

## The Accreditation Requirements and Descriptions of the **Accreditation Council for** Continuing Medical Education (ACCME)

#### **Updated February 2014**

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## NOTE FOR THE FEBRUARY 2014 EDITION

#### SIMPLIFICATION

We have updated this document to reflect the simplification changes adopted by the ACCME in February 2014. These changes include the simplification and elimination of some of the requirements.

#### INTEGRATION

We have incorporated several operational policies and the annual report glossary here, so that all accreditation requirements are in one document, for your convenience. There are **no new requirements**.

#### ACCREDITATION CRITERIA

Criterion 1 has been simplified. Criteria 4, 14, and 15 have been eliminated. The criteria that have been eliminated are noted in **red**. To avoid confusion, the numbering of the criteria has not changed.

#### STANDARDS FOR COMMERCIAL SUPPORT

Standard 4.2 incorporates the requirements related to Internet CME and journal-based CME that previously were included in the policies. These changes are noted in **blue**.

#### TERMINOLOGY

We have replaced the term "joint sponsorship" with "joint providership" throughout the requirements, including in the Standards for Commercial Support and in the Accreditation Statement Policy. We replaced the term "Essentials" in the accreditation statement with the term "accreditation requirements."

#### **POLICIES**

#### CME Program and Activity Administration

The Organizational Mission and Framework Policy has been eliminated.

The CME Program and Activity Administration section now includes the following policies which were moved from other requirements into this document:

- English As Official Language for Accreditation and Recognition Procedures
- HIPAA Compliance Attestation
- Administrative Deadlines

This section also includes the following policy which was moved from the Enduring Materials Policy, so that it now accompanies other policy related to content validation.

• Content Validity of Enduring Materials

#### CMF ACTIVITY TYPES

This CME Activity Types section in the policies has been eliminated. Some of the special requirements for Internet CME, enduring materials, regularly scheduled series, and journal I-based CME, were eliminated as part of the simplification process. The remaining requirements related to the Standards for Commercial Support and therefore have been incorporated into the Standards, as described above. Previously, these policies also included descriptions of these activity types. These are not requirements—but rather, ACCME descriptions, used by accredited providers for annual reporting. The ACCME incorporates these descriptions into the annual reports to present the diversity of accredited CME. We have Incorporated these descriptions into our annual report glossary, which is now included in this document.

#### **Annual Report Glossary**

The annual report glossary includes descriptions of CME activity types that previously were included in the policies, as well as other explanations and descriptions related to annual reporting. This glossary is also published in the annual reports.

## ACCREDITATION CRITERIA

The Accreditation Criteria are divided into three levels. To achieve Provisional Accreditation, a two year term, providers must comply with Criteria 1, 2, 3, and 7–12. Providers seeking full Accreditation or reaccreditation for a four-year term must comply with Criteria 1–13. To achieve Accreditation with Commendation, a six-year term, providers must comply with all Criteria.

<u>Criterion 1</u> The provider has a CME mission statement that includes expected results articulated in terms of changes in competence, performance, or patient outcomes that will be the result of the program.

<u>Criterion 2</u> The provider incorporates into CME activities the educational needs (knowledge, competence, or performance) that underlie the professional practice gaps of their own learners.

<u>Criterion 3</u> The provider generates activities/educational interventions that are designed to change competence, performance, or patient outcomes as described in its mission statement.

**Criterion 4** This criterion has been eliminated effective February 2014.

<u>Criterion 5</u> The provider chooses educational formats for activities/interventions that are appropriate for the setting, objectives, and desired results of the activity.

<u>Criterion 6</u> The provider develops activities/educational interventions in the context of desirable physician attributes [eg, Institute of Medicine (IOM) competencies, Accreditation Council for Graduate Medical Education (ACGME) Competencies].

<u>Criterion 7</u> The provider develops activities/educational interventions independent of commercial interests. (SCS 1, 2, and 6).

<u>Criterion 8</u> The provider appropriately manages commercial support (if applicable, SCS 3 of the ACCME Standards for Commercial Support<sup>SM</sup>).

<u>Criterion 9</u> The provider maintains a separation of promotion from education (SCS 4).

