

IMPLEMENTING THE NEW *STANDARDS FOR INTEGRITY AND INDEPENDENCE IN ACCREDITED CONTINUING EDUCATION*





IMPLEMENTING THE NEW STANDARDS

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IMPLEMENTING THE NEW STANDARDS

What We've Accomplished Together!

Beginning in January 2019, our goal was to streamline, clarify, and modernize the Standards, and to ensure their continued relevance and effectiveness in the changing healthcare environment.

We benefitted from your feedback and involvement and were gratified to take an inclusive approach for CE for the health professions—with welcome endorsements and alignment across accreditor colleagues!



Information Package

- Message from the President and CEO
- Accrediting Bodies That Have Adopted the Standards
- Introduction
- New Standards at a Glance
- Standards for Integrity and Independence in Accredited Continuing Education
- Reorganization of the ACCME Accreditation Criteria

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Supporting Providers

- ✓ Tools for Identifying, Mitigating, and Disclosing Relevant Financial Relationships
- ✓ Tools for Ensuring Valid Clinical Content
- ✓ Quick Tool to Simplify Educational Planning When Identification, Mitigation, and Disclosure is Not Required





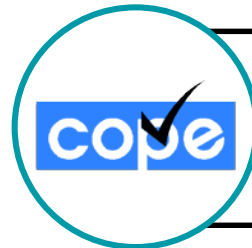
Accreditation Council for
Continuing Medical Education
(ACCME)



American Nurses Credentialing
Center (ANCC)



Accreditation Council for
Pharmacy Education (ACPE)



Association of Regulatory
Boards of Optometry's Council
on Optometric Practitioner
Education (ARBO/COPE)



American Academy of Family
Physicians (AAFP)



Joint Accreditation for
Interprofessional Continuing
Education™



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Let's hear from our Colleague Accreditors...

Amy L. Smith, MBA

Director CPD Accreditation,
American Academy of Family Physicians

Dimitra V. Travlos, PharmD

Assistant Executive Director & Director,
Continuing Pharmacy Education Provider Accreditation
Accreditation Council for Pharmacy Education

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Changes in the Structure/Terminology

Structural Revisions:

- ✓ New name to better reflect the Standards
- ✓ New overview explaining the Standards
- ✓ Re-organization based on applicability
- ✓ Policies and definitions integrated into the Standards themselves
- ✓ Brief introductions to each Standard

New Terms:

- ✓ Eligible/Ineligible
- ✓ Mitigate
- ✓ Accredited continuing education

IMPLEMENTING THE NEW STANDARDS

What's New

Content Validity

- Policies and expectations incorporated into the Standards.

No Sales/Marketing

- Prohibits faculty from promoting or selling products or services in accredited education.
- Requires learner consent if information shared.

Identification/Mitigation/Disclosure of Financial Relationships

- Individuals disclose all, and accredited providers determine relevance of, financial relationships. Disclosure period extended from 12 months to 24 months. The requirement that individuals disclose the financial relationships of their spouse/partner was removed.
- Disclose to learners that all relevant financial relationships have been mitigated.

Ancillary marketing and nonaccredited activities

- Defined how much time (30-minute interval) must separate accredited activities and marketing or nonaccredited activities if they are held in the same educational space.

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One Year Transition Phase

- Providers can immediately stop complying with requirements *that have been removed*.
- Accredited providers will be expected to comply with *new or changed* requirements by **January 1, 2022**. We expect to begin measuring compliance after the transition phase.

***Note:** *This transition phase applies to providers that are ACCME-accredited, state-accredited, or jointly accredited. Providers accredited by other accrediting bodies that have adopted the Standards should contact their accreditor for information about the timeline.*

IMPLEMENTING THE NEW STANDARDS

Preamble & Eligibility

- Background and intent of the Standards
- Shared values around trust, independence, valid content, clear separation between education and marketing/sales
- Definitions of eligible organizations and ineligible companies
- Acceptable and unacceptable roles for owners and employees of ineligible companies

STANDARD 1: ENSURING CONTENT IS VALID

Standard 1 applies to all accredited continuing education.

Ensure that education is fair and balanced... clinical content supports safe, effective patient care.

1. All recommendations based on current science, evidence, and clinical reasoning, while giving a fair and balanced view of diagnostic and therapeutic options.
2. All scientific research referred to, reported, or used...must conform to the generally accepted standards of experimental design, data collection, analysis, and interpretation.
3. Discuss, debate, and explore new and evolving topics... facilitate engagement with these topics without advocating for, or promoting, practices that are not/not yet adequately based on current science, evidence, and clinical reasoning.
4. Cannot advocate for unscientific approaches to diagnosis or therapy, or promote recommendations, treatment, or manners of practicing healthcare that are determined to have risks or dangers that outweigh the benefits or are known to be ineffective...

STANDARD 1: ENSURING CONTENT IS VALID

Questions

1. What do we do if we need to teach about content that is unknown or unproven, e.g., COVID19? How do we ensure balance?

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Guidance is in the Standard

STANDARD 2: PREVENT COMMERCIAL BIAS AND MARKETING IN ACCREDITED CONTINUING EDUCATION

Standard 2 applies to all accredited continuing education.

