Optometric Guidelines for Independent Continuing Education June 2009

Introduction

Continuing education is an integral and essential element of the profession of Optometry. In addition to being a requirement for relicensure by every state board of optometry, this education is vital to professionals as they pursue the process of life-long learning. Continuing education enables doctors to provide state-of-the-art eye care to their patients, as they are kept abreast of innovations in technology, pharmacology and management modalities. Whatever the subject matter or venue, maintaining an independent learning environment for doctors of optometry is of paramount importance.

Financial support by industry has been and continues to be an integral part of optometric education. Without such support, quality continuing education could become cost-prohibitive. However, financial support of a program has the potential to introduce bias, which can threaten the scientific integrity of educational activities. Industry has already taken significant steps to separate educational grants from promotional activities, and it is widely recognized that doctors and patients are better served with fair and balanced education. Voluntary self-regulation and adherence to the guidelines by the entire optometric community is essential in order to create a culture of scientifically sound and commercially unbiased optometric education.

The Steering Committee for Independent Continuing Education for Optometry, with representation from AAO, AOA, ARBO, ASCO and SECO, has written these guidelines with input from stakeholders across the profession, with the intent of creating a new culture in optometric continuing education. Promotional activities must be kept separate from educational activities, and while both serve a valuable purpose, the boundaries are sometimes confusing. Providers of education and industry alike are encouraged to adopt these guidelines as a blueprint for ethical relationships between corporate supporters who provide funding for educational activities and the organizations that plan and put on those activities.

The purpose of this document is to establish voluntary guidelines for the profession to help ensure the independence of accredited optometric continuing education. The guidelines do not pertain to non-credit promotional activities of a particular product or products, which should be clearly identified as such from the outset. The guidelines are not meant to serve as a detailed set of enforceable rules and regulations. They are not meant to micro-manage the activities of speakers or providers of education. Rather, with the same intent as the voluntary PhRMA Code on Interactions with Healthcare Professionals, and the voluntary AdvaMed Code of Ethics, Optometry's Guidelines for Independent Continuing Education are meant to assist doctors, meeting planners, and industry partners alike create and administer quality educational programs in an era of increasing transparency. Although the Optometric Guidelines for Independent Continuing Education (ICE) are meant to serve as a code of conduct rather than a mandatory set of regulations like the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support, their intent is the same. They are also separate from any rules that the Association of Regulatory Boards in Optometry (ARBO) may establish regarding COPE-approved continuing education courses and events required by some state boards for maintenance of licensure.

Representatives from the American Academy of Optometry (AAO), the American Optometric Association (AOA), the Association of Regulatory Boards in Optometry (ARBO), the Association of Schools and Colleges of Optometry (ASCO), and SECO International, LLC (SECO) formed the National Steering Committee on Optometric Guidelines for Independent Continuing Education. The Committee developed the following guidelines for optometric continuing education, including issues related to industry support, disclosure and advertising.

The Steering Committee acknowledges and appreciates the valuable perspective and insights provided to this process from our industry partners.

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1. <u>Independence of Continuing Education (ICE)</u>

Meeting administrators are responsible for making all decisions regarding educational activities they are providing, including:

- A. Educational needs of attendees
- B. Objectives
- C. Format and educational methods
- D. Content
- E. Speaker(s)
- F. Course evaluation tools
- G. Audience selection

2. <u>Appropriate Commercial Support</u>

Support given to meetings of any type should be in the form of educational grants. Commercial support can be either monetary or in-kind support. Commercial support cannot include conditions regarding speaker, author, or audience selection, course objectives, format or content.

2.1 Administrators/providers must:

- A. Make all decisions regarding the disbursement of commercial support related to a specific event
- B. Determine appropriate honoraria and reimbursement policies
- C. Screen courses for scientific integrity, fairness and balance
- D. Assure that educational content promotes improvements or quality in eyecare and healthcare, and not a specific product of a commercial interest
- E. Identify and resolve all conflicts of interest prior to the educational activity being delivered to the attendee
- 2.2 For all continuing education programs, speakers must be paid by the administrator/provider only and never directly (in part or in full) by the industry partner.

3. Promotion of Commercially Supported Education

Industry partners allocate significant resources to support educational programs and exhibits at meetings, and should be recognized. However, that recognition must not compromise the content of the educational program. Promotional copy and activities must be kept appropriately separate from educational content and activities.

- 3.1 While discussion of products, drugs and instruments is inherent in most educational programs, such discussions and supporting written materials such as PowerPoint slides or handouts cannot contain any company advertising or promotional messages of any kind. Product performance discussions must be fair, balanced and based on scientific evidence from unbiased sources. Discussion of off-label uses of such products is appropriate, but must be identified to the audience.
- 3.2 Distribution of company or product promotion materials, exhibit tables, or product specific advertisements of any type are prohibited inside the room where the educational activity is being held. Recognizing that some smaller meetings may have an exhibition area outside the meeting room or rooms, attendees should never be placed in a position where they are forced to stop and interact with exhibitors if they choose not to do so.
- 3.3 During a CE activity, representatives of a company cannot engage in sales or promotional activities in the space where the CE activity is being held.

