



SECTION: 14 Faculty Affairs

AREA: Continuing Medical
Education

NUMBER: 14.05.09

SUBJECT: Disclosure, Mitigation and Commercial Support in Continuing Medical Education

I. Purpose and Scope

- A. This policy defines procedures for identifying and managing conflicts of interest in accredited continuing medical education (CME) activities at the Tilman J. Fertitta Family College of Medicine (Fertitta College of Medicine). The policy ensures compliance with the *ACCME Standards for Integrity and Independence in Accredited Continuing Education*.
- B. It applies to all faculty, staff, planners, reviewers, speakers, panelists, moderators and external collaborators involved in CME planning and delivery.

II. Policy

- A. As an accredited continuing medical education (CME) provider, the Fertitta College of Medicine Office of Continuing Medical Education provides education that is professionally appropriate, unbiased and based on best practices and evidence. Anyone with control over the educational content and who is involved in the accredited continuing education activity is required to disclose information about **all** personal conflicts of interest and financial relationships in accordance with the Accreditation Council for Continuing Medical Education (ACCME) *Standards for Integrity and Independence in Accredited Continuing Education*.
- B. Completed Financial Disclosures forms for each person in control over educational content are due to the Office of Continuing Medical Education no less than two (2) weeks prior to the start of an activity.
- C. The Office of Continuing Medical Education will review the financial information provided and the Office of Continuing Medical Education will determine whether a potential conflict exists. Conflicts of interest are created when individuals have an opportunity to affect the content of the educational activity with information that promotes the proprietary business interests of an ineligible company. If the financial relationship provided is relevant to the educational content presented, the Office of Continuing Medical Education will mitigate any potential or actual conflict of interest prior to the activity.

III. Procedure

- A. Prior to the activity a Financial Disclosure Form is distributed and collected from each person involved in the educational content for the activity which includes Planning Committee members, course director, activity coordinator, speakers, moderators, panelists, and reviewers.
- B. The Office of Continuing Medical Education reviews each submitted Financial Disclosure Form.
 1. **If no relevant conflict of interest exists, no action is required.** The Office of Continuing Medical Education will disclose to the audience no relevant financial relationships by adding the following text to the activity flyer/agenda/syllabus, the presentation disclosure slide, and sign in sheet for the activity under the accreditation statement:
 - a. “The presenter nor the planners for this educational activity have relevant financial relationship(s) to disclose with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.”
 2. If a relevant conflict of interest exists, the mitigation process of Financial Disclosure is implemented.
 3. If a conflict of interest is present, the *Office of Continuing Medical Education Potential Conflict of Interest Mitigation Form* in conjunction with the *ACCME Flowchart for the Identification and Resolution of Personal Conflicts of Interest* is used to guide the conflict-of-interest process and resolve the conflict in one of the following ways as outlined below. The method of resolution will be documented on the *Office of Continuing Medical Education Potential Conflict of Interest Mitigation Form* and may include one or more of the following actions:
 - a. **Step One:** The Course Director (or planning committee member or reviewer, if the course director also has a conflict of interest) reviews the educational content (slides) of the presentation prior to the activity and determines if a conflict of interest exists. The recommendations below mitigate a conflict of interest and will be disclosed to the learners at the activity.
 - i. If the content of activity/presentation has no therapeutic recommendations for patients/patient care, otherwise known as a basic science talk. This includes content such as pre-clinical research and drug discovery, or the methodologies of research, AND does not make patient care recommendations.
 - ii. The content of the activity is not related to the business lines or products of the ineligible company with whom the person has a financial relationship.
 - iii. The CME activity/presentation is not related to patient care, such as leadership or communication skills.

- iv. Not providing CME credit for the presentation because the conflict of interest cannot be resolved.
 - v. Selecting an alternative speaker for the presentation. The individual can terminate their relationship with the ineligible company. However, this information must be disclosed to the learners.
 - vi. Planning committee members, course directors, and activity coordinators with a conflict of interest must be disclosed to the learners. The individual will be recused from making decisions on content in areas where the individual has a conflict. If the course director has a conflict of interest related to topics being discussed in the activity the planning committee must have two (2) to three (3) other members that have no conflicts of interest to approve all topics and speakers to ensure the activity is free from bias and that the ineligible companies are not influencing the education.
 - vii. Employees of ineligible companies are not allowed to serve on the planning committee as the course director and must be recused from their position immediately.
- b. **Step Two:** Communicate with speaker regarding the expectations of the presentation(s) which needs to include the following:
- i. Any discussion of products or services of a commercial interest is presented in a balanced and unbiased fashion.
 - ii. Any clinical recommendations are based on the best available evidence.
 - iii. If pharmaceutical/medical device products or services are discussed, generic names are used. If trade names are also used, they are used for all products/services.
 - iv. All scientific research referred to conforms to the generally accepted standards of experimental design, data collection and analysis.
 - v. Any off-label or non-approved use of a drug or medical device is disclosed.
 - vi. No ineligible company logos are used.
 - vii. Document all conversations and resolutions on the Potential Conflict of Interest Mitigation form.
- c. **Step Three:** Disclose how the conflict of interest was mitigated. The learners must be made aware of any disclosures prior to engaging with the accredited education. To accomplish this, the Office of Continuing Medical Education will list any disclosures on the activity flyer/agenda/syllabus, the presentation disclosure slide, and the sign in sheet for the activity under the accreditation statement.

