



# Analysis of the New ACCME Standards for Integrity and Independence

## Introduction

On December 10, 2020, the Accreditation Council for Continuing Medical Education (ACCME) announced the release of the long-awaited replacement for the Standards for Commercial Support, now called the *Standards for Integrity and Independence in Accredited Continuing Education*. To support our clients and their educational partners, Passin Associates has developed the following analysis of the new Standards to assist in making the necessary changes and adjustments to your processes and policies.

As always, Passin Associates will also be developing updated master policies and procedures that reflect these important changes.

## General Organization of the New Standards

The release from the Accreditation Council for Continuing Medical Education (ACCME) was organized into seven major sections covering the new five Standards plus a Preamble and Eligibility Sections:

- The Preamble
- Eligibility

- **Standard 1:** *Ensure Content is Valid*
- **Standard 2:** *Prevent Commercial Bias and Marketing in Accredited Continuing Education*
- **Standard 3:** *Identify, Mitigate, and Disclose Relevant Financial Relationships*
- **Standard 4:** *Manage Commercial Support Appropriately*
- **Standard 5:** *Manage Ancillary Activities Offered in Conjunction with Accredited Continuing Education*

## The Preamble

Key themes contained in the Preamble are as follows:

- Since healthcare professionals serve as the legally mandated gatekeepers of medications and devices . . . they must protect their learning environment from industry influence to ensure they remain true to their ethical commitments.
- Organizations accredited to provide continuing education . . . are responsible for ensuring that healthcare professionals have access to learning and skill development activities that are trustworthy and are based on best practices and high-quality evidence. These activities must serve the needs of patients and not the interests of industry.
- . . . independence is the cornerstone of accredited continuing education. Accredited continuing education must . . . [have] a protected space to learn, teach, and engage in scientific discourse free from influence from organizations that may have an incentive to insert commercial bias into education.



The ACCME has expanded upon the types of organizations that are eligible to be accredited providers. The new list is as follows:

- Ambulatory procedure centers
- Blood banks
- Diagnostic labs that do not sell proprietary products
- Electronic health records companies
- Government or military agencies
- Group 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 medicine or health science universities
- Software or game developers

The list of companies that are ineligible for accreditation are as follows (new entities are bolded):

- Advertising, marketing, or communication firms whose clients are ineligible companies (*this does not include medical education companies whose mission is education and not marketing*)
- Biomedical 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



### *New Terms and Terminology:*

| Old Term                                | New Term  |
|---|---|
| Commercial Interest                     | Ineligible Companies, Eligible Organizations, Ineligible Companies                                    |
| Resolve COI                             | <b>Mitigate</b> COI or Mitigate Relevant Financial Relationships                                      |
| <i>Standards for Commercial Support</i> | <i>Standards for Integrity and Independence</i> (in Accredited Continuing Education)                  |
| Accredited CME                          | Accredited CE (this acknowledges other affected accrediting organizations, such a Joint Accreditation |

## Standard 1: Ensure Content is Valid

*The theme of Standard 1: Accredited providers are responsible for ensuring that their education is fair and balanced and that any clinical content presented supports safe, effective patient care.*

The three sections of Standard 1 are as follows (**changes are marked in bold**):

1. All recommendations for patient care in accredited continuing education must be 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 in accredited education in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection, analysis, and interpretation.
3. **Although accredited continuing education is an appropriate place to discuss, debate, and explore new and evolving topics, these areas need to be clearly identified as such within the program and individual presentations. It is the responsibility of accredited providers to facilitate engagement with these topics without advocating for, or promoting, practices that are not, or not yet adequately based on current science, evidence, and clinical reasoning.**



*Discussion and New Requirements*—This is a new section entirely even though previous Standards do discuss unproven treatments. Importantly, the provider must identify aspects of the content that “explores new and evolving topics.” This means that the provider must call out these topics in course materials and in the course agenda in particular. Moreover, the CME/CE Office must be prepared to facilitate communication to planners and faculty such that topics that are not as yet and/or are not adequately based on current science, evidence and clinical reasoning do not advocate or promote such practices. NOTE new language on “clinical reasoning,” which offers opportunities for discussions in areas where clinical guidelines have not yet been promulgated and thus gives some flexibility for discussions of emerging or new practices.

4. Organizations cannot be accredited if they advocate for unscientific approaches to diagnosis or therapy, or if their education promotes 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 in the treatment of patients.

## Standard 2: Prevent Commercial Bias and Marketing in Accredited CE

*Theme of Standard 2: Accredited continuing education must protect learners from commercial bias and marketing. This area has been expanded upon and there are several changes.*

The three sections of Standard 2 are as follows (**changes are marked in bold**):

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.



