



Association of Regulatory Boards of Optometry

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Council of Optometric Practitioner Education (COPE) Standards for Commercial Support (SCS)

The ARBO COPE Committee and Board of Directors have worked diligently since the National Optometric Continuing Education Conference (NOCEC) in May 2006 to address the issues identified by the Conference attendees. The NOCEC was well attended and represented all aspects of the optometric profession.

One need identified by the NOCEC was the establishment of standards for commercial support for optometric CE, and is addressed in the ARBO COPE SCS. A draft of proposed standards was released in a press conference during the 2008 SECO meeting in Atlanta. An initial 6-month comment period was announced to receive input from the optometric community. During the comment period, ARBO agreed to temporarily postpone the implementation of the proposed standards to allow for a more thorough review.

Beginning in late 2008, ARBO participated on a profession-wide multi-organizational Steering Committee formed to examine the issues surrounding commercial support of optometric CE. The committee is composed of a distinguished group of appointees representing the AAO, AOA, ARBO, ASCO, SECO and industry. Chaired by Dr. Paul Ajamian, the Steering Committee has worked diligently on developing a voluntary "code of ethics" to address issues related to commercial support of CE, disclosure and advertising. We applaud the substantial efforts of Dr. Ajamian, the members of this committee, and their respective organizations in addressing these critical issues facing our profession. The guidelines were finalized and adopted by the respective organizations in June of 2009.

The code of ethics developed by the Steering Committee is of great value to ARBO and COPE as we continue to evolve and address the needs of our member licensing boards and the constantly changing CE environment.

After months of discussion and exchange of information and presentations to the optometric community, ARBO is releasing the COPE SCS. These standards supplement the existing guidelines for COPE approved administrators/providers and add requirements to manage corporate support of COPE accredited CE with the highest integrity and free of commercial bias.

The COPE SCS will benefit the relationship between corporate supporters and optometric CE, and gives clear direction to CE administrators/providers, CE instructors and CE supporters. By ensuring compliance with these standards, licensing boards are ensured transparent, commercial interest free CE, corporate supporters are insulated, optometric CE is shielded, the profession benefits from subsidized education, and the public is protected.

The COPE SCS does not attempt to eliminate the participation of corporate supporters in optometric educational activities. Corporate supporters have indicated they plan to continue supporting the profession, desire a level playing field with established boundaries. Although it is not the primary intent of COPE, these standards will provide a safe environment where corporate funding could grow as it has with other professions.

The COPE SCS contained in this document were released in December of 2009. Post release is a six-month training and implementation period through July 1, 2010. Oversight and enforcement during this period will consist of notification of non-compliance and assistance with compliance issues. Full compliance will be required as of January 1, 2011.

ARBO's commitment is to continue to provide salient and unbiased CE that is not influenced by any company, product or brand. Our responsibility is to provide and implement the standards necessary for establishing and protecting the integrity of optometric CE.

COPE Standards for Commercial Support (COPE SCS)

Standard 1: Independence

COPE Accredited CE must be identified, developed and presented free from the control of a commercial interest.

1. A "commercial interest" is defined as any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. Providers of clinical service directly to patients are not considered commercial interest. Non-profit or government organizations and non-health care related companies are not considered commercial interests.
2. COPE Approved Administrators/Providers must ensure that any decisions regarding content, format, speaker selection and evaluation are made without any influence from or control of a commercial interest. COPE Approved Administrators/Providers should develop curriculum based on identification of CME needs with determination of educational objectives.
3. Instructors of COPE Accredited CE must develop course material and information independent from any influence from commercial interest.
4. Under no circumstances can a commercial interest produce or deliver COPE Accredited CE or take the role of non-accredited partner in a joint sponsorship relationship.

Standard 2: Resolution of Personal Conflicts of Interest

Every person in a position to impact the content of COPE Accredited CE must disclose all relevant financial relationships to the COPE Approved Administrator/Provider and to the Learners.

1. The COPE Approved Administrator/Provider must be able to show that everyone who is a position to control the content of an educational activity has disclosed all relevant financial relationships with any commercial interest.
2. Relevant financial relationships are financial relationships in any amount occurring within the past 12 months that create a conflict of interest.
3. An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a COPE Accredited CE instructor or an author of CE, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the COPE Accredited CE.
4. COPE Approved Administrators/Providers must have implemented a mechanism to identify and manage all conflicts of interest prior to the education activity being delivered to the learners.

Standard 3: Appropriate Use of Commercial Support

In order for a CE event to be COPE accredited, all commercial support must be in the form of an educational grant or letter of agreement between the COPE Approved Administrator/Provider and the Corporate Supporter.

