

**Standards for Integrity and Independence...**

**Standard 3 – Identify, Mitigate, and Disclose Relevant Financial Relationships**

[www.accme.org/standards](http://www.accme.org/standards)

Old and New Terminology

OLD TERMINOLOGY	NEW TERMINOLOGY
<p><i>Non-Commercial Interest –</i> Any entity that does not produce, market, re-sell, or distribute healthcare goods and services.</p>	<p><b>Eligible (Organization /) Company –</b> Those organizations whose mission and function are: (1) providing clinical services directly to patients; or (2) the education of healthcare professionals; or (3) serving as fiduciary to patients, the public, or population health; and other organizations that are not otherwise ineligible. Examples can be found at: <a href="https://accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce/eligibility">https://accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce/eligibility</a></p>
<p><i>Commercial Interest –</i> Any entity producing, marketing, re-selling, or distributing healthcare goods or services consumed by or used on patients, or an entity that is owned or controlled by an entity that produces, markets, re-sells or distributes healthcare goods or services consumed by, or used on, patients.</p>	<p><b>Ineligible (Organization /) Company –</b> Those organizations whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. Examples can be found at: <a href="https://accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce/eligibility">https://accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce/eligibility</a></p>
<p><i>Relevant Relationships –</i> Relationships that are expected to result in financial benefit from a commercial interest organization, the products or services of which are related to the content of the educational activity. Such relationships include employment, management positions, independent contractor relationships, other contractual relationships, consulting, speaking, teaching, researcher role, membership on an advisory committee or review panel, board membership, and other activities from which remuneration is received or expected. Evidence of remuneration includes but is not limited to receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (stock and stock options), grants, contracts, or other financial benefit directly or indirectly from the commercial interest.</p>	<p><i>Relevant Relationships –</i> Financial relationships with of any dollar amount are defined as relevant if the educational content is related to the business lines or products of the ineligible company.  Examples of financial relationships include employee, researcher, consultant, advisor, speaker, independent contractor (including contracted research), <b>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.</b> <b>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.</b></p>
<p><i>Conflict of Interest –</i> Presence of relevant financial relationship.</p>	<p><i>Presence of <b>relevant financial relationship</b> between individuals in control of educational content and ineligible companies</i> <b>The term “Conflict of Interest” is no longer used.</b></p>

<p><i>Employees / Owners -</i> Employees or owners of commercial interest organizations are not permitted to serve as planners, speakers, presenters, authors, and/or content reviewers if the content of the educational activity is related to the products or services of the commercial interest organization.</p> <p>Employees or owners of commercial interest organizations are permitted to serve as planners, speakers, presenters, authors, and/or content reviewers if the content of the educational activity is NOT related to the products of the commercial interest organization.</p>	<p><i>Employee / Owner -</i> Owners/employees of ineligible companies are excluded from participating as planners or speakers unless one of the three exceptions apply:</p> <ul style="list-style-type: none"> <li>• When the content of the activity is not related to the business lines or products of their company.</li> <li>• <b>When the content of the approved 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</b></li> <li>• <b>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.</b></li> </ul>
<p><i>Resolution –</i> Method of solving the problem of a conflict of interest by taking one of the actions listed on page 3 of the WNA Conflict of Interest Form.</p>	<p><i>Mitigation -</i> Taking steps to prevent all those with relevant financial relationships from inserting commercial bias into content.</p> <ul style="list-style-type: none"> <li>• Mitigate relationships prior to the individuals assuming their roles.</li> <li>• Take steps appropriate to the role of the individual. For example, steps for planners will likely be different than for faculty and would occur before planning begins.</li> <li>• Document the steps taken to mitigate relevant financial relationships.</li> <li>• <b>Mitigation strategies: See step 4 in the “Process” table below.</b></li> </ul>
<p><i>Disclosures –</i> Information provided to learners before the start of the educational activity content delivery.</p> <ul style="list-style-type: none"> <li>• See Step 6 in the “Process Table” below for requirements.</li> </ul>	<p><i>Disclosure to Learners –</i> Information provided to learners before the start of the educational activity content delivery.</p> <ul style="list-style-type: none"> <li>• Includes all previous requirements: See Step 6 in the “Process Table” below.</li> <li>• Financial disclosure to learners now includes: <ol style="list-style-type: none"> <li>1) Name</li> <li>2) Name of ineligible company with which there is a relationship</li> <li>3) Nature of the relationship</li> <li><b>4) Statement that all relevant financial relationships have been mitigated.</b></li> </ol> </li> </ul>

