Accreditation Council for Continuing Medical Education
Suite 2150 515 North State Street Chicago, IL 60610-4377 (312) 755-7401 FAX (312) 755-7496

October 1, 2004

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Washington, DC 20201

Re: 42 CFR 411 and 424 Medicare Program; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II); Interim Final Rule

Dear Dr. McClellan:

The document released March 26, 2004 states that free continuing medical education or other training at a hospital "...could constitute remuneration to the physician, depending on the content of the program and the physician's obligation to acquire CME credits." (Federal Register Vol. 69, No.59, March 26, 2004). As such and according to other sections of the document this free CME would be interpreted as a payment to the physicians and prohibited as an inducement or potential kick back for referral of Medicare services.

Thank you for the opportunity to point out the potential pitfalls inherent in such an assertion and the potential threat to the health and well being of the public that such an approach might generate.

I ask you to consider the following:

1. **These activities are a major component of the U.S. CME Enterprise**: Hospital/academic medical center based CME includes free standing topic or theme based 'events' as well as regularly scheduled conferences (RSCs)[1]. The RSCs alone account for about 40% of the CME for credit in the United States. There are almost 4 million individual physician participants in this part of the CME enterprise that includes over 450,000 hours of CME in about 48,000 different series (ex: Pediatric Grand Rounds, Morbidity and Mortality Conferences). The rest of the CME activities of the hospital/academic medical center-based CME providers accounts for an additional 25% of the U.S. CME enterprise.

	Regularly Scheduled Conferences	All ACCME Providers' Activities	Proportion of whole US CME Enterprise
Physician Participants	3,809,720	8,592,303	44%
Activities or series	48,256	143,218	34%
Hours	473,523	1,141,076	41%

Regularly Scheduled Activities (source ACCME 2003 Annual Report Data, see www.accme.org)

2. **These activities are effective in changing practice:** The literature reports that when properly designed and appropriately placed in a sequence of learning these activities will be effective in modifying the physician's practice.

3. **The quality and content of the activities are regulated:** The ACCME requires the content to be valid[II], to be free of commercial bias and the content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest[III].

I respectfully request that CMS <u>not</u> consider free or subsidized CME from these organizations as remuneration nor to consider it the basis for a financial relationship.

1. **Who pays for it is not the issue:** The value of CME is directly correlated to the how well the content matches a physician's practice-based needs and the activities' effectiveness in improving patient health. The more positive impact on improving the quality patient care or enhancing patient safety then the greater the value. CME that is linked to patient-based needs data is quite distinct from activities that are based entirely on expanding the business of an institution. **New ACCME Standards for Commercial Support prohibit commercial interests from controlling the content of CME related to their products or services**.

2. **CME is open to all**: These activities are usually available to all members of the medical community and health care team inside and outside of the medical staff or referring physicians' of an institution. Many non-employees attend CME sessions of an institution. Physicians work in communities of consultants, colleagues and institutions and they tend to participate in the learning opportunities of these networks. The only thing that should be important is that the content is true and important to their patients.

3. **Most education a 'donated service'**: The majority of this intra-profession CME is peer-to-peer and is effectively donated by the speakers. Grand rounds, case conferences and even day long symposia are usually mostly local presenters speaking to the other physicians from their community. Most is not commercially supported but rather a donated service.

4. **Promotes team based patient centered care**: Institutional education activities provide an opportunity for community-based physicians to mix with the other professionals who care for their patients, in addition to being a mechanism for fulfilling their professional responsibilities for maintenance of licensure. This interaction clarifies roles and expectations as well as exposing potential gaps or inadequacies of knowledge, competence and/or performance of any and all members of the team. Patients will benefit from this.

5. **Fundamental to the process of maintenance of competence**: Hospital-based CME has always been a critical component of the process of maintenance of competence and licensure. Trainees learn how to learn and learn how to teach in these activities. Professionals across the ages and stages of their professional development have the opportunity to participate. The many professions interact. The various specialties debate.

Again, I respectfully request that CMS **<u>not</u>** consider free or subsidized CME from these organizations as remuneration nor to consider it the basis for a financial relationship. This education is a community-based professional obligation and expectation that is essential to the well being of the patients being served by the physicians.

As in the past, I ask that if CMS has an issue with content validity of CME or the ethical framework in which it is practiced that CMS hold ACCME accountable. I am hoping that CMS will be able to clearly state that CME developed and presented in compliance with the medical professions' various guidelines, standards and

regulations is a professional practice recognized by CMS as important in improving patient care and is not considered remuneration.

Thank you for the opportunity to comment.

Yours truly,

Murray Kopelow, MD, MSC, FRCPC
Chief Executive

MK/lrc

---

[i] Daily, weekly, or monthly CME activities of ACCME accredited providers that are primarily planned by and presented to the provider's professional staff (regularly scheduled conferences or RSC's – such as Grand Rounds, Morbidity/Mortality Conferences, Tumor Boards). Hospitals, healthcare delivery systems and schools of medicine are typically the only types of organizations that provide RSC's.

[ii] All the recommendations involving clinical medicine in a CME activity must be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients.

All scientific research referred to, reported or used in CME in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection and analysis.

Providers are not eligible for ACCME accreditation or reaccreditation if they present activities that promote recommendations, treatment or manners of practicing medicine that are not within the definition of CME, or known to have risks or dangers that outweigh the benefits or known to be ineffective in the treatment of patients. ACCME policy 2002-B-09.

[iii] Extracted from *2004 ACCME Updated Standards fro Commercial Support and Standards to Ensure the independence of CME Activities adopted April 1 2004.*