



ENTITY <b>University of Wisconsin – Interprofessional Continuing Education Partnership: School of Medicine and Public Health School of Nursing School of Pharmacy</b>	NUMBER <b>UW ICEP-COI</b>
MANUAL <b>Policy and Procedure</b>	EFFECTIVE DATE <b>2/22/2021</b>
SUBJECT <b>Identification, Mitigation and Disclosure of Conflicts of Interest</b>	

**I. PURPOSE (SCS 3/JAC 12)**

To ensure the integrity and independence of accredited continuing education activities provided by the University of Wisconsin—Madison Interprofessional Continuing Education Partnership (UW—Madison ICEP): School of Medicine and Public Health, School of Nursing, School of Pharmacy, in accordance with Joint Accreditation Criteria 12 and the *ACCME Standards for Integrity and Independence in Accredited Continuing Education*, this policy on Identification, Mitigation and Disclosure of Conflicts of Interest (COI) exists to provide guidance to ensure the following decisions are made free of the control of any ineligible company: a) identification of needs; b) determination of educational objectives; c) selection of and presentation of content; d) selection of all persons and organizations who will be in a position to control the content of the activity; e) selection of educational methods; and f) evaluation of the activity.

**II. BACKGROUND**

The UW—Madison ICEP affirms that accredited continuing education (CE) content must remain free of commercial bias. As such, this policy (1) reviews the guiding principles relating to conflict of interest (COI) in accredited continuing education and (2) defines how the UW-Madison ICEP will identify and mitigate COI related to its overall CE programming via a COI management process. This process includes mechanisms to collect disclosure information from all individuals who are in a position to control content, reviews processes to identify COIs, delineates actions to mitigate COI, and outlines requirements to make disclosure transparent to learners.

**III. GUIDING PRINCIPLES RELATING TO CONFLICT OF INTEREST**

CE activities accredited by the UW—Madison ICEP are guided by what is in the best interests of patients and the public, always assuring independence from commercial interests, while presenting learners with only accurate, balanced, scientifically justified recommendations and clinical content that supports safe, effective patient care. In addition, UW—Madison ICEP ensures the separation of CE content from product promotion and implements a robust content validation process to assure high quality education. These are the guiding principles for the identification mitigation and disclosure of COI.

**IV. DEFINITIONS**

**Accredited CE**

Accredited CE are those continuing education activities accredited for Continuing Medical Education (CME) AMA PRA Category 1™ credit, Continuing Nursing Education (CNE) contact hours, Continuing

Pharmacy Education (CPE) credit and/or other continuing education credit by the Interprofessional Continuing Education Partnership, a Joint Accreditation™ provider.

### **Commercial Support**

The Joint Accreditation Criteria (ACCME Standards for Integrity and Independence in Accredited Continuing Education) defines commercial support as financial or in-kind support from ineligible companies, which are used to pay all or part of the costs of an accredited CE activity.

### **Conflict of Interest**

Conflict of Interest occurs when individuals have both a relevant financial relationship with an ineligible company and the opportunity to affect the content of an accredited activity that is related to the business lines or products of the ineligible company.

### **Eligible Organizations**

Eligible Organizations are those whose mission and function are: 1. Providing clinical services directly to patients; or 2. Educating healthcare professionals; or 3. Serving as fiduciary to patients, the public, or population health; and other organizations that are not otherwise ineligible.

#### Examples:

Ambulatory procedure centers	Infusion centers
Blood banks	Insurance or managed care companies
Diagnostic labs that do not sell proprietary products	Nursing homes
Electronic health records companies	Pharmacies that do not manufacture proprietary compounds
Government or military agencies	Publishing or education companies
Group medical practices	Rehabilitation centers
Health law firms	Schools of medicine or health science
Health profession membership organizations	University
Hospitals or healthcare delivery systems	Software or game developers

### **Financial Relationships**

#### Examples of financial relationships with ineligible companies include:

Employee	Royalties or patent beneficiary
Researcher*	Executive role
Consultant	Ownership interests (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds)
Advisor	Other financial benefits
Speaker	
Independent contractor (including contracted research*)	

\*Research funding from ineligible companies should be disclosed by the principal or named investigator even if that individual's institution received the research grant and manages the funds.

## Ineligible Companies

Ineligible companies are those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

### Examples:

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

Eligibility is based on the characteristics of the organization 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.

## Relevant Financial Relationship

Financial relationships are relevant if the following three conditions are met:

- ✓ A financial relationship, in any amount, exists between the person in control of content and an ineligible company.
- ✓ The financial relationship existed in the past 24 months.
- ✓ The content of the education is related to the products of an ineligible company with whom the person has a financial relationship.

## V. CONFLICT OF INTEREST MANAGEMENT PROCESS

Determination of conflicts and mitigation must be completed during the activity-planning phase. The following process allows for identification of relevant financial relationships, mitigation and disclosure of those relationships during the planning of the activity, as well as for monitoring during and after the activity in order to continuously ensure compliance with Joint Accreditation™ criteria and UW—Madison ICEP standards.

