



COPE Standards for Integrity and Independence in Accredited Continuing Education FAQ

What is COPE's definition of an "ineligible company" (formerly known as a "commercial interest")?

COPE has incorporated eligibility information directly into the Standards for Integrity and Independence in Accredited Continuing Education. Companies that are ineligible to be accredited as COPE

Administrators/Providers (ineligible companies) are **those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.**

Examples of such organizations include:

- Advertising, marketing, or communication firms whose clients are ineligible companies
- Bio-medical startups that have begun a governmental regulatory approval process
- Compounding pharmacies that manufacture proprietary compounds
- Device manufacturers or distributors
- Diagnostic labs that sell proprietary products
- Growers, distributors, manufacturers or sellers of medical foods and dietary supplements
- Manufacturers of health-related wearable products
- Pharmaceutical companies or distributors
- Pharmacy benefit managers
- Reagent manufacturers or sellers

How is an "ineligible company" under the new Standards different from a "commercial interest" under COPE's SCS?

Aside from the terminology, there is no difference between the definition of an "ineligible company" and a "commercial interest."

How can I determine if my organization is an ineligible company?

COPE defines ineligible companies as "those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients." COPE provides a set of self-assessment questions that can help an organization determine whether it falls under the definition of an ineligible company. These questions are listed below:

1. Does your organization, or a part of your organization, produce, market, re-sell, or distribute healthcare products used by or on patients?
2. Does your organization advocate for, or on behalf of, an ineligible company?
3. Does your organization have a parent company that...
 - produces, markets, re-sells, or distributes healthcare products used by or on patients, and/or...
 - advocates for, or on behalf of, an ineligible company?
 - (A "parent company" is a separate legal entity that owns or fiscally controls an organization.)
4. Does your organization have a sister company that...

- produces, markets, re-sells, or distributes healthcare products used by or on patients, and/or...
- advocates for, or on behalf of, ineligible companies?
- (A "sister company" is a separate legal entity which is a subsidiary of the same parent company that owns or fiscally controls an organization).

4a. If Yes to 4, does your organization share management, employees, or governance structure with the sister company? (An example of a corporate structure that meets COPE's requirements for independence can be found here.)

4b. If Yes to 4, are any owners, employees, or agents of the sister company involved in the planning, development, or implementation of educational content?

4c. If Yes to 4, does the sister company control or influence, in whole or in part, the operations of your organization?

If your organization answers yes to any of these questions, it would likely be defined by COPE as an ineligible company. If after answering these questions your organization still has questions regarding its status, please contact COPE Staff for clarification.

What type of organization is eligible to become a COPE Administrator/Provider?

Organizations eligible to become COPE Administrators/Accredited Providers (eligible organizations) are those whose mission and function are: (1) providing clinical services directly to patients; or (2) the education of healthcare professionals; or (3) serving as fiduciary to patients, the public, or population health; and other organizations that are not otherwise ineligible. Examples of such organizations include:

- Ambulatory procedure centers
- Blood banks
- Diagnostic labs that do not sell proprietary products
- Electronic health records companies
- Government or military agencies
- Group optometric or medical practices
- Health law firms
- Health profession membership organizations
- Hospitals or healthcare delivery systems
- Infusion centers
- Insurance or managed care companies
- Nursing homes
- Pharmacies that do not manufacture proprietary compounds
- Publishing or education companies
- Rehabilitation centers
- Schools of optometry or medicine or health science universities
- Software or game developers

Can an owner or employee of an ineligible company plan or instruct COPE accredited Continuing Education?

Owners and employees of ineligible companies are considered to have unresolvable financial relationships and must be excluded from participating as planners or faculty, and must not be allowed to influence or control any aspect of the planning, delivery, or evaluation of COPE accredited CE. There are three exceptions to this exclusion. Employees of ineligible companies can participate as planners or faculty in these specific situations:

1. When the content of the activity is not related to the business lines or products of their employer/company.
2. When the content of the accredited activity is limited to basic science research, such as pre-clinical research and drug discovery, or the methodologies of research, and they do not make care recommendations.
3. When they are participating as technicians to teach the safe and proper use of medical devices, and do not recommend whether or when a device is used.

What is the definition of an "owner" and "employee" of an ineligible company?

Owners and employees are individuals who have a legal duty to act in the company's best interests.

- Owners: individuals who have an ownership interest in a company, except for stockholders of publicly traded companies, or holders of shares through a pension or mutual fund.
- Employees: individuals hired to work for another person or business (the employer) for compensation and who are subject to the employer's direction as to the details of how to perform the job.

Can a COPE Administrator/Provider ask an ineligible company for suggestions related to topics or speakers for COPE CE?

No. COPE Administrators/Providers cannot receive guidance, either nuanced or direct, from an ineligible company on the content of the activity or on who should deliver that content. If the COPE Administrator/Provider implements the suggestions of the ineligible company then this creates a situation where the independence of COPE CE from the ineligible company is undermined. COPE Administrators/Providers must ensure that the content of and the process to develop COPE CE remains beyond the control of any ineligible company.

