



COUNCIL OF MEDICAL SPECIALTY SOCIETIES

COMMITTED TO EXCELLENCE IN PROFESSIONALISM, EDUCATION AND QUALITY OF CARE

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August 15, 2008

Murray Kopelow, MD, MS (Comm), FRCPC
Chief Executive Officer
Accreditation Council for Continuing Medical Education
515 North State Street, Suite 1801
Chicago, IL 60654

Dear Dr. Kopelow:

The Council of Medical Specialty Societies (CMSS), with 32 medical specialty society members, representing more than 500,000 physicians, appreciates the opportunity to comment on ACCME's position that "the manner of interaction between potential commercial supporters, or their agents, and some Accredited Providers may need to be altered."

- I. Call for Comment: ACCME will ensure current processes of attaining commercial support will not undermine the independence of continuing medical education: Limiting the Interactions between Accredited Providers and Commercial Interests over Commercial Support**

ACCME call for comment item 1:

"Accredited providers must not receive communications from commercial interests announcing or prescribing any specific content that would be preferred, or sought-after, topic for commercially supported CME (e.g., therapeutic area, product-line, patho-physiology) – as such communication would be considered 'direct guidance on the content of the activity' and would result in Non Compliance with Standard 1 of the ACCME Standards for Commercial SupportSM."

CMSS position:

The Council of Medical Specialty Societies supports the clarification of the ACCME Standards for Commercial Support as in item 1 above.

Background:

CMSS recognizes that a commercial interest provides commercial support for a CME activity that is often (although not always) within the scope of that commercial interest's business objectives. This is only logical. Even non-commercial interests (organizations that fall outside the definition of a commercial interest as defined by the ACCME) generally support activities that further the mission or the objectives of the supporter. For example, the prestigious Gerber Foundation whose mission is "to enhance the quality of life of infants and young children in nutrition, care, and development" would most likely not support a CME program that addresses Alzheimer's dementia in the older patient.

SCS 1 rightly places the burden of documentation and truth upon the provider to ensure complete independence from commercial interest bias or control. Commercial interests in the pharmaceutical industry have recently changed their behavior to comply with regulation from the OIG, and in so doing, are avoiding communicating desired content areas for grants to be submitted for potential support. In this light, the proposed ACCME clarification would be consistent with current behaviors of commercial interests and CME providers, and of the intent of the ACCME Standards for Commercial Support.

ACCME call for comment item 2:

"Receiving communications from commercial interests regarding a commercial interest's internal criteria for providing commercial support would also be considered the receipt of 'guidance, either nuanced or direct, on the content of the activity or on who should deliver that content.'"

CMSS position:

The Council of Medical Specialty Societies supports the clarification of the ACCME Standards for Commercial Support as in item 2 above.

Background:

The CMSS member organizations invest significant resources, both human and capital, in addressing their missions to provide continuing professional development for their members. To address these missions demands that the organization look beyond the member's dues/CME registration fees to other sources of revenue. Corporate support is one such revenue alternative.

Many, if not most, commercial interests have initiated a grant process that standardizes the application and levels the playing field for fair evaluation of requests. It appears reasonable for potential grantees to seek to understand the criteria for a grant request to comply with grant requirements. Such *process* communication between grantee and grantor is common practice with private philanthropies (such as the Robert Wood Johnson Foundation) and with the federal government (such as AHRQ), as well as with industry, and is considered standard operating procedure.

However, it would be inappropriate for an accredited provider to request, or for a commercial interest to communicate *content* preferences, such as preferred topics (see ACCME 1 above), in discussions prior to submitting a grant. Again, SCS 1 rightly places the burden of documentation and truth upon the CME provider to ensure independence from commercial interest bias or control. In this light, the proposed ACCME clarification would be consistent with current behaviors of commercial interests and CME providers, and of the intent of the ACCME Standards for Commercial Support.

**II. Call for Comment: The ACCME believes that due consideration be given to the elimination of commercial support of continuing medical education activities:
*The proposal is that the commercial support of continuing medical education end.***

CMSS position:

The Council of Medical Specialty Societies does not support the proposal that commercial support of continuing medical education end.

Background:

CMSS fully supports the ACCME Standards for Commercial Support and enthusiastically champions the 2004 updates. These Standards require that CME providers, in this case medical specialty societies, clearly and completely separate educational content from commercial bias, which may be perceived as resulting from commercial support. CME providers may offer and physicians may claim CME credit for participating in certified CME activities.

The public and political climate in the United States, particularly concerning the high cost of drugs in the Medicare program, has resulted in intense scrutiny of ACCME, as well as of many CME providers. This climate of fault-finding, blame and threat, couched as inquiry, has understandably stimulated organizations to react, and to sometimes over-correct in immediate response.

