

Policy on Identification, Resolution and Disclosure of Conflicts of Interest

I. Definitions

A. Commercial Interest

A commercial interest is any entity producing, marketing, reselling or distributing health care goods or services consumed by, or used on patients. Providers of clinical services directly to patients are not considered commercial interests.

B. Financial Relationships

Financial relationships are those relationships in which the individual or the individual's spouse/partner 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 and research funding where the institution receives the grants, manages the funds and the individual is the principal or a named investigator on the grant), consulting, speaking and teaching, membership on advisory committees or review panels, board membership and other activities from which remuneration is received, or expected.

C. Relevant Financial Relationships

Relationships are considered to be relevant when they meet two criteria: 1) They are current or have occurred within the 12-month period preceding the time that the individual assumes a role controlling content of the Continuing Medical Education (CME) activity, and 2) These relationships relate to the content of the educational activity. The value of the financial benefit received is irrelevant.

D. Conflict of Interest (COI)

Per the Accreditation Council for Continuing Medical Education (ACCME) a financial relationship creates 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 the CME about the products or services of that commercial interest.

If the person involved in the CME activity is employed by a commercial interest, the ACCME considers there to be a non-resolvable conflict of interest and thus this employee may not participate in the planning or teaching of the CME activity. The only exception is if the course content is unrelated to products or services provided by the commercial interest. See ACCME Policy

<http://www.accme.org/education-and-support/video/tutorials/ensuring-independence-role-employees-accme-defined-commercial> and ACCME Compliance Reminders — Standards for

Commercial Support: Standards to Ensure Independence in CME ActivitiesSM

<http://www.accme.org/news-publications/highlights/compliance-reminders-%E2%80%94-standards-commercial-support-standards-ensure> for clarification.

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II. Policy

The intent of this policy is to ensure that Continuing Medical Education activities are developed free from the control of commercial interests and are balanced, objective and scientifically rigorous. The Stanford University School of Medicine 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, instructors, authors, reviewers, etc.) must disclose to the Course Director, CME Coordinator, or the Stanford Center for Continuing Medical Education (SCCME) any financial relationships with a commercial interest that are relevant to the CME activity. The SCCME uses the mechanisms described below to identify and resolve all conflicts of interest at specific times based upon individual roles prior to the CME activity taking place. If any individual who is in a position to control content of CME refuses to disclose relevant financial relationships to SCCME, he/she will be automatically disqualified from any role in planning, management, presentation or evaluation of that CME activity.

III. Identifying and Managing Conflicts of Interest

The disclosure of relevant financial relationships or the absence thereof is accomplished by the use of the SCCME's standardized CME Disclosure Form that captures information on the financial relationships of the individual in control of content for a CME activity and his/her spouse/partner.

Conflicts of Interests (COIs) are identified by reviewing information on this form to determine whether the disclosed financial relationships are related to the activity's content taking into consideration the individual's role in the activity.

Individuals also complete an SCCME Attestation Form on which they attest that: 1) Their contributions to the CME activity will be free from commercial bias, 2) Any and all clinical recommendations made for patient care will be based on the best available evidence, 3) A balanced view of therapeutic options will be given, and 4) Their contribution will serve public interest by improving the quality of healthcare.

For Course Directors and Planners, such disclosures and subsequent resolutions of any COIs should occur before topics and speakers are chosen. For activity Speakers, Moderators, or Authors such disclosures and subsequent resolutions of any COIs must occur before the presentations are made or the enduring material is finalized/released.

For Content Reviewers, disclosure and attestation forms should be completed prior to conducting the content review and submitted to a non-conflicted physician Course Director (or non-conflicted physician Planner when the Course Director is conflicted) for review and determination if any conflicts exist. Content Reviewers must be non-conflicted so resolution of conflict of interest is not necessary. Content Reviewers must have expertise in the subject to be reviewed.

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IV. Procedure to Resolve COIs for Course Directors and Planners

The SCCME will provide Disclosure and Attestation Forms for the initial planning meeting. The forms should be completed at this meeting and if not completed, the SCCME will send the forms for immediate completion. Physician Course Directors without a conflict of interest ('non-conflicted') are responsible for resolving planners' identified conflict of interests prior to their involvement in CME activity planning. If the Course Director is conflicted, then a non-conflicted physician planner must take the action necessary to resolve the conflict(s). The CME application will not be reviewed or certified until all completed disclosures, attestations and resolution of conflict of interest forms are submitted to the SCCME. If a COI is identified, any of the mechanisms listed below may be used to resolve it. The mechanism used is documented on the Resolution of COI form by the non-conflicted Course Director or his/her non-conflicted physician designee.

