Test Your Knowledge: Compliance Versus Noncompliance

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Session Objectives

• Explore common areas of noncompliance
• Cite resources for further information related to the ACCME/TMA Accreditation Requirements and Process

TMA-Accredited Providers

Compliance Results for 2013 & 2014 Cohorts

[Bar chart showing compliance results for TMA-Accredited Providers]
Let’s Get Started!

- Use voting cards
  - Yes/A
  - No/B
  - Maybe/Depends/C
  - I'm Clueless/D

- Discussion at table

- Report from selected tables or volunteers

Case #1

“The field of transplant surgery is constantly evolving at a rapid pace and the healthcare team needs to keep up with advances in clinical care. Annual updates on the latest surgical techniques, patient selection, and treatment during post-transplant care are needed to provide patients with the best care available.”

Does this provider’s statement meet expectations for activity planning with regards to Criterion 2?

Case #2

“Our participants want to hear more about ophthalmic surgery.”

Does this provider’s statement meet expectations for activity planning with regards to Criterion 2?
Case #3
In the self-study, the provider, The Fabulous Hospital described a list of documents, including standards of training, a suggested outline for technical courses, procedural skills, and technique proficiencies for a specific clinical discipline.

Does this provider’s statement meet expectations for activity planning with regards to Criterion 6?

Case #4
The Fabulous Hospital, uses an "activity application" that lists the six Accreditation Council for Graduate Medical Education (ACGME) and American Board of Medical Specialties (ABMS) Competencies, and planners are required to indicate which competencies will be addressed.

Does this provider’s statement meet expectations for activity planning with regards to Criterion 6?

Standards for Commercial Support
The CME Coordinator from The Fabulous Hospital emails the ten presenters for their upcoming Annual Dermatology Conference. He asks them to respond to him, listing theirs and their spouses’ relationships with “any proprietary entity producing health care goods or services” within the past 12 months.

Once he has gathered all of their information via email, he forwards the data to the CME Committee Chair to review and assess if any of their mechanisms for resolution of conflict of interest need to be enacted (SCS 2).

Does this meet ACCME/TMA’s expectations for resolving conflicts of interest?

Commercial Interest Definition

- A **commercial interest** is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

- To have a relevant financial relationship, a person must be
  - in control of the content of the CME activity
  - have had, within the past 12 months, a financial relationship with an ACCME-defined commercial interest
  - the financial relationship is also considered relevant if it is a relationship that the spouse/partner of the person (who controls the content) possesses

Six Questions to Determine if a Company is Commercial Interest

1) Does the organization, or a part of the organization, produce, market, re-sell, or distribute health care goods or services consumed by or used on patients?

2) Does the organization have a parent company that produces, markets, re-sells, or distributes health care goods or services consumed by, or used on, patients? (A “parent company” is a separate legal entity that owns or fiscally controls an accredited provider or non-accredited organization.)
Six Questions to Determine if a Company is Commercial Interest (cont.)

3) Does the organization have a sister company that produces, markets, re-sells, or distributes health care goods or services consumed by, or used on, patients? (A “sister company” is a separate legal entity which is a subsidiary of the parent company and which maintains a governance structure and activities separate from both the parent company and the accredited provider or non-accredited joint provider. The sister company does not control or direct, in whole or in part, the operations of the accredited provider or non-accredited organization.)

4) Does the organization advocate for an ACCME-defined commercial interest?

Six Questions to Determine if a Company is Commercial Interest (cont.)

5) Does the organization have a parent company that advocates for an ACCME-defined commercial interest?

6) Does the organization have a sister company that advocates for an ACCME-defined commercial interest

Within the context of this definition and limitation, the ACCME considers the following types of organizations to be eligible for accreditation and free to control the content of CME:

- 501-C Non-profit organizations
- Government organizations
- Non-health care related companies
- Liability insurance providers
- Health insurance providers
- Group medical practices
- For-profit hospitals
- For-profit rehabilitation centers
- For-profit nursing homes
- Blood banks
- Diagnostic laboratories
Case #6
Leadership Live is a medical education company whose entire program of CME addresses physician leadership skills and faculty development – no healthcare goods or services are discussed. The provider has determined that they do not need to gather disclosure information because there is no opportunity for a conflict of interest. (SCS 2)

Does this meet ACCME/TMA’s expectations for identifying conflicts of interest?

Yes

Case #7
At the top of the sign in sheet for a monthly grand rounds, The Fabulous Hospital has included the following information:

"None of the members of The Fabulous Hospital’s CME Committee, who planned the CME activity, have any financial relationships to disclose relating to the content of the activity. Dr. Smith, who is presenting this session has no relevant financial relationships to disclose."

Does this meet ACCME/TMA’s expectations for disclosure to learners of relevant financial relationships to disclose?

Yes

Case #8
Are the following examples of provider performance considered a valid mechanism to "resolve all conflicts of interest prior to the education activity being delivered to learners" per Criterion 7, Standard 2.3?

Example 1:
Each faculty member participates in a ‘planning interview’ with CME staff in which they discuss approaches to reduce bias in the CME activity. After content for the activity is submitted to the CME office, CME staff communicate with the faculty via e-mails regarding modifications to the content (evidenced in the performance-in-practice activity files).

Yes
Example 2:

After the CME activity, an electronic survey is sent to each of the attendees that asks whether they perceived commercial bias during the educational session. The results of the electronic survey are summarized and shared with the faculty from the CME activity and included in the provider’s Self Study Report.

