

Keck School of Medicine of **USC**
Office of Continuing Medical Education

INDEPENDENCE, CONTENT VALIDATION AND DISCLOSURE POLICY

INTRODUCTION:

The Keck School of Medicine of the University of Southern California (KSOM) is accredited by the Accreditation Council for Continuing Education (ACCME) to provide continuing medical education (CME) for physicians. The Office of CME (OCME) is responsible for ensuring compliance with the ACCME's Essential Areas, Elements, Criteria, Policies and Standards for Commercial Support. The policy on independence, content validation and disclosure ensures that activities are free of commercial control and bias and are in the interest of providing quality continuing medical education which best serves the public interest.

POLICY:

1. All accredited activities will be in compliance with ACCME's Essential Areas, Elements, Criteria, Policies and Standards for Commercial Support.
2. Commercial Interests -- defined as "any entity producing, marketing, re-selling or distributing health care goods or services consumed by, or used on, patients." -- will have no role in identification of needs, determination of learning objectives, content development, faculty selection, activity format or evaluation, and therefore all decisions will be free of the control of commercial interests. In addition, no commercial interest shall have input into meeting planning, materials, marketing strategies or distribution of CME materials.
3. The content and format of the activity and materials must promote improvements or quality healthcare and not specific proprietary business interests of commercial interests.
4. No commercial interest can take the role of joint sponsor.
5. As the Accredited Provider, the OCME is responsible for the quality of content, ensuring it meets the stated educational objectives. Content must be based on generally accepted practices. Commercial supporters cannot influence or direct the planning, development or delivery of content. Faculty will be asked to sign a statement that they will develop and deliver content to ensure balance, independence, objectivity and scientific rigor.
 - All the recommendations involving clinical medicine in a CME activity are based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contra-indications in the care of patients (ACCME July 2002);
 - All scientific research referred to, reported, or used in a CME activity in support or justification of a patient care recommendation conforms to the generally accepted standards of experimental design, data collection and analysis (ACCME July 2002); and
 - Research findings and therapeutic recommendations are based on scientifically accurate, up-to-date information and are presented in a balanced, objective manner (AMA 2002).
6. Activity directors, planning committee members, teachers/authors, and others planning or participating in CME activities must disclose any relevant financial relationships with commercial interests to the audience prior to the activity. Learners must also be informed if the individual has declared no financial relationships. Any individual who refuses to disclose (using the Faculty Disclosure Form) will be disqualified from any role in the activity. All identified conflicts of interest must be resolved according to the Conflict of Interest Resolution Policy listed on the back of all Faculty Disclosure Forms.
7. Presentations and CME materials must give a balanced view of therapeutic options. Use of generic names contributes to impartiality. If materials include trade names, where available, trade names from several companies should be used, not just trade names from a single company. Product recommendations should not be included. Educational materials such as presentations, abstracts and handouts cannot contain any advertising, trade names or product message.
8. Off-label, unlabeled, experimental or investigational products or procedures are required to be disclosed to the learners.

9. The OCME (or its educational designee) must approve all commercial support associated with the activity and its disbursement. The source and nature of all commercial support will be disclosed to the learners, in writing, prior to the activity. All commercial interests must sign a Commercial Support Letter of Agreement indicating the terms and conditions. No other payment from a commercial interest shall be given to any person or entity involved in the CME activity.
10. A signed Commercial Support Letter of Agreement with the commercial interest is required for acknowledgment to take place. No commercial funds will be acknowledged in advance of receipt of this signed agreement.
11. Social events or meals cannot compete with or take precedence over the educational activity. They shall be for activity participants only, should be modest, and will be planned by the OCME or its designee.
12. All honoraria and out of pocket expenses will be paid in compliance with the KSOM OCME Honorarium and Expense Reimbursement Policies. Honorarium amounts are set by the Course Director with oversight by the OCME.
13. Commercial funds may not be used to pay travel, lodging, honoraria or personal expenses for non-faculty participants of the activity. Funds may be used to pay for staff.
14. Exhibit fees are not considered commercial support. Exhibits shall be separate from the educational activity and must not interfere with the learning experience. Representatives of commercial interests may attend the activity as a learner but may not engage in sales or promotional activities while in the space or place of the CME activity.