

## Outline for the Pre-Application for ACCME Accreditation – NOT FOR SUBMISSION

This document includes the information and questions that you will find in the online Pre-Application for ACCME Accreditation for which the ACCME will provide a link. You must complete and submit the Pre-Application for ACCME Accreditation using the online form. Submissions in other formats, such as Word and PDF documents, will not be accepted or reviewed.

#### Overview

As a next step in the process of applying for ACCME accreditation, please complete and submit the Pre-Application for ACCME Accreditation and the nonrefundable pre-application fee. The ACCME Accreditation Fee Schedule is posted here on the ACCME's website.

To remit fee, reference ACCME Pre-Application Review.

For payment by check, make payable to ACCME: Fifth Third Bank Lockbox Operations ACCME Lock Box #201051 6111 N. River Road, Rosemont, IL 60018

For ACH and Domestic Wire payment:

Bank Name: Fifth Third Bank

Bank Address: 5050 Kingsley Drive Cincinnati, OH 45227

Routing# for ACH: 071923909

Routing# for Domestic Wire: 042000314

Account#: 0000125658

For International Wire payment: Bank Name: Fifth Third Bank

Bank Address: 5050 Kingsley Drive Cincinnati, OH 45227

Wire Transfer ABA: 042000314 Fifth Third SWIFT: FTBCUS3C

Beneficiary Account Name: Accreditation Council for Continuing Medical Education Beneficiary Account Address: 401 North Michigan Avenue, Suite 1850, Chicago, IL 60611

Account number: 0000125658

The purpose of the pre-application is to provide you with an opportunity to demonstrate, with narrative descriptions and examples, that your organization has mechanisms already in place to fulfill the <u>ACCME's accreditation requirements</u> in the CME activities that you are producing, or have produced. The evidence you submit must come from an activity that has occurred within the 24 months that precede the date of your preapplication submission.

The ACCME encourages you to take advantage of the resources and educational opportunities regarding ACCME accreditation that you can learn about on the <u>ACCME's website</u>. Familiarize yourself with all the information to <u>Become Accredited</u> and <u>sign up</u> to receive ACCME newsletters and other email announcements and keep up-to-date with new ACCME developments.

Once your organization has submitted the pre-application and fee, the ACCME will review the materials to verify that mechanisms are in place for your organization to meet ACCME requirements. You will receive a response within approximately 4 weeks of receipt of the completed document and fee, including formative feedback, if applicable, about your organization's policies, procedures, or practices, which, if implemented, would not meet the ACCME's requirements.

The ACCME's approval of your pre-application is a determination that your organization is eligible to engage in the ACCME's initial accreditation review process. It is NOT a guarantee that your organization will receive Provisional Accreditation as a result of the initial accreditation review. The ACCME determines compliance during the initial accreditation review process based on three data sources: the self-study report, evidence of performance-in-practice, and the accreditation interview. A single finding of noncompliance with the Core Accreditation Criteria will result in a status of Nonaccreditation.

## Organization Name as it should appear on ACCME documents:

Mailing Address

## **Name of Primary CME Contact**

Title

**Email** 

Phone Number

## Name of Billing Contact

Title

Email

Phone Number

### Name of CEO:

The CEO contact is the person in a leadership role who is ultimately responsible for the organization's ACCME accredited CME program.

Title

**Email** 

**Phone Number** 

#### Section I

#### ORGANIZATIONAL INFORMATION

- **1.** Upload your Request for an ACCME Pre-Application form. You received this via email when your request was submitted.
- 2. Provide a brief history of your organization. What does your organization do? Who are your learners?
- **3.** Learner Geographic Distribution
  - **A.** My organization is a state medical society, LCME-accredited or COCA-accredited school of medicine, US-based national physician membership organization, or U.S-based national medical society.

OR

**B.** My organization is based in the United States or its territories and is an "Other National Organization" (as defined on your Request for Pre-Application).

If you checked YES to Q3B, you must show that your program of CME serves physician learners, more than 30% of whom are from beyond the state and contiguous states in which you are located. Provide data from the last two years (or less if you have not been producing CME that long) to verify that the geographic distribution of your physician learners is consistent with this requirement.

Please enter the number and percentage for physician learners from state in which your CME program is located and contiguous states and physician learners from other states. Please indicate that the data presented represents physician enrollment from MONTH/YEAR through MONTH/YEAR. (Enter N/A if this does not apply to you)

#### OR

**C.** My organization is located or incorporated outside the United States or its territories.

NOTE: The ACCME requires an accredited provider to operate the business and management policies and procedures of its CME program (as it relates to human resources, financial affairs, and legal obligations) so that its obligations and commitments are met.

