EVERYTHING STANDARD 3
- Including the Kitchen Sink –

April 2023
STANDARD 3: IDENTIFY, MITIGATE, AND DISCLOSE RELEVANT FINANCIAL RELATIONSHIPS
STANDARD 3 applies to **ALL** accredited continuing education

Many healthcare professionals have financial relationships with ineligible companies.

These relationships must not be allowed to influence accredited continuing education.
1ST PHASE: IDENTIFICATION, WHICH INVOLVES “COLLECTION”

You must collect from all individuals in control of content.

- Planners:
  - CME Staff, Course Director, CME Committee
- Faculty Presenters:
  - Speakers, Panelists, Moderators
- Reviewers:
  - Peer reviewers, CME Staff
WHAT DO YOU COLLECT?

• **All** of their financial relationships with ineligible companies (commercial interests).
  - Regardless of the amount
  - Regardless of their view of the relevance of the relationship to the education*
  - Within the prior 24 months

The CME provider is now fully responsible for determining relevancy.*
A Disclosure Form is one mechanism that providers can use.

Other mechanisms could include:

- Collecting the information verbally and recording it in a spreadsheet, table, or database
- Collecting disclosure information electronically (i.e., via e-mail, web-based form, or database)
FOR EACH FINANCIAL RELATIONSHIP, DISCLOSURE INFORMATION MUST INCLUDE:

- Name of ineligible company
- Nature of the relationship
  - Consultant
  - Speakers Bureau
  - Grant/Research Support
  - Principal Investigator
  - Board Member
  - Stock Shareholder
  - Employee/Owner
  - Other
WHAT IF A RELATIONSHIP HAS ENDED?

If a relationship has ended within the last 24 months, you no longer have anything to mitigate.

However, you should still disclose the financial relationships to your learners.

<table>
<thead>
<tr>
<th>Nature of Financial Relationship</th>
<th>Name of Ineligible Company(s)</th>
<th>Has the relationship ended?</th>
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</thead>
<tbody>
<tr>
<td>☐ Consultant</td>
<td>Click here to enter text.</td>
<td>☐ Yes</td>
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<td>☐ Board Member</td>
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<tr>
<td>☐ Stock Shareholder (Privately held, self-managed)</td>
<td>Click here to enter text.</td>
<td>☐ Yes</td>
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<tr>
<td>☐ Stock Shareholder (Publicly traded, pension/mutual fund and/or self-managed)</td>
<td>Click here to enter text.</td>
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<tr>
<td>☐ Full-time/part-time Employee/Owner*</td>
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<tr>
<td>☐ Other (Describe):</td>
<td>Click here to enter text.</td>
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MANAGING USE OF EMPLOYEES/OWNERS OF INELIGIBLE COMPANIES

These individuals must be excluded from controlling content or participating as planners or faculty in accredited education.

There are three exceptions to this exclusion!
WHAT ARE THE EXCEPTIONS?

EXCEPTION #1
When the content of the activity is not related to the business lines or products of their employer/company.
EXCEPTION #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.
EXCEPTION #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.
DOES STOCK OWNERSHIP CREATE AN EMPLOYEE/OWNER RELATIONSHIP?

If an individual is an owner of stock in a company that is **privately held**, that individual would be considered by ACCME to be an owner of the company. This relationship is not mitigatable.

If stock/stock options are in **publicly traded companies**, and the financial relationships are relevant to the CME content, those relationships are mitigatable and should be disclosed to learners.

**NOTE:**
ACCME does not require individuals who control CME content to disclose **diversified mutual funds**, but any other stocks or stock options should be disclosed to the provider.
**Publicly Traded Company**

A company that has sold all or a portion of itself to the public via an initial public offering, meaning shareholders have a claim to part of the company’s assets and profits.

They can tap the financial markets by selling stock to raise capital.

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**Privately Held Company**

The company is owned by its founders, management, or a group of private investors.

A private company cannot dip into the public capital markets and must rely on private funding.
ISMA now differentiates on our Financial Disclosure Form

<table>
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<tr>
<td>Other (Describe):</td>
<td>Click here to enter text.</td>
<td>☐ Yes</td>
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*Requires Owner/Partner verification.
Are patent holders who receive royalty payments from ineligible companies considered to be owners of those companies?

