



**Global and Continuing Education**

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

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

**Policy on the Use of Employees of An ACCME-Defined Commercial Interest in Continuing Medical Education Activities**

Effective Date: June 3, 2014; Revised April 29, 2016

**POLICY**

The use of employees of an ACCME-defined commercial interest as planners, faculty, or in other roles where they are in a position to control content of accredited CME **is prohibited**, except in the specific circumstances identified by the ACCME that maintain independence and serve the public interest. The ACCME defines a *commercial interest* as any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The ACCME defers to the US Internal Revenue Service definition of “employee” as a guideline in determining whether an individual is an employee of a commercial interest. According to the IRS: *“Generally, you must withhold income taxes, withhold and pay Social Security and Medicare taxes, and pay unemployment tax on wages paid to an employee.”*

**PLEASE NOTE:** Per an update from the ACCME on September 2, 2016, in situations where a person in control of CME content discloses that their spouse or partner is an employee of a commercial interest and the content being controlled is related to the products/services of that commercial interest, then that person will now be considered to have a relevant financial relationship. (Previously, that person would have been considered a commercial interest employee because of their spouse/partner’s employment.) As with any relevant financial relationship, providers are required to implement mechanisms to resolve these conflicts of interest per SCS 2.

***An employee of an ACCME-defined commercial interest may not plan, present, review, or make recommendations on content that relates to the business lines or products of its employer in an accredited CME activity. The ACCME considers this relationship as a non-resolvable conflict.***

However, there are **three** specific circumstances where employees of an ACCME-defined commercial interest may participate in a CME activity:

1. The content is not related to the business lines or products of their employer. This includes but is not limited to therapeutics, clinical examination, physical diagnosis, and on the care of patients.
2. The content is limited to basic science research (e.g., pre-clinical research, drug discovery) or the processes/methodologies of research, unrelated to a specific disease or compound/drug.
3. The employee serves as a technician to teach the safe and proper use of a medical device. The employee may have no control over the content that is related to clinical recommendations concerning the business lines or products of their employer.

***Each circumstance must be reviewed and approved by Harvard Medical School Global and Continuing Education prior to the beginning of the activity.***

**PROCESS TO ALLOW AN EMPLOYEE OF AN ACCME-DEFINED COMMERCIAL INTEREST TO PARTICIPATE IN A CME ACTIVITY**

The following process is in place to ensure that in the three special-use cases where an employee of an ACCME-defined commercial interest may participate in a CME Activity that they cannot control or influence the content of continuing medical education and to ensure compliance with the ACCME Standards for Commercial Support<sup>SM</sup>.

1. The Course Director should indicate in the Activity Proposal that an employee of an ACCME-defined commercial interest may be recruited to participate in the activity. If this is not possible at the time of the proposal submission, it is required that the Course Director notifies the assigned HMS GCE Program Coordinator whenever he/she first becomes aware that an employee of a commercial interest may be participating in the course or at a minimum at least 30 days prior to the beginning of the course, unless there are extenuating circumstances.
2. The Course Director and HMS GCE must ensure that the following decisions were made free of the control of an ACCME-defined commercial interest: (a) identification of CME needs; (b) determination of educational objectives; (c) selection and presentation of content; (d) selection of all persons and organizations that will be in a position to control the content of the CME; (e) selection of educational methods; (f) evaluation of the activity.
3. HMS GCE and the Course Director will ensure that the selection of content for presentation is based on its relevance and importance to the learners and that topic selection is overseen by individuals free of relevant financial relationships.
4. Once the course is approved, a meeting will be scheduled between the Course Director and/or Senior Associate Dean of Global and Continuing Education, and/or the Faculty Director, and/or the Executive Director, and /or the Director of Educational Development & Accreditation to discuss whether or not it is appropriate to utilize an employee of an ACCME-defined commercial interest to participate in the course based on the requirements outlined above.
5. The employee of an ACCME-defined commercial interest will sign a written attestation that they will not plan or present any content in the area that is related to the business lines or products of their employer.
6. An employee of an ACCME-defined commercial interest is required to submit his/her presentation to the Course Director at least 30 days prior to the beginning of the CME activity. A non-conflicted Course Director and/or another physician-appointed representative who does not have any relevant financial relationships will review the employee's presentation and ensure that it meets the requirements outlined in this document.
7. As part of the HMS monitoring process, the Course Director or employee must also submit the presentation to the HMS GCE Program Coordinator at least 25 days prior to the CME activity for validation and review by HMS GCE to ensure that no discussion of the company's products or services are included.
8. HMS GCE may require exclusion of certain content or changes based on the validation and review process. Changes must be made prior to the beginning of the employee's presentation. If the Course Director or employee of an ACCME-defined commercial interest does not wish to make the required changes, HMS GCE reserves the right to rescind *AMA PRA Category 1 Credit™* for the employee's presentation and/or prohibit the employee from presenting at the CME activity.
9. Disclosure of the employee's relationship with the ACCME-defined commercial interest will be provided to the learners prior to the beginning of the CME activity.
10. The Course Director or the Course Director's designee is required to monitor the presentation of the employee of an ACCME-defined commercial interest to ensure all accreditation requirements are met. If the faculty member discusses products or services during his/her presentation, the monitor will immediately intercede and prevent further discussion. In addition, the Course Director will contact HMS GCE so that *AMA PRA Category 1 Credit™* is not awarded for the presentation.

11. If HMS GCE is not notified well in advance of the CME activity that an employee of an ACCME-defined commercial interest is being recruited and/or if the Course Director is not able to meet the above requirements or adhere to all HMS policies and procedures, HMS GCE reserves the right to rescind *AMA PRA Category 1 Credit™* for the employee's presentation and/or prohibit the employee from presenting at the CME activity.

**Policy Related to the Use of Employees of an ACCME-Defined Commercial Interest**

- *Policy on Commercial Support for Continuing Medical Education Activities*