### a. Identification of All Financial Relationships (Standard 3/JAC 12)

The UW-Madison ICEP requires that every individual who is in a position to control content must disclose **all** financial relationships they have/had with ineligible companies within the **prior 24 months** in advance of being formally selected to participate in an activity. These individuals include planners, activity faculty (speakers, presenters, authors), moderators, reviewers, course directors, staff, and others as determined by UW—Madison ICEP. This provision excludes individuals involved only in logistics or non-educational support services.

- I. UW—Madison ICEP will inform all individuals who are invited to serve in any role that may impact the content of the educational activity of the key points of the Policy on the Identification, Mitigation and Disclosure via a standard faculty communication template.
- II. Individuals will submit disclosure information electronically via the AAMC Convey Global Disclosure System for each activity to which they contribute content or plan.

- III. Disclosures must be received by UW—Madison ICEP in a timely manner to ensure appropriate review and mitigation of COI. Deadlines will be communicated in the standard faculty community template.
- IV. Individuals who are in a position to control content and who refuse to complete or do not complete their disclosure by the established deadline will be excluded from participating in the accredited CE activity.
- V. Individuals must disclose **ALL** financial relationship the have/had with ineligible entities during the previous 24-month period. There is no minimum financial threshold. Individuals must disclose regardless of their view of the relevance of the relationship to the education.
- VI. Disclosure of financial relationships must include:
  - ✓ The name of the ineligible company
  - ✓ The nature of the financial relationship (the role they play or service they provide in exchange for some form of compensation from an ineligible company) such as:

Employee	Royalties or patent beneficiary
Researcher*	Independent contractor (including contracted research)
Consultant	Executive role
Advisor	Ownership interest**
Speaker	

\*Research funding from ineligible companies should be disclosed by the principal or named investigator even if that individual’s institution received the research grant and manages the funds.

\*\*Individual stock and stock options should be disclosed; diversified mutual funds do not need to be disclosed.

- VII. All persons in control of content must disclose when they intend to reference unlabeled/unapproved uses of drugs or products in their content.

**b. Identification of Relevant Financial Relationships (Standard 3/JAC 12)**

Once the disclosure information regarding financial relationships is obtained, a systematic process is conducted to analyze this information and identify relevant financial relationships for each person who is in a position to control content. Disclosed financial relationships will be reviewed by the UW—Madison ICEP accreditation specialists, appropriate activity coordinator, along with activity chairs in order to determine which relationships are relevant and steps for mitigation.

- I. Owners and Employees of Ineligible Companies

The owners and employees of ineligible companies are considered to have unresolvable financial relationships and will be excluded from participating as planners, and will not be allowed to influence or control any aspect of the planning, delivery, or evaluation of accredited continuing education. Faculty (speakers, presenters, authors) may be allowed in these limited circumstances:

- When the content of the accredited 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.

II. Other Financial Relationships with Ineligible Companies

Accreditations specialists will consult with subject matter experts who have reported relevant financial relationships to determine if the disclosed financial relationships are relevant. A relationship is relevant if:

- ✓ The financial relationship, in any amount, exists between the person in control of content and an ineligible company; and
- ✓ The financial relationship existed during the past 24 months; and.
- ✓ The educational content that the individual can control is related to the business lines or products of the ineligible company.

**c. Mitigation of Relevant Financial Relationships**

The following actions for mitigating relevant financial relationships are available to the UW—Madison ICEP accreditation specialists in consultation with the activity chair, and/or appropriate designee in order to prevent all those with relevant financial relationships from inserting commercial bias into the accredited activity. The appropriate actions will be implemented before the individual assumes their role in the activity. The results of the mitigation process will be discussed with the individual and agreed to prior to confirming participation in the activity. Final actions will be documented in the activity file. The UW—Madison ICEP Chair is the final arbiter as to whether or not the conflict of interest has been mitigated.

- Not Applicable – No relationships with ineligible companies were disclosed; confirm participation in the activity.
- Not Applicable – Disclosed relationship(s) with ineligible companies were found not to be relevant; explanation required (Employee/Owner relationships must include an explanation that clearly delineates how the business lines of the company are not related to the educational content); confirm participation in the activity.
- Removed individual from participating in all parts of this educational activity
- Revised individual’s role in the activity so the relevant financial relationship is no longer relevant; explanation required; confirm participation in the activity.
- Mitigation of Planner Relationships:
  - Recusal from controlling aspects of the planning and content with which there is a relevant financial relationship.
  - Peer review of planning decisions by persons without relevant financial relationships. Documentation that only planning committee members who are free from relevant relationships made decisions about the activity.
- Mitigation of Speaker/Author Relationships:
  - Peer review of the educational activity  
The role of peer reviewer is an acknowledged expectation of the activity chair and planning committee members who are subject matter experts and are free from relevant financial relationships. If the activity chair and planning committee members report a relevant financial relationships, a content reviewer who is a subject matter expert without relevant financial

relationships will be designated early in the planning process. Activities with a large volume of topics or educational materials may require the use of more than one reviewer. Peer review will occur when a relevant financial relationship is identified. The UW—Madison ICEP Chair (or designee) may indicate the need for more than one reviewer, an outside reviewer, or the review of an additional subject matter expert based on the complexity or controversial nature of the topic or other issues that might arise during activity planning. The peer reviewer will complete the content review form and return the recommendations to the UW—Madison ICEP accreditation specialist and activity coordinator.

