Policy on Commercial Support & Conflict of Interest

Introduction
The Hawaii Consortium for Continuing Medical Education (HCCME) adheres to The ACCME Standards for Commercial Support SM (Standards to Ensure Independence in CME Activities). The individual responsible for the HCCME certified CME activity must see that the Standards are observed.

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 does not consider providers of clinical service directly to patients to be commercial interests.

A commercial interest is not eligible for ACCME accreditation. Within the context of this definition and limitation, the ACCME considers the following types of organizations to be eligible for accreditation and free to control the content of CME:

- 501-C non profit organizations (Note: ACCME screens 501-c organizations for eligibility. Those that advocate for 'commercial interests' as a 501-c organization are not eligible for accreditation in the ACCME system. They cannot serve in the role of joint sponsor, but they can be a commercial supporter.)
- Government organizations
- Non-health care related companies
- Liability insurance providers
- Health insurance providers
- Medical group practices
- Hospitals
- Health systems
- Rehabilitation centers
- Nursing homes
- Blood banks
- Diagnostic laboratories.

CME activities must also conform to the American Medical Association Council on Ethical and Judicial Affairs (CEJA) opinions that address the ethical obligations that underpin physician participation in CME, 8.061 "Gifts to physicians from industry" and 9.011, "Ethical issues in CME". (For more information on CEJA ethical opinions visit www.ama-assn.org/go/cega)

Summary: It is the policy of the HCCME to ensure balance, independent, objective, and scientific rigor in all its individually certified educational activities. All individuals who may influence content, such as planners, speakers, authors, department chairpersons or others must disclose relevant financial relationships with commercial interests that pertain to the activity. Should a conflict of interest (COI) be identified, the COI must be resolved prior to the activity. Individuals, in the position to influence content, who refuse to provide disclosure information, will be disqualified from being a part of the planning or implementation of the activity. The presence and absence of relative financial relationships with commercial interests will be provided, in writing, to participants prior to the start of the activity. It is also

Source: ACCME & ACME SCS Tool-kit
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HCCME Handbook, Rev. 5-2010
recommended that speakers verbally state such relationships as part of the introduction to the presentation.

The HCCME's practice and mechanisms to ensure independence in CME activities follow.

1.0 Independence

1.1 The HCCME, through committees of the Hawaii Medical Association (HMA), departments and programs of the John A. Burns School of Medicine, University of Hawaii (JABSOM), and joint sponsors conduct the following aspects of CME planning independently and free from the control of any commercial interests:

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 materials;

f) Evaluation of the activity.

1.1.1 The CME provider is prohibited from asking a commercial interest for suggestions related to topics or speakers for CME. If the provider implements the suggestions of the commercial interest then a situation is created where the independence of CME from the commercial interest is seriously undermined. Accredited providers must not allow commercial interests to directly (SCS 1.1) or indirectly (SCS3.2) control the content of CME. (Source: Ask ACCME)

1.1.2 Employees of commercial interests may serve as planners or speakers in accredited CME activities if the content of the CME that the employee of the commercial interest controls DOES NOT relate to the business lines and products of its employer. (Source: Ask ACCME)

1.1.3 Accredited CME activities on research that was controlled in some way by a commercial interest, either through funding, collaboration, or involvement of the commercial interests' staff in the research itself may be offered as long as the CME activity complies with the ACCME's Accreditation criteria, including the ACCME Standards for Commercial SupportSM. It is understood and accepted that industry conducts its own research and that industry partners, as funder or collaborator, in research projects. An important step in the translation of discovery to practice is the dissemination of the results of this research. There are several layers of internal and external controls already in place to manage the conduct of research (e.g., Institutional Review Boards, Government agencies) and the dissemination of results (e.g., editors, peer review, international standards.) The ACCME does not intend to interfere with these carefully managed phases.

However, when an organization chooses to base its CME content on research, the organization assumes responsibilities related to CME, including compliance with the ACCME Standards for Commercial SupportSM. The CME content (not the research that has already taken place or is taking place) cannot be controlled by a commercial interest. As an example, industry employees cannot deliver oral presentations and cannot author enduring materials that are accredited CME if the CME content relates to business lines or products of their employer. (Source: Ask ACCME, new 3/2009)

1.1.4 Education on devices is a special-use case in accredited CME. Some equipment contains "labeling requirements" set by the FDA that include the requirement for instruction prior to use. Each set of circumstances needs to be taken on a case-by-case basis as the conflicts of interest of industry employees are irreconcilable in CME, so they can never take the usual role as teacher or author in accredited CME.
Industry employees can demonstrate the operational aspects of the use of a device under the umbrella of a provider's ACCME accreditation - but they must only demonstrate the operational aspects. They can do this without contributing in any way to any decision making about the elements of SCS 1 of the ACCME Standards for Commercial SupportSM. It is critical that the employees never expand their input into areas of clinical medicine while involved in accredited CME.

