

CME Policy on Collection and Resolution of Conflicts of Interest (C7 SCS2)

PURPOSE

In accordance with the ACCME's *Standards for Commercial Support of Continuing Medical Education*, the Policy on Collection and Management of Conflict of Interest (COI) exists to provide guidance for staff, instructors, planners and managers of CME activities sponsored by Sunrise Health System (and applicable educational partners). This policy addresses the underlying philosophy of disclosure to learners, mechanisms to collect disclosure information and the parties from which COI shall be collected, the mechanisms to resolve COI, and requirements to make actual disclosure to learners.

GUIDING PRINCIPLES RELATING TO COI AND ITS DISCLOSURE

Sunrise Health System is guided by what is in the best interest of the public, always deferring to independence from commercial interests, and keeping CME separate from product promotion. These are the basic guiding principles for the collection and management of COI.

POLICY

Identifying Potential Conflicts of Interest

A Conflict of Interest Disclosure Form shall be provided to individuals involved with a CME activity that have the following roles:

- Instructor/Faculty
- Reviewer/Planner/RSS Director
- Staff and members of the Planning Committee who manage the content/development of the CME activity (not logistics)
 - Includes Joint Sponsorship/Educational Partners

Recipients of COI forms must complete and return the document within **two** weeks of receiving it as a condition for participation in the role of planner/reviewer/activity director/faculty/instructor for the CME activity. Reporting guidance is as follows:

- Any personal financial relationship during the previous 12-month period represents a potential conflict of interest, and therefore must be reported. This also includes spouses and life partners.
- A COI is present when both (a) the relationship is financial and occurred within the past 12 months and (b) the individual has the opportunity to affect the content of CME about the products or services of that commercial interest.

Guidelines for Interpreting COI

The guidelines for interpreting COI are illustrated below:

Reported COI	Guidelines for Interpreting COI	Prescribed Action for Resolution	Suggested Language for Conflict Resolution Form
LEVEL 1: No reported COI	N/A	No action required; faculty letter instructs presenter on rules.	No action required
LEVEL 2: Discloser has relationship(s) with commercial interests (e.g., speakers' consultancies, research, etc.) <u>which do not relate to the activity</u>	Validates expertise with review of CV. Activity Director determines that presentation topic(s) do not relate to speaker's relationship with commercial interests.	No action required; Faculty letter instructs presenter on rules.	Activity Director or non-conflicted Content Reviewer has reviewed the reported <u>relationships</u> and has concluded that there are no potential conflicts of interest for this activity and no further action is required
LEVEL 3: Discloser has relationship(s) with commercial interests (e.g., speakers' consultancies, research, etc.) <u>which relate to the activity</u>	Activity Director to validate speaker's expertise with review of CV.	Independent review of presentation(s) required by non-conflicted activity director or physician member of planning committee (content reviewer); <u>faculty may be restricted to discussion of evidence-based information.</u>	Activity Director or non-conflicted Content Reviewer has reviewed the <u>presentation</u> and deemed it be fair, balanced and free of commercial bias.
LEVEL 4: Discloser has significant relationships with commercial supporter(s) of activity	Activity Director to validate speaker's expertise with review of CV.	Independent review of presentation(s) required by non-conflicted activity director or physician member of planning committee (content reviewer); <u>faculty restricted to presentation of scientific data only.</u>	Activity Director or non-conflicted Content Reviewer has reviewed the <u>presentation</u> and deemed it be fair, balanced and free of commercial bias <u>and contains only scientific data.</u>
LEVEL 5: Discloser has employment relationship with commercial supporter	Speaker was chosen based on expertise and clinical knowledge that is not replicable by another presenter.	Independent review of presentation(s) required by non-conflicted activity director or physician member of planning committee (content reviewer); <u>faculty restricted to presentation of scientific data only; no discussion of treatment options permitted.</u>	Activity Director or non-conflicted Content Reviewer has reviewed the <u>presentation</u> and deemed it be fair, balanced and free of commercial bias <u>and contains only scientific data and no treatment recommendations.</u>

The Activity Director and Planners are responsible for the initial invitation to potential faculty and the request for them to complete the Conflict of Interest (COI) Reporting Form. The Activity Director must review the returned COI Reporting Form, determine if there is a potential conflict of interest and take the appropriate steps to resolve the conflict and document its resolution. If the Activity Director is unable to resolve a potential COI, he/she may refer the issue for peer review by members of the Education and Library Committee.

The COI disclosures for the Activity Director and Planning Committee members must be completed and potential conflicts resolved before the CME application is submitted to the Sunrise Health System Office of CME. The COI disclosures for all faculty members must be completed and potential conflicts resolved by an activity director, physician planning committee member without conflicts, or the Office of CME before the activity takes place.

Processing COI Forms

- Activity Director has the primary responsibility for initial processing of COI forms and documenting level 1 resolution.
- In addition, staff activity coordinators will provide COI documentation for levels 2, 3, 4 and 5 to the Activity Director of the CME Program for resolution when indicated.
- The CME Committee will be consulted with cases in which the resolution is unclear or where disqualification of the speaker is the chosen recommendation.
- The Chief Medical Officer is an additional resource for resolution of COI when the physician program activity coordinator is not available or in cases when he recuses himself.
- Options for resolution of COI include:
 - Substitution of a person with no COI or minimal levels of COI
 - Development of a stringent Peer Review Process in which content is validated
 - Referencing the best available evidence in all CME activities in which potential conflicts exist
 - Requesting the instructor or planner to sever financial relationships with the commercial interest
 - Relegating the person with COI to a role in which therapeutic options will not be recommended
 - Excluding that part of the instruction or disqualification of the presenter
 - Consider not certifying specific lectures by conflicted presenters for credit

Documenting Resolution of COI

- Completed COI Disclosure Forms will be maintained in the activity file.
- The resolution of COI by staff and/or applicable activity director will be documented on the Resolution of COI Form.

IMPLEMENTATION

- **For Instructors**
 - COI Disclosure Forms will be attached to the Faculty Letter with clear instructions on due date process for planning.
 - Failure to return financial disclosure information will result in disqualification.
 - Instructors that have current promotional relationships with a CI(on the same topic as the CME activity have an irreconcilable COI and will be disqualified.
- **For Planners and Managers**
 - As soon as all internal and external physician planners and reviewers for the activity are identified, a COI Disclosure Form must be provided to them in writing with instructions to complete and immediately return.
 - All CME Committee members will complete a COI Disclosure Form annually and that information shall be transparent to the learners.
 - Staff that affects the content of CME will complete a COI Disclosure Form annually and that information shall be transparent to the learners.

Transparency to Learners

Learners will be provided with information on identified COI (or lack thereof) from any of the above categories of persons that affect the content of CME, and that information will be positioned in course materials such that it is read by learners prior to the execution of the CME activity. This will include:

- For live activities, disclosure must be provided in printed form to the learners. This information may be included in disclosure slides presented prior to each presentation, the course announcement, sign in sheet, handout, evaluation form, and final program or syllabus materials.
- For journal CME, the disclosure will be provided prior to the article being certified for CME credit.