



ENTITY University of Wisconsin – Interprofessional Continuing Education Partnership: School of Medicine and Public Health School of Nursing School of Pharmacy	NUMBER UW ICEP-COI
MANUAL Policy and Procedure	EFFECTIVE DATE 1/1/2018
SUBJECT Identification, Resolution and Disclosure of Conflicts of Interest	

I. PURPOSE (SCS 1.1/JAC 9)

To ensure the integrity and independence of educational 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 the Joint Accreditation Criteria 9A-D and ACCME *Standards for Commercial Support: Standards to Ensure Independence in CME Activities*. This Policy on Identification, Resolution and Disclosure of Conflicts of Interest (COI) exists to provide guidance to ensure the following decisions are made free of the control of a commercial interest: 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 manage COIs 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 resolve COIs, and outlines requirements to make disclosure transparent to learners.

III. GUIDING PRINCIPLES RELATING TO CONFLICT OF INTEREST

CE activities sponsored by the University of Wisconsin ICEP are guided by what is in the best interest of the public, always assuring independence from commercial interests, separation of CE from product promotion, and application of content validation to assure quality education. These are the guiding principles for the identification and management of COI.

IV. DEFINITIONS

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

B. Commercial Support

The Joint Accreditation Criteria (*ACCME Standards for Commercial Support*) defines commercial support as financial or in-kind contributions given by a commercial interest, which are used to pay all or part of the costs of an accredited CE activity.

C. 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. Contracted research includes research funding where the institution receives the grant and also manages the funds. Importantly, the Joint Accreditation Criteria (*ACCME Standards for Commercial Support*) considers relationships of the person involved in the CE activity, to include financial relationships of a spouse or partner.

D. Conflict of Interest

Conflict of Interest occurs when individuals have both a financial relationship with a commercial interest and the opportunity to affect the content of an accredited activity that is about the products or services of that commercial interest. The Joint Accreditation Criteria (*ACCME Standards for Commercial Support*) considers “content of CME about the products or services of that commercial interest” to include content about specific agents and/or devices, but not

necessarily about the class of agents and/or devices, and not necessarily content about the whole disease class in which those agents and/or devices are used.

E. Commercial Interest

A commercial interest is defined as *any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on patients.*

<http://www.accme.org/requirements/accreditation-requirements-cme-providers/policies-and-definitions/definition-commercial-interest>

The ACCME does not consider providers of clinical service directly to patients to be commercial interests - unless the provider of clinical service is owned, or controlled by, an ACCME-defined commercial interest.

A commercial interest is not eligible for ACCME accreditation. (SCS 1.2/JAC 9) Commercial interests cannot be accredited providers and cannot be joint providers. Within the context of this definition and limitation, the ACCME considers the following types of organizations to be eligible for accreditation and free to control the content of CME:

- 501-C Non-profit organizations (Note, ACCME screens 501c organizations for eligibility. Those that advocate for commercial interests as a 501c organization are not eligible for accreditation in the ACCME system. They cannot serve in the role of joint provider, but they can be a commercial supporter.)
- Government organizations
- Non-health care related companies
- Liability insurance providers
- Health insurance providers
- Group medical practices
- For-profit hospitals
- For-profit rehabilitation centers
- For-profit nursing homes
- Blood banks
- Diagnostic laboratories
- Entities not listed that may be considered on a case-by-case basis

V. CONFLICT OF INTEREST MANAGEMENT PROCESS

Determination of potential conflicts and resolution must be completed during the activity-planning phase. The following process allows for conflict of interest identification, management and disclosure

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 AND RESOLUTION OF CONFLICTS OF INTEREST (SCS 2.1-2.3/JAC 9a)

The UW-Madison ICEP requires that every individual who is in a position to control content must disclose all relevant personal financial relationships with commercial interests. These individuals include planners, speakers (faculty), 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.

1. 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 Policy on the Identification and Resolution of Conflict of Interest.
2. Disclosure information will be submitted electronically. If needed, a financial relationships disclosure paper form will be utilized as a backup to collect the required information.
3. Disclosures must be received by UW-Madison ICEP accreditation specialists or the appropriate activity coordinator in a timely manner to ensure review and resolution of COI, if needed.
4. Individuals who are in a position to control content but who refuse to complete or do not complete their disclosure by the established deadline will be excluded from participating in the CE activity. UW-Madison ICEP will clearly indicate the deadline for completing the financial relationships disclosure in correspondence that delineates the expectations and responsibilities for an instructor/manager/planner of an activity.

Reporting guidance is as follows:

1. Any relevant financial relationship with a commercial interest during the previous 12-month period represents a potential conflict of interest, and therefore must be reported.
2. The UW-Madison ICEP requires that all persons in a position to control content must also include any relevant financial relationships of a spouse or partner with commercial interests (i.e., they should consider the financial relationships of their spouse or partner as their own) during the previous 12-month period.

