

Pre-Application for Intra-State Accreditation Florida Medical Association

Purpose of Accreditation

Accreditation is a mark of quality continuing medical education (CME) activities that are planned, implemented, and evaluated by accredited providers in accordance with Core Accreditation Criteria, Standards for Integrity and Independence in Accredited Continuing Education, and policies. Accreditation assures the medical community and the public that such activities provide physicians with information that can assist them in maintaining or improving their practice of medicine, to help them bridge the gap between today's care and what care should be. In addition, accredited CME activities are free of commercial bias and based on valid content.

Purpose of Pre-Application

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 FMA's accreditation requirements in the CME activities that you are producing or have produced. The evidence you submit must come from activities that occurred within the 24 months that precede the date of your pre-application submission.

The ACCME and FMA

The Accreditation Council for Continuing Medical Education (ACCME) is the organization that sets educational standards and policies for CME activities and does the following:

- Accredits organizations that serve a national target audience of physicians if more than 30% of the physician target audience in your proposed CME Program comes from outside Florida and its contiguous states, or if your organization is an LCME-accredited school of medicine, contact the ACCME for national accreditation.
- Recognizes state medical societies as accrediting partners within the states that choose to operate as
 accreditors. Florida Medical Association (FMA) is recognized by the ACCME as an accreditor of CME providers
 in Florida. FMA's system of accreditation is equivalent to that of the ACCME's national system of accreditation;
 therefore, you will see some references to ACCME policies. Additional information about the ACCME,
 headquartered in Chicago, IL, can be found at <u>www.accme.org</u>.

Expectations

- Eligible organizations that decide to apply for FMA accreditation should be prepared to both describe and furnish evidence that demonstrates compliance with the accreditation requirements. For this reason, organizations considering applying for FMA accreditation must plan, implement and evaluate <u>at least three CME</u> activities (15-20 CME credits) within the 24-month period prior to the submission of materials for initial accreditation. One of these activities should be completed before the pre-application is completed and used as the example in the pre-application. These three activities can be offered via joint providership with any accredited organization (ACCME or FMA–accredited).
- FMA expects its accredited providers to monitor their overall CME program on a regular basis for compliance with the accreditation requirements and to fulfill annual reporting requirements.
- Payment of certain fees is required to obtain and maintain FMA accreditation. Standard accreditation fees and other types of fees are provided in the FMA Accreditation Manual. The manual can be accessed at www.flmedical.org.

Pre-Application Process

For initial applicants, the accreditation process takes approximately nine to eighteen months. The first step in becoming accredited is completion of the pre-application for FMA Accreditation; after you have planned and offered at least three activities (15-20 credits) according to accreditation standards. Once your organization has submitted the pre-application and non-refundable fee, FMA will review the materials to verify that mechanisms are in place for your organization to meet FMA requirements. You will receive a response within approximately six 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 FMA requirements. FMA may request additional information during this review period or notify your organization in writing whether or not it is eligible to continue with the initial accreditation process.

FMA's approval of your pre-application is a determination that your organization is eligible to engage in FMA'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. FMA 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.

As you engage in the pre-application process, FMA encourages you to take advantage of resources available at <u>www.flmedical.org</u> and <u>www.accme.org</u>. Core Accreditation Criteria, Standards for Integrity and Independence in Accredited Continuing Education, and policies are included in the FMA Accreditation Manual.

FMA looks forward to supporting your efforts to become an FMA-accredited CME provider. Contact FMA's Education Department at 800.762.0233 or <u>education@flmedical.org</u> for any additional questions regarding the pre-application or accreditation requirements.

When there is a question regarding eligibility, FMA reserves the right to make decisions on the issue.

PRE-APPLICATION FOR INITIAL CME ACCREDITATION

Instructions: Organizations applying for initial accreditation are required to complete the **Pre-Application for Initial Accreditation**. To complete the form, click the boxes \Box to make a selection and gray boxes Click here to enter text. to enter text. Fill out the form completely. **Please do not edit, delete, or modify content in this form.**

Submission of the Pre-application for Initial Accreditation and Attachments: Send the completed form in a Word document (not pdf) and labeled attachments in a single email to: <u>mcarter@flmedical.org</u>.

