

Case Western Reserve
University School of Medicine
CME Policy and Procedures:
Standards for Integrity &
Independence in Accredited
Continuing Education

Contents

Ensuring Content is Valid	2
Preventing Commercial Bias and Marketing in Accredited Continuing Education.....	2
Identifying, Mitigating, and Disclosing Relevant Financial Relationships	3
Identify	3
Mitigate.....	4
Disclosure to Learners.....	5
Managing Commercial Support Appropriately	6
Managing Ancillary Activities Offered in Conjunction with Accredited Continuing Education	7
Exhibit Space for Promotional Purposes.....	8
Definitions	8
Additional Resources	9

Case Western Reserve University School of Medicine CME Policy on Standards for Integrity & Independence in Accredited Continuing Education

Ensuring Content is Valid

The Case Western Reserve University (CWRU) School of Medicine CME Office works with the course director who ensures that the content presented is valid. The CME office is committed to ensuring activities are educational, fair and balanced.

Accredited providers are responsible for ensuring that their education is fair and balanced and that any clinical content presented supports safe, effective patient care.

1. 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.
2. All discussions and debates must be clearly identified as such within the program and individual presentations. It is the responsibility of the Case Western Reserve University School of Medicine CME Activity Director or designee 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.
3. Organizations cannot be accredited if they advocate for unscientific approaches to diagnosis or therapy, or if their 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.

Preventing Commercial Bias and Marketing in Accredited Continuing Education

The following criteria applies to all accredited continuing education:

1. Case Western Reserve University School of Medicine CME must ensure that all decisions related to the planning, faculty selection, delivery, and evaluation of accredited education are made without any influence or involvement from the owners and employees of an ineligible company
2. Accredited education must be free of marketing or sales of products or services. Faculty must not actively promote or sell products or services that serve their professional or financial interests during accredited education. All CME syllabi, brochures, course websites, lecture slides, etc. must be free of commercial marketing such as logos & slogans.
3. Case Western Reserve University School of Medicine CME must not share the names or contact information of learners with any ineligible company or its agents without the explicit consent of the individual learner.

Identifying, Mitigating, and Disclosing Relevant Financial Relationships

To ensure each activity represents an unbiased, evidence-based approach, relevant financial relationships must be identified, mitigated, and disclosed prior to approving the activity for accreditation.

Relevant financial relationships are financial relationships of any amount with ineligible companies if the educational content is related to the business lines or products of the ineligible company (those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients).

Identify

The Activity Director and/or the staff of the CWRU CME Office will review the information about financial relationships to determine which relationships are relevant. Financial relationships are relevant if the educational content that an individual can control is related to the business lines or products of the ineligible company.

1. All planners, faculty, and others in control of educational content are required to complete a Disclosure of Relevant Financial Relationship Form listing all their financial relationships with ineligible companies within the prior 24 months.
2. Owners or employees of ineligible companies must be excluded from controlling content or participating as planners or faculty in accredited education. There are three exceptions to this exclusion—employees of ineligible companies can participate as planners or faculty in these specific situations:
 - a. When the content of the activity is not related to the business lines or products of their employer/company.
 - b. 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.
 - c. 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.
3. 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.

Disclosure information must include:

1. The name of the ineligible company with which the person has a financial relationship.
2. The nature of the 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 that individual's institution receives the research grant and manages the funds.

3. Identify relevant financial relationships: Review the information about financial relationships to determine which relationships are relevant. Financial relationships are relevant if the educational content an individual can control is related to the business lines or products of the ineligible company.

