

# Let's Review: The ACCME Standards for Commercial Support: Standards for Independence in CME Activities

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## Learning Objective

Upon completion of this presentation, learners should be better able to:

- Assess your CME program for potential issues which could lead to a finding of noncompliance with ACCME Criterion 7
- Implement processes to ensure compliance with the ACCME Standards of Commercial Support.



## Disclosures

- John Juchniewicz and Paul Minter have no relevant disclosures to make.



## Disclaimer

- This presentation includes the opinions of the presenters which are based on our experience working for an accredited provider and as volunteer accreditation surveyors.
- The presenters do not speak on behalf of the ACCME.

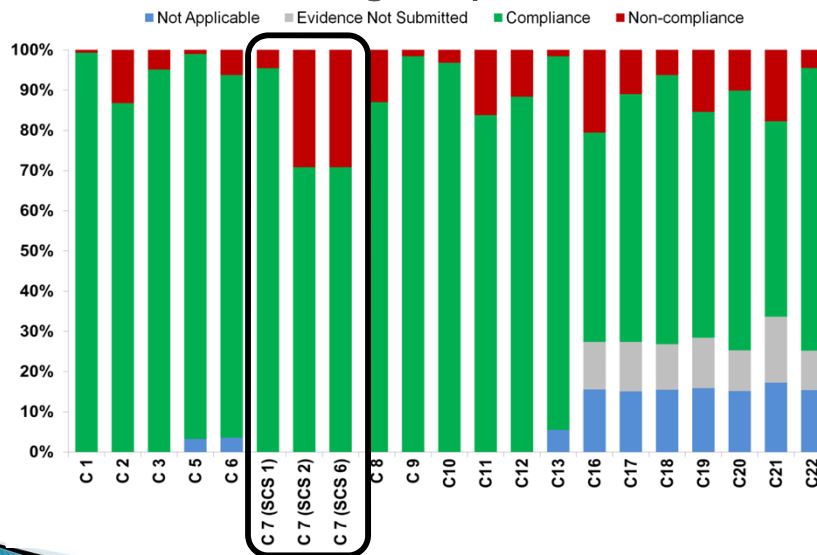


## SCS Apply to All Providers

- ▶ Standards apply to the development, planning and execution of every CME activity – regardless of commercial support funding.
- ▶ These standards are about independence of a CME activity.



### Overall Compliance Results for November 2008 through July 2014 (n=1,007)



Slide Courtesy of ACCME

## Compliance with SCS: NJ

- ▶ Issues with SCS 2
  - Especially SCS 2.3 – identification, resolution and documentation.
- ▶ Issues with SCS 6
  - Especially SCS 6.1, 6.2 and 6.5 and documentation.

## Standard 1.1

- ▶ A CME provider must ensure that the following decisions were made free of the control of a commercial interest. (See [www.accme.org](http://www.accme.org) for a definition of a "commercial interest" and some exemptions.) (a) Identification of CME needs; (b) Determination of educational objectives; (c) Selection and presentation of content; (d) Selection of all persons and organizations that will be in a position to control the content of the CME; (e) Selection of educational methods; (f) Evaluation of the activity.

Source: <http://www.accme.org/requirements/accreditation-requirements-cme-providers/standards-for-commercial-support>

## Compliance with SCS

- ▶ Check your LOA and other forms yearly to confirm that they are up-to-date and in compliance with SCS 1.1
  - Still come across Letters of Agreement (LOAs) in the performance in practice files that contain obsolete language, i.e. that commercial entities can help with providing speakers and/or assist with developing/reviewing slides.

## Standard 2.1

- ▶ 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.

The ACCME defines “relevant financial relationships” as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

Source: <http://www.accme.org/requirements/accreditation-requirements-cme-providers/standards-for-commercial-support>

## Noncompliance with Standard 2.1

- ▶ Missing documentation/disclosures
- ▶ Disclosures signed after the date of the activity
- ▶ Not asking about potential COIs of spouse/partner on the disclosure form
- ▶ Not using the current ACCME definition of a commercial interest on the disclosure form
  - A commercial interest is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.<sup>1</sup>

1. <http://www.accme.org/requirements/accreditation-requirements-cme-providers/policies-and-definitions/definition-commercial-interest>

## Standard 2.2

- ▶ An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

Source: <http://www.accme.org/requirements/accreditation-requirements-cme-providers/standards-for-commercial-support>

## Noncompliance with Standard 2.2

- ▶ Disclosures not signed prior to the activity date
- ▶ Have seen disclosure forms that include an option for the person to refuse to disclose. This could be seen by the faculty/planner as a valid option (when it's not).

