

## ACCME SUBSTANTIVE EQUIVALENCY FRAMEWORK

ACCME's Substantive Equivalency program recognizes a continuing medical education/continuing professional development (CME/CPD) accreditation system as being Substantively Equivalent with the accreditation system of the ACCME based upon an assessment of whether the applicant system meets the expectations of ACCME's Standards for Substantive Equivalency. This framework document includes the Standards as well as the program's process and its glossary.

Substantive Equivalency between accrediting bodies allows stakeholders to know that the accredited education in support of improved patient care and patient safety meets the same level of independence, rigor, content validity, quality of design, and outcome measures.

### Standards for Substantive Equivalency

Systems that wish to be considered for Substantive Equivalency will be asked to demonstrate how their rules, processes and decision-making meets the following standards:

#### **Standard 1: Eligibility and Responsibilities of an Accrediting Body**

This standard defines which organizations are eligible to apply for Substantive Equivalency and describes the administrative roles and responsibilities of an eligible accrediting body.

#### **Standard 2: Independence and Transparency in Accredited Education**

This standard focuses on requirements that seek to ensure that educational activities are designed and implemented independent from the influence of ineligible companies, defined as companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

#### **Standard 3: Needs Assessment Used in Planning Accredited Education**

This standard focuses on the data sources used to identify the educational needs of individual doctors, healthcare teams, patients, and communities.

#### **Standard 4: Content Validity in Accredited Education**

This standard focuses on the process of developing content for accredited education that reflects the latest scientific evidence and technological advances to continuously enhance the quality and safety of care provided to patients.

#### **Standard 5: Quality of Educational Design in Accredited Education**

This standard focuses on the design of educational formats in addressing the identified needs of the intended target audience.

#### **Standard 6: Outcomes from Accredited Education**

This standard focuses on assessment of the effectiveness and educational impact of accredited education on knowledge, skills, competencies, performance, and/or the health status of patients.

## Standard 1: Eligibility and Responsibilities of an Accrediting Body

The purpose of continuing medical education/continuing professional development (CME/CPD) is to promote maintenance and continuous improvement of the competence and performance of individual healthcare professionals and healthcare teams in providing exemplary healthcare for patients.

Accreditation systems are intended to serve individual healthcare professionals and healthcare teams by determining that accredited education has complied with established accreditation standards. Given the importance of accreditation in supporting improved healthcare for patients, ACCME-defined ineligible companies cannot play the role of an accrediting body seeking Substantive Equivalency with the ACCME.

The eligibility for an organization to function as an accrediting body and the Standards that outline their roles/responsibilities are listed below:

### 1.1 The accrediting body must be:

- I. a legal entity or a collaboration among two or more legal entities;
- II. led by, or include the perspective of, the profession of medicine; and
- III. accountable to the public through transparent reporting of governance, accreditation decisions, and finances on a regular basis.

### 1.2 The accrediting body must not be:

- I. an ineligible company, defined by the ACCME as any company whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients, or any entity under the direct or indirect control of an ineligible company;
- II. under direct or indirect control or influence of an accredited provider or an organizer of accredited education with respect to governance, finances, rules, and procedures of the accreditation process. This does not preclude, that under strictly defined conditions, accrediting bodies (e.g. legally authorized bodies, including those organized under the principle of self-governance, or bodies accredited by another accrediting body), might also act as an accredited provider or organizer of accredited education; and
- III. controlled solely by individuals as stakeholders for personal gain.

### 1.3 The accrediting body must:

- I. identify which organizations are eligible to apply for accreditation;
- II. define and communicate a fair and transparent accreditation process that includes peer review by the medical profession and due process safeguards including a complaint process and reconsideration/appeal processes;
- III. require the review of both descriptions of compliance and demonstration of compliance, that is performance-in-practice, from organizations seeking accreditation or reaccreditation;
- IV. facilitate routine audit or inspection of accredited CME/CPD providers and accredited educational activities;
- V. engage with accredited CME/CPD providers and organizers of accredited education to improve understanding of the accreditation requirements and development of high quality, independent education for doctors and healthcare teams;
- VI. require accredited CME/CPD providers or organizers of accredited education to improve areas found to be in noncompliance with the accreditation requirements;
- VII. ensure that accreditation decisions, as well as supporting documentation, are maintained by the accrediting body according to applicable national law or professional licensing requirements; and
- VIII. ensure that accredited CME/CPD providers or organizers of accredited education retain records related to compliance with the accreditation requirements, as well as learner completion, for a time period defined by the accrediting body.

