

New Commercial Standards For Commercial Support

*ARBO Approved Documents
for Review / Input*

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CHANGE

AIN'T EASY

**BUT SOMEONE TOLD ME,
ADAPTING TO IT IS A SIGN OF YOUTH
SO I GUESS I BETTER ADOPT IT!**

Players

- ✓ Instructor - Expert
- ✓ Administrator – Sponsor (Producer)
- ✓ Industry – Supporter
- ✓ Optometric Organizations – AAO, AOA, etc.
- ✓ Consumers – ODs, Technicians & Admin.
- ✓ Public - Watchdog
- ✓ Government – Oversight, Policies & Enforcement (SFC, OIG)
- ✓ COPE
 - Receptive to All above Groups
 - Accreditation Agency

Accreditation Council for CME
Murray Kopelow, MD, Chief Executive

“We need to ask: Can collaboration with industry and independence from industry coexist in CME?”

The terms *industry partners* and *collaboration with industry* imply a relationship that's not consistent with the spirit of the ACCME's Standards for Commercial Support.” A conflict of interest?

Comments

Medicine (ACCME) and Industry

- Trend – Moving away from 3rd Party Support
- ACCME – Outcome Assessment for CME

✓ COPE

- Separate Marketing from Education
- Desires only to change the environment of established relationships, not to end them!

✓ Perception vs. Reality

TERMS

- Instructor = Lecturer, Presenter, Faculty, Teacher, Professor, etc.
- Administrator = Sponsor, Vender, Venue
- Company = Industry, Supporter
 - Companies Include:
 - Pharmaceutical
 - Instrument, Device or Product
 - Contact Lens
 - Service
 - Other for Profit



Standards for Commercial Support

“Instructors”

Approved Documents for Review / Input



Changes to COPE Protocols

- Company can not be an Administrator
 - Lecturer or Administrator can submit course, not Company. (However, Lecturer must sign)
- Company support of a CE Event must be in the form of an Unrestricted Educational Grant
 - Lecturer paid by Administrator, not Company
- Lecturer should not seek COPE approval if presentation is for the purpose of promoting product(s), instruments, devices or services.



Company Directed CE vs. COPE Approved CE / CEE

COMPANY

ADMINISTRATOR

INSTRUCTOR



Principles – Standards for Commercial Support and Disclosure

- Independence
- Resolution of personal conflicts of interest
- Appropriate use of commercial support
- Appropriate management of associated commercial promotion
- Content and format without commercial bias
- Disclosures relevant to potential commercial bias



COMMERCIAL DISCLOSURE

- 1. I have read and will comply with the COPE **requirements for course qualification** (INSERT LINK). I further agree to notify COPE in writing should any information provided above, including financial/proprietary information, change at any time during the three year qualification period of this course.
- I Agree _____



COMMERCIAL DISCLOSURE

- 2. I agree that I will keep my presentation free from commercial interest or bias. I will maintain independent control over the content of my presentation, so that it is balanced, objective, presented with scientific rigor and not be for the purpose of promoting products, equipment, etc. (Therefore, my presentation should not be perceived by attendees as a commercial.) I further agree that I will not change the basic content of my presentation following approval.
- I Agree _____



COMMERCIAL DISCLOSURE

- 3. I agree to disclose to the audience the existence of any **significant financial/professional relationships** with the manufacturer(s) of any commercial product(s) and/or the provider(s) of any commercial service(s) discussed in the educational presentation. (Said relationships can include such things as grant/research support, employment, consulting and/or speakers bureau arrangements, major stock ownership, etc.) I will disclose any of these relationships, whether or not there is direct commercial support for the CE activity. This disclosure is made to provide the audience the information on which they can make judgments as to a presenter's objectivity.
- I Agree _____



COMMERCIAL DISCLOSURE

- 4. I agree to disclose the attendees; a) when products or procedures being discussed are **off label, unlabeled, experimental, and/or investigational** (not FDA approved); b) any limitations on the information that is presented, such as data that are preliminary or that represent ongoing research, interim analyses, and/or unsupported opinion.
- I Agree _____



COMMERCIAL DISCLOSURE

- 5. I agree I have an **ethical responsibility** to make appropriate decisions related to my presentation, and all issues involving financial remuneration. (Considerations in this regard could include kickback schemes or multiple remunerations for a single event.)
- I Agree _____



COMMERCIAL DISCLOSURE

- DATE: _____
- SIGNATURE: _____
- **No one other than the Principle Instructor can sign this document.** This digital signature is a legal signature.
- I understand violating any of the above agreements could result in the revocation of the COPE approval for this course w/o return of fees. I further understand COPE could deny approval of this or other courses for a defined period.



COMMERCIAL DISCLOSURE

Mandatory Slide

- The content of this course was prepared independently by Dr. _____ without input from members of the ophthalmic industry.
 - Dr. _____ is affiliated with _____ (Company, Companies) as a consultant, speaker, or other relationship (describe).
 - Dr. _____ has no direct financial or proprietary interest in any companies, products or services mentioned in this presentation. (Or disclose details)
 - Dr. _____ has (has not) received commercial support from _____ in the form of _____ (Administrator or member(s) of the ophthalmic industry).
 - The content and format of this course is presented without commercial bias and does not claim superiority of any commercial product or service.
- OR-
- The content and format of this course may reflect commercial bias and may claim or imply superiority of a particular commercial product or service.



