ACPE Standards for CPE

Standard 5: Standards for Commercial Support (SCS)

1. Describe the elements of the Standards for Commercial Support.
2. Given identified relevant financial relationships, illustrate methods to resolve conflicts of interest.
3. Outline the documentation and evidence providers are expected to have in place related to the Standards for Commercial Support.

Guidelines

AMA: Gifts to Physicians from Industry 1990's
AMA's "Guidelines on Gifts to Physicians from Industry" Dec 1990; Code of Medical Ethics (CEJA Ethical Opinion 8.061)

PhRMA Code on Interactions with Healthcare Professionals 2002

OIG: 2003 Compliance Program Guidance for Pharmaceutical Manufacturers
http://oig.hhs.gov/fraud/complianceguidance.html

AdvaMed Code of Ethics on Interactions with Healthcare Professionals 2004
http://www.advamed.org/publicdocs/coe.html
Guidelines
ACCME: 2004 Updated ACCME Standards for Commercial Support (SCS)
http://www.accme.org/index.cfm/fa/EssentialAreas.home/EssentialAreas.cfm
ACCP Position Paper Pharmacists and Industry: Guidelines for Ethical Interactions
http://www.accp.com
PhRMA Code on Interactions with Healthcare Professionals, July 2008
IOM: Conflict of Interest in Medical Research, Education, and Practice (2009)

National Faculty Education Initiative
http://www.nfeinitiative.org

Standards for Commercial Support Guidelines
• Interprofessional Adoption & Implementation

Accreditation Council for Continuing Medical Education (ACCME)
American Nurses Credentialing Center (ANCC)
Accreditation Council for Pharmacy Education (ACPE)
Provider Web Tool Page – Data Source

Grant Support Tab
• Required for every CPE activity entered

ACPE Actions
• Updated CPE Evaluation Form (submit)
• Internal monitoring: questions in the provider web tool
• Selection of activities where commercial support was received

Standards for Commercial Support

• Guideline 5.1: Independence
  – The following must be free of the control of commercial interest: needs, educational objectives, presentation/content, faculty, evaluation
  – Commercial Interest cannot partake in a cosponsorship relationship

Commercial Interest: any entity producing, marketing, reselling, or distributing health care goods or services consumed by, or used on, patients

Standard 5 Exercise

STOP

Please complete the exercise:

How would you answer the question on the following slide?
Standards for Commercial Support (SCS) Independence

Can pharmaceutical company employees serve as faculty for CPE activities?

If the content of CPE that the employee of the commercial interest controls relates to the business lines and products of its employer – NO.

If the content of CPE that the employee of the commercial interest controls DOES NOT relate to the business lines and products of its employer – YES.

Standards for Commercial Support (SCS) Independence

What kind of topics do not relate to the business lines or products of the employer?

• Teaching about the scientific or discovery process itself and not about treatment options
• Reporting research results that would be considered at the level of biology, physiology, or physics but not about products
• Participating in CPE beyond the scope of the employer’s firm (e.g., an employee of a pharmaceutical manufacturer who volunteers to develop an activity on disaster management)
Standards for Commercial Support

• Guideline 5.2: Resolution of Personal Conflicts of Interest
  – Everyone in a position to control the content of a CPE activity must disclose all relevant (within the past 12 months) financial relationships with any commercial interest
  – Anyone who refuses to disclose are to be disqualified from any involvement
  – Provider must have implemented a mechanism to identify and resolve all relevant financial relationships that create conflicts of interest prior to the educational activity

Conflict of Interest: occurs when an individual has an opportunity to affect CPE content about products/services of a commercial interest with which he/she has a financial relationship.

Standards for Commercial Support

• Guideline 5.2: Resolution of Personal Conflicts of Interest

Role Assignment:
  ➢ Choose another speaker
  ➢ Limit the content to report without recommendations
  ➢ Change the content so it does not relate to the COI

Use of External Validation
  ➢ Utilize “peer review”
  ➢ Ask faculty to reference the “best available sources”

Standard 5 Exercise

STOP

Please complete the exercise:

How would you answer the question on the following slides?
Standards for Commercial Support (SCS)
Conflict of Interest

T/F Disclosure and resolution of conflict of interest is only for the CPE faculty

A. False... everyone in a position to control content must disclose relevant financial relationships and the provider must resolve conflicts (e.g., utilization of advisory committees, peer review, editorial board, evidence base, advisors, etc.)

