Accreditation Council[®] for Continuing Medical Education *learn well*

Call For Feedback Protecting the Integrity and Independence of Accredited Continuing Education

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Call for Feedback

Protecting the Integrity and Independence of Accredited Continuing Education

The Accreditation Council for Continuing Medical Education (ACCME®) is pleased to open a call for feedback to review the rules that protect the independence and integrity of accredited continuing education (CE) for healthcare professionals. The initiative supports the ACCME's <u>strategic goal</u> to assure the quality of accreditation and seeks to be responsive to stakeholders who have identified potential improvements over the past several years.

Independence is the cornerstone of accredited CE: First adopted in 1992 and updated in 2004, the <u>ACCME Standards for Commercial Support</u>: <u>Standards to Ensure Independence in CME</u> <u>Activities[™] (the Standards)</u> are designed to create a clear, unbridgeable separation between accredited CE and industry marketing and to ensure that accredited CE serves the needs of patients and the public.

This survey seeks your perspective about new and existing challenges to the independence of accredited CE and your recommendations about potential revisions to the Standards that will ensure their continued relevance and effectiveness.

This information package includes the Standards and related policies, as well as the survey questions, to enable you and your stakeholders to review the materials before submitting comments. More information is available on our <u>website</u>.

Please complete our survey by March 8, 2019 at 5 PM Central.

We welcome all perspectives and look forward to engaging with you. Our goal is to work together to create strategies for maximizing our ability to safeguard independence, maintain the credibility of accredited CE, and continue to demonstrate our accountability to the health professions and the public.

If you have questions, please contact info@accme.org.

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 <u>www.accme.org</u> 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 nonaccredited 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. **X**

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

Call for Feedback: Protecting the Integrity and Independence of Accredited Continuing Education Page 3 of 14 798_ 20190122 (printed or electronic advertisements) promotional activities must be kept separate from CME.

- For **print**, advertisements and promotional materials will not be interleafed 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 <u>and</u> 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 interleafed between computer 'windows' or screens of the CME content. Also, ACCMEaccredited 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 andpromotional 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

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.



The Accreditation Council for Continuing Medical Education (ACCME[®]) is pleased to invite you to participate in a review of the rules that protect the independence and integrity of accredited continuing education (CE) for healthcare professionals.

This survey seeks your perspective about new and existing challenges to the independence of accredited CE, and your suggestions about potential revisions to the ACCME Standards for Commercial Support: Standards to Ensure Independence in CME Activities[™] (the Standards) and related policies that will ensure their continued relevance and effectiveness.

Your feedback will be most impactful if you provide specific observations and recommendations.

Please complete this survey by March 8, 2019 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.

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.

More information about the call for feedback is available here.

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

Thank you for your participation.

Start Survey

Standard 1: Independence

Review Standard 1 here.

What new or existing challenges have you seen related to the separation of accredited CE from commercial influence that the ACCME should address? (1,500 character limit; about 250 words)

Describe ways in which the ACCME should modernize the requirements about the independence of accredited CE from commercial influence to reflect the changing healthcare environment. (1,500 character limit; about 250 words)

Standard 2: Resolution of Personal Conflicts of Interest

Review Standard 2 here.

What new or existing challenges have you seen related to the identification and resolution of conflicts of interest in accredited CE that the ACCME should address? (1,500 character limit; about 250 words)

Describe ways in which the ACCME should modernize the requirements about identification and resolution of personal conflicts of interest to reflect the changing healthcare environment. (1,500 character limit; about 250 words)

Standard 3: Appropriate Use of Commercial Support

Review Standard 3 here.

What new or existing challenges have you seen related to the appropriate management of commercial support of accredited CE that the ACCME should address? (1,500 character limit; about 250 words)

Describe ways in which the ACCME should modernize the requirements about appropriate management of commercial support of accredited CE to reflect the changing healthcare environment. (1,500 character limit; about 250 words)

Standard 4: Appropriate Management of Associated Commercial Promotion

Review Standard 4 here.

What new or existing challenges have you seen related to the appropriate management of associated commercial promotion that the ACCME should address? (1,500 character limit; about 250 words)

Describe ways in which the ACCME should modernize the requirements about appropriate management of associated commercial promotion to reflect the changing healthcare environment. (1,500 character limit; about 250 words)

Standard 5: Content and Format without Commercial Bias

Review Standard 5 here.

What new or existing challenges have you seen related to accredited CE content and format without commercial bias that the ACCME should address? (1,500 character limit; about 250 words)

Describe ways in which the ACCME should modernize the requirements about accredited CE content and format without commercial bias to reflect the changing healthcare environment. (1,500 character limit; about 250 words)

Standard 6: Disclosures Relevant to Potential Commercial Bias

Review Standard 6 here.

What new or existing challenges have you seen related to disclosures relevant to potential commercial bias in accredited CE that the ACCME should address? (1,500 character limit; about 250 words)

Describe ways in which the ACCME should modernize the requirements about disclosures relevant to potential commercial bias in accredited CE to reflect the changing healthcare environment. (1,500 character limit; about 250 words)

Policies Supplementing the Standards for Commercial Support: Standards to Ensure Independence in CME Activities[™]

ACCME Policy: Definition of a Commercial Interest

Current definition: 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. Review the complete policy here.

What new or existing challenges have you seen related to the ACCME definition of a commercial interest that the ACCME should address? (1,500 character limit; about 250 words)

Should the ACCME definition of a commercial interest be:

- Expanded
- Narrowed
- Unchanged

Please explain. (1,500 character limit; about 250 words)

Should the <u>list of organizations</u> that are not defined as commercial interests and therefore are eligible for accreditation be modified?

○ Yes

○ No

Please explain. (1,500 character limit; about 250 words)

ACCME Policy: Financial Relationships and Conflicts of Interest

Review the policy here.

What new or existing challenges have you seen related to the ACCME policy on financial relationships and conflicts of interest that an evolved policy should address? (1,500 character limit; about 250 words)

Should the ACCME definition of financial relationships and conflicts of interest be:

- Expanded
- Narrowed
- Unchanged

Please explain. (1,500 character limit; about 250 words)

Additional Feedback

Are there additional standards or policies that would help to ensure that accredited CE remains independent of commercial influence and free of promotion and marketing activities? (1,500 character limit; about 250 words)

Are there modifications to the construct and organization of the Standards that would be helpful in ensuring independence? (1,500 character limit; about 250 words)

Do you have recommendations for literature or research that we should review when considering changes to the Standards? (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.

*Please enter the following information:

*First name	
*Last name	
*Email	
*Organization	

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

Accredite	ad CE	provider
		provider

- Nonaccredited CE provider
- Recognized Accreditor (state/territory medical society)
- CE accreditor
- O Clinician/healthcare professional
- Certifying or licensing board
- Government agency
- Advocacy organization
- O Medical/healthcare association
- O Patient, caregiver, member of the public
- O Commercial interest (e.g., pharmaceutical, device, life-science company)
- Other

*Accredited by:

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- Recognized Accreditor (state/territory medical society)
- O 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)
- O Nonprofit (other)
- Publishing/education company
- O School of medicine
- Other