



Global and Continuing Education

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Policy on Commercial Support for Continuing Medical Education Activities

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I. PURPOSE

Harvard Medical School's (HMS) Global and Continuing Education (GCE) *Policy on Commercial Support for Continuing Medical Education Activities* provides information for Course Directors, staff, faculty, joint providers and anyone in a position to control the content of the activity to comply with the Accreditation Council for Continuing Medical Education (ACCME) *Standards for Commercial Support of Continuing Medical EducationSM: Standards to Ensure Independence in CME Activities* (hereafter referred to as "the Standards" or "SCS") for certified activities with the exception of Regularly Scheduled Series (RSS), sponsored by HMS.

RSS activities that receive commercial support may not be certified for *AMA PRA Category 1 Credit™* through Harvard Medical School.

II. DEFINITIONS

Commercial Support is defined as monetary or in-kind contributions given by an ACCME-defined commercial interest to a CME provider that is used to fund all or part of the costs of a CME activity. In accordance with the Standards of the ACCME, all funds accepted from commercial sources to support CME activities must be in the form of an educational grant. In-kind support may include the use of donated equipment, supplies, space, specimen, or services.

Commercial Interest is defined by the ACCME as any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The ACCME does not consider providers of clinical service directly to patients to be commercial interests. A commercial interest is not eligible for ACCME accreditation.

ACCME-Accredited Provider is an organization accredited by the ACCME as a provider of continuing medical education. ACCME-accredited providers represent a range of organizational types and offer CME primarily to national or international audiences of physicians and other health care professionals.

III. POLICY

A. Independence.

The selection of overall content, specific topics, faculty, and evaluation must be completely independent of any influence by a commercial interest.

The identification of needs, determination of educational objectives, selection and presentation of content, selection of all persons and organizations that control the CME content, selection of educational methods, and evaluation is the sole responsibility of HMS in collaboration with the Course Director/planning committee and any educational partner or joint provider, if applicable. A commercial interest cannot take the role of non-accredited partner in a joint providership relationship (ACCME SCS 1.1-1.2; 3.2).

B. Support - HMS Multi-Funder Rule.

Support of HMS-certified CME activities by a single commercial interest is prohibited. Support by more than one company is permitted, provided that (i) no single company accounts for more than 50% of the activity's budget (i.e. not more than 50% of the budgeted expenses) and (ii) support among the commercial interests is relatively equitable, with no one company accounting for more than 70% of the commercially supported

portion of the activity's overall budget (i.e. not more than 70% of the commercial support obtained). Support includes both cash and in-kind support.

Examples:

An HMS-certified CME activity may be funded using the following distribution of support:

- A Course Director for an activity that has expenses of \$100,000 may fund an activity's expenses by accepting the following distribution of support:
 - \$50,000 from Pharma X (50% of the budgeted expenses and 67% of the total commercial support obtained).
 - \$25,000 from Medical Device Company Y (25% of the budgeted expenses and 33% of the total commercial support obtained).
- A Course Director for an activity that has expenses of \$100,000 may fund an activity's expenses by accepting the following distribution of support:
 - \$50,000 of support from Pharma X (50% of budgeted expenses and 62.5% of the total commercial support obtained).
 - \$20,000 of support from Foundation Z (This support is not included in the calculations as it comes from a non-commercial interest).
 - \$30,000 of support from Medical Device Company Y; Medical Device Company Y provided three devices to be used at the course with a value equivalent to 30% of the support. (30% of budgeted expenses and 37.5% of the total commercial support obtained).

An HMS-certified CME activity may not be funded using the following distribution of support:

- A Course Director for an activity that has expenses of \$100,000 may not fund an activity's expenses by accepting the following distribution of support:
 - \$51,000 from Pharma X (51% of the budgeted expenses).
 - \$49,000 from Medical Device Company Y (49% of the budgeted expenses).

In this example, Pharma X is funding more than 50% of the activity's budgeted expenses.

