



THE ACCME'S ESSENTIAL AREAS AND THEIR ELEMENTS

The ACCME recognizes that the professional responsibility of physicians requires continuous learning throughout their careers, appropriate to the individual physician's needs. The ACCME also recognizes that physicians are responsible for choosing their CME activities in accordance with their perceived and documented needs, individual learning styles, and practice setting requirements and for evaluating their own learning achievements. The Essential Areas and policies, therefore, are designed to encourage providers to consider the needs and interests of potential physician participants in planning their CME activities and to encourage the physicians to assume active roles in the planning process.

In the Essential Areas and policies, the ACCME has identified certain elements of structure, method, and organization that contribute to the development of effective continuing medical education. The Essential Areas and policies are the practices that a provider must implement for accreditation.

ESSENTIAL AREA 1: PURPOSE AND MISSION

The provider must,

Elements	1.1	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.
	1.2	Demonstrate how the CME mission is congruent with and supported by the mission of the parent organization, if a parent organization exists.

ESSENTIAL AREA 2: EDUCATIONAL PLANNING AND EVALUATION

The provider must,

Elements	2.1	Use a planning process(es) that links identified educational needs with a desired result in its provision of all CME activities.
	2.2	Use needs assessment data to plan CME activities.
	2.3	Communicate the purpose or objectives of the activity so the learner is informed before participating in the activity.
	2.4	Evaluate the effectiveness of its CME activities in meeting identified educational needs.
	2.5	Evaluate the effectiveness of its overall CME program and make improvements to the program.

ESSENTIAL AREA 3: ADMINISTRATION

The provider must,

Elements	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
	3.2	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.
	3.3	Present CME activities in compliance with the ACCME's policies for disclosure and commercial support. (see full text attached)

THE ACCME'S DECISION-MAKING CRITERIA

Measurement criteria have been developed for each *Element* in the *Essential Areas* to measure whether the accredited provider meets the basic level of accreditation. **A provider's documentation of the measurement criteria will be the ACCME's primary source of information for determining compliance with the Elements.**

The following classification of compliance will be used:

- Noncompliance
- Partial Compliance
- Compliance
- Exemplary Compliance

ESSENTIAL AREA 1 – PURPOSE AND MISSION

Element 1.1		The provider must 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.
Criteria	Noncompliance	Has no mission statement.
	Partial Compliance	Has a mission statement, but omits one or more of the basic components.
	Compliance	Has a mission statement that includes all of the basic components.
	Exemplary Compliance	Has a mission statement that includes all of the basic components with a strong emphasis on assessment of results.
Element 1.2		The provider must demonstrate how the CME mission is congruent with and supported by the mission of the parent organization, if a parent organization exists.
Criteria	Noncompliance	CME not mentioned in the parent organization mission statement and no support provided.
	Partial Compliance	CME mentioned in the parent organization mission statement but no support provided, <u>or</u> CME not mentioned in the parent organization mission statement but support provided.
	Compliance	CME mentioned in the parent organization mission statement and supported with financial, facility, and human resources; or a CME mission statement reviewed and approved by the governing body of the parent organization on a regular basis.
	Exemplary Compliance	CME mentioned in the parent organization mission statement and supported with financial, facility, <u>and</u> human resources, plus promotion of the function; and a CME mission statement that is reviewed, evaluated, and approved by the governing body of the parent organization on a regular basis.

ESSENTIAL AREA 2 – EDUCATIONAL PLANNING AND EVALUATION

Element 2.1		The provider must use a planning process(es) that links identified educational needs with a desired result in its provision of all CME activities.
Criteria	Noncompliance	Planning process(es) not used
	Partial Compliance	Planning process(es) used inconsistently or does not reflect a link between identified educational needs and desired result.
	Compliance	Planning process(es) used consistently that link(s) identified educational needs and desired result.
	Exemplary Compliance	Innovative and creative planning process(es) used consistently, with documentation that identified educational needs contribute to appropriate methodology and desired results for the offered activities.
Element 2.2		The provider must use needs assessment data to plan CME activities.
Criteria	Noncompliance	Needs assessment data are not used.
	Partial Compliance	Needs assessment data are inconsistently used.
	Compliance	Needs assessment data are consistently used.
	Exemplary Compliance	Needs assessment data from multiple sources are consistently used to plan and evaluate activities.
Element 2.3		The provider must communicate the purpose or objectives of the activity so the learner is informed before participating in the activity.
Criteria	Noncompliance	Purpose or objectives of the activity are not communicated to the learner.
	Partial Compliance	Purpose or objectives of the activity are inconsistently communicated to the learner.
	Compliance	Purpose or objectives of the activity are consistently communicated to the learner.
	Exemplary Compliance	Purpose or objectives of the activity describe learning outcomes in terms of physician performance or patient health and are consistently communicated to the learner.

