



## Examples of Compliance and Noncompliance

### **Findings Based on the ACCME Standards for Commercial Support: Standards to Ensure Independence in CME Activities**

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#### **About Examples**

ACPE is sharing the Accreditation Council for Continuing Medical Education's (ACCME) examples of providers' practices, programs, strategies or procedures. The goal of these examples is to enable providers and CE stakeholders to learn from each other and to understand how ACPE determines compliance and noncompliance with its requirements.

The reader should understand that these are examples only, not prescribed practices, nor do they represent a list of options from which providers must choose. They are what some providers have chosen to do to fulfill the expectation of the ACPE Standards.

#### **ACCME Standards for Commercial Support<sup>SM</sup> [Adopted by ACPE (Effective January 1, 2008) – Standard 5]**

**The provider develops activities/educational interventions independent of commercial interests. (SCS 5.1, 5.2, and 5.6)**

**ACPE Note:** Accredited continuing education is always designed and presented in a manner whereby the accredited provider retains control of the content of CE. Providers are expected to ensure that activity planning and implementation is in the hands of the provider. The provider must obtain information from all those in control of content (e.g., planners, teachers, and authors) so as to allow for the management and resolution of potential conflicts of interest. The provider must disclose to learners the relevant financial relationships of all those who control the content of CE.

#### **Examples of Compliance:**

- Example 1.** The information submitted describes a planning process that clearly delineates the roles and responsibilities of the provider, its planners and faculty. The provider ensures that there is no control or input from commercial interests. All planners' and teachers' conflicts of interest have been identified and resolved. Disclosure of relevant, or no, financial relationships to learners has occurred. (SCS 5.1)
- Example 2.** After identifying all relevant financial relationships for its planners and faculty, the provider resolves conflicts of interest using methods that include modifying the individual's control over the content and independent content validation. (SCS 5.2a, SCS 5.2c)
- Example 3.** The provider has developed a database that tracks financial relationship information as well as areas of expertise. The provider collects disclosures of relevant financial relationships from all those in a position to control the content of CE. The provider reviews the disclosures and uses several methods to resolve the conflicts of interest that are identified. The provider begins the process in the pre-planning stages of activity development by selecting course directors who have no relevant financial relationships. The provider resolves conflicts of interest for faculty through a content validation process consisting of three parts: vetting of

content by clinical staff, re-review of the content by the faculty, and inclusion of evidence-based resources in their presentation materials. (SCS 5.2)

