

Working Together Within the Guidelines: *Interactive Case Studies*

September 22, 2011

Objectives

- Present actual case situations that test the boundaries of regulations/guidelines which impact CME providers, physician learners and industry
- Analyze cases from the perspective of the audience and the individuals representing various stakeholders, regulations or guidelines
- Compare and contrast how various regulations/guidelines apply in each case

Faculty

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Moderator

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Speaking to AMA Council on Ethical & Judicial Affairs Opinions

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Speaking to ACCME Standards for Commercial SupportSM

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Speaking to the FDA Guidance on Industry-Supported Scientific and Educational Activities

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Representing accredited CME provider perspective

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Representing commercial supporter perspective

Disclaimer

Panelists in this session may not directly represent the organizations listed. Information provided is a potential perspective and should not be considered an official policy of those companies for which the panelists are employed. Information is for educational purposes only, and should not be considered policy.

Session Format

- Present case
- Audience response question
- Audience reaction to case
- Non-regulator panelists' perspectives
- Regulator panelists' perspectives
- Audience questions of panel

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Case 1

ABC Pharmaceuticals issues an RFP for a satellite symposia at a specialty society annual conference; they have allocated a maximum funding level of \$300,000 for certified CME activities on emerging treatments and research in one of the specialty society's content areas. No other direction of any type is provided. Multiple proposals were submitted to ABC Pharmaceuticals, of which one was selected based on scientific and educational merit, compliance and cost.

Does this scenario cross the boundaries of any regulations, standards, codes or guidelines?

- A. Yes
- B. No
- C. I don't know
- D. Need more information

Case 2

An energy drink company contracts with an accredited academic medical center to develop a series of certified CME activities for physicians who specialize in sports medicine on caffeine, physical endurance and recovery. In their letter of agreement, the energy drink company stipulates that all final CME content must be approved by its Science Director.

Does this scenario cross the boundaries of any regulations, standards, codes or guidelines?

- A. Yes
- B. No
- C. I don't know
- D. Need more information

Case 3

An accredited MEC develops a strategy related to addressing opioids. One component is a certified live CME activity addressing class-wide drug issues. A second part of the strategy is an optional, non-certified education session that is held in a different room immediately after the certified seminar. This second session invites participants to attend small-group discussions led by pharmaceutical employees to address specific safety, labeling, and other issues associated with particular drugs/therapies.

Does this scenario cross the boundaries of any regulations, standards, codes or guidelines?

- A. Yes
- B. No
- C. I don't know
- D. Need more information

Case 4

A cancer institute recruits a new physician from a "big name" hospital. He decides to host a conference and boasts to the CME Director that at his former hospital "I could raise \$600,000 for a single meeting! Everyone in the CME Office loved me!" He provides the institute's CME office with a long list of commercial supporters from which to request grants. Some companies agree to provide support, but most requests are turned down.

Without consulting the CME Office, this physician starts calling his contacts from those commercial interests that denied funding. About 2 weeks before the conference, checks from these companies start arriving in the mail without letters of agreement. LOAs are sent, but several arrive after the conference has taken place.

Does this scenario cross the boundaries of any regulations, standards, codes or guidelines?

- A. Yes
- B. No
- C. I don't know
- D. Need more information

Case 5

A hospital holds a certified Tumor Board Conference once a month. Generally, there are about 20 participants, most of whom are physicians. Everyone in attendance will participate in the discussion during the Tumor Board.

The physician moderator provides a disclosure statement indicating he has no relevant relationships but no one else has signed a disclosure statement since they are not considered presenters or moderators. During one Tumor Board, a new oncologist mentions a promising treatment for a particular cancer and specifically names a drug that is in clinical trials; she does not mention that her husband is a principal investigator for the experimental treatment.

Does this scenario cross the boundaries of any regulations, standards, codes or guidelines?

