

## **How to Manage Financial Relationships in Continuing Education Activities**

To maintain a learning environment free from industry bias and to ensure that all content is evidence-based, we need to identify and appropriately manage financial relationships with certain companies. This ensures transparency and fairness.

### **The person (*the Reviewer*) mitigating a disclosure should:**

- Not have any financial relationships with ineligible companies.
- Should be a planning committee member of the educational activity.
- Review and mitigate, if necessary, every financial relationship disclosed by the individual (planning or faculty member)

\*\*\*\*Complete Step 1 on disclosure form

## **Key Steps to Address Financial Relationships**

### **1. Identify financial relationships**

- Review **all** financial relationship(s), within the last 24 months of anyone in control of content. You are looking for all relationships with an ineligible company.

**Definition:** An **ineligible company** is an entity whose primary business is producing, marketing, selling, re- selling or distributing healthcare products used by **or on patients**. Another term for ineligible is commercial.

Examples include :

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

**All financial relationships regardless of the amount should be disclosed including the:**

- Name of the company
- Role/Nature of the relationship (*i.e., employee, contractor, royalties, advisor, consultant, etc.*)

**2. Owner/employee relationships**

- Is the individual an owner or employee of any ineligible company?

\*\*\*\*Complete Steps 2 on disclosure form

**3. Privately held Stock**

- Does this person own any privately held stock? Privately held stock is stock from a company that is not traded on the stock exchange, usually a start-up company.

\*\*\*\*Complete Step 3 on disclosure form

**4. Government Regulatory Process**

- If the person owns private stock, check to see if the company has started the government regulatory process for any of their products. To do this please visit, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm> Here you can search to see if the company has entered the regulatory process.

The screenshot shows the 'Establishment Registration & Device Listing' page on the FDA website. At the top, there are navigation links for 'FDA Home', 'Medical Devices', and 'Databases'. The main content area is divided into two columns. The left column contains a search form with the following fields: 'Establishment or Trade Name', 'Owner/Operator Name', 'Proprietary Name', 'Product Code', 'Establishment State (U.S.)', 'Registration or FEI Number', 'Owner/Operator Number', 'Classification Device Name', 'Establishment Type', and 'Establishment Country \*'. There are 'Quick Search', 'Clear Form', and 'Search' buttons at the bottom of the form. The right column is titled 'Other Databases' and lists various FDA resources such as '510(k)s', 'De Novo', 'Medical Device Reports (MAUDE)', 'CDRH Export Certificate Validation (CECV)', 'CDRH FOIA Electronic Reading Room', 'CFR Title 21', 'CLIA', 'Device Classification', 'FDA Guidance Documents', 'Humanitarian Device Exemption', 'Medsun Reports', 'Premarket Approvals (PMAs)', 'Post-Approval Studies', 'Postmarket Surveillance Studies', 'Radiation-Emitting Products', 'Radiation-Emitting Electronic Products Corrective Actions', 'Recalls', 'Standards', 'Total Product Life Cycle', and 'X-Ray Assembler'.

\*\*\*\*Complete Step 3A of the disclosure form

**5. Diagnostic/Therapeutic Options**

- Will diagnostic and/or therapeutic options be presented or discussed in the educational activity?

\*\*\*\*Complete Step 3B of the disclosure form

## 6 Determine Relevance

- Determine if any of the financial relationship(s) are relevant to the content.



*CME content does not have to explicitly mention or promote the business lines or products of an ineligible company for there to be an opportunity for commercial bias. Financial relationships are relevant if the educational content an individual **CAN** control is related to the business lines or products of the ineligible company.*

*It is insufficient to simply refrain from discussing the specific product or service of the company. Ask yourself, is there an opportunity to insert bias towards the company(ies) disclosed/and its products.*



For example, if the educational content is about *Treating 4 Common Types of Cardiovascular Disease*, and the speaker disclosed a financial relationship (as a consultant) with Pfizer, then the content does relate to the business lines of the eligible company (Pfizer).

\*\*\*\*Complete Step 4 of the disclosure form

## 7. Determine which financial relationships need to be mitigated

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

\*\*\*\*Complete Step 5 of the disclosure form

## 8. Choose a mitigation strategy

If you selected any of the boxes above, we must mitigate the relationship.

Using the list below, choose a mitigation strategy(ies). This must be done,

before the person assumes their role.



Please pay close attention to the *individual's role* in the activity. If they are a planner, you must choose a mitigation strategy from the **For Planners ONLY** section. If an individual is both a planner and a faculty member then each role must be mitigated by choosing an option in **each** column.

Select a mitigation strategy from the list below and from the appropriate column.

<u>Choose Your Mitigation Strategy</u>	
<u>For Planners ONLY</u>	<u>For Faculty and Others</u>
<ul style="list-style-type: none"><li>Recusal from controlling aspects of planning (including faculty selections and selections of content) with which there is a financial relationship.</li></ul> <p><b>This strategy means the planner did not participate in selecting the faculty and/or content.</b></p>	<ul style="list-style-type: none"><li>Peer review of content by persons without relevant financial relationships.</li></ul> <p><b>This strategy means a planning member without any relevant financial relationships will review the content.</b></p>
<ul style="list-style-type: none"><li>Peer review of planning decisions by persons without relevant financial relationships.</li></ul> <p><b>This strategy means planning decisions will be reviewed by another planning member without any relevant financial relationships.</b></p>	<ul style="list-style-type: none"><li>Attest that clinical recommendations are evidence-based and free of commercial bias (i.e. <i>peer-reviewed literature, adhering to evidence-based practice guidelines</i>)</li></ul> <p><b>This strategy is used to have the IPCE office send an attestation letter to the individual with relevant financial relationships.</b></p>
<ul style="list-style-type: none"><li>Divest the financial relationship/relationship has ended.</li></ul> <p><b>This means the financial relationship is over and no longer exists.</b></p>	<ul style="list-style-type: none"><li>Divest the financial relationship/relationship has ended.</li></ul> <p><b>This means the financial relationship is over and no longer exists.</b></p>

#### Documenting the Mitigation Strategy

It is very important to document all the mitigation strategies that were used for relevant financial relationships. Make sure to be specific in your documentation.

In the first column, provide the name of the person who has disclosed the financial relationship and their role in the activity (*i.e., planner, faculty, reviewer, consultant speaker, etc.*)

The second column should document the steps taken to mitigate the relevant financial relationship. Remember, the name(s) of the individual(s) who are conducting the disclosure review must be included.

<b>Name of Person with Relevant Financial Relationship and their Role in Activity</b>	<b>Step(s) Taken to Mitigate Relevant Financial Relationship</b> Choose at least one option from the mitigation strategies listed above. Be specific in your description and provide names if necessary	<b>Date Implemented</b> (must be before persons' role is assumed)
<i>Example: Jane Doe, Planner</i>	<i>Peer review of planning decisions by persons without relevant financial relationships – reviewed by (provide name)</i>	<i>Enter date mitigation was done</i>
<i>Example: John Doe, Faculty</i>	<i>Peer review of content by persons without relevant financial relationships</i>	<i>Enter date mitigation was done</i>
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Rush Conflict of Interest Form Updated 1024