## Process Steps for Identifying, Mitigating, and Disclosing Relevant Financial Relationships

	OLD PROCESS	NEW PROCESS
WHEN TO DO THIS:	<p>The Nurse Planner (NP) needs to identify, evaluate, resolve, and disclose relevant financial relationships reported from those in control of content.</p> <p>Exception: When a topic could not be related to the products or services of a commercial interest.</p>	<p>The Nurse Planner (NP) needs to identify and evaluate <b>all</b> financial relationships <u>disclosed</u> from those in control of content; <b>mitigate</b> relevant financial relationships; <u>disclose to learners</u> the relevant financial relationships of those who can control content.</p> <p>Exceptions:</p> <ul style="list-style-type: none"> <li>• The content of the activity will only address a <b>non-clinical topic</b> (e.g., leadership, precepting, communication skills training).</li> <li>• <b>RARE:</b> It is for a learner group that is in control of the content entirely (e.g., spontaneous case discussion conversation among peers).* <u>This DOES NOT include CASE CONFERENCES and similar planned activities.</u></li> <li>• <b>RARE:</b> It is a self-directed educational activity where the learner will control their educational goals and report on changes that resulted.*</li> </ul> <p><b>DO NOT identify, evaluate, mitigate, and disclose for non-clinical topics. This will be considered incorrect.</b></p>
Step 1	<p>Identify Relevant Financial Relationships for those in control of content–</p> <ul style="list-style-type: none"> <li>• Ask for information about relevant financial relationships.</li> <li>• Ask for relevant relationships in the past 12 months.</li> <li>• Ask about person and their partner / spouse.</li> <li>• Must include definition of commercial interest (and relevant relationship) when you collect the information.</li> <li>• There is no minimum financial threshold; individuals must disclose relevant financial relationships with ineligible companies, regardless of the amount.</li> <li>• NP signs all COI forms except own.</li> <li>• NP with COI cannot serve as NP.</li> </ul>	<p>Identify <b>all</b> Financial Relationships for those in control of content–</p> <ul style="list-style-type: none"> <li>• Ask them to provide information about <b>all</b> their financial relationships with ineligible companies.</li> <li>• Ask about relationships over the previous <b>24 months</b>.</li> <li>• You <b>no longer ask about spouse / partner</b>.</li> <li>• <b>You must use this definition when you collect the information:</b> “Ineligible companies are those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.”</li> <li>• There is no minimum financial threshold; individuals must disclose all financial relationships with ineligible companies, regardless of the amount.</li> <li>• <b>No NP signature is needed</b> but the NP is considered responsible for the process of correctly identifying, evaluating, mitigating, and disclosing relevant financial relationships.</li> <li>• NP cannot mitigate their own relevant relationship.</li> </ul>
Step 2	<p>Review relationships and exclude owners and employees of a commercial interest from participating in any educational role.</p>	<p>Review <b>all</b> relationships and exclude owners and employees of ineligible companies from participating in any educational role.</p> <p>There are only three exceptions to this rule:</p> <ol style="list-style-type: none"> <li>1. When the content of the activity is not related to the business lines or products of their employer/company; OR</li> </ol>

