

New Terms	Notes
<p><b>Eligible entities:</b> Organizations that are eligible for accreditation in the ACCME System.</p>	
<p><b>Ineligible entities:</b> 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.</p>	
<p><b>Mitigate:</b> 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.</p>	
<p><b>Accredited continuing education:</b> 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.</p>	

## 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.

Eligible Entities		Notes
<p>Types of Organizations That May Be Accredited in the ACCME System</p> <p><b>Eligible Entities:</b> 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:</p>		
<ul style="list-style-type: none"> <li>• Ambulatory procedure centers</li> <li>• Blood banks</li> <li>• Diagnostic labs (that do not sell proprietary products)</li> <li>• Electronic health records companies</li> <li>• Government or military agencies</li> <li>• Group medical practices</li> <li>• Technology or data management companies (non-health related)</li> <li>• Health law firms</li> <li>• Health profession membership organizations</li> </ul>	<ul style="list-style-type: none"> <li>• Hospitals or healthcare delivery systems</li> <li>• Infusion centers</li> <li>• Insurance or managed care companies</li> <li>• Nonprofit organizations</li> <li>• Nursing homes</li> <li>• Pharmacies</li> <li>• Publishing or education companies</li> <li>• Software or game developers</li> <li>• Rehabilitation centers</li> <li>• Schools of medicine or health science universities</li> </ul>	

Ineligible Entities		Notes
<p style="text-align: center;">Types of Organizations That Cannot Be Accredited in the ACCME System</p> <p><b>Ineligible Entities:</b> 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:</p>		
<ul style="list-style-type: none"> <li>• Advertising, marketing, or communication firms (whose clients are ineligible entities)</li> <li>• Bio-medical startups (that have begun an approval process through the FDA)</li> <li>• Compounding pharmacies (that manufacture proprietary compounds)</li> <li>• Device manufacturers or distributors</li> </ul>	<ul style="list-style-type: none"> <li>• Diagnostic labs (that market or sell proprietary products)</li> <li>• Growers, distributors, or sellers of medical foods and dietary supplements</li> <li>• Pharmaceutical companies or distributors</li> <li>• Pharmacy benefit managers</li> <li>• Reagent manufacturers/sellers</li> <li>• Manufacturers of health-related wearable products</li> </ul>	

Current Standards	New Proposed Standards	Summary of Proposed Standards	Notes
<p><b>STANDARD 1.1</b> A CME provider must ensure that the following decisions were made free of the control of a commercial interest. (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.</p> <p><b>STANDARD 1.2</b> A commercial interest cannot take the role of non-accredited partner in a joint provider relationship.</p>	<p><b>Standard 1: Ensure Content is Valid</b></p> <p>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.</p> <ol style="list-style-type: none"> <li>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.</li> <li>2. Accredited education must give a fair and balanced view of diagnostic and therapeutic options.</li> <li>3. All scientific research referred to, reported, or used in accredited education in support or</li> </ol>	<p><b>Standard 1: Ensure Content Is Valid</b></p> <ul style="list-style-type: none"> <li>• Incorporates the current CME Clinical Content Validation Policy.</li> <li>• 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.</li> </ul>	

	<p>justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection, and analysis.</p> <p>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.</p> <p>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.</p>		
<p><b>STANDARD 2.1</b> The provider must be able to show that everyone who is in a position to control the content of an education activity has</p>	<p>Standard 2: Prevent Marketing or Sales in Accredited Continuing Education Standard 2 applies to all accredited continuing education.</p>	<p>Standard 2: Prevent Marketing or Sales in Accredited Continuing Education</p> <ul style="list-style-type: none"> <li>• Updates and simplifies the guidance for independence.</li> </ul>	

<p>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.</p> <p><b>STANDARD 2.2</b> 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.</p> <p><b>STANDARD 2.3</b> The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.</p>	<p>Accredited continuing education must protect learners from marketing and commercial bias.</p> <p>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.</p>	<ul style="list-style-type: none"> <li>• New: Prohibits faculty from marketing or selling their products or services. See Standard 2.2.</li> <li>• New: Accredited providers must receive consent from learners before sharing their names or contact information with ineligible entities. See Standard 2.3</li> </ul>	
<p><b>STANDARD 3.1</b> The provider must make all decisions regarding the</p>	<p>Standard 3: Identify, Mitigate, and Disclose Relevant Financial Relationships with Ineligible</p>	<p>Standard 3: Identify, Mitigate, and Disclose Relevant Financial Relationships with</p>	

