



**Global and Continuing Education**

401 Park Drive, Suite 504 West, Boston, MA 02215

T: (617) 384-8600 hms.harvard.edu/cme

**Policy on Identification and Resolution of Conflicts Of  
Interest for  
Continuing Medical Education Activities**

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**I. Definitions**

**A. Commercial Interest**

A commercial interest is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. Providers of clinical services directly to patients are not considered commercial interests.

**B. Financial Relationships and Benefits**

Financial relationships are those relationships in which the individual receives some form of financial benefit. Examples of relationships include:

- Employment
- Management position
- Independent contractor (including contracted research and clinical trials—including where the institution receives the grant and manages the funds and the person is the principal or named investigator on the grant)
- Consultant
- Speaker's bureau<sup>1</sup> and teaching
- Membership on advisory committees or review panels
- Board membership
- Other activities when remuneration is received or expected

Relationships are considered to be “relevant” when they have occurred within 12 months of involvement with the CME activity and they could create a conflict of interest. The value of the financial benefit received is irrelevant.

Financial benefits include:

- Salary or other income
- Royalties, including milestone payments, license fees and royalties flowing through the institution
- Intellectual property rights
- Consulting fees
- Honoraria
- Ownership interests (stocks, stock options, or other ownership interests excluding diversified mutual funds not under the individual's control)

**C. Conflict of Interest (COI)**

The Accreditation Council for Continuing Medical Education (ACCME) considers financial relationships to create actual conflicts of interest in CME when individuals (or their spouse/partner) have both a financial relationship with a commercial interest and the opportunity to affect the content of CME that discusses, reviews or could otherwise impact the products or services of that commercial interest. When the provider's interests are aligned with those of a commercial interest, the interests of the provider could be in “conflict” with

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<sup>1</sup> All HMS faculty members must comply with the *Harvard University Faculty of Medicine Policy on Conflicts of Interest and Commitment* in the planning and development of CME activities. Consistent with that policy, HMS faculty members must retain intellectual independence over the content of any educational material they present. HMS absolutely prohibits its faculty from receiving compensation for presenting educational materials developed by commercial interests.

the interests of the public. The interests of the people controlling CME must always be aligned with what is in the best interest of the public; therefore, ACCME and Harvard Medical School (HMS) require that any identified conflict be resolved prior to delivery of CME.

## II. Policy

Continuing medical education should be developed free from the control of commercial interests and be balanced, objective, and scientifically rigorous. HMS is committed to providing lifelong learning opportunities to providers of medical care, medical education, and medical research and has an obligation to lead high quality, evidence-based CME. HMS recognizes that to ensure transparency of financial relationships and eliminate commercial bias in CME activities, anyone who is in a position to control CME content (e.g. planners, instructors, reviewers, etc.) must disclose to their HMS course director or HMS GCE staff person any financial relationships with a commercial interest that are relevant to the proposed CME activity. This is in order for HMS, through its course directors and HMS Global and Continuing Education (GCE), to use the mechanisms described below to identify and resolve all conflicts of interests prior to the CME activity taking place. If any individual who is in a position to control content of CME refuses to disclose relevant financial relationships to HMS, he/she will be automatically disqualified from any role in planning, management, presentation or evaluation of that CME activity.

## III. Mechanisms to Identify COIs

All individuals in a position to control content of a CME activity must provide disclosure of their relevant financial relationships to HMS GCE. Most frequently this is accomplished through the use of HMS GCE's standardized Disclosure and Content Attestation forms. COIs are identified by reviewing this information to determine whether the disclosed financial relationship is related to the content of the proposed CME activity via the following methods:

Individual In Control of Content *	Deadline for Disclosure Submission	Mechanism to Identify COI
Course Director	Submitted to GCE with CME Activity Proposal	Review by GCE staff, CME Reviewer, or non-conflicted physician
Academic Planner	Submitted to GCE with CME Activity Proposal	Review by GCE staff, CME Reviewer, or non-conflicted Course Director or physician
Faculty, including Speakers, Moderators, and Authors	Submitted to GCE 60 days prior to the activity date	Review by non-conflicted Course Director, non-conflicted physician or GCE staff
CME Reviewer	Submitted annually to the Accreditation Coordinator	Review by GCE staff
Physician Reviewer	Submitted annually to the Accreditation Coordinator	Review by GCE staff
Educational Committee Member	Submitted annually to the Accreditation Coordinator	Review by GCE staff

\*If any individual discloses that they or their spouse or partner are an employee of an ACCME-defined commercial interest, this relationship must be reviewed by the Director of Educational Development and Accreditation to discuss whether it is appropriate for the individual to be engaged in the CME activity. See *HMS Policy on the Use of Employees of an ACCME-Defined Commercial Interest in Continuing Medical Education Activities*.