## Standard 2.3

- ▶ The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.

Source: <http://www.accme.org/requirements/accreditation-requirements-cme-providers/standards-for-commercial-support>

## Noncompliance with Standard 2.3

- ▶ Lack of a process to identify conflicts of interest
  - ie collecting disclosures but not doing anything with the information collected
- ▶ Lack of a process to resolve identified conflicts of interest
- ▶ Using activity monitoring as a means of resolving conflicts of interest
- ▶ Not documenting in the activity file how conflicts of interest are resolved for the activity

## Additional Thoughts on Standard 2.3

- ▶ Employees of a commercial interest are not permitted to act as faculty or planners when the presentation topic may concern the product line or services of their employer except in VERY LIMITED circumstances.<sup>1</sup>
- ▶ Collecting disclosures the day of the activity will not likely allow time enough to identify and resolve COIs.

1. <http://www.accme.org/ask-accme/can-provider-allow-oral-or-written-reporting-scientific-research-employee-commercial>



## Some Methods of Resolution

- ▶ The person having the potential COI divested themselves of the relationship
- ▶ Revising the role of the individual so the financial relationship is no longer relevant.
- ▶ Having the speaker sign a form in advance of their participation in the activity attesting that the content will be free of bias, based on the latest evidence, and present a balanced view of therapeutic options AND the DME has a conversation with the person (which is documented) to discuss the expectations outlined on the form

## Some Methods of Resolution (continued)

- ▶ Internal/in-house Review
- ▶ External Review
- ▶ Removing the individual from participating in all parts of the educational activity (or at least those parts related to the COI).

## Standard 6.1

- ▶ An individual must disclose to learners any relevant financial relationship(s), to include the following information: The name of the individual; The name of the commercial interest(s); The nature of the relationship the person has with each commercial interest.
  - “Relevant” refers to financial relationships in any amount occurring within the past 12 months that create a conflict of interest

Source: <http://www.accme.org/requirements/accreditation-requirements-cme-providers/standards-for-commercial-support>

## Noncompliance with Standard 6.1

- ▶ Not identifying the name and/or relationship with each commercial interest
- ▶ Having wording on your disclosure form that qualifies the amount of the financial relationship
  - ie “significant” financial relationships, “Those greater than \$500”, etc

## Standard 6.2

- ▶ For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

Source: <http://www.accme.org/requirements/accreditation-requirements-cme-providers/standards-for-commercial-support>

## Noncompliance with Standard 6.2

- ▶ Not telling learners that the speakers have nothing to disclose
- ▶ Not telling learners that planners have nothing to disclose

## Standard 6.3

- ▶ The source of all support from commercial interests must be disclosed to learners. When commercial support is "in-kind" the nature of the support must be disclosed to learners.

Source: <http://www.accme.org/requirements/accreditation-requirements-cme-providers/standards-for-commercial-support>

## Noncompliance with Standard 6.3

- ▶ Not including all the organizations that provided commercial support
- ▶ Failing to disclose or document disclosure of commercial support that was received at the last minute (after the learner handout was printed)
- ▶ Failure to disclose in-kind support from a commercial interest

## Standard 6.4

- ▶ 'Disclosure' must never include the use of a corporate logo, trade name or a product-group message of an ACCME-defined commercial interest.

Source: <http://www.accme.org/requirements/accreditation-requirements-cme-providers/standards-for-commercial-support>

## Standard 6.5

- ▶ A provider must disclose the above information to learners prior to the beginning of the educational activity.

Source: <http://www.accme.org/requirements/accreditation-requirements-cme-providers/standards-for-commercial-support>

## Noncompliance with Standard 6.5

- ▶ Not disclosing before the activity
- ▶ Not having evidence that the disclosure was made
  - Asking the question on the evaluation form is not evidence that the disclosure was made

## Questions

- ▶ What questions do you have regarding the Standards of Commercial Support?

