

New Standards for Integrity and Independence for Accredited Continuing Education



Two Truths and a Lie

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The moderator and panelists are all CME providers and not employees of the ACCME. These scenarios and answers are based solely on their own experiences and research.

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New Standards for Integrity & Independence

SHERYL: Scenario: A CME provider is updating their policies and procedures to transition to all the new ACCME Standards for Integrity and Independence that will begin on January 1, 2022. They compiled a list of the new definitions:

- a) **ROKEENA: TRUTH** Ineligible companies: Organizations that are not eligible for accreditation.
- b) **AMY: TRUTH** Mitigate: The term mitigate replaces resolve, in guidance related to relevant financial relationships, to clarify that accredited providers are expected to mitigate the potential effect of these relationships on accredited continuing education.
- c) **TOM: LIE** **Eligible learners: Physicians that are eligible to receive CME credit.**

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New Standards for Integrity & Independence Explanation of “Lie” and Resources

Eligible learners: This is not a term at all!!! There is an Eligible organization: Organizations that are eligible to be accredited in the ACCME System.

Another new term: “Accredited Continuing Education”. The term accredited continuing education replaces continuing medical education to be inclusive of all health professions. We include accredited to explicitly differentiate between accredited and nonaccredited education providers and education.

The complete list of new terms can be found under the Information Package:
https://accme.org/sites/default/files/2021-01/881_20201210_New_Standards_Info_Package%20%284%29.pdf

Deadline to have everything implemented is January 1, 2022.

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Standard 2: Prevent Commercial Bias and Marketing in Accredited Continuing Education

JENNIFER: Scenario: At a medical specialty society's Annual Meeting, a presenter in an educational session references cases from a medical atlas that he authored.

- a) **AMY: TRUTH** Speakers can reference their textbooks during a presentation.
- b) **TOM: TRUTH** The speaker also informs the audience that he has the books available to purchase while they are at the conference.
- c) **ROKEENA: LIE** **To make it easier for attendees to purchase his book, he placed them for sale at the back of the session room, so attendees can buy it on their way out of the session.**

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Standard 2: Prevent Commercial Bias and Marketing in Accredited Continuing Education

Explanation of “Lie” and Resources

Standard 2.1: The accredited provider must ensure that all decisions related to the planning, faculty selection, delivery, and evaluation of accredited education are made without any influence or involvement from the owners and employees of an ineligible company.

Speakers can refer to texts they authored when the content of the text is pertinent to their presentation. It is also permissible to inform the audience where the text could be purchased as long as the comments are not promotional. However, the speaker is not permitted sell the books within the session room or ‘educational space’. A more appropriate location for either in person or virtual events would be the exhibit hall, society resource center or another common area outside the educational space.

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Standard 2: Prevent Commercial Bias and Marketing in Accredited Continuing Education

JENNIFER: Scenario: In an evaluation form for a grand rounds, the provider asks learners to evaluate their perception of bias in speaker presentations.

- a) **AMY: LIE** Including this question on evaluations is an ACCME requirement.
- b) **SHERYL: TRUTH** The provider's policy is to use this as a mechanism to monitor relevant financial relationships in the grand rounds.
- c) **TOM: TRUTH** The provider reviews the results and any speaker who receives a bias score of over 5% must attend a faculty training on providing balanced presentations and then have their content peer reviewed prior to their next presentation.

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Standard 2: Prevent Commercial Bias and Marketing in Accredited Continuing Education Explanation of "Lie" and Resources

Standard 2.2: Accredited education must be free of marketing or sales of products or services. Faculty must not actively promote or sell products or services that serve their professional or financial interests during accredited education.

While many providers may use this question to monitor relevant financial relationships in their activities

- It is not required by ACCME
- It is not a mechanism to mitigate relevant financial relationships
- It is not evaluated during the accreditation review.

Providers can use the data gleaned from evaluation responses to this question to determine if their mitigation methods were effective, but this is not a **mechanism to mitigate relevant financial relationships.**

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Standard 2: Prevent Commercial Bias and Marketing in Accredited Continuing Education

JENNIFER: Scenario: A medical education company (MEC) sets up a registration portal for an upcoming course.

- a) **TOM: TRUTH** Within the portal, attendees may opt out of providing their contact information to any interested companies.
- b) **SHERYL: TRUTH** The MEC has an internal policy of only sharing postal mailing addresses with ineligible companies and will not share phone or email, if requested.
- c) **ROKEENA: LIE** A few weeks later, ineligible Company B asks to purchase the list of registrants. The provider must contact registrants again to reconfirm consent to share their contact information.

