



**ACPE Accreditation Standards for Continuing Pharmacy Education (CPE)
Guidelines for Standards for Commercial Support - CPE Standard 5
(Adapted with permission from the Accreditation Council for Continuing Medical Education)
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Standards for Commercial Support, 5.1: Independence

1. What is a commercial interest? (SCS 5.1a)

At the January 2008 ACPE Board of Directors Meeting, the members approved adoption of the Accreditation Council for Continuing Medical Education's (ACCME's) updated policies released in August 2007 including the updated definition of a commercial interest. A 'commercial interest' is any entity producing, marketing, reselling, or distributing health care goods or services consumed by, or used on, patients. Providers of clinical service directly to patients are not 'commercial interests.'

2. What principles guide ACPE in evaluating an organization as a commercial interest?

What follows are guiding principles developed by ACPE in the evaluation of organizations as it pertains to the definition of a commercial interest:

- If entities are owned and operated by or on behalf of providers of patient care, then they should not be deemed commercial interests (e.g., hospitals, long-term care facilities, hospice)
- If there is a parent company that is not a commercial interest and it has two independent subsidiaries (corporation A and corporation B), where corporation A includes the CPE unit and corporation B provides branded products, then corporation A should not be deemed a commercial interest. (A "parent company" is a separate legal entity that owns or fiscally controls an accredited provider or non-accredited organization.)
- If a company provides pharmacist-provided patient care services (i.e., pharmacies), then the company should not be deemed a commercial interest.
- Whereas the Office of the Inspector General has stated that manufacturers should not be involved in the content of CPE, then a company designated as an FDA manufacturer (e.g., manufacturers pharmaceuticals and/or sells patented or licensed products) should be deemed a commercial interest.
- If a company provides proprietary formulas and/or formulations and the company has influence (on patients and/or prescribers) on the prescribing of the resultant product(s), then that company should be deemed a commercial interest.

3. ACPE defines a commercial interest as "any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients." Providers of clinical service directly to patients are not commercial interests. If an accredited provider believes that its organization is now defined as a commercial interest, what action(s) does ACPE recommend in order to ensure independence and continued eligibility for accreditation? (SCS 5.1a)

ACPE expects that providers will make changes to their organizational structure so that the CPE program is independent from the organization that markets, re-sells, or distributes health care products and services. In this way, the following decisions are made free of the control of the commercial interest: (a) identification of CPE 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 CPE; (e) selection of educational methods; and (f) evaluation of the activity.

The independence of the CPE program from the commercial interest can be accomplished in different ways. An example of an organizational structural change would be when an accredited provider that is a corporation sets up two additional wholly owned corporations: one corporation that markets, re-sells, or distributes health care products or services and the CPE corporation that does not market, re-sell, or distribute health care products or services. The corporation that is the CPE provider: 1) is not owned or controlled by a commercial interest; 2) has separate management; 3) is the employer of record; 4) has a governance structure separate from the governance structure of the commercial interest; and 5) receives any funds from a commercial interest only as commercial support.

4. How will the change in the definition of a commercial interest announced in February 2008 affect already accredited providers that might be owned by a commercial interest? (SCS 5.1a)

ACPE will work individually with accredited providers that might be affected by this definition as they transition to an independent corporate structure that is acceptable in the context of ACPE's Standards for Commercial Support. It is ACPE's expectation that any accredited provider that is, or is currently owned by, a commercial interest will transition to a different corporate structure (or will withdraw from accreditation).

5. The August 2007 definition of commercial interest seems to lump the people that secure the ads for the journal [i.e., publishers] into the camp of "promotion." Are entities that publish journals commercial interests? (SCS 5.1a)

No. ACPE has never intended that organizations (e.g., text-book/journal publishing company, specialty society) or people in organizations that are responsible for the production, layout, administrative, and operational aspects of a medical journal or text-book be defined as commercial interests. These organizations or people may sell advertising space to entities that are commercial interests, but that **does not** make them involved in the marketing of a commercial interest's product. The person or organization that creates or buys the advertising space on behalf of a commercial interest is involved in marketing.

However, the people that are publishers and the people that are executives of accredited providers that generate income from the sale of advertising and promotional space have financial relationships with commercial interests as a result of these transactions. ACPE **does** consider these financial relationships to create conflict of interest in CPE if, or when, the publisher and/or executive have control of CPE content. As for all such conflicts in CPE the accredited provider will be expected to have mechanisms in place to identify and resolve these conflicts of interest as necessary. (See ACPE Standards for Commercial Support, Standard 5.2 for more information.)

6. Can an accredited provider ask a commercial interest for suggestions related to topics or speakers for CPE? (SCS 5.1a)

No. There is no reason for the CPE provider to request suggestions for speakers or topics from commercial interests -- since it is unacceptable to act upon their suggestions. ACPE believes that CPE can receive commercial support from industry without receiving any advice or guidance, either nuanced or direct, on the content of the activity or on who should deliver that content. If the provider implements the suggestions of the commercial interest then this creates the situation where the independence of CPE from the commercial interest is seriously undermined. The provider must ensure that the content of the CPE remains beyond the control of any commercial interest. The process to develop the CPE must be independent of any commercial interest. Accredited providers must not allow commercial interests to directly (SCS 5.1a) or indirectly (SCS 5.3b) control the content of CPE.

7. What is the Provider to do if a commercial supporter of an activity says the content of the activity is not accurate -- or unreasonably favors their product? (SCS 5.1a)

There is no CPE reason for commercial supporters to review and comment on CPE content prior to its delivery to learners. ACPE believes that CPE can receive commercial support from industry without receiving any advice or guidance, either nuanced or direct, on the content of the activity or on who should deliver that content.

