



ACCREDITATION COUNCIL
FOR PHARMACY EDUCATION



Standard 5: Standards for Integrity and Independence in Accredited Continuing Education

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Standards for Integrity and Independence



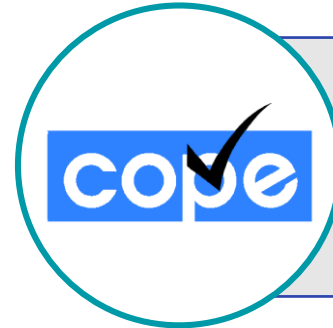
Accreditation Council for
Continuing Medical Education
(ACCME)



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™

Standards for Integrity and Independence

Changes in Structure/Terminology

- **Structural Revisions:**
 - New name
 - Re-organization
 - Policies and definitions integrated into the Standards
- **New Terms:**
 - Eligible/Ineligible
 - Mitigate
 - Accredited continuing education

One-year transition phase; effective January 1, 2022



What's New?

Content Validity

- Expectations incorporated into the Standard.

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 financial relationships and providers determine relevance.
- 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 non-accredited activities

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



Standards for Integrity and Independence

Eligible Organizations: those whose mission and function are

- Providing clinical services directly to patients
- Educating healthcare professionals
- Serving as fiduciary to patients, the public, or population health

Examples

Hospitals, healthcare systems

Group medical practices

Ambulatory procedure centers

Nursing homes, rehabilitation centers

Pharmacies that don't manufacture compounds

Diagnostic labs that don't sell proprietary products

Government or military agencies

Health profession membership organizations

EHR companies

Software/game developers

Insurance or managed care companies

Schools of pharmacy/medicine

Publishing or education companies



Standards for Integrity and Independence

Ineligible Companies

- Primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients
- Owners/employees considered to have unresolvable financial relationships
- Must be excluded for participating as planners/faculty

Examples

Pharmaceutical companies or distributors

Device manufacturers or distributors

Growers, distributors, manufacturers, or sellers of medical foods/dietary supplements

Manufacturers of health-related wearable products

Advertising, marketing, or communication firms whose clients are ineligible

Bio-medical startups that have begun a governmental regulatory approval process

Compounding pharmacies that manufacture proprietary compounds

Pharmacy Benefit Managers



Standards for Integrity and Independence

Elements

1. Ensuring content is valid
2. Prevent commercial bias and marketing
3. Identify, mitigate and disclose relevant financial relationships
4. Manage commercial support appropriately
5. Manage ancillary activities



Standards for Integrity and Independence

Guideline 5.1: Ensuring Content is Valid

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

1. Recommendations **must be based on current science, evidence, and clinical reasoning**, while giving a **fair and balanced** view of diagnostic and therapeutic options.
2. Scientific research **conforms to generally accepted standards** of experimental design, data collection, analysis and interpretation.
3. Does not advocate for, or promote, practices that are not/not yet adequately based on current science, evidence, and clinical reasoning.
4. Does not advocate for unscientific approaches to diagnosis or therapy or promote unsafe, high-risk, or ineffective treatment of patients.



Standards for Integrity and Independence

Guideline 5.1: Ensuring Content is Valid

Presentations must provide a balanced view of therapeutic options

- "Balanced view of therapeutic options"
- No single product or service is over represented



Standards for Integrity and Independence

Content Validity

Can discussion of “off-label” uses of FDA-approved drugs occur in a CPE activity?

Discussion of off-label uses is allowed in CPE activities. Recommendations are to be based on current science/evidence where scientific research conforms to generally accepted standards.

Providers should guide faculty to include the level of evidence regarding all clinical and therapeutic recommendations. Credible sources cited should present a balanced view of the evidence.



Standards for Integrity and Independence

Guideline 5.2: Prevent Commercial Bias and Marketing

CE must protect learners from commercial bias and marketing

1. All decisions must be made without any influence or involvement from the owners and employees of an ineligible company.
2. Education must be free of marketing or sales of products or services; faculty must not actively promote or sell products or services during accredited education.
3. The provider 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**.