<u>Criterion 10</u> The provider actively promotes improvements in health care and NOT proprietary interests of a commercial interest (SCS 5).

<u>Criterion 11</u> The provider analyzes changes in learners (competence, performance, or patient outcomes) achieved as a result of the overall program's activities/educational interventions.

<u>Criterion 12</u> The provider gathers data or information and conducts a program-based analysis on the degree to which the CME mission of the provider has been met through the conduct of CME activities/educational interventions.

<u>Criterion 13</u> The provider identifies, plans and implements the needed or desired changes in the overall program (eg, planners, teachers, infrastructure, methods, resources, facilities, interventions) that are required to improve on ability to meet the CME mission.

**Criterion 14** This criterion has been eliminated effective February 2014.

Criterion 15 This criterion has been eliminated effective February 2014.

#### ACCREDITATION WITH COMMENDATION

<u>Criterion 16</u> The provider operates in a manner that integrates CME into the process for improving professional practice.

<u>Criterion 17</u> The provider utilizes non-education strategies to enhance change as an adjunct to its activities/educational interventions (e.g., reminders, patient feedback).

<u>Criterion 18</u> The provider identifies factors outside the provider's control that impact on patient outcomes.

<u>Criterion 19</u> The provider implements educational strategies to remove, overcome or address barriers to physician change.

<u>Criterion 20</u> The provider builds bridges with other stakeholders through collaboration and cooperation.

<u>Criterion 21</u> The provider participates within an institutional or system framework for quality improvement.

<u>Criterion 22</u> The provider is positioned to influence the scope and content of activities/educational interventions.

# STANDARDS FOR COMMERCIAL SUPPORT: STANDARDS TO ENSURE INDEPENDENCE IN CME ACTIVITIES

#### STANDARD 1: INDEPENDENCE

STANDARD 1.1 A CME provider must ensure that the following decisions were made free of the control of a commercial interest. (Seethe Policies Supplementing the Standards for Commercial Support 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.

STANDARD 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

STANDARD 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.

STANDARD 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.

STANDARD 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

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

STANDARD 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.

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

STANDARD 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.

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

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

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.

*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.

STANDARD 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.

STANDARD 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.

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

STANDARD 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.

STANDARD 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

*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.

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.

• 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 and are not paid for by the commercial supporters of the CME activity.

- For computer based, 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. (Supplemented February 2014; the information in blue previously appeared in ACCME policies. No changes have been made to the language.) 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 computer based CME activities, advertisements and promotional materials may 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.
- 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.
- (Supplemented, February 2014; the information in blue previously appeared in ACCME policies. No
  changes have been made to the language.) 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.

STANDARD 4.3 Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or a product-group message.

*STANDARD 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.

STANDARD 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

*STANDARD* 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.

*STANDARD* 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

*STANDARD 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.

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

STANDARD 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.

STANDARD 6.4 'Disclosure' must never include the use of a trade name or a product-group message.

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

## **ACCME** POLICIES

The ACCME issues policies that supplement the ACCME Criteria and Standards for Commercial Support. Accredited providers must adhere to the ACCME policies that are relevant to their organizations, as well as to the Accreditation Criteria and the ACCME Standards for Commercial Support.

ACCME Notes, which provide explanatory information about the policies, and other educational resources are available at <a href="https://www.accme.org">www.accme.org</a>.

#### **ACCME GOVERNANCE**

#### Public and Confidential Information about Accredited Providers

The following information is considered *public information*, and therefore may be released by the ACCME. Public information includes certain information about accredited providers, and ACCME reserves the right to publish and release to the public, including on the ACCME Web site, all public information:

- 1. Names and contact information for accredited providers;
- 2. Accreditation status of provider;
- 3. Some annual report data submitted by the accredited provider, including for any given year:
  - Number of activities;
  - Number of hours of education;
  - Number of physician participants;
  - Number of nonphysician participants;
  - Accepts commercial support (yes or no);
  - Accepts advertising/exhibit revenue (yes or no);
  - Participates in joint providership (yes or no);
  - Types of activities produced (list)

Note: The ACCME will <u>not</u> release any dollar amounts reported by individual accredited providers for income, expenses, commercial support, or advertising/exhibits.

