

Self-Study Report for FMA Accreditation

Applicant Name: Click or tap here to enter text.

Instructions: Read the *Guide to the Process for FMA Accreditation* before completing this form.

Organizations applying for <u>Initial Accreditation</u> (2-year term), continued <u>Accreditation</u> (4-year term), or continued <u>Accreditation with Commendation</u> (6-year term) are required to complete this form.

Organizations pursuing <u>Accreditation with Commendation</u> are also required to complete the **Self-Study Report** — **Accreditation with Commendation** form and submit along with this form. Demonstrating compliance with the Commendation criteria is optional for CME providers and not required to achieve Accreditation (4-year term).

Terminology: *Descriptions* are narrative explanations — use complete sentences. If you refer to a form, policy, etc. that is not included as a required Attachment, please describe the contents of the item in your description. *Attachments* are specific documents/documentation.

Submission of the Self-Study Report and Attachments: Send the following items in a single email to mcarter@flmedical.org:

- > Self-Study Report Reaccreditation and Initial Accreditation (send as a Word document, not pdf)
- Self-Study Report Accreditation with Commendation (if applicable), (send as a Word document, not pdf), and
- > Separate and properly labeled Attachments

Organization Information: Answer the following questions about your organization.
Applicant Name: Click or tap here to enter text.
ACCME ID#: Click or tap here to enter text.
Applicant Status: □ Initial Accreditation or □ Re-accreditation
Applying for Commendation: □ Yes or □ No
Commercial Support Accepted: ☐ Yes or ☐ No
Engage in Joint Providership: ☐ Yes or ☐ No
Person Completing the Self-Study: Click or tap here to enter text.

Organizational Contacts

Chair of CME Committee

Name: Click here to enter text Title: Click here to enter text

Address: Click here to enter text Address: Click here to enter text

Phone: Click here to enter text Email: Click here to enter text

Primary CME Staff Contact

Name: Click here to enter text Title: Click here to enter text

Address: Click here to enter text Address: Click here to enter text

Click here to enter text Click here to enter text

CEO or Organization's Administrator Responsible for Oversight of CME

Name: Click here to enter text Title: Click here to enter text

Address: Click here to enter text Address: Click here to enter text

Phone: Click here to enter text Email: Click here to enter text

Others Who Should Receive Copies of CME Correspondence (if any

Name: Click here to enter text Title: Click here to enter text

Address: Click here to enter text Address: Click here to enter text

Phone: Click here to enter text **Email:** Click here to enter text

Applicant Agreement to Policies and Conditions:

- Florida Medical Association (FMA) shall have no financial obligation in connection with the organization and its sponsorship of continuing medical education.
- The applicant shall defend and indemnify FMA against any and all liability for claims asserted against FMA arising out of or in connection with FMA's accreditation of this organization that the organization caused through its own negligence or intentional acts.
- Accreditation of the organization's continuing medical education program does not indicate nor imply FMA's endorsement of the program in any way.
- The applicant agrees to fully adhere to all policies and standards as described in the FMA Accreditation Manual.
- It is understood that accreditation by FMA indicates only FMA's verification that the program is in adequate compliance with the accreditation requirements and policies.
- Every provider applying for either initial accreditation or reaccreditation must attest to the following: "The materials we submit for (re)accreditation (Self-Study Report, activity files, and other materials) will not include individually identifiable health information, in accordance with the Health Insurance Portability and Accountability Act (HIPAA), as amended."

\square By checking this box, you certify that you have read, understand, and agree/attest to the above Florida Medical
Association policies and conditions for the accreditation of your organization.

Budget Summary of Income and Expenses

The FMA requires accredited providers to demonstrate an organizational structure that provides the necessary resources to support its CME Mission. Complete this budget page to indicate how the CME Program complies with these requirements. The FMA understands that some of these figures may be estimations. For the CME staff It is not acceptable to leave this page blank. Total expenses should be at least equal to or less than the total income outlined above.

Budget Is for Calendar Year or			
Budget Is for Fiscal Year	to	Total Dollars	
Income Sources		Amount	
Funds Allocated/contributed by the Provider (include medical staff contributions and/or administrative contributions to support human resources, food & beverage, etc.)			
CME Activity Registration Fees			
Commercial Support			
Advertising and Exhibit Income			
Other Income (specify)			
	Income Total		
<u>Expenses</u>			
CME Chair/Director - CME Hours Per Week	<mark>If paid</mark>		
CME Support Staff - CME Hours Per Week	*See note below		
Faculty Expenses (honoraria paid/travel expe	nses reimbursed)		
Food/Catering			
Marketing Expenses			
Printing, Supplies and Equipment			
Fees Associated with Accreditation:			
Workshops/Conferences			
Annual Fee			
Re-accreditation Fee			

Total Expenses

*Estimate the number of hours per week CME support staff works and estimate the salary this represents.

