



## Minimizing Commercial Influence on Education Policy

**EFFECTIVE:** November 1, 2011

**APPROVED:** March 26, 2011 by the IBLCE Board of Directors

**PURPOSE:** To develop standards to govern interactions between providers of educational activities eligible or approved by the International Board of Lactation Consultant Examiners (IBLCE) for Continuing Education Recognition Points (CERPs) [hereafter referred to as “CERP Provider”] and companies or commercial interests<sup>1</sup> [hereafter referred to as “Company”], including standards for any exhibitors at conferences for which CERPs are provided.

**RATIONALE:** IBLCE has the obligation to set standards for the lactation consultant profession in avoiding, through effective self-regulation, most real or perceived conflicts of interest<sup>2</sup> that might unduly influence International Board Certified Lactation Consultants (IBCLCs). IBLCE also has publicly and organizationally endorsed the Code for Interaction with Companies developed by the U.S. Council of Medical Specialty Societies. “By adopting this code, societies demonstrate their commitment to the highest level of ethical standards in their activities and to providing the best possible care for patients and populations.”

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<sup>1</sup> A company or commercial interest [Company] is defined by IBLCE as a for-profit entity that develops, produces, markets, distributes or sells pharmaceuticals, products, services or therapies used to diagnose, treat, monitor, or manage healthcare conditions, including lactation and breastfeeding; infant and young child feeding and care; and maternal and child nutrition. This definition excludes nonprofit entities; entities through which lactation consultants or other healthcare professionals provide clinical services directly to patients; and entities outside of the healthcare, lactation and breastfeeding, infant and young child feeding, maternal and child nutrition, and maternal and child care sectors.

For example, entities excluded from this definition include, but are not limited to:

- International Lactation Consultant Association (ILCA) and its affiliates
- Other nonprofit professional associations
- La Leche League International (LLL)
- Australian Breastfeeding Association (ABA)
- Publishing companies
- Health insurance providers
- Independent educators whose sole purpose is to provide education
- For-profit hospitals and other clinical practice settings, including IBCLCs in private practice

This definition includes, but is not limited to, the following entities:

- Companies whose products fall within the scope of the *International Code of Marketing of Breast-milk Substitutes* (e.g. infant formula, bottles and teats)
- Breast pump companies
- Pharmaceutical companies
- Entrepreneurs who market breastfeeding and baby items such as nipple creams, baby slings, strollers, breastfeeding pillows, nursing stools, etc.

<sup>2</sup> A conflict of interest occurs when an individual or organization is involved in multiple interests, one or more of which could possibly compete with or corrupt the motivation for an act by another individual or organization.

**BACKGROUND:** IBLCE received permission from the American Council on Continuing Medical Education (ACCME) to adopt and/or modify in its entirety their Standards to Ensure Independence in Continuing Medical Education (CME) activities. IBLCE has adopted the entire set of ACCME Standards, modifying terminology when appropriate to apply specifically to the lactation consultant profession. IBLCE also modified the definition of company/commercial interest to apply to the specific and unique conflicts of interest encountered in the lactation and breastfeeding field.

**SUPPORTING DOCUMENTS:**

- [Frequently Asked Questions \(FAQs\) Regarding the Minimizing Commercial Influence on Education Policy](#)
- [Sample written agreement documenting terms of support](#)

**Please Note:** The term “CERP” when used to describe an educational activity means that the educational activity is either eligible for or has already been approved for Continuing Education Recognition Points (CERPs).

CERP Providers are placed in positions of judgment that require them to take extra steps to ensure that their private interests do not compete with their professional duties to provide education suitable for the continued learning needs of IBCLCs. In turn, IBCLCs are placed in positions of judgment that require them to take extra steps to ensure that Companies do not compete with their professional duties to the clients they serve.

CERP Providers and all individuals connected to the CERP Provider shall protect the interests of IBCLCs by disclosing competing interests that might assert undue influence on IBCLCs.

**POLICY:**

**STANDARD 1: Independence**

- 1.1 A CERP Provider must ensure that the following decisions were made free of the control of a Company:
  - a) Identification of continuing education needs;
  - b) Determination of educational objectives;
  - c) Selection and presentation of content;
  - d) Selection of all persons and organizations that will be in a position to control the content of the CERP educational activity;
  - e) Selection of educational methods; and
  - f) Evaluation of the educational activity.