- 4. Aggregated accreditation finding and decision data broken down by provider type;
- 5. Responses to public calls for comment initiated by the ACCME;
- 6. Executive summaries from the ACCME Board of Directors' Meetings (exclusive of actions taken during executive session); and

7. Any other data/information that ACCME believes qualifies as "public information."

The ACCME will maintain as *confidential information*, except as required for ACCME accreditation purposes, or as may be required by legal process, or as otherwise authorized by the accredited provider to which it relates:

- 1. To the extent not described as public information above, information submitted to the ACCME by the provider during the initial or reaccreditation decision-making processes for that provider;
- 2. Correspondence to and from ACCME relating to the accreditation process for a provider; and
- 3. ACCME proceedings (e.g., Board minutes, transcripts) relating to a provider, other than the accreditation outcome of such proceedings.

In order to protect confidential information, ACCME and its volunteers are required:

- 1. Not to make copies of, disclose, discuss, describe, distribute or disseminate in any manner whatsoever, including in any oral, written, or electronic form, any confidential information that the ACCME or its volunteers receive or generate, or any part of it, except directly for the accreditation or complaint/inquiry decision-making purposes;
- 2. Not to use such confidential information for personal or professional benefit, or for any other reason, except directly for ACCME purposes.

#### RULE-MAKING POLICY

- 1. The notice and comment procedures utilized by ACCME for the adoption of rules and policies that directly impact members and accredited providers (the "Notice and Comment Procedures") shall not apply to matters relating to internal ACCME structure, management, personnel or business policy/practices.
  - a. The Notice and Comment Procedures will only apply to matters which directly and materially impact the ability of accredited providers to conduct business.
  - b. The ACCME, in its sole discretion, will assess if any particular rule or policy will be subject to the Notice and Comment Procedures.
- 2. If the ACCME decides to seek and accept public comment or input, then the ACCME will publish the proposed rule or policy on its website and state that interested persons have an opportunity to submit written data, views, or arguments with or without opportunity for oral presentation.
- 3. If the ACCME decides to seek and accept public comment or input, then at least 30 days will be given to provide that comment or input; provided, however, that if the ACCME determines that there is a pressing need for issuance of a rule or policy on an expedited basis, the ACCME may either shorten or eliminate the period of time during which public comments may be submitted.

- 4. After any period for public comment, the proposed rule or policy will be submitted to the AC-CME Board of Directors. The ACCME Board of Directors may modify, reject, defer, and/or adopt the proposed rule or policy. Subject to the rights of ACCME Members contained in Article III, Section 2(c) of the ACCME Bylaws, the decision of the ACCME Board of Directors shall be final and there shall be no appeal there from.
- 5. The final rule or policy as approved by the ACCME Board of Directors will be posted on the ACCME website, which will include an effective date for the final rule or policy.

#### CME PROGRAM AND ACTIVITY ADMINISTRATION

ORGANIZATIONAL MISSION AND FRAMEWORK This policy has been eliminated effective February 2014.

#### CME Program Business and Management Procedures

The accredited provider must operate the business and management policies and procedures of its CME program (as they relate to human resources, financial affairs, and legal obligations), so that its obligations and commitments are met.

### ENGLISH AS OFFICIAL LANGUAGE FOR ACCREDITATION AND RECOGNITION PROCEDURES

ACCME conducts its affairs in English. ACCME standards do not require that providers or accreditors conduct all their business or continuing medical education in English. However ACCME does require that.

- 1. All written or electronic communications or correspondence with ACCME (irrespective of medium) is in English.
- 2. Any application and/or self-study reports for accreditation or recognition be submitted to ACCME in English.
- 3. ACCME is provided with English translations of any written materials requested by ACCME in the course of its accreditation, recognition, or monitoring process.
- 4. Any ACCME interview for accreditation or recognition be conducted in English, or have the services of an English translator, acceptable to ACCME, provided and paid for by the applicant organization.

#### HIPAA COMPLIANCE ATTESTATION

Every provider applying for either for initial accreditation or reaccreditation must attest to the following:

"The materials we submit for reaccreditation (self-study report, activity files, other materials) will not include individually identifiable health information, in accordance with the Health Insurance Portability and Accountability Act (HIPAA), as amended."