Example 3:

The CME activity content is sent out to an outside reviewer who is asked to complete an ‘Activity Review Form’. The Performance-in-Practice files include these completed forms along with notes about changes made by the CME staff prior to the activity.

Example 4:

If you disclosed a relevant financial relationship, please read the letter and sign the attestation line on the back of the disclosure form and then submit your completed form to the CME Office. By signing the back of the form, you are attesting that you will ensure that the content of your presentation will not contain information related to the clinical area of the financial relationships that you provided on the front side of the form.
Dr. Smith is presenting information on diagnosing and treating different types of pediatric cancer at the 2nd Annual Pediatric Cancer Conference and indicates on her disclosure form that she works one week every other month at the pharmaceutical company, Cure-All Pediatric Cancers and the remainder of her time at The Fabulous Hospital's outpatient clinic. To resolve the conflict of interest, The Fabulous Hospital has done the following:

- Reviewed Dr. Smith’s slides and reviewed no bias in the presentation
- The provider included a slide at the beginning of the presentation which disclosed Dr. Smith’s relationship and the name of the company and that the planner and reviewers had nothing to disclose
- Additionally, the evaluation form included a question asking participants if they detected bias during the session and the summary of the results indicated that the participants did not detect bias in the presentation

Does this support compliance with Criterion 7, SCS 2?

Does this mean that employees of ACCME-defined commercial interest can play no role in accredited CME?
Three Special-Use Cases:

#1
Employees of ACCME-defined commercial interests can control the content of accredited CME activities when the content of the CME activity is not related to the business lines or products of their employer.

#2
Employees of ACCME-defined commercial interests can control the content of accredited CME activities (e.g., as planners, authors, or speakers [including poster presentations]) when the content of the accredited CME activity is limited to basic science research (e.g., pre-clinical research, drug discovery) or the processes/methodologies of research, themselves unrelated to a specific disease or compound/drug. In these circumstances, the accredited provider must be able to demonstrate that it has implemented processes to ensure employees of ACCME-defined commercial interests have no control of CME activity content that is related to clinical recommendations concerning the business lines or products of their employer.

#3
Employees of ACCME-defined commercial interests can participate as technicians in accredited CME activities that teach the safe and proper use of medical devices. In this circumstance, the accredited provider must demonstrate that it implements processes to ensure that employees of ACCME-defined commercial interests have no control of CME activity content that is related to clinical recommendations concerning the business lines or products of their employer.
Case #10

Self Study Report:
In the self study narrative, the provider describes that it measures the impact of its Regularly Scheduled Series (RSS) via an electronic survey issued on a quarterly basis to all “Grand Rounds” (e.g., RSS) attendees that asks the questions: “Did the educational activity help to increase your knowledge of this topic?” and “Are you going to make a change in your practice as a result of your participation in the Internal Medicine Grand Rounds?” The narrative includes data tables that compare and contrast the number of respondents who responded “Yes” or “No” to the questions for each CME activity it conducted during each of its accreditation term. Through the written explanation, the provider draws the conclusion that its CME Program has had a positive impact on changing physicians’ knowledge, competence and performance across several topic areas.

Performance-in-Practice Files:
Each of the activity files includes a blank (e.g., not-completed) printed version of the electronic survey used for that activity. No other data or information (about changes in learners) is included in this file.

Which of the following statement(s) most accurately describes the reason(s) for the provider’s noncompliance finding for Criterion 11?

A. The provider did not demonstrate that it has information about what specific changes (e.g., competence/strategies, performance) learners make to their practice as a result of the educational activities.
B. The provider did not provide data or information describing learner change in its Performance-in-Practice documentation.
C. The provider’s electronic survey tool, as an assessment of learner change, should not include questions about changing participants’ knowledge.
D. All of the above.

Case #11

In its Self-Study Report, for C12, The Fabulous Hospital has identified that offering enduring materials would help it to better meet its CME mission. During the accreditation interview, the provider explained that it released its first enduring material activity 2 months prior to writing the self-study report. A handful of participants have completed the activity. No additional information was shared by the provider.

Is this compliant for C12? C13?
Case #12
Which of the following two examples demonstrate The Fabulous Hospital operating in a manner that integrates CME into the process for improving professional practice?
A. In its self-study report and supplemental materials, the provider describes that its CME planning and design processes are, “designed to help facilitate changes in physician performance.”
B. The provider describes integrating CME into point of care settings using a number of different educational methods.
C. The provider has developed performance improvement activities for venous thromboembolism and reduction mammoplasty based on evidence-based clinical practice guidelines for reduction mammoplasty that it has developed. In addition, the provider develops self-assessment tools that assist members to improve and modify their practice.
D. The provider works with its Risk Management department on the development of its regularly scheduled series activities as part of the solution for the prevention of sentinel events. Other examples include performance improvement activities in six clinical areas, including ADHD, osteoporosis, and improving outcomes of acute coronary syndromes.

Case #13
Which of the following example(s) does not demonstrate The Fabulous Hospital building bridges with other stakeholders through collaboration and cooperation?
A. The provider participates in a variety of collaborations and cooperative initiatives, including those with a university (on safety issues), an institute and a hospital association (on improving quality of care).
B. The provider lists its joint providership relationships.
C. The provider described multiple partners and collaborators, including work with government agencies, quality improvement entities, and other medical societies, and coalitions.
D. All of the above.

Resources
- TMA
  - TMA Manual
    - Standards for Commercial Support
  - Examples of Compliance and Non-compliance at www.texmed.org
- ACCME
  - FAQ’s/Videos
  - Examples of Compliance and Non-compliance at www.acccme.org
Contact Information

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