INTRODUCTION / BACKGROUND

This document outlines the CEPD Office protocol pertaining to the support of continuing medical education activities or resources by commercial supporters (e.g. pharmaceutical companies, instrument and device manufacturers). Such activities or resources include but are not restricted to courses, conferences, workshops, Internet courses, and the production of learning resources, e.g. CD-ROM or videotape, designed for use by health professional learners.

The following documents have been employed in the preparation of these statements and form the basis for the protocol.

- College of Family Physicians of Canada "A Guide to Mainpro Accreditation" http://www.cfpc.ca/uploadedFiles/CPD/_PDFs/A%20Guide%20to%20Mainpro%20Accreditation_ APR2011(final).pdf
- 2) Royal College of Physicians and Surgeons of Canada "CPD Program Guide" http://rcpsc.medical.org/opa/cpd/prog-guide_e.pdf
- Rx&D Code of Ethical Practices January 2010 https://www.canadapharma.org/en/commitment/healthcare/pdfs/2010%20-%20Code%20of%20 Ethical%20Practices_en.pdf
- 4) Canadian Medical Association "Guidelines for Physicians in Interactions with Industry" http://policybase.cma.ca/dbtw-wpd/Policypdf/PD08-01.pdf
- 5) Committee on Accreditation of Continuing Medical Education "The Accreditation of Canadian University CME/ CPD Offices" http://www.efmc.co/pdf/EINAL_CACME_Standards_2010_ENCLISH.pdf

http://www.afmc.ca/pdf/FINAL_CACME_Standards_2010_ENGLISH.pdf

DEFINITIONS OF TERMS

Accreditation (applies to organizations only): The official recognition by the Council on Accreditation of CEPD that a medical school has undergone a review process and has proven its ability to plan, present and evaluate CEPD programs that meet recognized standards of quality. The Committee on Accreditation of CME accredits Canadian Medical Schools' CME divisions; The Royal College of Physicians and Surgeons of Canada has an accreditation process for National Specialty Societies; The College of Family Physicians of Canada has an accreditation process for CME programs for family doctors.

Approval (applies to CEPD courses, events and educational resources): For the purposes of this policy, approval implies the successful review of an educational activity or resource by the CEPD Planning Committee. Upon approval, the CEPD Office, Faculty of Medicine may assign credits of the College of Family Physicians of Canada, the Royal College of Physicians and Surgeons of Canada and the American Medical Association. *Only approved CME events (or other activities) may use NOSM's name and logo*.

Conference/Meeting: The American Medical Association Council on Ethical and Judicial Affairs defines a legitimate "conference" or "meeting" as any activity, held at an appropriate location, where "the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and the main incentive of bringing attendees together is to further their knowledge on the topic(s) being presented".

Enduring materials: Any printed or similar learning material such as a monograph, self assessment quiz or other *item* meant to provide educational information to learners.

Provider: Normally non-profit, physician-led organizations or groups planning and delivering CEPD or continuing professional development (CPD) activities. This definition **excludes** pharmaceutical companies or their advisory groups, medical and surgical supply companies, communication companies, and other for-profit organizations and ventures/activities.

Sponsor: The institution under whose auspices a course is being held.

Supporter: A company, individual, organization, institution, government agency or other entity (for-profit or not- for-profit) which contributes financial resources to a CE course or other activity.

Faculty: Members of the Faculty of Medicine and/ or other content experts invited by the NOSM CEPD Office as workshop leaders, lecturers and speakers. The term faculty may also be taken to mean small group facilitators, workshop leaders, and developers of educational resources such as web-based learning modules or printed materials.

1. SELECTION OF SUBJECTS/CLINICAL AREAS

CEPD planners are strongly encouraged to use all needs assessment means at their disposal including reflection on the appropriateness, evidence and clinical burden regarding a specific disease, disorder or subject area, prior to any negotiation with potential commercial supporters.

Following this exercise, and to ensure scientific integrity, the selection of topics, speakers, course materials and enduring materials is entirely the responsibility of the program organizer. If a resource person is recommended by a commercial organization, he or she must be acceptable to the course director and his/her planning committee. In this way, CEPD providers may be assured that teachers deliver current, objective and unbiased, scientifically rigorous, and expert coverage of the subject at hand. As a condition of contributing funds or services, a CEPD provider cannot be required to accept advice or services concerning the selection of teachers, authors, participants or other education matters, including content, from a commercial supporter as a condition of contributing funds or services.

