

**POLICY ON DISCLOSURE, CONFLICT RESOLUTION,
AND PAYMENT OF HONORARIA IN CME AND IPCE ACTIVITIES**

In accordance with the Accreditation Council for Continuing Medical Education (ACCME) *Standards for Commercial Support: Standards to Ensure Independence in CME Activities*, it is the policy of the Perelman School of Medicine at the University of Pennsylvania and Penn Medicine to ensure balance, independence, objectivity, and scientific rigor in all its continuing medical and interprofessional education activities.

DISCLOSURE OF FINANCIAL RELATIONSHIPS: Accordingly, all individuals who are in a position to control the content of an educational activity must first disclose all relevant financial relationships with any commercial interest to the Office of Continuing Medical Education (CME) and Interprofessional Continuing Education (IPCE) (Office of CME & IPCE) as the administrative unit of the Perelman SOM at the U of Penn and Penn Medicine responsible for national accreditation by the Accreditation Council for Continuing Medical Education (ACCME) and the Joint Accreditation for Interprofessional Continuing Accreditation (JA).

Individuals subject to this requirement include, but are not limited to: activity course directors and program chairs, planning committee members, faculty/speakers/presenters, authors and editors, expert reviewers, moderators and panel members. This disclosure must be provided in writing on the standardized *Disclosure of Relevant Financial Relationships and Unapproved Uses of Products* (Disclosure) form.

In addition, all faculty (speaker, editor, presenter, moderator, panelist), are required to disclose to the learners:

- When products or procedures are being discussed out-of-label and/or as investigational (not FDA approved for use under discussion);
- Any limitation on the information that is presented (e.g., data that is preliminary, represents ongoing research, interim analysis, anecdotal evidence, and/or unsupported opinion)

An individual who refuses to (or chooses not to) disclose relevant financial relationships will be disqualified from participating as a planning committee member, a faculty member, facilitator, or an author of CME, and cannot have control of, or responsibility for the development, management, presentation or evaluation of the Perelman School of Medicine at the University of Pennsylvania or Penn Medicine certified CME or IPCE activity.

RESOLUTION OF CONFLICTS OF INTEREST (COI): Based on the disclosed information, the Education Committee in the Office of CME and IPCE will identify actual conflict(s) of interest. Once a conflict of interest is identified, one or more of the following mechanisms may be employed to resolve (manage or mitigate) the conflict prior to the activity being delivered to the learners:

- In the case of a course director or program chair responsible for developing agenda and proposing presenting faculty, a review and feedback by the Educational Committee in the Office of CME and IPCE will be provided and in some instances peer review outside of the institution may be sought. Additional Planning Committee members without relevant financial relationships may be required in the instance when all proposed Course Director(s) and Planning Committee members have reported relevant conflicts of interest. In addition, Course Directors and Planning Committee members with COIs will be asked to recuse themselves from selecting faculty and directing content in the area of their specific conflict.

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- Individual presentations, or initial drafts of a conflicted faculty member’s lectures will undergo several levels of peer review and may need to be modified accordingly:
 - Initial review will be provided by the OCME Senior Peer Reviewer and CME/IPCE or Penn Medicine Nursing leadership.
 - Feedback will be requested from the course director or program chair.
 - If necessary, separate expert peer review will be conducted under the direction of the OCME.
 - Final feedback related to the content and potential perceived commercial bias in individual presentations as well as the CME/IPCE in general will be requested from the learners immediately following the educational activity. Results will be shared with individual presenters and program chair(s), analyzed and used in planning future educational activities.
- An individual without a conflict of interest may replace the conflicted individual.
- The scope of the conflicted individual’s role may be restricted so that he/she may no longer control the content, or he/she may be asked to refrain from providing clinical recommendations within a given educational activity.

ADDITIONAL STRATEGIES AND RESOURCES: All faculty will receive instructions in individual faculty confirmation letters about the standards of practice in CE and details about and Safeguards Against Commercial Bias. Specifically, information concerning expectations related to the content of CE that:

- Must **Not** promote proprietary interests of any commercial interest
- Must give a balanced view of therapeutic options
- All the recommendations involving clinical medicine in a CE activity must be based on evidence that is accepted within the health profession being addressed as adequate justification for their indications and contraindications in the care of patients. All scientific research referred to, reported or used in CE in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection and analysis.

The Education Committee of the Penn Office of CME & IPCE will serve as an ongoing resource to provide training and answer questions from coordinators, course directors, presenting faculty, educational partners/joint sponsors and potential grantors (commercial interests) related to standards of practice in CME & IPCE, ACCME *Standards for Commercial Support* and *Penn CE Disclosure, Conflict Resolution, and Payment of Honoraria in CME Activities Policy* and practice.

Annual workshops and training tutorials related to policies and practice of CME/IPCE will be presented for coordinators and faculty and instructional materials will be available on the Penn CME & IPCE website as an additional resource to all individuals involved in planning, controlling, developing and presenting in Penn certified CE activities.

