

·
· STATE UNIVERSITY OF NEW YORK
·
· DOWNSTATE MEDICAL CENTER
·



OFFICE OF
CONTINUING MEDICAL EDUCATION

POLICY FOR INDUSTRY SUPPORT OF CONTINUING
MEDICAL EDUCATION

450 CLARKSON AVENUE
BROOKLYN, N.Y. 11203

OCME

SCOPE OF POLICY

This policy will apply to continuing educational programs (grand rounds series, annual conferences and symposia) accredited by the Office of Continuing Medical Education (OCME) at SUNY Downstate Medical Center and our affiliated partners.

The OCME policy is to comply with the Industry Policy of the State University of New York. It is the policy of the OCME that industry grants for continuing medical education must comply with the Standards for Commercial Support of the Accreditation Council for Continuing Medical Education (ACCME) and be executed by the Office of CME.

PROCEDURE

THE OFFICE OF CME AT THE STATE UNIVERSITY OF NEW YORK WILL COMPLY WITH THE ETHICS IN GOVERNMENT ACT SET FORTH BY THE BY THE STATE UNIVERSITY OF NEW YORK, <http://www.suny.edu/InternalControls/NYSEthics.cfm> AND CONFLICT OF INTEREST POLICY SET BY SUNY DOWNSTATE.

All CME activity directors must comply with the Industry Support Policy of the OCME. The ACCME believes that independence from commercial interests will help ensure that CME is free of commercial bias and, therefore would be in the best interest of the public. As a result, the OCME, CME affiliates and joint-sponsors will comply with the Standards of Commercial Support and follow these procedures:

- The OCME will monitor all activities to ensure that they are free from the control of commercial interests. SUNY Downstate OCME does not allow commercial interests to play any role in providing access to CME activities. A commercial interest is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.
1. CME Activity Directors and planning committee members are responsible for identifying professional practice gaps and needs; determining their educational objectives, selecting content, faculty, teaching methods, and evaluation methods for their activities.
 2. All planning committee members will provide full disclosure. In addition, all annual conferences are reviewed by a CME sub-committee.
 3. Approval of the activity is dependent upon ensuring that the educational needs have been identified, objectives have been determined, that the content is valid and serves the best interest of the public, and that there is no influence from a commercial interest.

4. **Commercial support shall be provided with the knowledge, consent, and written approval of the Office of Continuing Medical Education (OCME) and shall be in the form of an educational grant. All General Sponsorship is considered commercial support.** No other payment from a commercial interest shall be given to the Activity Director, planning committee members, faculty (speakers or presenters), authors, joint sponsor, or any others involved with the supported CME activity.

5. **Content without commercial bias**

Each CME Activity Director signs a policy and procedure statement attesting that their activity promotes improvements or quality in health care and is not in the proprietary interest of a commercial interest, that the content is balanced and that they will comply with the mission of the SUNY Office of CME.

CME certified activities will be free from control of commercial interests in both planning, and implementation. The use of peer and content review to ensure data validity is encouraged. A balanced view of therapeutics should be included in content, and disclosure should be made to participants regarding the source and type of evidence use for content.

6. **Disclosure of relationships to participants**

All individuals who are involved with the content of an educational activity are required to disclose all relevant financial relationships in any amount occurring within the past 12 months related both to content and to commercial supporters of the activity including:

 - ☒ The name of the individual
 - ☒ The name of the commercial interest(s)
 - ☒ The nature of the relationship the individual has with each commercial interest.
 - ☒ Any individual who does not disclose relevant financial relationships will be disqualified from participating in the planning and implementation of educational activities.
 - ☒ All relationships and source of support whether in-kind or otherwise must be disclosed in a text format (print, slide, online) to participants prior to the presentation of the content of the activity; if no relationship exists, this must be disclosed in the same manner.
 - ☒ The source and type of evidence for key teaching points must be made clear to participants
 - ☒ The OCME will monitor all activities to identify and resolve all conflicts of interest prior to the educational activity being delivered to learners.

