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Disclosure and Commercial Support: Resolving Financial Conflicts of Interest

Background:

This policy on full disclosure is designed to permit AAAP to pursue its academic and educational missions with regard to continuing medical education (CME) without undue influence by any individuals or groups associated with these CME activities. It is recognized that AAAP faculty and staff may enter into financial or other materially beneficial relationships with commercial organizations. However, it is important that CME content be based on learner needs and not be biased by commercial or marketing interests.

The ACCME considers financial relationships to create actual conflicts of interest in CME when individuals have both a financial relationship with a commercial interest that occurred within the past 12 months **and** the opportunity to affect the content of CME about the products or services of that commercial interest.

Bias in CME activities may include overstating the performance of a company's product, omitting information about products of competing companies, or, more subtly, simply emphasizing a company's product so that the CME participants become most familiar with it.

Although a conflict of interest may create the potential to bias a presentation, it is accepted that most professionals associated with CME do not knowingly bias information. They recognize the conflicts of interest and put their reputations, their institutions¹ reputations, and their position of trust ahead of personal gain that could result from their relationships with a commercial organization.

In the medical and academic communities there is an increasing concern that commercial relationships may change an individual's presentation without the presenter recognizing the bias. Hence, the appearance of bias is an equally important concern, as the mere appearance of a conflict of interest may cast doubt on the objectivity of a presentation and undermine public trust. Full disclosure of conflicting or potentially conflicting interest is considered the primary and usual means to protect the integrity of AAAP CME activities. Therefore, it is necessary at times to take disclosure one step further. For these reasons in order to meet the requirements of the *2004 Updated Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support: Standards to Ensure the Independence of CME Activities*, AAAP has a policy based on the below guiding principle.

Guiding Principle:

The perception of a conflict of interest is as important as an actual conflict. Any relationship that exists between an individual and a commercial organization that suggests or implies a financial or contractual relationship or one that if brought to public attention would in any way diminish the reputation of the individual, AAAP, or the commercial organization must be reported to AAAP CME/CPD Committee during the initial planning stages of the activity. This conflict must also be reported to the audience participating in the CME activity.

Generally, an individual who is in the position to control the content of a CME and reports a relationship with industry as defined by the ACCME definition of a financial relationship will not be allowed to present a CME activity such as a symposium, workshop, webinar, poster or paper.

An individual who refuses to disclose relevant financial relationships will be disqualified and cannot have control of, or responsibility for, the development, management, presentation, or evaluation of the CME activity.

Individuals considered to be a "Ghost writer" or "Ghost presenter" will be not be permitted.

¹ Much of this statement was developed from "Developing an institutional policy on conflict of interest in CME activities." Harrison, RV. Journal of Continuing Education in the Health Professions. 11 (2) 1991, pp 101-128.

Recusal shall be required when it appears that a member of the CME/CPD Committee will be unable to fairly judge a potential conflict raised by a disclosure statement. All such potential conflicts of interest of committee members must be disclosed to the committee in advance of the proceedings, and the committee will vote to determine whether recusal is required.

Definition: Financial relationships are defined by the ACCME as those relationships (to the individual or family) 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), consulting, and speaker's bureau/speaking and teaching, membership on advisory committees or review panels, board membership, and other activities for which remuneration is received or expected. The ACCME has not set a minimum dollar amount for relationships to be significant. Inherent in any amount is the incentive to maintain or increase the value of the relationship.

Purpose: To outline procedure by which AAAP will identify and resolve financially relevant relationships that create the appearance of or an actual conflict of interest.

Process:

1. Send Presenter/Content Developer/Faculty/Author/Planning Committee Member a Conflict of Interest and Disclosure Attestation Form included (Attachment). Everyone in the position to affect the content of the activity will be required to disclose. Those that do not sign the Conflict of Interest and Disclosure Attestation Form will not be allowed to participate.
2. Determine via review by AAAP CPD/CME Committee of a signed Conflict of Interest and Disclosure Attestation Form if those involved in planning or presenting content within a CME activity have financial relationships related to that content.
3. If it is determined that a planner, presenter or author has a financial relationship that creates the appearance of or a real conflict of interest, **one or all** of the following mechanisms will be used:
 - AAAP CPD/CME Committee will ask presenter to recuse him/herself from the educational Content and another presenter or content developer will be selected.
 - AAAP CPD/CME Committee will organize multiple levels of effective peer review to validate content prior to presentation or publication to ensure the content is valid, evidence-based and is aligned with the interest of the public. If it is a live CME presentation, the content will be submitted by the presenter at least 3 weeks in advance of the presentation release date so that it can undergo an effective peer review process.
 - Presenters, authors, planners and reviewers will be instructed to present evidence-based medicine with data to support the content.
 - AAAP CPD/CME Committee will change the presenter's role in the content therefore minimizing her/his ability to influence content by assigning the presenter an area of content that is unrelated to the area of conflict or excusing the individual from their obligation to participate in the activity.
 - In cases where a presenter has disclosed a conflict, it is managed and the presenter allowed to participate, all financial relationships will be disclosed prior to an activity to alert participants (audience, readers) of the potential for conflict of interest and commercial bias.
 - In cases where a presenter who has disclosed a conflict is allowed to participate, the presentation will be delivered with several other presentations offering information on drug therapies to balance out the presentation as a whole. A situation like this will be reviewed on a case-by-case basis.
 - Faculty with identified relevant conflicts may be asked to complete this training on Conflicts of Interest: <http://www.nfeinitiative.org/>
 - Participants will be asked to evaluate the objectivity of the presentation or publication, and to identify any perceived commercial bias. This information will be used to determine if the presenter will be asked to participate as faculty in future CME presentations.

