

## **Disclosure & Conflict of Interest Resolution for Continuing Education Programs**

### **I. POLICY**

The Division of Education (DOE) Continuing Education (CE) Section must be able to show that everyone who is in a position to control the content of a continuing education activity has disclosed all relevant financial relationships with any commercial interests. Disclosure of relevant financial relationships will be made in accordance with the Standards for Commercial Support provided by the Accreditation Council for Continuing Medical Education (ACCME), the Policies on Disclosure of the Pennsylvania Medical Society, American Nurses Credentialing Center (ANCC) Commission on Accreditation Operational Requirements and Pennsylvania State Nurses Association (PSNA) Policies for Commercial Support. All persons with the ability to control content including planners and faculty participating in continuing education programs sponsored by Lehigh Valley Health Network (LVHN) are expected to disclose any real or apparent conflict(s) of interest related to the content of their presentation(s). Relevant financial relationships of a spouse or partner of a person in a position to control content must also be disclosed.

### **II. SCOPE**

All persons in a position to control content in continuing education programs offering CME or CNE credit through LVHN.

### **III. DEFINITIONS.**

Continuing Medical Education (CME) – Continuing Medical Education consists of educational activities that serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, the public, or the profession. The content of CME is that body of knowledge and skills generally recognized and accepted by the profession as within the basic medical sciences, the discipline of clinical medicine, and the provision of health care to the public.

Continuing Nursing Education (CNE) – Systematic professional learning experiences designed to augment the knowledge, skills, and attitudes of nurses and therefore enrich the nurses' contributions to quality health care and their pursuit of professional career goals.

Social Work - Continuing education programs must be directed toward the enhancement of social workers', clinical social workers', marriage & family therapists' and professional counselors' knowledge and practice skills related to helping people achieve adequate and productive personal, interpersonal, and social adjustments in their individual lives, families, and community.

Commercial Interest – A 'commercial interest' is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients with the exemption of the following:

- 501-C Non-profit organizations
- Government organizations
- Non-health care related companies
- Liability insurance providers
- Health insurance providers
- Group medical practices

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- For-profit hospitals
- For-profit rehabilitation centers
- For-profit nursing homes

Relevant Financial Relationship – A relevant financial relationship is any financial relationship with a commercial interest in any amount occurring within the past 12 months.

Conflict of Interest – When an individual has both a financial relationship with a commercial interest and the opportunity to affect continuing education content about the products or services of that commercial interest.

### **IV. PROCEDURE**

- Activities must be planned in compliance with the ACCME's Standards for Commercial Support. All activity planners, presenters/content experts and others that will be in a position to control the content of the continuing education activity must disclose any relevant financial relationship(s) with commercial interests. Disclosures must include:
    - The name of the individual
    - The name of the commercial interest(s)
    - The nature of the relationship the person
  - For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.
  - The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific-proprietary business interest of a commercial interest (SCS 5.1)
  - Design elements that are part of a product-promotional campaign shall not be used in the educational material for a CME activity discussing that product.
  - Presentations must give a balanced view of therapeutic options. Generic names must be used. If the CME educational material or content includes trade names, trade names from several companies must be used, not just trade names from a single company.
  - CME activity content and format shall comply with the American Medical Association (AMA) definition of continuing medical education and Ethical Opinion 9.011 [AMA Regulations and Opinions]
  - When unlabeled commercial products are addressed in the educational activity, the presenter must disclose to the participants that the product under discussion is not labeled for use or announce that the product is investigational.
- A. The activity director or designee is responsible for obtaining disclosure information from everyone in a position to control content. Completed disclosure information needs to be submitted to the DOE CE Section with application documentation prior to the event.
  - B. Should anyone in a position to control content of a CE activity refuse to disclose financial relationships with commercial interests, they must be disqualified from being a planning committee member, teacher, or author of content, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the activity.
  - C. If a relevant financial relationship is disclosed, the potential conflict must be investigated and resolved prior to the activity. If an identified conflict of interest cannot be resolved, the speaker/content expert must be disqualified from being a planning committee member, faculty, or an author of the activity, and cannot have control of, or responsibility for, the development, management, content, presentation or evaluation of the activity.

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- D. Resolution of an identified potential conflict of interest must be documented using the Conflict of Interest Resolution Form.  
Ways to resolve conflict (monitoring and evaluation of the activity are valuable but not sufficient, in and of themselves):
1. Determine that the role of the individual in the activity is unrelated to the conflict of interest
  2. Eliminate the relationship with the commercial entity (still must be disclosed if within 12 months of the activity)
  3. Restrict the scope of an individual's participation
  4. Limit the sources of the individual's recommendations (evidence-based literature)
  5. Independent review of content
  6. Offer a forum during the activity in which experts will react to the presentation
  7. Provide a "point-counterpoint" forum
- E. The source of all support from commercial interests must be disclosed to learners. The nature of non-monetary, or in-kind, commercial support must be disclosed to learners.
- F. If a product being discussed in a presentation has not been labeled for the use under discussion, the activity director must assure this is disclosed to the learner. Off-label use refers to using a pharmaceutical agent for a purpose other than the purpose for which it was approved by the FDA.
- G. The activity director or designee must assure disclosure information is shared with learners prior to the beginning of the educational activity. This disclosure must be documented.  
Disclosure can be communicated to an audience in the following manner:
1. The Disclosure Announcement form can be completed, read to the audience prior to the beginning of the activity, and then signed by the moderator.
  2. Disclosure information may be printed in the handout materials which are distributed to the learner at the beginning of the activity.
- For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.
- H. Disclosure to participants must never include the use of a trade name or a product group message.

### V. **ATTACHMENTS**

Disclosure of Financial Relationships  
Biographical Data Form  
Audience Disclosure Announcement  
Conflict of Interest Resolution Form

### VI. **DISTRIBUTION**

Continuing Education Policy and Procedure Manual

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**VII. APPROVAL**

_____	Associate Director, Continuing Education	_____
Signature	Title	Date
_____	Chair, Continuing Education <u>Advisory Board</u>	_____
Signature	Title	Date

**VIII. POLICY RESPONSIBILITY**

Associate Director, Continuing Education

**IX. REFERENCES**

Pennsylvania Medical Society, Commission for Continuing Medical Education. (November 2005 Edition). *Manual for providers Seeking Accreditation to Award Credit for CME in Category 1 of the AMA's Physician Recognition Award*, Harrisburg, PA.

Accreditation Council for Continuing Medical Education. (April 2004 Edition). *Standards for Commercial Support: Standards to Ensure the Independence of CME Activities (revised July 2006)*.

Pennsylvania State Nurses Association, (R-2006 Edition Effective January 1, 2007) *Continuing Education Approval Program Manual*, Harrisburg, PA.

**X. DISCLAIMER STATEMENT**

This policy and the implementation procedures are intended to provide a description of recommended courses of action to comply with statutory or regulatory requirements and/or operational standards. It is recognized that there may be specific circumstances, not contemplated by laws or regulatory requirements that make compliance inappropriate. For advice in these circumstances, consult with the department of Risk Management and /or Legal Services.

**XI. DATES**

Origination:	September 1999
Reviewed/Revised:	December 2003
	December 2004
	June 2005
	November 2006
	September 2007
	December 2010