

WSU Guidelines for Ensuring Integrity and Independence in Accredited Continuing Medical Education (CME)

Adapted from the Accreditation Council for Continuing Medical Education (ACCME) <u>Standards for Integrity and Independence in Accredited Continuing Education</u> © 2020 ACCME

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Related Forms, Handouts, and Appendices

WSU College of Medicine Conflict of Interest Policy
WSU College of Medicine Compliance and Ethical Conduct Policy
ACCME Standards for Integrity and Independence in Accredited Continuing Education
ACCME Planning Guide for Independence in Accredited Continuing Education

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1.0 Overview and Purpose

The Washington State University (WSU) College of Medicine (COM) Continuing Medical Education (CME) Unit is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. WSU CME endorses and adheres to the Criteria, Standards, and Policies set forth by the Accreditation Council for Continuing Medical Education (ACCME).

In particular, the ACCME's <u>Standards for Integrity and Independence in Accredited Continuing Education</u>, released in 2020, reflect the values of the continuing education community, and have been adopted by WSU's CME Unit. Independence from industry is the cornerstone of accredited continuing education. These guidelines help WSU CME assure the delivery of high-quality learning experiences and sustain the protection from industry bias and marketing that accreditation rules deliver.

2.0 Applicability

This guideline is intended for anyone involved with planning, producing, reviewing, overseeing, and participating in / completing live or asynchronous Continuing Medical Education (CME) activities at WSU. This may include practicing health professionals and/or subject matter experts who are external or internal to WSU, faculty members or other teaching faculty, WSU employees, students, volunteers, stakeholders, and external clients.

This guideline should be used by CME planning committees and accreditation applicants when developing or updating educational programs and courses, to ensure compliance with ACCME and WSU standards for maintaining integrity and independence in continuing education.

In line with ACCME's Standards, these guidelines are meant to:

- Ensure that accredited continuing education serves the needs of patients and the public.
- Present learners with only accurate, balanced, scientifically justified recommendations.
- Assure healthcare professionals and teams that they can trust accredited continuing education to help them deliver safe, effective, cost-effective, compassionate care that is based on best practice and evidence.
- Create a clear, unbridgeable separation between accredited continuing education and marketing and sales.

Referenced in the first section of these Guidelines is the WSU College of Medicine's Conflict of Interest Policy, which applies to anyone developing and delivering educational content at WSU.

3.0 Definitions

Ineligible Company: The ACCME defines an ineligible company as "any entity producing, marketing, re-selling, or redistributing health care goods or services consumed by or used by patients." See ACCME definition and examples of ineligibility: https://accme.org/rule/eligibility/

Educational Grant: Grants awarded, or monies given with nothing provided in exchange for the funds by an ineligible company to support CME are considered "Commercial Support" of CME by the ACCME. Commercial Support is managed under ACCME Standard 4.

Corporate Sponsorship: Funding provided by an ineligible company in exchange for goods or services provided by the WSU COM in connection with a CME activity fall under the following categories: Advertising or exhibiting and is not considered "Commercial Support" – this funding is managed under ACCME Standard 5.

In-Kind Support: Non-cash or non-monetary contributions (e.g., materials, equipment, devices, etc.) provided by an ineligible company. The ACCME considers in-kind support from ineligible companies to be Commercial Support.

Non-CME Informational/Educational Program or Product: ACCME requirements are outlined under Standards to Ensure Independence and Integrity in Accredited Education: https://accme.org/rule/manage-ancillary-activities-offered-in-conjunction-with-accredited-continuing-education/

Financial Relationship: The exchange of money or stock directly between an individual and an ineligible company. Financial relationships of any dollar amount are to be disclosed. Research funding given to an institution is only disclosed by the named Principal Investigator.

Relevant Financial Relationships: Per the ACCME, WSU CME is responsible for identifying relevant financial relationships between individuals in control of educational content and ineligible companies and managing these to ensure they do not introduce commercial bias into the education.

Financial relationships of any dollar amount are defined as relevant if the educational content is related to the business lines or products of the ineligible company.

Owner/Employee: 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.

Charitable Contributions (Donations): Funding provided to WSU COM by an organization that does not fall under the definition of an ineligible company.

Mitigation: The process undertaken by WSU COM to manage bias that may be introduced into accredited education because of the financial relationships' individuals in control of CME content have with ineligible companies. Individuals may not mitigate their own bias because of their relationships; WSU COM must control the process.

4.0 ACCME Standards

The standards below apply to all accredited continuing education.

4.1 ACCME Standard 1: Ensure Content Is Valid

WSU CME ensures education is fair and balanced and that any clinical content presented supports safe, effective patient care.

- **4.1.1** 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.
- **4.1.2** 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.
- **4.1.3** 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 WSU CME 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.
- **4.1.4** Accredited continuing education cannot 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.

4.2 <u>ACCME Standard 2</u>: Prevent Commercial Bias and Marketing in Accredited Continuing Medical Education

Accredited continuing education must protect learners from commercial bias and marketing.

- **4.2.1** WSU CME ensures 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.
- **4.2.2** WSU CME ensures accredited education is 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.
- **4.2.3** WSU CME will not share the names or contact information of learners with any ineligible company or its agents without the explicit consent of the individual learner.