- A. Yes
- B. No
- C. I don't know
- D. Need more information

Case 6

An accredited provider awards *AMA PRA Category 1 Credit™* for completion of an online course related to the content of a safety letter written by a pharmaceutical company's medical director. The letter was based on an FDA requirement to address a safety issue; the accredited provider used the FDA requirement to develop course content. The letter was posted on a public website, and was sent by the pharmaceutical company to all healthcare providers involved in prescribing the product.

Does this scenario cross the boundaries of any regulations, standards, codes or guidelines?

- A. Yes
- B. No
- C. I don't know
- D. Need more information

Case 7

An accredited provider receives support from a commercial interest to pilot a series of educational interventions that would ensure appropriate DVT prophylaxis in surgical patients. The terms of the LOA for this activity stipulate that if the results of this pilot are successful, the commercial interest will fund additional activities. After the pilot is implemented, the provider submits an outcomes report to the commercial interest. Data in the report show that the hospital demonstrated significant improvement in the percentage of patients who were appropriately prophylaxed. The accredited provider then requests funding from the commercial interest to extend the original program to 20 additional hospitals with a need in this area. The commercial interest awards the extension willingly based on the impressive outcomes and quality of the activity.

Does this scenario cross the boundaries of any regulations, standards, codes or guidelines?

- A. Yes
- B. No
- C. I don't know
- D. Need more information

Case 8

The Department of Medicine at an accredited academic medical center is developing the agenda for its certified annual update course. A member of the faculty has approached the course director to propose a presentation on interpreting data generated by an innovative new imaging technology. The faculty member discloses that he led the team that initially designed and tested the technology and is a consultant to ABC Diagnostics, which now manufactures the technology.

Does this scenario cross the boundaries of any regulations, standards, codes or guidelines?

- A. Yes
- B. No
- C. I don't know
- D. Need more information

Case 9

An accredited hospital is offering *AMA PRA Category 1 Credit*[™] for a half-day workshop comparing established and new treatment options in a particular therapeutic area with support from multiple funders, including the manufacturers of two of the treatment options to be discussed. Faculty include two physicians from the community, one of whom participated in a multi-center industry-funded Phase III trial of one of the new treatment options under discussion, and an academic physician who was recently awarded an RO1 grant for new research in this therapeutic area.

At the outset of the presentation, the moderator thanks the commercial funders by name for their support; briefly introduces each panelist and describes the individual's financial relationships relevant to the presentation; and informs the audience that panelists' talking points were peer-reviewed by the program development committee and two outside experts.

Does this scenario cross the boundaries of any regulations, standards, codes or guidelines?

- A. Yes
- B. No
- C. I don't know
- D. Need more information

Case 10

An accredited hospital opens a new "Center for Gynecologic Oncology." As part of marketing services in the Center, a hospital administrator sends the following email to the hospital's CME manager:

"Please produce at least 5 new certified CME activities in 2012 that attract as many gynecologists and gynecologic oncologists in our four-state region as possible."

Does this scenario cross the boundaries of any regulations, standards, codes or guidelines?

- A. Yes
- B. No
- C. I don't know
- D. Need more information

Case 11

An accredited MEC outsources hotel contracting and other non-content related logistics for CME activities to Media Promotions Partners (MPP). While it works to provide logistics support on some certified CME projects, MPP also provides services to support marketing activities for the commercial interest providing funds to the MEC.

Does this scenario cross the boundaries of any regulations, standards, codes or guidelines?

- A. Yes
- B. No
- C. I don't know
- D. Need more information

Case 12

ABC Pharmaceuticals employs a number of physicians. In an effort to alert these physician employees to opportunities for CME credit to maintain their professional licenses, ABC maintains a directory of all certified activities relevant to its scientific interests on an internal website, accessible only by employees. This directory includes activities supported both by ABC and other commercial interests. Each quarter ABC Pharmaceuticals sends an e-blast to its physician employees to remind them of the availability of this education.