NO

The ACCME advises that 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 to mitigate.
IDENTIFICATION INVOLVES “DETERMINING RELEVANCY”

The accredited provider is responsible for identifying relevant financial relationships.

- Faculty/speakers can no longer self determine relevancy -

**RINSE + REPEAT**

Individuals must disclose regardless of their view of the relevance of the relationship to the education.
WHEN ARE FINANCIAL RELATIONSHIPS “RELEVANT?”

Standard 3.3 states:

“Financial Relationships are relevant if the educational content an individual can control is related to the business lines or products of the ineligible company.”

This is plural and not singular
Consider the process you use to determine which financial relationships are relevant to the educational content.

LET'S HEAR FROM YOU
Did you find the content of the CE activity the person can control is related to the products or business lines of the ineligible company?

- Faculty
- Content
- Business Line
ALWAYS DO YOUR ONLINE RESEARCH OF THE INELIGIBLE COMPANY(S)
If the ineligible company has a product line related to the topic, but the subject matter is not related to the planner or speaker’s area of practice/expertise………………

• Is there a conflict of interest?
• Is the relationship with the company relevant?
• Do you need to disclose the relationship to the learners?
2\textsuperscript{ND} PHASE: MITIGATION

Before a person assumes their role in a CME activity, you must take steps to prevent all those with relevant financial relationships from inserting commercial bias into the content.
STEPS FOR PLANNERS WILL LIKELY BE DIFFERENT THAN FOR FACULTY

And would occur before planning begins.
MITIGATION FOR PLANNERS

Those making decisions related to the scope and direction of the content, educational goals, identification of practice gaps and needs, selecting speakers, authors, and reviewers. If a planner or reviewer discloses a financial relationship, here are options that can be considered to mitigate the relationship.

• **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
MITIGATION FOR FACULTY/PRESENTERS

This is teaching, writing, producing and delivering education. If a faculty presenter discloses a financial relationship, here are options that can be considered to mitigate the relationship.

- **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 that clinical recommendations are evidence-based and free of commercial bias** (e.g., peer-reviewed literature, adhering to evidence-based practice guidelines)
MITIGATION IN GENERAL

• Planners and other content experts can help determine relevance of relationships, if necessary.

• Keep in mind that simply monitoring the CME content for commercial bias at the time of presentation is **not** an acceptable mitigation mechanism.

• When providers identify relevant relationships, they must direct authors/teachers to take actions to assist in the mitigation.
DOCUMENT THE STEPS TAKEN TO MITIGATE RELEVANT FINANCIAL RELATIONSHIPS

You will be asked about this at reaccreditation time during PIP activity review.
## COI Mitigation (Resolution) Spreadsheet for Use with Individual Activities

<table>
<thead>
<tr>
<th>Name of Individual</th>
<th>Individual's Role(s) in Activity</th>
<th>Name of Commercial Interest(s)</th>
<th>Nature of Relationship(s)</th>
<th>Mechanism(s) implemented to resolve conflict of interest appropriate to role(s) in the activity</th>
</tr>
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<tbody>
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</tbody>
</table>

Record the steps you took in a spreadsheet, table, or database
This is another mechanism providers might use.