4. Disclosures Relevant to Potential Commercial Bias

In order to be fully transparent to the attendees of an educational program, any conflict of interest or the appearance of such a conflict shall be disclosed. This includes full disclosure of all financial relationships with any commercial interest as follows:

- 4.1 Everyone who is in a position to control educational content must disclose to the Administrator/Provider all personal financial relationships (and family member financial relationships) with any commercial interest, related to health care, during the last 12 months.
- 4.2 Speakers must disclose to the audience all such relevant financial relationships, to include the following:
 - The name of all commercial interests with which the individual or family member has a financial interest
 - The nature of the relationship the individual has with each interest, such as employment, management position, independent contractor including contracted research, consulting, speaking, teaching, membership on advisory or review panels, board membership, and other activities from which remuneration is received or expected
 - The nature of the commercial interest, such as salary, royalty, intellectual property rights, consulting fee, honorarium, or ownership interest such as stock options, with which the individual or family member has a financial interest
 - Any participation on an industry speaker's bureau giving non-CE informational talks when the same or similar content is being covered in the CE program
 - If there are no relevant financial relationships, that should be so stated.
- 4.3 All commercial support must be disclosed by the administrator to the audience.
- 4.4 All disclosures mentioned above should be made prior to the beginning of each lecture and displayed on the opening slide, or at the end of a journal article or online CE program.

ICE Definitions

Commercial Support:

Financial, or in-kind, contributions of any amount given by a commercial interest, which is used to pay all or part of the costs of a CE activity, or reduce the expenses of such activity.

Commercial Interest:

Any entity producing, marketing, reselling, or distributing health care goods or services consumed by, or used on, patients. This includes any consulting services related in any way to the ophthalmic or health care industry.

Conflict of Interest:

A conflict of interest exists when an individual has an opportunity to introduce bias into a CE program related to products or services of a commercial interest with which he/she, or a member of his or her immediate family, has a financial relationship.

Educational Grant:

Educational grants are provided by companies to support programs that are intended to benefit patients and health care professionals, by providing information that advances the practice of medicine. Educational grants may include funding for educational events administered by a professional society, fellowships, independent continuing education (CE) programs, and educational materials for dissemination to practitioners or patients (e.g. as part of disease management programs). Education grants are intended to support legitimate, non-promotional, educational functions, and are not contingent on past or future product purchases.

Financial Relationships:

Relationships in which the individual (or spouse, partner or family member) benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honorarium, ownership interest (e.g., stock, stock options, or other ownership interest, excluding diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as

employment, management position, independent contractor (including contracted research), consulting (either as an employee or owner of a consulting company), speaking and teaching, membership on advisory or review panels, board membership, and other activities from which remuneration is received or expected. Equipment loaned to an individual or practice for evaluation for greater than 30 days constitutes a financial relationship as well.

Family Member:

Anyone related by blood or affinity whose close relationship with the speaker is the equivalent of a family relationship. This includes, but is not limited to; the speaker's spouse, parents, and spouse's parents, children, including stepchildren and adopted children, and their spouses, brothers and sisters, and their spouses.

Lecturer/Speaker:

An individual who develops and/or presents content for optometric continuing education.

Provider/Administrator/Meeting Planner:

Any individual, not-for-profit organization, or for-profit company that conducts optometric continuing education in any setting (face-to-face, web-based, in print, etc.) or formal lecture, workshop, seminar, symposium, grand rounds, peer review article or case report. A commercial interest cannot take on the role of Administrator in any request for funding or administration of a CE activity.

Frequently Asked Questions

Are the Optometric Guidelines for Independent Continuing Education different than the ARBO/COPE Standards for Commercial Support? Yes. The ICE Guidelines are voluntary, profession-wide guidelines that will serve to guide the relationships between corporate partners and the organizations that conduct continuing education activities for optometrists. These are separate from any rules that ARBO may establish regarding COPE-approved continuing education courses and events required by some state boards for maintenance of licensure.

May a commercial interest designate which speakers are to be used by the Provider at an educational event?

No. Inherent in the guidelines is the expectation that the provider makes all decisions related to the choice of speaker without being directed or influenced by commercial interests. This does not preclude a company from providing suggestions on knowledgeable and skilled speakers in response to an unsolicited request by the provider.

Can a commercial interest provide direct reimbursement of expenses related to CE activities?

No. The support must go to the provider or a provider's joint sponsor or a provider's educational partner.

Can a commercial supporter supplement their contributions to a CE program by additional direct payments to speakers or others involved in the program?

No. All commercial support must be stipulated by written agreement and must flow through the provider. Only the provider can make payments to speakers or others for their role in the CE activity.

Can a commercial supporter direct the content of CE?

No. The provider must ensure that the content of the CE truly remains beyond the control of the commercial supporter/industry partner. The process to develop CE must be independent of the commercial interest. Providers must not allow commercial supporters/industry partners to directly or indirectly contribute to or control the content of the CE.

I am an employee of a commercial interest, but also a speaker. Do the guidelines mean I can no longer speak at meetings?

Not necessarily. Course content presented by a company employee should be unrelated to the specific products manufactured by that company. For example, an employee of a perimetry company could still lecture on the general topic of visual fields and glaucoma, but without reference to any specific instruments or studies related to that company's instrument.

Can I talk about off label uses of drugs/products?

Yes. As long as you disclose to the audience that the use you are discussing is off-label.

What is the best way to provide disclosure information on relevant financial relationships?

Every provider organization should have the speaker or committee member sign a disclosure statement. In addition, an opening disclosure slide should be presented to the audience prior to each and every lecture given.

Can an industry employee, consultant or representative be in the audience of an educational program, that is either sponsored by his/her company or the company of a competing sponsor?

Yes. However, those representatives should refrain from asking questions or offering comments. Questions may occasionally be directed by the speaker to the industry representative for specific factual content without commercial bias. The industry representative must first identify him or herself and his or her industry affiliation prior to answering the question. Furthermore, if the response shows evidence of anything other than specific factual answers to particular questions, it is the obligation of the speaker to stop the industry representative from speaking further.

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