CME Conflict of Interest Policy

Background

It is an essential duty of every physician to place the welfare of their patients before their own financial interest. This duty is affirmed in the oaths physicians take upon graduation, the American Medical Association’s Code of Medical Ethics, and the World Medical Association’s International code of Medical Ethics.

By extension of this duty, physicians and medical educators are obligated to provide educational programs that serve the interests of patients and the public. Accordingly, medical education programs must be based on sound evidence and an objective, unbiased presentation of this evidence.

The need for ethical guidelines is evidence that conflicts between the interests of patients and those of others, including the physician, are a part of life. Such conflicts of interest cannot be eliminated and often cannot be avoided. Accordingly, they must be addressed and resolved. The intent of this policy is to provide practical steps that medical educators should take to assure that their activities best serve the interests of patients and the public.

The College of Medicine’s General Conflict of Interest Policy

The University of Arizona College of Medicine at the Arizona Health Sciences Center (the Accredited Provider) has a stated interest in managing circumstances where “… a faculty, staff, student or trainee of the University of Arizona College of Medicine may have a significant financial or other personal consideration that may compromise, or have the appearance of compromising, their professional judgment or integrity in clinical responsibilities, teaching, conducting or reporting research, or performing other College obligations.” The College has a faculty Conflict of Interest Policy that is broader and more general than its CME Conflict of Interest Policy. Specifically, the College of Medicine prohibits faculty acceptance of gifts from industry, limits the access of industry sales representatives, and requires full disclosure of all outside financial relationships. The College incorporates the Accreditation Council for Continuing Medical Education’s (ACCME’s) Standards for Commercial Support into its Policy and Guidelines for Interactions Between The University of Arizona College of Medicine and Commercial Interests.

CME Conflict of Interest Definitions

For CME purposes, the key ACCME definitions are:

- **Commercial Interest**: 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**: Financial relationships are those relationships in which the individual, their spouse, or their significant other/partner receive(s) 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 from a commercial interest.

- **Relevant Financial Relationships:** Financial relationships in any amount occurring within the past 12 months are deemed “relevant” for purposes of determining whether or not a conflict of interest exists.

- **Conflict of Interest:** The situation that exists when individuals have a relevant financial relationship with a commercial interest and the opportunity to affect the content of CME about the products or services of that commercial interest.

**Summary of CME Conflict of Interest Requirements**

1. If the CME activity plans to discuss “...health care goods or services consumed by, or used on, patients,” then there is a potential for conflicts of interest and the introduction of commercial bias. If the activity does not plan to discuss such goods or services (for example, a program dealing with basic science findings or physician/patient communication), then there is no possibility for commercial bias. Regardless, you must advise learners before the activity begins whether or not any of the people in a position to control the content of the program have conflicts of interest.

2. Persons involved in the planning of a CME activity should not have a conflict of interest. This is a University of Arizona Office of CME requirement. If a member of the Planning Committee discloses a conflict of interest, that person should cease participation in the planning process. This person may participate as a faculty member in the activity if the conflict is resolved appropriately (see below). Exceptions to this portion of the policy may be considered in extraordinary circumstances on a case-by-case basis, but will be rare, and will require extensive justification and documentation.

3. The University of Arizona CME Office will not approve a CME activity until all Planning Committee members’ disclosures are received. As persons involved in the planning of a CME activity should not have a conflict of interest, you should not submit a New Activity Proposal Form if it includes a Planning Committee member who has disclosed a conflict of interest.

4. All conflicts of interest must be resolved prior to the start of the activity or those speakers with unresolved conflicts cannot be involved with the CME-approved activity. The resolution process must be documented and reported to us (see below). Any proposed speaker who refuses to complete a conflict of interest form also cannot be involved with the CME-approved activity.

5. All conflicts of interest must be disclosed to learners before the activity begins. We also require that you clearly advise learners how any conflicts were resolved. As stated above, you must further advise learners when conflicts of interest do not exist. These disclosures are usually presented in writing, via slide, syllabus, handout, website, or other similar means. You can find appropriate conflict of interest disclosure statements for various situations further below.

**Required Documentation**

1. If there is any potential for commercial bias, you must submit signed Conflict of Interest Disclosure Forms for all Planning Committee members together with your New Activity Proposal Form. As stated above, persons with a conflict of interest should not be Planning Committee members, though exceptions may be considered in extraordinary circumstances on a case-by-case basis.

2. If there is any potential for commercial bias, then before the activity occurs you must also submit signed Conflict of Interest Disclosure Forms for all faculty/presenters/moderators. If
faculty/presenters/moderators disclose a conflict, each conflict must be resolved before the activity occurs and we must be advised of how the conflict was resolved in writing before the activity occurs.

3. We must receive documentation that statements declaring the presence or absence of conflicts of interest and their resolution were presented to learners before your activity occurs. This can be, for example, via copies of relevant handouts, syllabus pages, presentation slides or via a written attestation from an auditor that appropriate verbal disclosures were made.

