

ALERT Arrival of New Standards! ACCME's "*Standards for Integrity and Independence in Accredited Continuing Education*"

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On December 10, 2020, ACCME notified accredited providers of its new *Standards for Integrity and Independence in Accredited Continuing Education*SM and corresponding toolkit. These standards have been adopted by the following accrediting bodies:

- Accreditation Council for Continuing Medical Education (ACCME)
- Accreditation Council for Pharmacy Education (ACPE)
- American Academy of Family Physicians (AAFP)
- American Nurses Credentialing Center (ANCC)
- Association of Regulatory Boards of Optometry's Council on Optometric Practitioner Education (ARBO/COPE)
- Joint Accreditation for Interprofessional Continuing Education™

It is important to note that compliance with the new, "Standards for Integrity and Independence in Accredited Continuing Education" is **January 1, 2022**.

To read more about this announcement, please click [here](#).

To access the ACCME's *Standards for Integrity and Independence in Accredited Continuing Education Resources*, please click [here](#).

To access ACCME's *Standards for Integrity and Independence in Accredited Continuing Education Toolkit*, please click [here](#).

Disclaimer: The review below provides insight to the significant standard changes and may not include all changes.

Terminology Changes

Because the Standards were last revised 15 years ago, the first change of note is the document title itself. The previous title, *Standards for Commercial Support: Standards to Ensure Independence in CME Activities*, changed to, *Standards for Integrity and Independence in Accredited Continuing Education*SM, reflects the ever-changing healthcare landscape. With the creation of Joint

Accreditation™, the new title reflects a shift in focus strictly from continuing medical education to accredited continuing education that is inclusive across many healthcare professions. Likewise, the term *continuing medical education* has changed to *Accredited Continuing Education (ACE)*.

Another significant change in terminology is the change of the term “commercial interests” to “ineligible companies.” It is important to note that while this terminology change is significant, the definition remains the same. Ineligible companies are defined by ACCME as,

“those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.”

Examples of eligible and ineligible organizations were also updated. The screenshot below includes ACCME’s provided examples:

Types of Organizations That May Be Accredited in the ACCME System

Organizations eligible to be accredited in the ACCME System (*eligible organizations*) are those whose mission and function are: (1) providing clinical services directly to patients; or (2) the education of healthcare professionals; or (3) serving as fiduciary to patients, the public, or population health; and other organizations that are not otherwise ineligible. Examples of such organizations include:

- Ambulatory procedure centers
- Blood banks
- Diagnostic labs that do not sell proprietary products
- Electronic health records companies
- Government or military agencies
- Group 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

Types of Organizations That Cannot Be Accredited in the ACCME System

Companies that are ineligible to be accredited in the ACCME System (*ineligible companies*) are those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. Examples of such organizations include:

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

Another terminology change that reflects a significant shift is the change from “resolution of COI” to “identify, **mitigate**, and disclose relevant financial relationships.” Mitigate replaces the term “resolve” from the former “*Standards to Ensure Independence in CME Activities*.” Accredited providers are responsible for determining which financial relationships are relevant and mitigating those to prevent introducing commercial bias into accredited continuing education content.

Standard 1: Ensure Content is Valid

There are no significant changes from the previous Content Validity policies. Key takeaways include:

- Patient care recommendations must be based on “current science, evidence, and clinical reasoning, while giving a fair and balanced view of diagnostic and therapeutic options. “
- Scientific research must adhere to “accepted standards of experimental design, data collection, analysis, and interpretation.”
- New and evolving topics can be discussed and explored during an accredited continuing education activity but cannot be “advocated for, or promoting, practices that are not, or not yet, ...based on current science, evidence, and clinical reasoning.”

