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IDENTIFICATION AND RESOLUTION OF CONFLICTS OF INTEREST

Introduction

The American Academy of Ophthalmology provides continuing medical education ("CME"), advocacy and public information to enhance the ophthalmologist's ability to deliver the highest possible quality of eye care for patients.

The Academy has a profound duty to its members, the larger medical community and the public to ensure the integrity of all of its scientific, educational, advocacy and consumer information activities and materials. Thus **each Academy Trustee, Secretary, committee Chair, committee member, taskforce chair, taskforce member, councilor, and representative to other organizations ("Academy Leader"), as well as the Academy staff and those responsible for organizing and presenting CME activities must disclose interactions with Companies¹ and manage conflicts of interest or the appearance of conflicts of interest that affect this integrity. Where such conflicts or perceived conflicts exist, they must be appropriately and fully disclosed and resolved.**

I DISCLOSURES OF INTERACTIONS WITH COMPANIES

A. All Academy Leaders and providers of Academy-sponsored CME must submit a Disclosure Form of financial and uncompensated interactions with Companies. In the context of this Conflict of Interest policy, "CME" encompasses the Academy's full spectrum of educational activities, including those qualifying for CME credit, as well as the Academy's non-credit-bearing educational initiatives, programming and products, including but not limited to O.N.E. development and content, practice management resources, quality of care research and publications, and *Journal* article authorship, selection and review.

B. Members of the Board of Trustees and members of the Committee of Secretaries will be asked to disclose additional information on the Academy Leader Disclosure Form indicating whether their disclosed direct financial relationships with Companies are under or over ten thousand dollars at the time of disclosure. Participants involved in the creation of Preferred Practice Patterns (PPPs), Ophthalmic Technology Assessments (OTAs) or other BOT-approved Academy guidelines (collectively "Academy Guidelines") will complete the Academy Leaders Disclosure form and likewise indicate whether their disclosed direct financial relationships with Companies are under or over ten thousand dollars at the time of disclosure. .

C. For PPP and OTA panels, and other taskforces or committees preparing Academy Guidelines, additional disclosure standards apply. The Chair, or at least one Co-Chair of two Co-Chairs, of the Academy Guideline panel must be free of direct financial relationships with companies and will be asked to remain free of direct financial relationships with Companies for one year following publication of

the Academy Guideline. For the Academy Guideline panels, a majority of panel members need to be free of direct financial relationships with Companies relevant to the subject matter of the PPP, OTA or other Academy Guideline. The Chairs of the umbrella OTA and PPP committees are not be required to be free of relationships with Companies, but they must disclose their relationships according to Section 1 (B).

D. The Academy staff shall send an annual reminder to Academy Leaders to submit an initial Academy Leader Disclosure Form, or to review and update the Disclosure on file. The Journal and Annual Meeting participants will follow the disclosure submission procedures established for these activities. The committee Secretary responsible for creation of an Academy Guideline will obtain an Academy Leader Disclosure Form from the Guideline's authors and reviewers.

E. The Academy may disqualify anyone who does not complete (or revise as appropriate) the applicable disclosure form after a second reminder.

1. A second reminder will state that the individual may not participate in relevant Board, committee, Secretariat, Council, Academy Representative activities, or in planning, developing or delivering any Academy CME without a current Disclosure on file. In addition, such notice will explain the consequences of not providing the Disclosure.
2. If the member does not provide adequate Disclosure within thirty days of the receipt of the second notice, the member will become ineligible to participate in the CME activity in any manner until the form is received. For Academy Leaders, failure to submit the Academy Leader Disclosure Form within thirty days of the second notice will disqualify the member from participation in the committee, other Academy body or representative activities until the disclosure is received. If the Academy Leader is unwilling to complete the form, (s)he will be asked to resign from the committee, other Academy body or representative position.
3. The appropriate Secretary shall be notified of the disqualification. If the disqualification is of a Secretary, the disqualification shall be reported to the BOT Executive Committee.

F. Academy Leaders and CME participants are responsible for updating their Disclosures throughout the year for every substantial change in actual or potential conflicts of interest, whether financial or non-financial.