## Standard 2: Independence and Transparency in Accredited Education

Since there are many competing interests within and external to the medical profession that interfere with rational and evidence-based decision-making in healthcare, every effort must be made to safeguard independence and transparency in accredited education. The accrediting body plays a critical role in setting eligibility standards that prohibit ineligible companies (any company whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients) from seeking accreditation and implementing policies that prohibit control, influence or involvement in the planning, delivery, and evaluation of accredited education by ineligible companies. If funding (commercial support) is provided by ineligible companies to offset the costs of accredited education, that funding must be handled in a transparent manner and disclosed to learners.

**2.1** The accrediting body must require accredited CME/CPD providers or organizers of accredited education to ensure that:

- I. ineligible companies have no influence, control, or involvement with the planning, content development, selection of educational methods, selection of who can deliver that content, selection of target audience, delivery of content, or any other aspect of the provision or evaluation of accredited education;
- II. all individuals involved in the planning and development, delivery or evaluation of the accredited education disclose the presence or absence of all financial relationships with ineligible companies to the provider;
- III. the accredited CME/CPD provider or organizer of accredited education actively mitigates the risk that relevant relationships could bias the content of the accredited education; and
- IV. prior to the learner engaging with the activity, learners are informed of the presence or absence of relevant relationships for those in control of content (planners and faculty) in a manner that must not include any corporate branding.

**2.2** The accrediting body must require accredited CME/CPD providers or organizers of the accredited education to ensure that:

- I. the conditions and methods of payment of commercial support, defined as financial or in-kind support from an ineligible company (any company whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients) that is used to pay all or part of the costs of a CME/CPD activity meets national legal requirements, in particular tax and anti-corruption law, as well as professional law;
- II. if professional law prohibits commercial support, then it cannot be accepted;
- III. the provision of commercial support never constitutes a relationship between accredited education planners, faculty, individual learners and the commercial supporter;
- IV. if the accredited provider or organizer of accredited education responds to a request for grant proposal issued by an ineligible company for commercial support, the accredited CME/CPD provider or organizer of accredited education retains control over the identification of needs, selection of faculty, selection of target audience, and all other aspects of planning, delivery, and evaluation of the education;
- V. commercial support is not used to pay the personal expenses (such as travel, accommodation, honoraria, or registration fees) of individual learners;
- VI. learners are informed prior to the start of the accredited education if commercial support is received, including the source of the commercial support; and
- VII. if promotional or sales activities are allowed, such as exhibits at accredited education, those interactions must be kept separate from the accredited education and learners must never be required to engage in such activities.

**2.3** The accrediting body must measure compliance by accredited CME/CPD providers or organizers of accredited education with the requirements stated in standards 2.1 and 2.2.

### **Standard 3: Needs Assessment Used in Planning Accredited Education**

Needs assessment is an essential building block for the planning, implementation, and evaluation of accredited education. Accrediting bodies value educational planning that is nimble and flexible, allowing for immediate needs of learners to be identified and addressed.

The accrediting body must have requirements in place that ensure accredited education is developed in response to an analysis of the needs of doctors, healthcare teams, patients, and communities. Educational needs may be identified from a variety of data sources including the expressed (perceived) needs of doctors and healthcare teams, practice gaps of doctors and healthcare teams, and/or the health status of patients and populations. The accredited education developed to address these needs may also address the range of competencies relevant to the professional practice of doctors.