## Scenario 1

- ▶ For a live meeting, Dr. Jones (on staff at the provider) is asked to present. On his disclosure, he indicates his spouse/partner owns shares of XYZ Pharmaceuticals. This company has a compound in phase III trial that (if approved) could be used to treat the condition which Dr. Jones will be speaking about.
- ▶ The provider reviews Dr. Jones' disclosure and determines that there is no conflict of interest that needs to be resolved.

## Scenario 2

- ▶ An institution asks all presenters and planners for a half-day meeting to complete the provider's disclosure form, which includes the following.

## Scenario 2 (continued)

- ▶ We are required to obtain full disclosure from all planners and faculty in a position to influence the content of a certified activity of financial relationships with a commercial interest for any significant amount occurring within the past 12 months.
- ▶ Financial relationships are those relationships with any proprietary entity producing health care goods or services in which the individual benefits by receiving a salary, royalty, intellectual property rights, non-scientific consulting fees, honoraria (do not include honoraria received from a CME/CE provider), ownership interest (e.g. stocks, stock options, or other ownership interest excluding diversified mutual funds), or other financial benefit directly or indirectly from a commercial interest.

## Example from American Academy of CME

### Disclosure of Relevant Financial Relationships

The American Academy of CME is an accredited provider of physician, nurse, pharmacist, and dietitian continuing education. We fully comply with all Standards and Criteria in the development of our CME/CE activities. We are required to obtain full disclosure from all individuals in a position to influence the content of a certified activity, in any amount occurring within the past 12 months. This includes financial relationships of a spouse/partner.

**PLEASE NOTE:** Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, non-scientific consulting fees, honoraria (do not include honoraria received from a CME/CE provider), ownership interest (e.g. stocks, stock options, or other ownership interest excluding diversified mutual funds), or other financial benefit directly or indirectly from a commercial interest\*. An individual who refuses to disclose any financial relationships will be disqualified from being a planning committee member, a faculty member, or an author/editor of an Academy's CME/CE activity and cannot have control of, responsibility for, the development, management, presentation, or evaluation of a certified activity.

**PRIOR TO FINAL APPROVAL TO PARTICIPATE IN AN ACADEMY CME/CE-CERTIFIED ACTIVITY,  
YOU MUST COMPLETE AND RETURN THE FOLLOWING:**

Name: **INSERT**

Title of Activity: **INSERT**

Date(s) of Activity: **INSERT**

Role: Check all that apply  Faculty  Panelist  Planning Committee  Joint Provider  Other \_\_\_\_\_

Have your or your spouse/partner had financial relationships or affiliations with any commercial entity in the past 12 months?

No. If no, go to page two

Yes If yes, please complete the following and page two:

Please print clearly



## Example from American Academy of CME

Nature of Relationship	Self/Spouse/Partner	List Name(s) of Commercial Entities
Advisory Board – for marketing purposes	<input type="checkbox"/> <input type="checkbox"/>	
Advisory Board – for scientific information	<input type="checkbox"/> <input type="checkbox"/>	
Consultant – for marketing purposes	<input type="checkbox"/> <input type="checkbox"/>	
Consultant – for clinical trial design	<input type="checkbox"/> <input type="checkbox"/>	
Employee	<input type="checkbox"/> <input type="checkbox"/>	
Officer or Board Member	<input type="checkbox"/> <input type="checkbox"/>	
Shareholder	<input type="checkbox"/> <input type="checkbox"/>	
Grant Recipient/Research Support— either directly or through institution Indicate whether you are the Principal Investigator and who receives the funds	<input type="checkbox"/> <input type="checkbox"/>	
Promotional Speaker's Bureau	<input type="checkbox"/> <input type="checkbox"/>	
Intellectual Property/Patents	<input type="checkbox"/> <input type="checkbox"/>	
Other Relationships (explain)	<input type="checkbox"/> <input type="checkbox"/>	

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

## Example from American Academy of CME

Page Two

Please list below the names of any product(s)/device(s) you plan to discuss that is/are non-FDA-approved or not approved for the use you are discussing.

I intend to discuss either non-FDA-approved or investigational use of the following:

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I do not yet know if I will discuss any non-FDA-approved or investigational use of any product/device.

I do not intend to discuss any non-FDA-approved or investigational use of any product/device.

I hereby certify that the above information is correct and that I will notify American Academy of CME, Inc. immediately if any of the above information changes.

