

American Academy of Pediatrics Policy on Disclosure of Financial Relationships and Mitigation of Conflicts of Interest for AAP CME Activities

Background

The AAP recognizes that there are a variety of financial relationships between individuals and ineligible companies/commercial interests that require review to identify possible conflicts of interest in a CME activity. This policy is designed to ensure quality, objective, balanced, and scientifically rigorous AAP directly and jointly provided Continuing Medical Education (CME) activities by identifying and mitigating all potential conflicts of interest prior to the confirmation of service of those in a position to influence and/or control CME content.

All AAP CME activities will strictly adhere to the *Accreditation Council for Continuing Medical Education (ACCME) Standards for Integrity and Independence in Accredited Continuing Education*. In accordance with these Standards, the following decisions will be made free of the control of an ineligible company: identification of CME needs, determination of educational objectives, selection and presentation of content, selection of all persons and organizations that will be in a position to control the content, selection of educational methods, and evaluation of the CME activity.

The purpose of this policy and its associated procedures is to ensure all potential conflicts of interest are identified and mechanisms to mitigate them prior to the CME activity are implemented in ways that are consistent with the public good.

Policy

The ACCME requires accredited CME providers to identify **and** mitigate all potential conflicts of interest with any individual in a position to influence and/or control the content of CME activities. A conflict of interest will be considered to exist if the individual has received financial benefits in any amount from an ineligible company/commercial interest within the past 24 months AND that individual is in a position to affect the content of CME regarding the products or services of the ineligible company.

As a CME provider accredited by the ACCME, the AAP requires all individuals* in a position to influence and/or control the content of AAP directly and jointly provided CME activities to disclose to the AAP and subsequently to learners that the individual either has **no financial relationships** or has **any financial relationships** with the manufacturer(s) of any commercial product(s) and/or provider(s) of commercial services discussed in CME activities. Individuals are required to disclose the following information:

- name of the individual**
- name of the ineligible company***
- nature of the financial relationship the individual has with each ineligible company****

“Disclosure” information provided by all those in a position to influence and/or control CME content must never include the use of a corporate logo, trade name or a product-group message of an ACCME-defined ineligible company. Disclosure information must first be disclosed to AAP staff for determination of potential conflicts of interest. All disclosure information must be provided to AAP CME activity participants prior to the beginning of the CME activity.

All potential conflicts of interest identified through the review of AAP *Full Disclosure Statement* forms must be mitigated in order for individuals in a position to influence and/or control CME content to be confirmed for the educational assignment. The mitigation process and outcomes must be documented in the CME activity file.

Employees/owners of ineligible companies are prohibited from participating in a CME activity, in any capacity, except in 3 specific circumstances as defined by ACCME (to present on basic science, to demonstrate the use of devices, and to speak to content not related to the healthcare products of their company).

The AAP requires that the content of directly and jointly provided CME activities provide balance, independence, objectivity, scientific rigor, and supports safe effective patient care. Planning must be free of the influence or control of an ineligible company and promote improvements or quality in healthcare. All recommendations in CME activities involving clinical medicine must be based on evidence accepted within the medical profession. The content or format of a CME activity and its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of an ineligible company/commercial interest. All AAP CME activities must be compliant with ACCME Standard 1:

- All recommendations for patient care in a CME activity must be based on current science, evidence, and clinical reasoning, while giving a fair and balanced view of diagnostics and therapeutic options.
- All scientific research referred to, reported or used in CME in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection analysis, and interpretation.
- New and evolving topics within CME activities will be clearly identified to participants and will not advocate for, or promote, practices that are not yet adequately based on current science, evidence and clinical reasoning.

Providers are not eligible for ACCME accreditation/reaccreditation if they advocate for unscientific approaches to diagnosis or therapy, or if they present activities that promote recommendations, treatment or manners of practicing healthcare that are not within the definition of CME or are known to have risks or dangers that outweigh the benefits or are known to be ineffective in the treatment of patients.

Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, where available trade names from several companies should be used and not just trade names from a single company. Educational materials that are part of a CME activity, such as slides, abstracts, and handouts, cannot contain any advertising, corporate logo, trade names without generic names (but listing of trade names from several companies is permissible), or a product-group message of an ACCME-defined ineligible company.

Any individual refusing to comply with the *AAP Policy on Disclosure of Financial Relationships and Mitigation of Conflicts of Interest for AAP CME Activities* and/or not disclosing all financial relationships on a timely basis (defined by the Committee on CME as the initial invitation and two reminders) will not participate in, have control of, or responsibility for, the development, management, presentation, or evaluation of AAP CME activities.

All AAP CME activities will be evaluated by learners and peer reviewers to determine if the content was free of commercial bias. All those identified as having influence and/or control of CME content perceived as either manifesting conflicts of interest or being biased may be disqualified from consideration as resources (planning group member, authors, faculty, etc.) in subsequent CME activities for a time to be determined by the Committee on CME.

*faculty; presenters; subject matter experts/authors (self-assessments, enduring materials, journals, etc); planners/CME planning groups/committees; CME editorial boards, AAP Committee on CME, AAP Section/Council program chairs; abstract reviewers; peer reviewers; abstract authors and presenters; trainers/moderators/coaches; staff serving as CME faculty or those directly impacting or managing CME content or activities

**ACCME considers relationships of the person involved in the CME activity to include all financial relationships, in any dollar amount, with ineligible companies.

***The ACCME defines an “ineligible company” as any company, entity, or other organization whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

**** The ACCME defines “financial relationships” as all financial relationships with ineligible companies, in any amount, occurring within the past 24 months. Conflicts of interest occur when individuals have both a financial relationship with an ineligible company and the opportunity to affect the content of CME about the products or services of that ineligible company. Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, patents, intellectual property rights, consulting fee, honoraria for promotional Speakers Bureau, ownership interest (e.g., stocks, stock options or other ownership interest excluding diversified mutual funds) or other financial benefits. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching (including Speakers Bureaus), membership on advisory committees or review panels, board membership, and other activities from which remuneration is received or expected.

***** Employees and owners are individuals who have a legal duty to act in the company's best interests. Employees are defined as individuals hired to work for another person or business (the employer) for compensation and who are subject to the employer's direction as to the details of how to perform the job. Owners are defined as individuals who have an ownership interest in a company, except for stockholders of publicly traded companies, or holders of shares through a pension or mutual fund. Note: Employees and owners of ineligible companies are considered to have unresolvable financial relationships and must be excluded from participating as planners or faculty and must not be allowed to influence or control any aspect of the planning, delivery, or evaluation of accredited continuing education, except in 3 limited circumstances (to present on basic science, to demonstrate the use of devices, and to speak to content not related to the healthcare products of their company).

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