

To comply with **Standard 3: Identify, Mitigate and Disclose Relevant Financial Relationships** of the **Standards for Integrity and Independence in Accredited Continuing Education**, <https://accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce>, all relevant financial relationships between individuals in control of content and **ineligible companies** must be mitigated.

**Ineligible companies** (previously referred to as a **commercial interest**) are those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

**The following steps must be followed prior to the individual assuming their role in the accredited CE.**



- Collect information about financial relationships
- Exclude owners or employees of ineligible companies (uncommon)
- Identify relevant financial relationships
- Mitigate relevant financial relationships
- Disclose to learners

#### ➤ **Collect information about financial relationships**

Any individual who may have a role in controlling the CE must complete the CCEHS COI Disclosure Form, <http://cce.upmc.com/COI>, to share all financial relationships with ineligible companies during the past 24 months. Disclosure information must include the name of the ineligible company with which the person has a financial relationship and the nature of the financial relationship.

#### **What are examples of ineligible companies?**

Examples of ineligible companies include:

- Pharmaceutical companies or distributors
- Device manufacturers or distributors
- Manufacturers of health-related wearable products
- Bio-medical startups that have begun a governmental regulatory approval process
- Diagnostic labs that sell proprietary products
- Pharmacy benefit managers
- Reagent manufacturers or sellers
- Compounding pharmacies that manufacture proprietary compounds
- Growers, distributors, manufacturers or sellers of medical foods and dietary supplements
- Advertising, marketing, or communication firms whose clients are ineligible companies

**Are there examples of companies that financial relationships do not need disclosed? For example, if an individual is a consultant for an electronic health records company, does this need disclosed?**

Financial relationships with the following types of companies do not need disclosed:

- Ambulatory procedure centers
- Blood banks
- Diagnostic labs that do not sell proprietary products
- Electronic health records companies
- Government or military agencies
- Group medical practices
- Health law firms
- Health profession membership organizations
- Hospitals or healthcare delivery systems
- Infusion centers
- Insurance or managed care companies
- Pharmacies that do not manufacture proprietary compounds
- Nursing homes
- Publishing or education companies
- Rehabilitation centers
- Software or game developers
- Schools of medicine or health science universities

### Who needs to disclose?

Anyone who may have a role in controlling the CE content to disclose all financial relationships they have had over the past 24 months with ineligible companies (drug, device, and other ineligible companies).

#### Planners

Examples: Planning committees, CE staff, editors, activity directors

#### Faculty/Teachers

Examples: Speakers, panelists, instructors, trainers, coaches, educational consultants

#### Authors

Examples: Writers, editors, instructional designers, content developers, educational researchers,

#### Reviewers

Examples: Peer reviewers, editors

### What are considered the general responsibilities of the planning committee?

The general responsibilities of the planning committee are making decisions related to the scope and direction of the content, educational goals, identification of practice gaps and needs, selecting speakers, authors, reviewers.

### What are the responsibilities of someone identified as faculty/teacher/speaker?

The responsibilities of someone identified as faculty/teacher/speaker are teaching, writing, producing and/or delivering education.

### What types of financial relationships need to be disclosed?

All financial relationships with ineligible companies regardless of the dollar amount or relevance to the education. **Examples include:**

- **Grant/Research Support:** 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.)
- **Consultant**
- **CE Speakers' Bureau**
- **Stockholder (privately held):** 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 planning or implementation of the education.
- **Stockholder (publicly traded):** Individuals who own stock in publicly traded ineligible companies are not considered owners or employees.
- **Other:** employee, owner, advisor, independent contractor, royalties or patent beneficiary

#### Note:

\*Mutual funds and pension plans do not need to be disclosed.

\*Owners or employees of an ineligible company must be excluded from planning or implementation of the CE

### Is there a minimum dollar amount?

There is no minimum financial threshold; individuals must disclose all financial relationships, regardless of the amount, **with ineligible companies.**

### Does the individual need to report relationships that they consider not relevant to the content of the CE?

Individuals must disclose regardless of their view of the relevance of the relationship to the education.

### Are there any exceptions that allow an individual to participate without providing disclosure information?

The only exception is if the content of the CE is non-clinical (i.e., communication, leadership). In this scenario, the course contact should work with CCEHS to document the exception.

### What happens if a person refuses to provide the requested disclosure information?

The Standards for Integrity and Independence require that individuals who refuse to provide this information are disqualified from involvement in the planning and implementation of accredited continuing education.

## ➤ Exclude owners or employees of ineligible companies (uncommon)

Review the disclosed relationships and **exclude owners and employees of ineligible companies** from participating as planners, faculty, or other roles.

### **Why are owners or employees of ineligible companies excluded from participating as planners, faculty/teachers, authors, and reviewers in accredited CE?**

Owners and employees of ineligible companies have a legal duty to act in their company's best interests. They are considered to have unresolvable financial relationships and must not be allowed to influence or control planning, delivery, or evaluation of accredited CE

### **Are there any exceptions?**

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. **Any exceptions must be approved by CCEHS.**

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 use

## ➤ Identify relevant financial relationships

Review the disclosed relationships and determine which financial relationships with ineligible companies are relevant to the content of the education.

**NOTE:** The **Management of COI Grid**, [http://cce.upmc.com/COI\\_grid](http://cce.upmc.com/COI_grid) must be completed and submitted to document the mitigation strategies. **Exception:** Regularly Scheduled Series (RSS) activities document the identification and mitigation of relevant financial relationships using the **CE Information Sheet**.