Mitigate

The Activity Director and CME Staff are responsible for mitigating relevant financial relationships identified during the disclosure process by completing the Mitigation of Relevant Financial Relationship Form using one of the following mechanisms. Conflicts must be resolved to assure that every reasonable effort is made to prevent or eliminate any commercial bias. The CME Advisory Committee in a peer review capacity has final oversight and discretion with respect to the resolution of any relevant financial relationship. Relevant financial relationships may be resolved in many ways, including:

Mechanisms for Speakers Mitigation of Relevant Financial Relationships with Ineligible Companies

- A. Activity Director communicated with the presenter and determined the financial relationship with an ineligible company was not relevant to the presentation and no conflict of interest exists.**
- B. Activity Director reviewed the content (slides) before the activity and determined no conflict of interest exists**
 - Content of activity/presentation has no therapeutic recommendations for patients/patient care
 - The disclosed relationship(s) with industry is(are) unrelated to the topic being discussed and/or presented
 - The CME activity is not related to patient care
- C. The speaker/planner has altered the financial relationship(s).**
- D. Altered control over content. An individual's control of content can be altered in several ways to remove the opportunity to affect content related to the products and services of an ineligible company by one of the following:**
 - Disqualified the speaker, author or planner and selected a replacement.
 - Choose someone else to control that portion of the content
 - Changed the focus of the CME activity
 - Changed the assigned content
 - Limited the content to a report without recommendation
 - Limited the sources for recommendations.
- E. Independent Content Validation – Conflict of interest may be mitigated if the presentation is peer reviewed and;**
 - All the recommendations involving clinical medicine are based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients or
 - All scientific research referred to, reported, or used in CME in support or justification of patient care recommendations conforms to generally accepted standards of experimental design, data collection and analysis

Mechanisms for Planners Mitigation of Relevant Financial Relationships with Ineligible Companies

A. Strategies used to resolve potential conflicts of interest among planners. (Check all that apply)

- Decisions related to topics and speakers were made by committee consensus.
- Suggestions for topics and speakers were reviewed by outside consultants or other independent reviewer(s).
- Planning committee members with relevant financial affiliations were excluded from making decisions regarding specific topics and speakers.

Disclosure to Learners

Learners must receive disclosure information, in a format that can be verified at the time of accreditation, before engaging with the accredited education. Therefore, at the time of the activity, it is mandatory that individual speakers disclose publicly (orally, within their PowerPoint presentation or by written handout) their financial relationships with ineligible companies. Disclosure to learners must not include ineligible companies' corporate or product logos, trade names, or product group messages. All activity evaluations ask learners to evaluate whether any bias was present. If bias is detected, learners are asked to indicate specifics about bias so it can be addressed post-activity.

Disclosure to learners must include each of the following:

1. The names of the individuals with relevant financial relationships.
2. The names of the ineligible companies with which they have relationships.
3. The nature of the relationships.
4. A statement that all relevant financial relationships have been mitigated.

Accredited providers do **not** need to identify, mitigate, or disclose relevant financial relationships for:

1. Accredited education that is non-clinical, such as leadership or communication skills training.
2. Accredited education where the learner group is in control of content, such as a spontaneous case conversation among peers.
3. Accredited self-directed education where the learner controls their educational goals and reports on changes that resulted, such as learning from teaching, remediation, or a personal development plan. When accredited providers serve as a source of information for the self-directed learner, they should direct learners only to resources and methods for learning that are not controlled by ineligible companies.

Managing Commercial Support Appropriately

Commercial support does not establish a financial relationship between the ineligible company and planners, faculty, and others in control of content of the education. The CME Director oversees the management of commercial support to ensure that the education remains independent of the ineligible company and that the support does not result in commercial bias or commercial influence in the education.

Process for Managing Commercial Support:

