



AMERICAN
OSTEOPATHIC ASSOCIATION

Adoption of the ACCME's Standards for Integrity and Independence

<https://zoom.us/j/6699930092>

(877)369-0926, Code: 6699930092#

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Use **Zoom Chat** to submit a question or
Email: aweir@osteopathic.org



Adoption of the ACCME's Standards for Integrity and Independence

Submit your questions.

*This session is being recorded and will be available for
On-Demand access.*



Welcome

Kevin M. Klauer, DO, EJD, CEO



Introduction

Jeff Fraler, Associate Vice President
Physician Education & CME

New ACCME Standards

ACCME's Standards for Integrity and Independence

- Released in December 2020, fully adopted by all ACCME accredited providers by January, 2022
- Goal is to streamline, clarify, and modernize the Standards to ensure their continued relevance and effectiveness in the changing healthcare environment.
- In addition to ACCME accredited providers, the following organizations have adopted the new standards
 - Accreditation Council for Pharmacy Education (ACPE)
 - American Academy of Family Physicians (AAFP)
 - American Academy of PAs (AAPA)
 - 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™



AOA Sponsorship vs ACCME Joint Providership

What the Standards mean for AOA CME Sponsors:

- AOA CME sponsors will ensure content is valid; prevent commercial bias and marketing in accredited CME; identify, mitigate, and disclose relevant financial relationships; manage commercial support appropriately, and manage ancillary activities in conjunction with accredited continuing education
- Acceptance of the Standards by the AOA does NOT mean that AOA CME sponsors can offer *AMA/PRA Credit* (unless, of course, they are or become an ACCME accredited provider)

ACCME Joint Providership

- The AOA continues to offer ACCME accreditation for CME activities to those organizations that are not accredited by the ACCME. For more information, please contact Amanda Weir.



AOA CME Sponsorship Eligibility Criteria

The ACCME has a large list of the types of organizations that can become an ACCME accredited provider.

While the AOA has adopted the Standards for Integrity and Independence, **the AOA has NOT adopted the ACCME's eligibility criteria.** The requirements to become an AOA CME Sponsor will remain in place.





Standards for Integrity and Independence

Amanda Weir, Senior Manager, Physician
Education and CME

Summarizing the Standards

Standard 1: Ensure content is valid

Education is fair and balanced: clinical content supports safe, effective patient care.

- Recommendations based on current science, evidence, and clinical reasoning.
- Scientific research used must conform to generally accepted standards.
- Discuss, debate, and explore new and evolving topics.
- Can't advocate for unscientific approaches to diagnosis or therapy, or to promote recommendations, treatments, or manners of practicing healthcare that are determined to have risks that outweigh the benefits.



Action Items

Standard 1: Ensure content is valid

Action items: None



Summarizing the Standards

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

- Ensure that all decisions are made without any influence or involvement from the owners and employees of an ineligible company.
- 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.
- Don't share the names or contact information of learners with any ineligible company or its agents without the explicit consent of the individual learner.

Ineligible Company: those whose primary business is producing, marketing, selling, reselling, or distributing healthcare products used by or on patients.



Examples of ineligible companies

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

Questions on ineligible companies? Email me: aweir@osteopathic.org



Action Items

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

Action items:

- Implement (or continue with) a process to ensure CME is free from all promotion.
- Look through contracts and processes to ensure learner names are not shared with ineligible companies without their explicit permission.



Summarizing the Standards

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

The following steps must be taken when developing your activity:

1. Collect information- **all financial relationships** with ineligible companies with in the **prior 24 months**.
2. Exclude owners or employees of ineligible companies from controlling content or participating as planners or faculty.
3. Identify relevant financial relationships
4. Mitigate relevant financial relationships
5. Disclose all relevant financial relationships to learners.



Accredited activities that do NOT need relevant financial relationships identified, mitigated, or disclosed

- Education that is non-clinical, like leadership or communication skills training.
- Education where the learner group is in control of content.
- 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.



Action Items

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

Action Items:

Update CME disclosure policy and form:

- You can use the [AOA's disclosure form if desired](#).
 - Removal of request for spouse/partner
 - Increase from past 12 months to 24

Implement process for mitigating relevant financial relationships.

- See the “Tips for Identifying and Mitigation of Relevant Financial Relationships of Planners, Faculty, and Others” handout for more details.



Summarizing the Standards

Standard 4: Manage Commercial Support Appropriately

If you choose to accept **commercial support**, you 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



Action Items

Standard 4: Manage Commercial Support Appropriately

Action Items:

- Mostly in line with current AOA CME policy.
- Review Standard 4 in its entirety and understand restrictions around using commercial support for individual learners or groups of learners.
- Ensure disclosure of commercial support from ineligible companies is shared with learners before activity begins (in print, on screen, etc.).

Questions? Email me: aweir@osteopathic.org



Summarizing the Standards

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

- Arrangements to allow ineligible companies to market or exhibit in association with accredited education can't:
 - Influence any decisions related to planning, delivery, and evaluation of education.
 - Interfere with the presentation of the education
 - Be a condition of the provision of the financial/ in-kind support from ineligible companies for the education.
- Learners must be able to easily distinguish
- Ineligible companies may not provide access to, or distribute, accredited education to learners.



Action Items

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

Action Items:

- Develop a process to easily distinguish CME from non-CME (agenda, sign placement).
- Understand the 30-minute rule.

