

## **MUSC Office of CME (OCME) Conflict of Interest Policies and Procedures**

### **Policy**

The Medical University of South Carolina, as an Accreditation Council for Continuing Medical Education (ACCME) accredited provider, endorses and strives to comply with the ACCME Standards for Integrity and Independence in Accredited Continuing Education, South Carolina statutes, Medical University of South Carolina policies and procedures, and associated federal and private regulations and guidelines on the need for disclosure and monitoring of proprietary and financial interests that may affect the scientific integrity and balance of content delivered in continuing medical education activities in our name.

The MUSC College of Medicine requires that all CME activities accredited through this institution be developed independently of ineligible companies and be scientifically rigorous, balanced and objective.

### **ACCME's Definition of an Ineligible Company**

ACCME has incorporated eligibility information directly into the Standards for Integrity and Independence in Accredited Continuing Education. Companies that are ineligible to be accredited in the ACCME System (ineligible companies) are those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. Examples of such organizations include:

- Advertising, marketing, or communication firms whose clients are ineligible companies
- Bio-medical startups that have begun a governmental regulatory approval process
- Compounding pharmacies that manufacture proprietary compounds
- Device manufacturers or distributors
- Diagnostic labs that sell proprietary products
- Growers, distributors, manufacturers or sellers of medical foods and dietary supplements
- Manufacturers of health-related wearable products
- Pharmaceutical companies or distributors
- Pharmacy benefit managers
- Reagent manufacturers or sellers

### **Medical University of South Carolina Office of CME Responsibilities**

MUSC Office of CME, as the designated ACCME entity for the College of Medicine, is responsible for identifying relevant financial relationships between individuals in control of educational content and ineligible companies and managing these to ensure they do not introduce commercial bias into the education. It is the responsibility of the Office of Continuing Medical Education to take the following steps when developing accredited continuing education. Exceptions are listed at the end of Standard 3.

1. 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:

- a. The name of the ineligible company with which the person has a financial relationship.
- b. 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.

2. 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 preclinical 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.

3. 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.

4. Mitigate relevant financial relationships: Take steps to prevent all those with relevant financial relationships from inserting commercial bias into content.

- a. 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.
- b. Document the steps taken to mitigate relevant financial relationships

5. Disclose all relevant financial relationships to learners: Disclosure to learners must include each of the following:

- a. The names of the individuals with relevant financial relationships.
- b. The names of the ineligible companies with which they have relationships.
- c. The nature of the relationships.
- d. 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.**

**Exceptions:** Accredited providers do not need to identify, mitigate, or disclose relevant financial relationships for any of the following activities:

1. Accredited education that is non-clinical, such as leadership or communication skills training.
2. Accredited education where the learner group is in control of content, such as a spontaneous case conversation among peers.
3. Accredited self-directed education where the learner controls their educational goals and reports on changes that resulted, such as learning from teaching, remediation, or a personal development plan. When accredited providers serve as a source of information for the self-directed learner, they should direct learners only to resources and methods for learning that are not controlled by ineligible companies.

## CONTENT VALIDATION

The Medical University of South Carolina Office of Continuing Medical Education is 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 the Medical University of South Carolina's Office of Continuing Medical Education 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.

## MITIGATION OF RELEVANT FINANCIAL RELATIONSHIPS

The Medical University of South Carolina Office of Continuing Medical Education identifies the presence or absence of relevant financial relationships for all planning committee members, course directors, invited faculty presenters/authors, and staff through the use of a standardized disclosure form. If a relevant financial relationship with an ineligible company has been identified, the Medical University of South Carolina Office of Continuing Medical Education selects one of the following mechanisms listed below to mitigate the relationship:

### Mitigation steps for planners

1. **Divest** the financial relationship
2. **Recusal** from controlling aspects of planning and content with which there is a financial relationship
3. **Peer review** of planning decisions by persons without relevant financial relationships

### Mitigation steps for faculty and others

1. **Divest** the financial relationship
2. **Peer review** of content by persons without relevant financial relationships
3. Attest that clinical recommendations are **evidence-based** and **free of commercial bias** (e.g., peer-reviewed literature, adhering to evidence-based practice guidelines)

## Educational planning and design of CME activities

The Medical University of South Carolina Office of Continuing Medical Education will continue its longstanding practice of integral involvement in all of its CME accredited activities. The planning process for both direct and jointly sponsored activities require early involvement of the MUSC Office of CME and active participation in the development and implementation of the CME activities.