II AWARENESS AND COMMUNICATION OF ACTUAL AND POTENTIAL CONFLICTS

A. All Disclosures of financial and potentially relevant non-financial Relationships shall be sent to the Committee/Taskforce chairperson ("Chair") responsible for the planning and implementation of Academy activities. Disclosures from Board of Trustee members and officers shall be reviewed by the Executive Committee, with Executive Committee members recusing themselves from reviewing their own disclosures.

B. The Chair shall alert all reviewers, panelists, committee members, and authors of all relevant financial and non-financial conflicts of interest relevant to a particular activity.

C. The Chair shall periodically remind all who are involved in planning and implementation of an activity to be cognizant of others' financial and non-financial disclosures, and encourage all to identify and discuss potential conflicts.

D. As set forth below, Academy staff will ensure that all financial relationships with all Companies are made known at beginning of every activity.

E. For print, web-based or recorded non-live materials ("Enduring Materials"), it is staff responsibility to ensure that adequate Financial Disclosures are included in each document.

F. For Journal Activities, Editor and Journal staff shall follow their own disclosure procedures.

G. All Academy staff members whose responsibilities include staffing a committee, are required to include the list of financial relationships for their Committee members, including the Committee Chair, in any and all meeting agendas and minutes, including conference calls. At the beginning of each meeting/conference call, the Committee Chair should make note that the list is included in the agenda for everyone's reference.

H. For Live Activities, staff shall:

1. Notify the activity organizer, all faculty, panelists, other presenters of their obligations to provide adequate disclosures.
2. Establish and enforce a "first slide" policy to ensure Financial Disclosure is made know to all participants prior to the activity.
3. Ensure that the intent of the "first slide" policy is served by adequate "dwell time" of the slide, commensurate with the length of the text shown; ideally with simultaneous verbal presentation of the first slide content.
4. Establish and enforce a policy to ensure that anyone who speaks from the audience also discloses any relevant financial interests, verbally or by other adequate means, at the time that the comments are made (moderators may need to prompt audience participants to disclose).
5. Monitor presentations as often as is practical to insure that the intent of the disclosure procedures is served, including recommendations for modifications in requirements as circumstances may require.

I. Credit-bearing CME

1. All credit-bearing CME ("CB-CME") activities are planned under the guidance of an Academy committee.
2. All CB-CME activities require the approval of a committee Chair.
3. In the event that the Chair is conflicted, approval is granted by another designated member of the Committee who is not.

4. The Academy CME Committee or other committee designated by the Board of Trustees shall review all Enduring Materials
5. Staff will review checklists for all submissions before a credit code is assigned (based on the Academy-customized version of the CB-CME Activity Documentation Checklist)
6. Every CB-CME activity must be evaluated by participant questionnaires.
7. Every evaluation questionnaire must address the participant's impression of the presence or absence of commercial bias.
8. The Observer Report Form shall include a request for the Observer's impression of the presence or absence of commercial bias. The Academy CME committee or other committee designated by the Board of Trustees will be advised of any significant allegations of commercial bias, based upon the frequency of the participant mentioned, and the specifics of the allegation.

III MANAGEMENT AND RESOLUTION OF CONFLICTS

A. FOR CME activities, a system of peer review, committee review, staff review and cross-checks to identify and recommend possible means of resolving a conflict shall be maintained.

1. The Course committees, Mid Year Forum Planning Group or Annual Meeting committees or their Board-approved designee body shall review all submissions and abstracts as well as the Faculty Financial Disclosure for Live Activities.
2. Objectivity and the use of best available evidence should be encouraged.
3. Each person involved in the planning or execution of a particular CME activity should be encouraged to make the Chair or other person responsible for the activity aware of the need to manage a specified conflict. For CB-CME activities, the Chair or responsible person shall review all Faculty Financial Disclosure Forms and course content prior to the activity.
4. If potential conflict of interest is detected, corrections will be recommended and implemented:

(a) Enduring Materials shall be edited as required.