AAAP American Academy of Addiction Psychiatry

Conflict of Interest: Disclosure and Attestation

Name: _____

Title & Organization: _____

Email Address: _____

Date: _____

The purpose of this form is to identify and resolve all potential conflicts of interests that arise from financial relationships with any commercial or proprietary entity that produces healthcare-related products and/or services relevant to the content you are planning, developing, or presenting for this activity. This includes any financial relationship within the last twelve months, as well as known financial relationships of your family (spouse/partner, children, parents, grandparents (if known)).

CHECK ONE OF THE BOXES BELOW:

- I have no financial relationships with a commercial entity producing health-care related products and/or services.
- I disclose the following financial relationship is with commercial entities that produce healthcare-related products or services relevant to the content I am planning, developing or presenting:

| Company | Type of Relationship* | Content Area (if applicable) |
|---------|-----------------------|------------------------------|
| | | |
| | | |
| | | |
| | | |

(Attach an additional sheet if you need more room)

* **Type of relationship may include:** full-time or part-time employee, independent contractor, consultant, research or other grant recipient, paid speaker or teacher, membership on advisory committee or review panels, ownership interest (product royalty/licensing fees, owning stocks, shares, etc.), board member or any other financial relationship.

- I believe that the commercial entities with which I have relationships do not produce health-care related products or services relevant to the content I am planning, developing or presenting for this activity.

ATTESTATION

Please indicate your understanding of and willingness to comply with each statement below. If you have any questions regarding your ability to comply, please contact the Miriam Giles Miriam@aaap.org as soon as possible.

Agree **Disagree**

- | | | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | I have disclosed to AAAP all relevant financial relationships, and I will disclose this information to learners verbally (for live activities) and in print. |
| <input type="checkbox"/> | <input type="checkbox"/> | The content and/or presentation of the information with which I am involved will promote quality or improvements in healthcare and will not promote a specific proprietary business interest of a commercial interest. Content for this activity, including any presentation of therapeutic options, will be well-balanced, evidence-based and unbiased. |
| <input type="checkbox"/> | <input type="checkbox"/> | I have not and will not accept any honoraria, additional payments or reimbursements from a commercial entity for my participation in this activity. |
| <input type="checkbox"/> | <input type="checkbox"/> | I understand that AAAP may need to review my presentation and/or content prior to the activity, and I will provide educational content and resources in advance as requested. |
| <input type="checkbox"/> | <input type="checkbox"/> | I understand that the AAAP may plan to record my presentation and may use it for future CME activities, at which time I will be contacted. |

Agree **Disagree** **N/A**

- | | | | |
|--------------------------|---|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | If I am presenting at a live event, I understand that a CME monitor will be attending the event to ensure that my presentation is educational, and not promotional, in nature. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | If I am providing recommendations involving clinical medicine, they will be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients. All scientific research referred to, reported or used in CME or supported of justification of a patient care recommendation will conform to the generally accepted standard of experimental design, data collection and analysis. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | If I am discussing specific healthcare products or services, I will use generic names to the extent possible. If I need to use trade names, I will use trade names from several companies when available, and not just trade names from any single company. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | If I am discussing any product use that is off label, I will disclose that the use or indication in question is not currently approved by the FDA for labeling or advertising. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | If I have been trained or utilized by a commercial entity or its agent as a speaker (e.g., speaker's bureau) for any commercial interest, the promotional aspects of that presentation will not be included in any way with this activity. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | If I am presenting research funded by a commercial company, the information presented will be based on generally accepted scientific principles and methods, and will not promote the commercial interest of the funding company. |
| <input type="checkbox"/> | I have carefully read and completed this form myself, and provided current and accurate information to the best of my ability. | | |

Sign Name (Electronic Signature is acceptable)