### Specific strategies include:

- Implement educational planning and design strategies that work to ensure that content is scientifically rigorous, evidenced-based and balanced and reflects the current standards of care and/or future directions of medicine and healthcare.

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- Monitor and manage its continuing medical education activities in accordance with the current standards, regulations and guidelines outlined by the constituencies involved in the delivery of continuing medical education, research and patient care.
- Document the processes for needs assessment, content validation, and educational design that provide for fair and balanced discussion of the desired topics.
- Encourage opportunities for interactive learning, to explore differences of opinion and/or dialogue which we believe serve as the foundation for professional development and continuous improvement in approaches to patient care.
- Monitor the execution of CME activities to validate the presence/absence of commercial bias and the consistent application of the standards of quality education for physicians and other healthcare professionals.

**Timing of the Identification, Management, and Resolution of Conflicts of Interest**

***Course Director(s) and Planning Committee Member(s):***

- Completion of the MUSC Office of CME disclosure and attestation, if applicable, **with** submission of the “Request for CME Certification” &/or the CME application. **Applications will not be reviewed until disclosure is completed and submitted to MUSC OCME.**
- Financial relationship(s) is/are reviewed by CME staff:
  - No relevant financial relationship identified: no action will be taken and planning process can continue.
  - When a relevant financial relationship is identified: CME staff will work with the activity director to mitigate the relationship based on the ACCME Standards for Integrity and Independence in Accredited Continuing Education

***Faculty/Speaker/Author:***

- No relevant financial relationship identified: no action will be taken and planning process can continue.
- When a relevant financial relationship is identified: CME staff will work with the activity director to mitigate the relationship based on the ACCME Standards for Integrity and Independence in Accredited Continuing Education.

***College of Medicine CME Advisory Committee Members:***

- Disclosure of financial relationships with commercial interest(s) must be obtained from all potential CME Advisory Committee Members.
- The Director reviews the disclosure statements to identify and resolve conflicts of interest.
- If this does not result in satisfactory resolution of all conflicts of interest, the process will continue through the following levels:
  - Director of CME Associate Dean of CME
  - CME Advisory Committee
  - Other resources with appropriate expertise
- After the process, conflicts are considered resolved if it is determined: No conflict exists;
  - No material conflict exists;
  - Material conflict exists but public good outweighs conflict
- If the conflict cannot be satisfactorily resolved, the Dean will request and accept the resignation of the involved CME Advisory Committee member.

## IMPORTANT

An individual who refuses to disclose relevant financial relationships will be disqualified from being an activity director, planning committee member, speaker or author for a CME activity and cannot have control of or responsibility for the development, management, presentation, or evaluation of the CME activity.

### When Conflict of Interest cannot be effectively resolved

While MUSC Office of Continuing Medical Education strives to be flexible, accessible and helpful in the development and implementation of CME certified activities, there are some situations where adequate resolution of COI may not be feasible. In these situations, CME certification will not be provided. Examples of these situations include:

- Requests for CME certification of the content after the majority of the planning for the CME activity has occurred with faculty and/or content selections already determined;
- Short planning timeframes that do not permit adequate planning and implementation of required ACCME and MUSC Office of CME policies and procedures;
- Inappropriate processes in educational planning and/or financial management that are not consistent with ACCME and/or MUSC Office of Continuing Medical Education policies and procedures.

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Approved by the Medical University of South Carolina College of Medicine  
CME Advisory Committee and William Basco, MD, MS, Associate Dean for  
CME

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