



## THE ISMA'S ESSENTIAL AREAS AND THEIR ELEMENTS

### ESSENTIAL AREA 1: PURPOSE AND MISSION

The provider must,

- Element 1 Have a written statement of its CME mission, which includes the CME purpose, content areas, target audience, type of activities provided, and expected results of the program.

### ESSENTIAL AREA 2: EDUCATIONAL PLANNING

The provider must,

- Element 2.1 Use a planning process(es) that links identified educational needs with a desired result in its provision of all CME activities.
- Element 2.2 Use needs assessment data to plan CME activities.
- Element 2.3 Communicate the purpose or objectives of the activity so the learner is informed before participating in the activity.
- Element 3.3 Present CME activities in compliance with the ISMA's policies for disclosure and commercial support.

[NOTE: The ISMA's policies for disclosure and commercial support are articulated in: **(1) *The Standards For Commercial Support: Standards to Ensure Independence in CME Activities***, as adopted by ISMA in September 2004; and **(2) ISMA policies applicable to commercial support and disclosure**. All materials can be found on [www.ismanet.org](http://www.ismanet.org).]

### Essential Area 3: Evaluation and Improvement

The provider must,

- Element 2.4 Evaluate the effectiveness of its CME activities in meeting identified educational needs.
- Element 2.5 Evaluate the effectiveness of its overall CME program and make improvements to the program.

### COMPLIANCE WITH THE FOLLOWING WILL BE DETERMINED AT PRE APPLICATION AND, AS REQUIRED, DURING THE PROVIDER'S TERM OF ACCREDITATION

#### ADMINISTRATION

The provider must,

- Element 3.1 Have an organizational framework for the CME unit that provides the necessary resources to support its mission including support by the parent organization, if a parent organization exists
- Element 3.2 The 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.

**2006 UPDATED DECISION-MAKING CRITERIA  
RELEVANT TO THE ESSENTIAL AREAS AND ELEMENTS**

Measurement criteria have been established for the Elements of the Essential Areas. If a provider meets the criteria for the Elements within the Essential Area, the provider will be deemed to be 'In Compliance.'

Essential Area and Element(s)		Criteria for Compliance
Essential Area 1: Purpose And Mission	<p>The provider must,</p> <p><b>E 1</b> Have a written statement of its CME mission, which includes the CME purpose, content areas, target audience, type of activities provided, and expected results of the program.</p>	<p><b>C 1</b> The provider has a CME mission statement that includes all of the basic components (CME purpose, content areas, target audience, type of activities, expected results) with expected results articulated in terms of changes in competence, performance, or patient outcomes that will be the result of the program.</p>
Essential Area 2: Educational Planning	<p>The provider must,</p> <p><b>E 2.1</b> Use a planning process(es) that links identified educational needs with a desired result in its provision of all CME activities.</p> <p><b>E 2.2</b> Use needs assessment data to plan CME activities.</p> <p><b>E 2.3</b> Communicate the purpose or objectives of the activity so the learner is informed before participating in the activity.</p> <p><b>E 3.3</b> Present CME activities in compliance with the ISMA's policies for disclosure and commercial support.</p>	<p><b>C 2</b> The provider incorporates into CME activities the educational needs (knowledge, competence, or performance) that underlie the professional practice gaps of their own learners.</p> <p><b>C 3</b> The provider generates activities/educational interventions that are designed to change competence, performance, or patient outcomes as described in its mission statement.</p> <p><b>C 4</b> The provider generates activities/educational interventions around content that matches the learners' current or potential scope of professional activities.</p> <p><b>C 5</b> The provider chooses educational formats for activities/interventions that are appropriate for the setting, objectives and desired results of the activity.</p> <p><b>C 6</b> The provider develops activities/educational interventions in the context of desirable physician attributes (e.g., IOM competencies, ACGME Competencies).</p> <p><b>C 7</b> The provider develops activities/educational interventions independent of commercial interests (SCS 1, 2 and 6).</p> <p><b>C 8</b> The provider appropriately manages commercial support (if applicable, SCS 3).</p> <p><b>C 9</b> The provider maintains a separation of promotion from education (SCS 4).</p> <p><b>C 10</b> The provider actively promotes improvements in health care and NOT proprietary interests of a commercial interest (SCS 5).</p>
<p>[Note: Regarding E 3.3 and C7 to C10 - The ISMA's policies for disclosure and commercial support are articulated in: (1) The Standards For Commercial Support: Standards to Ensure Independence in CME Activities, as adopted by ISMA in September 2004; and (2) ISMA policies applicable to commercial support and disclosure. All these materials can be found on <a href="http://www.ismanet.org">www.ismanet.org</a>.]</p>		