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 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. ACCME is poised to assume a position to strictly enforce its criteria, thus providing evidence to outside pressures that the system of professional voluntary self-regulation works well.

Although there is the potential for added burden to medical specialty societies and other CME providers, the environment, and professional reaction, is stimulating debate in the societies about commercial support. Debate among leaders, executive staff, and members is occurring in many medical specialty societies concerning the levels of industry support they receive for CME activities. Several societies have plans to reduce or curtail industry support and move to alternative types of funding for CME.

CMSS agrees with ACCME “that the profession (taken to mean physicians), the public (taken to mean patients) and the CME enterprise (taken to mean accredited CME providers) weigh in on the subject...with colleagues (taken to mean other accrediting organizations), with other professions (taken to mean nursing and pharmacy), with students (taken to mean participants in the continuum of medical education), with government (taken to mean agencies related to Medicare/Medicaid), and with stakeholders of CME (taken to mean commercial/non-commercial interests related to CME), including the public.”

CMSS suggests that the venue for this discussion, with the potential inclusion of additional interested parties, exists in the Conjoint Committee on Continuing Medical Education (CCCME).

The CCCME is a “multi-organizational committee, members of which are key stakeholders in the continuum of medical education.” CCCME participating organizations include: the Association of American Medical Colleges (AAMC), Accreditation Council for Continuing Medical Education (ACCME), Accreditation Council for Graduate Medical Education (ACGME), Alliance for Continuing Medical Education (ACME), American Academy of Family Physicians (AAFP), American Board of Medical Specialties (ABMS), American Hospital Association (AHA), American Medical Association (AMA), American Osteopathic Association (AOA), Association for Hospital Medical Education (AHME), Council of Medical Specialty Societies (CMSS), Federation of State Medical Boards (FSMB), Joint Commission (JC), Liaison Committee on Medical Education (LCME), National Board of Medical Examiners (NBME), and the Society for Academic Continuing Medical Education (SACME).

This Committee was initially convened in 2002 and has sustained an active, stimulating dialog about CME and more broadly, the continuum of medical education in the United States. The CCCME has prepared a report, *Reforming and Repositioning Continuing Medical Education*, that contains recommendations and next steps in seven key areas related to CME: 1) the medical education continuum; 2) self-assessment and lifelong learning; 3) core curricula and competencies; 4) valid content: evidence-based medicine; 5) performance and continuous improvement; 6) metrics to measure and recognize physician learning and behavioral change; and 7) resources and support.

CMSS recommends that the Conjoint Committee on CME be tapped to frame and conduct this debate and examine the three scenarios proposed by ACCME: 1) the status quo with commercial support of CME as an acceptable funding mechanism (governed by tight adherence to the ACCME SCS) 2) the complete elimination of commercial support of CME, and/or 3) a new paradigm (for commercial support of CME as well as other possible scenarios which may emerge from the Committee's discussions).

CMSS further suggests that the CCCME be provided with adequate funding, time, and proper resources to engage this debate in a form and fashion as to realize the end result of settlement of this debate and an action plan for the future. Such funding should include the necessary monies to conduct research into the possible effects of influence and reciprocity on physicians' behavior. CCCME should be asked to begin to address this task as soon as possible.

III. Call for comment: ACCME proposes a new paradigm where ACCME accreditation will continue to reflect only what is in the best interests of the public. The ACCME proposes that if the following conditions were all met, then the commercial support of individual activities would be in the public interest and could continue to be allowed:

- 1) When educational needs are identified and verified by organizations that do not receive commercial support and are free of financial relationships with industry (eg, US Government), and
- 2) If the CME addresses a professional practice gap of a particular group of learners that is corroborated by *bona fide* performance measurement (eg, National Quality Forum) of the learner's own practice, and
- 3) When the CME content is from a continuing education curriculum specified by a *bona fide* organization, or entity, (eg, AMA, AHRQ, ABMS, FSMB), and
- 4) When the CME is verified as free of commercial bias.

Alternately, these conditions could provide a basis for a mechanism to distribute commercial support derived from industry-donated, pooled funds.

CMSS position:

The Council of Medical Specialty Societies does not support the new paradigm in its current draft format, as described above, but rather recommends modifications to ensure the separation of bias from commercial support of CME, and further recommends a process for debate and discussion of the proposed new paradigm, so that it may ultimately come to be as universally accepted as are the ACCME Standards for Commercial Support..

Background:

- 1) **“When educational needs are identified and verified by organizations that do not receive commercial support and are free of financial relationships with industry (eg, US Government), and...”**

Currently, accredited providers are charged with the responsibility of determining educational needs. Medical specialty societies, in particular, consider it their responsibility to fulfill needs assessment in planning CME for members. It does not seem logical to separate needs assessment from those providers which are in the best position to determine needs, and which are responsible for designing CME to meet those identified needs.

