

WORKING TOGETHER TO SUCCESSFULLY TRANSITION TO THE *STANDARDS FOR INTEGRITY AND INDEPENDENCE IN ACCREDITED CONTINUING EDUCATION*

October 28, 2021
1:00 – 2:30 pm CT



We Want To Engage With You!

Question and Answer Box Will Be Open

- ✓ Slide Presentation is Available For Download
- ✓ New Standards Resources are Available Now at <http://www.accme.org/standards-resources>
- ✓ Archived Recording of This Webinar Will Be Available Next Week on <http://www.accme.org>
- ✓ E-mail [**info@accme.org**](mailto:info@accme.org) with specific questions

ACCME Facilitators



**Graham McMahon,
MD, MMSc**
President & CEO



Dion Richetti
*Vice President of
Accreditation and
Recognition*



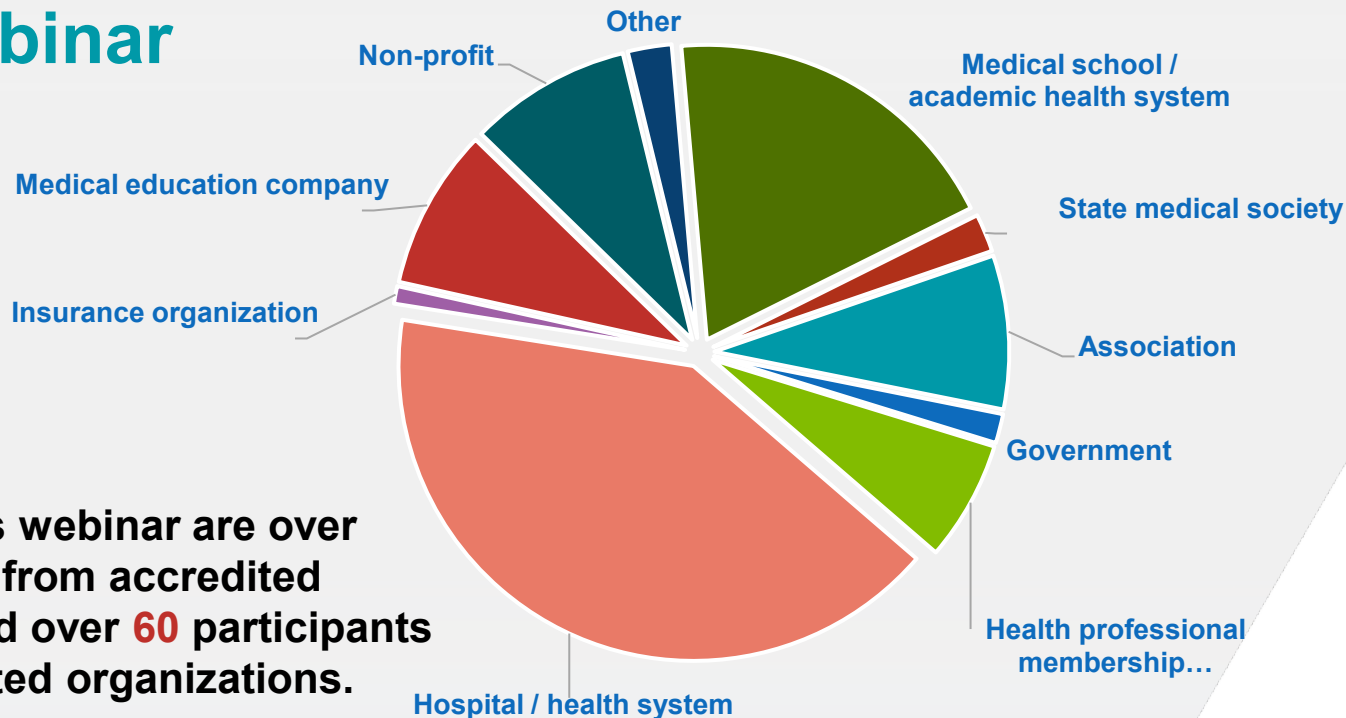
Marcia Martin
*Director of Provider
Education*



Steve Singer, PhD
*Vice President of
Education and
Outreach*

On The Webinar

Accredited Provider Organization Types



Joining us on this webinar are over **1200** participants from accredited organizations, and over **60** participants from non-accredited organizations.

Agenda for Today

- **Review the Revised Standards**
- **Hear from colleagues regarding implementation**
- **Review range of resources from ACCME**
- **Some cases**
- **Answers to your questions**

ACCME's Vision & Mission

ACCME's VISION is a world where our community of educators supports clinicians in delivering optimal healthcare for all.

ACCME's MISSION is to assure and advance quality learning for healthcare professionals that drives improvements in patient care.

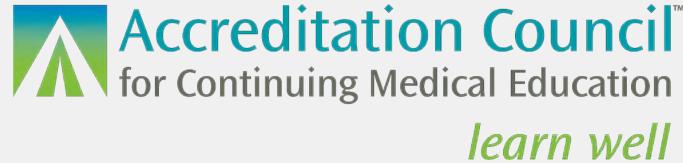
How Do We Meet Our Mission?