This special use-case, if it is going to remain compliant, requires careful supervision by the accredited provider's faculty and staff and proper professional behavior by industry staff. (Source: Ask ACCME, new 3/2009)

1.2 The HCCME will not enter into a joint sponsorship relationship with a commercial interest.

2.0 Resolution of Personal Conflicts of Interest
2.1 Everyone who is in a position to control the content of an educational activity must disclose all relevant financial relationships with any commercial interests. The mechanism used to collect the information is the HCCME Disclosure Declaration and Attestation Form.

Relevant financial relationships are those where the individual (including the individual's spouse/domestic partner) has a personal financial (any amount) with a commercial interest within the past 12 months. The absence of relevant relationships must also be disclosed.

2.2 Individuals who refuse to disclose relevant financial relationships cannot have a role in the CME activity.

2.3 Resolution of Conflicts of Interest (COI)
Conflicts of interest are present when an individual has a current relevant personal financial relationship with a commercial interest. The fully executed Disclosure Declaration/Attestation Forms are collected by the activity staff and forwarded to the individual responsible for the CME activity. Upon review, COI's are identified and the appropriate measure for resolution is selected and taken. Resolution may be accomplished with guidance from a member of the HCCME committee. The measures taken for resolving COI in CME include, but are not limited to, the following:

- Review of the educational content by peers who have the authority to alter content of any educational material that has commercial bias.
- Alteration or limitation of the role(s) of the individual so that the financial relationship is no longer relevant.
- Excluding the individual from participating in content development or delivery.
- Denial of CME certification for selection portions of the educational activity.

Actions taken to resolve COIs is documented with the use of the 'Resolution of Conflict of Interest Form'.

3. Appropriate Use of Commercial Support
3.1 All CME activity planners must obtain the HCCME's approval in advance of any solicitation of commercial support and the HCCME must make all decisions regarding appropriate disposition and disbursement of commercial support. Funds from commercial interests are to be awarded in the form of an unrestricted educational grant as to its use within the content of the topic area. Unused funds may be returned to the commercial interest as a condition of the grant. The HCCME may request that inappropriate expense items be removed from the proposed activity budget.

3.2 Conditions - no prerequisite conditions, except for the designation of topic areas under which the educational grant is given, will be allowed with regard to the receipt of the commercial support funds.
3.3 All commercial support associated with a CME activity will be given with the full knowledge and approval of the HCCME. No other payments shall be given to the director of the activity, planning committee members, teachers or authors, joint sponsor, or any others involved with the supported activity. Other support associated with the CME activity (e.g. distributing brochures, preparing slides, etc.) must be given with the full knowledge and approval of the HCCME.

Written agreement documenting terms of support
3.4 The HCCME requires that a written letter of agreement (LOA) be signed between itself and the commercial supporter. The terms, conditions, and purposes of the commercial support must be documented in the written agreement. The HCCME has developed a standard LOA; however, it is acceptable to use LOAs from external organizations so long as all the key components of the HCCME LOA are present. The HCCME will not retroactively accept a grant from a commercial interest. Commercial support sent without a fully executed LOA will be returned to the commercial interest.

3.5 The written agreement must specify the commercial interest that is the source of commercial support.

3.6 Both the commercial support and the HCCME Compliance & Accreditation Manager must sign the written agreement between the commercial supporter and the provider.

Expenditures for an individual providing CME
3.7 & 3.8 All honoraria and out-of-pocket expenses for speakers/faculty are paid directly by the HCCME, the joint sponsor, or a designated educational partner. Honoraria amounts are determined by the individual/planning group responsible for the CME activity and for University of Hawaii faculty, in accordance with the University of Hawaii Professional Assembly 2003-2009 Faculty Contract, Article III Conditions of Service. The application for credit designation requires that a proposed budget be submitted for review by the HCCME CME committee. (See HCCME Policy on Honoraria & Expense Reimbursement).

3.9 It is also the policy of the HCCME that supporters of an activity are prohibited from entering into any other compensation arrangement with planners, managers, and faculty relative to that CME activity.

3.10 Speakers will only be reimbursed for expenses incurred for the portion of the CME activity in which they participate in a teaching role. Expense amounts are reimbursed in accordance with the Honoraria Policy.

Expenditures for Learners
3.11 The HCCME acknowledges the importance of peer interaction and recognize that much of the learning goes on during conversations with colleagues. Social events, such as receptions, may not compete with or take precedence over the educational events.

