

# SELF-STUDY REPORT OUTLINE FOR INITIAL ACCREDITATION

For reference by organizations receiving accreditation decisions  
in March, July, and November 2023

In the Self-Study Report, you will provide the information requested in concise narrative explanations and statements, in tables provided, and with attached documents to verify that your CME program meets the North Carolina Medical Society's (NCMS) requirements. We encourage you to be succinct, answer the questions directly, and avoid extraneous information.

## PROLOGUE

### CME PROGRAM HISTORY

Enter a brief history of your continuing medical education program.

### ORGANIZATIONAL CHART

Attach an organizational chart that shows the leadership and structure of your CME program.

## CME MISSION AND PROGRAM IMPROVEMENT

### MISSION (Formerly Criterion 1)

The provider has a CME mission statement that includes expected results articulated in terms of changes in competence, performance, or patient outcomes that will be the result of the program.

**Enter the expected results component of your CME mission statement. The expected results must be articulated in terms of competence, performance, or patient outcomes.**

**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.

**Describe your conclusions on the degree to which you have met the expected results 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.**

**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.

**Describe the needed or desired changes in the overall 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.

**Describe what you do to ensure your organization identifies the professional practice gaps of your learners and the educational needs that underlie the practice gaps.**

## 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.

**Describe what you do to ensure your organization designs activities to change the competence, performance, or patient outcomes of your learners.**

## 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.

**Explain why the educational formats chosen are appropriate for the settings, objectives, and desired results of your activities.**

## COMPETENCIES (Formerly Criterion 6)

The provider develops activities/educational interventions in the context of desirable physician attributes (competencies).

**Describe what you do to ensure your activities/educational interventions are developed in the context of desirable physician attributes.**

**ANALYZES CHANGE (Formerly Criterion 11)**

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

**Describe the strategies you use to obtain data on changes in learners' competence, performance or patient outcomes and your conclusions as to whether or not you were able to change learner competence, performance or patient outcomes across your overall program of accredited activities.**

## **STANDARDS FOR INTEGRITY AND INDEPENDENCE IN ACCREDITED CONTINUING EDUCATION**

**STANDARD 1: ENSURE CONTENT IS VALID (Formerly CME Clinical Content Validation Policies and Criterion 10 SCS 5.2)**

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.

**Describe what you do to ensure that the content of CME activities and your accredited CME program meet all four elements of Standard 1.**

**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.

**Describe what you do to ensure that the content of your accredited activities and your accredited CME program meet expectations of elements 1 AND 2 of Standard 2.**

**Describe what you do to ensure that names or contact information of learners are not shared with any ineligible company or its agents without the explicit consent of learners.**

**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.

Collect information: 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:

- When the content of the activity is not related to the business lines or products of their employer/company.
- When the content of the accredited activity is limited to basic science research, such as preclinical research and drug discovery, or the methodologies of research, and they do not make care recommendations.
- 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.

Identify relevant financial relationships: 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.

Mitigate relevant financial relationships: 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.

Disclose all relevant financial relationships to learners: 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.

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

Disclose absence of relevant financial relationships. 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.

Describe the process(es) you had in place to collect information from all planners, faculty, and others in control of educational content about **all RELEVANT financial relationships** with ineligible companies for activities **occurring prior to January 1, 2022.**

Describe the process(es) you have in place to collect information from all planners, faculty, and others in control of educational content about **all financial relationships** with ineligible companies for activities **occurring January 1, 2022, and subsequently.**

Attach a single example of each of the form(s) or mechanism(s) that you use to collect information that meets the expectations of Standard 3.1 as of January 1, 2022. Ensure that this/these mechanism(s) include:

- a. the complete definition of an ineligible company
- b. the individual completing the form/mechanism is instructed to include ALL financial relationships with ineligible companies for the prior 24 months.

Does your organization use employees or owners of ineligible companies in its accredited activities?

Yes  No

If yes, describe the process(es) you have in place to meet the expectations of Standard 3.2 (a-c).

Describe the process(es) you use to determine which financial relationships are relevant to the educational content.

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

**Describe the method(s) you use to inform learners of the presence or absence of relevant financial relationships of all individuals in control of content.**

**Describe the method(s) you use to inform learners that all relevant financial relationships have been mitigated.**

**Describe what you do to ensure that your organization does NOT engage in joint providerships with ineligible companies.**

#### **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. **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.

**Does your organization accept commercial support?**

Yes  No

**If yes, describe what do you do to ensure your organization meets the expectations of all four elements of Standard 4.**

**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.

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.

**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

**If yes, describe what you do to ensure that your organization meets the expectations of all three elements of Standard.**

## CME ACTIVITY AND ATTENDANCE RECORDS RETENTION POLICY

1. Attendance Records: 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. The ACCME does not require sign-in sheets.
2. Activity Documentation: An accredited provider is required to retain activity files/records of CME activity planning and presentation during the current accreditation term or for the last twelve months, whichever is longer.

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

**Attach an example of the information or report(s) your mechanism can produce for an individual participant.**

**Describe what your organization does to ensure that activity files/records of CME activity planning and presentation are retained during the current accreditation term or for the last twelve months, whichever is longer.**