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# Compliance with (Some) New ACCME Rules Not So Easy

By **John Mack**

At the end of September 2004, the seven member organizations of the Accreditation Council for Continuing Medical Education (ACCME®) unanimously approved the 2004 Updated ACCME Standards for Commercial Support: Standards to Ensure the Independence of CME. When these rules go into effect in July 2005, it is unclear how they will affect industry participation and support of CME or how these rules change the status quo for Providers soliciting CME support from industry.

A panel of experts at the recent CBI 5th Annual Continuing Medical Education conference in Princeton, NJ tackled these and other issues raised by the new ACCME rules.

**OIG Oversight**

According to the panel moderator, Marc Wilenzick, Senior Corporate Counsel, Pfizer Inc., "Violating [ACCME] rules by seeking to influence the content of independent CME can subject a program to challenge by the Department of Health and Human Services' Office of the Inspector General (OIG) and other governmental agencies, and could result in civil or criminal prosecution if the conduct constituted off-label promotion or a false claim scheme." Consequently, pharma CME supporters and CME providers that depend upon commercial support are concerned about compliance with the rules as well as what impact the rules may have on the quality of CME.

**Disclosure is Hard to Do Right**

Several panel members and other presenters at the conference acknowledged that the most troublesome ACCME rule is the one regarding conflict of interest (COI) disclosure.

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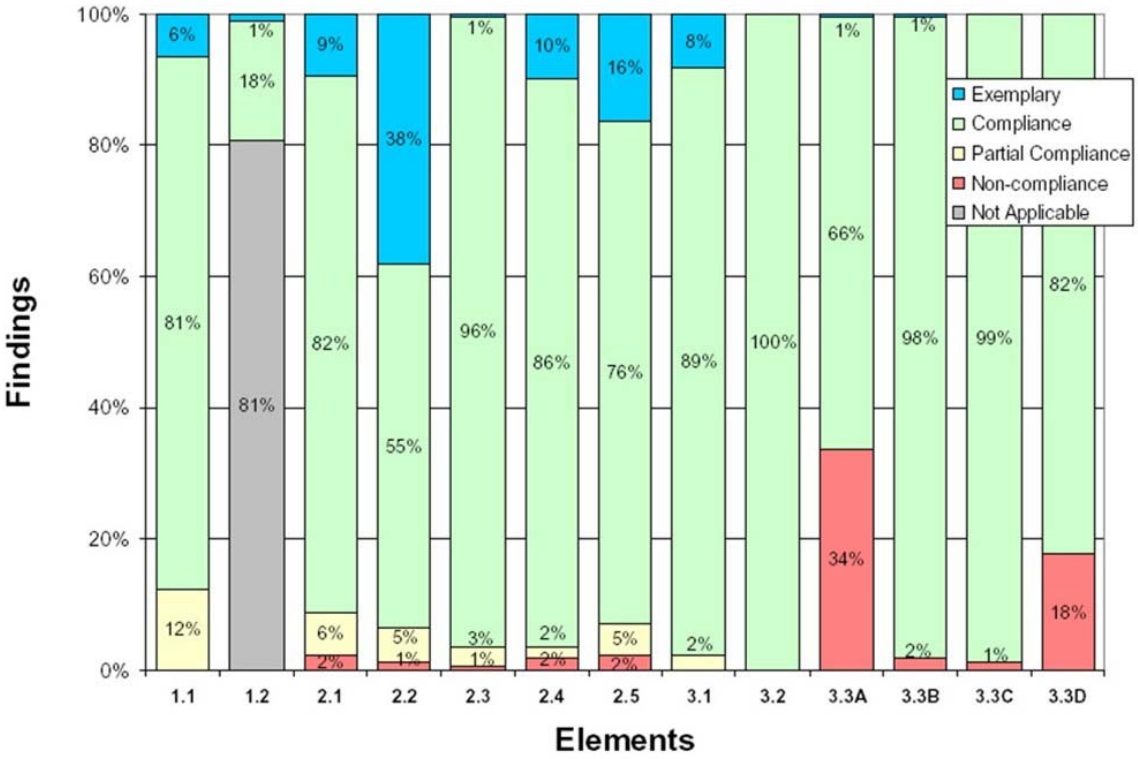


FIGURE 1: Compliance with the Essential Areas and Elements. Element 3.3A is "Consistently discloses required information and relationships". Source: ACCME 2004 Annual Report.

  

There is broad agreement that disclosure of financial conflicts of interest is critical to the integrity of CME and a lack of compliance with disclosure rules could affect physicians' perception of whether a CME program is biased. It is very important, therefore, to get disclosure right.

"I think it is hard to do disclosure right," said John Kamp, Executive Director, Coalition for Healthcare Communication. Indeed, the 2004 ACCME Annual Report and audit revealed that 34% of CME providers were non-compliant with the old disclosure rule (see FIGURE 1, previous page).

An audience member suggested that "a fairly large portion of the non-compliance percentage deals with off-label disclosures rather than disclosure of financial interests." That is, many CME providers may not instruct faculty to disclose off-label investigational content. This requirement is not part of the new ACCME rules.

