

## **COPE Standards for Commercial Support (COPE SCS)**

### ***Frequently Asked Questions***

#### **Why is COPE setting new standards for support?**

##### **a. COPE is being proactive**

The federal government has taken renewed interest in the relationships between industry and healthcare. Since 2000, new regulatory policies aimed at consumer protection and controlling healthcare costs have placed new restrictions on industry interactions with healthcare professionals. Many previously accepted activities are now being questioned. As a result, more industry support has been moved into grants for continuing education activities creating potential conflicts of interest issues for all healthcare professionals. In 2004 the Accreditation Council for Continuing Medical Education (ACCME) addressed these issues by releasing their "Standards for Commercial Support" and in December of 2006 there was federal scrutiny of the effectiveness of these standards. In response, CE accrediting organizations are implementing guidelines implemented guidelines to appropriately manage industry relationships and support of CE activities to ensure transparency, fair balance, content free of commercial bias and an effective system of oversight.

COPE has taken notice of these events and is being proactive.

##### **b. To provide a structured environment**

Parallel to government inquiry, various Industry groups developed their own voluntary codes on relationships with healthcare professionals. PhRMA and AdvaMed have been in existence since 2003 and have proven to be subject to differences in interpretation. Boundaries need clarification and non-biased interpretation. To operate in a fair and impartial manner, COPE can provide a safe environment for all to operate. Therefore COPE is strengthening the existing guidelines and providing a system of oversight.

##### **c. There is a general consensus**

In 2006, leaders from the AOA, NBEO, ASCO and ARBO gathered in Chicago Illinois to ... "develop a profession-wide consensus-driven approach to the future of continuing education and optometric competence for the benefit of the public" From this meeting there was agreement that new guidelines were needed for commercial support of optometric continuing education events.

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.

**d. It's the right thing to do**

The integrity of our CE system has played an important historical role in the advancement of our profession.

Mandatory continuing education is a requirement of licensure recognized by all fifty state boards. Continued improvement and protection of the integrity of this system is important for our profession and the public welfare to ensure continued competence.

**What is the timeline for the new COPE standards for corporate support implementation?**

In its November 2009 meeting, the ARBO Board of Directors approved the final timeline for the release and implementation of the new COPE Standards for Commercial Support. The standards, including an implementation toolkit, has been released in December of 2009 to all COPE Stakeholders, and will be available to everyone on the ARBO website ([www.arbo.org](http://www.arbo.org)). January through June 2010 will be a six-month training period, followed by a six-month implementation phase. Oversight and enforcement during 2010 will consist of notification of non-compliance and assistance with compliance issues. Full compliance to the standards for all COPE accredited CE will be required as of January 1, 2011. For more information as it becomes available, please continue to check the ARBO website, [www.arbo.org](http://www.arbo.org).

**Do these guidelines apply to all commercially supported events?**

These guidelines apply only to COPE Accredited CE courses and events. They do not necessarily apply to other state board approved CE events. In addition, industry remains able to organize speaker bureaus and conduct regional and state informational seminars that are not COPE accredited.

**Does this mean that a commercial interest can no longer act as a COPE Administrator/Provider?**

In order to ensure that commercial interest support of CE does not influence content, there must be separation between financial support and the control of all processes that occur in the administration of the CE event. Processes that carry potential for commercial bias include speaker and topic selection, distribution of promotional materials, and the development of presentation materials. Due to this potential conflict of interest, commercial entities will no longer be approved as COPE Administrators/Providers. Commercial support of a COPE approved CE event can only occur through an unrestricted grant to a COPE-approved Administrator/Provider. This is a major change from current COPE policy.

### **Can an Instructor also act as a COPE Approved Administrator/Provider?**

Instructors may be COPE Approved Administrators/Providers, but cannot serve in both roles at the same time for COPE Accredited CE.

### **Under the new standards, the Instructor is required to submit a course, not a commercial interest. What about Administrators?**

An Administrator can submit a course on behalf of the instructor but must attach to the course submission a form dated and signed by the Instructor confirming the Instructor authored the course and will comply with the COPE rules and regulations.

### **Under the new standards, can a commercial interest pay the Instructor directly?**

No, the company support may come to the COPE Approved Administrator/Provider by way of a contracted educational grant. The COPE Approved Administrator/Provider will be responsible for the Instructor honoraria and expense reimbursement under its own policies. This also means that all contact with the Instructor must be from the COPE Approved Administrator/Provider and not from the commercial interest.

### **What kind of documentation of commercial support is expected?**

Upon request, COPE expects to be able to review income and expense statements for all commercially supported CE activities. These statements must reflect:

- *Significant sources of income:* Including income from commercial support, advertising and exhibit fees, tuition and registration fees, internal budget allocations and any other source that represents greater than 20% of total income.
- *Significant expenses:* Including staff salaries, meeting costs, honoraria, faculty travel expenses and any other item that represents greater than 20% of total expense.

### **What about COPE accreditation for presentations designed for the purpose of promoting products, instruments or devices?**

They will not be approved. This was true under the old guidelines as well, but to be clear, courses that promote a product, service, instrument and/or device will not be approved for COPE Accredited CE.

### **Will commercial interest employees be able to serve as COPE Approved Instructors?**

Yes, providing the Instructor can demonstrate that the information presented in the course will be transparent, balanced and without bias in the course submission process that includes a mandated disclosure form. This information is also required to be disclosed to the learners.

### **What about consultants under contract to commercial interests?**

Yes they may also continue to serve as Instructors, providing they meet the general standards set for all Instructors.