- The Peer Reviewer ensures that:
  - a. All recommendations for patient care are based on current science, evidence and clinical reasoning.
  - b. Content presents a fair and balanced view of diagnostic and therapeutic options.
  - c. All scientific research referred to, reported, or used in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection, analysis, and interpretation.
  - d. New and evolving topics for which there is a lower (or absent) evidence base, are clearly identified as such within the education and individual presentations.
  - e. The content avoids advocating for, or promoting, practices that are not, or not yet, adequately based on current science, evidence, and clinical reasoning.
  - f. The content excludes any advocacy for, or promotion of, unscientific approaches to diagnosis or therapy, or 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.
- Results of Peer Review

There are three potential outcomes of the peer review process. The educational content may be considered (1) acceptable, (2) acceptable with modifications to content if commercial bias or invalid content are identified, or (3) unacceptable and credit for that portion of the activity is not possible.

If the peer reviewer determines that content revision is needed, feedback is provided to the faculty (speakers, presenters, or authors) and a timeline for addressing the changes is communicated. Completed revisions are returned to the peer reviewer for final approval. The process selected and final results will be documented in the activity file.

- Not awarding credit for a portion of or all of the educational activity. Agendas and learning space will be developed to allow learners to easily distinguish between accredited education and other activities.
- Other procedures to mitigate COI must be approved by the UW—Madison ICEP Chair or designee.

## **VI. DISCLOSURE OF FINANCIAL RELATIONSHIPS TO LEARNERS (Standard 3.5/JAC 12)**

For all CE activities provided by the UW—Madison ICEP, all of the relevant financial relationships of everyone in a position to control content will be compiled and disclosed to learners prior to the start of the accredited activity. Disclosure will include the following information: the name of the individual(s) with relevant financial relationships, the name of the ineligible companies with which they have relationships, the nature of the relationship and a statement that all relevant financial relationships have been mitigated.

In the case of individuals who report no relevant financial relationships with ineligible companies, the learners will be informed that no relevant financial relationships with ineligible companies exist.

Disclosure information may be given to the learners electronically, in print, or verbally. If verbal disclosure is planned for a CE activity, UW—Madison ICEP requires written verification that appropriate verbal disclosure occurred prior to the start of the CE activity. A representative of UW—Madison ICEP or an approved designee who was in attendance at the time of the verbal disclosure must attest in writing that verbal disclosure did occur prior to the start of the educational activity.

Disclosure will never include the use of a corporate logo, trade name or a product-group message of an ineligible company.

Prior to the start of the activity, all persons in a position to control the content of the accredited activity must also disclose to the learners when they intend to reference unlabeled/unapproved uses of drugs or products in their content.

## **VII. DISCLOSURE OF COMMERCIAL SUPPORT TO LEARNERS (Standard 3.5/JAC 12)**

UW—Madison ICEP will disclose to learners the names of all ineligible companies that provided monetary or in-kind support prior to the beginning of the educational activity. When commercial support is in-kind, the nature of the support must be disclosed to the learners. Importantly, the disclosure of support from a commercial interest must never include the use of a corporate logo, trade name or a product-group message.

When it is not possible to make a disclosure in writing, a representative of the UW—Madison ICEP or an approved designee who was in attendance at the time of the verbal disclosure must attest in writing that the verbal disclosure was made prior to the start of the educational activity.

## **VIII. CONTINUOUS IMPROVEMENT OF POLICY AND PROCESS**

In support of continuous quality improvement, the UW—Madison ICEP accreditation specialist will ask learners to judge whether the activity in which they participated was commercially biased. An open ended commercial bias question on post-activity evaluations allows learners to enter comments. Comments will be reviewed by the UW—Madison ICEP accreditation specialist. If the comments raise concern about commercial bias, staff members from UW—Madison ICEP will review the content to determine if bias was present. If the presence of bias is confirmed, that information will be relayed to all persons who were in a position to control content. Findings will be discussed with the activity chair and the UW—Madison ICEP Chair (or designee), and an action plan will be devised if needed (in an effort to prevent similar situations in the future).

APPROVED: University of Wisconsin—Madison ICEP Leadership Committee on February 22, 2021.