Specifically, the course planner must ensure that the following decisions are made free of the control of a commercial interest:

- (a) Identification of CEPD needs industry may submit a proposal to develop a mutually beneficial program which meets physicians' needs. It will be reviewed by the planning committee to ensure that it is consistent with our own needs assessments.
- (b) Determination of educational objectives.
- (c) Selection, development and presentation of content.
- (d) Selection of all persons and organizations that will be in a position to control the content of the CEPD.
- (e) Selection of educational methods.
- (f) Logistics associated with planning and hosting the event or activity.
- (g) Evaluation of the activity.
- (h) Feedback to faculty.

The invitation to participate in planning must emanate from the CEPD provider (course director), not from the commercial organization.

2. EXTENT AND NATURE OF COMMERCIAL SUPPORT

As a general guiding principle, commercially supported social events at continuing education activities should not compete with, nor take precedence over, educational events. (See note 1) Further, registrants' travel arrangements, hotel accommodation and other activities should be in keeping with arrangements normally made without commercial support and follow NOSM policies on travel. They must not be in the control of, or handled by, commercial supporters. (See also Section 9.)

3. DISCLOSURES

Disclosure of affiliations, sponsorships, honoraria, monetary support, and other potential conflicts of interest (e.g. financial stock options, patents, research grants) must be made by any faculty at NOSM approved CEPD activities.

As outlined in Disclosure of Potential Conflicts of Interest on the "CEPD Speaker Contract", the faculty member presenting is responsible for conveying to the CEPD Office and to participants verbally and in writing, any potential conflicts relevant to the topic area of the presentation. Faculty disclosures should cover relevant relationships for a period of two years prior to the course. Disclosures maybe made in the course syllabus or handouts. They should be included as the first or second slide in the speakers' presentations and, should be referred to by the speakers. If there are no handouts or slides, a one-page summary of declared relationships should be distributed to participants. The Course Chair is responsible for conveying to participants any funding received by the course through an unrestricted educational grant Commercial supporter representatives participating on planning committees must be so designated on course brochures and other relevant materials.

4. UNBIASED PRESENTATION OF CONTENT

Topics chosen for presentation during a CEPD activity must not be product or promotion oriented, and presentations must give a balanced view of all relevant therapeutic options available. Use of generic names is required wherever possible. Any products, procedures, or techniques that are defined as experimental, investigative, or "off label" (i.e. non-recognized indication) must be disclosed to the participants.

Under certain circumstances, balance may not be possible, in which case the rationale for the inclusion of a one-sided presentation should be explained to the participants (e.g., the discussion of a new product within a class of drugs or medical devices, and software or in the instance of research presentations which focus on only one drug within a class and for which there is no drug class evidence).

Use of the NOSM logo or name in a manner that constitutes promotion of a product is prohibited.

All speaker and overall course evaluation forms should include a question concerning commercial bias, e.g., "Did the program avoid commercial bias or influence?" Compilations or summaries of evaluation forms must be made available to the planning

committee and participating faculty at the conclusion of each approved CEPD activity.

5. COMMERCIAL DISPLAYS

When commercial exhibits are part of the program, arrangements for these should be considered separately so as to not influence planning or interfere with the presentation of CEPD activities. A single commercial organization may support a course and provide a relevant exhibit of its products. Exhibits (including banners which name products) may not be placed in the same room as the educational event.

6. SATELLITE SYMPOSIA

Many conferences and meetings are held in proximity (either spatially or temporally) to "satellite" symposia. These are separate meetings, frequently produced by commercial interests, often without the restrictions of commercial support policies and guidelines. Registrants may perceive such programs as integral to the approved event and be unaware of commercial bias. Thus, conference organizers must take care to ensure that: 1) registrants at the approved program are aware that such satellite symposia are not approved by the NOSM CEPD Office; 2) such activities are promoted (marketed or 'branded') in a way which *clearly* identifies the satellite activity as distinct from the approved event; and 3) the satellite symposia are located in an area separate from the NOSM CEPD sponsored event, where possible.