*Explicit consent = the learner is aware and gives permission



Standards for Integrity and Independence Prevent Commercial Bias and Marketing

Can a faculty member reference a book he/she wrote during a CPE activity?

Referencing the book as a resource or part of the faculty person's credentials is acceptable. Selling the book during an accredited educational session would not meet expectation of the Standard.



Standards for Integrity and Independence

Guideline 5.3: Identify, Mitigate and Disclose Potential Relevant Financial Relationships

Step 1: Collect information (before you begin planning) from all individuals in control of content about **all their financial relationships** with ineligible companies* within the **prior 24 months**.

- Includes advisory committees, planning committee members, faculty, etc.
- There is no minimum financial threshold; all financial relationships with ineligible companies must be disclosed.

Information to collect:

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

*Ineligible company: primary business is producing, marketing, selling, re-selling or distributing healthcare products used by or on patients



Standards for Integrity and Independence

Guideline 5.3: Identify, Mitigate and Disclose Potential Relevant Financial Relationships

Step 2: Review and exclude owners and employees of ineligible entities

Review 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.

There are three exceptions to this exclusion:

- Content is not related to business lines or products of the employer/company.
- Content 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.
- Individual is participating as a technician to teach safe and proper use of medical devices and do not recommend whether or when a device is used.



Standards for Integrity and Independence

Guideline 5.3: Identify, Mitigate and Disclose Potential Relevant Financial Relationships

Step 3: Identify relevant financial relationships:

Review financial relationships to identify those that are relevant

- ✓ A financial relationship, in any amount, exists between the individual and an ineligible company
- ✓ The financial relationship existed during the past 24 months
- ✓ The content is related to the products or business lines of the ineligible company



Standards for Integrity and Independence

Guideline 5.3: Identify, Mitigate and Disclose Potential Relevant Financial Relationships

Step 4: Mitigate relevant financial relationships

Prevent 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
- Steps for planners will differ than for faculty and occur before planning begins
- Document the steps taken to mitigate relevant financial relationships



Standards for Integrity and Independence

What happens when there is a relevant financial relationship?

Provider takes an active role to mitigate conflicts by:

- Recusing individual from controlling aspects of planning and content with which they have a conflict
- Using peer-review of planning decisions (for planners) by individual(s) that do not have a conflict of interest related to the content
- Using peer-review of content (for authors/presenters) by individual(s) that do not have conflicts of interest related to the content
- Ensuring that clinical recommendations are evidence-based and free of commercial bias



Standards for Integrity and Independence

Guideline 5.3: Identify, Mitigate and Disclose Potential Relevant Financial Relationships

Step 5: Disclose all relevant financial relationships to learners

Disclosure to learners must include each of the following:

- The names of the individuals with relevant financial relationships
 - The names of the ineligible companies with which they have relationships
 - The nature of the relationships
 - **A statement that all relevant financial relationships have been mitigated**
- Learners must receive disclosure information before engaging with the accredited education.
- Remember to provide disclosure in a way that provides documentation.



Standards for Integrity and Independence

Guideline 5.3: Identify, Mitigate and Disclose Potential Relevant Financial Relationships

Exception: If the CPE activity will only address a non-clinical topic (leadership, communication skills, etc.), providers do not need to identify, mitigate, or disclose relevant financial relationships



Standards for Integrity and Independence

Guideline 5.3: Mitigation of Personal Conflicts of Interest

Providers will not be in compliance with Guideline 5.3 if they:

- Only collect information about *significant* financial relationship or set a minimum dollar amount for disclosure
- Do not gather information about relationships within the 24 months prior to the educational activity
- Use a definition of illegible company that is incomplete, outdated, or different than the current ACPE definition



Standards for Integrity and Independence ***Identify, Mitigate and Disclose***

Can employees of an ineligible company serve as planners or faculty for CPE activities?