As has always been the case, issues could be brought directly to ACPE by commercial supporters if commercial supporters believe that a provider does not meet ACPE's expectations under the Standards for Commercial Support (e.g., freedom from bias, balance). This will contribute significantly to ACPE's ability to enforce its policies.

8. Why will ACPE not allow commercial interests to act as joint providers? (SCS 5.1b)

Joint providers are educational partners and are expected to routinely have a role in making decisions about the elements of the planning process specified in SCS 5.1a. Since these decisions must be "made free of the control of a commercial interest" as per SCS 5.1a, the joint provider cannot be a commercial interest.

9. Can employees of commercial interests serve as planners or speakers in our accredited 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.

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

Since the adoption of the Standards for Commercial Support, ACPE has worked closely with accredited providers as they have adapted their CPE programs to comply with ACPE policy regarding the role of commercial interest employees in accredited CPE. Accredited providers have offered the following examples:

- 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)

11. Can we offer accredited CPE activities on scientific research that was controlled in some way by a commercial interest, i.e., through funding, collaboration, or involvement of the commercial interests' staff in the research itself?

Yes, as long as the CPE activity complies with ACPE's *Accreditation Standards for Continuing Pharmacy Education*, including the Standards for Commercial Support. It is understood and accepted that industry conducts its own research and that industry partners, as funder or collaborator, in research projects. An important step in the translation of discovery to practice is the dissemination of the results of this research. There are several layers of internal and external controls already in place to manage the conduct of research (e.g., Institutional Review Boards, Government agencies) and the dissemination of results (e.g., editors, peer review, international standards.) ACPE does not intend to interfere with these carefully managed phases.

When a provider chooses to base its CPE content on research, the provider assumes responsibilities related to CPE, including compliance with the Standards for Commercial Support. The CPE content (not the research that has already taken place or is taking place) cannot be controlled by a commercial interest.

12. Can providers exclude presentations from an accredited CPE activity rather than getting involved in maintaining control of content or ensuring factors are in place to prevent conflict of interest?

Yes. The provider always has the option to exclude portions of content from an accredited CPE activity or present the content in an activity where CPE credit is not offered but may occur in conjunction with an accredited CPE activity.

QUESTIONS RELATED TO SCS 5.2a

1. Does the ACPE require a signed disclosure form as the means to demonstrate compliance with Standard for Commercial Support (SCS) 5.2a?

No. ACPE does not require that providers use a disclosure form to gather information about relevant financial relationships of all persons in control of the content of an educational activity. A disclosure form is one mechanism that providers may use to obtain (and show that they possess) this information. Other examples could include:

- Collecting the information verbally and recording it in a spreadsheet, table, or database
- Collecting disclosure information electronically (for example, via e-mail, web-based form, or database)

The obtaining of information about relevant financial relationships must be a key component of several processes in order to ensure the independence of educational activities. Providers may choose the mechanism(s) to obtain this information that best suit their organizational needs and can be used to demonstrate compliance to ACPE.

2. Is it necessary to collect disclosure information on relevant financial relationships from a speaker each and every time the speaker participates in a CPE activity?

No. It is not necessary to collect disclosure information on relevant financial relationships from a speaker, planner, or author each and every time that individual has control over the content of a CPE activity. The provider must be able to show ACPE that everyone who has control of CPE content has disclosed all relevant financial relationships with any commercial interest to the provider. Disclosure can occur by the provider utilizing disclosure information from a database, previous CPE activities, or another institution and then verifying that those relationships (or lack of relationships) are current and applicable to the applicable CPE activity.

3. What financial relationships need to be disclosed to the accredited provider?

Individuals need to disclose relationships with a commercial interest if both (a) the relationship is financial and occurred within the past 12 months and (b) the individual has the opportunity to affect the content of CPE about the products or services of that commercial interest. Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities for which remuneration is received or expected. ACPE considers relationships of the person involved in the CPE activity to include financial relationships of a spouse or partner. ACPE has not set a minimum dollar amount for relationships to be considered relevant. Inherent in any amount is the incentive to maintain or increase the value of the relationship.

4. What is the difference between significant financial relationships and relevant financial relationships?

Relevant financial relationships are financial relationships in any amount, which occurred in the twelve-month period preceding the time that the individual was asked to assume a role controlling content of the CPE activity, and which relate to the content of the educational activity, causing a *conflict of interest*. ACPE does not use the term *significant* to describe financial relationships.

To be compliant with SCS 5.2 and SCS 5.6, accredited providers should be obtaining disclosure of *relevant* financial relationships from all persons in control of content. If providers are asking those individuals in control of content to disclose *significant* financial relationships or setting a minimum dollar amount for disclosures, they will not be compliant with SCS 5.2 and SCS 5.6.

5. When do relationships create "conflicts of interest?"

ACPE considers financial relationships to create actual conflicts of interest in CPE when individuals have both a financial relationship with a commercial interest **and** the opportunity to affect the content of CPE about the products or services of that commercial interest.

6. Where is the 'conflict?'

When the provider's interests are aligned with those of a commercial interest the interests of the provider are in 'conflict' with the interests of the public. The interests of the people controlling CPE must always be aligned with what is in the best interests of the public.

7. How do these circumstances create a conflict of interest?

The potential for increasing the value of the financial relationship with the commercial interest creates an incentive to influence the content of the CPE – an incentive to insert commercial bias. Commercial bias is prohibited in CPE.

