Test Your Knowledge
Compliance versus Noncompliance

Casey Harrison, MBA
Paige Green, MEd
Texas Medical Association

Session Objectives

- Identify common areas of noncompliance
- Analyze cases for compliance or non-compliance with accreditation criteria and policies
- Cite resources for further information related to the ACCME/TMA accreditation requirements and policies

Let’s Get Started!

- Use voting cards
  - Yes/A
  - No/B
  - Maybe/Depends/C
  - I’m Clueless/D
- Discussion at table
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?

Yes - The provider has incorporated into this CME activity the learners’ educational needs (i.e., keeping up with advances in clinical care) that underlie the professional practice gaps of providing, “patients with the best care available” (through application of) latest surgical techniques, patient selection, and treatment during post-transplant care.

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?
No - This provider has offered a statement that, taken alone, does not meet the expectation of Criterion 2 because there is no expression of an educational need or the professional practice gap that underlies that need.

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?

No - because the provider did not describe a link between these documents and the development of their program of CME. The evidence did not demonstrate that the provider developed activities in the context of desirable physician attributes.
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

Texas Medical Association
Physicians Caring for Texans
Case #5

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?

No, it does not meet expectations:
- Obtaining the information via email is fine (no disclosure form required) and
- Forwarding the information to the Committee Chair is also fine, BUT
- the definition of commercial interest is not complete and
- the scenario does not address planners, including the Committee Chair

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?

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?

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

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

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?

Eligible for Accreditation

- 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
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, this meets expectations. Standard 2.1 states that, “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.” For a financial relationship to be relevant, it needs to relate to the content of the educational activity, causing a conflict of interest. If no healthcare goods or services are discussed, then there is no relationship with a commercial interest that can be relevant. NOTE: Be sure that participants understand that disclosures of “no relevant financial relationships” still needs to be made to learners in the activity. (SCS 6)

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 - what if the information the information in this case was announced at the beginning of the presentation and not in writing, would this meet expectations? Yes, if a representative of the provider who was in attendance at the time of the verbal disclosure attested in writing – that the verbal disclosure did occur and itemize the content of the disclosed information (SCS 6.1) or that there was nothing to disclose (SCS 6.2). What information would need to be include in that announcement? Name, Entity and nature of relationship. The documentation that verifies the adequate disclosure did occur must be completed within one month of the activity.

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).
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.
No - in this case, the provider’s approaches for resolving conflicts of interest (Criterion 7, Standard 2.3) do not meet the expectations for compliance. An attestation (e.g., via the Faculty Disclosure Form) is not—by itself—sufficient to satisfy the expectation that the Provider resolves conflicts of interest. Standard 2.3 expects that the Provider identifies and resolves conflicts of interest through its active engagement with those who possess relevant financial relationships. Attestation alone is not a mechanism to resolve conflicts of interest. (SCS 2)

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?
No - Dr. Smith disclosure indicates that she is an employee of a commercial interest. Per Criterion 7, Standard 1, employees of a commercial interest cannot have a role in planning or implementation of CME activities.

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

2. Employees of ACCME-defined commercial interests can control the content of accredited CME activities when the content of the accredited CME activity is limited to basic science research 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 applications of the research/discovery or clinical recommendations concerning the business lines or products of their employer.

#3

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:** The provider describes that it measures the impact of its RSS via an electronic survey issued on a quarterly basis to all Grand Rounds attendees that asks the questions:

1. "Did the educational activity help to increase your knowledge of this topic?" and
2. "Are you going to make a change in your practice as a result of your participation in the Internal Medicine Grand Rounds?"

The report 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 the 4 years of its accreditation term.

<table>
<thead>
<tr>
<th>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.</th>
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<td>Which of the following statement(s) most accurately describes the reason(s) for the provider’s noncompliance finding for Criterion 11?</td>
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| 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. |
In the case scenario, the provider's electronic survey to measure change in its learners asks for a “Yes” or “No” response to whether the learner will change their practice as a result of the educational activity. This data is not sufficient to fulfill the expectation of Criterion 11 that the Provider, “analyzes changes in learners’ competence, performance, or patient outcomes.” In order to satisfy that requirement, Providers need to have data or information about what specific changes have occurred in learners’ competence (strategies), performance or patient outcomes.

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?

No for C12 – the expectation for Criterion 12 is not met. While the provider described a desire to offer a new activity type in order to better meet its mission, a program-based analysis on the degree to which the expected results of the CME mission were met is not available.

Yes for C13 – would meet expectation (plan to offer enduring material)
Resources

- TMA
  - TMA Manual
    - Standards for Commercial Support
- ACCME
  - FAQ’s/Videos
  - Examples of Compliance and Non-compliance at www.accme.org

Contact Information

Casey Harrison
Director, CME
Texas Medical Association
800-880-1300, ext. 1446
casey.harrison@texmed.org

Paige Green
Manager, CME
Texas Medical Association
800-880-1300, ext. 1447
paige.green@texmed.org