

# Key Steps for the Identification, Mitigation, and Disclosure of Relevant Financial Relationships

For more information, visit accme.org/standards

Questions? E-mail info@accme.org



# **Note for Continuing Education Staff**

If any of the following statements apply to the education, you **do not** need to identify, mitigate, or disclose relevant financial relationships for this accredited continuing education:

- ✓ It will only address a non-clinical topic (e.g., leadership or communication skills training).
- ✓ It is for a learner group that is in control of the content entirely (e.g., spontaneous case conversation among peers).
- ✓ It is a self-directed educational activity where the learner will control their educational goals and report on changes that resulted (e.g., learning from teaching, remediation, or a personal development plan). When accredited providers serve as a source of information for the self-directed learner, they should direct learners only to resources and methods for learning that are not controlled by ineligible companies.

**STEP 1:** Before you begin planning your education, collect information from all planners, faculty, and others who would be in positions to control content. Ask them to provide information about **all** their financial relationships with ineligible companies over the previous **24 months**.

Ensure you use this definition: Ineligible companies are those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

Hint: Use the **Template for Collecting Information about All Financial Relationships from Planners, Faculty, and Others**. There is no minimum financial threshold; individuals must disclose all financial relationships, regardless of the amount, with ineligible companies.

**STEP 2:** Review the disclosed relationships and **exclude owners and employees of ineligible companies from participating as planners, faculty, or other roles** unless the educational activity meets one of the exceptions listed below.

There are only three exceptions that allow for owners and/or employees of ineligible companies to participate as planners or faculty in accredited continuing education.

- 1. When the content of the activity is not related to the business lines or products of their employer/company.
- 2. When the content of the accredited activity is limited to basic science research, such as pre-clinical research and drug discovery, or the methodologies of research, and they do not make care recommendations.
- 3. When they are participating as technicians to teach the safe and proper use of medical devices, and do not recommend whether or when a device is used.

**STEP 3:** Determine which financial relationships are **relevant** to the content of the continuing education activity, **mitigate** those relevant financial relationships to prevent commercial bias, and **disclose** the presence or absence of all relevant financial relationships to learners prior to the activity.



Determine relevant financial relationships for all who will be in control of educational content.

Financial relationships are relevant if the following three conditions are met for the individual who will control content of the education:

- ✓ A financial relationship, in any amount, exists between the person in control of content and an ineligible company.
- ✓ The financial relationship existed during the past 24 months.
- ✓ The content of the education is related to the products of an ineligible company with whom the person has a financial relationship.



Mitigate relevant financial relationships prior to individuals assuming their roles in the education.

Hint: Use the Worksheet for the Identification and Mitigation of Relevant Financial Relationships of Planners, Faculty, and Others to implement mitigation strategies appropriate to their role(s) in the educational activity.



Before the learner engages in the education, **disclose** to learners the presence or absence of relevant financial relationship for all persons in control of content.

Hint: Use the **Examples of Communicating Disclosure to Learners** to share all of the appropriate information before the activity.





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- ✓ It is a self-directed educational activity where the learner will control their educational goals and report on changes that resulted (e.g., learning from teaching, remediation, or a personal development plan). When accredited providers serve as a source of information for the self-directed learner, they should direct learners only to resources and methods for learning that are not controlled by ineligible companies.

At the beginning of your planning process, use the sample language below to communicate with prospective planners, faculty, and others who may be in control of content for the education. It is important to identify financial relationships before activity planning begins so that relevant financial relationships can be mitigated in a manner that is appropriate to each person's role.

#### Dear Prospective Planner/Faculty Member:

### Why am I receiving this communication?

<Insert Accredited Provider Name> is accredited by the <a href="Accreditor">Accreditor</a>. we appreciate your help in partnering with us to follow accreditation guidelines and help us create high-quality education that is independent of industry influence. In order to participate as a person who will be able to control the educational content of this accredited CE activity, we ask that you disclose all financial relationships with any ineligible companies that you have had over the past 24 months. We define ineligible companies as those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. There is no minimum financial threshold; you must disclose all financial relationships, regardless of the amount, with ineligible companies. We ask you to disclose regardless of whether you view the financial relationships as relevant to the education. For more information on the Standards for Integrity and Independence in Accredited Continuing Education, please visit accme.org/standards.