8. If at the first planning meeting for a CPE activity, all committee members are asked to disclose, and each member responds that he/she has nothing to disclose (or disclose something), and this information is reflected in the minutes of the meeting – is that enough documentation that disclosure was sought?

Yes. That documentation would help verify that the first step of a mechanism for identifying conflicts of interest is in place. That would document for ACPE that the provider knew the relevant financial relationships of the Committee members.

9. Following up on that question, do we need committee members to sign a disclosure statement at every meeting while planning the same activity?

No. Compliance with the standard requires that disclosure is made. Disclosing the same information repeatedly to the same provider is not necessary. With the original disclosure information, the provider is able to implement its mechanism to resolve any conflicts of interest.

10. What information do I need to collect in order to be compliant with SCS 5.2?

SCS 5.2 says that providers "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." Therefore, the provider must do both of the following:

1. Collect information from everyone in control of content, meaning anyone that has the opportunity to affect the content, including, but not limited to planners, faculty, authors, committee members, content reviewers, editors, and staff depending on the accredited provider's processes for developing educational activities
2. Collect information about relevant relationships with any commercial interest, meaning
 - o financial relationships in any amount,
 - o including financial relationships of their spouse or partner,
 - o within the 12 months prior to the educational activity,
 - o with an ACPE-defined commercial interest, and
 - o that relate to the content of the educational activity

Providers will not be in compliance with SCS 5.2 if they do any or all of the following:

- Only collect information about *significant* financial relationship or set a minimum dollar amount for disclosure
- Do not advise individuals that they should also report the relevant financial relationships of their partners or spouses
- Do not gather information about relationships within the 12 months prior to the educational activity
- Use a definition of commercial interest that is incomplete, outdated, or different than the complete, current ACPE definition

In addition, providers will not be able to demonstrate compliance with SCS 5.6, disclosing relevant financial relationships to the learner, if they have not gathered the correct information in SCS 5.2.

QUESTIONS RELATED TO SCS 5.2b

11. Is failure to return or provide disclosure information on relevant financial relationships the same as a refusal to disclose?

Yes. Refusal to disclosure is not limited to the explicit act of saying "no" to a provider's request for such information. Unresponsiveness that precludes the provider from implementing a mechanism to identify and resolve COI is equivalent to a refusal.

12. Is it acceptable to provide some latitude in disqualifying individuals who "refuse" to disclose by giving everyone one chance to refuse to disclose before actually disqualifying them?

No. ACPE expects providers to disqualify all individuals each time they refuse to provide information on their relevant financial relationships.

13. What do we do when we appoint a person to speak at the last minute and when the person arrives at the activity they refuse to disclose relationship information?

You must not carry on with the activity under these circumstances. The person cannot participate if they refuse to disclose because conflicts of interest can neither be identified nor resolved.

QUESTIONS RELATED TO SCS 5.2c

14. Can a provider leave it up to an individual who controls content to determine if his/her relevant financial relationship creates a conflict of interest that needs to be resolved?

No. The provider cannot delegate the responsibility for resolving the conflict of interest to the person with the conflict of interest. However, an individual who controls CPE content can be involved in the mechanism by being expected to take specific actions to resolve his/her conflict (ex: removing bias, using an evidence-based approach) under the supervision of the provider.

15. Can a provider choose to implement a mechanism to resolve conflicts of interest only for relationships they deem to have created "substantial" conflicts of interest?

No. If there is any relevant financial relationship, there is a conflict of interest. A mechanism to resolve conflicts of interest must be implemented in all such cases.

16. What do we do when we appoint a person to speak at the last minute and we have not had time to analyze disclosure information, never mind try to resolve any conflicts of interest?

It is reasonable to expect that providers would have plans to manage this contingency as part of their institutional mechanisms for resolving conflicts of interest. Each provider is free to develop the strategy

that best suits their circumstances.

17. What if, based on the disclosure information that we collect, we believe there is a conflict of interest? Does ACPE have any examples of mechanisms to resolve conflicts of interest?

Please keep in mind that these are only suggested mechanisms. Each provider will want to design and adopt a mechanism that works best for its structure and type of activities. The intent of the Standards is that any content about products is aligned with the best interest of the pharmacist learners, pharmacy technicians and their patients. Some suggestions are:

- a. **"Peer review" of CPE is often already in place and is a mechanism to resolve conflict of interest:** Scientific abstracts or free-standing papers or articles in enduring materials are often already peer reviewed or judged against predetermined criteria to ensure the data supports the conclusions before they are accepted for presentation or publication. When people have relationships but are presenting the abstract or paper within a peer review process, the conflict may well be resolved by that peer review process. Similarly, groups of people working together to do reviews of activity content prior to publication can resolve conflicts of interest by ensuring the content is valid and aligned with the interest of the public. Multiple levels of peer review to validate content are also effective mechanisms for resolving conflict of interest.
- b. In the presence of some form of oversight by the provider, **referencing the "best available evidence" is also an important mechanism for resolving conflict of interest.** Consider the situation where a person who does promotional education on a particular drug for a commercial interest is asked to analyze an important, very new, clinical trial report on that drug and present recommendations for how to use that drug in clinical practice. The content of the activity (in this case the faculty recommendations) can be aligned with what is in the best interests of the public by the teacher referencing the best available evidence in the literature, the grade or level of that evidence and by identifying the conclusions that the evidence support. Through integrating what this best available evidence supports with what the new study has revealed the person can go on to draw conclusions or formulate recommendations. When nested within some form of peer-review or oversight process there is even external validation of the conclusions.

18. How does a provider implement a mechanism for resolving conflicts of interest? It all seems very abstract and daunting, and seems to imply that experts with financial relationships must be excluded.