- OR (for the same activity):
 - \$50,000 from Pharma X (50% of the budgeted expenses and 83% of the total commercial support obtained).
 - \$10,000 from Medical Device Company Y (10% of the budgeted expenses and 17% of the total commercial support obtained).

In this example, Pharma X is supplying more than 70% of the commercial support.

C. Appropriate Use of Commercial Support.

Receipt of Funds. In accordance with the Standards of the ACCME, all funds accepted from commercial interests to support CME activities must be made payable to the President and Fellows of Harvard College, a HMS teaching affiliate, a joint provider, or a designated educational partner with which HMS is collaborating to develop and implement the CME activity. Faculty, Course Directors, or planners must never receive payment directly from a commercial entity (ACCME SCS 3.8-3.9).

Knowledge of Funds and In-kind Support. All commercial support associated with a CME activity must be given with the full knowledge and approval of HMS. No additional funds or in-kind support will be provided to the Course Director, planning committee members, teachers, or authors, joint providers, educational partners or any others involved with the supported activity beyond those defined in the budget and commercial support agreement (ACCME SCS 3.3; 3.9).

Letter of Agreement. All commercial support associated with an HMS CME activity must be documented in a written Letter of Agreement (LOA) between HMS and the specific commercial supporter and must include educational partners, if applicable. The LOA must specify the commercial interest providing the support and be signed by HMS and the commercial supporter prior to the start of the educational activity. It must also specify the total dollar value of the support, and the support's terms, conditions and purposes. The LOA must reflect that as the accredited provider, HMS is solely responsible for the administration, content (i.e. identification of CME needs, determination of educational objectives, selection and presentation of content, selection of all individuals and organizations involved in control of the CME content, selection of educational methods and activity evaluation), quality, and integrity of the CME activity. HMS does not accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as conditions of contributing funds or services. HMS GCE must be directly involved in the contractual process between the activity receiving commercial support and the entity providing commercial support, this includes instances of joint providership (ACCME SCS 3.2; 3.4-3.6).

Use of Funds and In-kind Support. HMS makes all decisions regarding the disposition and disbursement of the commercial and in-kind support received for CME activities. Commercial funding will be used upon its receipt in accordance with ACCME requirements, the Letter of Agreement with the commercial supporter, and the approved activity budget. Expenses and honoraria of invited faculty will be paid by HMS, its teaching affiliates, joint providers or educational partners rather than directly from a commercial source. Faculty may never receive an honorarium or travel reimbursement directly from any commercial source. All commercial support receipt and expenditures must be documented and provided to HMS GCE; and upon request, to the commercial supporter. Commercial support may not be used to pay for travel, lodging, honoraria or personal expenses for non-teacher or non-author participants of a CME activity. If teachers or authors are listed on the agenda as facilitating or conducting a presentation or session, but participate in the remainder of an educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their teacher or author role only. Funds may be used to pay for travel, lodging, and honoraria for employees and volunteers of HMS and its affiliated institutions, joint provider or educational partner (ACCME SCS 3.1; 3.3; 3.8-3.10; 3.12-3.13).

Use of Funds for Food and Beverage Expenses During a Certified CME Activity.

Tuition and/or departmental funds should be used to pay for any food and beverage expenses.

D. Management of Commercial Promotion.

Exhibits. Commercial exhibits are permitted as part of the overall CME activity; however, arrangements for these exhibits must not influence planning or interfere with the presentation of CME activities. Exhibit placement should not be a condition of commercial support for a CME activity (ACCME SCS 4.1).

Exhibit Display. No commercial promotional materials may be displayed or distributed in the educational room immediately before, during, or after a CME activity, or in the direct pathway of participants attending the activity (ACCME SCS 4.2, and *HMS Conflict of Interest and Commitment Policy*).