Accredited continuing education must protect learners from commercial bias and marketing.

1. ...must ensure that all decisions ... are made without any influence or involvement from the owners and employees of an ineligible company.
2. ...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.**
3. ...must not share the names or contact information of learners with any ineligible company or its agents **without the explicit consent of the individual learner.**

STANDARD 2: PREVENT COMMERCIAL BIAS AND MARKETING IN ACCREDITED CONTINUING EDUCATION

Questions

1. Can a faculty member reference a book that she wrote or would that be considered “sales?”
2. Can we raffle off a book written by a faculty member?
3. Do we need to ask learners if they perceived any sales, marketing or commercial bias during the education?
4. What is meant by “explicit consent” of learners in terms of getting permission to share their information with ineligible companies?

STANDARD 2: PREVENT COMMERCIAL BIAS AND MARKETING IN ACCREDITED CONTINUING EDUCATION

Questions

1. Can a faculty member reference a book that she wrote or would that be considered “sales?” *Yes*
2. Can we raffle off a book written by a faculty member? *Yes*
3. Do we need to ask learners if they perceived any sales, marketing or commercial bias during the education? *No*
4. What is meant by “explicit consent” of learners in terms of getting permission to share their information with ineligible companies? *Positive response*

STANDARD 3: IDENTIFY, MITIGATE, AND DISCLOSE RELEVANT FINANCIAL RELATIONSHIPS

Standard 3 applies to all accredited continuing education.

Accredited providers must take the following steps when developing accredited continuing education.

1. **Collect information:** Collect information from all ... about **all their financial relationships** with ineligible companies within the **prior 24 months**. There is no minimum financial threshold; individuals must disclose all financial relationships, regardless of the amount, with ineligible companies. Individuals must disclose regardless of their view of the relevance of the relationship to the education.

Disclosure information must include:

- a. The name of the ineligible company with which the person has a financial relationship.
- b. The nature of the financial relationship...

STANDARD 3: IDENTIFY, MITIGATE, AND DISCLOSE RELEVANT FINANCIAL RELATIONSHIPS (CONT.)

2. **Exclude owners or employees of ineligible companies:** Review the information about financial relationships to identify individuals who are owners or employees of ineligible companies. These individuals must be excluded from controlling content or participating as planners or faculty in accredited education. There are three exceptions to this exclusion:
 - 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 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.

STANDARD 3: IDENTIFY, MITIGATE, AND DISCLOSE RELEVANT FINANCIAL RELATIONSHIPS (CONT.)

3. **Identify relevant financial relationships:** Review the information about financial relationships to **determine which relationships are relevant**. Financial relationships are relevant if the educational content an individual can control is related to the business lines or products of the ineligible company.
4. **Mitigate** relevant financial relationships: Take steps to prevent all those with relevant financial relationships from inserting commercial bias into content.
 - a. 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.
 - b. Document the steps taken to mitigate relevant financial relationships.

STANDARD 3: IDENTIFY, MITIGATE, AND DISCLOSE RELEVANT FINANCIAL RELATIONSHIPS (CONT.)

5. **Disclose all relevant financial relationships to learners:** Disclosure to learners must include each of the following:
- a. The names of the individuals with relevant financial relationships.
 - b. The names of the ineligible companies with which they have relationships.
 - c. The nature of the relationships.
 - d. **A statement that all relevant financial relationships have been mitigated.**

...

Learners must receive disclosure information, in a format that can be verified at the time of accreditation, before engaging with the accredited education.

STANDARD 3: IDENTIFY, MITIGATE, AND DISCLOSE RELEVANT FINANCIAL RELATIONSHIPS (CONT.)

Exceptions: Accredited providers do not need to identify, mitigate, or disclose relevant financial relationships for any of the following activities:

1. Accredited education that is non-clinical...
2. Accredited education where the learner group is in control of content...
3. Accredited self-directed education where the learner controls their educational goals and reports on changes that resulted, such as learning from teaching, remediation, or a personal development plan...

STANDARD 3: IDENTIFY, MITIGATE, AND DISCLOSE RELEVANT FINANCIAL RELATIONSHIPS

Questions

1. If we collect disclosure information from our planners and faculty on an annual basis, how and when should we change to collecting 24-months of relationships?
2. Do we still need to collect the relationships of “spouses or partners” during this year of transition?
3. Can we use our planners or other content experts to help determine relevance of relationships?
4. Can we ask planners/faculty to attest to “using best available evidence” as the mitigation strategy at the time the planners/faculty give us all their financial relationships?
5. Are regularly scheduled series (case conferences, grand rounds, tumor boards) considered an exception to Standard 3?
6. Are “ethics” and “resiliency” examples of accredited education that is non-clinical, and therefore exceptions?