- Example 4.** The provider collects disclosure information from all individuals in control of content. Those who refuse to disclose this information are disqualified from participating. For any person who reports a relevant financial relationship, the provider uses a peer review process to resolve the potential conflict of interest. For presentations that have the greatest potential for bias, the provider asks an independent third party reviewer to conduct a second peer review as an additional mechanism to resolve conflicts of interest. (SCS 5.2a, SCS 5.2b, SCS 5.2c)
- Example 5.** The provider collects disclosure information from all persons in control of content, including planners, course directors, and faculty. The staff of the Office of CE reviews the information to identify any conflicts of interest. The provider uses a disclosure form that asks the person completing it to suggest a method for resolving conflicts of interest that are identified through the disclosure process. A content expert reviews the form to determine if the proposed method to resolve the conflict is adequate. If it is not deemed adequate, the reviewer suggests another method to resolve the conflict. Once approved, the individual is prompted to resolve their conflict and to verify they have taken the approved actions. (SCS 5.2a, SCS 5.2c)
- Example 6.** The provider's CE committee reviews disclosures and recommends strategies to resolve conflicts of interest. The committee documents its findings and then sends a letter to the faculty informing them of the recommended strategies for resolving conflicts of interest. These strategies include guiding the faculty with regard to the content, requiring the speaker to use best available published evidence and information, or requiring content review prior to the activity. (SCS 5.2c)
- Example 7.** A computer-based speaker registration system is used to identify potential conflicts of interest. Directors, review committee members, and staff also complete the same information in the registration system. If a relevant financial relationship is identified by the provider, all slides and presentations are reviewed prior to the activity. Lastly, relevant financial relationships are disclosed to learners by including them in the course syllabus. (SCS 5.2a, SCS 5.2c, SCS 5.6)
- Example 8.** The provider ensures that everyone in a position to control content discloses relevant financial relationships prior to the activity, utilizing a mixture of online- and paper-based processes. These disclosures can be tracked by staff through the provider's intranet. The resolution of conflicts of interest is also coordinated and monitored through an online process with three levels of review: staff pre-selection/screening, content leader review, and chair's final review. This multi-stage process allows for initial screening by staff, leading to a risk appraisal ranging from "No Action Needed" (e.g., no relevant financial relationships) to "Content Review: Highest risk of bias." Content leaders have access to these ratings and provide verification that the strategies selected for each individual are appropriate. Chairs complete final review. Once conflict of interest resolution strategies have been approved, CE staff implement them. The following strategies are utilized: 1) Letter – a letter pointing out the conflict of interest is sent to the individual with a reminder that the individual has signed an agreement to abide by the organization's policies and instructions related to developing content to utilize evidence-based recommendations. 2) Slide review – an initial review by CE staff with a summary to the content leader or Chair. If changes are warranted the presenter is asked to resubmit their presentation. 3) In addition, the provider may require an Audit, in which case the entire session becomes slated for audit. Audits can result in feedback to the author/presenter, based upon the results of the audit. (SCS 5.2)
- Example 9.** Course directors, planners, and faculty disclose to the provider every 12 months to ensure information regarding relevant financial relationships is current. At times, institutional conflict of interest disclosure processes and databases are used to augment the CE disclosure process. Regularly Scheduled Series (RSS) course directors are responsible for ensuring conflicts of interest are resolved and submit documentation on a quarterly basis. The provider shows evidence of conflict of

interest resolution for its RSS activities using a reporting form completed by the course director. For other activities, the provider documents the process with a table that describes who reviewed the content, what was found, and what was done to resolve the conflict of interest. (SCS 5.2a, SCS 5.2c)

- Example 10.** The provider’s final program for its Annual Meeting includes disclosure of relevant financial relationships for all faculty and members of the Program Planning Committee. For those who have no relevant financial relationships, the program lists those individuals with a notation that they, as a group, have nothing to disclose. For those who have relevant financial relationships, all the required information is disclosed to learners. In addition, the moderator verbally announces the disclosures of the speakers involved in each educational session, as evidenced by written documentation completed at the time of the activity. (SCS 5.6a, SCS 5.6b)
- Example 11.** A standardized CE information page that includes all disclosures is provided to participants prior to the educational activity. Regularly Scheduled Series (RSS) are monitored on a regular basis for compliance through unannounced site visits by CE office staff. For all RSS, a CE coordinator is assigned to ensure that disclosures of relevant financial relationships for those in control of content are provided to learners prior to the beginning of the activity. Acknowledgement of commercial support is also included in the CE information page. (SCS 5.6a, SCS 5.6c, SCS 5.6e)
- Example 12.** At the provider’s annual conference, name badges are issued together with the printed program. The program includes the disclosure of relevant financial relationships of all persons in control of CE content for every session at the meeting. All learners are required to have the name badge for entrance into a CE activity, as a means of ensuring the attendees received the printed program disclosures. The program also includes the disclosure of the sources of all commercial support, including in-kind contributions. The provider also publishes this information prior to the activity on its Web site. (SCS 5.6a, SCS 5.6c, SCS 5.6e)
- Example 13.** For CE courses and conferences, disclosure information is announced on the day of the activity, prior to the start of the activity, because the materials used to promote these activities are distributed before all commercial support is known. For regularly scheduled series (RSS), disclosure of commercial support is listed on the series flyer in advance of educational sessions. Every Internet enduring material activity is funded internally without commercial support. The CE Office ensures verbal disclosure occurs correctly at RSS through observation and auditing of 50 percent of the RSS sessions. (SCS 5.6c, SCS 5.6e)

