Office of Continuing Professional Development

Important Accreditation Updates: Standards for Integrity and Independence in Accredited Continuing Education



In support of improving patient care, University of Minnesota, Interprofessional Continuing Education is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.



Purpose

•The information provided within this document is to inform Course Directors and Planning Committee Members of the Accreditation Council for Continuing Medical Education's (ACCME) recent updates to their Standards for Commercial Support, now known as Standards for Integrity and Independence in Accredited Continuing Education and OCPD's policies and procedures to ensure compliance with the Standards.

- •For more information, view <u>ACCME's Website</u>
- •For questions or support regarding how this information impacts your role, email cme@umn.edu

ACCME's Standards for Integrity and Independence in Accredited Continuing Education are effective as of January 1, 2022



Standard 1: Ensure Content is Valid

•Overview:

•Accredited education must be fair and balanced and that any clinical content presented supports safe, effective patient care.

•OCPD Process:

- •Application materials address the Planning Committee's commitment to provide education based on current science, evidence and clinical reasoning while giving a fair and balanced view of diagnostic and therapeutic options.
- •All faculty are advised via the attestation form that they should ensure that all scientific research referred to must conform to the generally accepted standards of experimental design, data collection, analysis and interpretation.



Standard 1: Ensure Content is Valid - continued

•OCPD Process:

- •All faculty are advised via the attestation form that if they plan to discuss/debate/explore new and evolving topics, they must clearly identify these topics as such and 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.
- •All faculty are advised via the attestation form that advocating 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, it is not eligible content for an accredited activity.



Standard 2: Prevent Commercial Bias and Marketing in Accredited CE

•Overview:

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

•OCPD Process:

- •OCPD is involved with planning the activity with the Education Partner to ensure that all decisions related to planning, faculty selection, delivery and evaluation are made without any influence from owners and employees of an ineligible company.
- •OCPD prohibits the marketing or sale of products or services. Faculty cannot actively promote or sell products/services that server their professional or financial interests during accredited education (i.e. no book sales, referral generation, etc.)
- •OCPD and/or the Education Partner cannot provide the names or contact information of learners with any ineligible company or its agents without explicit consent from the individual learner.



•Overview:

•Many healthcare professionals have financial relationships with ineligible companies. These relationships must not be allowed to influence accredited continuing education. The accredited provider 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.

Definition: Ineligible companies are those whose primary business is producing, marketing, selling, reselling, or distributing healthcare products used by or on patients. For more information, including a list of examples see <u>ACCME's webpage</u>.

- •1. Collect Information OCPD Process:
 - OCPD collects information from all Planning Committee Members, faculty and others in control of the educational content about **ALL** of their financial relationships with ineligible companies within the prior **24** months. Financial relationships of any dollar amount must be reported.
 - OCPD uses an online form via our CE Portal to collect this information. The form asks:
 - the name of the ineligible company with which the person has a financial relationship
 whether or not the financial relationship has ended.
 - the nature of the relationship (e.g. 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.

IMPORTANT NOTE: The individual completing the form must report ALL financial relationships with ineligible companies, not just those they deem as relevant. OCPD will work with the Course Director to review relevance of disclosed relationships. Furthermore, spouse/partner relationship disclosure is no longer required.

•2. Exclude owners or employees of ineligible companies - OCPD Process:

- •Owners or employees of ineligible companies must be EXCLUDED as planners or faculty in an accredited CE activity.
- •There are three exceptions to this exclusion. OCPD is responsible for reviewing the exceptions with the Course Director to determine if they are applicable:
 - •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 pre-clinical 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 do not recommend whether or when a device is used.



- •3. Identify relevant financial relationships OCPD Process:
 - •OCPD will compile the responses from all Planners and faculty and share with the Planning Committee. OCPD and the Planning Committee will 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. Mitigate relevant financial relationships OCPD Process:
 - •OCPD will take steps to mitigate relationships prior to the individuals assuming their roles and will take steps appropriate to the role of the individual.
 - This requires all Planning Committee members to submit their financial disclosure forms at the time of an activity certification request to ensure mitigation steps for any members of the Planning Committee can be taken prior to the initiation of planning the CE activity.
 - Faculty members are expected to submit their financial relationships early in the planning process to ensure OCPD and the Planning Committee are aware of all financial relationships and can make plans for mitigation as needed. Faculty members should be aware that a common mechanism for mitigation is peer review and an expectation is that a copy of the presentation slides and/or content will be due in advance of the course date to allow time for review.