<p>disposition and disbursement of commercial support.</p> <p><b>STANDARD 3.2</b> 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.</p> <p><b>STANDARD 3.3</b> All commercial support associated with a CME activity must be given with the full knowledge and approval of the provider.</p> <p><b>STANDARD 3.4</b> 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.</p>	<p>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</p>	<p>Ineligible Entities</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Simplified definition of relevant financial relationships. See Standard introduction and Standard 3.1.</li> <li>• Clarification that owners or employees of ineligible entities must be excluded from controlling content. Includes exceptions to this exclusion. See Standard 3.2.</li> <li>• Simplified guidance on identifying, mitigating, and disclosing relevant financial relationships. See Standards 3.3–3.5.</li> <li>• 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.</li> </ul>	
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<p>STANDARD 3.5 The written agreement must specify the commercial interest that is the source of commercial support.</p> <p>STANDARD 3.6 Both the commercial supporter and the provider must sign the written agreement between the commercial supporter and the provider.</p> <p>STANDARD 3.7 The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.</p> <p>STANDARD 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.</p> <p>STANDARD 3.9</p>	<p>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</p>	<ul style="list-style-type: none"> <li>• New: Exception for self-directed education, including the role of accredited providers.</li> </ul>	
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<p>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.</p> <p><b>STANDARD 3.10</b> 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.</p> <p><b>STANDARD 3.11</b> Social events or meals at CME activities cannot compete with or take precedence over the educational events.</p> <p><b>STANDARD 3.12</b> 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</p>	<p>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. Call for Comment: Standards for Integrity and Independence in</p>		
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<p>travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, joint provider or educational partner.</p> <p><b>STANDARD 3.13</b> The provider must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support.</p>	<p>Accredited Continuing Education Page 14 of 28 833_20200106 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 mitigated Learners must receive this information before engaging with the accredited education. Identify ineligible</p>		
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	<p>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 selfdirected learner, they should direct learners only to resources and methods for learning that</p>		
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	are not controlled by ineligible entities.		
<p>STANDARD 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.</p> <p>STANDARD 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.</p> <p>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</p>	<p>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</p>	<p>Standard 4: Manage Commercial Support Appropriately</p> <ul style="list-style-type: none"> <li>• Simplified guidance about decision making and disbursement, agreements, accountability, and disclosure to learners.</li> <li>• New: Accredited providers must pay or reimburse expenses to individuals such as faculty; joint providers cannot make these payments. See Standard 4.1b.</li> </ul>	

<p>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,</p>	<p>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, Call for Comment: Standards for Integrity and Independence in Accredited Continuing Education Page 15 of 28 833_20200106 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</p>		
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<p>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.  <b>STANDARD 4.3</b>  Educational materials that are part of a CME activity, such as slides, abstracts and handouts,</p>	<p>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.</p>		
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<p>cannot contain any advertising, corporate logo, trade name or a product-group message of an ACCME-defined commercial interest.</p> <p><b>STANDARD 4.4</b> 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.</p> <p><b>STANDARD 4.5</b> 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.</p>			
<p><b>STANDARD 5.1</b> 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.</p>	<p>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</p>	<p>Standard 5: Manage Ancillary Marketing around Accredited Continuing Education</p> <ul style="list-style-type: none"> <li>• Simplified, updated guidance about the separation of accredited education and marketing by ineligible entities.</li> </ul>	

<p><b>STANDARD 5.2</b> 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.</p>	<p>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-</p>	<ul style="list-style-type: none"> <li>• 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.</li> </ul>	
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	<p>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</p>		
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	not provide preferential access to or distribute accredited education to learners.		
<p><b>STANDARD 6.1</b> 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.</p> <p><b>STANDARD 6.2</b> For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.</p> <p><b>STANDARD 6.3</b> 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.</p> <p><b>STANDARD 6.4</b> Disclosure must never include the use of a corporate logo, trade name or a product-group</p>			

message of an ACCME-defined commercial interest.			
STANDARD 6.5 A provider must disclose the above information to learners prior to the beginning of the educational activity.			