What follows is an example of how several tactics can be tied together by the provider into a mechanism to resolve conflicts of interest that could demonstrate the provider's compliance with the ACPE requirements, and preserve participation of experts with financial relationships.

1. Determine through disclosure mechanisms if those involved in planning or presenting content within a CPE activity have financial relationships related to that content.
2. If planners, presenters or authors have financial relationships that create conflict of interest,
 - a. The conflict can be resolved by an **effective peer review of content** prior to presentation or publication to ensure the content is valid and aligned with the interest of the public. Various methods of peer review to validate content can be effective mechanisms for resolving conflict of interest. One way to resolve the conflict of interest is to have scientific abstracts or free-standing papers or articles, peer reviewed or judged by commercially disinterested peers before they are accepted for presentation or publication.

b. In addition, requiring that all financial relationships be disclosed prior to an activity will alert participants (audience, readers) of the potential for conflict of interest and commercial bias.

Participants should be asked to evaluate the objectivity of the presentation or publication, and to identify any perceived commercial bias.

c. Also, presenters, authors, planners and reviewers could be **instructed to reference the best available evidence**.

19. If disclosure information cannot be analyzed in a timely fashion, is it appropriate for the activity or presentation to go on without formal CPE credit?

ACPE has never recommended withholding CPE credit at the last minute as an alternative to producing CPE that is in compliance with accreditation requirements. It does not seem fair to the physician learners. Assuming that in this scenario there is financial relationship information to disclose to the learners, a mechanism to resolve conflicts of interest could still be put in place. For example, the participants could be asked to evaluate the objectivity of the presentation **and** the Provider could make it clear to the faculty that there is an expectation that the information presented must be based on evidence as accepted in the literature by the healthcare professions.

20. Could a faculty disclosure/attestation form be used as a part of a mechanism to identify and resolve conflicts of interest?

Yes. A form could be a tool for collecting data and helping to identify individuals who control content within an activity who have no relevant financial relationships and those who do have relevant financial relationships. A form may also serve to inform faculty/authors about a provider's expectations of the faculty/authors in the context of the provider's plans for identifying and resolving conflict of interest. Merely the existence of a form, however, does not in itself meet the ACPE's requirements for resolving conflicts of interest. ACPE expects that individuals might be directed to take action by a disclosure/attestation form...and those actions would represent the provider's mechanism(s) to resolve conflicts of interest. For example, the disclosure/attestation form may ask those who control content and have conflicts of interest to base their presentations on the best available evidence and be prepared to have some or all of their materials reviewed by peers. In this example, the use of the disclosure/attestation form allows for and serves to document compliance with SCS 5.2a (identifying conflicts of interest) and the actions of those who are directed by the form demonstrate compliance with SCS 5.2c (implement a mechanism to resolve conflicts of interest).

21. Can faculty take an active role in the provider's mechanism(s) to resolve conflicts of interest?

Yes. Resolving conflicts of interest means individuals taking explicit actions prior to the educational activity to create CPE content that is valid and free of commercial bias -- even in the presence of relevant financial relationships. In the construct of the current CPE system, the development and presentation of CPE content is most often the responsibility of faculty/authors. Therefore, ACPE considers faculty/authors to be a part of the accredited provider. So, when the provider directs faculty/authors to take actions to assist in the identification and resolution of conflict of interest, a provider's mechanism is being implemented. The provider might then monitor the effectiveness of the actions taken by the faculty/authors to resolve conflicts of interest. Keep in mind that simply monitoring the CPE content at the time of presentation is not and cannot be the resolution mechanism.

22. We use "peer review" as our mechanism to resolve conflicts of interest. We read the content of each presentation, looking for commercial bias and content that is not supported by evidence. Does this resolve conflict of interest?

No. *"We read the content of each presentation, looking for commercial bias and content that is not supported by evidence"* is a mechanism to identify commercial bias and invalid content but it does

nothing to change the content so that the bias is gone and the content is valid. As described, it is a monitoring or screening process. If used before the activity it is a screening process -- and action needs to be taken to revise the content if commercial bias or invalid content are identified. If used after the activity, it is a monitoring process -- and could produce information on the effectiveness of the provider's mechanism to resolve conflicts of interest. System improvements may follow, if warranted.

Standards for Commercial Support, 5.3: Appropriate Use of Commercial Support

QUESTIONS RELATED TO SCS 5.3a

1. Can a provider offer commercial interests different levels of designation for different amounts of commercial support, e.g., gold, silver, and bronze categories for commercial support at three different levels?

Yes. A provider can implement practices to designate different categories of commercial supporters for different amounts of commercial support.

2. What is "commercial support?"

Commercial Support is financial, or in-kind, contributions given by a *commercial interest*, which is used to pay all or part of the costs of a CPE activity.

3. Can the commercial support be spent directly by the commercial supporter on costs (i.e. honorariums, meals, etc.) related to the CPE activity?

No. The commercial support must go first to the provider or a provider's joint provider or a provider's educational partner.

QUESTIONS RELATED TO SCS 5.3b

4. Can a commercial supporter direct the content of CPE?

No. The provider must ensure that the content of the CPE truly remains beyond the control of the commercial supporter. The process to develop the CPE must be independent of the commercial interest. Providers must not allow commercial supporters to directly (SCS 5.1a) or indirectly (SCS 5.3b) control the content of CPE.

5. How should an accredited CPE provider respond to a request by a commercial supporter to review materials for an upcoming CPE activity?