1. Except for a jointly provided activity, all grants must be payable to Case Western Reserve University, the accredited CME provider. No direct payment from an ACCME-defined ineligible company may be given to the director of an activity, any planning committee members, teachers or authors, or any others involved in an activity.
2. All grants must include a letter of agreement (LOA) stating conditions under which the grant is made. Terms, conditions, and purposes of the commercial support are documented in the Letter of Agreement between the ineligible company and Case Western Reserve University
3. Letters of agreement from ineligible companies should be forwarded to the CWRU CME Program immediately upon receipt for review by the CWRU Office of Counsel for legal acceptability. Authorization is made by the CME Director and the Chief Financial Officer of CWRU. Direct LOAs to Amy Pisman (amy.pisman@case.edu) or Takia Gardner (Takia.Gardner@uhhospitals.org).
4. If the CWRU CME Program's letter of agreement is used instead of an LOA provided by an ineligible company, review by CWRU Office of Counsel is unnecessary since the CWRU LOA was already approved by legal counsel. Authorization is made by the CME Director and the Chief Financial Officer of CWRU.
5. The accredited provider must disclose to the learners the name(s) of the ineligible company(ies) that gave the commercial support, and the nature of the support (i.e., if it was in-kind), prior to the learners engaging in the education. Disclosure must not include the ineligible companies' corporate or product logos, trade names, or product group messages.
6. Ineligible companies must not pay directly for any of the expenses related to the education or the learners.
7. The accredited provider may use commercial support to fund honoraria or travel expenses of planners, faculty, and others in control of content for those roles only.
8. The accredited provider must not use commercial support to pay for travel, lodging, honoraria, or personal expenses for individual learners or groups of learners in accredited education.
9. The accredited provider may use commercial support to defray or eliminate the cost of the education for all learners.
10. When grants are received by the department providing the education, documentation for the CME Program must include (a) a fully executed letter of agreement (signed by a representative of the ineligible company and the SOM); (b) a photocopy of the grant check; (c) itemized reconciliation of how the funds were spent (honoraria, travel-reimbursement, catering, etc.) Item (c) may be part of your income and expense summary; and (d) completed commercial support and honorarium trackers.

11. The CME Financial Administrator deposits all grant monies, reconciles all funds and keeps records for each accredited activity
12. The CME Financial Administrator submits a completed financial statement to the course director thereby closing the project.

Managing Ancillary Activities Offered in Conjunction with Accredited Continuing Education

Accredited providers are responsible for ensuring that education is separate from marketing by ineligible companies—including advertising, sales, exhibits, and promotion—and from non-accredited education offered in conjunction with accredited continuing education.

1. Arrangements to allow ineligible companies to market or exhibit in association with accredited education must not:
 - a. Influence any decisions related to the planning, delivery, and evaluation of the education.
 - b. Interfere with the presentation of the education.
 - c. Be a condition of the provision of financial or in-kind support from ineligible companies for the education.
2. The accredited provider must ensure that learners can easily distinguish between accredited education and other activities.
 - a. Live continuing education activities: Marketing, exhibits, and non-accredited education developed by or with influence from an ineligible company or with planners or faculty with unmitigated financial relationships must not occur in the educational space within 30 minutes before or after an accredited education activity. Activities that are part of the event but are not accredited for continuing education must be clearly labeled and communicated as such.
 - b. Print, online, or digital continuing education activities: Learners must not be presented with marketing while engaged in the accredited education activity. Learners must be able to engage with the accredited education without having to click through, watch, listen to, or be presented with product promotion or product-specific advertisement.
 - c. Educational materials that are part of accredited education (such as slides, abstracts, handouts, evaluation mechanisms, or disclosure information) must not contain any marketing produced by or for an ineligible company, including corporate or product logos, trade names, or product group messages.
 - d. Information distributed about accredited education that does not include educational content, such as schedules and logistical information, may include marketing by or for an ineligible company.
3. Ineligible companies may not provide access to, or distribute, accredited education to learners.

(Refer to ACCME standards at ACCME Standard 5)

Exhibit Space for Promotional Purposes

Advertising and exhibits are promotional activities and not commercial support. Therefore, monies paid by commercial interests to providers for these promotional activities are not considered to be commercial support under the ACCME Standards for Integrity and Independence in Accredited Continuing Education.