#### **ACCREDITATION STATEMENT**

The accreditation statement must appear on all CME activity materials and brochures distributed by accredited organizations, except that the accreditation statement does not need to be included on initial, save-the-date type activity announcements. Such announcements contain only general, preliminary information about the activity such as the date, location, and title. If more specific information is included, such as faculty and objectives, the accreditation statement must be included.

The ACCME accreditation statement is as follows:

For directly provided activities: "The (name of accredited provider) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians."

For jointly provided activities: "This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of (name of accredited provider) and (name of nonaccredited provider). The (name of accredited provider) is accredited by the ACCME to provide continuing medical education for physicians."

There is no "co-providership" accreditation statement. If two or more accredited providers are working in collaboration on a CME activity, one provider must take responsibility for the compliance of that activity. Co-provided CME activities should use the directly provided activity statement, naming the one accredited provider that is responsible for the activity. The ACCME has no policy regarding specific ways in which providers may acknowledge the involvement of other ACCME-accredited providers in their CME activities.

#### CME CONTENT: DEFINITION AND EXAMPLES

Continuing medical education consists of educational activities which serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, the public, or the profession. The content of CME is that body of knowledge and skills generally recognized and accepted by the profession as within the basic medical sciences, the discipline of clinical medicine, and the provision of health care to the public.

#### CME 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.

#### CONTENT VALIDITY OF ENDURING MATERIALS

Providers that produce enduring materials must review each enduring material at least once every three years or more frequently if indicated by new scientific developments. So, while providers can review and re-release an enduring material every three years (or more frequently), the enduring material cannot be offered as an accredited activity for more than three years without some review on the part of the provider to ensure that the content is still up-to-date and accurate. That review date must be included on the enduring material, along with the original release date and a termination date.

## CME CONTENT AND THE AMERICAN MEDICAL ASSOCIATION PHYSICIAN'S RECOGNITION AWARD

All CME educational activities developed and presented by a provider accredited by the ACCME system and associated with AMA PRA Category 1 Credit™ must be developed and presented in compliance with all ACCME accreditation requirements - in addition to all the requirements of the AMA PRA program. All activities so designated for, or awarded, credit will be subject to review by the ACCME accreditation process as verification of fulfillment of the ACCME accreditation requirements.

#### CME ACTIVITY AND ATTENDANCE RECORDS RETENTION

- 1. Attendance Records: An accredited provider must have mechanisms in place to record and, when authorized by the participating physician, verify participation for **six years** from the date of the CME activity. The accredited provider is free to choose whatever registration method works best for their organization and learners. The ACCME does not require sign-in sheets.
- 2. Activity Documentation: An accredited provider is required to retain activity files/records of CME activity planning and presentation during the current accreditation term or for the last twelve months, whichever is longer.

#### ADMINISTRATIVE DEADLINES

ACCME-accredited providers and Recognized Accreditors are accountable for meeting ACCME administrative deadlines. Failure to meet ACCME administrative deadlines could result in (a) an immediate change of status to Probation, and (b) subsequent consideration by the Board of Directors for a change of status to Nonaccreditation or Nonrecognition.

#### FEES FOR ACCME-ACCREDITED PROVIDERS

ACCME-accredited providers are accountable for timely submission of fees that are required either to attain or maintain accreditation. Failure to meet ACCME deadlines could result in an immediate change of status to Probation, and subsequent consideration by the Board of Directors for a change of status to Nonaccreditation. For a list of current fees and related information, see the <a href="ACCME-accredited provider fee schedule">ACCME-accredited provider fee schedule</a>.

#### ACCME LOGO USAGE

ACCME and the ACCME logo are service marks of the Accreditation Council for Continuing Medical Education. These service marks may be used publicly only with the permission of ACCME.

ACCME-accredited providers, ACCME recognized state medical societies, and intrastate accredited providers have permission to use the ACCME logo for educational and identification purposes. ACCME-accredited providers may also use the logo in <u>announcements</u> related to their attainment of ACCME accreditation.

ACCME Logo, Color

ACCME Logo, Black & White

#### JOINT PROVIDERSHIP

The ACCME defines joint providership as the providership of a CME activity by one accredited and one nonaccredited organization. Therefore, ACCME accredited providers that plan and present one or more activities with non-ACCME accredited providers are engaging in "joint providership." Please note: the ACCME does not intend to imply that a joint providership relationship is an actual legal partnership. Therefore, the ACCME does not include the words partnership or partners in its definition of joint providership or description of joint providership requirements.