3.11.1 A general guideline is not to have any social event greater than 50% of the total time together.

3.11.2 A social activity should be one of the minor items on the brochure.

3.11.3 A social activity should be free of the appearance of impropriety.

3.11.2 Meals associated with the educational activity are to be modest (less than $100.00 per person).
3.12 No commercial support may in any way be used to defray any part of the cost of attending a CME activity sponsored by the HCCME.

3.13 The HCCME will maintain records of receipt and disposition of commercial support grants.

4.0 Appropriate Management of Associated Commercial Promotion

4.1.1 The HCCME may accept arrangements for exhibits and/or advertisements from commercial interests associated with a CME activity.

4.1.2 Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.

4.2 Exhibits, ads or any form of promotion are kept separate from the CME activity as follows:

4.2.1 For live activities, promotional materials are not displayed or distributed in the educational space immediately before, during, or after a CME activity; displays may not be placed in the obligate path to the educational space; representatives of commercial interests may not promote their products while in the space or place of the CME activity.

4.2.2 For print activities, no advertisement may be interleaved within the pages of the CME content; advertisements may face the first or last pages of printed CME content so long as those ads are not related to the CME content and are not paid for by the commercial supporter of the activity.

4.2.3 For computer-based activities, advertisements will 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.

4.2.4 For audio and video activities, advertisements will not be included within the video activity nor will there be any commercial breaks during which an advertisement may be shown or heard.

4.2.5.1 Educational materials, such as syllabi, handouts, and slides may not contain any advertisements, trade names, or product group messages.

4.2.5.2 Print or electronic information distributed about the non-CME elements of a CME activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions, may contain advertisements.

5.0 Content and Format Without Commercial Bias

5.1.1 The content and materials of HCCME CME activities promote improvements or quality in healthcare.

5.1.2 The specific proprietary interests of a commercial interest are not promoted in CME activities sponsored by the HCCME although products may be referenced in the context of a balanced presentation that is scientifically objective.

5.2.1 CME activities offered by the HCCME must give balanced views of therapeutic options.

5.2.2 It is the policy of the HCCME to use generic, scientific names of products wherever possible to promote impartiality.
5.2.3 If CME educational material or content includes trade names, then the trade names of all referenced products are to be used.

6.0 Disclosures Relevant to Potential Commercial Bias

Relevant financial relationships of those with control over CME content

6.1 Relevant financial relationship information is collected from all individuals, as well as the individual's spouse/partner, who have control over CME content. Relevant financial relationships are disclosed to learners. Whenever possible, this will occur in writing. The information disclosed will include the following:

6.1.1 The name of the individual
6.1.2 The name of the commercial interest(s)
6.1.3 The nature of the relationship the person has with each commercial interest.

6.2 For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

Commercial support for the CME activity.

6.3.1 The HCCME discloses to learners the name(s) of commercial interest(s) supporting each CME activity. When possible, information about the support is provided in the CME activity announcement.

6.3.2 When commercial support is 'in-kind', the nature of that 'in-kind' contribution is disclosed to the learner.

6.4 The verbiage of the disclosure to learners must never include the use of a trade name or a product-group message.

Timing of disclosure

6.5.1 All disclosure information, including acknowledgement of commercial support, is communicated to learners in advance of the start of the CME activity. For conferences, written disclosure typically occurs in the first several pages of the CME syllabus or handout materials and is followed with verbal disclosures by the moderator or speaker.

6.5.2 For regularly scheduled series sessions, written disclosure may occur in the print or electronic announcement when the commercial support is received well in advance. Typically, disclosure information is printed on the evaluation form.

Guide to Implementation

1.0 Planning committee members must disclose relevant financial relationships with any commercial supporter in a timely manner or face dismissal from participation in the activity.

1.1 The fully executed forms completed by the planning group are reviewed by the activity chair during the early planning stages. Identified COI are subject to resolution as per 2.3. The disclosure forms are attached to the application for credit designation for review by the HCCME CME committee.
1.2 The activity chair issues to all individuals in the position to control the content of the CME activity the Disclosure/Attestation Form that is used to collect information on relevant financial relationships including the name of the commercial interest(s) and the nature of the relationship. Financial relationships that need to be disclosed are those that were in place over the preceding twelve month period of any amount for the individual and his/her spouse or life partner.

1.3 Chairperson reviews the forms and identifies potential conflicts of interests.

1.4 Chairperson takes action to resolve and manage the conflicts of interests prior to the activity. Resolution may include limiting the scope of the presentation, peer review of the slides, and divestiture of stock. In the event the conflicts of interest cannot be resolved or managed, the presenter may be disqualified. The chairperson is encouraged to consult a member of the HCCME to participate in the resolution process. Documentation of the intervention used to resolve the COI is recorded on the "Resolution of Conflict of Interest Form."