Prologue

- 1. **Provide** a brief history of your continuing medical education program. Click here to enter text
- Attach an organization chart to your submission email that shows the leadership and structure of your <u>CME Program</u>. Label your documentation and email attachment: Attachment 1 – Organizational Chart
- **3.** List current CME committee members, including specialty or area represented. If you are a multi-facility, include the facility the members represent. If you need additional rows right click on the last row in the table, select **Insert**, then select **Insert Rows Below**.

Name	Specialty/area represented	Facility represented (if multi-facility)

CME MISSION AND PROGRAM IMPROVEMENT

MISSION (formerly Criterion 1) The provider has a CME mission statement, approved by the governing board, that includes expected results articulated in terms of changes in competence, performance, or patient outcomes that will be the result of the program.

- 4. Enter the expected results component of your CME mission statement. The expected results must be articulated in terms of changes to learners' competence, and/or performance, and/or patient outcomes. Attach a copy of the entire Mission Statement.
 Label your documentation and email attachment: Attachment 2 CME Mission Statement Click here to enter text
- **5. Enter** the name of your governing body (this would be any group above the CME Committee and serves to ensure the organization is aware of the value and plans of the CME program) that approves the CME mission statement: Click here to enter text
- 6. Attach evidence to your submission email, showing your governing body's most recent review and approval of the CME mission. If the document is several pages, underline/highlight the requested information. Label your documentation and email attachment: Attachment 3 Approval of CME Mission Statement

PROGRAM ANALYSIS (formerly Criterion 12) The provider gathers data or information and conducts a program-based analysis on the degree to which the CME mission of the provider has been met through the conduct of CME activities/educational interventions.

7. Describe your conclusions on the degree to which you have met the <u>expected results</u> of your mission. These conclusions should be based on the data you have obtained in your analysis of learner change across your overall program of accredited activities.

Click here to enter text

Attach the aggregate evaluation data and/or performance/patient care date that you used for this analysis. Label your documentation and email attachment: Attachment 4 – Aggregate evaluation data

PROGRAM IMPROVEMENTS (formerly Criterion 13) The provider identifies, plans, and implements the needed or desired changes in the overall program (e.g., planners, teachers, infrastructure, methods, resources, facilities, interventions) that are required to improve on ability to meet the CME mission. (Optional for initial applicants)

8. Describe the needed or desired changes in the <u>overall</u> program required to improve on your ability to meet your CME mission that have been identified, planned, and implemented during the accreditation term.

EDUCATIONAL PLANNING AND EVALUATION

EDUCATIONAL NEEDS (formerly Criterion 2) The provider incorporates into CME activities the educational needs (knowledge, competence, or performance) that underlie the professional practice gaps of their own learners.

- **9. Describe** how your organization identifies the following:
 - A. Professional practice gaps of your learners.

Click here to enter text

B. Educational needs that underlie the identified professional practice gaps.

Click here to enter text

DESIGNED TO CHANGE (formerly Criterion 3) The provider generates activities/educational interventions that are designed to change competence, performance, or patient outcomes as described in its mission statement.

10. Describe how your organization designs its activities to change the competence, performance or patient outcomes of your learners.

Click here to enter text

APPROPRIATE FORMATS (formerly Criterion 5) The provider chooses educational formats for activities/interventions that are appropriate for the setting, objectives, and desired results of the activity. (Optional for initial applicants)

11. Describe how your organization chooses educational formats that are appropriate for the setting, objectives and desired results of the activities.

Click here to enter text

COMPETENCIES (formerly Criterion 6) The provider develops activities/educational interventions in the context of desirable physician attributes (competencies). (Optional for initial applicants)

12. Describe how your activities/educational interventions are developed in the context of desirable physician attributes.

Click here to enter text

ANALYZES CHANGES (formerly Criterion 11) The provider analyzes changes in learners' (competence, performance, and/or patient outcomes) achieved as a result of the overall program's activities/educational interventions.

13. Describe the methods you use to obtain data on change in learners' competence, performance, and/or patient outcomes.

AND

Describe the conclusions you reached as to whether or not you were able to change learner competence, performance, and/or patient outcomes across your <u>overall program</u> of accredited activities. This description should be based on the aggregate evaluation data you attached as Attachment 4.

STANDARDS FOR INTEGRITY AND INDEPENDENCE IN ACCREDITED CONTINUING EDUCATION

STANDARD 1: ENSURE CONTENT IS VALID (formerly CME Clinical Content Validation Policies)

Accredited providers are responsible for ensuring that their education is fair and balanced and that any clinical content presented supports safe, effective patient care.

- 1. 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.
- 2. 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.
- 3. 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.
- 4. 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.
- **14. Describe** how you ensure that the content of CE activities and your accredited CE program meet all four elements of Standard 1.

Click here to enter text

STANDARD 2: PREVENT COMMERCIAL BIAS AND MARKETING IN ACCREDITED CONTINUING EDUCATION (formerly Criterion 7 SCS 1 and Criterion 10 SCS 5.1)

Accredited continuing education must protect learners from commercial bias and marketing.

- 1. 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.
- 2. 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.
- 3. 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.
- **15. Describe** how you ensure that the content of accredited activities and your accredited CME program meet expectations of elements 1 AND 2 of Standard 2.

