

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

Background

The AAP CME program aims to develop, maintain, and increase the competency, skills, and professional performance of pediatric healthcare professionals by providing high quality, relevant, accessible, and effective educational experiences. The AAP CME program provides activities to meet participants' identified educational needs and to support their life-long learning towards a goal of improving care for children and families (*AAP CME Program Mission Statement, October 2006*).

The AAP recognizes that there are a variety of financial relationships between individuals and 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 sponsored or jointly sponsored Continuing Medical Education (CME) activities by identifying and resolving 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 Commercial Support: Standards to Ensure the Independence of CME Activities*. In accordance with these Standards, the following decisions will be made free of the control of a commercial interest: 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 (ACCME Standard 1.1).

The purpose of this policy and its associated procedures is to ensure all potential conflicts of interest are identified and mechanisms to resolve 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 resolve** 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 a commercial interest within the past 12 months AND that individual is in a position to affect the content of CME regarding the products or services of the commercial interest.

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 sponsored CME activities to disclose to the AAP and subsequently to learners that the individual either has **no relevant financial relationships** or has **any relevant 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 per ACCME Standard 6.1:

- name of the individual**
- name of the commercial interest(s)***
- nature of the financial relationship the individual has with each commercial interest****
- discussion of “off label” use (per AAP policy)

“Disclosure” information provided by all those in a position to influence and/or control CME content must never include a trade name or a product-group message (ACCME Standard 6.4). 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 (ACCME Standard 6.5).

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

Beyond disclosure of financial relationships, AAP CME faculty and authors are required to disclose to the AAP and to learners when they plan to discuss or demonstrate pharmaceuticals and/or medical devices that are not approved by the FDA and/or medical or surgical procedures that involve an unapproved or “off-label” use of an approved device or pharmaceutical.

The AAP requires that the content of directly and jointly sponsored CME activities provide balance, independence, objectivity, and scientific rigor. Planning must be free of the influence or control of a commercial entity, 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 commercial interest (ACCME Standard 5.1). All AAP CME activities must be compliant with the ACCME content validation statements (ACCME policy 2002-B-09):

- All the recommendations involving clinical medicine in a CME activity must 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 in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection and analysis.

Providers are not eligible for ACCME accreditation or reaccreditation if they present activities that promote recommendations, treatment or manners of practicing medicine that are not within the definition of CME, or known to have risks or dangers that outweigh the benefits or 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, trade names from several companies should be used and not just trade names from a single company (ACCME Standard 5.2). Educational materials that are part of a CME activity such as slides, abstracts, and handouts cannot contain any advertising, trade names without generic names (but listing of trade names from several companies is permissible), or product-group advertising (ACCME Standard 4.3).

Any individual refusing to comply with the *AAP Policy on Disclosure of Financial Relationships and Resolution of Conflicts of Interest for AAP CME Activities* and/or not disclosing relevant 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 (live and online courses); authors of journal articles, self assessments, enduring materials (eg. CD ROM, video, etc); CME planning groups/committees; CME editorial boards, AAP Committee on CME, AAP Section program chairs; abstract reviewers; peer reviewers; abstract presenters; staff serving as CME faculty and those directly impacting CME content; spouse/partner

**ACCME considers relationships of the person involved in the CME activity to include financial relationships, in any dollar amount, of a spouse or partner.

***The ACCME defines a “commercial interest” as any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

**** The ACCME defines “relevant financial relationships” as financial relationships in any amount occurring within the past 12 months that create a conflict of interest. Financial relationships are those relationships 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 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. A personal financial relationship does NOT exist when a company contracts with an institution to perform research and the institution then independently employs individuals to work on the institution’s project.