3. Reportable personal financial relationships include the following:
 - a. Salary (e.g., employed by a commercial interest)
 - b. Receipt of intellectual property rights / patent holder
 - c. Royalty
 - d. Consulting fees (e.g., advisory boards, expert panels)
 - e. Fees received for promotional services, regardless of their source (e.g., speakers' bureau presentations that are not certified as a CE activity)
 - f. Contracted research (i.e., a grant from a commercial interest even if the institution receives the grant and manages the funds but the person is the principle or named investigator)
 - g. Ownership interest (including stocks, stock options and other forms of ownership, excluding mutual fund investments)
4. All persons in control of content must disclose when they intend to reference unlabeled/unapproved uses of drugs or products in their content.
5. Persons being considered for a role as a planner, author, reviewer, or speaker must submit financial relationship information "in advance" of being formally selected to participate in an activity. UW-Madison ICEP expects to utilize content experts with very few relevant financial relationships as much as possible. Vetting potential speakers, authors and reviewers prior to confirming participation in the activity will help achieve that goal.
6. Faculty and academic staff of the University of Wisconsin will be expected to submit this information on an annual basis. If an individual's financial relationships change during the year, UW-Madison ICEP expects that faculty and academic staff will electronically update that information promptly.
7. Individuals who are not faculty or academic staff of the University of Wisconsin will be expected to report their relevant financial relationships with commercial interests upon invitation to participate in the activity. They will be given instructions on how to submit the information, as well as a clear deadline, when they are sent correspondence that delineates expectations.

Analysis of Information (SCS 2.3/JAC 9a)

Once the disclosure information regarding financial relationships is obtained, a systematic process will be conducted to analyze this information and determine the potential risk of COI for each person who is in a position to control content.

1. Disclosures will be reviewed by the UW-Madison ICEP accreditation specialists and/or appropriate activity coordinator, who will, based on the reported information, implement the process for conflict resolution (see section IV. D. for the definition of a relevant conflict of interest).
2. *Relevant financial relationships* are financial relationships in any amount, which have occurred in the twelve-month period preceding the invitation to assume a role controlling the content of the CME activity, and which relate to the content of the educational activity. The relationship is relevant if the content is about the products and services of the commercial interest including specific agents and/or devices of the commercial interest, but not necessarily about the class of agents and/or devices, and not necessarily content about the whole disease class in which those agents and/or devices are used.
3. The following options for resolving conflicts are available:
 - Not Applicable – No relationship(s) with a commercial interest were disclosed; confirm participation in the activity.
 - Not Applicable – Disclosed relationship(s) were found not to be ‘relevant’ (Explanation required); confirm participation in the activity.
 - Relevant relationship(s) with a commercial interest were identified (COI exists)
 - One or more of the following ACTIONS TO RESOLVE THE COI will be taken by the UW-Madison ICEP accreditation specialist, activity chair, and/or appropriate designee: (methods of resolution will be discussed with the individual and agreed to prior to confirming participation in the activity).
 - Removed individual from participating in all parts of this educational activity
 - Revised individual’s role in the activity so the financial relationship is no longer relevant (Explanation required)
 - Not awarding credit for a portion of or all of the educational activity
 - Conduct content review of the educational activity for evidence of integrity/absence of bias

- Other procedures to resolve COI (must be approved by the UW-Madison ICEP Chair or designee)

In most cases, content review will serve as the primary mechanism of the UW-Madison ICEP COI management system. The purpose of content review is to ensure valid content is free from all commercial influence, is fair and balanced, and is based on evidence that is accepted within the professions of medicine, nursing and/or pharmacy, and conforms to generally accepted standards of experimental design, data collection and analysis. The role of content reviewer is an acknowledged expectation of the activity chair. If the activity chair reports a relevant conflict, a content reviewer without relevant conflicts 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. Content review will occur when a relevant financial relationship is reported. 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 clinical content expert based on the complexity or controversial nature of the topic or other issues that might arise during activity planning. The content reviewer will complete the content review form and return the recommendations to the UW-Madison ICEP accreditation specialist and activity coordinator. There are three potential outcomes based on the content review. 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 content reviewer determines that content revision is needed, feedback is provided to the speaker/faculty/author and a timeline for changes is determined. Completed revisions are returned to the content reviewer for final approval. The process selected and final resolution 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 resolved.

B. DISCLOSURE OF FINANCIAL RELATIONSHIPS TO LEARNERS (SCS 6.1-6.2, 6.5/JAC 9a)

For all CE activities provided by the UW-Madison ICEP, all relevant information related to the financial relationships of anyone 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, the name of the commercial interest(s), and the nature of the relationship the person has with the commercial interest(s)*. In the case of an individual who reports no personal financial relationships with commercial interests to ICEP, the learners must be informed that *no relevant financial relationships* exist. Disclosure information may be given to the learners electronically, in print,

or verbally. Disclosure will never include the use of a corporate logo, trade name or a product-group message of a Joint Accreditation/ACCME defined commercial interest.

If verbal disclosure is planned for a CE activity, the UW-Madison ICEP requires written verification that appropriate verbal disclosure occurred at the CE activity. 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 verbal disclosure did occur prior to the start of the educational activity. In addition, they must itemize the content of the disclosed information or state that there was nothing relevant to disclose.

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.

C. DISCLOSURE OF COMMERCIAL SUPPORT TO LEARNERS (SCS 6.3-6.5/JAC 9a)

The source of all support from commercial interests must be disclosed to learners *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. However, acknowledgement of commercial support may state the name, mission, and areas of clinical involvement of the company or institution, as long as they are not product promotion in nature.

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.

POST ACTIVITY

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 October 19, 2017.