Under ACPE Standards and policies, there is no requirement for an accredited provider to share the content of an independent CPE activity prospectively or retrospectively with any person or organization. An accredited provider would be out of compliance with SCS 5.1a and 5.3b if it were obligated to allow a content review by a commercial supporter as a condition of its contributing funds or services.

6. Can providers be required by potential commercial supporters to share the list of expected authors or speakers with commercial supporters, during the process of applying for an educational grant?

No. ACPE cannot control what a commercial interest asks of an accredited provider but there is no CPE reason for the provider to share the names of speakers/authors with commercial supporters. An accredited provider that submits to the requirement of a commercial supporter to supply the names of speakers and authors could be participating in a process whereby the commercial supporter is controlling the selection of speakers and authors in accredited CPE. The provider may be found in noncompliance with the ACPE Standards for Commercial Support.

QUESTIONS RELATED TO SCS 5.3c

7. Can there be commercial support that the provider does not know about?

No. The provider or its agents (e.g., staff, managers, educational partners or joint providers) must decide what commercial support will be accepted and how it will be spent or used.

8. How does the CPE provider pay for its services in the production and distribution of a CPE activity? Can they take a portion of the grant monies to pay for their activity-related expenses, e.g., statements of credit, mailings?

Yes. The funds from commercial support may be used by the provider to pay for the cost of the activity including for example, the distribution of statements of credit and other mailings, as required.

QUESTIONS RELATED TO SCS 5.3d,e,f

9. As more commercial interests are moving to online and electronic commercial support application processes, is there any type of confirmation or verification regarding the written agreement for commercial support that can be used as a surrogate for a signature?

Yes. ACPE accepts electronic signatures as evidence that written agreements are signed. In addition, ACPE has received a few examples of online and electronic commercial support application processes that provide a structure and specific terms that meet ACPE's expectations for written agreements. ACPE is continuing to review commercial interests' online and electronic application processes and requests that providers contact ACPE if the need arises for affirmation of the adequacy of a specific online system in fulfilling ACPE's requirements for a written agreement and/or signature(s) on the agreement.

However, a provider will be found in Noncompliance with SCS 5.1a and SCS 5.3b if the provider enters into a commercial support agreement where the commercial supporter specifies the manner in which the provider will fulfill the requirements of ACPE's Policies and Standards.

10. Must the commercial support be given as a single lump sum grant or payment?

No. Commercial support does not have to be in a single payment or grant.

11. Can you tell us what elements must be included in the written agreement?

When there is commercial support there must be a written agreement that:

- Itemizes how the provider will use the commercial support in the development and presentation of the CPE activity;
- Itemizes the organizations involved in the activity (e.g., joint providers, education partners, managers);
- Specifies the organizational name of the commercial interest(s) that supplied the funds;
- Specifies what funds or in-kind services will be given by the commercial supporter to support the provider's activity; and
- Is signed and dated by the commercial interest and the accredited provider prior to the activity taking place.

12. Can the commercial supporter require that the payment of the funds to the provider be conditional upon the provider delivering the activity, as promised?

Yes.

13. Can a commercial supporter require in the written agreement that unexpended funds be returned to the commercial supporter?

Yes.

14. Can we use a letter of agreement written by a commercial supporter?

Yes. The agreement must describe the terms, conditions and purposes of the commercial support grant and be signed by the commercial supporter and the accredited provider.

15. Can a commercial supporter stipulate that if they do not approve of what was said -- or what will be said -- that they will not pay the commercial support?

No. This stipulation implies a control of content and acts as a disincentive to professional autonomy that is unacceptable in continuing pharmacy education.

16. When an accredited provider is working in joint providership or has designated a third party to receive and disburse commercial support funds for a CPE activity, what organization's names and signatures must be included on the written agreement for commercial support? What is the time frame in which the written agreements must be signed?

ACPE expects that written agreements for commercial support will:

- be between the accredited provider and commercial supporter. (This means that the accredited provider's name and commercial supporter's name must be included in the written agreement as the parties entering into the agreement for commercial support.)
- include the name of the joint provider or third party that would be receiving and disbursing the funds (when applicable).
- be signed by both the accredited provider and the commercial interest providing the commercial support. Third parties and/or joint providers may also sign the written agreement but may not sign it instead of the accredited provider.
- be signed prior to the activity taking place.

17. If an accredited provider is working in joint providership with a non-accredited entity, and it authorizes the commercial support to be paid directly to the non-accredited joint provider, does the accredited provider have to report that commercial support?

Yes. The accredited provider must report the full amount of commercial support received, even if the commercial support is distributed to other non-accredited joint providers.

18. What does ACPE mean by 'control' in its expectation that a provider make certain decisions free from the 'control' of a commercial interest?

ACPE expects that the provider makes decisions related to the planning and implementation of CPE activities without being directed or influenced by commercial interests.

19. Can an accredited provider be added as a party to a written agreement for commercial support after the original agreement was executed?

Yes. An accredited provider can fulfill the expectations of SCS 5.3d to 5.3f by adopting a previously executed agreement between an accredited provider and a commercial supporter and indicating in writing their acceptance of the terms and conditions specified and the amount of commercial support they will receive.

QUESTIONS RELATED TO SCS 5.3g,h

20. Why is ACPE requiring that providers have their own policies and procedures governing honoraria?

ACPE intends for the CPE provider to be the one to decide how much people are paid for their services as planners, faculty, and authors in CPE activities.

QUESTIONS RELATED TO SCS 5.3i

21. Can a commercial supporter supplement their contributions to the activity by additional direct payments to people involved in the activity?

No. All commercial support must be stipulated by a written agreement and must flow through the provider and/or its educational partner. Only the provider and/or its educational partner can make payments to people for their role(s) in the activity.

