COUNCIL OF MEDICAL SPECIALTY SOCIETIES

COMMITTED TO EXCELLENCE IN PROFESSIONALISM, EDUCATION AND QUALITY OF CARE

230 E. Ohio St., Suite 400, Chicago, IL 60611
(312) 224-2585 Telephone • (312) 644-8557 Fax
www.cmss.org

February 25, 2009

Regina M. Benjamin MD MBA
Chair, Council on Ethical and Judicial Affairs
Claudette C. Dalton MD
Chair, Council on Medical Education
American Medical Association
515 N. State St.
Chicago, Illinois 60654

Dear Drs. Benjamin and Dalton,

The Council of Medical Specialty Societies (CMSS), with 32 medical specialty society members, representing more than 500,000 physicians, has as its vision to be a leading advocate for professionalism, including lifelong learning of physicians.

CMSS appreciates the opportunity to contribute to the deliberations of the Councils on Ethical and Judicial Affairs, and Medical Education, of the American Medical Association, on "Ethical and Practical Issues in Commercial Support of Continuing Medical Education."

Three related issues have been raised by the AMA Councils for comment:

1. Ethically preferable practice with respect to commercial funding for CME;
2. Ethically permissible practice, including strategies for managing or mitigating potential conflict of interest or bias; and
3. Ethically permissible practice in situations involving uniquely qualified but unavoidably conflicted parties.

CMSS considers that practices in the contribution, receipt and use of commercial funding for CME should be demonstrated by CME providers in a manner which:

- *adheres to national standards of appropriate and acceptable behavior (in this case, the Standards for Commercial Support (SCS): Standards to Ensure the Independence of CME Activities, of the Accreditation Council for Continuing Medical Education), and*
- *eliminates both real (evaluated and measured) and perceived (by learners and observers) promotional bias.*

Professionalism – the Profession's Responsibility -

The two primary components of professionalism include: altruism, defined as putting the interests of patients first; and voluntary self-regulation. Nowhere is adherence to the standards of professionalism more necessary than in dealing with commercial support of CME.

Insertion of promotional bias into CME threatens to, and gives the appearance of putting the interests of for-profit companies before those of patients. Similarly, meeting the challenges associated with the contribution, receipt and use of commercial support demands effective voluntary professional self-regulation. Failure to meet these challenges will inevitably result in the reaction of the public through consumerism, calling for external governmental regulation.

Commercial Relationships – Grants to CME Providers or Direct Payments to Physicians -

Certified CME programs are those educational programs produced by CME Providers which are accredited by one or more of the three national accreditors of CME, the American Academy of Family Physicians (AAFP, since 1948), the American Osteopathic Association (AOA, since 1973) and the Accreditation Council for Continuing Medical Education (ACCME, since 1980). ACCME accredited providers are authorized to award AMA PRA credit, which has been available to physicians since 1968.

All three national CME accreditors have adopted, implemented and enforce the *ACCME Standards for Commercial Support(SCS): Standards to Ensure the Independence* of *CME Activities.* These standards require that CME providers, in this case medical specialty societies, clearly and completely separate educational content from commercial support. CME providers may offer and physicians may claim CME credit for participating in certified CME activities.

Recognizing incomplete enforcement of the separation of commercial influence, in 2004 the ACCME made significant changes to its standards to require significantly tighter procedures by professional organizations to effectively exclude bias from certified CME. CME providers are now being judged by those tighter standards. The attention of the Senate Finance Committee to tighter adherence has similarly made the national CME accreditors attend to tight enforcement of the separation of industry influence from certified CME.

Were the receipt of commercial support by CME providers the only relationship to be considered, strict adherence to national professional standards (here the ACCME SCS) would address *"ethically preferable practice with regard to commercial funding for CME."* However, complicating relationships include those falling into the category of direct payments, so-called "gifts" to physicians who may play roles in CME. Financial relationships between individual physicians and commercial entities create a conflict of interest for those physicians who participate in CME.

In the evolution of establishing standards for managing commercial relationships, disclosure of such relationships was considered necessary. Over time, such disclosure, while necessary, was deemed in many cases to be insufficient to manage such relationships. As referenced above, these conflicted relationships may be found in "uniquely qualified but unavoidably conflicted parties."

In this challenging set of relationships, demonstrably successful ethical solutions have been implemented by many CME providers through mechanisms developed and taught at the national conferences of the National Task Force on CME Provider Industry Collaboration.

Managing "Unavoidable" Conflicts of Interest – When Conflicted Expertise is Essential in CME -

The SCS, currently and appropriately, require accredited providers to implement a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners (C7, SCS 2.3). When conflicts of interest cannot be sufficiently managed and resolved to eliminate commercial bias from CME, then such conflicts are considered irreconcilable, and the individual who has disclosed such conflict of interest may not participate in the planning or delivery of CME. ACCME has defined full-time employees of commercial interests as having irreconcilable conflicts of interest.

