

### The ACCME Accreditation Requirements

### October 2019

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### ACCREDITATION CRITERIA

Initial applicants seeking to achieve Provisional Accreditation, a two-year term, 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.

<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.

# MENU OF CRITERIA FOR ACCREDITATION WITH COMMENDATION

Accredited CME providers have the option to aim to achieve Accreditation with Commendation, a six-year term. Providers seeking commendation in March 2020 and subsequent decision cohorts must demonstrate compliance with Criteria 1-13, in addition to the Menu of Commendation Criteria (C23-C38), shown below.

Note: Providers that received accreditation decisions through November 2019 had the choice of demonstrating compliance with Commendation Criteria 16-22 or the Menu of Commendation Criteria (C23-C38) to seek Accreditation with Commendation. Criteria 16-22 are shown on page 4.

<u>Criterion 23</u> Members of interprofessional teams are engaged in the planning and delivery of interprofessional continuing education (IPCE).

Criterion 24 Patient/public representatives are engaged in the planning and delivery of CME.

<u>Criterion 25</u> Students of the health professions are engaged in the planning and delivery of CME.

Criterion 26 The provider advances the use of health and practice data for healthcare improvement.

Criterion 27 The provider addresses factors beyond clinical care that affect the health of populations.

<u>Criterion 28</u> The provider collaborates with other organizations to more effectively address population health issues.

Criterion 29 The provider designs CME to optimize communication skills of learners.

Criterion 30 The provider designs CME to optimize technical and procedural skills of learners.

<u>Criterion 31</u> The provider creates individualized learning plans for learners.

<u>Criterion 32</u> The provider utilizes support strategies to enhance change as an adjunct to its CME.

<u>Criterion 33</u> The provider engages in CME research and scholarship.

<u>Criterion 34</u> The provider supports the continuous professional development of its CME team.

<u>Criterion 35</u> The provider demonstrates creativity and innovation in the evolution of its CME program.

Criterion 36 The provider demonstrates improvement in the performance of learners.

<u>Criterion 37</u> The provider demonstrates healthcare quality improvement.

Criterion 38 The provider demonstrates the impact of the CME program on patients or their communities.

### COMMENDATION CRITERIA 16-22

<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. (See the 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 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, ACCME-accredited providers may not place their CME activities on a Web site owned or controlled by a commercial interest. With clear notification that the learner is leaving the educational Web site, links from the Web site of an ACCME accredited provider to pharmaceutical and device manufacturers' product Web sites are permitted before or after the educational content of a CME activity, but shall not be embedded in the educational content of a CME activity. Advertising of any type is prohibited within the educational content of CME activities on the Internet including, but not limited to, banner ads, subliminal ads, and pop-up window ads.
- For audio and video recording, advertisements and promotional materials will not be included within the CME. There will be no 'commercial breaks.'
- For live, face-to-face CME, advertisements and promotional materials cannot be displayed or distributed
  in the educational space immediately before, during, or after a CME activity. Providers cannot allow
  representatives of Commercial Interests to engage in sales or promotional activities while in the space
  or place of the CME activity.
- For Journal-based CME, none of the elements of journal-based CME can contain any advertising or product group messages of commercial interests. The learner must not encounter advertising within the pages of the article or within the pages of the related questions or evaluation materials.

STANDARD 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.

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 corporate logo, trade name or a product-group 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.

### **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 designated AMA PRA Category 1 Credits<sup>™</sup>;
  - Competencies that activities were designed to address;
  - 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 *not* release any dollar amounts reported by individual accredited providers for income, 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
- Any other data/information that ACCME believes qualifies as "public information."

The ACCME reserves the right to use and/or share anonymized PARS data for research purposes, in keeping with the guidance of the ACCME Board of Directors.

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:

- 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

- 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 ACCME 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.

### ACCME ACCREDITED PROVIDER MARKS

Providers accredited within the ACCME System (providers directly accredited by the ACCME and those accredited by ACCME Recognized Accreditors) are welcome to use the ACCME Accredited mark for educational and identification purposes, and in <u>announcements</u> related to their attainment of ACCME accreditation. While the mark may be resized, the original aspect ratio should be maintained (it should not be stretched or condensed in a way that causes it to become distorted). Except for resizing, no other changes can be made.

ACCME-accredited and state-accredited providers that have achieved Accreditation with Commendation may also use the ACCME Accredited with Commendation mark for educational and identification purposes and in <u>announcements</u> related to their attainment of Accreditation with Commendation.

#### Accredited Provider Mark

Accredited with Commendation Provider Mark

### 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.

### 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.

### CME ACTIVITY AND ATTENDANCE RECORDS RETENTION

- 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.

### 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.
- 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.

### 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<sup>TM</sup> 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 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 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.

### 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.

### ENGLISH AS OFFICIAL LANGUAGE OF THE ACCME

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.

