

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 www.accme.org for a definition of a "commercial interest" and some exemptions.) (a) Identification of CME needs; (b) Determination of educational objectives; (c) Selection and presentation of content; (d) Selection of all persons and organizations that will be in a position to control the content of the CME; (e) Selection of educational methods; (f) Evaluation of the activity.

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 interleaved within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as these materials are not related to the CME content they face and are not paid for by the commercial supporters of the CME activity.

For computer based, advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleaved between computer 'windows' or screens of the CME content.

Also, ACCME-accredited providers may not place their CME activities on a Web site owned or controlled by a commercial interest. With clear notification that the learner is leaving the educational Web site, links from the Web site of an ACCME accredited provider to pharmaceutical and device manufacturers' product Web sites are permitted before or after the educational content of a CME activity, but shall not be embedded in the educational content of a CME activity. Advertising of any type is prohibited within the educational content of CME activities on the Internet including, but not limited to, banner ads, subliminal ads, and pop-up window ads.

For audio and video recording, advertisements and promotional materials will not be included within the CME. There will be no 'commercial breaks.'

For live, face-to-face CME, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Providers cannot allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CME activity.

For Journal-based CME, none of the elements of journal-based CME can contain any advertising or product group messages of commercial interests. The learner must not encounter advertising within the pages of the article or within the pages of the related questions or evaluation materials.

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 of commercial support 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.

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 & 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.

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

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.