- 1.2 A Company cannot take the role of non-approved partner in a joint sponsorship relationship.

**STANDARD 2: Resolution of Personal Conflicts of Interest**

- 2.1 The CERP Provider must be able to show that everyone who is in a position to control the content of an educational activity has disclosed to the CERP Provider all relevant financial relationships

with any Company. IBLCE defines "relevant financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

- 2.2 An individual who refuses to disclose relevant financial relationships to the CERP Provider will be disqualified from being a planning committee member, a teacher, or an author of a CERP educational activity, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CERP educational activity.
- 2.3 The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the CERP educational activity being delivered to learners.

### STANDARD 3: Appropriate Use of Commercial Support

- 3.1 The CERP Provider must make all decisions regarding the disposition and disbursement of commercial support.
- 3.2 A CERP Provider cannot be required by a Company to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a Company as conditions of contributing funds or services.
- 3.3 All commercial support associated with a CERP educational activity must be given with the full knowledge and approval of the CERP Provider.

#### Written agreement documenting terms of support

- 3.4 The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the CERP Provider and its educational partner(s). The agreement must include the CERP Provider, even if the support is given directly to the CERP Provider's educational partner or a joint sponsor.
- 3.5 The written agreement must specify the Company that is the source of commercial support.
- 3.6 Both the commercial supporter and the CERP Provider must sign the written agreement between the commercial supporter and the CERP Provider.
- 3.7 The CERP Provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.
- 3.8 The CERP Provider, the joint sponsor, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of-pocket expenses in compliance with the CERP Provider's written policies and procedures.
- 3.9 No other payment shall be given to the director of the educational activity, planning committee members, teachers or authors, joint sponsor, or any others involved with the supported educational activity.

- 3.10 If teachers or authors are listed on the agenda as facilitating or conducting a presentation or session, but participate in the remainder of an educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their teacher or author role only.

#### Expenditures for learners

- 3.11 Social events or meals at CERP educational activities cannot compete with or take precedence over the educational events.
- 3.12 The CERP Provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CERP educational activity. The CERP Provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the CERP Provider, joint sponsor or educational partner.

#### Accountability

- 3.13 The CERP Provider must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support.

### STANDARD 4: Appropriate Management of Associated Commercial Promotion

- 4.1 Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation of the educational activity, nor can they be a condition of the provision of commercial support for CERP educational activities.
- 4.2 Product-promotion material or product-specific advertisement of any type is prohibited in or during CERP educational activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CERP educational activities. All advertisements should be clearly identified as such.
- 4.3 Educational materials that are part of a CERP educational activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or a product-group message.
- 4.4 Print or electronic information distributed about the non-CERPs-eligible/approved elements of a CERP educational activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions, may include product promotion material or product-specific advertisement.
- 4.5 A CERP Provider cannot use a Company as the agent providing a CERP educational activity to learners, e.g., distribution of self-study CERP activities or arranging for electronic access to CERP activities.

### STANDARD 5: Content and Format without Commercial Bias

- 5.1 The content or format of a CERP educational activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a Company.
- 5.2 Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CERP educational material or content includes trade names, where available, trade names from several companies should be used, not just trade names from a single company.

#### STANDARD 6: Disclosures Relevant to Potential Commercial Bias

- 6.1 Relevant financial relationships of those with control over CERP content.
  - a) An individual must disclose to learners any relevant financial relationship(s), to include the following information:
    - The name of the individual
    - The name of the Company or Companies
    - The nature of the relationship the person has with each Company.
  - b) For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.
- 6.2 Commercial support for the CERP educational activity.
  - a) The source of all support from Companies must be disclosed to learners. When commercial support is "in-kind" the nature of the support must be disclosed to learners.
  - b) "Disclosure" must never include the use of a trade name or a product-group message.
- 6.3 Timing of disclosure
  - a) A CERP Provider must disclose the above information to learners prior to the beginning of the CERP educational activity.