STANDARD 3: IDENTIFY, MITIGATE, AND DISCLOSE RELEVANT FINANCIAL RELATIONSHIPS

Questions

1. If we collect disclosure information from our planners and faculty on an annual basis, how and when should we change to collecting 24-months of relationships? *Don't wait*
2. Do we still need to collect the relationships of “spouses or partners” during this year of transition? *No*
3. Can we use our planners or other content experts to help determine relevance of relationships? *Yes*
4. Can we ask planners/faculty to attest to “using best available evidence” as the mitigation strategy at the time the planners/faculty give us all their financial relationships? *No*
5. Are regularly scheduled series (case conferences, grand rounds, tumor boards) considered an exception to Standard 3? *No*
6. Are “ethics” and “resiliency” examples of accredited education that is non-clinical, and therefore exceptions? *Yes*

STANDARD 4: MANAGE COMMERCIAL SUPPORT APPROPRIATELY

Standard 4 applies only to accredited continuing education that receives financial or in-kind support from ineligible companies.

Accredited providers that choose to accept *commercial support* are responsible for ensuring that the education remains independent of the ineligible company and that the support does not result in commercial bias or commercial influence in the education.

1. Decision-making and disbursement...
2. Agreement...
3. Accountability...
4. Disclosure to learners...

(Note: the proposed change that would have prohibited joint providers from reimbursing faculty expenses using commercial support was removed from the final standard.)

STANDARD 4: MANAGE COMMERCIAL SUPPORT APPROPRIATELY

Questions

1. Are there any changes in the requirement of how commercial support can be accepted and managed by the accredited provider?
2. Do we still need to have and demonstrate compliance with a policy on honoraria and expense reimbursement for our volunteers?
3. Do we have to have a policy that outlines how we manage commercial support?
4. Can we charge different groups of learners different registration fees, e.g., students, members?

STANDARD 4: MANAGE COMMERCIAL SUPPORT APPROPRIATELY

Questions

1. Are there any changes in the requirement of how commercial support can be accepted and managed by the accredited provider? *No*
2. Do we still need to have and demonstrate compliance with a policy on honoraria and expense reimbursement for our volunteers? *No*
3. Do we have to have a policy that outlines how we manage commercial support? *No*
4. Can we charge different groups of learners different registration fees, e.g., students, members? *Yes, but not using commercial support*

STANDARD 5: MANAGE ANCILLARY ACTIVITIES OFFERED IN CONJUNCTION WITH ACCREDITED CONTINUING EDUCATION

Standard 5 applies only when there is marketing by ineligible companies or nonaccredited education associated with the accredited continuing education.

Accredited providers are responsible for ensuring that education is separate from

- marketing by ineligible companies—including advertising, sales, exhibits, and promotion—and from
- nonaccredited education offered in conjunction with accredited continuing education.

Arrangements to allow ineligible companies to market or exhibit in association with accredited education...

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

- Live continuing education activities...must not occur in the educational space within **30 minutes before or after** an accredited education activity
- Print, online, or digital continuing education activities...
- 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...
- 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.

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

STANDARD 5: MANAGE ANCILLARY ACTIVITIES OFFERED IN CONJUNCTION WITH ACCREDITED CONTINUING EDUCATION

Questions

1. What is the definition of “educational space?”
2. Is the “30 minute” separation requirement between marketing/non-accredited education and accredited education applicable only to live, in-person activities? What about live streamed, online activities?
3. Can marketing or non-accredited education take place at the same time as accredited education as long as it is in a different room and is clearly communicated to learners?

STANDARD 5: MANAGE ANCILLARY ACTIVITIES OFFERED IN CONJUNCTION WITH ACCREDITED CONTINUING EDUCATION

Questions

1. What is the definition of “educational space?” *Where the learner is engaging with content, material, & faculty*
2. Is the “30 minute” separation requirement between marketing/non-accredited education and accredited education applicable only to live, in-person activities? What about live streamed, online activities? *All live*
3. Can marketing or non-accredited education take place at the same time as accredited education as long as it is in a different room and is clearly communicated to learners? *Yes*

General Questions...

1. Does the ACCME have sample forms or other resources to assist with the collection of disclosure information from our planners and faculty?
2. Will the ACCME issue a new flowchart for identifying, mitigating and disclosing relevant financial relationships?
3. Will the ACCME update its structured abstract and any other accreditation-related forms to reflect the new Standards and the re-ordered Criteria?
4. Will we be held accountable for compliance with the old Standards for Commercial Support when we come up for reaccreditation (after 2021)?

General Questions...

1. Does the ACCME have sample forms or other resources to assist with the collection of disclosure information from our planners and faculty? *Yes, the Toolkit*
2. Will the ACCME issue a new flowchart for identifying, mitigating and disclosing relevant financial relationships? *Yes, in the Toolkit*
3. Will the ACCME update its structured abstract and any other accreditation-related forms to reflect the new Standards and the re-ordered Criteria? *Yes*
4. Will we be held accountable for compliance with the old Standards for Commercial Support when we come up for reaccreditation (after 2021)?
Only the requirements that are the same



THANK YOU!

Email us at info@accme.org with your questions and how we can best support you.

A recording of this webinar will be posted soon on www.accme.org.

Please take a few minutes to fill out the brief survey you will receive after this call.