### COI Mitigation (Resolution) Form

**FOR CME OFFICE USE ONLY**

#### MITIGATION OF CONFLICTS OF INTEREST

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Owners/ Employees of Ineligible Company (IC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>Not an employee/owner of IC (go to Step 2)</td>
</tr>
<tr>
<td>☐</td>
<td>Planning Committee employee/owner of IC (choose from below):</td>
</tr>
<tr>
<td>☐</td>
<td>No planning has occurred – individual is fully recused from committee</td>
</tr>
<tr>
<td>☐</td>
<td>Planning has occurred – activity will not be accredited</td>
</tr>
<tr>
<td>☐</td>
<td>Faculty/speaker employee/owner of IC (choose from below):</td>
</tr>
<tr>
<td>☐</td>
<td>Faculty/speaker is not allowed to present</td>
</tr>
<tr>
<td>☐</td>
<td>Activity will not be accredited</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 2</th>
<th>Conflict of Interest (COI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>No relevant financial relationship (no COI)</td>
</tr>
<tr>
<td>☐</td>
<td>Potential COI – presenter (choose from below):</td>
</tr>
<tr>
<td>☐</td>
<td>Presentation materials reviewed to ensure fair balance, scientific objectivity and no commercial bias</td>
</tr>
<tr>
<td>☐</td>
<td>Presenter will refrain from making recommendations on topics of COI</td>
</tr>
<tr>
<td>☐</td>
<td>All recommendations for patient care are based on peer review data</td>
</tr>
<tr>
<td>☐</td>
<td>Discontinue contracted services that create financial relationship – must disclose such relationship to audience for 24 months</td>
</tr>
<tr>
<td>☐</td>
<td>Individual excluded from content creation and delivery, was replaced with another presenter</td>
</tr>
<tr>
<td>☐</td>
<td>Activity will not be accredited</td>
</tr>
<tr>
<td>☐</td>
<td>Potential COI - planner</td>
</tr>
<tr>
<td>☐</td>
<td>Planner recused from planning content relevant to reported COI</td>
</tr>
<tr>
<td>☐</td>
<td>Another non-conflicted planner will participate in planning to ensure fair balance; non-conflicted planner will review proposed content to ensure it is free from potential bias; non-conflicted planner will oversee selection of faculty</td>
</tr>
</tbody>
</table>
NEW EXCEPTIONS TO DISCLOSURE

Accredited providers do not need to identify, mitigate, or disclose relevant financial relationships for any of the following activities:

• Education that is non-clinical in nature, or
• Where the learner group is in control of content, such as spontaneous case conversations among peers (also referred to as Peer-to-Peer, At the Elbow CME).
WHAT CONSTITUTES A NON-CLINICAL TOPIC?

Education is considered **non-clinical in nature** when it is not providing any type of clinical recommendations in caring for patients but is directly related to their professional work.

When it is not directly related to their professional work, it does not fall within ACCME’s definition of CME content.
EXAMPLES OF NON-CLINICAL TOPICS

- Advocacy and Legislation
- Employment Contracting
- Billing, Coding and Reimbursement
- Telehealth Fraud
- Electronic Medical Records (EMR)
- Social Determinants of Health
- Diversity, Equity and Inclusion
- Improving Physician Communication with Patients
- Practice Management
- Starting Your Own Medical Practice
- Connecting Practice to Research
- Physician Burnout and Well-Being
- Physician Leadership
- Education Basics for Teaching Patients, Families/Caregivers
- Financial Planning for Physicians – Personal Finance for Physicians at Every Stage of Their Career
IN DOUBT WHETHER A TOPIC IS CLINICAL VS. NON-CLINICAL IN NATURE?

I would err on the side of caution and collect disclosure.

FOR EXAMPLE:

The field of Medical Ethics encompasses both practical application in clinical settings and scholarly work in philosophy, history, and sociology. Ethics consultants offer clinical and non-clinical recommendations.

Thus, if an Ethics topic is being presented to you as a non-clinical topic, but you have not yet seen any content or outline for content, you have every right as the accredited provider to question and make the final decision.
WHAT CONSTITUTES SPONTANEOUS CASE CONVERSATIONS?

The exception is meant to apply to spontaneous learning opportunities that previously might not have been considered CME, like team huddles and impromptu leadership discussions.

In these cases, with the guidance of the CME Department, learners can describe the learning opportunity (problem-in-practice and change that resulted)
WHAT SPONTANEOUS CASE CONVERSATIONS ARE NOT!

- Regularly scheduled series
- Case conferences
- Tumor boards

These are not considered “spontaneous case conversations among peers.”

The exception does not apply to conferences or grand rounds that have set times and dates and have traditionally been planned as accredited CME.
The ACCME’s new Quick Tool provides a good framework for planning both of these types of learning opportunities.
The Quick Tool is Part of ACCME’s new Toolkit

https://www.accme.org/standards-resources
Tools and Forms

The ACCME’s new Toolkit contains resources to assist providers in transitioning to the new Standards.

The initial collection of tools focuses on:
- Standard 1: Ensuring Content is Valid

These 2 standards are applicable to all accredited providers, whether or not commercial support is received. Use of these resources is completely optional.
Is there a financial disclosure statement that should be provided to learners for non-clinical program topics?

- No, accredited providers do not need to identify, mitigate, or disclose relevant financial relationships for non-clinical topics.