The accredited provider must take responsibility for a CME activity when it is presented in cooperation with a nonaccredited organization and must use the appropriate accreditation statement.

#### INFORMING LEARNERS

The accredited provider must inform the learner of the joint providership relationship through the use of the appropriate <u>accreditation statement</u>. All printed materials for jointly provided activities must carry the appropriate accreditation statement.

"This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of (name of accredited provider) and (name of nonaccredited provider). The (name of accredited provider) is accredited by the ACCME to provide continuing medical education for physicians." — ACCME Accreditation Statement Policy

#### **FFFS**

The ACCME maintains no policy that requires or precludes accredited providers from charging a joint providership fee.

#### COMPLIANCE AND NONCOMPLIANCE ISSUES

The ACCME expects <u>all</u> CME activities to be in compliance with the accreditation requirements. In cases of joint providership, it is the ACCME accredited provider's responsibility to be able to demonstrate through written documentation this compliance to the ACCME. Materials submitted that demonstrate compliance may be from either the ACCME accredited provider's files or those of the nonaccredited provider.

#### PROVIDERS ON PROBATION

If a provider is placed on Probation, it may not jointly provide CME activities with nonaccredited providers, with the exception of those activities that were contracted prior to the Probation decision. A provider that is placed on Probation must inform the ACCME of all existing joint providership relationships, and must notify its current contracted joint providers of its probationary status.

#### POLICIES SUPPLEMENTING THE STANDARDS FOR COMMERCIAL SUPPORT

#### 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.

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.

#### 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.

#### Disclosure of Financial Relationships to the Accredited Provider

Individuals need to disclose relationships with a commercial interest if both (a) the relationship is financial and occurred within the past 12 months and (b) the individual has the opportunity to affect the content of CME about the products or services of that commercial interest.

## COMMERCIAL SUPPORT: DEFINITION AND GUIDANCE REGARDING WRITTEN AGREEMENTS

**Commercial Support** is financial, or in-kind, contributions given by a commercial interest which is used to pay all or part of the costs of a CME activity.

When there is commercial support there must be a written agreement that is signed by the commercial interest and the accredited provider <u>prior</u> to the activity taking place.

An accredited provider can fulfill the expectations of SCS 3.4 - 3.6 by adopting a previously executed agreement between an accredited provider and a commercial supporter and indicating in writing their acceptance of the terms and conditions specified and the amount of commercial support they will receive.

A provider will be found in Noncompliance with SCS 1.1 and SCS 3.2 if the provider enters into a commercial support agreement where the commercial supporter specifies the manner in which the provider will fulfill the accreditation requirements.

Element 3.12 of the ACCME's Updated Standards for Commercial Support applies only to physicians whose official residence is in the United States.

#### VERBAL DISCLOSURE TO LEARNERS

Disclosure of information about relevant financial relationships may be disclosed verbally to participants at a CME activity. When such information is disclosed verbally at a CME activity, providers must be able to supply the ACCME with written verification that appropriate verbal disclosure occurred at the activity. With respect to this written verification:

- 1. A representative of the provider who was in attendance at the time of the verbal disclosure must attest, in writing:
  - a. that verbal disclosure did occur: and
  - b. itemize the content of the disclosed information (SCS 6.1); or that there was nothing to disclose (SCS 6.2).
- 2. The documentation that verifies that adequate verbal disclosure did occur must be completed within one month of the activity.

#### COMMERCIAL SUPPORT: ACKNOWLEDGMENTS

The provider's acknowledgment of commercial support as required by SCS 6.3 and 6.4 may state the name, mission, and areas of clinical involvement of the company or institution and may include corporate logos and slogans, if they are not product promotional in nature.

#### COMMERCIAL EXHIBITS AND ADVERTISEMENTS

Commercial exhibits and advertisements are promotional activities and not continuing medical education. Therefore, monies paid by commercial interests to providers for these promotional activities are not considered to be *commercial support*. However, accredited providers are expected to fulfill the requirements of SCS 4 and to use sound fiscal and business practices with respect to promotional activities.