If the content of CPE that the employee of the ineligible company controls relates to the business lines and products of its employer – NO.

If the content of CPE that the employee of the ineligible company controls DOES NOT relate to the business lines and products of its employer – YES.



What kind of topics do not relate to the business lines or products of the employer?

- Participating in CPE beyond the scope of the employer's firm (e.g., an employee of a pharmaceutical manufacturer serves as faculty for an activity on disaster management)
- Content is limited to basic science research or research methodologies and not about treatment recommendations.
- Participating as technicians to teach the safe and proper use of medical devices and do not recommend whether or when a device is used.



Standards for Integrity and Independence Identify, Mitigate and Disclose

T/F Disclosure and mitigation of relevant financial relationships is only required to occur for the CPE faculty.

False... Everyone in a position to control content must disclose financial relationships, and the provider must identify and mitigate relevant financial relationships.



Standards for Integrity and Independence Identify, Mitigate and Disclose

In planning/developing CPE activities for an annual meeting, disclosure information was obtained for each presenter. If any relevant financial relationships were identified, the planning committee was asked to mitigate conflicts through peer review. Disclosure information for all presenters was then provided in the conference materials.

Is the provider in compliance?



Standards for Integrity and Independence *Identify, Mitigate and Disclose*

Partially. While peer review can be an effective method to mitigate conflicts, the provider must document what actions were taken if a conflict was identified (e.g., content revisions if commercial bias or invalid content identified).



Standards for Integrity and Independence

Guideline 5.4: Manage Commercial Support Appropriately

- Applies to providers that accept commercial support
- Responsible for ensuring that the education remains independent and that commercial support does not result in commercial bias or influence the education.
- Support does not establish a financial relationship between the ineligible company and planners, faculty, and others in control of content.



Standards for Integrity and Independence

Guideline 5.4: Manage Commercial Support Appropriately

Decision-making and disbursement: The accredited provider must make all decisions regarding receipt and disbursement of the commercial support.

1. Ineligible companies must not pay directly for any of the expenses related to the education or the learners.
2. The accredited provider may use commercial support to fund honoraria or travel expenses of planners, faculty, and others in control of content for those roles only.
3. The accredited provider must not use commercial support to pay for travel, lodging, honoraria, or personal expenses for individual learners or groups of learners in accredited education.
4. The accredited provider may use commercial support to defray or eliminate the cost of the education for *all* learners.



Standards for Integrity and Independence

Guideline 5.4: Manage Commercial Support Appropriately

Agreement:

- Agreement to document the terms, conditions, and purposes of the commercial support
- The agreement must be executed prior to the start of the accredited education.

Accountability: The accredited provider must keep a record of the amount or kind of commercial support received and how it was used, and must produce that accounting, upon request, by the accrediting body or by the ineligible company that provided the commercial support.



Standards for Integrity and Independence

Guideline 5.4: Manage Commercial Support Appropriately

Disclosure to learners: The accredited provider must disclose to the learners prior to engaging in the activity:

- Name(s) of the ineligible company(ies) that provided commercial support
- Nature of any support if it was in-kind

Disclosure **must not include** the ineligible companies' corporate or product logos, trade names, or product group messages.



Standards for Integrity and Independence Manage Commercial Support Appropriately

Can commercial support be disclosed to participants on a slide that displays during the first break in a CPE activity?

As with disclosure of relevant financial relationships, disclosure of commercial support must occur prior to the learners engaging in the education.



Standards for Integrity and Independence

Guideline 5.5: Manage Ancillary Activities Offered in Conjunction with Accredited Continuing Education

Activities offered for CE credit must be separated from marketing by ineligible companies—including advertising, sales, exhibits, and promotion—**and from nonaccredited education** offered in conjunction with accredited continuing education.

Marketing or exhibits in association with accredited education must not:

- Influence any decisions related to the planning, delivery, and evaluation of the education.
- Interfere with the presentation of the education.
- Be a condition of the provision of financial or in-kind support from ineligible companies for the education.



