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**ACPE Standards for Continuing Pharmacy Education (CPE)**

**Standard 5: Standards for Integrity and Independence**

**Frequently Asked Questions**

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| **5.3: Identify, Mitigate, and Disclose Relevant Financial Relationships** |

**Who are examples of "others" in control of content as described in Standard for Integrity and Independence in Accredited Continuing Education, Guideline 3?**

Guideline 3.1 states that the provider must "Collect information from all planners, faculty, and others in control of educational content about all their financial relationships with ineligible companies within the prior 24 months." If someone in connection to the activity has the opportunity to affect the content, they are "in control of content." Those individuals in a position to control the content of an educational activity might include (but are not limited to):

* Planners
* Faculty
* Authors
* Committee members
* Content reviewers
* Editors
* Staff (depending on the accredited provider's processes for developing educational activities)

Providers sometimes make the mistake of only collecting information about financial relationships from faculty or authors but do not collect that information from others, such as committee members, who may be in control of content. This would be a cause of noncompliance.

**Is it necessary to collect information on financial relationships from a speaker each time the speaker participates in a CE activity?**

No. It is not necessary to collect information on financial relationships from a speaker, planner, or author each and every time that individual has control over the content of a CE activity. Collection can occur by the provider utilizing disclosure information from a database, previous CE activities, or another institution and then verifyingthat those financial relationships (or lack of relationships) are current and determining relevance to the applicable CE activity.

**Should I collect financial disclosures as we create the content for each activity or on a yearly basis?**

Providers can choose whether to collect information on financial relationships with each activity or on a periodic basis, such as annually or biannually. If you choose to collect the information periodically, it is important to ask the person to update the information if anything changes to ensure you have up-to-date, accurate information.

Remember that providers must collect information from all planners, faculty, and others in control of educational content about all their financial relationships with ineligible companies within the prior 24 months of their involvement with an accredited CE activity.

**Does ACPE require a signed disclosure form as the means to demonstrate compliance with Standard for Integrity and Independence, Guideline 3?**

No. ACPE does not require that providers use a disclosure form to collect information about financial relationships of all persons in control of 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)

ACPE requires accredited providers to obtain information about the financial relationships of all persons in control of content. The obtaining of this information is a key component of the process 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.

**Can individuals disclose financial information to a provider verbally?**

Providers may accept verbal disclosure of financial information from those in control of content in accredited CE. Providers must be able to verify for ACPE that the individual was given the definition of an [ineligible company](https://accme.org/faq/what-accmes-definition-ineligible-company) and was informed that they must disclose **all**financial relationships with ineligible companies over the 24-month period prior to their involvement in accredited CE.

**If content of a CE activity is not related to the products or services of an ineligible company, do I still need to obtain information regarding the financial relationships of those that control content of the activity?**

No. Standards for Independence and Integrity Guideline 3 requires the provider to identify *relevant financial relationships*of those who control the content of a CE activity. Two things must be present for there to be a relevant financial relationship: financial relationship(s) with an ineligible company(ies) **and** the ability to control content *related*to products/services of the ineligible company(ies). If no financial relationships exist, or the content of the CE activity is not related to the products or services of an ineligible company there are no *relevant financial relationships* to identify or mitigate.

**What is the difference between significant financial relationships and relevant financial relationships?**

Financial relationships in any amount are relevant if the educational content an individual can control is related to the business lines or products of the ineligible company. ACPE does not use the term *significant* to describe financial relationships.

To be compliant with Guideline 3, accredited providers should be obtaining information on financial relationships from all persons in control of content and reviewing the information to determine which relationships are relevant. 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.

**Is failure to return or provide information on 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 mitigate relevant financial relationships is equivalent to a refusal.

**Do I need to use different approaches to mitigate relevant financial relationships for planners than I use for other persons in control of content, such as authors, speakers and reviewers?**

Most likely, yes. Some mechanism(s) that providers employ to mitigate relevant financial relationships for authors, speakers, and reviewers (e.g., peer-review of content) do not address the role(s) that planners have in controlling decisions that occur before content is developed for a CE activity. This influence may include choosing topics and faculty for the CE activity. To mitigate the relevant financial relationships of individuals involved in the planning of CE activities, the provider needs to implement mechanisms that ensure independence in the planning process, itself, prior to the development of educational content and instruction.