Resolving Conflicts of Interest

As stated above, a conflict exists when an individual has 1.) a relevant financial relationship with a commercial interest and 2.) the opportunity to affect the CME activity in a way that could benefit that interest. If those two conditions are not met, then a conflict of interest does not exist. You can still disclose non-conflicting financial relationships to us and to the learners if you want, but technically these relationships do not need to be disclosed or resolved per the ACCME Standards for Commercial Support. However, such disclosures can create confusion unless you also explain to learners that there is no conflict between the disclosed relationships and the educational activity. [NOTE: This approach differs from the manner in which some other organizations, such as the International Committee of Medical Journal Editors, address conflicts of interest, whereby all financial relationships must simply be disclosed, whether or not they create an actual conflict of interest.]

When a CME conflict of interest is present, it can be resolved in several ways. If the conflict exists for a proposed Planning Committee member, that person cannot be involved in the planning process and must be removed from the Planning Committee (although they can still serve as a faculty member if their conflict of interest is resolved). For faculty/presenters/moderators, there are a number of acceptable strategies to resolve conflicts of interest:

1. Replace the faculty/presenter/moderator with someone who does not have a conflict.

2. Request the faculty/presenter/moderator alter their presentation to avoid areas of conflict(s), then review the presentation using a “Conflict of Interest Resolution” form that we will provide to you in order to ensure that the presentation does not contain any biased and/or promotional material. Return the completed, signed Conflict of Interest Resolution form to us for our review and approval. You must also send us the speaker’s presentation in electronic format so that we can review the presentation as well. If we concur that the conflict has been managed and resolved appropriately, then the speaker can deliver the presentation as planned.

3. If the proposed faculty/presenter moderator is an employee of an ACCME-defined commercial interest, we will only consider allowing that person’s inclusion if the nature of their content involves the reporting of data from the discovery phase of product development and that they are uniquely qualified to present. You will be required to complete a “Justification for Including Industry Representatives” form. If we agree with your justification, you will also need to follow the same conflict resolution and management process described above.

4. If for any speaker we are unable to confirm that the conflict has been resolved and managed appropriately, you can opt to have the presentation reviewed by a non-conflicted subject matter expert of our choice and at your additional cost.

5. If you do not wish to continue resolving the conflicted speaker’s conflict of interest, then a.) CME credit will not be awarded for that speaker, and b.) should you nevertheless choose to include that speaker in a non-CME-approved presentation at this same CME-approved activity, the speaker
cannot deliver any presentation in the same educational meeting room as any other CME-approved speaker. Violation of this requirement will jeopardize our ability to approve future CME activities from your organization or department.

**Disclosing Conflicts of Interest or Lack Thereof**

You must disclose to your learners whether or not there are conflicts of interest with anyone in a position to control the content of your CME activity. This includes your Planning Committee members, your faculty/presenters/moderators, and the CME Office Reviewer(s). For any identified conflicts of interest, you must also explain how those conflicts of interest were resolved. You must communicate this information before the activity begins.

Below are example statements demonstrating:

1. Disclosure of lack of conflict,
2. Disclosure of lack of conflict, except for one faculty member, and
3. Disclosure of a financial relationship that does not constitute a conflict of interest.

1.) Lack of Conflict for All Involved with the Activity:

“All Faculty, CME Planning Committee Members, and the CME Office Reviewers have disclosed that they do not have any relevant financial relationships with commercial interests that would constitute a conflict of interest concerning this CME activity.”

2.) Lack of Conflict for All Involved Except a Single Faculty Member:

“All Faculty, CME Planning Committee Members, and the CME Office Reviewers have disclosed that they do not have any relevant financial relationships with commercial interests that would constitute a conflict of interest concerning this CME activity, with the exception of the following:

Dr. John Smith has disclosed that he has the following relevant financial relationship(s) with the following commercial interest(s):

a.) [SPEAKER’S BUREAU – GRANT SUPPORT – CONSULTANT, ETC.] with [NAME OF COMMERCIAL INTEREST].

b.) [SPEAKER’S BUREAU – GRANT SUPPORT – CONSULTANT, ETC.] with [NAME OF COMMERCIAL INTEREST].

c.) ETC., if required.

His presentation will consider one or more products made by this/these commercial interest(s). His presentation was reviewed by the Activity Director [or CME Planning Committee] for evidence of bias. The Activity Director [or CME Planning Committee] determined that the
presentation gave a well-balanced, evidence-based, and unbiased approach to diagnostic and therapeutic options related to quality patient care.”

3.) Lack of Conflict for All Involved, Yet One Faculty Member Insists on Disclosing a Financial Relationship:

“All Faculty, CME Planning Committee Members, and the CME Office Reviewers have disclosed that they do not have any relevant financial relationships with commercial interests that would constitute a conflict of interest concerning this CME activity.

However, Dr. Sue Smith wishes to disclose a financial relationship with [NAME(S) OF COMMERCIAL INTEREST(S) OR OTHER COMPANIES/ORGANIZATIONS], though her presentation at this CME activity will not discuss any products/services produced/offered by that company [OR COMPANIES], and therefore, a conflict of interest does NOT exist.”

Regarding Non-Compliance with the UA CME Office Conflict of Interest Policy

Developing CME activities that best serve the interests of patients and the public is the mission of the University of Arizona College of Medicine. Recognizing and managing conflicts of interest that could adversely affect this mission is essential to our success. Thus, we require a good faith effort to comply with this conflict of interest policy. Failure to amend procedures and comply fully with this policy will lead to removal of CME sponsorship for your present and/or future activities and loss of any CME sponsorship fees paid.