1. Case Western Reserve University School of Medicine CME will collect an “exhibit fee” from a company wishing to set up a display table/virtual room at the live activity. Exhibitors should sign CWRU SOM CME’s Exhibit Booth Agreement.
2. This fee is in addition to and separate from any funds that were given in the form of an educational grant and must be received prior to the activity.
3. Exhibit fees shall be set by the Activity Director for each activity prior to solicitation and will be standard for that activity. The Activity Director may set a different fee for industry, not for profit organizations/foundations, and publishers. There cannot be variability within any category. Potential exhibitors shall have equal access to purchasing exhibit space (first come first serve).
4. All exhibitors must be in a room or area separate from the education and the exhibits must not interfere or in any way compete with the learning experience prior to, during, or immediately after the activity.
5. Ineligible company representatives may attend CME/CE activities at the discretion of CWRU SOM CME for the direct purpose of the representatives’ own education; however, they may not engage in sales or marketing activities while in the space or place of the educational activity.

Definitions

1. **Advertising and Exhibits Income:** Advertising and exhibits are promotional activities and not commercial support. Therefore, monies paid by commercial interests to providers for these promotional activities are not considered to be commercial support under the ACCME Standards for Integrity and Independence in Accredited Continuing Education. Arrangements for these activities must be made in compliance with the Standards, specifically Standard 5: Manage Ancillary Activities Offered in Conjunction with Accredited Continuing Education.
2. **CME Activity:** An educational offering that is planned, implemented, and evaluated in accordance with the ACCME Accreditation Criteria, Standards for Integrity and Independence in Accredited Continuing Education, and policies; the AMA Physician’s Recognition Award CME credit system standards and policies; and the AMA Council on Ethical and Judicial Affairs pertinent opinions.
3. **Commercial Bias:** Content or format in a CME activity or its related materials that promotes the products or business lines of an ineligible company. As described in the Standards for Integrity and Independence in Accredited Continuing Education, providers are responsible for protecting learners from commercial bias and marketing. In addition to preventing influence from ineligible companies, the Standards prohibit faculty from actively promoting or selling products or services that serve their professional or financial interests.
4. **Commercial Support:** Financial or in-kind support from an ACCME-defined ineligible company that is used to pay all or part of the costs of a CME activity. The requirements for receiving and managing commercial support are explained in the ACCME Standards for Integrity and Independence in Accredited Continuing Education, specifically Standard 4: Manage Commercial Support Appropriately.

5. **Faculty:** The individuals responsible for teaching, authoring, or otherwise communicating the activity content to learners.
6. **Financial Relationships:** Accredited providers must collect information from all planners, faculty, and others in control of educational content about all their 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 financial relationships with ineligible companies regardless of their view of the relevance of the relationship to the education. See also relevant financial relationships.
7. **In-kind Commercial Support:** In the context of the ACCME's Standards for Integrity and Independence in Accredited Continuing Education, non-monetary support provided by an ineligible company used for a CME activity. Examples of in-kind support include use of equipment and supplies.
8. **Ineligible Company:** 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.
9. **Learner:** An attendee at an accredited educational activity.
10. **Relevant Financial relationships:** Relevant financial relationships, as defined in the Standards for Integrity and Independence in Accredited Continuing Education, specifically, Standard 3: Identify, Mitigate, and Disclose Relevant Financial Relationships, relevant financial relationships are financial relationships of any amount with ineligible companies if the educational content is related to the business lines or products of the ineligible company. Providers are required to collect information from all those individuals in control of educational content about all their financial relationships with ineligible companies within the prior 24 months. The provider is then responsible for determining which relationships are relevant. the time that the individual was asked to assume a role controlling content of the CME activity.
11. **Standards for Integrity and Independence in Accredited Continuing Education:** For all accredited programs, the Accreditation Council for Continuing Medical Education (ACCME) has set requirements designed to ensure that accredited continuing education serves the needs of patients and the public that is based on valid content and is free from commercial influence. The Standards comprise five standards: Ensure Content is Valid; Prevent Commercial Bias and Marketing in Accredited Continuing Education; Identify, Mitigate, and Disclose Relevant Financial Relationships; Manage Commercial Support Appropriately; Manage Ancillary Activities Offered in Conjunction with Accredited Continuing Education. Released in December 2020, the Standards for Integrity and Independence replace the Standards for Commercial Support.

Additional Resources:

<https://cwru.cloud-cme.com/about/resources?p=1200>