## IV. Mechanisms to Resolve COIs

HMS must ensure compliance with the ACCME's Accreditation Criteria and policies. To that end, HMS GCE has established mechanisms to manage and resolve all conflicts of interest for individuals involved with the planning and implementation of certified CME activities. HMS GCE is actively involved during the early stages of the planning processes for both directly and jointly provided activities and has implemented the following strategies to support objective, balanced and non-commercially biased education:

- Educational planning and design processes to ensure that content is objective, balanced, evidence-based, and scientifically rigorous and reflects the current standards of care, administration, teaching and research and/or future directions in these areas.
- Documentation of the processes for activity development (including assessment of practice gaps, educational needs, learning objectives, desired outcomes, and educational formats and methodologies) and content validation to support fair and balanced presentation of the content.
- HMS GCE monitors and manages CME activities by implementing and enforcing current standards, regulations, and guidelines developed by organizations (e.g. ACCME's Standards for Commercial Support, PhRMA's Code on Interactions with Healthcare Professionals, etc.) and government bodies (e.g. FDA's Final Guidance on Industry-Supported Scientific and Educational Activities, Massachusetts Department of Health 105 CMR 970.000: Pharmaceutical and Medical Device Manufacturer Conduct, etc.) involved in the delivery of CME, research and patient care, as well as by HMS.

#### A. Mechanisms Addressing Individuals with COIs

As part of HMS' disclosure and conflict resolution process, all individuals who control CME content must complete the *Disclosure and Resolution of Conflicts of Interest for CME Activities* form, which requires individuals to attest that "research findings and therapeutic recommendations in my content will be based on scientifically accurate, up-to-date information and be presented in a balanced, objective manner" and that the content will be developed in accordance with the ACCME's Content Validation policy. This is the first step that HMS takes to ensure content is free from commercial bias.

When an individual has a COI there are multiple mechanisms that can be used to resolve it. These mechanisms are described below based on the role of the individual with the conflict.

Individual with COI	Mechanism to Resolve COI
Course Director	Review of CME Activity Proposal by CME and medical reviewers or GCE staff and if bias is found, make appropriate changes to remove the bias. If a Course Director has a conflict of interest, they are required to recuse themselves from participating in planning the part of the activity related to the conflict, appoint a non-conflicted physician to plan content in the area of the conflict and resolve all reported conflicts of interest for the activity.
Academic Planner	Course director requests that the individual recuse him/herself from planning content in the conflicted area.
Faculty, including Speakers and Authors	Peer review of content and may use of one of the mechanisms listed below.**
Moderators (without content)	Limit the moderator's role to introduction of presenters, fielding questions, and moderating the flow of discussion between participants and presenters.
Individual (or Spouse/Partner) Employed by a Commercial Interest	Contact the Director of Educational Development and Accreditation, GCE to discuss whether it is appropriate for the individual to be engaged in the CME activity. See HMS <i>Policy on the Use of Employees of an ACCME-Defined Commercial Interest in Continuing Medical Education Activities</i> .
CME Reviewer Medical Reviewer	Removal from review or seek an additional non-conflicted reviewer.
Educational Committee Member	Recusal from discussion and voting on the educational

	activity.
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Documentation for the resolution of conflicts of interest is provided on the *Disclosure and Resolution of Conflicts of Interest for CME Activities* form.