The following items ask for information to substantiate that this framework is in place.

4. Is your organization an employer of staff?

If yes, upload the table of contents from your organization's human resources and financial policies or procedures manual. If your organization does not have a policies or procedures manual, attach materials to demonstrate that the human resource, financial affairs, and legal obligations and commitments are met (for example, organization's bylaws or membership guidelines).

- **5.** Upload an organizational chart that shows the structure and staff reporting relationships for your CME Program. If your CME program is part of a larger institution, upload an organizational chart that shows the position of the CME program in relation to the institution's overall structure.
- **6.** If your CME program has annual audited financial statements, attach a copy of these statements for the past year, or, if your CME program does not have annual audited financial statements, upload an income and expense statement for your CME program for the past year.

## Section II ESTABLISHING ELIGIBILITY

NOTE: Companies whose primary business is producing, marketing, re-selling, or distributing healthcare goods or services used by or on patients are ineligible for ACCME accreditation.

- **1.** Does your organization, or a part of your organization, produce, market, re-sell, or distribute healthcare products used by or on patients?
- 2. Does your organization advocate for an ineligible company?

- **3.** Does your organization have a non-primary business function that includes producing, marketing, reselling or distributing of healthcare products used by or on patients and/or advocating for, or on behalf of an ineligible company?
  - **A.** If you answered YES to Q3, is the nonprimary business function, which led you to answer yes, conducted by a separate legal entity with separate management and staff from the entity applying for accreditation?
  - **B.** If you answered NO to Q3A, describe the organizational and procedural safeguards that are in place to ensure that the CME entity is separate from any ineligible company within the larger corporate structure of your organization.
  - **C.** If you answered NO to Q3A, upload an organizational chart that includes the names of the persons in each position to depict these safeguards.
- **4.** Does your organization have a parent company that ...
  - o produces, markets, re-sells, or distributes healthcare products used by or on patients, and/or...
  - o advocates for, or on behalf of, an ineligible company?
  - (A "parent company" is a separate legal entity that owns or fiscally controls an organization.)
- **5.** Does your organization have a sister company that ...
  - o produces, markets, re-sells, or distributes healthcare products used by or on patients, and/or... o advocates for, or on behalf of, ineligible companies?
  - (A "sister company" is a separate legal entity which is a subsidiary of the same parent company that owns or fiscally controls an organization.
- **6.** If you answered YES to Q5, does your organization share management, employees, or governance structure with the sister company?
- **7.** If you answered YES to Q5, are any owners, employees, or agents of the sister company involved in the planning, development, or implementation of educational content?
- **8.** If you answered YES to Q5, does the sister company control or influence, in whole or in part, the operations of your organization?

NOTE: If you answered YES to Q1-8, your organization would likely be defined by the ACCME as an ineligible company.

## Section III MECHANISMS TO SUPPORT COMPLIANCE WITH ACCME CORE ACCREDITATION CRITERIA

Within the context of your organization's processes and mechanisms, please describe and demonstrate all the steps your organization takes to incorporate the <u>ACCME's accreditation requirements</u> into your overall CME program (the organization or part of the organization that is responsible for the CME educational activities) and, where indicated, from a CME activity you have planned or conducted recently.

#### **CME Mission and Program Improvement**

Demonstrate that you have a CME mission statement that includes expected results articulated in terms of changes in competence, performance, or patient outcomes [MISSION].

1. Upload your CME mission statement with the expected results of your CME program underlined.

Demonstrate that you gather data or information and conduct a program-based analysis on the degree to which the CME mission has been met through the conduct of CME activities/educational interventions. [PROGRAM ANALYSIS]

#### AND

Demonstrate that you identify, plan, and implement the needed or desired changes in the overall program (e.g., planners, teachers, infrastructure, methods, resources, facilities, interventions) that are required to improve on your ability to meet the CME mission. [PROGRAM IMPROVEMENTS]

2. Based on data and information gathered about changes achieved in learners' competence OR performance OR patient outcomes, provide your program-based analysis on the degree to which the expected results component of your CME mission has been met through the conduct of your CME activities/educational interventions, including the conclusions you have drawn as to whether, or not, your CME mission has been met, and why or why not. In addition, describe the needed or desired changes in your overall CME program required to improve on your ability to meet your CME mission that have been identified, planned, and implemented.