SIGNATURE: \_\_\_\_\_ DATE: \_\_\_\_\_

## Scenario 3

- ▶ For a full day meeting, the provider submitted grant requests to 5 commercial interests (CIs) to support a full-day program on type 2 diabetes.
- ▶ Three CIs approved grants, and letters of agreement were signed with each. Disclosure of the support was included in the program handout.

## Scenario 3 (continued)

- ▶ The day before the meeting, a 4<sup>th</sup> commercial interest approves a grant for the meeting.
- ▶ Both the provider and the supporter sign the letter of agreement that day (the day before the meeting).
- ▶ Because the program handout was already printed, the provider asks the chair to verbally disclose the 4<sup>th</sup> supporter at the beginning of the meeting.

## Scenario 4

- ▶ The provider asks all planners and speaker to complete a disclosure form prior to planning an activity.
- ▶ The provider's disclosure does not ask the planner/speaker to indicate if they will be discussing off-label uses of approved products.

## Scenario 5

- ▶ For a grand rounds activity on antimicrobial resistance, Dr. Smith is invited to present. On her disclosure, she indicates her spouse is an employee of XYZ Pharmaceuticals. This company markets a product used to treat MRSA.
- ▶ After requesting additional information from Dr. Smith, you learn her husband is a distribution supervisor in a manufacturing plant for XYZ Pharmaceuticals.

## Scenario 5

- ▶ The provider reviews the disclosure and identifies the potential conflict and recommends the following to resolve the conflict (per the provider's policy for COI resolution):
  - discussion with faculty about the providers policies and procedures on independence
  - independent peer review
  - disclosure of conflict with participants
- ▶ In the file for this activity, the provider includes notes documenting that each of the above took place

## Scenario 6

- ▶ The provider hands out a one-page sheet that includes the CME information for a 1-hour live activity. The handout includes (among other things) learning objectives, accreditation statement, credit statement, and the following disclosures:
  - Planners for this activity have no relevant disclosures to make.
  - Dr. Carr discloses they have financial relationships with ABC Device Co.
  - Dr. Ellis has no relevant disclosures to make.

## Scenario 7

- ▶ One week before a grand rounds activity, Dr. Jenkins contacts the provider and says that they will be unable to speak due to a conflict in scheduling. He recommends Dr. Plat (who he says will “do a good job”) and offers to let Dr. Plat use his slides, which have already been through CME review.
- ▶ Dr. Plat agrees to participate, but is on service till the day before the activity and will not have time to do anything during the coming week (She is grateful for being able to use Dr. Jenkins’ slides).

## Scenario 7

- ▶ Because Dr. Plat is so busy and the program is coming up quickly, the provider pulls up Dr. Plat’s disclosure which Dr. Plat signed for another activity 6 months ago and swaps out Dr. Jenkin’s disclosures and replaces them with the information on Dr. Plat’s form.
- ▶ The disclosure to the learners reads as follows:
  - Dr. Plat discloses that she is consultant for ACE Pharma.
  - Planners for this activity have nothing to disclose.

## Scenario 8

- ▶ Dr. Markenson completes a disclosure form for the provider that states he is a shareholder for “DTL Devices (small number of shares),” who make a device Dr. Markenson will be discussing in his presentation.
- ▶ To resolve this conflict, the provider asks Dr. Markenson to agree to, sign and return the following form.

\_\_\_ I agree to comply with the following requirement for content validation:

*“All the recommendations involving clinical medicine in a CME/CE activity must be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients.”*

*All scientific research referred to, reported or used in CME/CE activities in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection, and analysis.”*

\_\_\_ I agree to prepare a fair and balanced presentation, which is objective and scientifically rigorous.

\_\_\_ I attest that any and all clinical recommendations that I make for patient care will be based on the best available evidence and a balanced view of therapeutic options will be given. I will also provide the level of evidence in all handout materials and/or slide materials.

\_\_\_ The content or format of my presentation will promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial entity.

\_\_\_ I agree not to receive any direct remuneration or gifts from any commercial interest, nor will I allow any guidance or input from any commercial interest regarding content of my presentation.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

## Scenario 9

- ▶ For each of their RSS series, the provider develops a “series” CME handout.
- ▶ As each learner enters the grand rounds activity, they receive a copy of the handout.
- ▶ In the disclosure section of the handout, the provider states: “Disclosures can be viewed upon request at the CME table in the back of the room.”