Examples of mitigation strategies for planners:

* End the financial relationship (including having ended the relationship within 24 months).
* Recuse individual from controlling aspects of planning and content with which there is a financial relationship.
* Peer review planning decisions and review determinations by persons without relevant financial relationships.

Examples of mitigation strategies for faculty:

* End the financial relationship (including having ended the relationship within 24 months).
* Recuse individual from controlling aspects of planning and content with which there is a financial relationship.
* Peer review of content by persons without relevant financial relationships.
* Attest those clinical recommendations are evidence-based and free of commercial bias (e.g., peer-reviewed literature, adhering to evidence-based practice guidelines).

**Can a provider leave it up to the individual who controls content to determine if his/her financial relationship is relevant and needs to be mitigated?**

No. The provider cannot delegate the responsibility for identifying relevant financial relationship solely to the person with the financial relationship.

**Can faculty take an active role in the provider's mechanism(s) to mitigate relevant financial relationships?**

Yes. ACPE considers faculty to be agents of the accredited provider. So, when the provider, after identifying that a financial relationship is relevant, directs teachers/authors to take actions to assist in the mitigation of relevant financial relationships, a provider's mechanism is implemented. The provider might then monitor the effectiveness of the actions taken by the teachers/authors to mitigate these relationships. Keep in mind that simply monitoring the CE content for commercial bias at the time of presentation is not an acceptable mitigation mechanism.

**We use "peer review" as our mitigation strategy. We read the content of each presentation, looking for commercial bias and content that is not supported by evidence.**
*"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 mitigation strategies. System improvements may follow, if warranted.

**We would like to include a person who is a paid Board member of a pharmaceutical company in an activity as a steering committee member and speaker. Is his participation acceptable and what are appropriate mitigation steps?**

While you may need to seek additional information about the nature of this individual's role as a Board member, ACPE has not generally considered the financial relationship of an individual to an ineligible company on whose board they serve to be an employee/owner relationship, unless they receive a salary for their work as a board member. If they are not an owner/employee, but still have a relevant financial relationship to the company, their participation would not be prohibited. It would be ACPE’s expectation that their relationships would be identified, mitigated, and disclosed in keeping with Guideline 3.

If an individual is participating as both a planner and faculty, it would likely be necessary to implement more than one mechanism for mitigation in keeping with their two different roles.

**If an individual reports that they own stock in an ineligible company, how should the provider manage the relationship?**

Individuals who may be in a position to control accredited continuing education are expected to disclose all their financial relationships with ineligible companies within the past 24 months to the provider.

* Individuals who own stock (not through a mutual fund or pension plan) in privately held ineligible companies are considered owners or employees and therefore must be excluded from controlling content or participating as planners or faculty in accredited CE, unless they meet the exceptions to the exclusion described in Guideline 3.
* Individuals who own stock in publicly traded ineligible companies are not considered owners or employees.  As described in Guideline 3, the provider is expected to determine if the relationship is relevant to the educational content. If so, the provider needs to take steps to mitigate the relationship and disclose the relationship to learners.

**If an individual reports that they have stock options with an ineligible company, how should the provider manage the relationship?**

Individuals who may be in a position to control accredited continuing education are expected to disclose all their financial relationships with ineligible companies within the past 24 months to the provider, including contracts to purchase stock at an agreed-upon price (stock options).

* As described in [Guideline 3](https://www.accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce/standard-3-identify-mitigate-and-disclose-relevant-financial-relationships), the provider is expected to determine if the relationship, in this case, stock options, is relevant to the educational content. If so, the provider needs to take steps to mitigate the relationship and disclose the relationship to learners.
* An individual who holds stock options in an ineligible company is not considered an owner or employee of that ineligible company.

**Are patent holders who receive royalty payments from ineligible companies considered to be owners of those companies?**

Individuals who receive patent royalties from ineligible companies are not considered owners or employees of those companies. Those individuals may control content in accredited continuing education, if the appropriate steps are taken:

* As described in Guideline 3, individuals who may be in a position to control accredited continuing education are expected to disclose all their financial relationships with ineligible companies within the past 24 months to the provider, including royalty payments.
* Providers must then determine if the relationship, in this case, royalty payments, is relevant to the educational content.
* If so, the provider needs to take steps to mitigate the relationship and disclose the relationship to learners.