QUESTIONS RELATED TO SCS 5.3j

22. Can providers pay some of the expenses of people who are both faculty and learners?

Yes, but CPE providers need ensure that these people have bona fide faculty roles. It is unacceptable for anyone other than the provider, or its agents, to receive direct financial benefit from commercial support.

QUESTIONS RELATED TO SCS 5.3k

23. How can meals or social events compete with educational events?

Meals or social events compete with educational events when they happen at the same time in a different location or when they are the main attraction at the educational activity.

24. How can meals or social events take precedence over educational events?

Using commercial support to pay for modest meals and social events at CPE activities has been allowed for years. However, providers must separate the serving of the meal and/or social event with the education.

25. Are meal-time speakers prohibited?

No they are not prohibited. Working and learning through meal time is an efficiency often included in bona fide CPE activities.

QUESTIONS RELATED TO SCS 5.3l

26. Whose expenses can be paid for out of the commercial support?

Commercial support underwrites the provider's expenses for developing and presenting an activity. Commercial support can be used to pay for the expenses of faculty and authors as well others who are working for the provider on the activity.

27. Many providers produce CPE activities paid for entirely by commercial support with no charge to the participants. Typically these activities include a modest meal. Commercial support has been used to pay for this meal as part of the activity. Are meals still allowed as part of CPE activities?

Yes. ACPE considers meals arranged by the provider in conjunction with an activity to be an appropriate part of the expenses of a meeting and can be paid for out of the commercial support. As a reminder, serving of meals should not interfere with the educational session.

QUESTIONS RELATED TO SCS 5.3m

28. What kind of documentation of commercial support is expected?

ACPE expects to be able to review income and expense statements for all CPE activities. These statements must reflect:

- *Significant sources of income:* Including income from commercial support, advertising and exhibit fees, tuition and registration fees, internal budget allocations and any other source that represents greater than 20% of total income.
- *Significant expenses:* Including staff salaries, meeting costs, honoraria, faculty travel expenses and any other item that represents greater than 20% of total expense.

29. Can a commercial supporter ask for an accounting of how their commercial support has been spent?

Yes. It is appropriate for an accounting of how the commercial support has been spent to be included in the written agreement between the provider and the commercial supporter.

30. Does an accredited provider have to give a list of its participants to its commercial supporters?

No. ACPE has no specific policy on this matter. The decision is an organizational one for the provider.

31. How should an accredited provider manage and report funds received from commercial interests to reserve space for a CPE activity that is held in conjunction with another organization's meeting?

All funds that originate from ACPE-defined commercial interests and are paid to reserve space to hold accredited CPE activities (sometimes called satellite symposia) in conjunction with other organizations' meetings are considered commercial support. As with all commercial support, these funds must be paid directly to the accredited provider responsible for the activity or to a designated non-accredited joint provider. The accredited provider responsible for the activity that is held in the reserved space must manage and report the funds as commercial support, in accordance with ACPE commercial support requirements.

Example: National Specialty Association announces that it is selling slots to hold satellite activities at its upcoming annual meeting for \$10,000. USA School of Pharmacy, an ACPE-accredited provider, plans to reserve one of the slots and submits a request for the funds to pay the fee from Pharma Inc. There is a signed written agreement for the funds and Pharma Inc., an ACPE-defined commercial interest, pays the funds directly to USA School of Pharmacy. USA School of Pharmacy uses the funds to pay National Specialty Association to reserve the space. Prior to the beginning of its activity, USA School of Pharmacy informs the learners about the commercial support from Pharma Inc.

Standards for Commercial Support, 5.4: Appropriate Management of Associated Commercial Promotion

QUESTIONS RELATED TO SCS 5.4a

1. Is it acceptable to say, "In exchange for \$5,000 of commercial support we will produce the CPE activity and as a commercial supporter you will get an acknowledgment and a 4 x 4 sq ft booth in the exhibit hall. In exchange for \$25,000 of commercial support, we will produce the CPE activity and you will get an acknowledgment and a 20 x 20 sq ft booth in the exhibit hall along with the opportunity for your sales staff to promote your products at an evening reception"?

No, in this scenario the commercial interest is giving commercial support and getting promotional and sales opportunities. Opportunities for advertising and promotion are being purchased with commercial support and have become a condition of the support. Both of these are **Not in Compliance** with this Standard.

The commercial interest should buy advertising and promotion opportunities with resources designated for that purpose. If an agreement for advertising or promotion is struck between the two parties it must be outside the written agreement for commercial support described in Standard 5.3 of the SCS.

With respect to commercial support, the terms and conditions of the support must be described in a written agreement between the accredited provider and the commercial supporter as delineated in Standard 5.3 of the SCS. Any event or product that contains advertising or promotional opportunities must not be part of the educational CPE activity and must not be paid for by commercial support. Normally these are assigned to the "exhibit hall," advertising pages or screens or promotional receptions or meals, all of which are clearly identified as such by the learner.

2. Are advertising and exhibit opportunities always to be offered to commercial supporters?

No. Payment and arrangements for advertising and exhibits are separate, business transactions. They are payment for the sale of promotional space.

3. Is the provider responsible for the content of advertising and exhibits?

No. The provider is not accountable to ACPE for the content of advertising and exhibits. The information transferred in an advertisement or exhibit is not part of the provider's program of continuing pharmacy education activities.

