

Opportunities and Challenges in the Evolving World of Continuing Medical Education (CME)

FROM THE FREELANCE WORKSHOP

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Karen M. Overstreet, EdD, RPh, FACME, ELS, described the evolving regulation of continuing medical education (CME) and implications of CME regulations for medical writers during the AMWA-DVC Fifth Annual Freelance Workshop, on April 21, 2007 in Blue Bell, Pa. An AMWA member, Overstreet is President of Indicia Medical Education, LLC, a company dedicated to the development and management of CME activities.

Increasing Regulation of CME

Government regulation of CME has increased since 1990. Several professional organizations and government agencies are involved in regulating and accrediting CME. The latest regulation was the Accreditation Council for Continuing Medical Education's Updated Accreditation Criteria in 2006.

Several factors have led to closer examination of CME activities, including increasing healthcare costs, media scrutiny, public perception, perceived bias in CME, and cases of undue pharmaceutical company influence on prescription practices. As of 2006, the Office of the Inspector General and states' attorneys general had more than 140 ongoing investigations, and virtually all pharmaceutical companies had been investigated.¹ In addition, the Senate Finance Committee has requested information from pharmaceutical companies and the Accreditation Council for Continuing Medical Education (ACCME) regarding the role of sales and marketing in educational grants.² At this time, only one CME provider has been investigated, but more may be investigated in the future.

Involvement of bigger players in the CME regulatory field (Office of the Inspector General, US Department of Health and Human Services, Office of the US Attorney, states' attorneys general) has also led to greater penalties for inappropriate execution of CME activities. Guideline violations may have previously resulted in a warning letter from the Food and Drug Administration (FDA) to the commercial supporter or in ACCME refusal to continue provider accreditation. Now, however, Office of the Inspector General investigation that reveals violation of the Anti-Kickback Statute or False Claims Act can lead to criminal penalties, civil monetary sanctions, and exclusion from federal healthcare programs. Other consequences of guideline violation may include fines for commercial supporters and fines or imprisonment for participating faculty, commercial supporter staff, and CME provider staff – including writers.

The Importance of Disclosure

Writers should be aware of CME guidelines and changes in the CME regulatory environment in order to provide the best possible service to their customers/clients/employers and to safeguard themselves and their customers/clients/employers against punitive action. For instance, disclosure of off-label

drug use in CME programs is no longer required by the ACCME. However, medical writers should be aware that the FDA still requires such disclosure. The ACCME Standards for Commercial Support also stipulate that individuals involved in the development of CME activities can be disqualified if they do not disclose financial interests and resolve conflicts of interest.³ Because impartial content review is one means of resolving conflicts of interest, medical writers can assist in resolving conflicts of interest by ensuring content quality in terms of balance, use of reliable references, etc. Medical writers can also assist in disclosure and conflict resolution by revealing their own financial relationships with program supporters and by encouraging the provider to include peer review as part of the content development process.

Disclosure is also important because all guidelines recommend the separation of educational and promotional activities. This stipulation can impact medical writer project participation. A writer with expertise in the cardiovascular therapeutic area may be excluded from developing content for a CME activity on hypertension if she or he has recently done promotional work for a client who markets a drug to treat hypertension. However, the writer may still be able to work on a CME project regarding lipid control. Therefore, it is important that writers are forthcoming regarding potential conflicts of interest.

How Writers Can Comply with CME Guidelines

Overstreet provided a list of things writers should do in order to ensure compliance with CME guidelines:

- **Know the rules** - Network and discuss the issues in order to stay abreast of changes. AMWA events and resources provide good opportunities for this.
- **Select partners with shared values** – It is best to select educational partners who adhere to CME guidelines in letter, spirit, and intent. Overstreet described considerations such as a company structure that separates educational and promotional activities, presence of a strong compliance program, accreditation status, and program assessment practices.
- **Learn about changes in physician education and practice** – ACCME accreditation criteria have been updated to meet new requirements for physician certification maintenance, such as lifelong learning and practice-based learning and improvement.⁴ Awareness of these changes will help writers to meet the needs of physicians and CME providers.
- **Use credible reference sources and verify data** – It is no longer appropriate to use “data on file.” Participants in a CME activity should be able to verify any information presented.
- **Encourage partners to use peer review of content** – This assists in resolving conflicts of interest.
- **Disclose relationships with commercial interests** – Overstreet recommended volunteering this information if it is not requested. Full disclosure protects the writer and the provider.

Overstreet also recommended that writers encourage providers and supporters to share their methods and results. This will help the entire industry by documenting which CME approaches are effective.

CME Resources

In closing, Karen Overstreet a list of resources that provide information on changes in the CME regulatory environment:

- Alliance for CME (www.acme-assn.org)
- NAAMECC (www.naamecc.org)
- *Medical Meetings*
- *PharmaVoice*
- *Medical Marketing & Media*.

¹*Inside Medical Education*. 2006:1(3):2.

²*Medical Meetings*. 2006 (Dec):13.

³ACCME Standards for Commercial Support. 2004. Available at: <http://www.accme.org>.

⁴Pelletier S. *Medical Meetings*. 2007 (Mar):11-17.

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