



B. Conflict of Interest Policy

CME should be developed free from the control of commercial interests and be balanced, objective, and scientifically rigorous. BCH 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. BCH 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 BCH course director any financial relationships with a commercial interest that are relevant to the proposed CME activity in order for BCH, through its course directors and DCME staff, 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 BCH, he/she will be automatically disqualified.

The intent of this policy is not to prevent a speaker with a potential conflict of interest from making a presentation. It is intended that any potential conflict should be identified openly so that the potential conflicts are resolved to the satisfaction of the accrediting body early in the planning process. In addition, program participants will have full disclosure of the facts to make an informed judgment.

BCH retains the right of final approval for all program faculty. The DCME has the right to reject any proposed faculty member if it determines that a potential conflict of interest compromises the perceived balance of the intended audience. This decision will be made by Director of CME in consultation with the CME Committee. Any faculty member who fails to disclose relevant relationships with a commercial supporter risks being disqualified from current and future continuing education programs.

Independence

Companies that provide external support in the form of an educational program grant are not to be involved in any aspect of the program development including needs, learning objectives, content, faculty, format or delivery and/or evaluation. A commercial interest cannot take the role of non-accredited partner in a co-sponsorship relationship.



Mechanisms to Identify COIs

All individuals in a position to control content of a CME activity must provide disclosure of their relevant financial relations to the DCME. This is accomplished through the use of standardized Disclosure and Content Attestation forms from the DCME. 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	Mechanism to Identify COI
Course Director*	Review by DCME staff, CME Reviewer, or non-conflicted Medical Reviewer chosen by DCME
Academic Planner† Faculty (Speakers/Authors/ Moderators)‡	Review by non-conflicted Course Director (or a non-conflicted physician proxy if Course Directors are conflicted)
CME Reviewer** Medical Reviewer**	DCME staff or Director of CME
CME Committee Member††	Review by DCME staff and Director of CME

*Disclosure submitted to DCME with CME Activity Proposal

†Disclosure submitted prior to beginning planning

‡Disclosure submitted prior to the date of the activity

**Disclosure submitted prior to conducting review

††Disclosure submitted annually at the beginning of the academic year

Mechanisms to Resolve COIs

BCH must ensure compliance with the ACCME's Accreditation Standards and Criteria. To that end, DCME has established mechanisms to manage and resolve all conflicts of interest for individuals involved with the planning and implementation of certified CME activities. DCME is actively involved during the early stages of the planning processes 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.

The DCME 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 BCH.

Mechanisms Addressing Individuals with COIs

Individual with COI	Mechanism to Resolve COI
Course Director¶	Review of CME Activity Proposal by DCME and medical reviewers and if bias is found, make appropriate changes to remove the bias
Academic Planner¶	Course director requests that the individual recuse him/herself from planning content in the conflicted area
Speakers, Authors¶	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 Employed by a Commercial Interest¶	Course Director/DCME will discuss the steps that must be taken to resolve the conflicts of such individuals
CME Reviewer¶ Medical Reviewer¶	Removal from review or seek an additional non-conflicted reviewer
CME Committee Member	Recusal from voting on CME Activity Proposal

¶A Resolution of Conflict of Interest form stating the action taken to resolve the COI must be completed and returned to DCME



The following are mechanisms that can be used to resolve speakers' and authors' COIs:

- Have the content peer-reviewed by a non-conflicted individual 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
- 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

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.

Should a proposed resolution be disputed, the DCME Medical Director will review the proposed resolution and reason for dispute and make a final determination as to resolution.

Monitoring for and Mitigating Commercial Bias

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

- The DCME promotion of opportunities within the educational setting for learner participation, debate and dialogue allows 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. 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.

- The DCME also monitors CME activities to determine if commercial bias is present and to take action to mitigate it if bias is identified.
- Learners are asked to identify any perceived commercial bias through the activity evaluation. If 7% or more of participants perceive 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 DCME Medical Director regarding appropriate corrective measures

Appropriate Use of Commercial Support

The DCME will make all decisions regarding the disposition and disbursement of commercial support. A commercial support cannot designate or advise the DCME concerning the program faculty or content of the educational program to be developed. All commercial support associated with the DCME activities must be given with the full knowledge and approval of the provider.

Disclosures Relevant to Potential Commercial Bias

BCH will disclose (including "in-kind") commercial support and financial relationships to participants prior to the participant beginning the educational activity. No trade names or product messages can be included in the "disclosure" announcement. BCH requires that for any individual or educational partner associated with the development of the educational program either:

- No relevant financial relationship exists, or



- A relevant financial relationship exists. This disclosure should include: the individual's name, the name of the commercial interest and the nature of the relationship.

All conflicts must be resolved by an effective peer-review of content prior to the educational activity to ensure the content is valid and aligned with the interest of the public. Resolutions for conflicts of interest can include, but not limited to: choose another speaker, limit the content to report without recommendations; change the content so it does not relate to the conflict of interest; utilize peer review; and/or ask faculty to reference the “best available sources”. All resolutions of conflicts of interest must be documented.

Disclosure of Financial Relationships to Learners

For all BCH sponsored 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.

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 trade name or product-group message. The acknowledgement, however, may state the name, mission, and areas of clinical involvement of the company or institution and may include corporate logos and slogans, if they are not product promotional in nature.