Exhibit Staff. Representatives of commercial interests may not engage in sales or promotional activities while in the space or place of the CME activity (ACCME SCS 4.2). Commercial interests intending to exhibit or advertise in proximity to a CME activity will be provided with HMS GCE policies and procedures related to exhibits and advertisements [See *HMS GCE Commercial Exhibitor Agreement Form*]

Exhibit Fees. The Course Director may determine the exhibit fee for commercial interests who wish to exhibit. Each similarly sized space must be offered to potential exhibitors at the same charge. Payment for exhibit space is separate from and should not be included within a commercial support agreement. If a commercial supporter agrees to rent exhibit space in addition to providing an educational grant, the fee for exhibiting cannot be included in the educational grant check and must be a separate transaction (ACCME SCS 4.1).

Exhibit Report. After completion of the CME activity, a list of companies that exhibited at the course must be submitted to HMS GCE along with the amount of funding received from each company. This information should be included in the “*Financial Reconciliation Form*” provided by HMS GCE as part of the course closing materials.

E. Product Promotion Material and Product Specific Advertisement. Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring materials (printed or electronic advertisements) promotional activities must be kept separate from CME. (ACCME SCS 4.2)

Live. Advertisements and promotional materials may not be displayed or distributed in the educational space immediately before, during, or after a CME activity. Representatives of commercial interests may not engage in sales or promotional activities while in the space or place of the CME activity. (ACCME SCS 4.2)

Print. HMS does not permit any advertisements or promotional materials to be interleaved within the pages of CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as the materials are not related to the CME content they face and are not paid for by commercial supporters of the CME activity (ACCME SCS 4.2).

Computer-based. Advertisements and promotional materials may not be visible on the screen at the same time as the CME content and not interleaved between computer ‘windows’ or screens of the CME content. Certified CME activities may not be placed on a website owned or controlled by a commercial interest. With clear notification that the learner is leaving the educational website, links from the HMS website to pharmaceutical and device manufacturers’ product websites are permitted before or after the educational content of a CME activity, but shall not be embedded in the educational content of a CME activity. Advertising of any type is prohibited within the educational content of CME activities on the Internet including, but not limited to, banner ads, subliminal ads, and pop-up window ads. For computer based CME activities, advertisements and promotional materials may not be visible on the screen at the same time as the CME content and not interleaved between computer windows or screens of CME content (ACCME SCS 4.2).

Audio and Video Recording. Advertisements and promotional materials may not be included within the CME. There will be no “commercial breaks.” (ACCME SCS 4.2).

Journal-based CME. None of the elements of journal-based CME can contain any advertising, or product group messages of commercial interests. The learner must not encounter advertising within the pages of the article or within the pages of the related questions or evaluation materials (ACCME SCS 4.2).

Educational Materials. CME activity materials, such as slides, abstracts, and handouts, cannot contain any advertising, corporate logo, trade name, or a product-group message of an ACCME-defined commercial interest (ACCME SCS 4.3).

Advertisement Report. After completion of the CME activity, a list of companies that provided advertisements associated with the activity must be submitted to HMS GCE along with the amount of funding received from each company.

Distribution of CME Activities to Learners. HMS does not allow commercial interests to provide CME activities to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities, nor distribution of activity brochures (ACCME SCS 4.5).

F. Disclosure of Commercial Support to Learners.

The source of all support from commercial interests must be disclosed to learners prior to the beginning of the educational activity. 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). The disclosure of commercial support must never include the use of a corporate logo, trade name or product-group message of an ACCME-defined commercial interest. (ACCME SCS 6.3 – 6.5)

G. HMS Affiliated Hospitals and Institutions Regulations.

Individuals responsible for the planning and development of an HMS certified CME activity must check with their affiliated hospital or institution to ensure that they are following their institution’s regulations on commercial support.

Policies and Reports Applicable to Commercial Support:

- *Policy on Content Validation for Continuing Medical Education Activities*
- *Policy on Identification and Resolution of Conflicts of Interest for Continuing Medical Education Activities*
- *Policy on Meals and Social Events for Continuing Medical Education Activities*
- *Policy on Honoraria for Continuing Medical Education Activities*
- *Policy on the Use of Employees of an ACCME-Defined Commercial Interest*
- *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*
- <http://www.accme.org/requirements/accreditation-requirements-cme-providers/standards-for-commercial-support>