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Standard 2: Prevent Commercial Bias and Marketing in Accredited Continuing Education

Explanation of “Lie” and Resources

Standard 2.3 requires providers to collect explicit consent (either through an opt in or opt out) from learners to share their information with ineligible companies. The provider only needs to request permission from registrants once during the registration process for that activity, not each time a request is made.

The ACCME does not dictate what types of information learners need to consent to share with ineligible companies. This is up to the providers internal policies.

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Standard 3 – Identify, Mitigate, and Disclose Relevant Financial Relationships

AMY: Scenario: As an accredited provider, you are collecting information from prospective faculty on their financial relationships with ineligible companies.

TRUTH OR LIE: Related to collection of financial relationships

- a) **SHERYL: TRUTH** Collect information about their financial relationships for the prior 24 months
- b) **TOM: LIE** You only need to collect *relevant* financial relationships
- c) **ROKEENA: TRUTH** Disclosure does not include financial relationships of a spouse or partner

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Standard 3 – Identify, Mitigate, and Disclose Relevant Financial Relationships Explanation of “Lie” and Resources

ANSWER EXPLANATION: Standard 3.1 Collect Information: From anyone with the ability to control content re: their financial relationships with ineligible companies

New: Individuals must disclose their financial relationships with ineligible companies within the prior 24 months (changed from the current requirement of 12 months). See Standard 3.1

New: Accredited providers must collect disclosure information from those individuals in control of content about all their financial relationships with ineligible companies. It is the accredited provider’s responsibility to then determine which relationships are relevant.

Removed: The requirement that individuals disclose the financial relationships of a spouse or partner was removed in the new Standards.

Source: https://accme.org/sites/default/files/2020-12/881_20201210_New_Standards_Info_Package_0.pdf

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Standard 3 – Identify, Mitigate, and Disclose Relevant Financial Relationships

AMY: Scenario: You identified a subject matter expert as a potential speaker for an upcoming accredited continuing education activity. His disclosure reveals that he and his spouse are employed by a pharmaceutical company which manufactures asthma medications. The activity topic is about strategies for treating patients with chronic respiratory conditions.

TRUTH OR LIE: Related to employees or owners of ineligible companies

- a) **TOM: TRUTH** He cannot be faculty and speak on treating patients with asthma, since his presentation would be related to the business lines or products of his employer
- b) **ROKEENA: TRUTH** He can be a speaker if the content he presents is limited to basic science research ie: pre-clinical research, drug discovery
- c) **JENNIFER: LIE** He can participate as a technician to teach how and when to use a peak flow meter device and recommend on whom it should be used

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Standard 3 – Identify, Mitigate, and Disclose Relevant Financial Relationships Explanation of “Lie” and Resources

Answer Explanation: Standard 3.2 Exclude owners or employees of ineligible companies/ Standard 3.3 Identify relevant financial relationships

The requirement that individuals disclose the financial relationships of a spouse or partner was removed from the new Standards.

Individuals who are owners or employees of ineligible companies must be excluded from controlling content or participating as planners or faculty in accredited education.

There are three exceptions to this exclusion— employees of ineligible companies can participate as planners or faculty in these specific situations:

- a. When the content of the activity is not related to the business lines or products of their employer/company.
- b. 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.
- c. When they participate as technicians to teach the safe and proper use of medical devices, and do not recommend whether or when a device is used.

Source: [ACCME Standards for Integrity and Independence in accredited continuing education](#)

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Standard 3 – Identify, **Mitigate**, and Disclose Relevant Financial Relationships

AMY Scenario: You identified several individuals involved in the planning of an accredited activity, who have relevant financial relationships with an ineligible company.

TRUTH OR LIE: Related to mitigation strategies for persons with relevant financial relationships

- a) **SHERYL: LIE** Relevant financial relationships of planners and faculty are mitigated in the same way
- b) **TOM: TRUTH** Relationships must be mitigated prior to the individuals assuming their roles
- c) **JENNIFER: TRUTH** The steps taken to mitigate relevant financial relationships must be documented

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Standard 3 – Identify, **Mitigate**, and Disclose Relevant Financial Relationships Explanation of “Lie” and Resources

Answer Explanation: Standard 3.4 Mitigate relevant financial relationships.

Take steps to prevent all those with relevant financial relationships from inserting commercial bias into content. Mitigate relationships prior to the individuals assuming their roles. Take steps appropriate to the role of the individual. For example, steps for planners will likely be different than for faculty and would occur before planning begins.