DISCLOSURE TO LEARNERS: Relevant financial relationships of those with control over CE content must be disclosed to learners *prior* to the continuing education activity in a “Disclosure Statement.” This information will be distributed in course syllabi, issued with handout materials, printed in enduring materials, or included in the Web CME/CE. This will include the following information:

- The name of the individual;
- The name of the commercial interest(s);
- The nature of the relationship the person has with each commercial interest.

Information that an individual has **no** relevant financial relationship(s) must also be provided to learners.

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Information about the source of all support from commercial interest(s) must be disclosed to learners.

When commercial support is “in-kind,” the nature of the support must be disclosed as well. This information must be disclosed to learners prior to the beginning of the educational activity and must never include the use of trade names, logos or product group messages.

It is the joint responsibility of the sponsoring academic or clinical department and the OCME & IPCE to ensure that all continuing education activities are implemented in accordance with this policy. All *Disclosure of Relevant Financial Relationships and Unapproved Uses of Products* forms must be received by OCME & IPCE before the individual’s role in the CE activity may be confirmed. OCME & IPCE will provide training, implementation tools and monitoring to coordinators within individual departments but will retain the final responsibility for the implementation of this policy. All faculty correspondence, disclosure forms and statements must be returned to the OCME & IPCE and maintained in activity records.

The intent of this policy is not to prevent expert faculty with relevant relationship(s) with commercial interest(s) from involvement in CME, IPCE, but rather to ensure that Penn CE-certified activities promote quality and safety, are effective in improving medical practice, are based on valid content, and are independent of control from commercial interests and free of commercial bias.

PAYMENT OF HONORARIA: It is often customary to provide honoraria, travel, lodging, and reimbursement of reasonable personal expenses to bona fide faculty and course/program chairs and planners involved in developing and presenting in continuing education activities. It is the policy of the Perelman School of Medicine at the University of Pennsylvania and Penn Medicine to allow payment of reasonable honoraria to be paid out of the activity budget that may include use of educational grants provided by commercial interest(s) in support of a CE activity under the following guidelines:

- No honoraria should be paid to internal (Penn) faculty providing presentations in regularly scheduled series (RSS), such as grand rounds, case conferences, tumor boards, etc. within the Perelman School of Medicine at the University of Pennsylvania or Penn Medicine/UPHS.
- In general, honoraria are not paid to Penn faculty for participation in Penn courses. Exceptions may be made in some circumstances (other than for grand rounds/regularly scheduled series) when budgets can support it and with the approval of the department chair and the course director/chair.
- In a situation where Penn faculty are approved to receive honoraria for CME courses, these may be provided as additional pay and are subject to the individual’s predetermined tax deduction and the charge of the standard additional percentage for employee benefits (currently 31.6%). Another option is to deposit the amount in the name of a faculty honorarium in the department’s educational account to be used by individual faculty (or department/division) for educational and professional development.
- Payment of honoraria to visiting faculty presenting in RSS (grand round lectures) and all other CME/IPCE courses and enduring materials is permitted. The amount may vary based on the budget, the availability of quality speakers, and the individual’s credentials and standing in the medical community. However, there should be no payment of honoraria for a single lecture/presentation in excess of \$5,000 or \$10,000 for multiple lectures/presentations within any one activity. Any exception to this rule must be approved by the Penn CME and IPCE Advisory Board.

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Reimbursement of reasonable out-of-pocket expenses for faculty, course/program chairs and planners participating in Penn CE is allowed and governed by the University of Pennsylvania Travel and Entertainment Policy No. 2351 through 2368.

Commercial support for CME/IPCE **may not** be used to pay for travel, lodging, honoraria, or personal expenses for **participants (learners)** in an accredited CE activity.

GLOSSARY OF TERMS

COMMERCIAL INTEREST: The ACCME defines a “commercial interest” as any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

RELEVANT 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. ACCME considers relationships of the person involved in the CME activity to include financial relationships of a spouse or partner.

With respect to personal **financial relationships**, ‘contracted research’ includes research funding where the institution receives the grant and manages the funds and the person is the principal or named investigator on the grant.

CONFLICT OF INTEREST: Circumstances create a conflict of interest when an individual has an opportunity to affect CME content about products or services of a commercial interest with which he/she has a financial relationship.

The ACCME considers **financial relationships** to create actual conflicts of interest in CME when individuals have both a financial relationship with a commercial interest and the opportunity to affect the content of CME about the products or services of that commercial interest. The ACCME considers “content of CME about the products or services of that commercial interest” to include content about specific agents/devices, but not necessarily about the class of agents/devices, and not necessarily content about the whole disease class in which those agents/devices are used.

With respect to **financial relationships** with commercial interests, when a person divests themselves of a relationship it is immediately not relevant to conflicts of interest but it must be disclosed to the learners for 12 months.

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