1.5 The presence and nature of relevant financial relationships are provided in writing to the learners prior to the activity. The absence of relevant financial relationships is also disclosed. CME activity promotional materials and educational handouts, as a matter of routine, include acknowledgement of commercial support. In handouts, the acknowledgements are placed in the introductory sections so participants may review the information prior to the start of the activity.

1.6 The HCCME provides an example of a faculty letter that advises speakers, moderators, authors, and instructors of the requirements relative to the ACCME Standards for Commercial Support.

Written Disclosure

The Accreditation Council for Continuing Medical Education (ACCME) has always required verification that disclosure of information about faculty/planner/provider relevant financial relationships with commercial interests to learners actually occurred. Written documentation has been the standard tool used. The following strategy demonstrates acceptable verification that disclosure information was transmitted to the learners in writing.

a) Planning group members and faculty are asked to complete, sign and return the HCCME Disclosure Declaration & Attestation Form to the designated department, division or program representative.

b) For conferences, the disclosure information is compiled on one sheet and inserted in the front of the syllabus. For regularly scheduled conference series, disclosure information is printed on the evaluation form and the activity moderator informs learners that written disclosure information is provided on the form. In order to fulfill ACCME’s faculty disclosure requirements, the following information must be provided to learners:

- Name & role in the activity
- Name of the commercial support or entity with which the faculty member has the relationship or affiliation; and
- Type(s) of relationship
- If faculty had nothing to disclose
- Statement regarding discussion unlabeled uses of products
Example: speaker has relationships to disclose and does not intend to discuss unlabeled uses of products.

  John Kelly, M.D. - speaker & moderator
  Grant/Research Support: Aventis, Lilly Oncology, Schering, OSI, Imclone.
  Consultant: AstraZeneca, BMS, Lilly Oncology.
  Speakers’ Bureau: AstraZeneca, BMS.
  Does not intend to discuss unlabeled uses of products.

Example: speaker has no relationships to disclose and intends to discuss unlabeled uses of products.

  Joan Kelley, M.D. - speaker, planning group
  Has no relevant financial relationships with commercial interests that pertain to this specific activity to report.
  Does not intend to discuss unlabeled uses of products.

c) Inclusion of the disclosure information on print and electronic announcements is encouraged as print deadlines allow.

Verbal Disclosure
ACCME policy allows for information about relevant financial relationships with commercial interests to be disclosed to participants verbally. For providers who choose to make disclosure to their learners verbally, a system that demonstrates compliance with policy 2003-B-13 (see below) must be in place for activities that occur after November 1, 2003.

ACCME policy 2003-B-12:
HCCME must be able to supply ACCME with written verification that appropriate verbal disclosure occurred at a CME activity. With respect to the documentation of verbal disclosure at CME activities: 1) A representative of the HCCME who was in attendance at the time of the verbal disclosure must attest, in writing: a: that verbal disclosure did occur; and b: itemize the content of the disclosed information (2000-B-14); or that there was nothing to disclose (1999-A-17). 2) The documentation that verifies that adequate verbal disclosure did occur must be completed within one month of the activity.

Strategies to Demonstrate Compliance When Disclosing Verbally

Written Attestation
The following is a strategy provided by the ACCME that demonstrates compliance with policy 2003-B-12. As with written disclosure, the process begins with faculty completing, signing and returning the HCCME Disclosure Declaration and Attestation Form to the designated department, division or program representative.

“A written attestation by the activity moderator, observer or staff member, that is signed and dated within a week of the activity, states that all the relevant disclosure information was made known to the participants. Stapled to the attestation is the full detail of the information that was disclosed. In this case, the detail can be found in the faculty disclosure forms required by the provider.”

Use of Moderator’s Script
Many departments provide the activity moderator with a written script. The script generally includes a welcome, housekeeping announcements, HCCME accreditation statement, credit designation statement,
introduction of HCCME observer, commercial support acknowledgement, evaluation form completion
reminders, statement of learning objectives, speaker introduction with the required disclosure information,
closing and thank you. A signature line could be added to the written script that serves as the moderator’s
written attestation that the ACCME disclosure requirements were fulfilled. The signed script becomes
part of the permanent file for the activity.

**Combination Written (Slide) and Verbal Disclosure**
The disclosure information may also be displayed on a slide that is projected on the screen prior to the
beginning of the activity. In this case, the moderator must verbally direct the learner’s attention to the
slide and allow time for the learner to read the information. A hard copy of the slide that is signed and
dated on the date of the activity that attests that the slide was displayed prior to the activity is to be made
part of the permanent file of the activity.

**Permanent File.** All required documents should be kept for the duration of the current HCCME
accreditation period. The documents include: the faculty disclosure statement, copy of the print
announcement, and written attestation.