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

There are new requirements included in this standard. Key takeaways include:

- Accredited providers must ensure that all aspects of accredited continuing education are planned and implemented without “influence or involvement” from **owners** and employees of an ineligible company.
- While the requirement that accredited continuing education “must be free of marketing or sales of products and services” is not new, **faculty** are prohibited from “promoting or selling products or services that serve their professional or financial interests during accredited continuing education.”
- **New:** Accredited providers must obtain learner consent if the plan to provide learner names and contact information with an ineligible company or its agents.

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

Definition of Relevant Financial Relationships: “Financial relationships of any dollar amount are defined as relevant if the educational content an individual can control is related to the business lines or products of the ineligible company.”

- **New:** The time period of declaration of financial relationships by those in a position to control content has changed from the previous 12 months to the previous 24 months. Those in control of content (i.e. Faculty, Planners, Moderators, etc.,) must

disclose **all** financial relationships. There is no financial threshold to financial relationships that must be report but **all** financial relationships must be declared. Additionally, those in a position to control the educational content may not determine which financial relationships are relevant to the educational content and those that are not – this is the responsibility of the accredited provider.

- Owners and employees of ineligible companies are excluded from serving as faculty or planners unless one of the following applies:

“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.”

- Mitigation of relevant financials relationships must occur **prior to** planners or faculty beginning their role.
- When disclosing financial relationships with ineligible companies, do so by name only – no logos, trade names or product group messages.
- Disclose when faculty, planners, etc. do not have financial relationships with ineligible companies.
- The following are exceptions where accredited providers do not need to identify, mitigate, or disclose relevant financial relationships:

1. Accredited education that is non-clinical, such as leadership or communication skills training.

2. Accredited education where the learner group is in control of content, such as a spontaneous case conversation among peers.

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. 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.

- **No longer required:** Disclosure of financial relationships of spouses or life partners.

Standard 4: Manage Commercial Support Appropriately

Do you accept commercial support, monetary or in-kind support, to support the development of accredited continuing education? If yes, then these standards apply to your ACE program.

- Ensure that the accredited continuing education activities remain free of commercial bias or commercial influence.
- The accredited provider is responsible for the receipt and disbursement of all commercial support.
- Ineligible companies may not directly pay for any activity or learner expenses.
- Accredited providers may use commercial support to pay for honoraria or travel expenses of this in control of content, faculty, planners, etc.
- Accredited providers may not use commercial support to pay for learner travel, lodging, honoraria or personal expenses.
- Commercial support can be used to defray or eliminate the cost of the education for **all** learners.
- There must be a written agreement for acceptance of commercial support.
- Accredited providers must records related to the use of the commercial support and provide accounting details if requested.
- Accredited providers must disclose to learners the name of the ineligible company that provided the commercial support – name only; no logos, trade names, or product group messages!
- Under the direction of the accredited provider, a joint provider may manage and use commercial support funds to reimburse planners or faculty for honoraria, travel, lodging or personal expenses.
- **New:** Accredited providers are no longer required to maintain a policy on Honoraria and Expense Reimbursement.
- **No longer required:** Policy on Honoraria will no longer be required within the self-study.

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

Do you allow marketing (i.e. exhibits, advertising, sales, etc.) by ineligible companies or offer non-accredited education associated with the accredited continuing education? If yes, then these standards apply to your ACE program.

- If you allow ineligible companies to exhibit or market in association with accredited education, the accredited provider must ensure that these efforts do 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.”

- **Live Activities:** Exhibits, marketing and/or non-accredited must not occur in the educational space 30 minutes before or after an ACE activity. The non-accredited activities must be clearly labeled and communicated to learners as such.
- **Print, online or digital Activities:** Marketing may not be included in these activities while the learner is engaging in the ACE activity.
- **Educational Materials:** Educational materials that are part of an ACE activity must not include marketing produced by or for an ineligible company. Likewise, logos, trade names, or product group messages cannot be included.
- **Information that does not include educational content:** may include marketing produced by or for an ineligible company. Examples include: schedules, logistical information, etc.
- Ineligible companies may not provide access to, or distribute, ACE activities to learners.

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