However, ISMA has begun including the following statement:

“There are no relevant financial relationships with an ineligible company to identify, mitigate or disclose because the content of this activity is non-clinical in nature.”
STANDARD DISCLOSURE
TO LEARNERS TO INCLUDE:
(either individually or as a group)

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

You may use a variety of these:

- Disclosure Grid
- Disclosure Slide @ beginning of presentation
- Disclosure Statement on flyer and/or other advertisement materials
- Verbal Disclosure to audience during presentation
VERBAL DISCLOSURE

The Nuance

While disclosure may be given **verbally** to participants, CME providers must be able to supply the ISMA with **written verification** that appropriate verbal disclosure occurred (especially if this is the only method you use).

A representative of the provider who was in attendance at the time of the education must attest in writing:

- That verbal disclosure did occur, and
- Itemize the content of the disclosed information, or that there was nothing to disclose
OTHER USEFUL TOOLS IN ACCME’S NEW TOOLKIT
Key Steps for the Identification, Mitigation, and Disclosure of Relevant Financial Relationships

A Checklist for CME Staff
providing an overview of the 3-step process and things that are important to consider.

STEP 1: Before you begin planning

STEP 2: Reviewing disclosures and excluding owners/employees of ineligible companies

STEP 3: Determining which relationships are relevant
Sample Letter to Explain Why Financial Relationship Information is Collected

At beginning of planning process, sample language CME providers can use to communicate with prospective planners, faculty and reviewers.

- Why they are receiving the communication
- Why the CME Office is collecting this information
- What the next steps are in the process of mitigation
Template for Collecting Information about All Financial Relationships from Planners, Faculty, and Others

<table>
<thead>
<tr>
<th>Template for Collecting Information about All Financial Relationships from Planners, Faculty, and Others</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>To be completed by education staff.</strong></td>
</tr>
<tr>
<td><strong>Name of Individual:</strong></td>
</tr>
<tr>
<td><strong>Title of Continuing Education:</strong></td>
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<tr>
<td><strong>Date and Location of Education:</strong></td>
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</tbody>
</table>

**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
- 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 us by mail.

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

**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**
An ineligible company is any entity whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. For specific examples of ineligible companies visit accme.org/standards.

**Example:** ABC Company

**Enter the Nature of Financial Relationship**
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 the individual’s institution receives the research grant and manages the funds.

**Has the Relationship Ended?**
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.

<table>
<thead>
<tr>
<th>Consultant</th>
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| In the past 24 months, I have not had any financial relationships with any ineligible company. |
| I attest that the above information is correct as of this date of submission. |

**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.
ISMA Financial Disclosure Form

ISMA did not adopt this form but did update ours to reflect changes in the new Standards.

• Did not change to term CE, but left CME (Continuing Medical Education)
• Removed mention of and request for disclosure of spouse/partner
• Removed columns in grid for Self vs. Spouse/Partner and added “Has relationship ended?”
• Changed look-back on relationships from 12 to 24 months
• Changed section on Relevant Financial Relationships to All Financial Relationships
• Changed term “commercial interest” to “ineligible company”
• Changed term “resolved” to “mitigated”
• Updated Statements/Rules of ISMA Content Validation on form to include:
  – 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 the accredited provider 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.

• Within Glossary of Terms, updated:
  – Definition of “Commercial Interest,” now called “Ineligible Entity”
  – Definition of “Relevant Financial Relationships”
ISMA Financial Disclosure Form

DISCLOSEMENT OF FINANCIAL RELATIONSHIP FORM

Name/Credentials: Click here to enter text.

Telephone Number: Click here to enter text. E-Mail Address: Click here to enter text.

Activity Name: Click here to enter text. Date: Click here to enter text.

Please indicate your role in this CME activity: [ ] Presenter/Faculty [ ] Course Director [ ] Moderator [ ] Planning Committee (Please check all that apply)

Purpose: It is the policy of the Indiana State Medical Association (ISMA) to ensure balance, independence, objectivity and scientific rigor in all of its sponsored educational activities. All participating faculty, course directors, and planning committee members are required to disclose to the program audience any financial relationships related to the subject matter of continuing medical education (CME) activities/programs. Disclosure information is reviewed in advance in order to manage and resolve any possible conflicts of interest. This information is necessary to allow for us to be able to move to the next steps in planning the CME activity.

