 words

Do you foresee challenges or unintended consequences implementing Standard 3?

- Yes
- No

Please explain.

1,500 character limit; about 250 words

What comments or questions do you have about Standard 3?

1,500 character limit; about 250 words

Standard 4: Manage Commercial Support Appropriately

Is Standard 4 clear as written?

- Yes
- No

What modifications do you suggest?

1,500 character limit; about 250 words

Do you foresee challenges or unintended consequences implementing Standard 4?

- Yes
- No

Please explain.

1,500 character limit; about 250 words

What comments or questions do you have about Standard 4?

1,500 character limit; about 250 words

Standard 5: Manage Ancillary Marketing around Accredited Continuing Education

Is Standard 5 clear as written?

- Yes
- No

What modifications do you suggest?

1,500 character limit; about 250 words

Do you foresee challenges or unintended consequences implementing Standard 5?

- Yes
- No

Please explain.

1,500 character limit; about 250 words

What comments or questions do you have about Standard 5?

1,500 character limit; about 250 words

Additional Feedback

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.

1,500 character limit; about 250 words

Demographic Information

The following information will help us analyze the needs and responses of stakeholders. Your contact information will enable us to follow up with you for additional feedback and to share results with you. We may publish respondent comments, identified only by type of organization. We will not publish respondents' contact information, including names, email addresses, or affiliations. Please note that we do not remove identifying information if it is included in the comments.

* First name

* Last name

* Email

* Organization

Please tell us which of the following describes you or your organization:

- Accredited continuing education provider
- Nonaccredited continuing education provider
- Recognized Accreditor (state/territory medical society)
- Continuing education accrediting body
- Clinician/healthcare professional
- Certifying or licensing board
- Government agency
- Advocacy organization
- Medical/healthcare association
- Patient, caregiver, member of the public
- Ineligible Entity (commercial interest, such as pharmaceutical, device, life-science company)
- Other

Accredited by:

- ACCME
- Recognized Accreditor (state/territory medical society)
- Joint Accreditation for Interprofessional Continuing Education
- Other

Please describe your organizational type:

- Government or military
- Hospital/healthcare delivery system
- Insurance company/managed-care company
- Nonprofit (physician membership organization)
- Nonprofit (other)
- Publishing/education company
- School of medicine
- Other

The ACCME Standards for Commercial Support: Standards to Ensure Independence in CME ActivitiesSM

STANDARD 1: Independence

1.1 A CME provider must ensure that the following decisions were made free of the control of a commercial interest. (See www.accme.org for a definition of a "commercial interest" and some exemptions.)

- (a) Identification of CME needs;
- (b) Determination of educational objectives;
- (c) Selection and presentation of content;
- (d) Selection of all persons and organizations that will be in a position to control the content of the CME;
- (e) Selection of educational methods;
- (f) Evaluation of the activity.

1.2 A commercial interest cannot take the role of non-accredited partner in a joint provider relationship.⌘

STANDARD 2: Resolution of Personal Conflicts of Interest

2.1 The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. The ACCME defines "relevant" financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

2.2 An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

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.⌘

STANDARD 3: Appropriate Use of Commercial Support

3.1 The provider must make all decisions regarding the disposition and disbursement of commercial support.

3.2 A provider cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as conditions of contributing funds or services.

3.3 All commercial support associated with a CME activity must be given with the full knowledge and approval of the provider.

Written agreement documenting terms of support

3.4 The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the provider and its educational partner(s). The agreement must include the provider, even if the support

is given directly to the provider's educational partner or a joint provider.

3.5 The written agreement must specify the commercial interest that is the source of commercial support.

3.6 Both the commercial supporter and the provider must sign the written agreement between the commercial supporter and the provider.

Expenditures for an individual providing CME

3.7 The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.

3.8 The provider, the joint provider, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of-pocket expenses in compliance with the provider's written policies and procedures.

3.9 No other payment shall be given to the director of the activity, planning committee members, teachers or authors, joint provider, or any others involved with the supported activity.

3.10 If teachers or authors are listed on the agenda as facilitating or conducting a presentation or session, but participate in the remainder of an educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their teacher or author role only.

Expenditures for learners

3.11 Social events or meals at CME activities cannot compete with or take precedence over the educational events.

3.12 The provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity. The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, joint provider or educational partner.

Accountability

3.13 The provider must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support. ⌘

STANDARD 4: Appropriate Management of Associated Commercial Promotion

4.1 Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.

4.2 Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring

(printed or electronic advertisements) promotional activities must be kept separate from CME.

- For **print**, advertisements and promotional materials will not be interleaved within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as these materials are not related to the CME content they face **and** are not paid for by the commercial supporters of the CME activity.
- For **computer based CME activities**, advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleaved between computer 'windows' or screens of the CME content. Also, ACCME-accredited providers may not place their CME activities on a Web site owned or controlled by a commercial interest. With clear notification that the learner is leaving the educational Web site, links from the Web site of an ACCME accredited provider to pharmaceutical and device manufacturers' product Web sites are permitted before or after the educational content of a CME activity, but shall not be embedded in the educational content of a CME activity. Advertising of any type is prohibited within the educational content of CME activities on the Internet including, but not limited to, banner ads, subliminal ads, and pop-up window ads.
- For **audio and video recording**, advertisements and promotional materials will not be included within the CME. There will be no 'commercial breaks.'
- For **live, face-to-face** CME, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Providers cannot allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CME activity.
- For **Journal-based CME**, None of the elements of journal-based CME can contain any advertising or product group messages of commercial interests. The learner must not encounter advertising within the pages of the article or within the pages of the related questions or evaluation materials.

4.3 Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, corporate logo, trade name or a product-group message of an ACCME-defined commercial interest.

4.4 Print or electronic information distributed about the non-CME elements of a CME activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions, may include product-promotion material or product-specific advertisement.

4.5 A provider cannot use a commercial interest as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities. ⌘

STANDARD 5: Content and Format without Commercial Bias

5.1 The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.

5.2 Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company. ⌘

STANDARD 6: Disclosures Relevant to Potential Commercial Bias

Relevant financial relationships of those with control over CME content

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);
- The nature of the relationship the person has with each commercial interest.

6.2 For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

Commercial support for the CME activity

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.

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.

Timing of disclosure

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



ACCME Policy

Definition of a Commercial Interest

A *commercial interest* is 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.

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:

- 501-C Non-profit organizations (Note, ACCME screens 501c organizations for eligibility. Those that advocate for commercial interests as a 501c organization are not eligible for accreditation in the ACCME system. They cannot serve in the role of joint provider, but they can be a commercial supporter.)
- 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

ACCME reserves the right to modify this definition and this list of eligible organizations from time to time without notice.



ACCME Policy

Clinical Content Validation

Accredited providers are responsible for validating the clinical content of CME activities that they provide. Specifically,

1. All the recommendations involving clinical medicine in a CME activity must be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients.
2. All scientific research referred to, reported, or used in CME in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection and analysis.
3. Providers are not eligible for ACCME accreditation or reaccreditation if they present activities that 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. An organization whose program of CME is devoted to advocacy of unscientific modalities of diagnosis or therapy is not eligible to apply for ACCME accreditation.



ACCME Policy

Financial Relationships and Conflicts of Interest

Financial relationships are 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 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.

The ACCME has not set a minimum dollar amount for relationships to be significant. Inherent in any amount is the incentive to maintain or increase the value of the relationship.

With respect to personal **financial relationships**, *contracted research* includes research funding where the institution gets the grant and manages the funds and the person is the principal or named investigator on the grant.

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 **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 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.

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.