Standards for Integrity and Independence

Guideline 5.5: Manage Ancillary Activities Offered in Conjunction with Accredited Continuing Education

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

Live continuing education 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 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.



Standards for Integrity and Independence

Guideline 5.5: Manage Ancillary Activities Offered in Conjunction with Accredited Continuing Education

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.



Standards for Integrity and Independence

Guideline 5.5: Manage Ancillary Activities Offered in Conjunction with Accredited Continuing Education

Educational materials (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.

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.



Standards for Integrity and Independence Manage Ancillary Activities

Can a provider distribute a CPE activity via a website, television channel, or other type of communication vehicle that is owned by an ineligible company?

In keeping with the intent of separation of education from promotion, utilization of a platform owned/controlled by an ineligible company and supported by marketing dollars should not be a means to transmit or distribute CPE to learners.



Standards for Integrity and Independence

Manage Ancillary Activities

Can a virtual exhibit or promotional event occur before/after an accredited activity in the same virtual space?

To ensure separation between virtual CE activities and associated promotion, ACPE is recommending providers create separate virtual exhibit spaces that a learner may link to from outside of the accredited educational space where the learner's move to the promotional/exhibit space is deliberate, voluntary, and informed.



Standard 5 Rubric: Attestation

ACPE Standards for Integrity and Independence - Policies and Procedures

Attestation Statement: As the Continuing Pharmacy Education (CPE) Administrator on record with ACPE, on behalf of our organization, I attest that we implement and follow the most current Standards for Integrity and Independence. We understand that our organization must have policies and procedures defining the organization's processes to implement the Standards for Integrity and Independence. We acknowledge that ACPE may request to review and evaluate the policies and procedures at any time, as part of the evaluation process, or as a component of a subsequent monitoring report.

CPE Administrator's Signature

Date

The following list identifies the policies and procedures that relate to the requirements for the Standards for Integrity and Independence.

Standards for Integrity and Independence		Meets Criterion	Needs Improvement
5.1	Ensure Content is Valid	Meets requirements per attestation statement unless Needs Improvement column is checked.	Needs Improvement <input type="checkbox"/> or Additional Docs Required <input type="checkbox"/>
5.2	Prevent Commercial Bias and Marketing in Accredited Continuing Education		Needs Improvement <input type="checkbox"/> or Additional Docs Required <input type="checkbox"/>
5.3	Identify, Mitigate, and Disclose Relevant Financial Relationships		