## **Educational Planning and Evaluation**

# Questions 3-6 should be answered in the context of how you planned a <u>RECENTLY COMPLETED</u> CME ACTIVITY.

Demonstrate that your organization incorporates into CME activities the educational needs (knowledge, competence, or performance) that underlie the professional practice gaps of your learners. [EDUCATIONAL NEEDS]

**AND** 

Demonstrate that your CME activities are designed to change either physician competence, or performance, or patient outcomes. [DESIGNED TO CHANGE]

**3.** State the professional practice gap(s) of your learners upon which the CME activity was based and the educational need(s) that you determined to be the cause of the professional practice(s) (knowledge need and/or competence need and/or performance need). In addition, describe what the activity was designed to change in terms of learners' competence or performance or patient outcomes.

Demonstrate that you choose educational formats for activities/interventions that are appropriate for the setting, objectives, and desired results of the activity. [APPROPRIATE FORMATS]

**4.** Describe how the chosen education format is appropriate for the setting, objectives, and desired results of the activity.

Demonstrate that you develop CME activities/educational interventions in the context of desirable physician attributes (competencies). [COMPETENCIES],

**5.** Describe how the CME activity was developed in the context of desirable physician attributes.

Demonstrate that you analyze changes in learners (competence, performance, or patient outcomes) achieved as a result of the overall program's activities/educational interventions. [ANALYZES CHANGE]

6. Describe the methods you used to obtain data on change in learners' competence, performance, or

patient outcomes and state your conclusions as to whether or not you were able to change learner competence, performance or patient outcomes across your overall program of activities.

# MECHANISMS TO SUPPORT COMPLIANCE WITH ACCME STANDARDS FOR INTEGRITY AND INDEPENDENCE IN ACCREDITED CONTINUING EDUCATION

#### Standard 1: Ensure Content is Valid

Demonstrate that your CME content is fair and balanced and that any clinical content presented supports safe, effective patient care.

- All recommendations for patient care in accredited continuing education must be based on current science, evidence, and clinical reasoning, while giving a fair and balanced view of diagnostic and therapeutic options.
- All scientific research referred to, reported, or used in accredited education in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection, analysis, and interpretation.
- Although accredited continuing education is an appropriate place to discuss, debate, and explore new and evolving topics, these areas need to be clearly identified as such within the program and individual presentations. It is the responsibility of accredited providers to facilitate engagement with these topics without advocating for, or promoting, practices that are not, or not yet, adequately based on current science, evidence, and clinical reasoning.
- Organizations cannot be accredited if they advocate for unscientific approaches to diagnosis or therapy, or if their education promotes recommendations, treatment, or manners of practicing healthcare that are determined to have risks or dangers that outweigh the benefits or are known to be ineffective in the treatment of patients.
- **7.** Describe the nature and scope of the content of your CME program and activities and how you ensure that the content meets all four elements of Standard 1.

## Standard 2: Prevent Commercial Bias and Marketing in Accredited Continuing Education

Demonstrate that your learners are protected from commercial bias and marketing.

- The accredited provider must ensure that all decisions related to the planning, faculty selection, delivery, and evaluation of accredited education are made without any influence or involvement from the owners and employees of an ineligible company.
- Accredited education must be free of marketing or sales of products or services. Faculty must not actively promote or sell products or services that serve their professional or financial interests during accredited education.
- The accredited provider must not share the names or contact information of learners with any ineligible company or its agents without the explicit consent of the individual learner.
- **8.** Describe how you ensure that all decisions related to the planning, faculty selection, delivery, and evaluation of CME activities are made without any influence or involvement from the owners and employees of ineligible companies.
  - **A.** Do you share the names or contact information of learners with any ineligible company or its agents? If you answered yes to 8A, provide the language and mechanism(s) you use to obtain the explicit consent of individual learners.