#### Examples of Non-compliance:

- Example 14.** The provider’s commercial support policy, presented as evidence in the self-assessment report, states “the provider may request suggestions for presenters or sources of possible presenters from a commercial supporter.” This is inconsistent with the ACPE’s requirement that a provider must ensure such decisions are made free of the control of a commercial interest. (SCS 5.1)
- Example 15.** The provider did not demonstrate that the following decisions were made independent of commercial interests: the identification of CE needs, the determination of educational objectives, the selection and presentation of content, the selection of persons and organizations that will be in a position to control the content of the CE, the selection of educational methods, and the evaluation of the activity. For example, the provider describes a planning process that involves planners and editors from ACPE-defined commercial interests. At the interview, the provider discussed how some activity topics come from individuals who work for an ACPE-defined commercial interest that shares office space with the provider. In addition, the provider indicated that it offered commercial supporters a courtesy review of its CE content in order to get supporter feedback. (SCS 5.1)
- Example 16.** The provider did not demonstrate independence in its CE activity development. Evidence presented to ACPE points to a planning process influenced by

commercial interests. A potential speaker is identified as preferred for several attributes, including the fact that she may have a relationship with a commercial interest (the same company from which commercial support would be solicited). (SCS 5.1)

- Example 17.** In its self-assessment report, the provider demonstrates that it identifies relevant financial relationships of faculty. However, the provider does not identify relevant financial relationships of planning committee members who are also involved in the content development of its CE activities. Without identifying this information from everyone who is in control of the content of the CE activities, the provider is unable to identify and resolve potential conflicts of interest. In addition, the provider shows that in its CE activities it discloses to learners, “only significant financial relationships between faculty speakers and commercial interests”. This is not consistent with the ACPE’s definition of “relevant financial relationships”. (SCS 5.2)
- Example 18.** For its test-item writing activities, the provider did not demonstrate the implementation of a mechanism to identify and resolve conflicts of interest for all persons in control of content, including for example, all faculty, reviewers, and CE committee members. Therefore, not all conflicts of interest could be identified or resolved prior to the activity. (SCS 5.2)
- Example 19.** The provider describes a mechanism to resolve conflicts of interest, but the implementation of a mechanism to resolve conflicts of interest was not consistently documented in the activities reviewed. In addition, evidence was not presented to demonstrate that all individuals in control of CE content disclose relevant financial relationships to the provider. (SCS 5.2)
- Example 20.** The provider did not have evidence of consistently implementing a mechanism to resolve conflicts of interest when persons in control of content reported relevant financial relationships. The only evidence provided was an attestation form signed by the speaker/planner/staff that stated, “I will ensure that any financial relationship that I have with a commercial interest will not affect the recommendations I make about clinical care.” Attestation alone is not a mechanism to resolve conflicts of interest. (SCS 2)
- Example 21.** In the self-assessment report, the evidence demonstrates that all persons in control of content, including planners and staff, for example, do not consistently disclose the presence or absence of relevant financial relationships to the provider. In addition, the provider defines a commercial interest as “any proprietary entity producing health care goods or services,” which is not consistent with the ACPE’s current definition of a commercial interest. For these reasons, not all conflicts of interest could be identified or resolved. (SCS 5.2)
- Example 22.** The evidence presented did not demonstrate that disclosure to learners included the presence or absence of relevant financial relationships for all persons in control of content, including, for example, journal editors or content reviewers. (SCS 5.6)
- Example 23.** In both its live activities and enduring materials, the provider did not consistently disclose to learners the presence or absence of relevant financial relationships of all who control CE content, for example, planners. The provider did not consistently disclose to learners the presence of relevant financial relationships that had been shared with the provider. In addition, when disclosure occurred verbally at the activity, the provider did not consistently have evidence regarding what disclosures were made. (SCS 5.6)
- Example 24.** The provider did not disclose to learners relevant financial relationships of all persons who control content. The provider’s disclosure to learners did not include the name of the commercial interest with which the individual had a relevant financial relationship. (SCS 5.6)
- Example 25.** The provider did not disclose to learners the relevant financial relationships of all persons who control content, including for example, all faculty, test-item writers and reviewers, and CE committee members. In addition, the provider did not consistently disclose commercial support. (SCS 5.6)