Persons who fail to provide this information in advance of the course (allowing for adequate time for review) are not eligible to be involved in this CME activity.

Participation: We are pleased that you are willing and able to participate in this CME activity, which is accredited by the ISMA. The ISMA is accredited by the Accreditation Council for Continuing Medical Education (ACCME). As such, we are required to meet the ACCME’s expectations for our practice of continuing medical education.

Step 1: Disclosure of All Financial Relationships

Please disclose all financial relationships that you have had in the past 24 months with ineligible companies (see definition in Glossary or Terms). 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, in any amount, with ineligible companies. You should disclose relationships regardless of the potential relevance of each relationship to the education.

Regarding your role in this CME activity (check one):

[ ] No. In the past 24 months, I have not had any financial relationships with an ineligible company.

[ ] Yes. I do have a personal financial relationship with an ineligible company (Provide information below)

Nature of Financial Relationship

Name of Ineligible Company(s)

Has the relationship ended?

[ ] Consultant

[ ] Speaker’s Bureau

[ ] Grant/Research Support

[ ] Principal Investigator

[ ] Board Member

[ ] Stock Shareholder (self-managed)

[ ] Full-time/part-time Employee/Owner*

[ ] Other (Describe): Click here to enter text.

* The ISMA PROHIBITS employees and owners of Ineligible Companies from participating on any CME PLANNING COMMITTEE and serving as presenters.

Additional information may be requested to address any perceived conflict of interest. All identified conflicts of interest must be mitigated in advance of the activity and disclosure information will be shared with activity participants.

Step 2: Speaker Disclosure of Off-Label and/or Investigational Uses

If at any time during my educational activity, I discuss an off-label/investigative use of a commercial product/device, I understand that I must provide disclosure of that intent.

[ ] No, I do not intend to discuss an off-label/investigative use of a commercial product/device.

[ ] Yes, I do intend to discuss off-label/investigative use(s) of the following commercial product(s)/device(s):

Click here to enter text.

Step 3: ISMA Statements & Rules to Ensure Content Validation

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 CME activities offering continuing education for patient care 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. Citations of the work are recommended.
- The content and/or presentation of the information with which I am involved will promote quality improvements in healthcare and will not promote a specific business interest of a commercial interest.
- Recommendations involving diagnosis and treatment discussed in the presentation are based on evidence which is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patient.
- 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 the accredited provider to facilitate engagement with these topics without advocating for, or promoting, practices that are not, or are not 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 manner 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.
- I understand that ISMA CME staff will review my presentation and/or content prior to the activity, and I will provide educational content and resources in advance, as requested.
- I understand that commercial entity corporate names or logos should not appear on any slides or handouts.
- I understand that ISMA CME staff may be attending the event to ensure that my presentation is educational, and not promotional, in nature.
- If I am discussing specific health care products or services, I will use generic names to the extent possible. If I need to use trade names, I will use trade names from several companies when available, and not just trade names from any individual company.
- If I have been trained or utilized by a commercial entity or its agent as a speaker (e.g. speaker's bureau for any ineligible company, the promotional aspects of the presentation will not be included in any way with this activity).
- If I am presenting research funded by a commercial company, the information presented will be based on generally accepted scientific principles and methods and will not promote the commercial interest of the funding company.
- If I am presenting research studies, I will include weaknesses and strengths of each study, in addition to harms and benefits of specific products. I will also discuss studies presenting different conclusions about the product, if available.

If you have any questions regarding your ability to comply, please contact Jessica Davis, CME Coordinator, at 317-261-2000, or by e-mail at jessica.davis@ismanet.org

Step 4: Declaration

I will uphold the ISMA CME standards to ensure balance, independence, objectivity, and scientific rigor in my role in the planning, development or presentation of this continuing education activity. I understand that CME accreditation guidelines prohibit me from accepting any reimbursement (financial, gifts, or in-kind exchange) for this presentation from any source other than the accredited CME provider or its educational partner (or fiscal agent).

Signature/Printed Name: Click here to enter text. Date: Click here to enter text.

If sending this completed document electronically, please type your name above and check this box:

[ ] By checking this box, I attest that the completed information is accurate. Please accept this as my signature.

Thank you for providing us with this information.