Element 2.4		The provider must evaluate the effectiveness of its CME activities in meeting identified educational needs.
Criteria	Noncompliance	Educational activities are not evaluated.
	Partial Compliance	Educational activities are evaluated inconsistently and/or documentation is inconsistent.
	Compliance	Educational activities are evaluated consistently for effectiveness in meeting identified educational needs, as measured by satisfaction, knowledge, or skills.
	Exemplary Compliance	Educational activities are evaluated consistently for effectiveness in meeting identified educational needs, as measured by practice application and/or health status improvement.

Element 2.5		The provider must evaluate the effectiveness of its overall CME program and make improvements to the program.
Criteria	Noncompliance	No mechanism in place to measure the program’s effectiveness or make improvements.
	Partial Compliance	Mechanism in place to measure the effectiveness of the program, but no documentation exists that the mechanism has been used or any changes have resulted from the process.
	Compliance	Mechanism in place to measure the effectiveness of the program, with evidence that improvements have been made.
	Exemplary Compliance	Innovative and creative mechanism(s) in place to measure the effectiveness of the program with evidence of improvements being made on a regular basis.

ESSENTIAL AREA 3 – ADMINISTRATION

Element 3.1		The provider must 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.
Criteria	Noncompliance	Organizational framework does not exist for the CME unit.
	Partial Compliance	Organizational framework does exist for the CME unit but not all components of the Element (resources and support) are present.
	Compliance	Organizational framework for the CME unit exists and all the components of the Element (resources and support) are present.
	Exemplary Compliance	Organizational framework for the CME unit exists, all components of the Element (resources and support) are present including a process to review and continually improve the organizational framework.

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.
Criteria	Noncompliance	Business and management policies and procedures (as they relate to human resources, financial affairs and legal obligations) are not in place or the provider does not meet its obligations and commitments under these policies and procedures.
	Partial Compliance	Not Available Option ¹
	Compliance	Business and management policies and procedures...are in place and are used by CME administration to meet its obligations and commitments. ²
	Exemplary Compliance	Innovative and creative business and management policies and procedures (as they relate to human resources, financial affairs and legal obligations) are in place to assist the CME administration in meeting its obligations and commitments. ¹

Element 3.3		The provider must present CME activities in compliance with ACCME's policies for disclosure and commercial support. (see full text attached)
Criteria	Noncompliance	<p>Provider</p> <ul style="list-style-type: none"> ▪ Does <u>not</u> disclose required information and relationships³, or ▪ Does <u>not</u> maintain control of content⁴, or ▪ Does <u>not</u> separate promotion from education⁵, or ▪ Does <u>not</u> have oversight of funds⁶.
	Partial Compliance	Not Available Option
	Compliance	<p>Provider</p> <ul style="list-style-type: none"> ▪ Consistently discloses required information and relationships; and ▪ Consistently in control of content; and ▪ Consistently ensures that promotion and education are separate; and ▪ Consistently demonstrates appropriate management of funds from commercial supporters.
	Exemplary Compliance	Provider is compliant with <u>all</u> aspects of ACCME's policies on disclosure and commercial support and has implemented a range of innovative and creative practices.

¹ Modified by Council Action, 2001-A-19

² The ACCME accreditation process shall not attempt , or attest, to measuring or determining compliance with or actual performance in practice of the management policies or procedures. (Council Action, 2001-A-19)

³ Receipt of funds from proprietary entity; investigational products or products not labeled for use disclosed; existence of significant financial interest or relationship of faculty or provider with manufacturer or commercial product disclosed; relationship(s) of faculty with commercial support of the activity.

⁴ Activities free from commercial bias; educational materials do not advance propriety interests of supporting company; mention of multiple companies' trade names, if applicable; research reported of a proprietary company conforms to accepted practices of experimental design, data collection, and analysis.

⁵ Exhibits do not interfere with CME activity presentations; exhibit placement is not a condition of support; exhibits are not displayed in the same room as the educational activity; proprietary company representatives do not engage in sales activities where the educational activity occurs.

⁶ Funds received are in an educational grant payable to the accredited provider; terms, conditions, and purposes of the educational grant are documented in a signed agreement between the provider and the supporter; honoraria and expenses for faculty are reasonable; no other funds are paid by the proprietary company to the director of the activity, faculty, or others involved with the supported activity.

⁷ Includes the Standards for Commercial Support, as adopted by the ACCME Board of Directors, April 1, 2004.

The Standards for Commercial Support
As Adopted by the ACCME Board of Directors on April 1, 2004

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 ACCME 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 sponsorship 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 ACCME 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. ⌘