7. A commercial interest cannot take the role of non-accredited partner in a jointly sponsored activity.

8. **Commercial Support Letter of Agreement (LOA)** must be completed and signed by both the Activity Director and company representative for each commercial support occurrence. **All letters of agreement requires the signature of the accredited provider.** This SUNY OCME form may be duplicated and used for each commercial support occurrence. Letter of Agreement Forms from Pharmaceutical companies may also be used. Devices on loan from commercial companies also require an LOA.

9. **Grants made payable to: SUNY - Office of CME.** The OCME will process all disbursements to the appropriate parties via the Research Foundation of SUNY. Please have the pharmaceutical representative contact the OCME for additional information. An administrative fee will be charged.
10. **Grants made payable to the Clinical Departments (SUNY and Affiliates).** With “full knowledge and approval” of the OCME, the clinical departments at SUNY and at our affiliates may make all disbursements. Signature of the Director of CME must be on all Letters of Agreement. A record must be kept of all disbursements and entered on your Final Budget form, which will be submitted to the OCME at the conclusion of the activity.
11. At no time should the commercial supporter pay an honorarium or other disbursements directly. This includes catering expenses or social events associated with the activity. No commercial support payment will be provided for tuition to CME program, lodging, or other course expenses to participants or their guests.
12. **Reimbursements:** For honorariums, reimbursements of travel, and catering expenses from a commercial source, you must provide the OCME with a W9 for the recipient, original receipts, and a letter/invoice requesting payment.
13. **CME Application Form** - On page 3 of the application, you will find a section to indicate whether or not commercial funds will be used. In this section, you must indicate whether the activity will be funded all or in part by departmental funds, commercial support, etc. **Please do not put “N/A”, as this is not acceptable.**
14. **Preliminary Budget Form** is to be submitted with your CME Certification Request form. The estimated costs for your activity, which includes your estimated commercial support funds, and the names of your supporters, must be included on the form.
15. **Final Budget Form** is to be submitted when your CME activity has concluded. The final reconciliation will outline total costs, which includes departmental or divisional funds, income from participant fees, and funding from commercial companies. It includes a breakdown of expenses, and a record of disbursements made from commercial support funding. Unused funds are returned as applicable. **Final budget information is essential to the completion and compliance of your CME activity.**
16. **Sponsorship:** “SUNY Downstate Medical Center” is the sponsor of all CME activities accredited by the ACCME; not the pharmaceutical company and not the Hospital. Therefore, when you read the Letter of Agreement, the word “sponsor” refers to SUNY Downstate.
17. **Signature:** All Letters of Agreement must be signed by the Office of CME at Downstate where “Provider” or “Sponsor” is indicated **before** the activity takes place.

Exhibit policy

Exhibit fees are considered a business transaction – they are not considered commercial support. However, it is the policy of the OCME that all exhibits, ads, or promotion are kept separate from the CME activity.

1. All exhibitors must sign the Exhibitor Agreement
2. Exhibitors must respect and adhere to the terms of the Agreement.
3. For **exhibits**, all exhibitors must be in a room or area separate from the educational activity, and the exhibits must not interfere or compete with the learning experience.
 - a. Arrangements for 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.
 - b. Educational materials such as slides, abstracts, and handouts must not contain any advertising or trade names, when they are part of a CME activity.
 - c. If a presentation must mention a trade name, it must be for more than one company. Otherwise, generic names must be used.

Conflict of Interest Resolution Policy

The ACCME considers financial relationships to create actual conflicts of interest in CME when individuals have both a financial relationship with a commercial interest and the opportunity to affect the content of CME about the products or services of that commercial interest.

The potential for increasing the value of the financial relationship with the commercial interest creates an incentive to influence the content of CME—an incentive to insert commercial bias. Commercial bias is prohibited in CME.

To resolve conflicts of Interest, the OCME has several options:

1. All RSCs and Annual Conferences presentation and reviewed by Activity Directors before the activity. If a conflict does not exist, no action is needed. If a conflict exist, Activity Directors asked the presenter to refrain from making recommendations on topics in which conflicts exists and to base recommendations on peer review data.
2. In addition, all conferences abstract are reviewed by a Sub-committee from three CME Board Members.
3. If a conflict arises during a presentation, Activity Director or appointed moderator asked questions or made comments to counter the commercial bias.
4. After each activity, program evaluations are reviewed for any perceived commercial bias. If no bias, no action is taken. If over 5% of audience perceived a bias, the OCME discusses the issue with the participant and Activity Director to avoid future incidents.