#### Why do we collect this information?

Since healthcare professionals serve as the trusted authorities when advising patients, they must protect their learning environment from industry influence to ensure they remain true to their ethical commitments. Many healthcare professionals have financial relationships with ineligible companies. By identifying and mitigating relevant financial relationships, we work together to create a protected space to learn, teach, and engage in scientific discourse free from influence from organizations that may have an incentive to insert commercial bias into education.

#### What are the next steps in this process?

After we receive your disclosure information, we will review it to determine whether your financial relationships are relevant to the education. Please note: the identification of relevant financial relationships does not necessarily mean that you are unable to participate in the planning and implementation of this educational activity. Rather, the accreditation standards require that relevant financial relationships are mitigated before you assume your role in this activity.

To help us meet these expectations, please use the form we have provided to share all financial relationships you have had with ineligible companies during the past 24 months. This information is necessary in order for us to be able to move to the next steps in planning this continuing education activity.



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- ✓ It is a self-directed educational activity where the learner will control their educational goals and report on changes that resulted (e.g., learning from teaching, remediation, or a personal development plan). When accredited providers serve as a source of information for the self-directed learner, they should direct learners only to resources and methods for learning that are not controlled by ineligible companies.

Use the sample language below to provide disclosure to learners in a format that can be verified at the time of accreditation. Disclosure must be provided to learners **before** engaging with the accredited education.

# What gets disclosed to learners before the education?

#### If there are NO relevant financial relationships:

Inform learners that planners, faculty, and others in control of content (either individually or as a group) have no relevant financial relationships with ineligible companies.

#### **EXAMPLES:**

"Dr. Xin Lee, faculty for this educational event, has no relevant financial relationship(s) with ineligible companies to disclose."

"Ruth Hopkins, Dr. Maryam Elbaz, and Ken Sanders, authors of this educational activity, have no relevant financial relationship(s) with ineligible companies to disclose."

"None of the planners for this educational activity have relevant financial relationship(s) to disclose with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients."

# If there ARE relevant financial relationships:

Disclose name(s) of the individuals, name of the ineligible company(ies) with which they have a relevant financial relationship(s), the nature of the relationship(s), and a statement that all relevant financial relationships have been mitigated.

#### **EXAMPLES:**

Nicolas Garcia, faculty for this educational event, is on the speakers' bureau for XYZ Device Company.

Dr. Yvonne Gbeho, planner for this educational event, has received a research grant from ABC Pharmaceuticals.

All of the relevant financial relationships listed for these individuals have been mitigated.

#### NOTE:

- If commercial support is received, the accredited provider must also disclose to the learners the name(s) of the ineligible company(ies) that gave the commercial support, and the nature of the support if it was in-kind, prior to the learners engaging in the education.
- ✓ Disclosure to learners must not include ineligible companies' corporate or product logos, trade names, or product group messages.
- ✓ It may be helpful to include definitions of terms to learners to support their understanding of your processes (e.g., ineligible companies, relevant financial relationships, etc...)



Use this sample template to communicate expectations to planners, authors, and faculty about ensuring valid clinical content for accredited education. For more information about these expectations, see Standard 1 of the Standards for Integrity and Independence at accme.org/standards.