RETURN TO: Jessica Davis, CME Coordinator, at jessica.davis@ismanet.org
ISMA Financial Disclosure Form

Glossary of Terms as Defined by the American Council on Continuing Medical Education (ACCME)

**Ineligible Company (formerly known as “Commercial Interest”)**

The ACCME defines an “ineligible company” as those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

**Financial Relationships**

Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received, or expected.

**Relevant Financial Relationships**

ACCME focuses on collecting information about all financial relationships with ineligible companies within the prior 24 months. There is no minimum financial threshold; individuals must disclose all financial relationships, regardless of the amount, with ineligible companies. Individuals must disclose regardless of their view of the relevance of the relationship to the education. Inherent in any amount is the incentive to maintain or increase the value of the relationship. The ACCME classifies financial relationships as “relevant” if the educational content an individual can control is related to the business lines or products of the ineligible company.

**Conflict of Interest**

Circumstances create a conflict of interest when an individual has an opportunity to affect CME content about products or services of an ineligible company with which he/she has a financial relationship. The ACCME considers “content of CME about the products or services of that commercial interest” to include content about specific agents/devices, but not necessarily about the class of agents/devices, and not necessarily content about the whole disease class in which those agents/devices are used.

### MITIGATION OF CONFLICTS OF INTEREST

#### Step 1

Owners/Employees of **Ineligible Company (IC)**

- [ ] Not an employee/owner of IC (go to Step 2)
- [ ] Planning Committee employee/owner of IC (choose from below):
  - [ ] No planning has occurred – individual is fully recused from committee
  - [ ] Planning has occurred – activity will not be accredited
- [ ] Faculty/speaker employee/owner of IC (choose from below):
  - [ ] Faculty/speaker is not allowed to present
  - [ ] Activity will not be accredited

#### Step 2

**Conflict of Interest (COI)**

- [ ] No relevant financial relationship (no COI)
- [ ] Potential COI – presenter (choose from below):
  - [ ] Presentation materials reviewed to ensure fair balance, scientific objectivity and no commercial bias
  - [ ] Presenter will refrain from making recommendations on topics of COI
  - [ ] All recommendations for patient care are based on peer review data
  - [ ] Discontinue contracted services that create financial relationship – must disclose such relationship to audience for 24 months
  - [ ] Individual excluded from content creation and delivery, was replaced with another presenter
  - [ ] Activity will not be accredited
  - [ ] Potential COI - planner
    - [ ] Planner recused from planning content relevant to reported COI
    - [ ] Another non-conflicted planner will participate in planning to ensure fair balance; non-conflicted planner will review proposed content to ensure it is free from potential bias; non-conflicted planner will oversee selection of faculty

Reviewed/Submitted by: ____________________________ Date: ______________

Updated: May 2021
Worksheet for the Identification and Mitigation of Relevant Financial Relationships of Planners, Faculty, and Others

Use this 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.
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, reselling, or distributing healthcare products used by or on patients. For information about exceptions to this exclusion, see acmec.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 planning decisions 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
- Recusal from topics/faculty selection
- Peer review of content by persons without relevant financial relationships
- Peer review of evidence-based clinical recommendations
- Use other methods (please describe):

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

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

Takes the place of the Flowchart for Resolution of Personal Conflicts of Interest

You may adopt this form to record/document how you mitigated individual relationships, if you desire.
What did that Flowchart for Resolution of Personal Conflicts of Interest look like? (established in 2017)
Examples of Communicating Disclosure to Learners

Uses sample terminology for disclosure statements when there are no relevant relationships AND when there are relevant financial relationships, in a format that can be verified at the time of reaccreditation.

Remember that disclosure must be provided to learners before engaging with accredited education.
Guidance for Planners, Authors, and Faculty: Ensuring Clinical Content is Valid

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 acmec.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 acmec.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 meritous 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”).

ISMA communicates the majority of this information within the Statements/Rules of ISMA Content Validation on pg. 2 of our Financial Disclosure Form.
An example of a tool to facilitate peer review to ensure that clinical content is valid.

The questions direct reviewers to share feedback about each of the requirements that comprise Standard 1.

ISMA will continue to use our own existing Content Review Form.
ACCME and ISMA encourage you to use this checklist to help you ensure nothing is forgotten.


It contains all the factors for you to consider:
- Review your processes
- Change your forms
- Communicate to faculty
Group Discussion