## ACCME® Annual Report Glossary

The terms and descriptions below only refer to organizations, programs, and activities within the ACCME accreditation system. For more information, visit <a href="www.accme.org">www.accme.org</a> .		
ACCME-accredited provider	An organization accredited by the ACCME as a provider of continuing medical education. ACCME-accredited providers represent a range of organizational types and offer CME primarily to national or international audiences of physicians and other health care professionals. See also state-accredited providers.	
Advertising and exhibits income	Advertising and exhibits are promotional activities and not continuing medical education. Therefore, monies paid by commercial interests to providers for these promotional activities are <b>not</b> considered to be <u>commercial support</u> .	
CME activity	A CME activity is an educational offering that is planned, implemented, and evaluated in accordance with the ACCME Accreditation Criteria, Standards for Commercial Support, and policies.	
Commercial interest	A <u>commercial interest</u> , as defined by the ACCME, 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. A commercial interest is not eligible for ACCME accreditation.	
Commercial support	Commercial support for a CME activity is monetary or in-kind contributions given by a commercial interest that is used to pay all or part of the costs of a CME activity. The requirements for receiving and managing commercial support are explained in the AC-CME Standards for Commercial Support <sup>SM</sup> . Advertising and exhibit income is <b>not</b> considered commercial support.	
Committee learning	Committee learning is a CME activity that involves a learner's participation in a committee process addressing a subject that would meet the ACCME definition of CME if it were taught or learned in another format.	
Course	A <u>course</u> is a live CME activity where the learner participates in person. A course is planned as an individual event. Examples: annual meeting, conference, seminar. For events with multiple sessions, such as annual meetings, accredited providers report one activity and calculate the hours of instruction by totaling the hours of all educational sessions offered for CME credit. To calculate the numbers of learners, accredited providers report the number of learners registered for the overall event. Accredited providers are not required to calculate participant totals from the individual sessions. If a course is held multiple times for multiple audiences, then each instance is reported as a separate activity.	
Directly provided	A <u>directly provided activity</u> is one that is planned, implemented, and evaluated by the accredited provider. This definition includes co-provided activities (offered by two accredited providers) reported by the accredited provider that awards the credit.	

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Enduring material	
(other)	An <u>enduring material</u> is an activity that is printed or recorded and does not have a specific time or location designated for participation. Rather, the participant determines where and when to complete the activity.
	Sometimes providers will create an enduring material from a live CME activity. When this occurs, ACCME considers the provider to have created two separate activities – one live activity and one enduring material activity. Both activities must comply with all ACCME requirements.
	Enduring materials can be available for less than a year, a year, or multiple years. Each enduring material is counted as 1 activity for each year it is available, whether it is active for the entire year or part of the year. The accredited provider reports the number of learners who participated during the year, as well as the income and expense related to the activity for that year. Accredited providers do not report cumulative data for an enduring material activity spanning multiple years. When reporting the number of participants for an enduring material activity, the accredited provider should count all learners who completed all or a portion of the activity and whose participation can be verified in some manner. ACCME would not consider individuals that only received the enduring material activity but did not actually complete all or a portion of it to be participants.
Expenses	Expenses are the total cost of goods, services, and facilities allocated to support the accredited provider's CME program. Examples: amounts spent for CME staff salaries, faculty honoraria, and meeting space.
Hours of instruction	Hours of instruction represents the total hours of educational instruction provided. For example, if a 1-day course lasts 8 hours (not including breaks or meals), then the total hours of instruction reported for that course is 8.
	Hours of instruction may or may not correspond to the number of credits designated for the American Medical Association Physician's Recognition Award. Accredited providers have the option to report the number of AMA PRA CATEGORY 1 CREDITS™ designated for activities but they are not required to do so.
In-kind commercial support	<u>In-kind contributions</u> are nonmonetary resources provided by a commercial interest in support of a CME activity. Examples of in-kind support include equipment, supplies, and facilities.
Internet (enduring materials)	An <u>Internet enduring material activity</u> is an "on demand activity," meaning that there is no specific time designated for participation. Rather, the participant determines when to complete the activity. Examples: online interactive educational module, recorded presentation, podcast.
	Internet enduring materials can be available for less than a year, a year, or multiple years. Each Internet enduring material is counted as one activity for each year it is available, whether it is active for the entire year or part of the year. The accredited provider reports the number of learners who participated during the year, as well as the income and expense related to the activity for that year. Accredited providers do not report cumulative data for an Internet enduring material activity spanning multiple years. When reporting the number of participants for an internet enduring material activity, the accredited provider should count all learners who completed all or a portion of the activity and whose participation can be verified in some manner. ACCME would not consider individuals that only downloaded or accessed the activity but did not actually complete all or a portion of it to be participants.