16	. Do you share the names or contact information of learners with any ineligible company or
	its agents?
	□ No
	\square Yes – if 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 (formerly Criterion 7 SCS 1, 2, & 6)

Accredited providers must take the following steps when developing accredited continuing education.

<u>Collect information</u>: Collect information from all planners, faculty, and others in control of educational content about all their financial relationships with ineligible companies within the prior 24 months. There is no minimum financial 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 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.

Exclude owners or employees of ineligible companies: Review the information about financial relationships to identify individuals who are owners or employees of ineligible companies. These individuals must be excluded from controlling content or 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.
- 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.

<u>Identify relevant financial relationships</u>: Review the information about financial relationships to determine which relationships are relevant. Financial relationships are relevant if the educational content an individual can control is related to the business lines or products of the ineligible company.

<u>Mitigate relevant financial relationships</u>: Take steps to prevent all those with relevant financial relationships from inserting commercial bias into content.

Mitigate relationships prior to the individuals assuming their roles. Take steps appropriate
to the role of the individual. For example, steps for planners will likely be different than for
faculty and would occur before planning begins.

Document the steps taken to mitigate relevant financial relationships.

<u>Disclose all relevant financial relationships to learners</u>: Disclosure to learners must include each of the following:

- 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.
- A statement that all relevant financial relationships have been mitigated.

<u>Identify ineligible companies by their name only.</u> Disclosure to learners must not include ineligible companies' corporate or product logos, trade names, or product group messages.

<u>Disclose absence of relevant financial relationships.</u> Inform learners about planners, faculty, and others in control of content (either individually or as a group) with no relevant financial relationships with ineligible companies.

Learners must receive disclosure information, in a format that can be verified at the time of accreditation, before engaging with the accredited education.

- **17. 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
- **18. Describe** how you collect information from all planners, faculty, and others in control of content about all their financial relationships with ineligible companies for activities that will be available to leaners or implemented beginning January 1, 2022.

 Click here to enter text
- 19. Attach evidence to your submission email a single example of each of the form(s) or mechanism(s) that you use to collect this information to meet the expectations of Standard 3.1. Ensure that this/these mechanisms include (a) the complete definition of an ineligible company and (b) the individual completing the form/mechanism is instructed to include ALL financial relationships with ineligible companies for the prior 24 months. Label your documentation and email attachment: Attachment 5 Financial Relationships

20.	Does your organization use employees or owners of commercial interests in its accredited
	activities?
	\square No
	☐ Yes – if yes, describe how you meet the expectations of Standard 3.2 (a-c)
	Click here to enter text

21. Describe the processes you use to determine which financial relationships are relevant to the educational content.

22. Describe the methods/steps you use to mitigate all relevant financial relationships appropriate to the role(s) of individuals in control of content. Note that the methods/steps used for planners are likely different than those used for faculty.

Click here to enter text

23. Describe the ways in which you inform learners of the presence or absence of relevant financial relationships of all individuals in control of content.

Click here to enter text

24. Describe what you do to ensure that learners are informed that all relevant financial relationships have been mitigated.

Click here to enter text

STANDARD 4: MANAGE COMMERCIAL SUPPORT APPROPRIATELY (formerly Criterion 8 SCS 3)

Accredited providers that choose to accept commercial support (defined as financial or in-kind support from ineligible companies) are responsible for ensuring that the 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. <u>Decision-making and disbursement:</u> 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. <u>Agreement:</u> 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. <u>Accountability:</u> 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. <u>Disclosure to learners:</u> 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.

25.	. Does your organization accept commercial support?
	□ No
	☐ Yes – if yes, describe how your organization meets the expectations of all four elements
	of Standard 4.
	Click here to enter text

STANDARD 5: MANAGE ANCILLARY ACTIVITIES OFFERED IN CONJUNCTION WITH ACCREDITED CONTINUING EDUCATION (formerly Criterion 9 SCS 4)

Accredited providers are responsible for ensuring that education is separate from marketing by ineligible companies – including advertising, sales, exhibits, and promotion – and from nonaccredited education offered in conjunction with accredited continuing education.

- 1. 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.
- 2. 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 productspecific 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.
- 3. Ineligible companies may not provide access to, or distribute, accredited education to learners.

26.	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?
	□ No
	\square Yes – if yes, describe how your organization meets the expectation of all three elements
	of Standard 5.
	Click here to enter text

Activity Records Retention

An accredited provider must have mechanisms in place to record and, when authorized by the participating physician, verify participation for six years from the date of the CME activity. The accredited provider is free to choose whatever registration method works best for their organization and learners. FMA does not require sign-in sheets.

27. Describe the mechanism your organization uses to record and verify physician participation for six years from the date of your accredited activities.

Click here to enter text

28. Attach an example to your submission email of the information or report(s) your mechanism can produce for an individual participant. Please do not attach the sign-in sheets for the activity – FMA is requesting the documentation a physician would receive if they were to contact you and request verification of their attendance for activities attended in your CME Program. Label your documentation and email attachment: Attachment 6 — Verification of Attendance