	<p>Exception - When the content of the activity is not related to the business lines or products of their employer/company.</p>	<p>2. <b>When the content of the approved activity is limited to basic science research</b>, such as pre-clinical research and drug discovery, or the methodologies of research, and they do not make care recommendations; OR</p> <p>3. <b>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.</b></p>
<p>Step 3</p>	<p>Evaluate which reported relevant relationships are relevant to the content of the educational activity.</p> <ul style="list-style-type: none"> <li>• Determine which relationships are with commercial interests and which are not.</li> <li>• Determine which relationships are relevant to the content of the activity.</li> </ul>	<p>Assess and determine (evaluate) which financial relationships are relevant to the content of the educational activity.</p> <p><b>Financial relationships are relevant if the following three conditions are met:</b></p> <ul style="list-style-type: none"> <li>• A financial relationship, in any amount, exists between the person in control of content and an ineligible company.</li> <li>• The financial relationship has existed at any time during the past <b>24 months</b>.</li> <li>• The content of the education is related to the products or business lines of an ineligible company with whom the person has a financial relationship.</li> </ul> <p>Evaluate which reported relevant relationships are relevant:</p> <ul style="list-style-type: none"> <li>• Determine which relationships are with ineligible companies.</li> <li>• Determine which relationships are relevant to the content of the activity.</li> </ul>
<p>Step 4</p>	<p>Resolve conflicts of interest by:</p> <ul style="list-style-type: none"> <li>• Revising the role of the individual so that the relationship is no longer relevant to the educational activity</li> <li>• Not awarding contact hours</li> <li>• Undertaking review of the educational activity to evaluate for balance in presentation, evidence-based content or other indicator of integrity, and absence of bias, AND monitoring the educational activity to evaluate for commercial bias.</li> <li>• Undertaking review of the educational activity to evaluate for balance in presentation, evidence-based content or other indicator of integrity, and absence of bias, AND reviewing participant feedback to evaluate for commercial bias in the activity.</li> <li>• Undertaking review of the educational activity by a <u>content reviewer</u> <b>AND</b> monitoring the educational activity to</li> </ul>	<p><b>Mitigate relevant financial relationships</b> to prevent commercial bias.</p> <p><b>Mitigation steps include at least one of the following:</b></p> <p>Planners:</p> <ul style="list-style-type: none"> <li>• <b>Divesting the relationship</b></li> <li>• Recusal from controlling aspects of planning and content with which there is a financial relationship</li> <li>• Peer review of planning decisions by persons without relevant financial relationships</li> <li>• Other methods – Must describe method in detail</li> </ul> <p>Presenters / Faculty / Others:</p> <ul style="list-style-type: none"> <li>• <b>Divesting the relationship</b></li> <li>• <b>Peer review</b> of content by person without relevant financial relationships</li> <li>• <b>Attestation that clinical recommendations are evidence-based and free of commercial bias</b> (e.g., peer-reviewed literature, adheres to evidence-based guidelines)</li> <li>• <b>Other methods – Must describe method in detail.</b> “Old” methods are acceptable.</li> </ul>

	evaluate for commercial bias in the presentation.	
Step 5	Check the method used on page 3 of the COI Form and sign / date.	<p><b>Document the mitigation strategies</b> used for each person with a relevant financial relationship on the <b>Nurse Planner Mitigation Work Sheet</b>.*</p> <ul style="list-style-type: none"> <li>• <b>One worksheet is used for the entire activity, not for each person.</b></li> <li>• Accuracy and completeness of the tables of planners and presenters in the Educational Activity Planning Documentation Form becomes more important.</li> </ul>
Step 6	<p>Disclose relevant financial relationships prior to the activity and make all other disclosures.</p> <ul style="list-style-type: none"> <li>• Presence or absence of relevant financial relationships for everyone in a position to control activity content</li> <li>• Approval statement of educational provider awarding contact hours (includes name of provider)</li> <li>• Criteria for awarding contact hours (successful completion requirements)</li> <li>• If applicable, a joint-provider statement</li> <li>• If applicable, commercial support information (names of commercial supporters – NO LOGOS)</li> <li>• For Enduring Materials (ONLY), the date after which contact hours will no longer be awarded for completion of the activity. (“Expiration Date”)</li> </ul>	<p>Disclose to learners prior to the activity relevant financial relationships and make all other disclosures.</p> <ul style="list-style-type: none"> <li>• Presence or absence of relevant financial relationships for everyone in a position to control activity content <ol style="list-style-type: none"> <li>1) Name</li> <li>2) Name of ineligible company with which there is a relationship</li> <li>3) Nature of the relationship</li> <li><b>4) Statement that all relevant financial relationships have been mitigated.</b></li> </ol> </li> <li>• Approval statement of educational provider awarding contact hours (includes name of provider)</li> <li>• Criteria for awarding contact hours (successful completion requirements)</li> <li>• If applicable, a joint-provider statement</li> <li>• If applicable, commercial support information (names of commercial supporters – NO LOGOS)</li> <li>• For Enduring Materials (ONLY), the date after which contact hours will no longer be awarded for completion of the activity. (“Expiration Date”)</li> </ul>

\*The Nurse Planner Mitigation Worksheet will be sent prior to the workshop as part of a Tool Kit for Approved Providers.