# UNIVERSITY OF COLORADO SCHOOL OF MEDICINE Office of Continuing Medical Education & Professional Development

## POLICY for DISCLOSURE and IDENTIFICATION and RESOLUTION of CONFLICTS of INTEREST

### **Purpose**

The University of Colorado School of Medicine (UCSM) 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 & Professional Development (OCME&PD).

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. The ACCME does not consider providers of clinical service directly to patients to be commercial interests. Financial relationships are those relationships in which the individual receives some form of 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 an advisory committees or review panel, 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. Relationships are considered to be relevant when they have occurred within 12 months of involvement with a CME activity and they could create a conflict of interest. The value of the financial benefit received is irrelevant. A financial relationship can create a conflict of interest in CME when individuals (or their spouse/partner) have both a financial relationship with a commercial interest and the opportunity to affect the content of CME that discusses, reviews or could otherwise impact the products or services of that commercial interest.

#### **Policy**

The UCSM requires that a rigorous behavioral and educational performance needs assessment is the driver of the content and the educational method, ensuring that the scientific content is evidence-based. UCSM 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 planners, faculty, authors and reviewers of CME) must disclose to OCME&PD a financial relationship with a commercial interest relevant to the proposed CME activity. The OCME&PD 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&PD, 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 the planning committee.

#### <u>Disclosure</u>

The OCME&PD 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. Our process entails the following steps:

- Provide a Disclosure of Financial Relationship form to all individuals in control of content for each CME activity.
- Disclosure of Financial Relationship forms must be submitted to the OCME&PD at least 30 days prior to the start of the CME activity to allow sufficient time for review and resolution of any potential conflicts of interest (if any).
- An individual who refuses to disclose, as reported to OCME&PD by the course director, will be disqualified from participating in any aspect of CME.
- Disclosure of Financial Relationship forms are maintained in related OCME&PD activity files.
- Disclosure of 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**

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

- 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.
- Alter control over content The individual with the COI is removed from the CME activity.
- Peer Review The course director reviews and validates all CME activity content to ensure it is evidence-based.

In the rare event that we are unable to resolve conflict, then we will not provide AMA PRA Category 1 Credit.

NOTE: The OCME&PD Disclosure of Relevant Financial Relationship form requires a signature outlining the following Terms and Conditions:

**Disclosure** – Faculty members must complete and submit a Faculty Disclosure 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 proprietary entity producing health care goods or services (excluding non-profit or government organizations) related 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.

Commercial Supporter Influence – All support associated with a CME activity, whether in the form of an educational grant or not, must be given with the full knowledge and approval of the accredited provider. No other funds from a commercial source shall be paid to the director of the activity, faculty, or others involved with the supporter activity. Presenters should not be subject to direct input from a commercial supporter regarding the content of the presentation.