It appears that the intent of “new paradigm 1)” is to ensure that needs assessment is separated from commercial influence, a premise with which CMSS completely agrees. Divorcing the CME provider, particularly the specialty society, from needs assessment appears to be “throwing the baby out with the bathwater.”

- 2) **“If the CME addresses a professional practice gap of a particular group of learners that is corroborated by *bona fide* performance measurement of the learner’s own practice, and...”**

On January 1, 2005, a “new CME” emerged as Performance Improvement CME, with criteria approved by the three national CME credit granting agencies (AAFP, AMA, AOA). PI-CME is standardized and designed to “address a professional practice gap of a particular group of learners that is corroborated by *bona fide* performance measures of the learner’s own practice.” PI-CME is offered by a variety, albeit still a few, CME providers, most notably medical specialty societies. Performance measures incorporated into PI-CME are generally, and should be derived from those endorsed by *bona fide* national organizations, such as NCQA, PCPI, NQF and AQA. CMSS recognizes the need and opportunity to facilitate the development of PI-CME among medical specialty societies. This should be a goal of ACCME, as well.

That said, a requirement that any industry-funded CME be based on established guidelines and parameters would eliminate much of the educational programming currently offered and needed. Many conditions do not yet have established practice parameters, as the data necessary to create these care standards are still being developed. Prohibiting commercial support for CME on such conditions would arbitrarily eliminate CME for many conditions for which needs assessment demonstrates a need, which would ultimately have a negative impact on patient care.

It appears that the intent of the proposed “new paradigm 2)” is to ensure the separation, from commercial bias, of the identification of physician practice gaps, as well as the inclusion of performance measures into physician education, a premise with which CMSS completely agrees. Divorcing the CME provider, particularly the specialty society, from identifying practice gaps measured against nationally accepted performance measures appears to be abrogating the CME provider from its educational responsibility in, and ability to offer PI-CME.

3) “When the CME content is from a continuing education curriculum specified by a *bona fide* organization, or entity, and...”

While CMSS agrees with the premise in 2) above that *bona fide* organizations should be charged with endorsing nationally accepted performance measures which are incorporated into PI-CME, we recognize that the *bona fide* organizations in the best position to develop educational curricula for medical specialists are medical specialty societies. The role of certifying boards (represented by ABMS) is to certify individual physicians, of state medical boards (represented by FSMB) is to license individual physicians, and of medical specialty societies (represented by CMSS) is to educate individual physicians. The appropriate role for specialty societies is to identify practice gaps of its members, as a group and as individuals, to create an educational curriculum based on practice gaps, and to incorporate nationally accepted performance measures into CME to address identified gaps among its members. This educational design is part of the responsibility inherent in professionalism.

It appears the intent of “new paradigm 3)” is to ensure the separation of commercial bias from the design of educational curricula, a premise with which CMSS completely agrees. Divorcing specialty societies from designing curricula for the education of its members appears to be a Solomonian solution of cutting a whole entity in half, resulting in non-viable educational programming.

4) “When the CME is verified as free of commercial bias.”

It appears that the intent of “new paradigm 4)” is to ensure that by separating 1) needs assessment; 2) identification of practice gaps of physicians, measured against nationally accepted performance measures; and 3) educational curriculum design, from entities that receive commercial support, even when those entities are in exemplary compliance with the ACCME Standards for Commercial Support for CME, only then can and will the perception of bias be eliminated from CME. Ironically, verification is the desire in this premise. Verification requires assessment of actuality, not design changes (1, 2 and 3 are design changes), and not management of perception.

CMSS does not believe that the proposed extreme solution to the problem of the perception of commercial bias in commercially supported CME, as outlined in the proposed "new paradigm", is appropriate or necessary, as it removes the responsibilities of CME providers, particularly specialty societies, from the design and implementation of CME which is free from commercial bias.

It is important to pause to recognize the practical realities of corporate support. In the absence of support for CME, currently approximately \$1 Billion annually, the likelihood that such support will find its way into Direct to Consumer Advertising, and more problematic, into promotional education, is strong. If the goal is to eliminate product bias from the education of physicians, it will be critical to avoid an unintended consequence of stimulating significantly increased product biased education through the mechanism of promotional education.

CMSS considers the concept of pooled funds for the commercial support of CME to be one of a series of potential viable options worth pursuing.

CMSS recognizes that the perception of the incorporation of commercial bias into commercially supported CME is real. We offer the venue of the Conjoint Committee on CME as an immediate vehicle for furthering the discussion, leading to a national solution that is as universally lauded and accepted as are the ACCME Standards for Commercial Support of CME.

Sincerely,

A handwritten signature in cursive script that reads "Norman Kahn Jr." with a stylized flourish at the end.

Norman B. Kahn, Jr., MD
Executive Vice President and Chief Executive Officer