Internet (live)	An Internet live activity is an online course available via the Internet at a certain time on a certain date and is only available in real-time, just as if it were a course held in an auditorium. Once the event has taken place, learners may no longer participate in that activity unless it is again presented on a specific date and time and is only available in real-time. If an Internet live activity is presented on multiple occasions, each event is counted as one activity. Example: webcast.
Internet searching and learning	Internet searching and learning CME is based on a learner identifying a problem in practice and then researching the answer online using sources that are facilitated by an accredited provider. For the purpose of ACCME data collection, the ACCME includes Internet point-of-care learning, as defined by the American Medical Association, in the category Internet searching and learning.
	Providers that offer Internet searching and learning CME aggregate their data from all learners and report it as a single activity. For hours of instruction, accredited providers specify the amount of time they believe a learner would take to complete the Internet searching and learning CME activity. The number of participants equals the total number of persons who participated in Internet searching and learning as a CME activity. Each participant is counted once, regardless of how many times they participated or how many pages they viewed.
	For example, a provider offers Internet searching and learning CME and 50 physicians participate. Each physician spent 30 minutes participating in this activity. The accredited provider reports this as 1 Internet searching and learning CME activity with 50 physician participants and .5 hours of instruction.
Jointly provided	A jointly provided activity is planned, implemented, and evaluated by the accredited provider and a nonaccredited entity.
Journal-based CME	A journal-based CME activity includes the reading of an article (or adapted formats for special needs), a provider stipulated/learner directed phase (that may include reflection, discussion, or debate about the material contained in the article(s), and a requirement for the completion by the learner of a pre-determined set of questions or tasks relating to the content of the material as part of the learning process.
	The ACCME does not consider a journal-based CME activity to have been completed until the learner documents participation in that activity to the provider.
	Each article is counted as 1 activity. To calculate hours of instruction, the accredited provider specifies the amount of time required to complete the activity. The number of participants reported by the accredited provider equals the total number of individuals who completed the activity. Each participant is counted once, regardless of how many times they worked on the activity.
	For example, an accredited provider produces a journal that contains an article that is designated as a journal-based CME activity. Twenty physicians read the article, reflect on the content, and complete questions related to the content of the article. The physicians spend 1 hour on this activity. The provider would report this as 1 journal-based CME activity with 20 physician participants and 1 hour of instruction.

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Learning from teaching	Learning from teaching activities are personal learning projects designed and implemented by the learner with facilitation from the accredited provider. The ACCME does not have special requirements for this activity type. The ACCME developed the learning from teaching label as a corollary to the AMA PRA CATEGORY 1 CREDITS™ awarded directly to physicians for "Teaching at a live activity."
	To report learning from teaching CME, accredited providers aggregate the data from all learners and count it as a single activity. For hours of instruction, accredited providers specify the amount of time they believe a learner would take to complete the learning from teaching CME activity. The number of participants equals the number of individuals who participated in this CME activity. Each participant is counted once, regardless of how many times they worked on the activity.
	For example, an accredited provider created a learning from teaching activity for 10 physicians. Each physician completed the CME activity in 2 hours. The accredited provider reports this as 1 learning from teaching CME activity with 10 physician participants and 2 hours of instruction.
Manuscript review	Manuscript review CME is based on a learner's participation in a manuscript's prepublication review process.
	When calculating the number of <b>manuscript review CME activities</b> , accredited providers report each journal for which the manuscript(s) is being reviewed as 1 activity regardless of the number of manuscripts or reviewers. For hours of instruction, accredited providers specify the amount of time they believe a learner would take to complete the manuscript review CME activity. The number of participants equals the total number of learners engaged in reviewing manuscripts as CME. Each participant is counted once regardless of how many manuscripts they reviewed.
	For example, an accredited provider publishes 1 journal. During the course of the year, 25 physicians reviewed manuscripts for this journal. Each physician spent 2 hours on the review. The accredited provider reports this as 1 manuscript review CME activity with 25 physician participants and 2 hours of instruction.
Nonphysician participants	Nonphysician participants are activity attendees other than MDs and DOs, such as nurses, physician assistants, and other health professionals. Residents are also included in this category.
Other income	Other income includes all income the accredited provider received for its CME activities and CME program that does not fall under commercial support or advertising and exhibit income. The most common examples of other income include activity registration fees, grants from government agencies or independent nonprofit foundations, and allocations from the accredited provider's parent organization or other internal departments to pay for the CME unit's expenses.