Name of organization as it should appear on FMA documents: Click here to enter text.

Primary CME Staff Contact

Name: Title: Phone: Email: Address:

Chair of CME Committee

Name: Phone: Email:

Address:

Chief Executive Officer or CME Designee (the person in a leadership role who is ultimately responsible for the organization's FMA accredited CME program)

Name: Title:

Email:

Address:

Others Who Should Receive Copies of CME Correspondence (if any)

Name:
Title:
Email:
Address:

Name: Title: Email: Address:

Section 1: Organizational Information

- 1. Is your organization located in Florida? □ Yes □ No
- 2. Do you serve a target audience of no more than 30% of physician learners from outside Florida and its contiguous states? □ Yes □ No
- 3. Select the type of organization applying for accreditation.
 - □ Hospital or Medical Center
 - □ **Multi-facility Hospital or Healthcare System** List the facilities and/or organizations that comprise the applicant entity:
 - □ Specialty Society
 - □ Physician Group
 - \Box Consortium

List the facilities and/or organizations that comprise the applicant entity:

- \Box **Other** please describe:
- **4.** Provide a brief history of your organization. What does your organization do? Who are your learners?

Click here to enter text.

NOTE: FMA 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 your obligations and commitments are met. The following items ask for information to substantiate that this framework is in place.

5. Is your organization an employer of staff? □Yes □No

If **yes**, attach the table of contents from your organization's human resources and financial policies or procedures manual – this is <u>not</u> your CME department's policies – to your submission email. 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. Label your documentation and email attachment: **Attachment 1 – Policies and Procedures**

- 6. Attach an organizational chart to your submission email that shows the structure and staff reporting relationships for your CME Program. If your CME program is part of a larger institution, include an organizational chart that shows the position of the CME Program in relation to the institution's overall structure. Label your documentation and email attachment: Attachment 2 Organizational Structure
- If your CME Program has annual audited financial statements, attach a copy of these statements for the past year to the submission email, or if your CME Program does not have annual audited financial statements, attach an income and expense statement (form provided by FMA) for your CME Program for the past year. Label your documentation and email attachment: Attachment 3 – Financial Statement

Section 2: Establishing Eligibility

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

- 8. Does your organization, or a part of your organization, produce, market, re-sell, or distribute healthcare products used by or on patients? □Yes □No
- **9.** Does your organization advocate for an ineligible company? \Box Yes \Box No
- **10.** 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? □Yes □No
 - A. If you answered **yes** to Q10, 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?

Click here to enter text.

B. If you answered no to Q10A, 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.
Click here to enter text

Click here to enter text.

- C. If you answered no to Q10A, upload an organizational chart that includes the names of the persons in each position to depict these safeguards.
 Click here to enter text.
- 11. Does your organization have a sister company that produces, markets, re-sells, or distributes health care products used by or on patients and/or 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.) □Yes □No
 - **A.** If you answered **yes** to Q11, does your organization share management, employees, or governance structure with the sister company? □Yes □No
 - **B.** If you answer **yes** to Q11, are any owners, employees, or agents of the sister company involved in the planning, development, or implementation of educational content? \Box Yes \Box No
 - **C.** If you answered **yes** to Q11, does the sister company control or influence, in whole or in part, the operations of your organization? □Yes □No

NOTE: If you answered YES to Q8-10, your organization would likely be defined by FMA as an ineligible company.

Section 3: Mechanisms to Support Compliance with FMA 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 FMA's accreditation requirements 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].

12. Attach your CME mission statement with the **expected results** of your CME program underlined. Label your documentation and email attachment: **Attachment 4 – CME Mission Statement**

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]

13. 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.

Click here to enter text.

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. Click here to enter text.

Education Planning and Evaluation

Questions 14-19 should be answered in the context of how you planned a <u>RECENTLY COMPLETED CME</u> <u>ACTIVITY</u>.

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]

- **14.** State the professional practice gap(s) of your learners upon which the CME activity was based. Click here to enter text.
- 15. State 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). Click here to enter text.

16. Describe what the activity was designed to change in terms of learners' competence or performance or patient outcomes.

Click here to enter text.

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

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

Click here to enter text.