Document the steps taken to mitigate relevant financial relationships

Sources:

- [ACCME Standards for Integrity and Independence in accredited continuing education](#)
- [Tools for Identifying Mitigating and Disclosing Relevant Financial Relationships](#)

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Standard 3 – Identify, Mitigate, and Disclose Relevant Financial Relationships

AMY Scenario: While planning an accredited continuing education virtual conference, you create a list of financial relationships to disclose to learners, for everyone who has the ability to control content

TRUTH OR LIE: Disclosure to learners must include:

- a) **ROKEENA: TRUTH** The names of the ineligible companies with which an individual has relationships
- b) **JENNIFER: LIE** **The amount of money received from the ineligible company**
- c) **SHERYL: TRUTH** A statement that all relevant relationships have been mitigated

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Standard 3 – Identify, Mitigate, and Disclose Relevant Financial Relationships Explanation of “Lie” and Resources

ANSWER EXPLANATION: Standard 3.5 Disclose all relevant financial relationships to learners.

The dollar amount received is not a requirement to disclose to learners. There are 4 required disclosures related to an individual’s financial relationships with an ineligible company.

Standard 3.5. Disclose all relevant financial relationships (or absence thereof) about planners, faculty, and others in control of content to learners: Disclosure to learners must include each of the following:

- 1) The names of the individuals with relevant financial relationships.
- 2) The names of the ineligible companies with which they have relationships.
- 3) The nature of the relationships.
- 4) A statement that all relevant financial relationships have been mitigated. (NEW)

Absence of relevant financial relationships with ineligible companies must also be disclosed

Reminder: Learners must receive disclosures before engaging in the education

Source: [ACCME Standards for Integrity and Independence in accredited continuing education](#)

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Standard 4 – Manage Commercial Support Appropriately

TOM Scenario: You are accrediting an annual conference that provides primary care clinicians training in the treatment of common orthopedic problems. The planning committee has decided to accept commercial support for the first time.

- a) **JENNIFER: TRUTH** Acceptance of this support will allow for lower registration fees across the board.
- b) **ROKEENA: LIE** **Commercial support is disclosed to participants on a slide that the course director shows during the first break.**
- c) **AMY: TRUTH** A major rehab center chain provides support on the condition that it is used to cover the honoraria and travel expenses for a nationally recognized speaker, who is a subject matter expert.

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Standard 4 – Manage Commercial Support Appropriately Explanation of “Lie” and Resources

a) **TRUTH.** Acceptance of this support will allow for lower registration fees across the board. Standard 4.1d. The accredited provider may use commercial support to defray or eliminate the cost of the education for all learners.

b) **LIE. Commercial support is disclosed to participants on a slide that the course director shows during the first break.**

Standard 4.4. The accredited provider must disclose to the learners the name(s) of the ineligible company(ies) that gave the commercial support, and the nature of the support if it was in-kind, prior to the learners engaging in the education.

c) **TRUTH.** A major rehab center chain provides support on the condition that it is used to cover the honoraria and travel expenses for a nationally recognized speaker, who is a subject matter expert.

A rehabilitation center is an eligible organization (unless owned by an ineligible company), so they can partner with you to develop the educational content.

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Standard 4 – Manage Commercial Support Appropriately

TOM: Scenario: You are accrediting an activity training 12 OB/GYN clinicians on the appropriate use of ultrasound in an academic medical center’s simulation center. An ineligible company agrees to provide the ultrasound equipment for the training as well as unrestricted monetary grant.

- a) **SHERYL: TRUTH** The commercial support is not disclosed to participants onsite at the training. It is only disclosed to participants on a tab on the online registration site where all participants must go to pay their registration fee before the training.
- b) **JENNIFER: LIE** You are successful in finding an additional company to provide ultrasound equipment for the training. Using equipment from only one company would result in commercial bias and be non-compliant with the ACCME.
- c) **AMY: TRUTH** The planning committee provides scholarships to two residents, which covers their registration and travel expenses.

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Standard 4 – Manage Commercial Support Appropriately Explanation of “Lie” and Resources

a) **TRUTH.** The commercial support is not disclosed to participants onsite at the training. It is only disclosed to participants on a tab on the online registration site where all participants must go to pay their registration fee before the training.

ACCME FAQs. Can we use tabs, links, or other electronic mechanisms to transmit disclosure information to learners as required by Standards for Integrity and Independence 3.5 and 4.4?

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

Please note ALL participants must be required to register online so they would all see the disclosures.

b) **LIE.** You are successful in finding an additional company to provide ultrasound equipment for the training. Using equipment from only one company would result in commercial bias and be non-compliant with the ACCME.