**STANDARD 6.Disclosures Relevant to Potential Commercial Bias**

**Relevant financial relationships of those with control over CME content**

6.1 An individual must disclose to learners any relevant financial relationship(s), to include the following information:

- The name of the individual;
- The name of the commercial interest(s);
- The nature of the relationship the person has with each commercial interest.

6.2 For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

**Commercial support for the CME activity.**

6.3 The source of all support from commercial interests must be disclosed to learners. When commercial support is 'in-kind' the nature of the support must be disclosed to learners.

6.4 'Disclosure' must never include the use of a trade name or a product-group message.

**Timing of disclosure**

6.5 A provider must disclose the above information to learners prior to the beginning of the educational activity. ⌘

FIGURE 2: New ACCME Rules Relating to Disclosure.

Nevertheless, the new standard for disclosure is far more rigorous than the old standard (see FIGURE 2). If CME providers had trouble with the old standard, there may be more problems ahead when the new standard comes into full effect. For example, ACCME's rules extend to conflicts of interest that a CME participant's "partner" may have. Wilenzick said he wasn't sure if a partner referred to a business partner or a social partner, or both and regarding the latter, what sort of relationship constituted "partnership," "There are still many questions to get clarification on," he noted.

**Conflict of Interest—Confusion Reigns**

It's not just CME providers that are grappling with disclosure—faculty and speakers are also affected.

CME providers must implement a mechanism to identify and resolve all conflicts of interest (COIs) prior to the CME activity being delivered (see FIGURE 3). Consequently, faculty and speakers are being asked to disclose conflicts of interest and, if a conflict exists, they could be barred from participating in planning or delivering CME unless the Accredited Provider chooses to manage the conflict through another mechanism, such as peer-review.

**STANDARD 2: Resolution of Personal Conflicts of Interest**

2.1 The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. The ACCME defines "'relevant' financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

2.2 An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

2.3 The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.⌘

FIGURE 3: New ACCME Rules Relating to Personal Conflict of Interest.

As a result, physicians who make presentations at CME events or help plan them can count on tighter controls over what they can speak about. "I suspect we are going to see a lot more peer-review of CME," Wilenzick predicted. "It's important that whatever mechanisms are used to manage conflicts of interest are sensible, well thought out, and pragmatic—and that CME Providers are held responsible for following them," he added.

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The new rule on COI has been criticized by medical societies such as the American Society of Cataract and Refractive Surgery (ASCRS), which is "concerned because the guidance requires censorship and other measures for dealing with potential conflicts of interest, which would undermine the value of CME programs."

"Although many of us had this concern after the initial announcement of the COI rules," said Kamp, "subsequent clarification by ACCME Chief Executive Murray Kopelow and others has addressed it." Specifically, ACCME issued guidance and clarification regarding resolution of "conflicts of interest," including "peer review" and reference to the "best available evidence," among other mechanisms. ACCME does not intend to require "censorship" in any but the clearest instances of a speaker either not disclosing conflicts or not willing to have the content reviewed and include balanced references. These assurances may have mollified the concerns of ASCRS as well as other CME providers.

CME speakers may have financial conflicts of interest other than "commercial" conflicts of interest. The new ACCME rules, however, only mandate management of the latter and not the former according to Wilenzick. He suggested that CME providers should focus on all conflicts of interest, not just on commercial relationships.

**Honoraria Also an Issue**

"Pharma industry supporters of CME," said Cecilia H. Burke, Senior Attorney, Wyeth Pharmaceuticals, "are also interested in the process providers have for determining honoraria." The question arose as to what the appropriate role of the supporter should be in negotiating honoraria. Burke suggested that supporters can have a dialogue with the provider about the rationale for the honoraria proposed, but "negotiation is not appropriate. At the end of the day the provider makes the final decision regarding honoraria as well as all other aspects of the CME program," Burke said

What about fair market value? Often a specialist will demand and get a much higher honorarium than a family physician, for example. A speaker making a presentation in a later session at the conference suggested that the honoraria paid to industry speaker bureau members—an unregulated area—drives higher fees paid to CME faculty because many of the same physicians participate in both activities.

Kamp pointed out that while "you get what you pay for and you have to pay market value," the OIG is going to be concerned about how much money might flow to somebody and whether or not that creates bias. "Providers," Kamp said, "must be sure to have a very good reason for paying what they pay to faculty."

**The future of CME**

"I'm concerned about the future of CME," Kamp said. "The ACCME has created a system that requires providers to be editors and make peer-review judgments. That puts a tremendous burden on CME providers." Kamp was especially concerned with "shoe-string" providers such as community hospitals that may not have the resources to comply.

An audience member proclaimed that "you cannot legislate ethics" and the panel moderator also wondered if better compliance with ACCME rules will make CME better.

Whether the new ACCME rules will improve the quality of CME or public trust in CME remains to be seen, but it's clear the CME providers will have to live with the rules and comply with them as best they can.

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