**If a University received a monetary gift from an ineligible company to fund a faculty position at the University and that faculty was identified as a speaker for a CPE activity, would that constitute a conflict of interest?**

A monetary gift to the general funds of an institution by an ineligible company, which are used to fund a position, would not be considered a financial relationship that must be disclosed to a CE provider by a person in control of CE content. If funds are given by an ineligible company to specifically fund an individual’s salary, that would be considered a financial relationship that would need to be disclosed by the person to an accredited provider for whom they are controlling accredited content.

**What do we do when we appoint a speaker at the last minute, e.g., replacement speaker?**

It would be important to ensure that you have obtained information from the person replacing the speaker on any financial relationships they may have with ineligible companies. It is acceptable to do this in conversation, being sure to record that you provided them with the complete definition of an ineligible company and requested those relationships they have had for the past 24 months. If you determine a relevant financial relationship exists, it will need to be mitigated before the presentation and disclosed to the learners. Disclosure may be done verbally, but it should be recorded so it can be verified.

**Is it acceptable for an employee of an ineligible company to serve as a speaker for a CE activity on statistical methodologies?**

It is possible that a presentation on statistical methodologies would fit within the parameters of exceptions for Guideline 3 as an activity where the content is either unrelated to the products of the company or limited to the methodologies of research. If you choose to allow an ineligible company employee or owner to control CE content, it is ACPE’s expectation that you will be able to demonstrate through written documentation that the use of that employee/owner fit within the exceptions.

It should be noted that ACPE does not consider the financial relationship of an individual with an owner or employee to an ineligible company to be able to be mitigated. A commonality shared by each of the three exceptions outlined in Guideline 3 is that they are scenarios in which there is no opportunity for the individual in control of content to insert commercial bias into the activity, either by virtue of that activity's content or that individual's role in the activity.

**For a journal-based CE activity, do I need to identify, mitigate, and disclose to learners the relevant financial relationships for the authors of the article?**

No. If you are creating a journal-based CE activity, ACPE does not expect you to identify, mitigate, and disclose to learners the relevant financial relationships of the article's authors and editors. That process is handled by the journal editors. Disclosure by authors is a standard component of published articles, and the editorial review process manages the mitigation of relevant financial relationships. The accredited provider does, however, need to identify, mitigate, and disclose relevant financial relationships for those involved in planning the journal-based CE activity, e.g., the person(s) choosing the article(s) and/or writing the evaluation mechanism.

ACPE has two expectations about the publication that issued the article:

* The publication cannot be owned by an ACPE-defined ineligible company.
* The publication must have in place a process that manages the disclosure of authors, editors, and peer reviewers involved in the process of reviewing and publishing the article. The process must be accepted within the scientific publication community. For example, the publication follows the International Committee of Medical Journal Editors' (ICMJE) Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals (<http://www.icmje.org/recommendations/>).

**Pertaining to disclosure to learners, what is meant by "format that can be verified at the time of accreditation"?**

As part of the accreditation process, ACPE will select a sample of CE activities to verify that learners received the appropriate disclosure information. Because ACPE is not present at the time the disclosure occurs, providers are asked to save documentation that will allow ACPE to verify it took place – in whatever format disclosure is made. Specifically, we will want to verify that disclosure to learners included:

1. The names of the individuals with relevant financial relationships.
2. The names of the ineligible companies with which they have relationships.
3. The nature of the relationships.
4. A statement that all relevant financial relationships have been mitigated.

**What does ACPE mean by nature of the relationship related to providing disclosure to learners in Standard for Independence and Integrity?**

The *nature of the relationship*means the role they play or service they provide in exchange for some form of compensation from an ineligible company (e.g., independent contractor including contracted research, consulting, promotional 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 disclosed. 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.

**Are we able to summarize the mitigation process to the learners for multiple individuals with relevant financial relationships, or do we need to have a separate mitigation statement for each individual?**

A single summative statement that all relevant financial relationships were mitigated may be used, even though more than one strategy for mitigation may have been used. Per Guideline 3, providers must still disclose the names of individuals with relevant financial relationships, the names of the ineligible companies with which they have those relationships, and the nature of those relationships.

**Can we use tabs, links, or other electronic mechanisms to transmit disclosure information to learners as required by Standards for Integrity and Independence?**

Yes. Providers can use tabs, links, or other electronic mechanisms to make disclosure information available to learners. Regardless of the method of disclosure, all required information specified in [Standards for Integrity and Independence](https://accme.org/standards) must be transmitted to the learner prior to the learner beginning the CE activity and should be clearly marked and accessible to learners.