

## **Purpose**

The purpose of this policy is to ensure that any potential conflict of interest (“COI”) is openly identified so participants can form their own opinions about the content of a presentation with the full disclosure of facts. This policy outlines the mechanism for resolving identified COI and provides guidelines for activity planners.

## **ACCME Definitions**

*Commercial Interest:* Any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. A commercial interest is not eligible for ACCME accreditation or participation in joint providership.

*Commercial Support:* Monetary or in-kind contributions given by an ACCME-defined commercial interest that is used to pay all or part of the costs of a CME activity.

*Conflict of Interest:* The ACCME considers financial relationships to create conflicts of interest in CME when individuals have both a financial relationship with a commercial interest and the opportunity to affect the content of CME about the products or services of that commercial interest. The potential for maintaining or increasing the value of the financial relationship with the commercial interest creates an incentive to influence the content of the CME—an incentive to insert commercial bias. See also “relevant financial relationships.”

*Relevant financial relationship:* A financial relationships in any amount that create a conflict of interest and that occurred in the twelve-month period preceding the time that the individual was asked to assume a role controlling content of the CME activity. Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria for promotional speakers’ bureau, ownership interest (e.g., stocks, stock options or other ownership interest, excluding

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diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received, or expected. See also “conflict of interest.”

### **Policy**

All individuals in a position of control of content of a CME activity must disclose any relevant financial relationship(s) that affect independent involvement in the proposed activity. An individual who refuses to disclose financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME and cannot have control of, or responsibility for, the development, management, presentation or evaluation of a CME activity. Planning committee members and speakers must indicate no COI or that disclosed COI has been resolved.

- Planning committee disclosures must be included in the initial application packet submitted to the Office of Medical Education.
- Speaker disclosures must be submitted no later than two weeks before the event.

If COI is identified, a Resolution of Conflict of Interest Form must be submitted to the Office of Medical Education prior to the event. All COI must be resolved during the planning stage of a program.

### **Procedure to Identify and Resolve COI**

#### **Procedure to Determine and Resolve COI:**

1. Communicate to everyone in control of content exactly what is expected of him/her as a participant in the activity.
2. Collect completed disclosure form(s).
  - a. Planning Committee disclosures must be completed upon the inception of the planning process.
  - b. Speaker disclosures must be completed at least two weeks before the event.

3. Review completed disclosure form(s) for any disclosed relevant financial relationship(s).
4. If a relevant financial relationship is identified, review educational material to further determine if any potential COI exists. Make note of questionable slides. Carefully review slides for trade names, logos, or biased content.
5. If a potential COI is identified, the course director and an independent peer adviser will review the presentation topic(s) and educational materials.

### **Mechanism to resolve conflict of interest prior to an activity:**

1. If COI is identified, select one or more of the following mechanisms to try and resolved the conflict
  - a. Presentation will include a validation of evidence-based content.
  - b. Speaker will offer no recommendations and limit content to scientific research data and results.
  - c. Peer review of content will be undertaken to ensure absence of bias and, if necessary, content will be restructured.
  - d. Speaker is either reassigned to a different topic that does not have the same potential for bias, or is not allowed to present.
  - e. Presentation topic(s) are assigned to another speaker.

### **Planning Committee and Speaker Guidelines**

#### **General Information:**

- **Contributed Funds:** All support, monetary and in-kind, must be paid or contributed with full knowledge and approval of the Continuing Medical Education Committee. Acceptance and disbursement of funds must comply with ACCME Standards of Commercial Support and YNHHS policies. (SCS3.1, 3.3)
- **Disclosure of Financial Relationships:** All individual in a position to influence the content of a certified CME activity must disclose whether or not relevant financial relationships exists within the past 12 months that may affect the independence of the proposed CME activity.
  - This information must be provided by the Planning Committee to the audience before the activity.
  - Company funding, and any relevant relationship between speaker, moderator any a financial interest will be disclosed prior to the activity.

- Planners or speakers who refuse to disclose relevant financial relationships will not be allowed to participate in the CME activity.
- **Conflict of Interest (COI) Resolution:** If anyone in position of control to influence content of a CME activity declares a COI, the planning committee must be aware of it and document the steps taken to ensure balance, independence, objectivity and scientific rigor in the CME activity.
  - The planning committee is responsible for resolving COI prior to the activity. If the speaker is retained

### **Planning Committee:**

The following will be undertaken free from influence of ACCME defined Commercial Interests.

- **Development:** The planning committee must identify and document need on the CME application.
  - The committee will establish overall activity objectives
  - Choose the activity title
  - Choose activity date and location
- **Selection of Speaker:** The planning committee will identify potential speakers.
- **Contributor Selection:** The planning committee will identify any potential contributors. All contributors must adhere to the ACCME Standards of Commercial Support and YNHHS policies.
- **Activity Content:** All CME developed and presented by Bridgeport Hospital must be done so in compliance with ACCME accreditation requirements in addition to the requirements of the AMA PRA program.

### **Speaker:**

- **Statement of Purpose:** The speaker agrees that the CME activity is for scientific or educational purpose. Any discussion of commercial products will be objective, balanced, and scientifically rigorous.
- **Limitations of Data:** The speaker must disclose any limitations on the research presented, such as data that represents ongoing research, interim analysis, preliminary data, or unsupported opinion,
- **Generic medications or more than one brand name:** Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names,

where available trade names from several companies should be used, not just trade names from a single company.

- **Content Validity:** Speakers participating in CME must assure that any clinical recommendations are valid for use in the care of patients. All scientific research recommended in support of patient care must conform to generally accepted standards of scientific rigor:
  - Recommendations must be based on evidence that is accepted within the medical profession.
  - All recommendations involving clinical medicine must be based on evidence that is accepted within the profession of medicine and as adequate justification of their indications and contraindication in the care of patients.
  - Recommendations on clinical care must be more than firmly held beliefs or hopes for efficacy
  - Data or information accepted within the profession of medicine must support the recommendation
  - The conclusions drawn from the data must be those that would be reasonably drawn from the data.

The validation of clinical content does not mean that every clinical in practice accepts the recommendation or that the recommendation is part of FDA-labeling. An important part of validity is the scientific integrity of the data from which the conclusions are drawn and the clinical recommendations crafted.

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