Why is 30 minutes the required wait time between COPE Accredited and other marketing, exhibits, and nonaccredited education developed or influenced by an ineligible company (or with planners or faculty with unmitigated financial relationships) being held in the same learning space (Standard 5.2)?

When COPE Accredited CE takes place in the same learning space as the nonaccredited activities listed above, there must be time to transition from one activity to the other while also allowing clear separation between what is accredited and nonaccredited. This policy has been in place since 2009 when the Standards for Commercial Support (SCS) were adopted by COPE. With the 2022 update and renaming of

the Standards for Integrity and Independence in Accredited Continuing Education, the required 30-minute timeframe provides more clarity and a timeline that allows COPE instructors and administrators to wrap up CE and answer any final questions, learners to take a stretch/bathroom break and pack up belongings/leave the room if they choose to do so and individuals involved with the non-accredited activity to set up and prepare for the upcoming presentation, or vice versa.

Is the 30-minute time interval (Standard 5.2) between COPE accredited and marketing, exhibits, and nonaccredited education developed or influenced by an ineligible company required regardless of when the nonaccredited activity takes place? For instance, before, during, or after the COPE accredited activity?

Yes. There needs to be a 30-minute interval between COPE accredited and marketing, exhibits, and nonaccredited sessions influenced by an ineligible company regardless of when the nonaccredited session or activity takes place- before COPE accredited CE, after COPE accredited CE, or both.) As noted in Standard 5.2, this time interval is required if the nonaccredited activity is either developed by or with an ineligible company, or if individuals with unmitigated, relevant financial relationships with ineligible companies are in control of content. The 30-minute interval can be used to the advantage of the COPE Administrator/Provider in the following ways:

- Provide a general Q&A session with the speaker
- Host a quick business meeting (if membership organization)
- Provide a stretch/email break
- Provide a refreshment/snack break
- Hold an icebreaker activity

Does there need to be a 30-minute interval (Standard 5.2) between COPE accredited education and nonaccredited education or activities that are NOT developed by or with an ineligible company OR individuals who have unmitigated, relevant relationships?

No. Nonaccredited education (or sessions) as described in the question, would not need to be separated from COPE CE by 30-minute intervals because those sessions are not "controlled by ineligible companies or include individuals with unmitigated, relevant financial relationships." Examples of these types of activities include a legislative briefing or an awards ceremony.

Does there need to be a 30-minute interval (Standard 5.2) between COPE accredited and marketing, exhibits, and nonaccredited education developed or influenced by an ineligible company in virtual activities?

The 30-minute interval is required for all activities, whether the activity takes place in-person or online. For interactive online activities, if the learner will remain in the same "virtual space" for a nonaccredited session, then the COPE Administrator/Provider must ensure that there is a 30-minute interval before or after accredited education. If the learner is required to leave the virtual space to transition between COPE accredited and nonaccredited activities, and will need to take an action, such as clicking a link that clearly communicates that they are leaving the accredited education, then there is no time-interval requirement.

Do online enduring materials released prior to July 1, 2022, that will be available for several years need to comply with the new Standards?

COPE Administrators/Providers are expected to demonstrate compliance with the Standards for Integrity and Independence with any activities that take place beginning July 1, 2022, or later. For activities that were planned or released prior to July 1, 2022, COPE does not expect COPE Administrators/Providers to make changes to or obtain new disclosure information from the individuals who were in control of content.

Standard 3.1: Should COPE Administrators/Providers collect financial disclosures as they create the content for each activity or on a yearly basis?

COPE Administrators/Providers can choose whether to collect disclosure information when planning each activity or on a periodic basis, such as annually or biannually. If they choose to collect the information periodically, it is important to ask the person to update the disclosure if anything changes to ensure they have up-to-date, accurate information.

Remember that information must be collected from all planners, faculty, and others in control of educational content about all their financial relationships with ineligible companies within the prior 24 months of their involvement with an accredited CE activity.

Can individuals disclose financial information to a COPE Administrator/Provider verbally?

Yes. COPE Administrators/Providers may accept verbal disclosure of financial information from those in control of content of COPE CE. Administrators/Providers must be able to verify for COPE that the individual was given the COPE definition of an ineligible company and was informed that they must disclose all financial relationships with ineligible companies over the 24-month period prior to their involvement in COPE CE.

Can a COPE Administrator/Provider include advertising in a printed or digital handout that contains abstracts if they don't provide COPE credit for the abstracts?

It would depend on what the handout, with abstracts, is used for in relation to the COPE activity. If the abstracts are referenced during the activity or serve as a component of the content, then there can be no advertising in the handout. If the abstracts are not referenced as part of the COPE CE content, and appear in the handout with other logistical information about the activity, then advertising is allowed.

If content of a COPE CE activity is related to a non-clinical topic such as leadership, communication skills training, etc., does a COPE Administrator/Provider still need to obtain information regarding the financial relationships of those that control content of the activity?