### Standard 3: Identify, Mitigate, and Disclose Relevant Financial Relationships

Demonstrate that you collect information from all planners, faculty, and others in control of educational content about all their financial relationships with ineligible companies with ineligible companies with the prior 24 months. There is no minimum threshold; individuals must disclose all financial relationships, regardless of the amount, with ineligible companies. Individuals must disclose regardless of their view of the relevance of the relationship to the education. Disclosure information must include:

- The name of the ineligible company with which the person has a financial relationship.
- The nature of the financial relationship. Examples of financial relationships include employee, researcher, consultant, advisor, speaker, independent contractor (including contracted research), royalties or patent beneficiary, executive role, and ownership interest. Individual stocks and stock options (that have been exercised) should be disclosed; diversified mutual funds do not need to be disclosed. Research funding from ineligible companies should be disclosed by the principal or named investigator even if that individual's institution receives the research grant and manages the funds.
- **9.** Describe how you collect information from all planners, faculty, and others in control of educational content about all their relevant financial relationships with ineligible companies.
  - **A.** Upload a single example of each of the form(s) or mechanism(s) that you use to collect this information that includes the complete definition of an ineligible company and instructs the individuals in control of content to include ALL financial relationships with ineligible companies for the prior 24 months.

Demonstrate that you exclude owners or employees of ineligible companies from controlling content or from participating as planners or faculty in accredited education. There are three exceptions to this exclusion—employees of ineligible companies can participate as planners or faculty in these specific situations: a.) when the content of the activity is not related to the business lines or products of their employer/company; b.) when the content of the accredited activity is limited to basic science research, such as pre-clinical research and drug discovery, or the methodologies of research, and they do not make care recommendations; and, c.) when they are participating as technicians to teach the safe and proper use of medical devices, and do not recommend whether or when a device is used.

**10.** If your organization uses employees/owners of ineligible companies as faculty, planners or in any other role associated with your CME activities, please describe how you are doing so in accordance with the three exceptions listed above. Otherwise, enter "We do not use employees/owners in association with our CME activities."

Demonstrate that you identify and mitigate all relevant financial relationships. Financial relationships are relevant if the educational content controlled by an individual is related to the business lines or products of the ineligible company.

**11.** Describe the process you use to determine whether or not financial relationships are relevant to educational content and what actions you take, appropriate to the role(s) of individuals in control of content, to mitigate all financial relationships that are determined to be relevant, to prevent all those with relevant financial relationships from inserting commercial bias in executing their CME responsibilities.

Demonstrate that you disclose to learners the presence of relevant financial relationships for all individuals in control of content, including: the names of the individuals with relevant financial relationships; the names of the ineligible companies with which they have relationships; the nature of the relationships; and, a statement that all relevant financial relationships have been mitigated. Ineligible companies must be identified by name only, and the disclosure must not include ineligible companies' corporate or product logos, trade names, or product group messages. Learners must also be informed about planners, faculty, and others in control of content with no relevant financial relationships (either individually or as a group). Learners must receive disclosure information, in a format that can be verified at the time of accreditation, before engaging with the accredited education.

- **12.** Describe the ways you inform learners of the presence or absence of relevant financial relationships of all individuals in control of content.
  - **A.** Upload an example from a completed CME activity that demonstrates that you transmitted required information about the presence or absence of relevant financial relationships to learners.

## **Standard 4: Manage Commercial Support Appropriately**

Demonstrate, if your organization chooses to accept commercial support, (defined as financial or in-kind support from ineligible companies) that you ensure accredited education remains independent of the ineligible company and that the support does not result in commercial bias or commercial influence in the education. The support does not establish a financial relationship between the ineligible company and planners, faculty, and others in control of content of the education.

Decision-making and disbursement: The accredited provider must make all decisions regarding the receipt and disbursement of the commercial support.

- Ineligible companies must not pay directly for any of the expenses related to the education or the learners.
- The accredited provider may use commercial support to fund honoraria or travel expenses of planners, faculty, and others in control of content for those roles only.
- The accredited provider must not use commercial support to pay for travel, lodging, honoraria, or personal expenses for individual learners or groups of learners in accredited education.
- The accredited provider may use commercial support to defray or eliminate the cost of the education for all learners.

Agreement: The terms, conditions, and purposes of the commercial support must be documented in an agreement between the ineligible company and the accredited provider. The agreement must be executed prior to the start of the accredited education. An accredited provider can sign onto an existing agreement between an accredited provider and a commercial supporter by indicating its acceptance of the terms, conditions, and amount of commercial support it will receive.

Accountability: The accredited provider must keep a record of the amount or kind of commercial support received and how it was used, and must produce that accounting, upon request, by the accrediting body or by the ineligible company that provided the commercial support.

Disclosure to learners: The accredited provider must disclose to the learners the name(s) of the ineligible company(ies) that gave the commercial support, and the nature of the support if it was in-kind, prior to the learners engaging in the education. Disclosure must not include the ineligible companies' corporate or product logos, trade names, or product group messages.