- Activity planning includes a non-conflicted physician planner and is based on identified practice gaps of learners, best available evidence, and developed in a fair and balanced manner.
- Planner recuses him/herself from topic selection relevant to his/her conflict of interest.
- Elimination of the individual from planning of the CME activity.

V. Procedure to Resolve COIs for Speakers, Moderators and Authors

Once the Speakers, Moderators, and/or Authors are identified by the Planner(s) of the CME activity, the CME Coordinator will send out the Disclosure and Attestation Forms. The CME Coordinator will confirm receipt of the forms and inform the Course Director if an individual fails to return the completed forms or if an individual has returned the form indicating a financial relationship. A physician Course Director or a non-conflicted physician designee must take the action necessary to review the relationship(s) and resolve the conflict(s). The mechanism used to resolve the COI must be documented on the Resolution of COI form for Speaker/Moderator/Author. Any of the mechanisms listed below may be used to resolve it:

- The CME materials (presentations, online course material, etc.) prepared by the conflicted individual will be peer reviewed -- normally a non-conflicted physician reviewer -- in advance of their presentation/publication for content validation and fair balance, and modified as needed according to the results of the review to remove any identified commercial bias.
- When presentation slides are not utilized, the Course Director will inform the individual of the following in advance of their participation: a) content must be valid and aligned with the interests of the public; b) all recommendations involving clinical medicine must be based on best available evidence; and c) all scientific research referred to, reported, or used in the CME activity in support of or as justification for patient care recommendations must conform to the generally accepted standards of experimental design, data collection, and analysis.
- Change the focus of the Speaker's/Moderator's/Author's content so the COI no longer exists.
- Elimination of the individual from the activity.

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VI. Monitoring and Mitigating Commercial Bias

In addition to resolving conflicts of interest, SCCME takes steps to monitor for and mitigate commercial bias. The steps include:

- SCCME promotes opportunities within the educational setting for learner participation, debate and dialogue to allow for discussion of alternatives and continuous improvement.
- For live activities, if commercial bias is perceived by the Course Director or his/her designee during the activity, the monitoring physician will take appropriate steps to mitigate the identified bias to the extent practicable prior to the activity ending.
- For enduring materials, content is reviewed for potential commercial bias prior to the activity's release.
- Learners are asked to identify any perceived commercial bias through post-activity evaluations. If 5% or more of participants have perceived bias in the activity content, the Course Director will take action to safeguard against future bias by taking one or more of the following actions: a) speak with the faculty member about the bias that was perceived and discuss how to avoid commercial bias in the future; b) not invite the faculty member to participate in future CME activities; or c) for enduring materials, revision of the content as needed to remove the bias from the activity.
- Support from industry for CME may be accepted only for activities that have undergone a two level review and approval process to ascertain that the activities have been independently developed without influence from commercial entities, focus on identified practice gaps, and are congruent with Stanford Medicine's identified needs and mission. See the Commercial Support of Continuing Medical Education Policy <https://med.stanford.edu/content/dam/sm/CME/documents/policies/commercial-support-policy.pdf> for additional information.

VII. Disclosure of Financial Relationships to Learners

For all Stanford University School of Medicine certified CME activities, relevant financial relationships are disclosed to learners prior to the start of the activity. Disclosure will include the following information: the name of the individual, the name of the commercial interest(s), the nature of the relationships the person has with each commercial interest, and the individual's role related to the activity (e.g. planner, speaker, reviewer, etc.) For individuals who have reported no relevant financial relationships, the learners are informed that no financial relationships exist. Disclosure information may be published in activity syllabi, handouts, presentation slides; posted with sign-in sheets; and for online activities made available on the front web page/tab.

VIII. Disclosure of Commercial Support to Learners

The source of all support from commercial interests must be disclosed to learners prior to the beginning of the CME activity. This information is provided through publication in activity syllabi, handouts, verbally, or online, acknowledging all in-kind and monetary support received for the CME activity. When in-kind support is received, the nature of the support is detailed in the disclosure (e.g. durable equipment, disposable supplies, animal parts or tissue). The disclosure may not contain the use of trade names, product group messages, or commercial interests' logos. Learners may also be informed if there is no commercial support for the activity.