Essential Area and	Criteria for Compliance
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Element(s)		
<b>Essential Area 3: Evaluation and Improvement</b>	<p>The provider must,</p> <p><b>E 2.4</b> Evaluate the effectiveness of its CME activities in meeting identified educational needs.</p> <p><b>E 2.5</b> Evaluate the effectiveness of its overall CME program and make improvements to the program.</p>	<p>C 11. The provider analyzes changes in learners (competence, performance, or patient outcomes) achieved as a result of the overall program's activities/educational interventions</p> <p>C 12. 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.</p> <p>C 13. The provider identifies, plans and implements the needed or desired changes in the overall program (e.g., planners, teachers, infrastructure, methods, resources, facilities, interventions) that are required to improve on ability to meet the CME mission.</p> <p>C 14. The provider demonstrates that identified program changes or improvements, that are required to improve on the provider's ability to meet the CME mission, are underway or completed.</p> <p>C 15. The provider demonstrates that the impacts of program improvements, that are required to improve on the provider's ability to meet the CME mission, are measured.</p>
<b>Accreditation with Commendation</b>	<p>In order for an organization to achieve the status Accreditation with Commendation, the provider must demonstrate that it fulfills the following Criteria 16 - 22, in addition to Criteria 1-15.</p>	<p>C 16. The provider operates in a manner that integrates CME into the process for improving professional practice.</p> <p>C 17. The provider utilizes non-education strategies to enhance change as an adjunct to its activities/educational interventions (e.g., reminders, patient feedback).</p> <p>C 18. The provider identifies factors outside the provider's control that impact on patient outcomes.</p> <p>C 19. The provider implements educational strategies to remove, overcome or address barriers to physician change.</p> <p>C 20. The provider builds bridges with other stakeholders through collaboration and cooperation.</p> <p>C 21. The provider participates within an institutional or system framework for quality improvement.</p> <p>C 22. The provider is positioned to influence the scope and content of activities/educational interventions.</p>

## THE STANDARDS FOR COMMERCIAL SUPPORT

### Standards to Ensure Independence in CME Activities

#### **STANDARD 1: INDEPENDENCE**

**1.1** A CME provider must ensure that the following decisions were made free of the control of a commercial interest. The ISMA defines a “commercial interest” as any proprietary entity producing health care goods or services, with the exemption of non-profit or government organizations and non-health care related companies.

- (a) Identification of CME needs;
- (b) Determination of educational objectives;
- (c) Selection and presentation of content;
- (d) Selection of all persons and organizations that will be in a position to control the content of the CME;
- (e) Selection of educational methods;
- (f) Evaluation of the activity.

**1.2** A commercial interest cannot take the role of non-accredited partner in a joint partnership relationship ☞

#### **STANDARD 2: Resolution of Personal Conflicts of Interest**

**2.1** The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. The ISMA defines “‘relevant’ financial relationships” as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

**2.2** An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

**2.3** The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.☞

#### **STANDARD 3: Appropriate Use of Commercial Support**

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

**3.2** A provider cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other

education matters, including content, from a commercial interest as conditions of contributing funds or services.

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

#### **Written agreement documenting terms of support**

**3.4** The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the provider and its educational partner(s). The agreement must include the provider, even if the support is given directly to the provider’s educational partner or a joint sponsor.

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

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

#### **Expenditures for an individual providing CME**

**3.7** The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.

**3.8** The provider, the joint sponsor, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of-pocket expenses in compliance with the provider’s written policies and procedures.

**3.9** No other payment shall be given to the director of the activity, planning committee members, teachers or authors, joint sponsor, or any others involved with the supported activity.

**3.10** If teachers or authors are listed on the agenda as facilitating or conducting a presentation or session, but participate in the remainder of an educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their teacher or author role only.

#### **Expenditures for learners**

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

**3.12** The provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity. The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, joint sponsor or educational partner.

#### Accountability

**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

**4.1** Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.

**4.2** Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (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.
- 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.

**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.

**4.4** Print or electronic information distributed about the non-CME elements of a CME activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions, may include product-promotion material or product-specific advertisement.

**4.5** A provider cannot use a commercial interest as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities. ☞

### STANDARD 5. Content and Format without Commercial Bias

**5.1** The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.

**5.2** Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company. ☞

### STANDARD 6. Disclosures Relevant to Potential Commercial Bias

#### Relevant financial relationships of those with control over CME content

**6.1** An individual must disclose to learners any relevant financial relationship(s), to include the following information:

- The name of the individual;
- The name of the commercial interest(s);
- The nature of the relationship the person has with each commercial interest.

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

#### Commercial support for the CME activity

**6.3** The source of all support from commercial interests must be disclosed to learners. When commercial support is 'in-kind' the nature of the support must be disclosed to learners.

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

#### Timing of disclosure

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