7. REGISTRANT ISSUES

a) Registration Fees

A registration fee is generally required from all nonteaching participants, since it is preferable that registrants bear some responsibility for the program and for attendance. Exceptions to this general rule include rounds, faculty development activities, and researchoriented programs or events. When a course is fully sponsored through unrestricted educational grant(s) the registration fee may be exempt.

Subsidies to underwrite the costs of continuing medical education conferences or professional meetings may contribute to the improvement of patient care and therefore are permissible. Since the giving of a subsidy directly to the physician by a commercial representative may create a relationship that could influence the use of the company's products, such funds should be received only by the conference organizer. He/she in turn may use the money to reduce the conference registration fee.

b) Registration Lists

Prior to a Course: Privacy restrictions preclude the distribution of registration lists prior to courses to commercial supporters or attendees under any circumstances. Such lists may be made available to course organizers and teachers in order to make workshop assignments or for other educational purposes (e.g. sending pre-course reading material). *During or after a Course:* Registrants' names, city, province/state and institution may be distributed only with registrant's consent.

c) Payments to Registrants

Course planners must avoid participating in arrangements through which inducements are offered to attend CEPD programs that might directly or indirectly influence participants' judgment of those products, procedures, devices, etc. that are subjects of the presentation. This includes accepting any support or emoluments that may induce feelings of indebtedness and thereby affect objectivity. Specifically, commercial supporters may not subsidize or provide travel, lodging, honoraria, or personal expenses directly to practicing health professional attendees or their guests.

8. DIRECTION OF FUNDS

All funds from a commercial source should be in the form of an unrestricted educational grant, as per the Canadian Medical Association Policy Summary on Physicians and the Pharmaceutical Industry, 2007 and made payable to the institution or organization sponsoring the *CEPDICPD* activity (e.g. NOSM). Subsidies specifically designated for hospitality should not be accepted.

9. PAYMENT OF TEACHERS

a) NOSM Faculty

No teacher who is a NOSM faculty member may directly receive funding by commercial organizations for taking part in NOSM sponsored CEPD activities.

Under some circumstances, NOSM faculty members may be paid a modest honorarium. At the discretion of the Director of CEPD, expenses incurred in making a presentation (e.g. parking) may be allowed, and small gifts (e.g., gift certificates) are acceptable.

b) Guest Faculty/Visiting Speakers

It is appropriate for guest faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for personal travel, lodging, and meal expenses. However, they may not be paid directly by commercial organizations. All expenses are to be paid through the CEPD provider.

10. ACKNOWLEDGEMENTS

The following outlines ways in which the NOSM CEPD Office may acknowledge commercial support in the following formats. Advertising for commercial products by name or by indication is not permitted.

(a) Course Brochures:

Educational grants are documented in course brochures under "Acknowledgements." Commercial supporters may not be listed in the schedule of activities, the list of faculty or on the front of multi page brochures.

(b) Posters, flyers and one-page brochures:

Acknowledgements may be listed at the bottom in an unobtrusive manner.

(c) Websites and other electronic formats:

In a one-page or one-screen format,

acknowledgements may be listed unobtrusively at the bottom; in a multi- page or multi-screen format, acknowledgements may not be on the main (home) page, on a list of faculty or with the learning activities. Advertisements and promotional materials must not be visible on the screen at the same time as the CEPD content and not interleafed between computer "windows" or screens of the CEPD content. Links to commercial supporters' home pages (but not to pages related to product) may be established, so long as disclaimers are clearly in place, indicating that NOSM is not responsible for the linked content. "Pop-ups" are not allowed. Links must open a new window, leaving the educational site open in the background.

(d) In printed CEPD handouts or syllabi:

Advertisements and *promotional* materials may not be interleafed within the pages of the CEPD content. They may be inserted at the end of the syllabus, not facing any content, and clearly marked as advertising/promotion.

(e) Live activities:

In live, face-to-face CEPD activities, advertisements and promotional materials may not be displayed or distributed in the educational rooms. Providers may not allow representatives of commercial interests to engage in sales or promotional activities while in the CEPD activity. Commercial supporters may be acknowledged on a slide by company name only.

Notes

(1) 'Precedence" is not taken in this clause as implying ordering of social and educational activities, rather it is taken in the sense of importance and duration: NOSM approved activities must give equal or greater weight to educational (vs. social) activities. For example, an event that featured a cocktail reception and dinner and a lecture of shorter duration would not qualify for approval.