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CME BRIEFING®

NEWS, OPINIONS, AND PERSPECTIVES IN CONTINUING MEDICAL EDUCATION • JULY–SEPTEMBER 2004

SPECIAL ISSUE

The Accreditation Council for Continuing Medical Education (ACCME) is nearing the end of the long quest to update the Standards for Commercial Support (the Standards). As it now stands, the ACCME Board of Directors has unanimously adopted the updated version. Member organizations (see Table 1) have until September 28, 2004, to make their decision on approval, at which time the transition/education process begins for accredited providers as they learn to operate under these updated standards.

TABLE 1. ACCME Member Organizations

The American Board of Medical Specialties
The American Hospital Association
The American Medical Association
The Association for Hospital Medical Education
The Association of American Medical Colleges
The Council of Medical Specialty Societies
The Federation of State Medical Boards of the United States

Will the updated Standards for Commercial Support clarify and support the efforts that are needed to achieve independence in CME activities? How will they make the job more difficult/challenging? Where do they fall short? In what ways do they really fit the bill?

This special edition of *CME Briefing* offers some insights and opinions from the CME community as we begin the final new phase of this journey—getting ready to implement the updated Standards.

Karen Overstreet

President, North American Association of Medical Education and Communication Companies

Because the new Standards leave *conflict of interest* undefined, I do not believe that they clarify and support the role of medical education and communication companies and other providers, who will have to be very vigilant in developing and adhering to policies regarding an ambiguous criterion. And they will have to be able to defend those policies. By not defin-

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ing *conflict of interest*, the ACCME seems to be relying on providers to define it for themselves and develop policies and procedures that are consistent with their own definition. The question is whether ACCME will find a provider's definition of and procedure for resolving conflict sufficient. What recourse does the ACCME have if they find a provider's definition and procedure insufficient? And what recourse does a provider have if it is cited by the ACCME for failing to comply with a standard that has no clear criteria?

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We will have to wait and see how providers and supporters respond, if and when the new Standards are implemented, before we know their true effect. But, without ACCME enhancing its monitoring efforts for accredited providers, I fear that the new Standards will not be as effective as many stakeholders hope. There will always be people who do not comply with guidelines, regardless of what the guidelines are—whether out of ignorance, laziness, or deceit. Without enhancing our monitoring and remediation efforts, the new rules won't address the important issues facing CME stakeholders today.

Joseph S. Green, PhD

Associate Dean of CME, Duke School of Medicine

I feel the updated Standards are going to take us closer to where we need to be, especially the requirements to have all those involved in creation of content having to disclose relevant relationships and having to create mechanisms to identify and resolve potential conflicts of interest. It was obvious that ACCME had to engage in very difficult discussions and compromises in order to "finalize" a document that met the needs of drastically competing interests.

It will certainly be a challenge to figure out how we can create these aforementioned systems for identifying, resolving, and/or managing conflicts. Some CME providers think they will provide faculty and planners with a definition of *conflict of interest* and ask them if: 1) they have no conflicts; 2) they may have relationships that could be perceived as a conflict; or 3) they definitely have relationships that meet the definition of a conflict. If they respond with "2" or "3," conflict management systems would be put in place, such as disclosure of off-label use, possible recusal, or inclusion of "levels of evidence" with any faculty recommendation for patient care, diagnosis, or treatment.

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There are still some areas that are unclear, but I have faith that after the Standards are approved, ACCME will come out with additional guidance, education, and supporting policies that will assist us in implementing the spirit of the new Standards; however, providers will also be required to make some difficult decisions internally about how to ensure compliance with faculty, departments, divisions, collaborators, and grantors, who don't want to hear about new or more stringent regulations. All of this

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CMEBriefing®

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detracts from the dialogue we should be having with all these groups: How can we help improve the quality and outcomes of our certified CME activities?

Marcia Jackson, PhD

President, Alliance for Continuing Medical Education

The draft Standards are clear, succinct, and easy to understand, and should assist in achieving independence in CME activities. These Standards are responsive to the comments received from the CME community when the first draft was circulated.

It will be necessary for all CME provider organizations to develop policies and procedures regarding the new section 2.3 (Implementing a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners). This may prove difficult and/or challenging, but will be essential.

Barbara Mierzwa

Assistant Dean and CME Director
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The requirement in the Standards to develop a mechanism for identifying and resolving conflicts of interest will help ensure greater independence. Even before we implement that mechanism, the participation of our medical school faculty in developing it will improve their understanding of the factors that contribute to genuine independence. Indeed, these faculty members are likely to become valuable "change agents" in their own departments and clinical settings.

The medical profession, governmental agencies, and even the public (via the media) have taken notice of CME; their scrutiny will reveal where the CME community needs to go next.

The challenge will be resolving conflicts of interest. Providers will need more information than simple disclosure about the relationships that speakers and program planners have with for-profit entities. Those relationships will have to be considered in light of the context, content, and funding source(s) for any activity. CME providers and planners may have to ask speakers for greater detail about the data, information, and recommendations they plan to present. Such planning and scrutiny will take more time and effort—and some tact and skillful communication.

Deficiencies in the 2004 version of the Standards, if any, will be revealed in practice. CME providers, planners, and presenters will discover what does and doesn't work. The medical profession, governmental agencies, and even the public (via the media) have taken notice of CME; their scrutiny will reveal where the CME community needs to go next.

The updated Standards clarify the roles of commercial interests and accredited providers (eg, a company may not be a joint educational partner with or distributor of CME activities for an accredited provider). However, as long as commercial support remains a primary source of funding for CME, commercial influences will affect the content (eg, topic areas where the companies' products are relevant). In general, physicians will get the CME activities that companies will pay for.

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Will the updated Standards for Commercial Support clarify and support the efforts that are needed to achieve independence in CME activities? We want to hear from you and share your thoughts with other *CME Briefing* readers!

Write to the Editor at PPSCME-Editor@pwcg.com

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In general, the new Standards are a contribution to the overall framework of enhancing CME provider and commercial supporter collaboration where values are mutually aligned. Specifically, the spirit of the guidelines to make decisions in favor of evidence that matters to patients is reinforced in many ways. In addition, the dialogue around the creation of the new standards has had a positive impact on raising awareness of some critical issues regarding commercial support that had not previously received enough attention.

Where the Standards fall short revolves around two issues: enforcement and design. Many felt that the most important way to improve compliance with the Standards was not through changing them, but through putting teeth into enforcement. It remains common knowledge that if one's intent is to circumvent the spirit of the guidelines, then all one needs to do is create the appropriate paperwork trail. That is the "moose on the table" we need to start acknowledging. There are accredited providers of every type that suffer because the providers of the same type do not adhere to the spirit of the Standards. This poses a particular problem for commercial supporters, who, because of the complexity of their own organizational systems, are rarely in a position to recognize this lapse in enforcement. Industry solutions to this, such as stereotyping provider types, will not solve the problem and can actually aggravate it under some circumstances. The solution must come from the CME community.

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This underscores the second shortcoming of the Standards. Their design, which is strictly process-driven, embodies a narrowly focused view of the potential role of commercial support that is out of step with the intent of the Essential Areas. Currently, it is entirely possible to follow the right process and achieve biased outcomes. It is also entirely possible to follow the wrong process and achieve nonbiased outcomes. The system we have in this country was not originally designed for the purpose of administering commercial support, so the solution is not as simple as it would seem, but we need to start engaging in this dialogue before there is a return to old patterns of behavior that put appropriate commercial support permanently at risk. I would like to see the Standards evolve in the direction of the Essential Areas, where a premium is placed on the educational process. If we could adopt a new commercial support standard that focuses more on outcomes, for example, we might give a boost to appropriate commercial support of CME. We would also be putting at risk (appropriately so from my perspective) some popular educational methods such as satellite symposia, which are very expensive, largely ineffective, and associated with a high risk of bias, even though they follow the Standards process.

For companies and CME providers, the benefit of this new way of viewing commercially supported CME would be CME that is more effective, lower in cost, and more aligned with the mutual values of CME and the company's overall mission to improve public health.

IMPORTANT SITES

Updated Standards for Commercial Support (SCS) available at: http://www.accme.org, under What's New, dated 4/2/2004

The Alliance for Continuing Medical Education offers a handy reference piece: a breakdown of the updated SCS text, with an explanation of the changes. Available at: http://www.acme-assn.org, click on 2004 Draft ACCME Standards for Commercial Support