- i. To disclose relevant financial relationships for one speaker the following example may be used:
 1. {First Name}{Last Name}, {credentials}, {role in activity such as speaker} for this educational activity is {nature of the financial relationship} for {ineligible company}.
 - Example: **Anthony Stark, MD, PhD**, is a consultant for Abbott Pharmaceuticals and is on the speakers' bureau for AbbVie.
 2. Then add the following statement to show you mitigated the conflict of interest:
 - a. "All of the relevant financial relationships have been mitigated."
 3. Lastly demonstrate the remaining individuals in control over the educational content were screened for any potential conflict of interest with the following statement:
 - a. "None of the other planners for this educational activity have relevant financial relationship(s) to disclose with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients."
- ii. If you have several financial relationships to disclose with many individuals, use the table format below:

Name of individual:	Nature of the financial relationship:	Name of the ineligible company:
Anthony Stark, MD, PhD	Consultant Speakers' Bureau	Abbott Pharmaceuticals AbbVie
Stephen Strange, MD, FAANS	Medical Advisory Board	Biogen

1. Add the following statement to demonstrate the mitigation for each conflict of interest:
 - a. "All of the relevant financial relationships listed for these individuals have been mitigated."
2. Last you need to demonstrate that the remaining individuals in control over the educational content were screened for any potential conflict of interest with the following statement:
 - a. "All of the others in control of content for this educational activity do not have relevant financial

relationship(s) to disclose with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.”

4. *Standards for Integrity and Independence in Accredited Continuing Education;*
Standard 3: Identify, Mitigate, and Disclose Relevant Financial Relationships.

- a. Many healthcare professionals have financial relationships with ineligible companies. These relationships must not be allowed to influence accredited continuing medical education. Fertitta College of Medicine, as an accredited provider, 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. Financial relationships of any dollar amount are defined as relevant if the educational content is related to the business lines or products of the ineligible company. The Office of Continuing Medical Education at the Fertitta College of Medicine must take the following steps when developing accredited continuing education. Exceptions are listed at the end of Standard 3.
- b. 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 twenty-four (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. Financial disclosure information must include:
 - i. The name of the ineligible company with which the person has a financial relationship.
 - ii. 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.
- c. **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.

- d. Owners or employees of ineligible companies may participate as planners or faculty in only these three (3) following specific situations:
 - i. When the content of the accredited activity is **not** related to the business lines or products of the employer/company.
 - ii. When the content of the accredited activity is limited to only basic science research, such as pre-clinical research and drug discovery, or the methodologies of research, and the owner or employee does not make patient care recommendations.
 - iii. When the employee is participating in the accredited activity as a technician to teach the safe and proper use of medical devices, and do not recommend whether or when a device is used.
- e. 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.
- f. Mitigate relevant financial relationships: Take steps to prevent all those with relevant financial relationships from inserting commercial bias into content.
 - i. 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.
 - ii. Document the steps taken to mitigate relevant financial relationships.
- g. Disclose all relevant financial relationships to learners: Disclosure to learners must include each of the following:
 - i. The names of the individuals with relevant financial relationships.
 - ii. The names of the ineligible companies with which they have relationships.
 - iii. The nature of the relationships.
 - iv. A statement that all relevant financial relationships have been mitigated.
- h. 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.
- i. 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.

