

Toolkit for the Standards for Integrity and Independence in Accredited Continuing Education

The ACCME is pleased to provide this toolkit of resources to assist accredited providers in transitioning to the new Standards for Integrity and Independence. For this initial collection of tools, we have focused on Standard 1: Ensure Content is Valid and Standard 3: Identify, Mitigate, and Disclose Relevant Financial Relationships. These two standards are applicable to all accredited providers. Use of these resources is completely **optional**. Many accredited providers have their own policies, procedures, forms, and mechanisms to facilitate the planning and delivery of accredited education—as you review your own practices, you may wish to check them against these resources to ensure you are positioned to meet expectations.

We look forward to working with the continuing education community to create and refine additional tools, as necessary. As always, we remain available for questions and assistance! Contact us at info@accme.org.



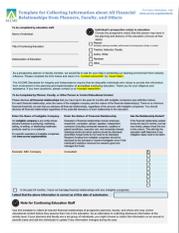
Key Steps

Overview of the 3-step process to identify, mitigate, and disclose relevant financial relationships.



Sample Letter

Language you can use to explain to prospective planners and faculty why financial relationship information is collected.



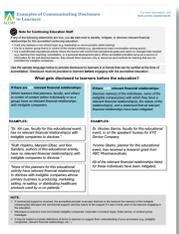
Template

Compare your process or forms to this sample template to collect the right information about financial relationships.



Worksheet

Step-by-step process for identifying and mitigating relevant financial relationships.



Examples

Sample language that shows you how to communicate disclosure to learners.



Guidance

An example of how to enlist help from planners and faculty to ensure that clinical content is valid.



Template

An example of a tool to facilitate peer review to ensure that clinical content is valid.



Quick Tool

Use this sample tool to simplify educational planning when identification, mitigation, and disclosure are not required.



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.*



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.

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**:

We are looking forward to having the opportunity to include you as a **<proposed role for person—e.g. planner, faculty, reviewer, etc...>** in the accredited continuing education, **<Insert activity title or working title and date/location information, if appropriate>**.

Why am I receiving this communication?

<Insert Accredited Provider Name> is accredited by the **<Accreditor>**. 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.

If you have questions about these expectations please contact us at **<provider contact information>**.



Template for Collecting Information about All Financial Relationships from Planners, Faculty, and Others

For more information, visit accme.org/standards

To be completed by education staff.

Name of Individual: _____

Title of Continuing Education: _____

Date and location of Education: _____



Individual's prospective role(s) in education

Identify the prospective role(s) that this person may have in the planning and delivery of this education (*choose all that apply*)

- Planner
Examples: planning committee, staff involved in choosing topics, faculty, or content
- Teacher, Instructor, Faculty
- Author, Writer
- Reviewer
- Other _____

As a prospective planner or faculty member, we would like to ask for your help in protecting our learning environment from industry influence. Please complete the form below and return it to **Contact Name/email** by **Date**.

The ACCME Standards for Integrity and Independence require that we disqualify individuals who refuse to provide this information from involvement in the planning and implementation of accredited continuing education. Thank you for your diligence and assistance. If you have questions, please contact us at **Contact Name/email**.

To be Completed by Planner, Faculty, or Others Who May Control Educational Content

Please disclose **all financial relationships** that you have had in the past 24 months with ineligible companies (see definition below). For each financial relationship, enter the name of the ineligible company and the nature of the financial relationship(s). There is no minimum financial threshold; we ask that you disclose all financial relationships, regardless of the amount, with ineligible companies. You should disclose all financial relationships regardless of the potential relevance of each relationship to the education.

Enter the Name of Ineligible Company	Enter the Nature of Financial Relationship	Has the Relationship Ended?
<p>An ineligible company is any entity whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.</p> <p>For specific examples of ineligible companies visit accme.org/standards.</p>	<p>Examples of financial relationships include employee, researcher, consultant, advisor, speaker, independent contractor (including contracted research), royalties or patent beneficiary, executive role, and ownership interest. Individual stocks and stock options should be disclosed; diversified mutual funds do not need to be disclosed. Research funding from ineligible companies should be disclosed by the principal or named investigator even if that individual's institution receives the research grant and manages the funds.</p>	<p>If the financial relationship existed during the last 24 months, but has now ended, please check the box in this column. This will help the education staff determine if any mitigation steps need to be taken.</p>
Example: ABC Company	Consultant	<input checked="" type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>

In the past 24 months, I have not had **any** financial relationships with any ineligible companies.

I attest that the above information is correct as of this date of submission.

Date _____



Note for Continuing Education Staff

Use this template to collect all relevant financial relationships of prospective planners, faculty, and others who may control educational content before they assume their role in the education. As an alternative to collecting disclosure information for each activity, if your planners and faculty are a set group of individuals, you might choose to collect this information on an annual or periodic basis and ask the individuals to update if any information changes during the year.