- •5. Disclose all relevant financial relationships to learners OCPD Process:
 - •OCPD will populate a course webpage that includes a faculty tab. That tab notes the following details:
 - •The names of all faculty and planners and their relevant financial relationships, including the nature of the relationship and the name of the ineligible company. The list will also note the absence relevant financial relationships.
 - •OCPD will provide the "Digital File of Learner Materials" to the Education Partner that includes important information to be shared with learners. The Digital File of Learner Materials will also include the Onsite Disclosure Summary details. This information must be shared on screen and/or as a handout with learners prior to the start of the education.



The Course Director and Planning Committee Members contact OCPD to initiate course planning. At the time they submit the Request for Activity Certification, they identify all individuals responsible for planning the activity. OCPD collects their financial disclosure information, and manages the review and mitigation of disclosed financial relationships prior to the start of course planning.

The Planning Committee selects the content areas and faculty for the course. OCPD collects financial disclosure information from all faculty, provides a summary to the Planning Committee to review for the relevance of the identified financial relationships and determines plans to appropriately mitigate the potential conflict of interest.

OCPD prepares the Onsite Disclosure Summary to ensure that learners have access to the Planners' and faculty members' financial relationships prior to the start of the activity.

There are various options to consider for conflict mitigation. Those options vary depending on the individual's role in the activity and the nature of their relationship. Common options include:

- Peer review (for faculty only)
- Remove the Planner or Faculty member and identify someone new
- Identify a co-presenter to help ensure balance
- And more

Remember that owners and employees of ineligible companies must be excluded from participating as Planners and/or Faculty in accredited continuing education.



It is important that Planners and Faculty submit their disclosures on time to ensure that there is sufficient time to review and mitigate potential conflicts of interest. Failure to do so can compromise the ability to qualify for credit.

Standard 4: Manage Commercial Support Appropriately

• Overview – if the course accepts commercial support (defined as financial or in-kind support (grants) from ineligible companies), we are responsible for ensuring the education remains independent of the ineligible company(ies) and that the support does not result in commercial bias or influence the education. The support does not establish a financial relationship

• OCPD Process

- OCPD must always be involved in the process of applying for grants, reviewing and executing the Letter of Agreement (LOA) for a grant award. The Education Partner/Planning Committee that is working with OCPD will receive guidance specific to their course and plans to seek education support. The guidance includes:
 - Funds must be received by the course, funding companies cannot pay expenses directly
 - Commercial support can be used to fund honoraria or travel expense of planners, faculty and others in control of content for those roles only.
 - Commercial support cannot be used to pay for travel, lodging, honoraria or personal expense for individual learners or group of learners
 - Commercial support may be used to defray or eliminate the cost of the education for *all* learners
 - OCPD must be a party to the Letter of Agreement (LOA), which must be executed prior to the start of the education. OCPD will work with the Education Partner to ensure compliance with the terms of the LOA, including any required reconciliation, reports and return of funds if applicable.
 - OCPD must receive a copy of the budget that details how funds were used.
 - OCPD will ensure that the required disclosure is made to learners regarding the Commercial Support received by the course. This is called the Acknowledgment of Support.



Standard 5: Manage Ancillary Activities Offered in Conjunction with Accredited Continuing Education

- Overview if the course offers exhibit or other marketing opportunities to ineligible companies or nonaccredited education associated with the accredited continuing education, we must ensure that the education is separate from marketing by ineligible companies. This includes advertising, sales, exhibits and promotion.
- OCPD Process
 - OCPD must always be involved in the process of drafting and reviewing the Exhibitor Agreement form and/or Prospectus. The information contained within will reflect the following terms:
 - Ineligible companies 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-kin support from ineligible companies for the education.
 - OCPD will provide specific guidance regarding course logistics for all course formats (in-person, virtual, hybrid and enduring materials) to ensure learners can easily distinguish between accredited education and other activities this includes the following rules:
 - 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.
 - Educational materials that are part of the accredited education can never include marketing for ineligible companies, including logos, trade names or product group messages.
 - OCPD will review and work with Planning Committees to ensure compliance with Standard 5.



Questions

The Education Consultant assigned to your course is your primary resource for information on accreditation rules and standards. Please contact them with any questions you might have.

The OCPD planning process has been developed to ensure compliance with the Standards for Integrity and Independence in Accredited Continuing. The information in this document is provided to give you background on the recent changes to ACCME's Standards and to help ensure that all Course Directors and Planning Committee Members recognize their role in ensuring compliance with all accreditation rules when developing a continuing education activity in collaboration with the University of Minnesota's Office of Continuing Professional Development.