#### Dear Prospective Planner/Faculty Member:

As an important contributor to our accredited education, we would like to enlist your help to ensure that educational content is fair and balanced, and that any clinical content presented supports safe, effective patient care. This includes the expectations that:

- ✓ All recommendations for patient care in accredited continuing education must be based on current science, evidence, and clinical reasoning, while giving a fair and balanced view of diagnostic and therapeutic options.
- ✓ All scientific research referred to, reported, or used in accredited education in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection, analysis, and interpretation.
- ✓ Although accredited continuing education is an appropriate place to discuss, debate, and explore new and evolving topics, these areas need to be clearly identified as such within the program and individual presentations. It is the responsibility of accredited providers to facilitate engagement with these topics without advocating for, or promoting, practices that are not, or not yet, adequately based on current science, evidence, and clinical reasoning.
- ✓ Content cannot be included in accredited education if it advocates for unscientific approaches to diagnosis or therapy, or if the education promotes recommendations, treatment, or manners of practicing healthcare that are determined to have risks or dangers that outweigh the benefits or are known to be ineffective in the treatment of patients.

These expectations are drawn from **Standard 1** of the ACCME Standards for Integrity and Independence in Accredited Continuing Education. For more information, see **accme.org/standards**. If we can help you to understand and/or apply these strategies to your education, please contact us at <a href="crowder-contact-information">crowder-contact-information</a>.



Please consider using these strategies to help us support the development of valid, high quality education.

# Consider using the following best practices when presenting clinical content in accredited CE:

- ✓ Clearly describe the level of evidence on which the presentation is based and provide enough information about data (study dates, design, etc.) to enable learners to assess research validity.
- ✓ Ensure that, if there is a range of evidence, that the credible sources cited present a balanced view of the evidence.
- ✓ If clinical recommendations will be made, include balanced information on all available therapeutic options.
- ✓ Address any potential risks or adverse effects that could be caused with any clinical recommendations.

Although accredited CE is an appropriate place to discuss, debate, and explore new and evolving topics, presenting topics or treatments with a lower (or absent) evidence base should include the following strategies:

- Facilitate engagement with these topics without advocating for, or promoting, practices that are not, or not yet, adequately based on current science, evidence, and clinical reasoning
- Construct the activity as a debate or dialogue. Identify other faculty who represent a range of opinions and perspectives; presentations should include a balanced, objective view of research and treatment options.
- Teach about the merits and limitations of a therapeutic or diagnostic approach rather than how to use it.
- Identify content that has not been accepted as scientifically meritorious by regulatory and other authorities, or when the material has not been included in scientifically accepted guidelines or published in journals with national or international stature.
- Clearly communicate the learning goals for the activity to learners (e.g., "This activity will teach you about how your patients may be using XX therapy and how to answer their questions. It will not teach you how to administer XX therapy").

Please answer the following questions regarding the clinical content of the education.	
Are recommendations for patient care based on current science, evidence, and clinical reasoning, while giving a fair and balanced view of diagnostic and therapeutic options? [Standards for Integrity and Independence 1.1]	Yes No
Comments:	
Does all scientific research referred to, reported, or used in this educational activity in support or justification of a patient care recommendation conform to the generally accepted standards of experimental design, data collection, analysis, and interpretation? [Standards for Integrity and Independence 1.2]	Yes No
Comments:	
Are new and evolving topics for which there is a lower (or absent) evidence base, clearly identified as such within the education and individual presentations? [Standards for Integrity and Independence 1.3]	Yes No
Comments:	
Does the educational activity avoid advocating for, or promoting, practices that are not, or not yet, adequately based on current science, evidence, and clinical reasoning? [Standards for Integrity and Independence 1.3]	Yes No
Comments:	
Does the activity exclude any advocacy for, or promotion of, unscientific approaches to diagnosis or therapy, or recommendations, treatment, or manners of practicing healthcare that are determined to have risks or dangers that outweigh the benefits or are known to be ineffective in the treatment of patients? [Standards for Integrity and Independence 1.4]	Yes No
Comments:	

One strategy to ensure the clinical content validity of accredited continuing education is to allow external (peer) review by persons with appropriate clinical expertise and no relevant financial relationships with ineligible companies, defined as those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. The questions above direct reviewers to share feedback about each of the requirements that comprise Standard 1 in the Standards for Integrity and Independence. For more information, see accme.org/standards.