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.**
3. **The accredited 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.**

*Discussion and New Requirements—This Standard strengthens requirements for individual faculty, clearly stating that they are not allowed to promote or sell products or services that serve their financial or professional interests within their presentations in accredited CME/CE. Providers should include mention of this rule in an invitation letter sent to potential faculty, or within the financial disclosure form to avoid any last-minute problems. In addition, it is now very clear that providers may not provide any contact information to an ineligible company or its agents without the written permission of the learners for marketing purposes. Providers should review/update their Letters of Agreement (LOA) and those of ineligible companies to be sure any reference to this is removed.*

## Standard 3: Identify, Mitigate, and Disclose Relevant Financial Relationships

*Theme of Standard 3: Many healthcare professionals have financial relationships with ineligible companies. These relationships must not be allowed to influence accredited continuing education.*

The five sections of Standard 3 are as follows (**changes are marked in bold**):

### 1. Collect information:

Accredited providers must collect information from all planners, faculty, and others in control of educational content 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. Examples of financial relationships include employee, researcher, consultant, advisor, speaker, independent contractor (including contracted research), royalties or patent beneficiary, **executive role**, and ownership interest. Individual stocks and stock options should be disclosed; diversified mutual funds do not need to be disclosed. Research funding from ineligible companies should be disclosed by the principal or named investigator even if that individual's institution receives the research grant and manages the funds.
  - c. The requirement that individuals disclose the financial relationships of their spouse/partner was removed due to privacy considerations.
  - d. The controversial proposed requirement in the original draft prohibiting joint providers from paying or reimbursing expenses to individuals (such as faculty) was removed.
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—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 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.**
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.**
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.**

**Identify ineligible companies by their name only:**

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

**Disclose absence of relevant financial relationships:**

Inform learners about planners, faculty, and others in control of content (either individually or as a group) with no relevant financial relationships with ineligible companies.

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

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

- Accredited education that is non-clinical, such as leadership or communication skills training.
- Accredited education where the learner group is in control of content, such as a spontaneous case conversation among peers.
- 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. When accredited providers serve as a source of information for the self-directed



**learner, they should direct learners only to resources and methods for learning that are not controlled by ineligible companies.**

*Discussion and New Requirements*—In this Standard, the bold-faced text above indicate requirements that are either new or for which greater clarification has been issued. Key changes include:

(1) *the period for which disclosures are made increases from one year to two years prior to the date of the disclosure. This means that disclosure forms must be updated accordingly.*

(2) *The individuals making disclosure must disclose ALL financial relationships with ineligible commercial interests within the two-year period instead of disclosing all RELEVANT financial relationships. The burden of determining which disclosures are relevant is the responsibility of the CME/CE provider and it must be mitigated and disclosed as such to the learners. This change will impact the CME/CE staff and budgeting for all CME/CE activities.*

(3) *Planner, faculty, and reviewers making disclosure must be instructed to disclose all financial relationships they have, not only those they deem “relevant”. This is a significant change for planners, faculty, authors, reviewers, etc. as they have been told over the years to only report “relevant” relationships. Forms will need to be updated, faculty will need to be educated and staff will need to assume more responsibility to determine what is relevant to the content of the course. Staff will have to document appropriate mitigation of the conflict of interest resulting from the disclosure.*

(4) *With respect to persons who own or are employed by an ineligible commercial interest, Standard 3 refers to “executives.” The definition of an executive is “having the power to put plans, actions, or laws into effect.” We don’t know if this is a conscious use of the word, but it is basically the same as before but adds some degree of clarity as to who at the ineligible CI constitutes an employee.*

(5) *Discussion in Standard 3 with respect to the mitigation of relevant financial relationships clarifies and reinforces that such mitigation is different for a planner and a faculty member; reinforces that mitigation must be determined and acted upon prior to those individuals performing their respective roles in the CME/CE activity. It also reinforces that the method of mitigation must be documented. The list of acceptable “mitigation methods” that are inserted into the Individuals In Control of Content Spreadsheet are still valid and should be utilized for documentation of mitigation purposes.*



(6) When making disclosure to learners of relevant financial relationships, the CME/CE provider must now include an additional sentence to the effect that “all relevant financial relationships have been mitigated.”

(7) Learners must receive disclosure information, in a format that can be verified at the time of accreditation, before engaging with the accredited education. In our opinion, this means that ACCME/JA is going back to an older rule that requires – and will look for evidence – that the learner was informed of financial relationship disclosures before engaging in the activity. When providers use tabs or other links to this information, they must be able to verify that the learners received this information prior to the commencement of the activity. This may impact how tabs are set-up for internet enduring activities and for the separate disclosure documents to which learners are referred that contain financial disclosure information.

