

UNIVERSITY OF COLORADO SCHOOL OF MEDICINE
Office of Continuing Medical Education

POLICY for DISCLOSURE and IDENTIFICATION
and RESOLUTION of CONFLICTS of INTEREST

Purpose

The University of Colorado School of Medicine (CUSOM) as an Accreditation Council for Continuing Medical Education (ACCME) provider, endorses and strives to comply with the ACCME Standards of Commercial Support on the need for disclosure and monitoring of proprietary and financial interests that may affect the scientific integrity and balance of content delivered in continuing medical education (CME) activities certified by the Office of Continuing Medical Education (OCME).

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. **Financial relationships** are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria for promotional speakers' bureau, 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 or clinical trials where the institution receives the grant and manages the funds and the person is the principal or named investigator of the grant), consulting, speaking and teaching, membership on advisory committees or review panel, board membership, and other activities from which remuneration is received, or expected. **Relevant financial relationships**, as defined by the ACCME, are financial relationships in any amount that create a conflict of interest and that occurred in the twelve-month period preceding the time that the individual was asked to assume a role controlling content of the CME activity. The ACCME has not set a minimal dollar amount – any amount, regardless of how small, creates the incentive to maintain or increase the value of the relationship. The ACCME considers relationships of the person involved in the CME activity to include financial relationships of a spouse or partner.

Policy

The OCME requires that a rigorous needs assessment based on professional practice gaps is the driver of evidence-based, scientific content and educational methodology in all CME activities. The OCME recognizes that to ensure transparency of financial relationships and eliminate commercial bias in CME activities, anyone who is in a position to control content of a CME activity (such as course directors, planners, faculty, authors, reviewers) must disclose to the OCME any relevant financial relationship(s) with a commercial interest specific to the proposed CME activity. The OCME uses the mechanisms described below to identify and resolve all conflicts of interest prior to the CME activity taking place. If an individual who is in a position to control content of CME refuses to disclose relevant financial relationships to the OCME, he/she will automatically be disqualified from any role in planning, management, presentation or evaluation of that CME activity. Commercial interests cannot take the role of a non-accredited provider in joint providership activities. Employees of commercial interests cannot be on a planning committee.

Disclosure

The OCME must be able to demonstrate that everyone who is in a position to control the content of a CME activity has disclosed all relevant financial relationships with any commercial interest specific to the CME activity. Our process entails the following steps:

- Provide a Disclosure of Relevant Financial Relationship form to all individuals in control of content for each CME activity.
- Disclosure of Relevant Financial Relationship forms must be submitted to the OCME at least 20 days prior to the start of the CME activity to allow sufficient time for OCME review and resolution of potential conflicts of interest.
- An individual who refuses to disclose, as reported to OCME by the course director, will be disqualified from participating in any aspect of the CME activity.
- Disclosure of Relevant Financial Relationship forms are maintained in related activity files.
- Disclosure of Relevant Financial Relationship forms provided on an annual basis are acceptable for CME committees/planners, regularly scheduled series committees/planner/speakers.

Identification and Resolution of Conflicts of Interest

The OCME coordinators review Disclosure of Relevant Financial Relationship forms for potential conflicts of interest (COI), and if a financial relationship is specific to the content, the COI is resolved by one of the following mechanisms, as approved by the OCME Advisory Committee and Associate Dean for OCME:

- **Recusal** – Course directors and planning committee members in the pre-application phase; the OCME contacts the individual with the relevant financial relationship, the individual recuses him/herself from planning any content relative to his/her relevant financial relationships and names another planning committee member without relevant financial relationships to plan content for the conflicted individual (if any).
- **Content validation** – Course faculty and speakers prior to the start of the activity; course director reviews all activity content prior to the start of the activity, verifies by signing form that content is based on evidence, generally accepted standards, does not contain commercial interest advertising, promotes improvements or quality in healthcare, and offers balanced view of therapeutic options.
- **Attestation** – Course faculty and speakers prior to the start of the activity
 - Employees of a commercial interest – These individuals are contacted by the OCME and can only control content/participate in an activity if they fall into one of three limited roles as defined by ACCME (content not related to employer business/product lines, content is related to basic science research or processes/methodologies of research, teaching technician). Based on their role and if the individual is allowed to participate in the activity, their content is reviewed by the course director prior to the start of the activity.
 - Stock/Shareholders/Royalties – These individuals are contacted by the OCME, discussion ensues to ensure individuals' content does not encompass content relative to business or product lines of their relevant financial relationship; content is reviewed by the course director prior to the start of the activity.
- **Alter the financial relationship** – Individuals may choose to discontinue or alter their relationship with a commercial entity and eliminate any bias associated with the proposed CME content.

NOTE: The OCME Disclosure of Relevant Financial Relationship form requires a signature outlining the following terms and conditions:

Disclosure – Faculty members must complete and submit a Disclosure of Relevant Financial Relationships form prior to the educational activity allowing sufficient time for provider to identify and resolve any conflicts of interest, and that disclosure form shall be complete and truthful to the best of the presenter's knowledge. Faculty members are required to disclose relevant financial relationship(s) involving themselves or their spouse/partner within the last 12 months with any commercial interest (excluding non-profit or government organizations) in any amount specific to the content of the activity.

Fair-Balance – Faculty members are required to prepare fair and balanced presentations that are objective and scientifically rigorous. The presentation will be educational, not promotional, based on the stated objectives of the program and the identified educational needs of the target audience. The presentation/participation is intended to promote improvements or quality in healthcare and in the public's best interest.

Unapproved Uses – Presentations that provide information whole or in part related to non-FDA approved uses for drug products and/or devices must clearly acknowledge the unlabeled indications or the investigational nature of their proposed uses to the audience. Faculty members who plan to discuss non-FDA approved uses for drug products and/or devices must advise the accredited provider of their intent.

Use of Generic versus Trade Names - When applicable, presenters should use scientific or generic names when referring to products in their lectures and discuss a balanced view of therapeutic options. Should it be necessary to use a trade name, the trade names of all products should be used.