QUESTIONS RELATED TO SCS 5.4b

4. Does SCS 5.4b represent a change for enduring materials?

This is a more detailed description of the requirements that must be followed if there is advertising in enduring materials. There can be advertising before and after the CPE content of an enduring material but those advertisements cannot be related to the content of the CPE and cannot have been paid for by the commercial supporter.

5. Where can providers put advertisements in printed and internet-based CPE and still be in compliance?

- In **journal-based CPE** there cannot be an advertisement within the pages of the article on which the activity is based. There can be advertisements between articles.

- In a **print enduring material** there can be advertisement at the end and the beginning of the CPE content but nowhere else in the enduring material.
- With clear notification that the learner is leaving the educational website, links from the website of the ACPE accredited provider to pharmaceutical and device manufacturers' product websites are permitted before or after the educational content of **internet-based CPE**, but shall not be embedded in the educational content of the activity.

6. What does ACPE mean by 'space or place?'

Twenty years ago, most CPE occurred in a lecture hall. Now, learning activities occur in many different environments including electronic media, and ACPE intends that all of these places and spaces of CPE activity need to be protected from encroachment by advertising, sales or promotional activity.

QUESTIONS RELATED TO SCS 5.4c

7. What can and what cannot have advertising?

ACPE insists on the separation of education from all promotional activities, materials and messages. Many providers create a print or text based document that goes along with an activity and provides information that is supplementary to the education content – like reproductions of slides, graphics or other handouts. These documents, in print or electronic, are an integral part of the education and as such cannot have any advertising, corporate logo, trade name or a product-group message of an ACPE-defined commercial interest associated with them.

8. Our program book has abstracts in it but we give no CPE credit for the abstracts – there is no problem having advertising in the program book – correct?

It depends on what the Program Book, with abstracts, is used for in relation to the CPE activity. If the abstracts are referenced during the activity or serve as a component of the content, then there can be no advertising in the Program Book. If the abstracts are not referenced as part of the CPE content, and appear in the Program Book with all other logistical information about the activity, then there can be advertising.

9. Why did the ACPE change Standards 5.4c and 5.6d to prohibit the use of ACPE-defined commercial interest logos in educational materials and disclosure of commercial support?

ACPE made these modifications because it determined that the logos of ACPE-defined commercial interests —as a form of corporate branding —are not appropriate in either educational materials or in the disclosure of commercial support of accredited continuing medical education. The prohibition against using commercial interest logos only applies within the parameters of SCS 5.4c and 5.6d. The modifications only apply to logos of ACPE-defined commercial interests, not to organizations that fall outside that definition.

10. The syllabus for our accredited CPE activity includes an agenda, PowerPoint presentations, and disclosures. If we accept commercial support for an activity, we include the names and logos of the supporting companies on the last page. Can we continue to print the logos of supporting companies on the very last page? Can we print the names and logos of exhibitors on the last page of our syllabus, if they are not providing commercial support?

No. Per SCS 5.6d, disclosure of commercial support to your learners cannot include the corporate logos of commercial supporters that are ACPE-defined commercial interests.

With respect to the corporate logos of your exhibitors, if they are ACPE-defined commercial interests, and since the syllabus described includes educational materials, the logos cannot be included even on the last page per SCS 5.4c. Logos of commercial supporters and exhibitors could be included in non-CPE materials per SCS 5.4d which states that “print or electronic information distributed about the non-CPE

elements of a CPE activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions, may include product-promotion material or product-specific advertisement.”

11. Does the prohibition of the use of corporate logos apply to exhibitors? I understand commercial exhibits are not commercial support but are subject to SCS 5.4.

The 2014 modifications to the Standards for Commercial Support are focused on prohibiting the corporate logos of ACPE-defined commercial interests when making disclosure of commercial support to learners (SCS 5.6d) or in educational materials (SCS 5.4c). How a provider chooses to list or acknowledge commercial exhibitors is not prescribed by ACPE. Per SCS 5.4c, if you include your list of exhibitors in your educational materials, you cannot include their corporate logos. Per SCS 5.4b and 5.4d, what happens outside of the educational materials and/or space may include advertising, including the corporate logos of ACPE-defined commercial interests.

QUESTIONS RELATED TO SCS 5.4d

12. Does SCS 5.4d refer to what we call a "program book"?

Yes. It contains logistical and organizational information and not education materials. It contains maps and floor plans but not slides and not abstracts.

QUESTIONS RELATED TO SCS 5.4e

13. Does this mean that ACPE is prohibiting commercial supporters and other commercial interests from distributing CPE enduring materials to physicians?

No. The regulation of commercial interests' promotional activities is not within the scope of ACPE's responsibility. SCS 5.4e is about the **providers'** role in separating promotion from education. ACPE is asking accredited providers to use their own distribution channels for CPE activities. For example, having a CPE enduring material created so as to be used in promotional visits to physicians' offices is **not** in keeping with the concept of separating CPE from promotion.

14. Can the provider use a commercial supporter to distribute promotional materials for CPE activities, e.g., "save the date cards, brochures?"

Yes.

15. What if a commercial entity is interested in buying a CPE product and approaches the CPE provider? Is it acceptable to sell the product to it?

Yes. A provider would not be out of compliance with the Standards for Commercial Support.

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

No. Communication or distribution mechanisms that are owned or controlled by a commercial interest cannot be used to transmit or distribute continuing pharmacy education activities to learners (e.g., a cable TV network or website owned and controlled by a commercial interest).

Although ACPE does not explicitly prohibit posting a link from a commercial interest's website to an accredited provider's website, the provider is cautioned that such an arrangement could lend itself to perceived bias by the learner. In establishing a web link, it must be clear that the participant is leaving the commercial interest's website and is being redirected to the ACPE accredited provider's website.