- **13.** Does your organization accept commercial support?
  - **A.** If you answered YES to Q13, describe how your organization meets all of the requirements of Standard 4 as delineated above. If you answered NO, indicate NOT APPLICABLE.
  - **B.** If you answered YES to Q13, upload an example from a completed CME activity that demonstrates you transmitted required information for all commercial support received for the CME activity. If you answered NO, indicate NOT APPLICABLE.

## Standard 5: Manage Ancillary Activities Offered in Conjunction with Accredited Continuing

#### Education

Demonstrate that your organization separates accredited education from marketing by ineligible companies – including advertising, sales, exhibits, and promotion – and from nonaccredited education offered in conjunction with accredited education.

Arrangements to allow ineligible companies to market or exhibit in association with accredited education must not:

- Influence any decisions related to the planning, delivery, and evaluation of the education.
- Interfere with the presentation of the education.
- Be a condition of the provision of financial or in-kind support from ineligible companies for the education.

The accredited provider must ensure that learners can easily distinguish between accredited education and other activities.

- Live continuing education activities: Marketing, exhibits, and nonaccredited education developed by or with influence from an ineligible company or with planners or faculty with unmitigated financial relationships must not occur in the educational space within 30 minutes before or after an accredited education activity. Activities that are part of the event but are not accredited for continuing education must be clearly labeled and communicated as such.
- Print, online, or digital continuing education activities: Learners must not be presented with marketing while engaged in the accredited education activity. Learners must be able to engage with the accredited education without having to click through, watch, listen to, or be presented with product promotion or product-specific advertisement.
- Educational materials that are part of accredited education (such as slides, abstracts, handouts, evaluation mechanisms, or disclosure information) must not contain any marketing produced by or for an ineligible company, including corporate or product logos, trade names, or product group messages.
- Information distributed about accredited education that does not include educational content, such as schedules and logistical information, may include marketing by or for an ineligible company.
- Ineligible companies may not provide access to, or distribute, accredited education to learners.
- **14.** Does your organization offer ancillary activities, including advertising, sales, exhibits, or promotion for ineligible companies and/or nonaccredited education in conjunction with your accredited CE activities?
  - **A.** If you answered YES to Q14, describe how your organization meets all of the requirements of Standard 5 as delineated above. If you answered NO to Q14, indicate NOT APPLICABLE.

### **Section IV**

#### **Attestation**

Before the ACCME will move forward with the accreditation process for your organization, your intentions, understanding, and commitment to abide by ACCME's expectations must be confirmed. Please read carefully each of the following confirmation statements and mark 'Yes' or 'No' as your attestation.

- **1.** We understand and attest that our organization must plan, implement, and evaluate at least two CME activities within the 24-month period prior to the initial ACCME accreditation interview.
- **2.** We understand and attest that our organization's activities adhere to the ACCME definition of CME found at <a href="https://www.accme.org">www.accme.org</a>.
- **3.** We understand and attest that by submitting a self-study report for initial accreditation and paying the initial accreditation fee to the ACCME our organization agrees to follow all relevant ACCME policies and procedures as specified by the ACCME at <a href="https://www.accme.org">www.accme.org</a>.
- **4.** We understand and attest that ACCME policies and procedures prohibit the provider from submitting to the ACCME, either with the completed self-study report or in any other material, any individually identifiable health information.
- **5.** We attest that all the materials submitted to the ACCME in any format will not contain any untrue statements, will not omit any necessary material facts, will not be misleading, will fairly present the organization, and are the property of the organization applying for accreditation.

- **6.** We acknowledge that we have read and understand the ACCME's policy on "Public and Confidential Information about Accredited Providers" found at <a href="https://www.accme.org">www.accme.org</a>.
- **7.** For organizations located in the state of California only: We attest to meeting the requirements of California's amended <u>Business and Professions Code</u>, <u>Section 2190-9196.9</u>. We understand that we may be subject to audit to determine how we are meeting the requirements by either the accreditor or the Medical Board of California.
- 8. For organizations located or incorporated outside the United States or its territories only:
  - **A.** We understand that a representative from our organization must attend an ACCME Accreditation Workshop prior to the submission of our application for initial accreditation and that our organization will not be scheduled for initial accreditation until this requirement has been met.
  - **B.** We understand that regarding the American Medical Association's (AMA) PRA Credit system, we must attest via this form to abide by the AMA rules to designate AMA PRA Category 1 Credit ™.

Electronic Signature of Primary CME Contact - Please type your name below. By doing so you are attesting to the accuracy of the information submitted in this form.