### **What is considered a relevant financial relationship?**

Financial relationships, in any amount during the past 24 months, between the individual in control of content and an ineligible company are relevant if the content of the education is related to the products of an ineligible company with whom the person has a financial relationship. The two questions below help determine if the relationship is relevant:

1. If the content is non-clinical (i.e., leadership skills, communication skills), the relationships are not relevant. is the content non-clinical?
2. If the content that the person can control is related to the products or business lines of the ineligible company, the relationship is relevant. Is the content of the CE activity that the person can control related to the products or business lines of the ineligible company?

### **Can the individual with the financial relationship determine if the relationship is relevant?**

No, the individual reporting the relationship cannot be the person to determine if the relationship is relevant. Generally, this is designated to the CCEHS contact assigned to the activity, the course director (or designee) or a member of the planning committee.

### **What if planning has already started at the time CE credits are requested?**

Accreditation guidelines require the identification and mitigation of relevant financial relationships **PRIOR TO** the individual assuming their role in the activity. For this reason, applications **MUST** be received early in the planning stages and include the disclosure of financial relationships of the planning committee.

-If relevant financial relationships are identified, the activity may be denied if the individual has already contributed to the content of activity.

-If planning has already started at the time CE credits are requested and there are no relevant relationships identified, CE credits may be considered.

## ➤ Mitigate relevant financial relationships

Before the individual assumes their role in the CE activity, steps must be taken to mitigate **relevant financial relationships** from inserting commercial bias into content.

**Note:** The **Management of COI Grid**, <http://cce.upmc.com/coi> must be completed and submitted to document the mitigation strategies. Exception: Regularly Scheduled Series (RSS) activities document the identification and mitigation of relevant financial relationships using the **CE Information Sheet**.

### **Who is responsible for mitigation?**

Generally, mitigation is the responsibility of a course director (or designee) or a member of the planning committee with no relevant relationships.

### **What if a course director has relevant relationships?**

If a course director has relevant relationships, these relationships should be mitigated by a co-course director with no relevant relationships or CCEHS. Alternatively, the mitigation can be delegated to CCEHS.

### **What are mitigation strategies?**

Mitigation strategies are approaches implemented to reduce or eliminate any opportunity for commercial bias influencing the content of the CE activity. The following mitigation strategies may be implemented depending on the individual's role in the CE activity.

- Mitigation of planning Committee (multiple may be used):
  - The content of the presentation is non-clinical (e.g., leadership, communication skills, etc.)
  - End the financial relationship (including having ended the relationship within 24 months).
  - Recuse individual from controlling aspects of planning with which there is a financial relationship.
  - Peer review planning decisions and determinations by persons without relevant financial relationships.
- Mitigation of faculty/teachers/presenters, authors (multiple may be used):
  - The content of the presentation is non-clinical (e.g., leadership, communication skills, etc.)
  - End the financial relationship (including having ended the relationship within 24 months).
  - Recuse individual from controlling aspects of content with which there is a financial relationship.
  - Peer review of content by persons without relevant financial relationships.
  - **(most common)** Attest that clinical recommendations are evidence-based and free of commercial bias (e.g., peer-reviewed literature, adhering to evidence-based practice guidelines).

**Note:** 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 planning or implementation of the education**.

### **What if mitigation strategies for faculty/presenters cannot be implemented prior to the individual assuming their role in the activity? Is it acceptable not to award credit for a specific presentation?**

If mitigation strategies cannot be implemented, CE credits should not be awarded for that content. In addition, the CCEHS must be notified of the change.

**Note:** If the credit is not awarded for content in conjunction with accredited content, learners must be able to easily distinguish between accredited and nonaccredited content and there must be 30-minute intervals between accredited and nonaccredited content. For specific guidance visit, <http://cce.upmc.com/coi> .

## ➤ Disclose to learners

**Before learners engage in the accredited CE**, disclose all relevant financial relationships to learners including:

- The names of the individuals with relevant financial relationships.
- The names of the ineligible companies with which they have relationships and the nature of the relationships.
- A statement that all relevant financial relationships have been mitigated or the absence of relevant financial relationships (if applicable).

**Note:** A template outlining audience disclosure requirements will be provided by CCEHS.

### **What statement is used if someone in control of content discloses relevant financial relationships?**

The following statement must be used if someone in control of content discloses relevant financial relationships:

All individuals in a position to control the content of this education activity have disclosed all financial relationships with any companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. All of the relevant financial relationships for the individuals listed below have been mitigated

- The names of the individuals with relevant financial relationships, the name(s) of the ineligible companies with which they have relationships, and the nature of the relationships.

No other members of the planning committee, speakers, presenters, authors, content reviewers and/or anyone else in a position to control the content of this education activity have relevant financial relationships with any companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

### **What statement is used if no relevant financial relationships with ineligible companies are identified?**

The following statement must be used if no relevant financial relationships with ineligible companies are identified:

No members of the planning committee, speakers, presenters, authors, content reviewers and/or anyone else in a position to control the content of this education activity have relevant financial relationships with any companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

### **Where is the statement(s) disclosed?**

Disclosure to learners must be in a format that can be verified at the time of accreditation. Generally, this information is included as the front matter of the course syllabus, landing page of online module/course page, first slide in a presentation or emailed electronically prior to the course, or a combination. It is acceptable to include in the CCEHS online course landing page if the audience has access to the page prior to the date of the activity.

### **Additional Resources:**

- Standards for Integrity and Independence in Accredited Continuing Education, <https://accme.org/standards>
- Conflict of Interest Disclosure Form, <http://cce.upmc.com/COI>
- Email [ccehssupport@upmc.edu](mailto:ccehssupport@upmc.edu)