What happens if a speaker or planner refuses to disclose relevant financial relationships?
Standards for Commercial Support (SCS)  
Conflict of Interest

What happens if a speaker or planner refuses to disclose relevant financial relationships?

If an individual in a position to control content of CPE refuses to disclose any relevant financial relationships, he/she cannot participate in the activity.

Standards for Commercial Support (SCS)  
Conflict of Interest

An accredited provider has planned and developed CPE activities for its annual meeting. The staff collected disclosure information from each presenter. If any presenter disclosed relevant financial relationships, the staff asked the planning committee to resolve conflicts through a peer review process. Disclosure information for all presenters was then provided in the conference materials. Is the provider in compliance?

Standards for Commercial Support (SCS)  
Conflict of Interest

Partially. SCS 5.2 states that the provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners. While peer review can be an effective method to resolve conflicts, the provider must document what actions were taken if a conflict was identified (e.g., revise content if commercial bias or invalid content identified).
Standards for Commercial Support

- Guideline 5.3: Appropriate Use of Commercial Support
  - The provider must make all decisions regarding the disposition and disbursement of commercial support
  - A provider cannot be required by a commercial interest as conditions of contributing funds or services
  - All commercial support must be given with the full knowledge and approval of the provider

Standards for Commercial Support

- Guideline 5.3: Appropriate Use of Commercial Support
  - Written agreement documenting terms of support
  - Expenditures for an individual providing CPE
  - Expenditures for learners
    - Social events or serving of meals cannot compete with CPE
  - Accountability

Standard 5 Exercise

Please complete the exercise:

How would you answer the question on the following slide?
Standards for Commercial Support (SCS)
Appropriate Use of Commercial Support

Can lunch be supported by a commercial interest during the CPE activity?

The serving of meals should be kept separate from the educational sessions. Additionally, the provider should arrange for the meals (logistics and payment).

Standards for Commercial Support

- Guideline 5.4: Appropriate Management of Associated Commercial Promotion
  - Commercial exhibits or advertisements in live or homestudy (print/computer/audio/video) cannot
    - Influence planning or be a condition of commercial support
    - Occur in or during CPE activities
    - Include advertising in educational materials
  - Advertising may occur in non-CPE materials
  - Provider cannot use a commercial interest as the agent providing CPE
**Standard 5 Exercise**

Please complete the following exercise:

How would you answer the question on the following slide?

**Standards for Commercial Support (SCS)  
Managing Commercial Promotion**

Can a CPE provider distribute a CPE activity via a website, television channel, or other type of communication vehicle that is owned by a commercial interest?

**Standards for Commercial Support (SCS)  
Managing Commercial Promotion**

Can a CPE provider distribute a CPE activity via a website, television channel, or other type of communication vehicle that is owned by a commercial interest?

In keeping with the intent of separation of education from promotion, utilization of a platform owned/controlled by a commercial interest and supported by marketing dollars should not be a means to transmit or distribute CPE to learners.
Standards for Commercial Support

• Guideline 5.5: Content and Format without Commercial Bias
  – The content and format of CPE activities must promote improvements or quality in healthcare
    • Not a specific proprietary business interest
  – Presentations must provide a balanced view of therapeutic options
    • Use of generic names
    • If trade names also used, include for all products

Standard 5 Exercise

Please complete the exercise:

How would you answer the question on the following slide?

Standards for Commercial Support (SCS) Content and Format without Commercial Bias

During an educational session at a state pharmacy association annual conference, a panel discusses several therapeutic options for treatment of Parkinson's Disease. All faculty conflicts of interest have been resolved. Only generic names are used by the faculty. In addition to approved uses of drugs, the panelists also discuss an unapproved use of an FDA-approved drug manufactured by the commercial interest supporting the activity. One of the handouts for the session is a reprint of a peer-reviewed article from a medical journal about this unapproved use. Is this acceptable?
Standards for Commercial Support (SCS)
Content and Format without Commercial Bias

The provider would be in compliance with SCS 5.5. Providers are no longer required to have a mechanism in place to ensure that off-label or investigational uses are disclosed as such. ACPE encourages providers to guide faculty to include the level of evidence regarding all clinical and therapeutic recommendations for educational activities.

