



Disclosure of Financial Relationships and Mitigation of Conflicts of Interest for Continuing Medical Education (CME) Activities Policy

Background

The goal of the Illinois Chapter of the American Academy of Pediatrics (ICAAP's) CME program is to support life-long learning of participants so they may better identify their personal educational needs and design appropriate self-directed learning activities to meet those needs while implementing new skills in clinical practice. ICAAP's CME program aims to provide relevant education for pediatric care providers to develop, maintain, and improve the necessary competencies, skills, and professional performance needed to provide high quality care for children. ICAAP establishes forums for the dissemination of information on current issues facing the specialty as a means for transmitting research and scholarly findings that affect the practice of pediatrics. ICAAP seeks to provide quality education that is relevant, accessible, and effective in addressing gaps in learning related to pediatric practice.

This policy is designed to ensure all ICAAP CME activities are objective, balanced, and free of bias by identifying and mitigating all potential conflicts of interest prior to an activity.

As of December 1, 2021, ICAAP CME activities will adhere to the updated *Accreditation Council for Continuing Medical Education (ACCME) Standards for Integrity and Independence in Accredited Continuing Education* published December of 2020 and available [here](#). The updated standards replace the *ACCME Standards for Commercial Support: Standards to Ensure the Independence of CME Activities* which expire December 31, 2021. In addition, ICAAP CME activities will continue to align with the *Accreditation Requirements and Descriptions for Illinois State Medical Society (ISMS) Providers of Continuing Medical 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, development of content, selection and presentation of content, selection of all persons and organizations that will be in a position to control content, selection of educational methods, and evaluation of the CME activity. (ACCME Standard 1: Ensure Content is Valid)

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 and ISMS require 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 exists if the individual has received financial benefits in any amount from an ineligible company (any entity whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients) within the past 24 months and that person is in a position to be able to affect the content of an activity regarding the products or services of an ineligible company. All individuals in a position to influence/control the content of a CME activity are required to disclose to ICAAP, and subsequently to learners, that they either have no financial relationships or any financial relationships with manufacturers of any commercial products and/or providers of commercial services discussed in an activity. All disclosure information provided will be reviewed by ICAAP staff responsible for the CME activity and CME staff to ensure that all conflicts of interest are mitigated prior to the confirmation of the individual for the educational assignment. Additional information may be requested. It is the responsibility of the individual to notify ICAAP of



any changes to this information after the submission of the Disclosure of Financial Relationships for CME form.

- Examples of **financial relationships** include employee, researcher, consultant, advisor, speaker, independent contractor (including contracted research), royalties or patent beneficiary, executive role, and ownership interest, individual stocks and stock options, (diversified mutual funds do not need to be disclosed) and research funding from ineligible companies should be disclosed by the principal or named investigator even if that individual's institution receives the research grant and manages the funds.
- Examples of **ineligible companies** are those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients such as advertising, marketing, or communication firms (whose clients are ineligible companies), bio-medical startups (that have begun a governmental regulatory approval process), compounding pharmacies (that manufacture proprietary compounds), device manufacturers/distributors, diagnostic labs (that sell proprietary products), growers/distributors/manufacturers/sellers of medical foods & dietary supplements, manufacturers of health-related wearable products, pharmaceutical companies/distributors, pharmacy benefit managers, and reagent manufacturers or sellers.

Any planning committee member, faculty, author, content reviewer, or anyone in control of content that has a financial relationship with an ineligible company and is in a position to influence content of the CME activity is considered to have a conflict of interest. In addition, it is expected that the content or format of all ICAAP CME activities must promote improvements or quality and not a specific proprietary business interest of a commercial interest. Disclosure information and questions regarding bias are included on ICAAP's CME activity evaluation form to monitor and prevent bias. It is required that the ICAAP evaluation template be used in addition to any other evaluation tool the planning committees developing the CME activities may wish to use.

The ICAAP requires completion of the *ICAAP Disclosure of Financial Relationships for CME Form* by individuals involved in the planning, review, presentation, or evaluation of content for a CME activity. Disclosure information must be made known to participants prior to the start of the activity. The ICAAP staff member responsible for the activity and the CME activity manager or Director (ICAAP staff) are responsible for reviewing all completed disclosure forms, identifying potential conflicts, and mitigating conflicts of interest. The mitigation process and outcomes should be clearly documented in the *CME Mitigation of Conflict-of-Interest Form* and included in the activity file.

Individuals are required to disclose the following information:

- Name and credentials of the individual with the financial relationship (spouse/partner no longer need to disclose)
- Role in the activity
- Whether individual has or had a financial relationship with an ineligible company in the last 24 months
- Written disclosure of name of ineligible companies with which individual has relationships within the past 24 months (from the date of completing the form)
 - An ineligible company is any entity whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.
- Written explanation of the nature of the financial relationship the individual has with each ineligible company
 - Examples of financial relationships include employee, researcher, consultant, advisor, speaker, independent contractor (including contracted research), royalties or patent beneficiary, executive role, and ownership interest. Individual stocks and stock options should be disclosed; diversified mutual funds do not need to be disclosed.
 - Research funding from ineligible companies should be disclosed by the principal or named investigator even if that individual's institution receives the research grant and manages the funds.



If a potential conflict is identified, ICAAP staff will review it and decide as to whether there is a conflict of interest. If no conflict exists, this will be so indicated on the disclosure grid and the activity file, and the participant will be eligible to participate. If a potential conflict exists, it will be brought to the attention of the non-conflicted lead pediatrician responsible for planning the CME activity to determine how to address the conflict and if the individual will be able to participate in the activity. For cases that are not clear, the potential conflict will also be brought to ICAAP's CME Committee Chair for review and determination.

The ICAAP requires that the content of CME activities provide balance, independence, objectivity, and scientific rigor. 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 commercial interest (ACCME Standard 5: Manage Ancillary Activities Offered in Conjunction with Accredited Continuing Education). All ICAAP CME activities must be compliant with the ACCME content validation policy (ACCME Standard 1: Ensure Content is Valid).

Accredited providers are responsible for ensuring that their education is fair and balanced and that any clinical content presented supports safe, effective patient care.

1. All recommendations for patient care in accredited continuing education must be based on current science, evidence, and clinical reasoning, while giving a fair and balanced view of diagnostic and therapeutic options.
2. All scientific research referred to, reported, or used in accredited education in support or justification of a patient care recommendation must conform to the accepted standards of experimental design, data collection, analysis, and interpretation.
3. Although accredited continuing education is an appropriate place to discuss, debate, and explore new and evolving topics, these areas need to be clearly identified as such within the program and individual presentations. It is the responsibility of accredited providers to facilitate engagement with these topics without advocating for, or promoting, practices that are not, or not yet adequately based on current science, evidence, and clinical reasoning.
4. Organizations cannot be accredited if they advocate for unscientific approaches to diagnosis or therapy, or if their education promotes recommendations, treatment, or manners of practicing healthcare that are determined 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, trade names from several companies should be used and not just trade names from a single company (ACCME Standard 5). 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: Manage Commercial Support Appropriately). Any individual refusing to comply with the *ICAAP Policy on Disclosure of Financial Relationships and Mitigation of Conflicts of Interest for CME Activities* and/or not disclosing relevant financial relationships on a timely basis (defined as the initial invitation and two reminders) will not participate in, have control of, or responsibility for, the development, management, presentation, or evaluation of ICAAP CME activities.