

**University of Oklahoma College of Medicine - Irwin H. Brown Office of Continuing Professional Development
Disclosure Policies and Procedures**

The University of Oklahoma College of Medicine Office of Continuing Professional Development (OU/CPD) is accredited by the Accreditation Council for Continuing Medical Education (ACCME). As an accredited provider, The OU/CPD office requires that all of its accredited continuing education activities adhere to the ACCME's Standards for Integrity and Independence in Accredited Continuing Education.

A. Relationships with Ineligible Companies. The OU/CPD office requires disclosure and mitigation of relevant financial relationships between planners, presenters/panelists, moderators, abstract or poster authors, course directors and course contacts and any organization/company defined by the ACCME as an ineligible company. Should it be determined that a relevant financial relationship is identified, this must be mitigated prior to the activity.

Course directors are required to provide all participants a disclosure and mitigation report within their handouts or syllabus that includes disclosures and mitigations for all of the accredited continuing education (CE) planners/presenters. The report must also disclose the absence of relevant financial relationships. This policy is designed to provide participants with an opportunity to review any affiliations between the CE planners/presenters and ineligible companies for the purpose of determining the potential presence of bias or influence over educational content.

B. Mitigation Strategies. It is the responsibility of the OU/CPD office to identify, and mitigate any relevant financial relationship with ineligible companies prior to the accredited continuing education activity. Presenters/panelists, moderators, planners, abstract or poster authors, course directors and course contacts who identify relevant relationships with ineligible companies must complete the mitigation strategies for relevant financial relationships with ineligible companies form. Additionally, the following actions must be completed for any presenters who identify relevant relationships with ineligible companies to ensure that all relationships have been mitigated:

1. The course director or designated planner will request the presentation slides for content validation and potential bias. The presenter will need to submit the presentation at least three weeks prior to the activity.
2. The presentation will be reviewed for content validation and potential bias by the course director or designated planner and then by the OU/CPD office staff. If further review is required the presentation will be reviewed by the associate dean of CPD. If time for previewing is not available, no CE credit will be offered for the presentation and the session will have to be moved to the end of the agenda, or a different present can be asked to fill the time slot. If it is determined that there is no bias within the presentation it will be approved.
3. Each presentation will be monitored by the course director or designated physician and the monitor will report the findings in writing to the OU/CPD office at the end of the course. Monitors are also required to ask questions or make comments to counter the commercial bias if presented.
4. The following questions regarding the presenter's presentation will be added to the course evaluation:
 - (a) Were clinical recommendations made during the presentation?
 - (b) Did you perceive any commercial bias during this presentation?
5. If the evaluation results show that more than 15% of the audience heard clinical recommendations or commercial bias, the presenter will not be asked to participate in future accredited activities.

C. Owners and Employees of Ineligible Companies. The *owners* and *employees* of ineligible companies are considered to have unresolvable financial relationships and must be excluded from participating as planners or faculty, and must not be allowed to influence or control any aspect of the planning, delivery, or evaluation of accredited continuing education, except in the limited circumstances outlined in Standard 3.2.

Owners and employees are individuals who have a legal duty to act in the company's best interests. Owners are defined as individuals who have an ownership interest in a company, except for stockholders of publicly traded companies, or holders of shares through a pension or mutual fund. Employees are defined as individuals hired to work for another person or business (the employer) for compensation and who are subject to the employer's direction as to the details of how to perform the job.

Ineligible companies are prohibited from engaging in *joint providership* with accredited providers. Joint providership enables accredited providers to work with nonaccredited eligible organizations to deliver accredited continuing education.

The ACCME determines eligibility for accreditation based on the characteristics of the organization seeking accreditation and, if applicable, any parent company. Subsidiaries of an ineligible parent company cannot be accredited regardless of steps taken to firewall the subsidiaries. If an eligible parent company has an ineligible subsidiary, the owners and employees of the ineligible subsidiary must be excluded from accredited continuing education except in the limited circumstances outlined in Standard 3.2.

- D. Non-Clinical Topics.** Although ACCME will exclude the requirement of disclosing and mitigating relevant financial relationships for non-clinical activities, it is the policy of the OU/CPD office that an entire activity must be identified as non-clinical in order for this exception to apply.
- E. Information for Learners.** Information on needs, expected results, and purpose or objectives will be provided to learners. These have been framed in terms of physician change or health status improvement which is in keeping with the OU/CPD mission.
- F. Safeguards against Commercial Bias/Independence.** The OU/CPD expects that the content or format of an accredited continuing education activities and related materials will promote improvements or quality in healthcare and not a specific proprietary business interest of an ineligible company. An accredited continuing education activity must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If educational material or content includes trade names, trade names from several companies should be used where available, not just trade names from a single company.
- G. Content Validation.** All the recommendations involving clinical medicine in an accredited continuing education activity must be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients. All scientific research referred to, reported, or used in an accredited continuing education activity in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection, and analysis. Please contact the OU/CPD office if you do not feel your presentation can meet these standards.
- H. Honoraria.** The OU/CPD has developed an honoraria policy in an ongoing effort to provide consumers of continuing medical education programs with objective and scientifically rigorous education. All honoraria must comply with the ACCME Standards for Integrity and Independence in Accredited Continuing Education and not influence the choice of presenter or the content of the presentation. Presenters are prohibited from accepting any reimbursement (financial, gifts or in-kind exchange) for their presentation from any source other than the accredited CE provider (OU/CPD) or its educational partner.
- I. Disclosures.** At the beginning of their presentations, presenters must verbally and visually disclose to learners any relevant financial relationship(s), to include the following information: the name of the presenter; the names of the ineligible companies; and the nature of the relationship the person has with each ineligible company. Disclosure must never include the use of a corporate logo, trade name, or a product-group message of an ACCME-defined ineligible company.
- Presenters with no relevant financial relationship(s) must inform the learners that no relevant financial relationship(s) exist.
- J. Discussion of Off-Label or Investigational Uses.** Activities formally designed as certified for *AMA PRA Category 1 Credit(s)*[™] by an organization accredited by the ACCME may allow presenters to discuss off-label or investigational uses of drugs, devices and/or therapies. When this occurs, however, the audience must be advised of the off-label or investigational status so that learners may take this information into consideration in making determination as to whether or not they will implement the information they learned in their medical practice.
- K. Measurements of Effectiveness.** The OU/CPD office will seek feedback from the learners on the effectiveness of this CME activity through session and/or overall course evaluations. Evaluations will include questions about undue commercial bias and the quality of the evidence cited.

Glossary of Terms

Types of Organizations That May Be Accredited in the ACCME System: Organizations eligible to be accredited in the ACCME System (*eligible organizations*) are those 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 (4) other organizations that are not otherwise ineligible. Examples of such organizations include:

- 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
- Nursing homes
- Pharmacies that do not manufacture proprietary compounds
- Publishing or education companies
- Rehabilitation centers
- Schools of medicine or health science universities
- Software or game developers

Types of Organizations That Cannot Be Accredited in the ACCME System: Companies that are ineligible to be accredited in the ACCME System (*ineligible companies*) are those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. Examples of such organizations 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 dietary supplements
- Manufacturers of health-related wearable products
- Pharmaceutical companies or distributors
- Pharmacy benefit managers
- Reagent manufacturers or sellers

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. Presenters/panelists, moderators, planners, abstract or poster authors, course directors and course contacts must identify **all** financial relationships in any amount occurring within the past 24 months.

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

Ineligible Organization: Company, Institution, etc.	What Role Example: Employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership and other activities (please specify)	What was received? 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
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