Worksheet for the Identification and Mitigation of Relevant Financial Relationships of Planners, Faculty, and Others

For more information, visit accme.org/standards



Note for Continuing Education Staff

Use this sample worksheet to identify and mitigate relevant financial relationships that you have identified for planners, faculty, and others who will control educational content for your education activity. Please make sure that (1) the mitigation strategy is appropriate to the person's role in the activity, and (2) that mitigation is implemented before each person takes on their role.

STEP 1: Review collected information about financial relationships and **exclude owners or employees of ineligible companies** from participating as planners or faculty.

After collecting all financial relationships from prospective planners, faculty, and others, exclude any persons who are owners or employees of ineligible companies. Ineligible companies are those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. For information about exceptions to this exclusion, see accme.org/standards.

STEP 2: Determine **relevant financial relationships**.

Review the information for all persons whom you did not exclude in Step 1 and determine whether each person's financial relationships with ineligible companies are relevant to the content of the education you are planning. Financial relationships are relevant if the following three conditions are met for the prospective person 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.

STEP 3: Choose a **mitigation strategy** for each person who has a relevant financial relationship and **implement** that strategy before the person assumes their role.

Using the lists below, identify which mitigation strategy(ies) will be used for **all persons** with relevant financial relationships who control the educational content of the educational activity. You may select multiple strategies but be sure to use strategies **appropriate to the role(s)** that each person has. You can also identify your own strategies for mitigation.

Mitigation steps for planners *(choose at least one)*

- ✓ **Divest** the financial relationship
- ✓ **Recusal** from controlling aspects of planning and content with which there is a financial relationship
- ✓ **Peer review** of planning decisions by persons without relevant financial relationships
- ✓ Use **other methods** *(please describe)*:

Mitigation steps for faculty and others *(choose at least one)*

- ✓ **Divest** the financial relationship
- ✓ **Peer review** of content by persons without relevant financial relationships
- ✓ Attest that clinical recommendations are **evidence-based** and **free of commercial bias** (e.g., peer-reviewed literature, adhering to evidence-based practice guidelines)
- ✓ Use **other methods** *(please describe)*:

Step 4: Document the mitigation strategy(ies) you used for each person with a relevant financial relationship.

A	B	C	D
NAME OF PERSON	ROLE(S) IN ACTIVITY	STEP(S) TAKEN TO MITIGATE RELEVANT FINANCIAL RELATIONSHIP	DATE IMPLEMENTED
<i>Example: Dr. Jones</i>	<i>Planner</i>	<i>Recusal from topic/faculty selection</i>	<i>10/28/21</i>



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.

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...)



Note for Continuing Education Staff

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 **<provider contact information>**.



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”).



Template for Peer Review: Ensuring that Clinical Content is Valid

For more information, visit
accme.org/standards

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:



Note for Continuing Education Staff

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.



What is your name and email?	Name: Email:
When will the education take place?	Date:
Do you have a title or brief description for the education? If yes, please note it to the right; if no, leave blank. Examples: Emergency Department team huddle; Leadership in a time of crisis; Well-being check-in	Title/Brief Description:
What practice-based problem (gap) will this education address? Examples: Improve care coordination; Better communication with patients and families; Want to give better feedback to students	Practice-based problem (gap):
What is/are the reason(s) for the gap? How are your learners involved? Examples: We need strategies to discuss difficult topics with family members; Don't know best ways to improve team collaboration	Reason(s) for the gap:
Review the three statements to the right. If you can check <u>any</u> of these boxes, you do not need to identify, mitigate, and disclose relevant financial relationships. If you unable to check any boxes, please contact your CE program administrator to implement processes for ensuring the integrity and independence of this education.	The education will... (check all that apply) <input type="checkbox"/> only address a non-clinical topic (e.g., leadership or communication skills training). <input type="checkbox"/> be for a learner group that is in control of the content (e.g., spontaneous case conversation among peers). <input type="checkbox"/> be 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).
What change(s) in strategy, performance, or patient care would you like this education to help learners accomplish? Examples: Eliminate stigmatizing language from communications with patients; Improve my management skills	Desired change(s) in strategy, performance, or patient care:
In order to award CME/CE credit, please indicate the duration of the education.	Education duration: _____ hours and _____ minutes <i>Please report time in 15-minute increments.</i>
Discuss with learners the changes they intend to make to their strategies, performance, or patient care that will result from this activity and list that information to the right. Example: I will use the evidence-based checklist we discussed to improve screening my patients for past military service.	Changes learners intend to make to strategies, performance, or patient care:
After the activity, please collect attendance and learner change information for the activity and send it to the continuing education department in order for credit to be awarded. You can also list the attendees on the back of this form.	



Note for Continuing Education Staff

This completed form provides the necessary information to demonstrate the professional practice gap and underlying needs, expected results, appropriate format, changes in learners, independence, and administrative information needed to award credit to learners. Please enter this activity in ACCME PARS following your usual process, and provide to learners your accreditation statement, the credit designation statement, and any applicable MOC statements. If you have awarded MOC credit, please report learners in PARS within 30 days of the education. For questions or assistance, contact ACCME at info@accme.org.