Standards for Commercial Support

• Guideline 5.6: Disclosures Relevant to Potential Commercial Bias
  – The following must be disclosed to learners
    • Disclosure of relevant financial relationships
      – Individuals name, commercial interest name, nature of relationship OR no relationships to disclose
    • Commercial support for the CPE activity
      – Source of all support from commercial interests
    • Timing of disclosure
      – Prior to the beginning of the CPE activity

Standard 5 Exercise

Please complete the exercise:

How would you answer the question on the following slide?
Standards for Commercial Support (SCS)

Disclosures Relevant to Potential Commercial Bias

An accredited provider is offering an online homestudy activity. Can the required disclosure information be provided via a link which participants can click on?

No. For activities in which the learner participates electronically, all required disclosure information must be transmitted to the learner prior to the learner beginning the CPE activity. In effect, the learner should be made to pass through this information prior to engaging in the activity.

The use of tabs, links, or other electronic means that allow learners to go directly to the CPE content and bypass the information are not acceptable methods.

Standards for Commercial Support

- Monitoring
  - Survey questions (e.g., activity evaluations) should allow participants to give details on sources of commercial bias if found in an activity
  - Provider should have processes to address identified sources of bias
  - Provides information on the effectiveness of the provider’s mechanism to resolve conflicts of interest; may yield systems improvements
**Standard 5 Exercise**

**STOP**

Please complete the exercise:

How would you address the following scenario?

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**Conflict of Interest/Disclosure Exercise**

Dr. Paul Hewson, who speaks as a part of a speaker’s bureau for two pharmaceutical manufacturers about their antipsychotic drugs and also serves as a consultant for one of the pharmaceutical manufacturers, has been invited to serve as a faculty member for a CPE activity on the risk versus benefit of psychotropic drug use in pregnancy. The activity will be a 1-hour live application-based activity to be presented at the American Association of Psychiatric Pharmacy Practitioners (AAPPP) annual conference. The provider has received an unrestricted educational grant from Janssen Pharmaceutica for this activity.

Dr. Hewson has disclosed the following relevant financial relationships:

<table>
<thead>
<tr>
<th>Commercial Interest</th>
<th>Nature of Relevant Financial Relationship (Include all those that apply)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eli Lilly</td>
<td>Honorarium</td>
</tr>
<tr>
<td>Eli Lilly</td>
<td>Consulting Fee</td>
</tr>
<tr>
<td>Janssen</td>
<td>Honorarium</td>
</tr>
</tbody>
</table>

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**Conflict of Interest Exercise**

Please answer the following questions:

1) Upon receipt of Dr. Hewson’s disclosure information, what steps should be taken to resolve conflicts of interest prior to putting forth the CPE activity?

2) What documentation should be submitted to ACPE if this activity was audited?
Standards for Commercial Support

Evidence

**SCS 5.1 - Independence**
- Policies/procedures pertaining to independence
- Activity announcements for selected CPE activities
- Grant agreements, if applicable

**SCS 5.2 - Resolution of Personal Conflicts of Interest**
- Policies/procedures pertaining to identification and resolution of COIs
- Evidence of disclosure of relevant financial relationships (e.g. executed disclosure forms)
- Evidence of identification and resolution of all COIs prior to the activity being delivered

**SCS 5.3 - Appropriate Use of Commercial Support**
- Policies/procedures pertaining to disposition and disbursement of commercial support
- Policies/procedures pertaining handling and documenting expenditures of activities
- Income and expense statements for requested commercially supported activities
- Grant agreements, if applicable
- Activity announcements for selected CPE activities

**SCS 5.4 - Appropriate Management of Commercial Promotion**
- Policies/procedures pertaining to management of associated promotion
- Activity announcements, educational materials, and summary of evaluation comments pertaining to bias for select CPE activities

**SCS 5.5 - Content and Format without Commercial Bias**
- Educational materials for selected CPE activities

**SCS 5.6 - Disclosures Relevant to Potential Commercial Bias**
- Policies/procedures pertaining to disclosure of relevant financial relationships to learners
- Evidence of disclosure to learners of relevant financial relationships and sources of all commercial support

**Monitoring**
- Activity evaluation forms for selected CPE activities
- Summary of activity evaluation feedback pertaining to bias, including free text comments, and evidence of provider follow-up on comments of bias, if identified

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