**\*\*The following are mechanisms that can be used to resolve COI for Faculty, including Speakers, and Authors:**

- Have the content peer reviewed by a non-conflicted physician and if commercial bias is found, make appropriate changes to remove the bias.
- Request the faculty member base his/her recommendations on peer reviewed best available evidence (this must be paired with another resolution method).
- Change the focus of the faculty member's content so the COI no longer exists.
- Limit the faculty member's content to data and information while other faculty members address the implications and make recommendations for clinical care.
- Limit or specify the sources for recommendations that the faculty member can use. For example, the individual could present summaries from the systematic reviews of the Cochrane Collaboration or research summaries from the AHRQ Effective Health Care Program.
- Exclude CME certification for the faculty member's portion of the activity.
- A combination of any of the methods listed above.

Two COI resolution methods which apply to all individuals are:

- Divestiture of the financial relationship with the commercial entity or alteration so that the COI no longer exists. This immediately eliminates the COI. The relationship, however, must continue to be disclosed to learners for 12 months after divestiture.
- Elimination from the activity.

#### **B. Dispute Resolution**

Should a proposed resolution be disputed, the HMS Senior Associate Dean Global and Continuing Education will review the proposed resolution and reason for dispute and make a final determination as to resolution. The Dean for Faculty and Research Integrity may be consulted as necessary.

### **V. Monitoring for and Mitigating Commercial Bias**

In addition to resolving conflicts of interest, HMS takes steps to monitor for and mitigate commercial bias. These steps include:

- HMS GCE promotion of opportunities within the educational setting for learner participation, debate and dialogue to allow for discussion of alternatives and continuous improvement.
- For activities where individuals have COIs, course directors, or non-conflicted medical reviewers appointed by the course director, monitor their CME activities for commercial bias, in the objective opinion of medical reviewer based on his/her knowledge of best available evidence. For live activities, if commercial bias is perceived by the course director or his/her designee, the monitoring physician shall take appropriate steps to mitigate the identified bias to the extent practicable prior to completion of the activity.
- HMS GCE may also monitor CME activities to determine if commercial bias is present and to take action to mitigate it if bias is identified.
- For enduring materials, content is peer reviewed by non-conflicted experts for potential bias prior to certification and certification is contingent on the elimination of such bias.

- Learners are asked to identify any perceived commercial bias through the activity evaluation. If 7% or more of participants have perceived commercial bias in the activity, the course director will take action to mitigate the bias and safeguard against future bias by taking one or more of the following actions:
  - Speaking with the faculty member about the bias that was perceived and discussing how to avoid commercial bias in the future
  - Notifying learners in writing of the identified bias and providing amended content, if appropriate
  - For revisable enduring materials, revision of the content as needed as part of the activity's annual review process
  - Not inviting the faculty member to participate in future activities
  - Requesting assistance from the HMS Associate Dean for Global and Continuing Education regarding appropriate corrective measures

#### **VI. Disclosure of Financial Relationships to Learners**

For all HMS certified CME activities, relevant financial relationships are disclosed to the learners prior to the start of the activity. Disclosure will include the following information: the name of the individual, the name of the commercial interest(s), the nature of the relationship the person has with each commercial interest, and the individual's role(s) related to the activity (e.g. planner, faculty, reviewer, etc.). For individuals who have reported no relevant financial relationships, the learners are informed that no relevant financial relationships exist. Disclosure information must be provided to learners either in print, via presentation slides, or on a web page.

#### **VII. Disclosure of Commercial Support to Learners**

The source of all support from commercial interests must be disclosed to learners. When commercial support is "in-kind" the nature of the support must be disclosed to learners (i.e. durable equipment, facilities/space, disposable supplies (non-biological), animal parts or tissue, human parts or tissue, other - description required). Importantly, the disclosure of support must never include the use of a corporate logo or slogan, trade name, or product-group message of an ACCME-defined commercial interest. The acknowledgement, however, may state the name, mission, and areas of clinical involvement of the company or institution.

#### **Policies and Reports Related to the Identification and Resolution of Conflicts of Interest for Continuing Medical Education Activities**

- *Policy on Commercial Support for Continuing Medical Education Activities*
- *Policy on the Use of Employees of an ACCME-Defined Commercial Interest in Continuing Medical Education Activities*
- *Harvard University Faculty of Medicine Policy on Conflicts of Interest and Commitment (2016)*
- *Harvard Medical School Faculty of Medicine Committee on Conflicts of Interest and Commitment 2009-2010 Review Report*