Performance improvement	<u>Performance improvement CME</u> is based on a learner's participation in a project established and/or guided by a CME provider. A physician identifies an educational need through a measure of his/her performance in practice, engages in educational experiences to meet the need, integrates the education into patient care, and then reevaluates his/her performance.
	To report performance improvement CME, accredited providers count each learning project as 1 performance improvement CME activity, regardless of whether it is created for an individual physician or a group of physicians. For hours of instruction, accredited providers specify the amount of time they believe a learner would take to complete the performance improvement CME activity. The number of participants equals the total number of learners who participated in the learning project. Each participant is counted once, regardless of how many times they worked on the activity.
	For example, an accredited provider established a performance improvement learning project. Three physicians participated; each completed the learning project in 20 hours. The accredited provider reports this as 1 performance improvement CME activity with 3 physician participants and 20 hours of instruction.
Physician participants	Physician participants are activity attendees who are MDs or DOs. Residents are not included in this category, but are included under nonphysician participants.
Regularly scheduled series	The ACCME defines a regularly scheduled series (RSS) as a course that is planned as a series with multiple, ongoing sessions, e.g., offered weekly, monthly, or quarterly; and is primarily planned by and presented to the accredited organization's professional staff. Examples include grand rounds, tumor boards, and morbidity and mortality conferences.
	Accredited providers report each RSS as 1 activity. In addition, accredited providers follow the following guidelines:
	The cumulative number of hours for all sessions within a series equals the number of hours for that activity and
	Each physician is counted as a learner for <b>each session</b> he/she attends in the series.  For example: Internal Medicine Grand Rounds is planned for the entire year as 1 series. Participants meet weekly during the year for 1 hour each week. The accredited provider reports the series as <b>1 activity</b> with 52 hours of instruction. If 20 physicians participated in each session, total physician participants would be 1,040 (20 physicians per session multiplied by 52 sessions) for that <b>single</b> activity.
State-accredited provider	State-accredited providers are accredited by a state/territory medical society that is recognized by the ACCME as an accreditor. State-accredited providers offer CME primarily to learners from their state or contiguous states as opposed to ACCME-accredited providers, which offer CME primarily to national or international audiences.

#### **Test-item writing**

<u>Test-item writing</u> is a CME activity based on a learner's participation in the prepublication development and review of any type of test item. Examples: multiple choice questions, standardized patient cases.

Test-item writing CME activities may consist of either of the following processes:

When questions are written for an item pool and are later used to build a variety of tests, then building the questions for a single pool is counted as 1 activity. Examples: the Pediatric Item Writing Committee of the National Board of Medical Examiners or the second year clerkship exams at a medical school.

When questions, items, or cases are created for 1 specific test, then each test is counted as a separate CME activity. Example: multiple choice questions for the 2012 clerkship exam in pediatrics.

For hours of instruction, accredited providers specify the amount of time they believe a learner would take to complete the test-item writing CME activity. The number of participants should equal the total number of persons who engaged in the test-item writing CME activity. Each participant is counted once regardless of how many test items they write.

For example, an accredited provider planned a CME activity where 5 physicians wrote test items for an American Board of Medical Specialties (ABMS) member board certification examination question pool. Each physician completed the test-item writing CME activity in 10 hours. The accredited provider reports this as a test-item writing CME activity with 5 physician participants and 10 hours of instruction.