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

18. Describe how the CME activity was developed in the context of desirable physician attributes. Click here to enter text.

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]

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

Click here to enter text.

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.

Section 4: 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.
- 20. 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.Click here to enter text.

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.
- **21.** 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.

- **22.** Do you share the names or contact information of learners with any ineligible company or its agents?
 - **A.** If you answered **yes**, provide the language and mechanism(s) you use to obtain the explicit consent of individual learners.

Click here to enter text.

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.
- 23. 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. Click here to enter text.
- 24. Attach 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. Label your documentation and email attachment: Attachment 5 Collection of Financial Relationships

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.

- 25. Does your organization use employees/owners of ineligible companies in its CME activities? □Yes □No
 - **A.** If you answered **yes**, describe how you are doing so in accordance with the three exceptions listed above.

Click here to enter text.

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.

26. Describe the process you use to determine whether or not financial relationships are relevant to educational content.
Click here to enter text

Click here to enter text.

27. Describe 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. Click here to enter text.

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.

- 28. Describe the ways you inform learners of the presence or absence of relevant financial relationships of all individuals in control of content.Click here to enter text.
- **29.** Attach 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. Label your documentation and email attachment: **Attachment 6 Disclosure 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.

- 1. Decision-making and disbursement: The accredited provider must make all decisions regarding the receipt and disbursement of the commercial support.
 - a. Ineligible companies must not pay directly for any of the expenses related to the education or the learners.
 - b. 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.
 - c. 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.
 - *d.* The accredited provider may use commercial support to defray or eliminate the cost of the education for all learners.
- 2. 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.
- 3. 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.
- 4. 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.
- **30.** Do you accept or plan to accept commercial support for CME activities? \Box Yes \Box No
 - A. If you answered **yes**, describe how your organization meets all the requirements of Standard 4 as delineated above.

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.
- **31.** 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? □ Yes □ No
 - **A.** If you answered **yes**, describe how your organization meets all the requirements of Standard 5 as delineated above.

Section 5: Attestation

Before FMA will move forward with the accreditation process for your organization, your intentions, understanding, and commitment to abide by FMA's expectations must be confirmed. Please carefully read each of the following confirmation statements.

- 1. We understand and attest that our organization must plan, implement, and evaluate at least three CME activities (15-20 credits) within the 24-month period prior to the initial FMA accreditation interview.
- 2. We understand and attest that our organization's activities adhere to the FMA definition of CME (Definition: Continuing medical education consists of educational activities which serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, the public, or the profession. The content of CME is that 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 health care to the public.)
- 3. We understand and attest that by submitting a self-study report for initial accreditation and paying the initial accreditation fee to FMA our organization agrees to follow all relevant policies and procedures as specified in the FMA Accreditation Manual.
- 4. We understand and attest that FMA policies and procedures prohibit the provider from submitting to FMA, 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 FMA 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 policy on "Public and Confidential Information about Accredited Providers" found in the FMA Accreditation Manual.
- 7. 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 [™].
- 8. Florida Medical Association (FMA) shall have no financial obligation in connection with the organization and its sponsorship of continuing medical education.
- 9. The applicant shall defend and indemnify FMA against any and all liability for claims asserted against FMA arising out of or in connection with Fs accreditation of this organization.
- 10. The applicant agrees to fully adhere to all policies and guidelines as described in the FMA Accreditation Manual.
- 11. Applicant acknowledges that published material on the accredited program and its activities may use FMA's name only as required in the accreditation statement.
- 12. It is understood that accreditation by FMA indicates only FMA's verification that the program is in adequate compliance with FMA accreditation requirements and policies as adopted by the Committee on CME & Accreditation.
- 13. Accreditation of the organization's continuing medical education program does not indicate nor imply FMA's endorsement of the program in any way.

Electronic signatures – please type in your name and date below on the signature line. By typing in your signature and checking the box next to your signature, you have read, understand, and attest/agree to the above Texas Medical Association policies and conditions for the accreditation of your continuing medical education program.

Name of CME Program:

Name of Person Completing Self-Study Report/Primary CME Contact:

□ Signature:

Date:

Name of Physician Responsible for CME

□ Signature: Date:

Name and Title of Administrator with CME Oversight

□ Signature:

Date: