

# **NEXt** *in Medical Education*

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## **Commercial Bias: Appearance Counts**

**W**hether or not you believe the saying, “looks aren’t everything,” in the heavily regulated healthcare environment, appearances are important.

The best-planned educational programs will fail if they do not meet the Standards for Commercial Support set by the Accreditation Council for Continuing Medical Education (ACCME). However, for most people, interpreting the Standards is hardly second nature.

How well do you know the Standards? You can test your knowledge with the case study below. Your answers to the questions that follow may reveal some learning needs—or validate your status as a maven of CME. As you answer the questions, keep in mind that although a practice does not *violate* the Standards, it may not be a *recommended* practice.

### **Case Scenario: Appropriate Role of the Supporter**

It is public knowledge that pharmaceutical company Treat-U-Right has several drugs in phase 3 clinical trials. A Med Ed company has been watching the trials with interest and has decided to prepare a pitch to gain the educational business for all products in the particular franchise (women’s health). After presenting some proposals, the company is invited to a face-to-face meeting with the Medical Affairs Department. During the discussion, Treat-U-Right shares some of its epidemiologic and market research data related to the new products. The Med Ed company’s proposal is accepted, and the company begins to develop several educational activities, including an interactive CD-ROM and a teleconference series, using the needs

assessment data presented by the pharmaceutical company and substantiated through additional literature searches.

### **Questions**

- Can the provider accept data from a supporter?  
*Yes. But the data from the supporter must be supplemented by additional data gathered by the provider, or supported by evidence gained through literature review, expert opinion, etc.*
- What other assistance can providers accept from supporters?  
*The supporter could recommend faculty if requested by the provider but may not mandate or have any contact with faculty.*
- Can representatives of the supporting organization attend planning meetings and other events associated with a CME activity?  
*Generally yes, but it is not recommended. Their presence gives the appearance of bias or control.*
- Can supporters review materials associated with a CME activity?  
*The standards don’t prohibit review per se, but this practice gives the appearance of control of content.*
- Can supporters be involved in distributing activity announcements?  
*Supporters can recruit participants for an activity (eg, distribute invitations to a symposium) with the permission of the provider. Distributing an activity (eg, a CME monograph) is a violation of the Standards.*
- What can providers do to mitigate the perception of too much involvement of the supporter?  
*Assume all of the responsibility for developing, managing, and implementing the activity.*

Did any of the answers surprise you? Remember, the Standards are not “law” but, like laws, are subject to interpretation. Practices that uphold the intentions of the guidelines and fall within them bode well for any organization. Look for more case scenarios in subsequent issues of *NEXt*.

## Conference ConNEXtion

Well-networked and involved in the CME community, Nexus staff attended conferences this fall related to the evolving world of medical education. Some key points from 2 of these meetings are provided below.

### ***Practical Strategies for Survival in the Guideline-Rich Environment of 2005: The 16<sup>th</sup> Annual Conference of the National Task Force on CME Provider/Industry Collaboration*** **Baltimore, MD; Oct 24–26, 2005**

This conference has been growing in each of the past few years. The 2005 conference had the highest attendance ever. Highlights from the meeting include:

- 75% of attendees reported that working in CME is harder than it was a year ago; 56% said the most difficult part of the job is dealing with industry attorneys' overreaction to the various guidelines
- CME—as long as it is developed independently of commercial influence—remains a safe harbor from FDA regulation, but it is not a safe harbor from the OIG's perspective
- CME providers have been the subject of OIG investigations, but none have yet been indicted; one area of high risk in CME activities is manufacturer influence of content or faculty
- Investigations by the OIG and states' attorneys are likely to increase once Medicare Part D is implemented in January 2006

### ***Repositioning CME Summit: Commitment, Communication and Collaboration*** **Rosemont, IL; Nov 17, 2005**

The theme of this one-day meeting, which was hosted by the Council of Medical Specialty Societies (CMSS), was unifying stakeholder efforts to improve CME. Pearls from the conference include:

- Typical assessment questions asked during CME activity post-tests (eg, multiple choice questions) are "low-fidelity simulations" of practice and as such, they measure the potential for clinicians to perform; CME providers need to adopt more high-fidelity simulations such as case studies and standardized patients
- A goal of the American Academy of Family Physicians is that by 2010, at least 50% of all CME credit will be earned through point-of-care or performance improvement initiatives (contact Nexus for more information about these types of activities)
- Most physicians are not "thirsty" for medical education, and so the CME community needs a "thirst inducer"; maintenance of certification (relicensure) may be it

- The Alliance for CME is developing a maintenance of competence professional development program for CME providers, based on the organization's 8 competencies; performance indicators are being developed and will be validated, and then self-assessment modules will be developed

## For More Information

To obtain more information about the material presented in this issue of *NEXt*, please contact Nexus or log on to the following Web sites:

- [www.cmss.org](http://www.cmss.org)—slides from the presentations during the Repositioning CME meeting are available on the CMSS Web site
- [www.fda.gov/cder/guidance](http://www.fda.gov/cder/guidance)—the text of the FDA guidelines pertaining to independent educational activities
- [www.oig.hhs.gov](http://www.oig.hhs.gov)—OIG's advisory opinions on concluded cases

### Happy Holidays!

Best wishes for a safe and healthy holiday season. We hope the *NEXt* year is happy and prosperous for all!

### Questions or comments?

Please send information, comments, or questions for future issues of *NEXt* to Karen Overstreet at [next@nexuscominc.com](mailto:next@nexuscominc.com).

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