1. The COPE Approved Administrator/Provider must make all decisions regarding the disposition and disbursement of commercial support.
2. The COPE Approved Administrator/Provider cannot be required by a commercial interest to accept advice or services concerning instructors, authors, or selection of participants, evaluation methods or other education matters, including content, from a commercial interest as conditions of contributing funds or services.
3. All commercial support associated with COPE Accredited CE must be given with the full knowledge and approval of the COPE Approved Administrator/Provider.
4. The terms, conditions, and purposes of the commercial support must be documented in a written agreement, such as a letter of agreement or educational grant, between the commercial supporter that includes the COPE Accredited Administrator/Provider and its educational partner(s). The agreement must include the COPE Accredited Administrator/Provider, even if the support is given directly to the COPE Accredited Administrator's/Provider's educational partner or a joint sponsor.
5. The written agreement must specify the commercial interest that is the source of commercial support.
6. Both the commercial supporter and the COPE Accredited Administrator/Provider must sign the written agreement between the commercial supporter and the COPE Accredited Administrator/Provider (electronic signature is acceptable).
7. The COPE Approved Administrator/Provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners and instructors.
8. The COPE Approved Administrator/Provider, the joint sponsor, or designated educational partner must pay directly any instructor honoraria or reimbursement of out-of-pocket expenses in compliance with the COPE Approved Administrator's/Provider's written policies and procedures.
9. No other financial incentives shall be given to the director of the activity, planning committee members, instructors or authors, joint sponsor, or any others involved with the supported activity.
10. If instructors are listed on the agenda as facilitating or conducting a presentation or session, but participate in the remainder of the COPE Accredited CE as a learner, their expenses can be reimbursed and honoraria can be paid for their instructor role only.
11. Social events or meals at COPE Accredited CE events cannot compete with or take precedence over the educational courses.
12. The COPE Approved Administrator/Provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-instructor

- participants of a COPE accredited event. The COPE Approved Administrator/Provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the COPE Approved Administrator/Provider, joint sponsor or educational partner.
13. In the event of an audit, the COPE Approved Administrator/Provider must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support.
 14. All financial support must be directed through the COPE Approved Administrator/Provider; under no circumstances can the supporter provide any person with influence over the content of the COPE accredited course or event with any direct financial incentive or direct reimbursement.

Standard 4: Appropriate Management of Associated Commercial Promotion

There must be a clear separation of any type of product, service, and instrument or device promotion with COPE Accredited Courses. These activities, such as commercial exhibits and advertisements must be physically separated from and not interfere with COPE Accredited Courses.

1. Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for COPE Accredited CE.
2. Product-promotion material or product-specific advertisement of any type is prohibited in or during COPE Accredited Courses. 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 COPE Accredited Courses.
 - a. For print, advertisements and promotional materials will not be interleaved within the pages of the CE content. Advertisements and promotional materials may face the first or last pages of printed CE content as long as these materials are not related to the CE content they face and are not paid for by the commercial supporters of the COPE Accredited CE.
 - b. For computer based, advertisements and promotional materials will not be visible on the screen at the same time as the CE content and not interleaved between computer 'windows' or screens of the CE content.
 - c. For audio and video recording, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during or after a CE event. COPE Approved Administrators/Providers cannot allow representatives of commercial interests to engage in sales or promotional activities while in the space or place of the CE course.

3. Educational materials that are a part of COPE Accredited CE, such as slides, abstracts and handouts, cannot contain any advertising or product-group message.
4. Print or electronic information distributed about the non-CE elements of a COPE Approved Event 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. There must always be a clear separation between advertising and product-group message and educational content.
5. COPE Approved Administrators/Providers cannot use a commercial interest as the agent providing COPE Accredited CE to learners, e.g., distribution of self-study CE activities or arranging for electronic access to COPE Accredited Courses.

Standard 5: Content and Format without Commercial Bias

All COPE Accredited Courses cannot deliver specific proprietary business interests and must give balanced coverage to treatment options.

1. The content or format of a COPE Accredited Course or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.
2. Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the COPE Accredited Course includes trade names, where available trade names from several companies should be used, not just trade names from a single company.
3. Instructors may have assistance in the development of a course, including the creation of handouts, slides and objectives, though not from a commercial interest. Any ghostwriting activity must be included in the disclosure to the CE Administrator/Provider and learners.

Standard 6: Disclosures Relevant to Potential Commercial Bias

To maintain transparency, financial relationships with commercial interests of any persons in a position to impact or control the educational content must be disclosed to the learners. This includes instructors and planning committee members.

1. An individual must disclose to learners any relevant financial relationship(s), to include the following information:
 - a. The name of the individual;
 - b. The name of the commercial interest(s); and,
 - c. The nature of the relationship the person has with each commercial interest.
2. For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.
3. Instructors must disclose ghostwriting activities.

4. The source of all support from commercial interests must be disclosed to learners. When commercial support is 'in kind' the nature of the support must be disclosed to learners.
5. 'Disclosure' must never include the use of a trade name or product-group message.
6. COPE Approved Administrators/Providers must disclose the above information to learners prior to the beginning of the educational activity.