No. Standard 3.1 requires the COPE Administrator/Provider to identify relevant financial relationships of those who control the content of a CE activity. Two things must be present for there to be a relevant financial relationship: financial relationship(s) with an ineligible company(ies) and the ability to control content related to products/services of the ineligible company(ies). If no financial relationships exist, or if

the education that is being planned addresses a non-clinical topic including leadership, communication skill, training, etc., you do NOT need to identify, mitigate, or disclose financial relationships.

Can a COPE Administrator/Provider leave it up to an individual who controls content to determine if their financial relationship is relevant and needs to be mitigated?

No. The COPE Administrator/Provider cannot delegate the responsibility for identifying relevant financial relationship solely to the person with the financial relationship.

Based on the expectations of Standard 4.1c, are scholarships to residents and fellows allowed?

Yes. Scholarships for Residents and Fellows is not a topic addressed by COPE in the Standards for Integrity and Independence. The existence of such scholarships and/or the compliance by the COPE Administrator/Provider in the administration of such scholarships will not be reviewed within COPE's accreditation process.

If a live activity is turned into an enduring material, do faculty disclosure and acknowledgement of commercial support still need to be made?

Yes. The new COPE activity must demonstrate compliance with all applicable COPE accreditation requirements, including the disclosure of relevant financial relationships to learners based on the disclosure information applicable at the time an individual last had control of content, and acknowledgement of any commercial support. This is true even if the commercial support was only for the original live activity.

Whose expenses can be paid for with commercial support?

Commercial support is used to underwrite the COPE Administrator's/Provider's expenses for developing and presenting an activity. Commercial support can be used to pay for the expenses of teachers and authors as well others who are engaged in the development of the activity for the COPE Administrator/Provider.

Can faculty take an active role in the COPE Administrator'/Provider's mechanism(s) to mitigate relevant financial relationships?

Yes. COPE considers faculty to be agents of the accredited provider. So, when the provider, after identifying that a financial relationship is relevant, directs teachers/authors to take actions to assist in the mitigation of relevant financial relationships, a provider's mechanism is implemented. The provider might then monitor the effectiveness of the actions taken by the teachers/authors to mitigate these relationships. Keep in mind that simply monitoring the CME content for commercial bias at the time of presentation is not an acceptable mitigation mechanism.

Can COPE Administrators/Providers use tabs, links, or other electronic mechanisms to transmit disclosure information to learners as required by Standards 3.5 and 4.4?

Yes. COPE Administrators/Providers can use tabs, links, or other electronic mechanisms to make disclosure information available to learners. Regardless of the method of disclosure, all required COPE information specified in Standards 3.5 and 4.4. must be transmitted to the learner prior to the beginning the COPE activity and should be clearly marked and accessible to learners.

Can commercial supporters distribute promotional materials for COPE CE activities, like "save the date announcements and brochures?"

Yes. Distributing promotional materials for accredited education such as save the date announcements and brochures, is not prohibited by COPE's Standards for Integrity and Independence. However, these documents, in print or electronic, cannot have any advertising, corporate logo, trade name or a product-group message of an ineligible company associated with them. Note that Standard 5.3 prohibits ineligible companies from providing access to (such as a link), or distributing, the accredited education itself to learners.

Does a COPE Administrator/Provider have to give a list of its participants to its commercial supporters?

No. If, however, a COPE Administrator/Provider chooses to do so, it must obtain the consent of each individual learner, per Standard 2.3.

Can a written agreement for commercial support be executed electronically, or does it need to be physically signed?

Yes, a written agreement that has been accepted electronically by a COPE Administrator/Providers, that originates from the commercial supporter would meet COPE's expectations as long as it is executed before the start or release of the COPE CE.

Where can advertising for ineligible companies appear related to COPE activities?

COPE requires the separation of education from all promotional activities, materials and messages. Many COPE Administrators/Providers create a print or text-based document that goes along with an activity and provides information that is supplementary to the education content - like reproductions of slides, graphics or other handouts. These documents, in print or electronic, are an integral part of the education and as such cannot have any advertising, corporate logo, trade name or a product-group message of an ineligible company associated with them. For live COPE activities- marketing, exhibits, and nonaccredited education developed by or with influence from an ineligible company or with planners or faculty with unmitigated financial relationships must not occur in the educational space within 30 minutes before or after the COPE CE. Activities that are part of the COPE activity but are not accredited for continuing education must be clearly labeled and communicated as such.

In Standard 1, what is meant by "giving a fair and balanced view of diagnostic and therapeutic options?"

COPE Accredited CE must be free of commercial bias, and must not promote products or services. COPE CE must promote improvements in healthcare. A "balanced view" means that recommendations or emphasis must fairly represent, and be based on, a reasonable and valid interpretation of the information available on the subject (e.g., "On balance the data support the following..."). A "balanced view of therapeutic options" also means that no single product or service is over represented in the education activity when other equal but competing products or services are available for inclusion.