COPE REVIEWS AND AUDITS

Approving & Monitoring COPE Approved CE / CEE

- SFC's criticism of ACCME was compliance
- COPE will enforce it's new guidelines via course auditors who are approved reviewers
- Reviewer go through on-line training module
- Structured disciplinary policies would follow at the appropriate time



Standards for Commercial Support

“Administrators”

Approved Documents for Review/Input



Standards for Commercial Support Unrestricted Educational Grants

- If your meeting will be receiving support, to qualify your Continuing Education Event as COPE Approved, it must be in the form of an Unrestricted Educational Grant. Support must be in the form of financial support only.
- This support would require a signed COPE “Supported CE Event Agreement” between the supporting Company and the COPE Qualified Administrator.

“Supported CE Event Agreement”

(Between the Company and the COPE Qualified Administrator)

The Following Eight Points Constitute This Agreement:

1. Principles inherent in COPE Standards for Commercial Support
2. Control over selection of speaker(s)
3. Control over scientific content in course(s)
4. Control of promotional exhibits/materials
5. Assure courses are free of commercial bias
6. Assure Administrator maintains overall control of all aspects of the program
7. Assure speakers disclose appropriate information
8. Purpose of the Company’s Educational Grant

1. Principles Inherent in COPE Standards for Commercial Support

- The Company and the COPE Qualified Administrator agree to **abide by all the principles inherent in the COPE Standards for Commercial Support for Continuing Education.**
- I agree _____

2. Control over Selection of Instructor(s)

- I will not allow the Company to exert **control over the selection of Instructors**, or other experts for the Supported CE Event. The Cope Qualified Administrator agrees to acknowledge (in an appropriate manner) commercial support granted by the Company.
- I agree _____

3. Control over Scientific Content in Courses

- I will not allow the Company to exert **control over the scientific content** of the Supported CE Event. The Company's role shall be to facilitate, not create or influence, scientific exchange.
- I agree _____

4. Control of Promotional Exhibits/Materials

- The Company, through the COPE Qualified Administrator, shall assure that **no promotional exhibits or advertisements or any other sales or marketing activity occurs** in an obligate path to or in the same room as the Supported CE Event. Any promotional exhibits or other sales or marketing activity must be clearly identified as promotional and separate from the Supported CE Event.
- I agree _____

5. Assure Courses are free of Commercial Bias

- The COPE Qualified Administrator agrees to assure the Supported CE Event will be free of commercial bias for or against any product and that, if the Supported CE Event concerns commercial products, objective information based on scientific methods generally accepted in the optometric/medical community regarding said products will be presented.
- I agree _____

6. Assure Administrator Maintains Overall Control of all aspects of the Program

- The COPE Qualified Administrator agrees that it is responsible for exercising **full control over the Supported CE Event** including selection of Instructor(s) for the Supported CE Event and that if such persons have any financial relationship with the Company, their recent and current relationships to the Company as well as all significant financial/professional relationships with the manufacturer(s) of any commercial product(s) and/or the provider(s) of any commercial service(s) discussed in the educational presentation will be fully disclosed. If the Instructor(s) declines to disclose said relationship(s), this will be made known to the audience.
- I agree _____

7. Assure Speakers Disclose Appropriate Information

- The COPE Qualified Administrator will make a good faith effort to **assure Instructor's disclosure** of unapproved use and limitations of data.
- This would include disclosure when products or procedures being discussed are off label, unlabeled, experimental, and/or investigational (not FDA approved); b) any limitations on the information that is presented, such as data that are preliminary or that represent ongoing research, interim analyses, and/or unsupported opinion.
- I agree _____

8. Purpose of Company Educational Grant

- The Company and the COPE Qualified Administrator acknowledge and agree that the educational grant provided herein has not been determined in a manner which takes into account the volume or value of any referrals, financial relationship(s) or other business arrangement(s) otherwise existing between the parties for which payment may be made, in whole or in part, under any federal or state health care program, including, without limitation, Medicare or Medicaid.
- I agree _____

Agreement and Signature Slides (4)



Criteria for Administrator Qualification

I have read and will comply with the COPE requirements for Criteria for Administrator Qualification (INSERT LINK). I further agree to notify COPE in writing should any information provided above, including financial/proprietary information, change.

I agree _____



CE Event Agreement

This **eight points above constitute the the Supported CE Event Agreement** (form - insert link) that constitutes the entire agreement between the parties relating to the Supported CE Event and supersedes all prior writings between the parties. This Agreement must be signed by both the Administrator and the Company. Any modifications must be reviewed by COPE Prior to the Event.

I agree _____



Ethical Agreement

I agree I have an **ethical responsibility** to make appropriate decisions related to this submitted CE Event, and all issues involving financial remuneration.

I Agree _____



Final Signature Page for CE Event

- DATE: _____
- SIGNATURE: _____
- No one other than the COPE Qualified Administrator can sign this document. This digital signature is a legal signature.
- I understand violating any of the above agreements could result in the revocation of COPE Qualified Administrator Status w/o return of fees.



Final Comment New Standards

- ✓ The New Standards - will require us to work together!
- ✓ Remember - All education does not have to be COPE Approved
 - **NON-COPE EDUCATION**
 - ◆ **MARKETING** – Promotional CE Programs sponsored by Industry
 - **COPE APPROVED EDUCATION**
 - ◆ **OD SUPPORTED EVENT**
 - ◆ **INDUSTRY RELATIONS** – “Support of Optometry” – Unrestricted Educational Grants (COPE)
 - **Both are needed – “True Partnership”**
 - **OD Practitioners – Retrain thinking to appreciate Industry Support w/o Direct Marketing**