**Example 26.** The provider uses a "Documentation Review Form for Verbal Disclosure," which lists the "name and role of individual discloser," but in the two activities presented, this is the name of a staffer and not the speaker. It is unclear from these forms what, exactly, is being disclosed to the learner. (SCS 5.6)

**The provider appropriately manages commercial support, if applicable. (SCS 5.3)**

**ACPE Note:** If they chose to accept commercial support, providers are expected to solicit, accept, and use commercial support appropriately and in accord with the parameters of Standard 5.3 of the ACPE Standards for Commercial Support. Even if the provider does not accept commercial support, the provider is still expected to have policies and procedures in place that govern how (if) they pay honoraria and reimburse expenses for those involved in the planning and presentation of their CE activities.

### **Examples of Compliance:**

**Example 1.** The provider included a narrative description (supported by activity file documentation) to evidence a comprehensive approach to ensuring the appropriate management of commercial support. The evidence included not only policies and forms that are used, but also examples of the processes being implemented within the provider's commercially-supported activities (e.g., communications between the provider and commercial supporter, signed letters of agreement, accounting of activity-related expenditures).

### **Examples of Noncompliance:**

**Example 2.** For the activities reviewed that accepted commercial support, some written agreements were not present, and some written agreements did not include the signature of the commercial supporter.

**Example 3.** The provider did not consistently have all written agreements for commercial support signed by both the provider and commercial supporter prior to the activity.

**Example 4.** The evidence presented for the activities reviewed did not demonstrate that the provider paid honoraria and expenses in compliance with its own policies. In several instances, the provider indicated/assumed the honoraria policy was not applicable because commercial support was not accepted.

**Example 5.** For its commercially supported activities, the provider had several written agreements that were signed only by the commercial supporter, and not by the provider.

**The provider maintains a separation of promotion from education (SCS 5.4).**

**ACPE Note:** Providers must ensure that their learners can participate in educational activities without seeing, reading or hearing promotional or marketing information from commercial interests. Further, accredited providers must ensure that the selling of advertising or exhibit space is a business transaction entirely separate from the acceptance of commercial support for accredited CE.

### **Examples of Compliance:**

**Example 1.** In the self-assessment narrative, the provider described its processes for ensuring that promotional events at its annual meeting (e.g., exhibit halls) are kept distinct and separate from CE activities by not only their location and time in the program schedule, but also in how these events are clearly described as "Promotional."

### **Examples of Noncompliance:**

**Example 2.** It was not clear that the provider appropriately maintained a separation of promotion from education. The provider's evidence demonstrated that meetings between learners and industry representatives in a commercial exhibitors' hall was

considered part of their educational activity. Although the exhibits were not in the same room as lectures and video demonstrations, discussion with representatives of the commercial interest at the exhibit was considered by the provider to be part of the learner's CE experience.

**The provider actively promotes improvements in health care and NOT proprietary interests of a commercial interest (SCS 5.5).**

**ACPE Note:** Providers are expected to ensure that their CE programs and activities advance the public interest without bias that would influence health professionals to overuse or misuse the products or services of a commercial interest.

**Examples of Compliance:**

**Example 1.** The provider demonstrated that all scientific content and clinical recommendations made within CE activities are reviewed by a three member "content review council." The criteria for that "clinical data and recommendations" address valid public health issues as defined by government resources like the Center for Medicare and Medicaid Services and the Agency for Healthcare Research and Quality.

**Examples of Noncompliance:**

**Example 2.** The provider presented at least one activity that promoted proprietary interests of a commercial interest. An enduring material CE activity presented in its self-assessment report focused on the clinical trials of a single drug made by the commercial supporter. The activity did not present a discussion of other therapeutic options.