Particularly in small specialties with small pools of experts, individuals considered the "best and the brightest" available to teach physicians often disclose relationships which constitute a conflict of interest. In recent years, accredited providers have been successful in these circumstances in implementing at least four interventions to ensure that commercial bias is eliminated from CME. Data from the CME accreditation system of the American Academy of Family Physicians, for example, reveals that commercial bias, as judged by learners and by trained observers, can be significantly reduced, and in most cases eliminated, through combinations of these four interventions.

Therefore, CMSS recommends that:

*Persons paid to create or present promotional materials on behalf of commercial interests, and who therefore disclose an "unavoidable" (but not irreconcilable) conflict of interest, may be included in accredited continuing medical education **if and only if** their conflict of interest can be resolved through one or a combination of the following interventions –*

Option 1 - Peer review:

Members of the planning committee, or other authors/speakers (both content experts and those trained to recognize bias) without a conflict of interest, review the final content that an author/speaker plans to use in a CME program, after which the author/speaker may not change that content.

Option 2 - Evidence-based CME content:

The author/speaker is required to present an evidence-based CME program that conforms to nationally accepted standards of Evidence-based CME, including disclosure of the source and level of evidence for all practice recommendations (it is insufficient to have the speaker merely attest that the CME content in question is "evidence-based").

Option 3 - Modify content:

The author/speaker may present on pathophysiology, research data, and other content, but may be asked to not make practice recommendations (these can be made by another author/speaker, who discloses no such conflicts of interest).

Option 4 - On-site monitoring of live presentations:

After a combination of options 1-3 above, trained monitors (volunteer physician and staff) attend the presentation and determine if subtle or overt bias was inserted into the presentation. Violations of the professional trust placed in the speaker can be dealt with both on-site through real-time confrontation (i.e. from a floor microphone) of the bias in the presentation, and after the fact (prospective recusal from future presentations). Similar consequences can be enforced of CME providers in the role of joint-sponsor.

Unique Challenges Facing Specialty Societies in CME –

Specialty societies have as their missions to provide education to their members so that those specialist physicians may in turn provide the highest quality, state-of-the-art care to their patients. Specialty society members represent the vast majority of physicians in the US. Traditionally, CME has been delivered through live lectures and courses, enduring materials and journals, any and all of which may also be delivered electronically. New models of CME have emerged since nationally standardized by the AMA Council on Medical Education, and promulgated beginning in 2005, including Point of Care CME and Performance Improvement CME.

Specialty societies use a combination of business models to develop, disseminate and evaluate continuing education for physicians, including charging a fee for CME products, and delivering free CME to members. Free CME may be either subsidized by the specialty society, or produced with external support. As non-profit organizations seek non-dues revenue to fulfill their missions, specialty societies seek non-dues revenue to fulfill their missions of delivering CME to the large majority of practicing physicians in the US, a significant financial challenge. Corporate support is one such revenue alternative.

Recent data on the effectiveness of CME have challenged specialty societies to develop new CME interventions, including evidence-based content, available "just-in-time" at the point of care. New procedures using new technologies are being developed regularly, and must be safely and effectively incorporated into the practices of experienced physicians.

The integration of performance measurement into practice has offered a new opportunity for CME to improve patient care.

The ACCME has current and relevant criteria requiring all CME providers to focus the goals of CME toward improvement of physician practice, thus improving the quality of patient care. These criteria also include stronger guidance on complete independence from bias associated with commercial support, as well as stronger procedures for the identification and resolution of conflicts of interest.

In Closing –

The Council of Medical Specialty Societies recognizes both the value to society of commercial support of CME, and the responsibility of the profession to accept and use such support in the best interests of patients and the public. As such, we recognize and accept the responsibility to voluntarily regulate our behavior as a profession to deliver CME free from bias; and to in identify, manage and resolve conflicts of interest disclosed in relationships of planners and faculty in CME. We are committed to utilizing standards set by the profession to ensure that our practices are of the highest ethical standards of the profession.

MEMBERS

American Academy of Allergy, Asthma & Immunology • American Academy of Dermatology • American Academy of Family Physicians • American Academy of Neurology American Academy of Ophthalmology • American Academy of Orthopaedic Surgeons • American Academy of Otolaryngology—Head and Neck Surgery • American Academy of Pediatrics American Academy of Physical Medicine and Rehabilitation • American College of Cardiology• American College of Emergency Physicians • American College of Medical Genetics American College of Obstetricians and Gynecologists • American College of Occupational and Environmental Medicine • American College of Physicians • American College of Preventive Medicine American College of Radiology • American College of Surgeons • American Medical Informatics Association • American Psychiatric Association • American Society for Clinical Pathology American Society for Reproductive Medicine • American Society for Therapeutic Radiology and Oncology • American Society of Anesthesiologists • American Society of Clinical Oncology American Society of Colon and Rectal Surgeons • American Society of Plastic Surgeon s • American Urological Association • Society of Critical Care Medicine Society of Neurological Surgeons • Society of Nuclear Medicine • Society of Thoracic Surgeons

ASSOCIATE MEMBERS

Accreditation Council For Continuing Medical Education • Accreditation Council For Graduate Medical Education Alliance For Continuing Medical Education • American Board Of Medical Specialties Association Of American Medical Colleges • Federation Of State Medical Boards National Board Of Medical Examiners