17. Can representatives from a commercial supporter be in the room during the educational session?

Yes. Representatives from a commercial supporter may be in the room during the educational session, however, cannot promote any product.

18. Can sales representatives distribute CPE offerings?

Sales representatives should not be involved in audience selection decisions. The provider is cautioned against using sales representatives as distributors of CPE offerings. The goal is to avoid any *perception* of bias.

19. Can a continuing education offering be conducted in an exhibit hall?

No. Continuing education activities should not be offered in an exhibit hall. Education should be kept separate from any type of promotional influence.

20. Can a commercial sponsor have a table to promote products in the same room as the educational session?

No. Education must be separate from promotion. Promotional materials must be out of the room and not necessarily in one's path so as to perceive possible commercialism.

QUESTIONS RELATED TO SCS 5.5a

1. What if an activity does in fact imply that a certain product or service is better than another?

CPE exists to support the practice change and learning -- so as to increase the pharmacists' ability to participate in providing quality healthcare or improved healthcare. ACPE expects that providers will always be able to demonstrate how each activity contributes to quality and/or improvement in healthcare, and is, therefore, aligned with what is in the best interest of the public.

2. Since the updated SCS do not mention off-label usage, does that mean that disclosure for off-label uses is no longer required or that discussion of off-label uses is not allowed in a CPE activity?

Discussion of off-label uses are certainly allowed in CPE activities. However, 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. Specifically, all the recommendations involving clinical medicine in a CPE activity [are] 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 CPE in support or justification of a patient care recommendation [conforms] to the generally accepted standards of experimental design, data collection and analysis.'

QUESTIONS RELATED TO SCS 5.5b

3. Does CPE have to give 'equal time' to all modalities of therapy (e.g., surgical vs. medical)? Does CPE have to give 'equal time' to all formulations of a drug or all products in a class of products?

CPE must be free of commercial bias. CPE must not promote products or services. CPE must promote improvements in healthcare. A 'balanced view' means that recommendations or emphasis must fairly represent, and be based on, a reasonable and valid interpretation of the information available on the subject (e.g., "On balance the data support the following ..."). A 'balanced view of therapeutic options' also means that no single product or service is over represented in the education activity when other equal but competing products or services are available for inclusion.

4. Can we discuss drugs by brand name?

Generic names should be used. If brand names are included, all brand names for a given generic product should be listed.

Standards for Commercial Support, 5.6: Disclosures Relevant to Potential Commercial Bias

QUESTIONS RELATED TO SCS 5.6a
-----**1. If we have taken appropriate steps to resolve conflicts of interest what is there left to disclose?**

Informed learners are the final safeguards in assuring that a CPE activity is independent from commercial influence. Regarding personal conflicts of interest, CPE providers are to have in place mechanisms to identify and resolve conflicts of interest. While these mechanisms should greatly reduce the potential for conflicts of interest to affect CPE content, a potential for influence remains. Disclosing to learners the relevant financial relationships that were present and resolved assists learners in assessing the potential for bias in information that is presented. ACPE believes this disclosure contributes to the transparency and accountability of the system.

2. What does ACPE mean by ‘nature of relationship’?

The ‘nature of the relationship’ means the role they play or service they provide in exchange for some form of compensation (e.g., employment, management position, independent contractor including contracted research, consulting, speaking and teaching, membership on advisory committees or review panels and board membership). ACPE has **not** set a minimum dollar amount for relationships to be significant. Inherent in any amount is the incentive to maintain or increase the value of the relationship therefore the dollar value of the relationship does **not** need to be disclosed.

QUESTIONS RELATED TO SCS 5.6b
-----**3. What does disclosure of no relevant financial relationships add to the system?**

This allows the learners to distinguish between missing disclosure information and the circumstances where there is nothing to disclose.

QUESTIONS RELATED TO SCS 5.6c
-----**4. Is disclosure of commercial support different than disclosure of financial relationships?**

Yes. Commercial support is given to the accredited provider and the accredited provider must disclose its existence to the learner. The presence of commercial support is critical information. The disclosure of commercial support is not an opportunity for product advertising but rather it must be restricted to the name of the corporate entity that provided the financial or specified in-kind support.

QUESTIONS RELATED TO SCS 5.6d,e
-----**5. Can a commercial supporter's logo be used to acknowledge support?**

No. According to SCS 5.6d, the acknowledgment of commercial support cannot contain the corporate logo of an ACPE-defined commercial interest.

6. We make disclosure of commercial support as required by Standard 6.4 to our learners on our online registration portal. The opening screen includes the names and logos of our commercial supporters. Is that acceptable?

No. Logos of ACPE-defined commercial interests are not permitted in the disclosure of commercial support. ACPE considers the disclosure of commercial support, as well as other information required by ACPE such as disclosure of relevant financial relationships, to be part of the educational materials. SCS 5.6d states that “Disclosure must never include the use of a corporate logo, trade name or a product-group message of an ACPE-defined commercial interest.”

7. If an activity that we produce is supported by a community health foundation that is not an ACPE-defined commercial interest, are we allowed to use its logo to acknowledge their support?

Yes. The organization you describe is not an ACPE-defined commercial interest.

8. Is it acceptable to provide a link within an internet CPE activity that participants can click on, if they choose, in order to access 'disclosure information' for the activity?

No. The required information specified in SCS 5.6 related to disclosure to learners of relevant financial relationship(s) must be transmitted, not only made accessible, to the learner prior to the learner engaging in the CPE activity. The learner should be made to pass through this information prior to engaging in the CPE 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 for complying with SCS 5.6.