**3.1** The accrediting body must require the accredited CME/CPD providers or organizers of the accredited education to ensure that identified needs are:

- I. based on an analysis of one or more of the following data sources:
  - a) the expressed needs of the target audience
  - b) the health status of individual patients, communities, or populations
  - c) gaps in the knowledge base of doctors and healthcare teams
  - d) variations in the knowledge, competence, or performance of doctors and healthcare teams
  - e) variations in systems of care
  - f) variation in the performance of teams;

- II. documented;
- III. used to inform the educational design of the accredited education;
- IV. used by those responsible for content development; and
- V. used to assess or evaluate the accredited education.

**3.2** The accrediting body must measure compliance by accredited CME/CPD providers or organizers of accredited education with the requirements stated in standard 3.1.

#### **Standard 4: Content Validity in Accredited Education**

The content presented in accredited education must present the latest scientific evidence and technological advances relevant to the practice of medicine and delivery of healthcare in order to continuously enhance the quality and safety of care provided to patients. In addition, faculty, authors, and others in control of content must ensure that the content is relevant, evidence-based, balanced, and free from commercial bias.

**4.1** The accrediting body must require that the accredited CME/CPD providers or organizers of the accredited education ensure that the content presented:

- I. is relevant and responsive to the identified needs of the target audience;
- II. addresses the range of competencies relevant to the practice of medicine;
- III. provides recommendations for patient care that are based on current science, evidence, and clinical reasoning, while giving a fair and balanced view of diagnostic and therapeutic options;
- IV. is balanced by informing learners about potential benefits and risks, especially if the content is based only on expert opinion; and
- V. is not influenced or controlled by ineligible companies.

**4.2** The accrediting body must measure compliance by accredited CME/CPD providers or organizers of accredited education with the requirements stated in standard 4.1.

#### **Standard 5: Quality of Educational Design in Accredited Education**

Educational design is critical to the provision of effective education. Based on the education literature, adults learn better when the education is multi-modal, episodic, and interactive. Adaptive education allows for learners with different or changing needs to participate and improve. The educational format of the accredited education should reflect the intended outcome. For example, enhancing procedural skills using only didactic lectures is less likely to be effective than hands-on, skills-based training. Workplace learning should be encouraged and supported by accrediting bodies.

**5.1** The accrediting body must require that accredited CME/CPD providers or organizers of the accredited education ensure the design of the accredited education:

- I. addresses the identified needs;
- II. utilizes educational formats appropriate to the intended goals and outcomes of the education;
- III. facilitates the translation of new knowledge, skills, and competencies into practice; and
- IV. supports thoughtful reflection within the educational setting.

**5.2** The accrediting body must measure compliance by accredited CME/CPD providers or organizers of accredited education with the requirements stated in standard 5.1.

#### **Standard 6: Outcomes from Accredited Education**

The assessment of the impact of, or outcomes from, accredited education allows the accredited CME/CPD provider or organizer of the accredited education to determine if the education has been effective and to identify additional educational needs.

**6.1** The accrediting body must require that accredited CME/CPD providers or organizers of the accredited education ensure the accredited education:

- I. includes one or more assessment methods (quantitative and/or qualitative) appropriate to the intended goals or outcomes of the accredited education;
- II. measures improvements in knowledge, skills, competencies, and/or intent-to-change during and/or after the accredited education; OR
- III. measures improvements in learner performance (where applicable); AND/OR
- IV. measures changes in patient health status (where practical).

**6.2** The accrediting body must measure compliance by accredited CME/CPD providers or organizers of accredited education with the requirements stated in standard 6.1.

## PROCESS FOR APPLYING FOR ACCME SUBSTANTIVE EQUIVALENCY

Organizations interested in applying for Substantive Equivalency should email the ACCME at [info@accme.org](mailto:info@accme.org) using the subject line, "Substantive Equivalency," indicating that they are interested in exploring ACCME's program of Substantive Equivalency. ACCME will reply to such emails with a request for information, and a virtual conversation may follow. If these initial interactions conclude with consensus that application is the next step, that process involves:

- Application—Completion of ACCME's Substantive Equivalency application.
- Fee—Applying for Substantive Equivalency incurs fees that cover ACCME's costs associated with the review process.
- Survey—ACCME staff meets with your leadership to discuss your program and review your application and supporting materials.