The Standards do not say in-kind donations must be received from more than one company. It may be best practice to have support from more than one company, but it may not always be possible. Some specialized equipment may in fact only have one manufacturer.

c) **TRUTH.** The planning committee provides scholarships to two residents, which covers their registration and travel expenses.

ACCME FAQs. Based on the expectations of Standard 4.1c, can we provide scholarships to residents and fellows?

Yes. Scholarships for Residents and Fellows fall under the purview of other organizations' guidelines and standards (e.g., See the Ethical Opinion 9.6.2 (<https://www.ama-assn.org/about-us/code-medical-ethics>) (d) of the Council of Ethical and Judicial Affairs of the AMA). It is not a topic addressed by the ACCME in the Standards for Integrity and Independence. The existence of such scholarships and/or the compliance by the provider in the administration of such scholarships will not be reviewed by the ACCME's accreditation process.

Please note this only applies to residents and fellows. Commercial funding cannot use to pay registration fees of other participants.

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Standard 5 – Manage Ancillary Activities Offered in Conjunction with Accredited Continuing Education

ROKEENA: Scenario: You are accrediting a live activity format with both face-to-face and live streaming. This hybrid meeting will include an exhibit hall of ineligible companies hosted concurrently during the accredited sessions.

- a) **SHERYL: TRUTH** You plan to acknowledge and market ineligible companies outside of the “educational space” with printed and digital that does not include educational content.
- b) **JENNIFER: TRUTH** You plan for the exhibiting to occur in a different room and Zoom URL to protect and separate the main educational space.
- c) **AMY: LIE** You plan during a 30 minute break in the main educational space to allow one premier exhibitor a 15-minute non-accredited talk. You clearly labeled the break as non-accredited on the agenda and communicated live to the learners that this session is non-accredited.

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Standard 5 – Manage Ancillary Activities... Explanation of “Lie” and Resources

LIE: You plan during a 30 minute break in the main educational space to allow one premier exhibitor a 15-minute non-accredited talk. You clearly labeled the break as non-accredited on the agenda and communicated live to the learners that this session is non-accredited.

Standard 5.2: The accredited provider must ensure that learners can easily distinguish between accredited education and other activities.

- a. Live continuing education activities: Marketing, exhibits, and non-accredited 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 an accredited education activity. Activities that are part of the event but are not accredited for continuing education must be clearly labeled and communicated as such.
- b. Print, online, or digital continuing education activities: Learners must not be presented with marketing while engaged in the accredited education activity. Learners must be able to engage with the accredited education without having to click through, watch, listen to, or be presented with product promotion or product-specific advertisement.
- c. Educational materials that are part of accredited education (such as slides, abstracts, handouts, evaluation mechanisms, or disclosure information) must not contain any marketing produced by or for an ineligible company, including corporate or product logos, trade names, or product group messages.
- d. Information distributed about accredited education that does not include educational content, such as schedules and logistical information, may include marketing by or for an ineligible company.

Reference [New Standards webinar](#) held on January 11, 2021 - ACCME refers to the “educational space” as where the learner is engaging with the materials and faculty while education is taking place

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Standard 5 – Manage Ancillary Activities Offered in Conjunction with Accredited Continuing Education

ROKEENA: Scenario: You are accrediting an annual live conference and plan to convert the recordings into internet enduring materials. You have several ineligible companies that provided commercial support and wants to market the activities.

What can Ineligible Companies do?

- a) **TOM: LIE** Distribute a direct link to the accredited enduring activity via email.
- b) **AMY: TRUE** Print and handout promotional materials such as brochures for the accredited education
- c) **JENNIFER: TRUE** Email promotional materials for accredited education such as save the date announcements that links to the registration page.

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Standard 5 – Manage Ancillary Activities... Explanation of “Lie” and Resources

LIE: Distribute a direct link to the accredited enduring activity via email.

Standard 5.3: Ineligible companies may not provide access to, or distribute, accredited education to learners.

The important item with the lie was the direct access to the accredited content. This would not meet the expectations of Standard 5.3.

Reference [New Standards webinar](#) held on January 11, 2021 - Distributing promotional materials for accredited education such as save the date announcements and brochures, is not prohibited by the ACCME's [Standards for Integrity and Independence](#). Distributing a general page from which the learners can access the CME activities, would meet the expectations of Standard 5.3.

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Additional Resources

Standards for Integrity and Independence in Accredited CME Resources
website: <https://accme.org/standards-resources>

Toolkit: https://accme.org/sites/default/files/2020-12/883_20201210_Standards%20for%20Integrity%20and%20Independence%20Toolkit.pdf