(8) Three exceptions have been clarified (and for the first time included in the written Standards) to eliminate the requirements for identifying and mitigating, and disclosing to learners relevant financial relationships when:

- a. *Accredited education is non-clinical, such as leadership or communication skills training.*
- b. *Accredited education in which the learner group is in control of content, such as a spontaneous case conversation among peers.*
- c. *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. When accredited providers serve as a source of information for the self-directed learner, they should direct learners only to resources and methods for learning that are not controlled by ineligible companies.*

*For many CME/CE providers who offer the above types of education, this requirement will reduce staffing resources and simplify requirements for planners and faculty of these types of activities. Adding clarification to planning documents, such as “clinical or non-clinical” will help to streamline this process before planning begins.*



## Standard 4: Manage Commercial Support Appropriately

**Theme of Standard 4:** *Accredited providers that choose to accept commercial support (defined as financial or in-kind support from ineligible companies) 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.*

The four sections of Standard 4 are as follows (**changes are marked in bold**):

1. **Decision-making and disbursement:** The accredited provider must make all decisions regarding the receipt and disbursement of the commercial support.
  - a. Ineligible companies must not pay directly for any of the expenses related to the education or the learners.
  - b. 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.
  - c. **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.**
  - d. The accredited provider may use commercial support to defray or eliminate the cost of the education for all learners.
2. **Agreement:** The terms, conditions, and purposes of the commercial support must be documented in an agreement between the ineligible company and the accredited provider. The agreement must be executed prior to the start of the accredited education. **An accredited provider can sign onto an existing agreement between an accredited provider and a commercial supporter by**



indicating its acceptance of the terms, conditions, and amount of commercial support it will receive.

3. **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.
4. **Disclosure to learners:** 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. Disclosure must not include the ineligible companies' corporate or product logos, trade names, or product group messages.

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#### *Discussion and New Requirements —*

*(1) This Standard does not mention any exception to the provision of funds for learner travel derived from commercial support to students. This is a practice used by some CME/CE providers to bring residents or fellows to a national conference. In the past this practice was allowed, but it does not appear to be so with the new Standards.*

*(2) The practice of a CME/CE provider being added onto an existing agreement for commercial support was always problematic under the old Standards, and this version clarifies that the practice is permitted by "signing on" to the existing agreement and indicating its acceptance of the terms and conditions. However, in our opinion it is unclear HOW this happens (e.g., through a Memo or Addendum).*

*(3) This version of the Standards clarifies and reinforces rules with respect to In-Kind Contributions and the requirement that the purpose of the in-kind contribution must be communicated to learners in the acknowledgement of receipt of commercial support in course materials.*



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

*Theme of Standard 5: 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.*

The three sections of Standard 4 are as follows (**changes are marked in bold**):

1. Arrangements to allow ineligible companies to market or exhibit in association with accredited education must not:
  - a. Influence any decisions related to the planning, delivery, and evaluation of the education.
  - b. Interfere with the presentation of the education.
  - c. Be a condition of the provision of financial or in-kind support from ineligible companies for the education.
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 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.



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

*Discussion and New Requirements—The changes in this Standard reinforces the fact that learners can easily distinguish between accredited education and non-accredited activities. Specific examples of the application of this rule are provided for types of activities.*

*(A) For live activities, for example, when nonaccredited education is offered at a CME event, such as a product theater that is planned and executed by an “ineligible company”, this Standard clarifies that it cannot be offered in the “educational space” within 30 minutes before or after the accredited activity. Furthermore, this Standard underscores that the non-accredited activity must be clearly identified as such to learners in the course materials and in other forms of communication (e.g., signage at the non-accredited activity).*



*(B) In online and digital educational activities, 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. The specificity in this section strengthens the rule that messaging during an activity relating to promotional events such as virtual exhibits should not occur. This is especially important in today's pivot to virtual meetings and the inclusion of virtual exhibits within those events.*

*(C) With respect to educational materials for CME/CE, the addition of "produced by or for an ineligible company," is new. CME/CE providers will need to notify faculty that they may not use any content/materials provided by an ineligible company and vet them thoroughly to ensure they do not promote the interests of the ineligible company or their products.*

*(D) This section of the Standards clarifies and reinforces that non-content aspects of a CME activity or event, such as schedules or logistical information, can contain promotion or advertisement from ineligible companies. This is not new, it is just clarified, to ensure there is no confusion. Program books produced by association or society provider, or syllabi that is logistical in its entirety can contain ads, but those materials cannot include actual CME/CE content including accreditation and credit designation statements, financial disclosures, learning objectives or anything else that is part and parcel of CME/CE content.*

*(E) This is a clarification of the previous section of this Standard, 4.5 which stated "a provider cannot use a commercial interest as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities."*

## General Note About our Advice

It should be noted that because the updated *Standards* are new and have not been tested through self-studies and surveyor reviews, we may see further clarification from the accrediting agencies as we move forward.





## Next Steps

1. The revised *Standards* must be implemented no later than January 1, 2022 or at any time earlier than the deadline. All areas of the previous standards that have been removed may be implemented immediately.
2. Passin Associates will begin the process of revising applicable policies and procedures to reflect the revised *Standards*. Updated documents and detailed guidance will be made available to current clients upon their development.
3. As always, if there are questions about this analysis or the revised *Standards* in general, please do not hesitate to email Steve Passin ([passin@passinassociates.com](mailto:passin@passinassociates.com)) and those questions will be shared with our full professional team including Judy Sweetnam and Susan O'Brien for prompt response.