### 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 feeschedule">ACCME-accredited provider feeschedule</a>.

### 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."

### Release of ACCME and its Volunteers, Choice of Forum, and Unethical Behavior

The Accreditation Council for Continuing Medical Education ("ACCME") accredits organizations that offer continuing medical education. ACCME offers accreditation through a multilevel process ("Process") to certify continuing medical education providers. Throughout the Process, various individuals, including, without limitation, ACCME's past and present directors, officers, employees, agents, volunteers, surveyors, content reviewers, attorneys, assigns, successors and insurers (collectively "Participants"), help inform ACCME's decision-making process. ACCME and the Participants (collectively "Released Parties") then use information gathered through the Process to make an accrediting decision.

Each organization which seeks accreditation from the ACCME or which is accredited by ACCME shall be referred to as a "Provider."

In consideration of the willingness of ACCME to: (a) process the application of a Provider which seeks accreditation; or (b) engage in the process of re-accreditation or provide any other services to a Provider who is accredited by ACCME, each Provider, agrees on behalf of itself and its shareholders, members, owners, directors, officers, employees, agents, volunteers, successors, assigns and anyone else who may claim on Provider's behalf or through Provider (collectively the "Releasing Parties") as follows:

- 1. <u>Release and Waiver</u> Releasing Parties knowingly and voluntarily: waive and generally release the Released Parties from any and all claims or causes of action arising out of the Process which the Releasing Parties may have at any time, now or in the future against any Released Party. This waiver and release includes, but is not limited to:
  - any and all claims, actions, causes of action or liabilities asserting that any of the Released Parties
    has violated the policies and procedures of the ACCME, any covenant of good faith and fair dealing,
    or any express or implied contract of any kind;
  - any and all claims, actions, causes of action or liabilities asserting that any of the Released Parties
    has violated public policy or statutory or common law, including claims for personal injury, invasion
    of privacy, defamation, intentional or negligent infliction of emotional distress and/or mental
    anguish, intentional interference with contract, negligence, detrimental reliance, failure to provide
    due process and/or promissory estoppel;
  - any and all claims, actions, causes of action or liabilities asserting that any of the Released Parties
    are in any way obligated for any reason to pay Releasing Parties damages, expenses, litigation
    costs (including attorneys' fees), compensatory damages, punitive damages, and/or interest; and
  - all claims of discrimination or retaliation based on such things as age, national origin, ancestry, race, religion, sex, sexual orientation, physical or mental disability or medical condition, and any purported membership or exercise of legally protected rights.

The Releasing Parties' waiver and release includes all claims, rights and causes of action that Releasing Parties have or may have under all contract, common law, federal, state and local statutes, ordinances, rules, regulations and orders. All of the items described in this paragraph and the preceding paragraph shall be referred to as the "Released Claims."

- 2. Covenant not to Sue and Indemnification In addition, the Releasing Parties, knowingly, intentionally and voluntarily: promise not to sue the Released Parties with respect to any Released Claims; and agrees to defend, indemnify and hold harmless the Released Parties from and against any and all losses, costs, claims, demands, causes of action, injury, damage, and liability whatsoever (including, but not limited to, court costs and attorneys' fees), whether presently known or unknown, with respect to any claim and/or litigation made or brought by the Releasing Parties with respect to the Released Claims. If any claim and/or litigation is made or brought by a Releasing Party against a Released Party with respect to a Released Claim, the Releasing Parties' obligation to provide a defense for such a claim and/or litigation shall be fulfilled by the Releasing Parties paying the attorney's fees of the Released Parties incurred in connection with such claim and/or litigation. The Releasing Parties expressly waive the benefits of any statutory provision or common law rule that provides that a release and waiver of liability does not extend to causes of action of which the Releasing Parties are unaware.
- 3. Governing Law; Choice of Forum All disputes and litigation between a Releasing Party and a Released Party shall be governed by the laws of the State of Illinois, without regard to its conflicts of laws principles. Any disputes and matters arising between a Releasing Party and a Released Party shall be litigated exclusively before a court located in Cook County, Illinois (or the Federal District for the Northern District of Illinois), and no Releasing Party shall bring any litigation related to a Released Party in any other forum. Each Releasing Party waives any argument that the forum designated by this paragraph is not convenient.
- 4. <u>Unethical Behavior</u> No Provider shall engage in: disparagement of any of ACCME, ACCME's past and present directors, officers, employees, agents, volunteers, surveyors, content reviewers, attorneys, assigns, successors and insurers; unethical behavior, including, without limitation, dishonest communications or conduct; or deceptive or misleading advertising. Failure to comply with the standard set forth in this paragraph shall be grounds for corrective action, including, without limitation, reduction or loss of a Provider's accreditation.

### 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

### **FEES**

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

#### COMPLIANCE AND NONCOMPLIANCE ISSUES

The ACCME expects *all* 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.

Providers that receive a decision of Probation in two consecutive accreditation terms are prohibited from jointly providing activities until they regain their accreditation status. If the provider is found to be working in joint providership while under this probation, the ACCME will immediately change the provider's status to Nonaccreditation.

### POLICIES SUPPLEMENTING THE STANDARDS FOR COMMERCIAL SUPPORT

### 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.

### 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 an ACCME-defined commercial interest but may *not* include corporate logos and slogans.

### 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 *prior* 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.

#### 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.

### 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.

### 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.

### 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.