**Can Instructors collaborate on a course, but have one speaker give the course at a time?**

Yes, providing the course submission disclosure information includes everyone who contributed to the preparation of the lecture and materials. This information is also required to be disclosed to the learners.

**Can commercial interests provide data to Instructors for COPE Accredited CE?**

Yes, that would be allowed. In some cases, company data on manufacturing processes or product material content could prove valuable in the presentation of some educational courses. The use of company slides with corporate logos will not be acceptable, however referencing the origin of the data (by company name, not including any product information) is mandatory. In all cases, Instructors must present courses that are fair balanced and free of commercial bias.

**Will all Instructors be required to include a disclosure slide during their presentation?**

Yes, a sample slide is included in the COPE SCS Tool Kit.

**Will information regarding the sponsorship and funding be required in all written materials such as handouts, event brochures and programs?**

Recognition of commercial interest support should be printed in all handouts, but is not required to be included in the event agenda or brochure. This recognition must be of the company, not of product(s). Guidelines for this recognition are included in the COPE SCS Tool Kit found on the ARBO website at [ww.arbo.org](http://ww.arbo.org).

**Is a physical separation of promotional activities and education required under the new standards?**

Yes. There must be a clear separation and distinction between promotional activities and educational activities at all COPE Accredited CE. This includes:

- Product promotion, product specific advertisements of any type is prohibited in the educational space immediately before, during, or after COPE Accredited CE
- For print and online distributed CE, promotional advertising cannot be interspersed within the CE educational materials.
- Commercial interest representatives cannot engage in sales or promotional activities while in the same space or place of the COPE Accredited CE. Commercial interest representatives may be present during COPE Accredited CE, but must refrain from addressing the learners during the course delivery.

**Can an Instructor remain after his/her presentation to mingle with the learners?**

A reasonable period of time is encouraged for the Instructor to answer questions about his/her lecture at the end of the course. However, even if the allotted CE time had ended, and the

education was considered over, it would not be appropriate for the Instructor to stay and talk about products.

**Must the COPE Approved Administrator/Provider be in attendance at every live COPE Approved Event?**

Yes. To ensure compliance with all COPE rules and regulations, the COPE Approved Administrator/Provider must be present at all in person COPE Approved Events. They also must directly manage all distance learning activities.

**Will a list of the COPE Approved Administrators/Providers be published anywhere?**

Yes, as the standards are implemented and Administrators/Providers are approved, they will be listed on the ARBO website at [www.arbo.org](http://www.arbo.org).

**Will these new standards impose any additional limits on off label discussion of product or services?**

No. The standards actually create an environment of independence for the lecturer that insulates them from federal guidelines, prohibiting off-label discussion. Although the lecturer is free to discuss off-label use, there are disclosure requirements that will ensure transparency.

**What happens to all the courses that are currently COPE-qualified and good for up to 3 more years? Can we no longer use them since we can't hold events?**

Full compliance to the guidelines will be mandated beginning January 1, 2011. Although you may still hold these events, the existing guidelines that prohibit promotion of products are still in effect until the implementation date. Speakers are still required to present lectures that are scientifically valid and without commercial bias. As of January 1, 2011, COPE Qualified Courses that are not constructed in an independent manner will be prohibited therefore existing speaker bureau type courses will be expired.

**My association has never handled Instructor honoraria and fees; it's always been worked out between the company and the speaker. How do I know what's appropriate?**

That must be decided between your association as the COPE Administrator/Provider and the lecturer. You should put policies in place to follow. The selection of the speaker and all payment and reimbursement decisions must be made independently by the COPE Approved Administrator/Provider, without input from the commercial interest.

**Will additional time need to be added to my event for courses where food will be served?**

Not necessarily, the COPE rules state that the meal cannot take precedence over the educational event. If a meal is served at the beginning of the hour and all attendees can see and hear the complete lecture without any distractions due to orders being taken, food being

served, plates being cleared, etc. then that would not be a problem. On the other hand, if there is a buffet line that many of the attendees are still going through when the lecture starts, there may be a lot of noise which could prevent the learners from hearing the speaker. In this case, it would be better to allow some extra time for the attendees to eat prior to beginning the lecture.

**We have a concern that funding of our state meeting will decrease if we implement these requirements.**

Although this is an acknowledged possibility, the experience of other professions indicates this is unlikely to occur. Industry has indicated they want to continue to support the profession. They have also indicated they want a level playing field and established boundaries. Although it is not the primary intent of COPE, the guidelines will provide a safe environment where industry funding could grow.

**Does COPE desire to reduce or eliminate corporate support of CE?**

No, the mission of COPE is to assist our member licensing boards by providing a standardized method by which optometric CE is accredited and administered. Encouraging or discouraging corporate support is not a part of the mission.

COPE recognizes that industry-subsidized continuing education can be effective and free of commercial bias. The requirement that industry support of COPE accredited CE is only secured through unrestricted educational grants reduces the potential for industry to influence content and delivery. This solution can lower costs and increase the availability of CE for Optometrists while ensuring transparency and content that is free of commercial bias. If managed appropriately, it can enable lifelong learning ... improve patient care ... and benefit the public welfare.

**Does COPE anticipate that the increased burden imposed by the new standards will reduce commercial support of optometric CE?**

No. This issue of concern is not unique to optometry. Other health care professions that have incorporated similar standards have documented a substantial increase in corporate support. These standards create the safe harbor as defined by the government for industry to provide support without fear of reprisal.