(b) Live Activity Presenters shall be notified of concerns regarding conflict or potential conflict of interest prior to the activity and the Chair/Program Director and Faculty shall work together to resolve or manage that conflict. Some possible steps that can be taken are:

- Have the content reviewed and revised as necessary by experts that do not have relationships with the entity where the conflict lies
- Limit the presentation to pathophysiology and mechanisms of disease rather than therapeutic recommendations
- Select another speaker to present clinical implications after the primary speaker (with COI) has reported scientific discovery

- Change focus of the presentation so that the content is not about products or services of the COI
 - Limit the presentation to research results and assign another speaker with no COI to the broader implications of clinical care if the speaker with COI is a principal investigator on a project funded by industry
 - Ask the speaker with COI to recuse him/herself
 - Ask the speaker to divest him/herself of all financial interests that have created the COI
5. If the steps in Section III A. 4 are not sufficient or applicable for managing the conflict or perceived conflict, or conflict is detected during a presentation the Chair or person responsible for a CME activity shall request that the Board of Trustees or a committee assigned by the BOT determine an appropriate response. The response may include:
- (a) Official notification and warning for the first occurrence, unless there is a failure to submit a required disclosure, as set forth in Section I above, which requires disqualification;
 - (b) For repeat offenses - Banning for a period of 2 years of the individual from currently scheduled or future Academy CME activity;
 - (c) The Academy CME committee will notify the Academy Board of Trustees of repeat offenders, with the recommendation that an ethics challenge be filed through the procedures set forth in the Code of Ethics.

B. Resolution of Disclosed Conflicts among Academy Leaders

The Academy recognizes that Leaders often have a wide range of medical, scholarly, humanitarian and financial relationships, and participate in organizations and activities outside of the Academy. As a natural consequence of these activities, conflicts or the perception of conflicts may arise from time to time for Academy Leaders. These conflicts may be disclosed by the Leader, or identified by another Leader in an atmosphere of cooperation, rather than confrontation. The goal of effective management of these conflicts is to arrive at a collaborative and consensual, resolution, as set forth in the procedures below.

1. The Academy Leader who discloses a conflict or potential conflict, or to whom a fellow Leader identifies a perceived conflict, prepares a statement describing the conflict and suggesting ways of resolving or managing it. If a challenged Leader believes that a conflict does not exist, a response may be submitted. If there is consensus that a conflict exists, methods for resolution include highly specific confidentiality agreements, recusal from specific discussions, activities or votes, voluntary resignation from committee Chair or other leadership positions or by other means. A "Statement of Conflict Management" is submitted by committee members to their Committee Chair, from a COS member to the COS Chair, and by BOT members to the BOT Executive Committee. If a chairperson or Executive Committee member is submitting the statement, the COS or BOT will appoint two of their members to review the Statement.
2. If the Statement of Conflict Management is accepted by the appropriate reviewer as sufficient to manage the conflict, the terms of the Statement will be accepted and distributed to the relevant committee or other Academy body.

3. If the Statement of Conflict Management is not accepted, then the reviewer will submit it to a three person review committee (Conflict Review Committee or "COR") comprised of a committee member, COS member and BOT member, appointed by the BOT Executive Committee. This review committee will work with the Academy Leader to revise the Statement of Conflict Management such that the resolution is acceptable to the Committee.
4. If the revised statement is acceptable, it shall be accepted and disseminated as above, with additional dissemination to be determined by the "COR". Note that in some instances, an acceptable Statement may include the requirement that the Academy Leader step down from a particular position of Leadership.

C. Further Resolution Procedure for Academy Leaders

1. If no revised statement is agreed to by the Academy Leader and the COR, the Academy Leader will have an additional opportunity to be heard. The Academy Leader and one member of the COR will present their respective positions to the Executive Committee of the BOT, which will make a recommendation of resolution to the full BOT. The BOT vote will be binding on the Academy Leader.
2. Proposals for resolution of a conflict may not affect an Academy Leader's membership status. Egregious violations of this policy for which suspension or termination of membership may be appropriate shall be referred to the Ethics Committee, and shall be adjudicated as set forth in the Administrative Procedures of the Code of Ethics.
3. This resolution process set forth in Sections III B and C shall apply to Academy Guideline participants.

1. "Companies", as defined by the *CMSS Code for Interactions with Companies*, are for-profit entities that develop, produce, market or distribute drugs, devices, services or therapies used to diagnose, treat, monitor, manage, and alleviate health conditions.

Approved by:

Board of Trustees, September 2010

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P.O. Box 7424 / San Francisco, CA 94120-7424 / 415.561.8500