- j. Learners must receive disclosure information, in a format that can be verified at the time of accreditation, before engaging with the accredited education.
 - k. Exceptions: As an accredited provider, the Fertitta College of Medicine does not need to identify, mitigate, or disclose relevant financial relationships for any of the following activities:
 - i. Accredited education that is non-clinical, such as leadership or communication skills training.
 - ii. Accredited education where the learner group is in control of content, such as a spontaneous case conversation among peers.
 - iii. 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.
5. Review and Resolution: Identified conflicts of interest may be reviewed by the Activity Course Director, Director of the Office of Continuing Medical Education, and/or the Chair of the Continuing Medical Education Committee and/or identified experts(s) in the field as appropriate. (Reviewers will also be asked to disclose their relevant financial relationships as a precaution against any conflict of interest they may have.) Additional information on a presentation may be collected for review.
6. Oversight: All financial relationships are required to be disclosed to the accredited activity learners. Learners and peer reviewers will evaluate the activity to determine if the content is free of bias and meets acceptable scientific standards.

IV. Definitions

- A. **Commercial Support:** Financial or in-kind contributions from an ineligible company to fund aspects of a CME activity.
- B. **Ineligible Company:** Any entity whose primary business involves producing, marketing, or selling healthcare products used by or on patients.
- C. **Conflict of Interest:** A situation in which an individual's financial relationship may influence, or appear to influence, the content of a CME activity.
- D. **Financial Relationship:** Any personal financial benefit received within the past 24 months, including honoraria, consulting fees, stock ownership, royalties, etc.

V. Supporting Policy Information

A. A. Maintaining Independence

- a. All educational decisions—including content, speakers, and materials—must be made by the continuing medical education planning team without influence from commercial entities.
- b. Commercial supporters may be acknowledged as sponsors; however, they may not serve as continuing medical education providers, co-hosts, or activity organizers.
- c. The selection of faculty must be based solely on expertise and be free of commercial bias or pressure.
- d. Speakers may not promote or sell products or services during continuing medical education activities.

B. Disclosure and Conflict Management

- a. All individuals involved in continuing medical education content must disclose all financial relationships using the Fertitta College of Medicine Financial Disclosure Form.
- b. Anyone who refuses to disclose will not be allowed to participate in the planning, presenting, or evaluating the accredited activity.
- c. The Office of Continuing Medical Education will review all disclosures and address potential conflicts in accordance with its **Conflict-of-Interest Mitigation Policy** prior to the start of the activity.

C. Commercial Support

- a. The University of Houston does not permit commercial support of any amount.
- b. Ineligible companies may not influence content, speakers, or educational design.
- c. Exhibits and advertisements must be separated from educational activities and clearly identified as promotional. 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 30 minutes before or 30 minutes after an accredited education activity. Location of the exhibits must be separated from an accredited activity. The Office of Continuing Medical Education recommends exhibits be set on a different floor or area of the Fertitta College of Medicine.

D. Honoraria and Funding Use

- a. Honoraria may be provided at the discretion of the Department. The Office of Continuing Medical Education does not provide honoraria.
- b. Commercial funds may not be used to pay speaker fees or reimbursements directly.
- c. All expenses for the accredited activities must be paid through Fertitta College of Medicine departmental channels.
- d. Modest meals and hospitality may be offered as part of the educational experience, not as a standalone benefit.

E. Separation of Promotion and Education

- a. Advertising and promotional content must be kept outside the educational space and materials.
- b. Continuing medical education materials, such as slides, handouts, agendas, flyers, etc. must be free of logos, trademarks, and product-specific content.
- c. Learner names and contact information will not be shared with exhibitors or ineligible companies.

F. Content Integrity and Balance

- a. Continuing medical education activities must be evidence-based, objective, and promote improved healthcare—not a specific commercial product.
- b. Faculty must present a balanced view of treatment options and are encouraged to use generic names.
- c. Commercial bias must be avoided in all formats and presentations.

G. Learner Disclosures

- a. Prior to the start of the activity, learners will be informed of any relevant financial relationships held by planners or faculty.
- b. This disclosure includes:
 - c. Individual's name
 - d. Company name(s)
 - e. Nature of the relationship
 - f. A statement that the conflict has been mitigated
 - g. Disclosures must not include logos or promotional language.
 - h. If presented verbally, a written verification must be completed by a CME Office representative and retained in the activity file.

VI. Disciplinary Action for Non-Compliance

- A. Failure to adhere to these policies may result in suspension or cancellation of CME credit for the activity and individuals may be removed from future activity planning roles.

VII. References

- A. Accreditation Council for Continuing Medical Education – www.accme.org
- B. AMA PRA Credit System – www.ama-assn.org
- C. Standards for Integrity and Independence in Accredited Continuing Education

VIII. Review and Responsibility

Responsible Party:	Director, Continuing Medical Education
Review:	Every 2 years
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Fertitta College of Medicine

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