4.3 ACCME Standard 3: Identify, Mitigate, and Disclose Relevant Financial Relationships

Many healthcare professionals have financial relationships with ineligible companies. These relationships must not be allowed to influence accredited continuing education. WSU CME is responsible for identifying *relevant financial relationships* between individuals in control of educational content and ineligible companies and managing these to ensure they do not introduce commercial bias into the education. Financial relationships of any dollar amount are defined as relevant if the educational content is related to the business lines or products of the ineligible company.

WSU CME takes the following steps when developing accredited continuing education:

4.3.1 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 regardless of their view of the relevance of the relationship to the education.

Disclosure information must include:

- The name of the ineligible company with which the person has a financial relationship.
- 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.
- **4.3.2 Exclude owners or employees of ineligible companies:** Review the information about financial relationships to identify individuals who are owners or employees 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—employees of ineligible companies may participate as planners or faculty in these specific situations:
 - When the content of the activity is not related to the business lines or products of their employer/company.
 - When the content of the accredited activity is limited to basic science research, such as preclinical research and drug discovery, or the methodologies of research, and they do not make care recommendations.
 - When they are participating as technicians to teach the safe and proper use of medical devices, and they do not recommend whether or when a device should be used.
- **4.3.3 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.
- **4.3.4 Mitigate relevant financial relationships**: Take steps to prevent all those with relevant financial relationships from inserting commercial bias into content.
 - a. Mitigate relationships prior to the individuals assuming their roles. 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.
 - b. Document the steps taken to mitigate relevant financial relationships.
- **4.3.5 Disclose all relevant financial relationships to learners**: Disclosure to learners must include each of the following:

- 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
- **4.3.6 Identify ineligible companies by their name only.** Disclosure to learners must not include ineligible companies' corporate or product logos, trade names, or product group messages.
- **4.3.7 Disclose absence of relevant financial relationships.** Inform learners about planners, faculty, and others in control of content (either individually or as a group) with no relevant financial relationships with ineligible companies. Learners must receive disclosure information, in a format that can be verified at the time of accreditation, before engaging with the accredited education.
- **4.3.8 Exceptions:** WSU CME does **not** need to identify, mitigate, or disclose relevant financial relationships for any of the following activities:
 - Accredited education that is non-clinical, such as leadership or communication skills training.
 - Accredited education where the learner group is in control of content, such as a spontaneous case conversation among peers.
 - 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 WSU CME serves 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.

4.4 ACCME Standard 4: Manage Commercial Support Appropriately

Standard 4 applies only to accredited continuing education that receives financial or in-kind support from ineligible companies.

If WSU CME agrees to accept commercial support (defined as financial or in-kind support from ineligible companies), WSU CME is responsible for ensuring 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. The support does not establish a financial relationship between the ineligible company and planners, faculty, and others in control of content of the education.

- **4.4.1 Decision-making and disbursement:** WSU CME makes all decisions regarding the receipt and disbursement of commercial support.
 - Ineligible companies must not pay directly for any of the expenses related to the education or the learners.
 - WSU CME may use commercial support to fund honoraria or travel expenses of planners, faculty, and others in control of content for those roles only.
 - WSU CME must not use commercial support to pay for travel, lodging, honoraria, or personal expenses for individual learners or groups of learners in accredited education.
 - WSU CME may use commercial support to defray or eliminate the cost of the education for all learners.
- **4.4.2 Agreement:** The terms, conditions, and purposes of the commercial support must be documented in an agreement between the ineligible company and WSU CME. The agreement must be executed prior to the start of the accredited education. WSU CME can sign onto an existing agreement between WSU CME and a commercial supporter by indicating its acceptance of the terms, conditions, and

amount of commercial support it will receive.

- **4.4.3 Accountability**: WSU CME will keep a record of the amount or kind of commercial support received and how it was used, and must produce that accounting, upon request, by the accrediting body or by the ineligible company that provided the commercial support.
- **4.4.4 Disclosure to learners:** WSU CME will disclose to the learners the name(s) of the ineligible company(ies) that gave the commercial support, and the nature of the support 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.

4.5 <u>ACCME Standard 5:</u> Manage Ancillary Activities Offered in Conjunction with Accredited Continuing Education

Standard 5 applies only when there is marketing by ineligible companies or nonaccredited education associated with the accredited continuing education.

WSU CME is responsible for ensuring that education is separate from marketing by ineligible companies—including advertising, sales, exhibits, and promotion—and from nonaccredited education offered in conjunction with accredited continuing education.

- **4.5.1** Arrangements to allow ineligible companies to market or exhibit in association with accredited education must not:
 - Influence any decisions related to the planning, delivery, and evaluation of the education.
 - Interfere with the presentation of the education.
 - Be a condition of the provision of financial or in-kind support from ineligible companies for the education.
- **4.5.2** WSU CME will ensure that learners can easily distinguish between accredited education and other activities.
 - Live continuing education activities: Marketing, exhibits, and nonaccredited 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.
 - 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.
 - 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.
 - 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.
- **4.5.3** Ineligible companies may not provide access to, or distribute, accredited education to learners.

5.0 References and Resources

Accreditation Council for Continuing Medical Education: https://accme.org/
CME Application Planning Tools at WSU: https://wsu.cloud-cme.com/about/resources?p=1200
Revisions:
REVISIONS.
08-09-2024 A. Keesey R. Nandagopal _v.