

FOR COUNCIL ACTION

TO: OFFICERS, COUNCILORS TRUSTEES
FROM: MSSNY Committee on Continuing Medical Education
RE: MSSNY Policy 50.995 ACCME Standards for Commercial Support

Recommendation: That the MSSNY Council accept the revised ACCME Standards for Integrity and Independence in Accredited Continuing Education (replacing Standards for Commercial Support). MSSNY, as an Accredited CME Provider, is required to follow the ACCME Standards for Integrity and Independence in Accredited Continuing Education as written. The previous version of the Standards for Commercial Support was accepted and approved by the Council in 2015, but the ACCME has made a number of significant changes to the Standards, including the name change, making the previous version obsolete.

Standards for Integrity and Independence in Accredited Continuing Education

The health professions are not only defined by expertise, but also by a dedication to put service of others above self-interest. When individuals enter the healthcare professions, they commit to upholding professional and ethical standards including acting in a patient's best interests, protecting the patient from harm, respecting the patient, fostering informed choices, and promoting equity in healthcare.

While the interests of healthcare and business sometimes diverge, both are legitimate, and collaboration between healthcare professionals and industry can advance patient care. Since healthcare professionals serve as the legally mandated gatekeepers of medications and devices, and trusted authorities when advising patients, they must protect their learning environment from industry influence to ensure they remain true to their ethical commitments.

As the stewards of the learning environment for healthcare professionals, the accredited continuing education community plays a critical role in navigating the complex interface between industry and the health professions. Organizations accredited to provide continuing education, known as accredited providers, 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.

This independence is the cornerstone of accredited continuing education. Accredited continuing education must provide healthcare professionals, as individuals and teams, with 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 Accreditation Council for Continuing Medical Education (ACCME[®]) acts as the steward of the Standards for Integrity and Independence in Accredited Continuing Education, which have been drafted to be applicable to accredited continuing education across the health professions.

The Standards are designed to:

- Ensure that accredited continuing education serves the needs of patients and the public.

- Present learners with only accurate, balanced, scientifically justified recommendations.
- Assure healthcare professionals and teams that they can trust accredited continuing education to help them deliver safe, effective, cost-effective, compassionate care that is based on best practice and evidence.
- Create a clear, unbridgeable separation between accredited continuing education and marketing and sales.

Terms used for the first time are written in *blue italics*, followed by the definition for the term.

Eligibility

The ACCME is committed to ensuring that accredited continuing education (1) presents learners with only accurate, balanced, scientifically justified recommendations, and (2) protects learners from promotion, marketing, and commercial bias. To that end, the ACCME has established the following guidance on the types of organizations that may be eligible to be accredited in the ACCME System. The ACCME, in its sole discretion, determines which organizations are awarded ACCME accreditation.

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:

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| <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • 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 |
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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:

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| <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • 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 |
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Owners and Employees of Ineligible Companies

The *owners* and *employees* of ineligible companies are considered to have unresolvable financial relationships and must be excluded from participating as planners or faculty, and must not be allowed to influence or control any aspect of the planning, delivery, or evaluation of accredited continuing education, except in the limited circumstances outlined in Standard 3.2.

Owners and employees are individuals who have a legal duty to act in the company's best interests. Owners are defined as individuals who have an ownership interest in a company, except for stockholders of publicly traded companies, or holders of shares through a pension or mutual fund. Employees are defined as individuals hired to work for another person or business (the employer) for compensation and who are subject to the employer's direction as to the details of how to perform the job.

Ineligible companies are prohibited from engaging in *joint providership* with accredited providers. Joint providership enables accredited providers to work with nonaccredited eligible organizations to deliver accredited education.

The ACCME determines eligibility for accreditation based on the characteristics of the organization seeking accreditation and, if applicable, any parent company. Subsidiaries of an ineligible parent company cannot be accredited regardless of steps taken to firewall the subsidiaries. If an eligible parent company has an ineligible subsidiary, the owners and employees of the ineligible subsidiary must be excluded from accredited continuing education except in the limited circumstances outlined in Standard 3.2.

Standard 1: Ensure Content is Valid

Standard 1 applies to all accredited continuing education.

Accredited providers are responsible for ensuring that their education is fair and balanced and that any clinical content presented supports safe, effective patient care.

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.
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 Continuing Education

Standard 2 applies to all accredited continuing education.

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

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.

Standard 3: Identify, Mitigate, and Disclose

Relevant Financial Relationships

Standard 3 applies to all accredited continuing education.

Many healthcare professionals have financial relationships with ineligible companies. These relationships must not be allowed to influence accredited continuing education. The accredited provider is responsible for identifying *relevant financial relationships* between individuals in control of educational content and ineligible companies and managing these to ensure they do not introduce commercial bias into the education. Financial relationships of any dollar amount are defined as relevant if the educational content is related to the business lines or products of the ineligible company.

Accredited providers must take the following steps when developing accredited continuing education. Exceptions are listed at the end of Standard 3.

1. **Collect information:** 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.
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:

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.

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* (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 support does not establish a financial relationship between the ineligible company and planners, faculty, and others in control of content of the education.

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.

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.

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.

(FOR COUNCIL APPROVAL)