Standard 5 Rubric

Standard 5: Standards for Integrity and Independence

Criterion and Evidence	Meets Criterion	Needs Improvement
Ensure Content is Valid		
Content Validity [5.1] (Attach process for ensuring information presented is fair, balanced, and evidence-based. Include relevant evidence, e.g. planning documents, educational material, references, etc.)	The provider ensures that CE is fair and balanced and clinical content presented supports safe, effective patient care. <ul style="list-style-type: none"> All recommendations are based on current science, evidence, and clinical reasoning, while giving fair and balanced view of diagnostic/therapeutic options. All scientific research in CE conforms to the generally accepted standards of experimental design, data collection, analysis, and interpretation. The provider facilitates engagement with new/evolving topics without advocating for, or promoting, practices that are not, or not yet, adequately based on current science, evidence, and clinical reasoning. 	The provider does not ensure that CE is fair, balanced and based on current science, evidence and clinical reasoning; or scientific research in CE does not conform to the generally accepted standards of experimental design, data collection, analysis, and interpretation; and/or CE content advocates or promotes practices that are not, or not yet, adequately based on current science, evidence, and clinical reasoning.
	Meets <input type="checkbox"/>	Needs Improvement <input type="checkbox"/> or Additional Docs Required <input type="checkbox"/>
Prevent Commercial Bias and Marketing in Accredited Continuing Education		
Preventing Commercial Bias and Marketing [5.2] (Attach process for ensuring CE protects learners from commercial bias and marketing. Include relevant evidence, e.g. activity announcements, grant agreements, planning documents, educational material.)	The provider ensures that CE protects learners from commercial bias and marketing. <ul style="list-style-type: none"> All decisions related to planning, faculty selection, delivery, and evaluation are made without influence or involvement from the owners and employees of an ineligible company. CE activities are free of marketing or sales of products or services. Faculty do not promote or sell products or services that serve their professional or financial interests. Names or contact information of learners is not shared with any ineligible company or its agents without the explicit consent of the individual learner. 	The provider does not ensure that all decisions related to planning, faculty selection, delivery, and evaluation are made without influence or involvement from the owners and employees of an ineligible company or that CE activities are free of marketing or sales of products or services. Faculty promote or sell products or services that serve their professional or financial interests. Or the names or contact information of learners is shared with an ineligible company or its agents without the explicit consent of the individual learner.
	Meets <input type="checkbox"/>	Needs Improvement <input type="checkbox"/> or Additional Docs Required <input type="checkbox"/>
Identify, Mitigate, and Disclose Relevant Financial Relationships		
Identify relevant financial relationships [5.3 (1-3)] (Attach evidence of identification of relevant financial relationships.)	The provider: <ul style="list-style-type: none"> Collects information from all planners, faculty, staff, and individuals in control of content about all financial relationships with ineligible companies within the prior 24 months, i.e. name of company and nature of relationship. Excludes owners or employees of ineligible companies. Identifies relevant financial relationships (if the educational content is related to the business lines or products of the ineligible company). 	The provider does not collect information from all individuals in control of content about all financial relationships with ineligible companies within the prior 24 months and/or does not exclude owners/employees of ineligible companies and/or does not identify relevant financial relationships.
	Meets <input type="checkbox"/>	Needs Improvement <input type="checkbox"/> or Additional Docs Required <input type="checkbox"/>
Mitigate relevant financial relationships [5.3 (4)]	Prior to the individuals assuming their roles, the provider take steps to prevent all those with relevant financial relationships from inserting	The provider does not take steps to prevent all those with relevant financial relationships from inserting commercial bias into content, and/or
		Needs Improvement <input type="checkbox"/> or Additional Docs Required <input type="checkbox"/>

Standards for Integrity and Independence
Effective January 1, 2022 2

(Attach evidence of mitigation of relevant financial relationships.) commercial bias into content

Accountability [5.4 (3)]

... does not occur prior to individuals assuming their roles, and/or the provider does not take the steps taken.

Needs Improvement
or Additional Docs Required

The provider does not disclose relevant financial information on the part of all individuals in a position of control content, and/or learners do not receive information before engaging in the activity, and/or disclosure includes product logos, trade names, or group messages of ineligible companies.

Needs Improvement
or Additional Docs Required

Education

... associated with accredited CE

... arrangements for marketing or exhibits by ineligible companies influence decisions by the planning, delivery, and evaluation of the accredited education, and/or interfere with the presentation of the education, and/or are a condition of the provision of financial or in-kind support from ineligible companies for the education.

Needs Improvement
or Additional Docs Required

... does not ensure that marketing by ineligible companies is kept separate from the educational activity.

... Live: Marketing and non-accredited education occur in the educational space within 30 minutes before or after an accredited activity.

... Print, online, or digital: Learners are presented with marketing while engaged in the activity. Learners but click through, watch, listen to, or be presented with product promotion or product-specific advertisement in order to engage with educational content.

Needs Improvement
or Additional Docs Required

... use written agreements that are approved by or for an ineligible company, including product logos, trade names, or group messages.

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or Additional Docs Required

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Needs Improvement
or Additional Docs Required

Thank You!

A recording of today's webinar will be made available shortly.

Please send questions about the Standards for Integrity and Independence to ceinfo@acpe-accredit.org.

For further information about CPE Standards and Policies, visit:
<https://www.acpe-accredit.org/continuing-education-provider-accreditation/>

