Policy on Identification, Mitigation and Disclosure of Conflicts of Interest

I. Definitions

A. Ineligible companies
An ineligible company (formerly referred to as 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 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 24-month period preceding the time that the individual assumes a role controlling content of the accredited Continuing Education (CE) 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 have both a financial relationship with an ineligible company and the opportunity to influence the content of the CME about the products or services of that ineligible company.

If the person involved in the CE activity is employed by an ineligible company, the ACCME considers there to be a non-mitigatable 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 ineligible company. See ACCME Policy https://www.accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce and ACCME Compliance Reminders — Standards for Commercial Support: Standards to Ensure Independence in CME Activities™ https://acme.org/publications/standards-for-integrity-and-independence-accredited-continuing-education-pdf 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 ineligible companies and are balanced, objective and scientifically rigorous. Stanford Medicine recognizes that to ensure transparency of financial relationships and eliminate commercial bias in CE activities, anyone who is in a position to control content of an accredited CE activity (such as planners, instructors, authors, reviewers, etc.) must disclose to the Course Director, Compliance Coordinator, or the Stanford Center for Continuing Medical Education (SCCME) all financial relationships with ineligible companies. The SCCME uses the mechanisms described below to identify and mitigate all conflicts of interest at specific times based upon individual roles prior to the accredited CE activity taking place. If any individual who is in a position to control content of accredited CE refuses to disclose financial relationships to SCCME, he/she will be automatically disqualified from any role in planning, management, presentation or evaluation of that CE 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 CE activity.

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

For Peer Reviewers, disclosure and attestation forms should be completed prior to conducting the peer 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. Peer Reviewers must be non-conflicted so mitigation of conflict of interest is not necessary. Peer Reviewers must have expertise in the subject to be reviewed.
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IV. Procedure to Mitigate COIs for Course Directors and Planners

The SCCME will request Disclosure Forms from all planners which need to be completed prior to planning the course. Physician Course Directors without a conflict of interest (‘non-conflicted’) are responsible for mitigating planners’ identified conflict of interests prior to their involvement in accredited education activity planning. If the Course Director is conflicted, then a non-conflicted physician planner must take the action necessary to mitigate the conflict(s). The CME application will not be reviewed or certified until all completed disclosures, attestations and peer review forms are submitted to the SCCME. If a COI is identified, any of the mechanisms listed below may be used to mitigate it. The mechanism used is documented on the Peer Review form by the non-conflicted Course Director or his/her non-conflicted physician designee.

• Attestation by persons without relevant financial relationships to ensure that planning decisions and content is based on the identified practice gaps, best available evidence, and developed in a fair and balanced manner.

• Disclosed financial relationship is NOT relevant to planning decisions or content (Detail below e.g. relationship is not with an ACCME defined ineligible company; content is focused on communication skills; patient diagnostics or treatment recommendations will not be addressed).

• Recusal from controlling aspects of planning and content with which there is a financial relationship (Detail below the topic area(s) from which the planner will be recused from).

• Individual's conflict has been deemed immitigable, and they will be considered ineligible to plan, present, author, or review any aspect of this activity.

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

Once the Speakers, Moderators, and/or Authors are identified by the Planner(s) of the CE 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 mitigate the conflict(s). The mechanism used to mitigate the COI must be documented on the Peer Review form. Any of the mechanisms listed below may be used to mitigate:

• Peer Review: The CE materials (presentations, online course material, etc.) prepared by the conflicted individual will be peer reviewed -- by 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 CE 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.
VI. Monitoring and Mitigating Commercial Bias

In addition to mitigating 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 accredited education may be accepted only for activities that have undergone a review and approval process to ascertain that the activities have been independently developed without influence from ineligible companies, 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](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 Medicine certified CE 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 ineligible company/s, the nature of the relationships the person has with each ineligible company, the individual’s role related to the activity (e.g. planner, speaker, reviewer, etc.) and that all relevant financial relationships for these individuals have been mitigated. 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 ineligible companies 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 CE 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 ineligible companies’ logos. Learners may also be informed if there is no commercial support for the activity.