Questions? Email me: aweir@osteopathic.org



Resources

- AOA CME Sponsor Resources:
 - <https://osteopathic.org/cme/cme-sponsor-accreditation/>
 - Will be updated next month for changes for 2023
- ACCME website
 - <https://www.accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce>
- Me 😊
 - aweir@osteopathic.org





Open Discussion

Kevin M. Klauer, DO, EJD, CEO



Adjourn

Kevin M. Klauer, DO, EJD, CEO



AOA CME: Tips for Ensuring Content is Valid

Adapted from the *ACCME Standards for Integrity and Independence* resources

Consider using the following best practices when presenting clinical content in accredited CME:

- Clearly describe the level of evidence on which the presentation is based and provide enough information about data (study dates, design, etc.) to enable learners to assess research validity.
- Ensure that, if there is a range of evidence, that the credible sources cited present a balanced view of the evidence.
- If clinical recommendations will be made, include balanced information on all available therapeutic options.
- Address any potential risks or adverse effects that could be caused with any clinical recommendations

Template for Peer Review: Ensuring that Clinical Content is Valid

Please answer the following questions regarding the clinical content of the education.

Are recommendations for patient care based on current science, evidence, and clinical reasoning, while giving a fair and balanced view of diagnostic and therapeutic options? *[Standards for Integrity and Independence 1.1]*

Does all scientific research referred to, reported, or used in this educational activity in support or justification of a patient care recommendation conform to the generally accepted standards of experimental design, data collection, analysis, and interpretation? *[Standards for Integrity and Independence 1.2]*

Are new and evolving topics for which there is a lower (or absent) evidence base, clearly identified as such within the education and individual presentations? *[Standards for Integrity and Independence 1.3]*

Does the educational activity avoid advocating for, or promoting, practices that are not, or not yet, adequately based on current science, evidence, and clinical reasoning? *[Standards for Integrity and Independence 1.3]*

Does the activity exclude any advocacy for, or promotion of, unscientific approaches to diagnosis or therapy, or 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? *[Standards for Integrity and Independence 1.4]*



AOA CME: Tips for Identification and Mitigation of Relevant Financial Relationships of Planners, Faculty, and Others

Adapted from the *ACCME Standards for Integrity and Independence* resources

Step 1: Review collected information about financial relationships and exclude owners or employees of ineligible companies from participating as planners or faculty.

- Ineligible companies are those whose primary business is producing, marketing, selling, reselling, or distributing healthcare products used by or on patients. For information about exceptions to this exclusion, see accme.org/standards

Step 2: Determine relevant financial relationships

- Financial relationships are relevant if:
 - A financial relationship, in any amount, exists between the person in control of content and an ineligible company.
 - The financial relationship existed during the past 24 months.
 - The content of the education is related to the products of an ineligible company with whom the person has a financial relationship.

Step 3: Choose a mitigation strategy for each person who has a relevant financial relationship.

Mitigation steps for planners (choose at least one)	Mitigation steps for faculty and others (choose at least one)
Divest the financial relationship	Divest the financial relationship
Recusal from controlling aspects of planning and content with which there is a financial relationship	Peer review of content by persons without relevant financial relationships
Peer review of planning decisions by persons without relevant financial relationships	Attest that clinical recommendations are evidence-based and free of commercial bias (e.g., peer-reviewed literature, adhering to evidence-based practice guidelines)
Use other methods (please describe):	

Step 4: Document the mitigation strategy(ies) you used for each person with a relevant financial relationship.

Name of person	Role(s) in Activity	Step(s) taken to mitigate relevant financial relationship	Date Implemented
Example: Dr. Smith	Faculty	Content peer reviewed by persons without relevant financial relationships to ensure content validity and fair balance.	7/26/2022
Example: Dr. Smith	Planner	Recusal from controlling aspects of planning and content with which there is a financial relationship (Dr. Smith left the room when planning and content for the cardiac arrest session due to a financial relationship with an ineligible company that produces CPR training equipment)	7/26/2022

Examples of Communicating Disclosures to Learners

If there are no relevant financial relationships	If there are relevant financial relationships
<i>Dr. Jane Smith, faculty for this educational activity, has no relevant financial relationship(s) with ineligible companies to disclose.”</i>	<i>Dr. Jane Smith, faculty for this educational activity, is on the speakers’ bureau for XYZ Device Company.</i>
<i>None of the planners for this educational activity have relevant financial relationship(s) to disclose with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.”</i>	<i>All of the relevant financial relationships listed for these individuals have been mitigated.</i>

Note: If commercial support is received, the accredited provider must also 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 to learners must not include ineligible companies’ corporate or product logos, trade names, or product group messages.



AOA CME: More Information on **Standard 5: Manage Ancillary Activities Offered in Conjunction with Accredited Continuing Education**

Here are more details on Managing ancillary activities.

- a. For Live activities: Marketing, exhibits, and nonaccredited education developed by or with influence from an ineligible company can't 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. For online activities: Learners shouldn't see any marketing while engaged in the accredited education activity. They must be able to engage with the accredited education without having to click through, watch, listen to product promotion or product-specific advertisement.

- c. Materials that are part of accredited education (such as slides, abstracts, handouts, evaluation mechanisms, or disclosure information) can't 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 like schedules and logistical information, can include marketing by or for an ineligible company.