The ACCME makes decisions three times a year (March, July, December), and these decisions are criterion-referenced and based upon detailed information submitted by you and confirmed through our survey process.

Successful completion of this process results in a four-year, renewable term of Substantive Equivalency, and the following annual requirements are then in place to maintain the status of Substantive Equivalency:

- An annual report, due by January 31<sup>st</sup> of each year, that:
  - ✓ details the accreditation activity of the preceding year, and
  - ✓ identifies any material changes to your continuing medical education accreditation requirements or processes related to the ACCME's Substantive Equivalency requirements.
- Payment of an annual Maintenance of Substantive Equivalency Fee.

## GLOSSARY

**Accredited Education (Activity)** – An educational offering that is planned, implemented, and evaluated in accordance with the accrediting body’s policies.

**Accredited Continuing Medical Education (CME) Provider** – An organization authorized by an accrediting body to assume the responsibility and accountability for the development of accredited CME.

**Accrediting Body** – The organization that sets and enforces the standards for CME/CPD activities and/or CME/CPD provider organizations through the review and approval of organizations or applications for the provision of CME/CPD and to monitor and enforce guidelines for these organizations or activities.

**Commercial Bias** – Content or format in a CME/CPD activity or its related materials that promotes the products or business lines of an ineligible company. Accredited providers and organizers of accredited education are responsible for protecting learners from commercial bias and marketing.

**Commercial Support** – Financial or in-kind support from an ACCME-defined ineligible company that is used to pay all or part of the costs of a CME/CPD activity.

**Competence** – In the context of evaluating effectiveness of a CME/CPD activity, the extent to which learners know how to implement (or stop doing) what the activity intended to teach them.

**Continuing Medical Education (CME)** – The educational activities that serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships a physician uses to provide services for patients, the public, or the profession. CME represents the 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 healthcare to the public. The content of CME can be focused not only on clinical care, but also on those attitudes/skills necessary for the individual to contribute as an effective administrator, teacher, researcher, and team member in the healthcare system. Note: CME is often used interchangeably with continuing professional development (CPD).

**Continuing Professional Development (CPD)** – Includes all activities that healthcare professionals undertake, formally and informally, including CME, in order to maintain, update, develop, and enhance their knowledge, skills, and attitudes in response to the needs of their patients.

**Credit/Units** – The “currency” assigned to accredited CME/CPD activities. Medical doctors and other healthcare professionals use credits to meet requirements for maintenance of licensure, maintenance of specialty board certification, credentialing, membership in professional societies, and other professional privileges.

**Independence in CME/CPD** – All elements of the design, development, and execution of the activity were made free from the control of an ineligible company and/or any other undesired influence.

**Ineligible Company** – Any company whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

**Knowledge** – In the context of educational needs for a CME/CPD activity, the extent to which learners have a need for new information.

**Needs Assessment** – Method(s) used to identify the perceived and unperceived needs of identified target learners.

**Organizer of Accredited Education** – Persons or entities deemed eligible to plan, present, and evaluate accredited education in an activity-based accreditation system.

**Patient Health** – The degree to which the health outcome of patients improves due to changes in the practice behavior of learners.

**Performance** – In the context of evaluating effectiveness of a CME activity, the extent to which learners do what the CME activity intended them to be able to do (or stop doing) in their practice.

**Relevant Relationships** – Financial relationships of any dollar amount are defined as relevant if the educational content is related to the business lines or products of the ineligible company.

**Substantive Equivalency** – Relationship between accrediting bodies based on shared principles and values, while recognizing and accepting differences. The purpose of substantive equivalency is to foster collaboration among accrediting bodies, facilitate continuous improvement in accreditation, expand opportunities for healthcare professionals and teams to participate in high-quality CME/CPD, and promote education that contributes to healthcare improvement for patients and their communities.