ACCME STANDARDS FOR COMMERCIAL SUPPORT

Please review the following ACCME Standards for Commercial Support carefully, so that you are knowledgeable of all of the required guidelines. This information is essential to everyone involved in planning CME activities, but especially important to those who routinely request grants in support of their CME activities.

Accreditation Council for Continuing Medical Education (ACCME)

STANDARDS FOR COMMERCIAL SUPPORT

Standards to Ensure Independence in CME Activities

PREAMBLE

The purpose of continuing medical education (CME) is to enhance the physician's ability to care for patients. It is the responsibility of the accredited provider of a CME activity to assure that the activity is designed primarily for that purpose. Accredited providers often receive financial and other support from non-accredited commercial organizations. Such support can contribute significantly to the quality of CME activities. The purpose of these Standards is to describe appropriate behavior of accredited providers in planning, designing, implementing, and evaluating certified CME activities for which commercial support is received.

STANDARD 1: Independence

1.1 A CME provider must ensure that the following decisions were made free of the control of a commercial interest. The ACCME defines a "commercial interest" as any proprietary entity producing health care goods or services, with the exemption of non-profit or government organizations and non-health care related companies.

- 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.

1.2 A commercial interest cannot take the role of non-accredited partner in a joint sponsorship relationship.

STANDARD 2: Resolution of Personal Conflicts of Interest

2.1 The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. The ACCME defines "relevant" financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

2.2 An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

2.3 The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.

STANDARD 3: Appropriate Use of Commercial Support

3.1 The provider must make all decisions regarding the disposition and disbursement of commercial support.

3.2 A provider cannot be required by a commercial interest to 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.

3.3 All commercial support associated with a CME activity must be given with the full knowledge and approval of the provider.

Written agreement documenting terms of support

3.4 The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the provider and its educational partner(s). The agreement must include the provider, even if the support is given directly to the provider's educational partner or a joint sponsor.

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

3.6 Both the commercial supporter and the provider must sign the written agreement between the commercial supporter and the provider.

Expenditures for an individual providing CME

3.7 The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.

3.8 The provider, the joint sponsor, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of-pocket expenses in compliance with the provider's written policies and procedures.

3.9 No other payment 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.

3.10 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.

Expenditures for learners

3.11 Social events or meals at CME activities cannot compete with or take precedence over the educational events.

3.12 The provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity. The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, joint sponsor or educational partner.

Accountability

3.13 The provider must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support.

STANDARD 4: Appropriate Management of Associated Commercial Promotion

4.1 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 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 (printed or electronic advertisements) promotional activities must be kept separate from CME.

- For **print**, advertisements and promotional materials will not be interleaved within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content, as long as these materials are not related to the CME content they face, **and** are not paid for by the commercial supporters of the CME activity.

- For **computer based**, advertisements and promotional materials 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.

- For **audio and video recording**, advertisements and promotional materials will not be included within the CME. There will be no ‘commercial breaks.’

- For **live, face-to-face CME**, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Providers cannot allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CME activity.

4.3 Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or a product-group message.

4.4 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 include product-promotion material or product-specific advertisement.

4.5 A provider cannot use a commercial interest as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities.

STANDARD 5: Content and Format without Commercial Bias

5.1 The content or format of a CME activity or its related materials must promote improvements or quality in health care and not a specific proprietary business interest or a commercial interest.

5.2 Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company.

STANDARD 6: Disclosures Relevant to Potential Commercial Bias - Relevant financial relationships of those with control over CME content.

6.1 An individual must disclose to learners any relevant financial relationship(s), to 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.

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 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.

6.4 ‘Disclosure’ must never include the use of a trade name or a product-group message.

Time of disclosure

6.5 A provider must disclose the above information to learners prior to the beginning of the educational activity.