- ✓ **Set the standards**
- ✓ **Perform audits and surveys**
- ✓ **Support and educate CME providers**
- ✓ **Produce reports**
- ✓ **Evolve to meet the community's needs**

Provide clinicians the reassurance that the education they're participating in is:

- Balanced and evidence-based
- Designed for relevance: real needs and gaps
- Evaluated to guide safe, effective care
- Free of commercial influence and marketing

Responsive to Our Community



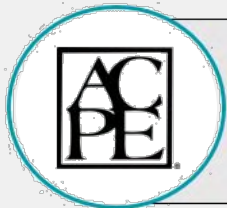
<http://www.accme.org/about-us/our-history>



Accreditation Council for Continuing
Medical Education (ACCME)



American Academy of PAs (AAPA)



Accreditation Council for Pharmacy
Education (ACPE)



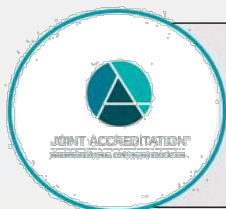
American Nurses Credentialing Center
(ANCC)



American Academy of Family
Physicians (AAFP)

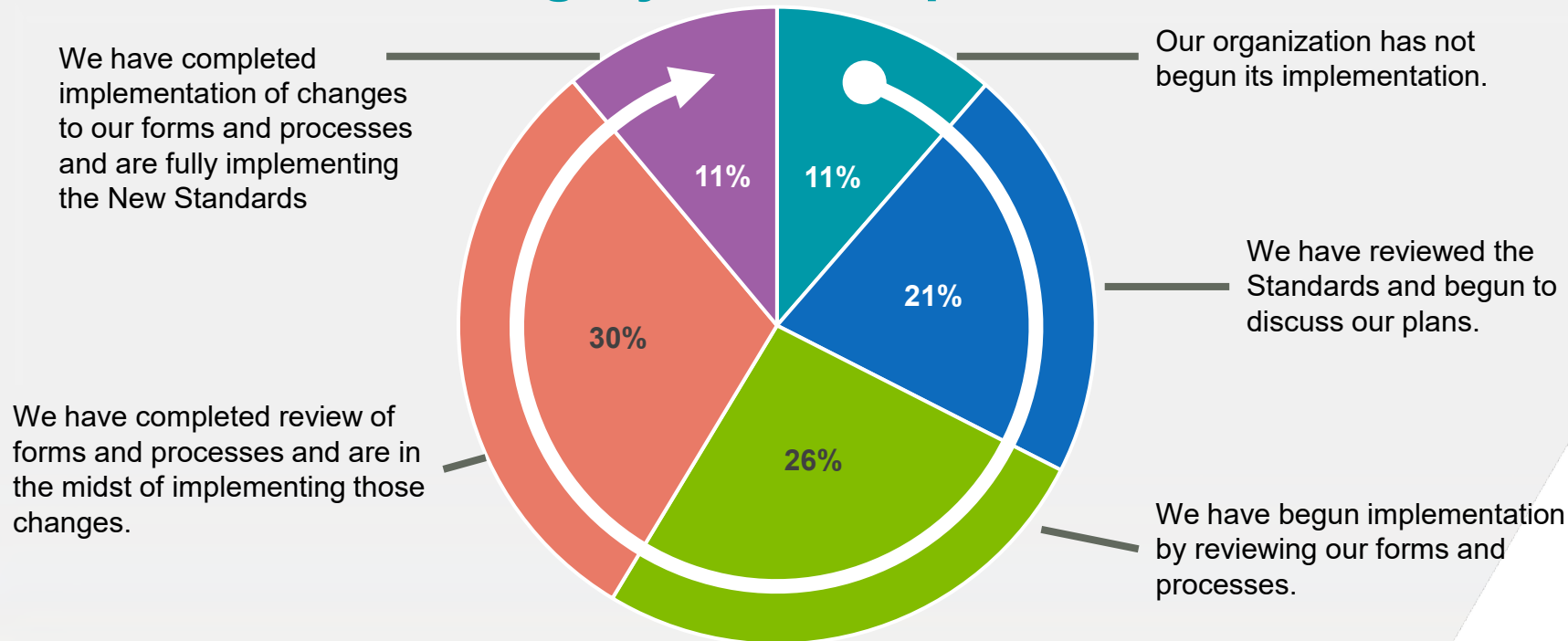


Association of Regulatory Boards of
Optometry's Council on Optometric
Practitioner Education (ARBO/COPE)



Joint Accreditation for Interprofessional
Continuing Education™

What is your progress towards implementing the Standards for Integrity and Independence?



What's New

Content Validity

- Policies and expectations incorporated into the Standards.

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, and accredited providers determine relevance of, financial relationships. 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 nonaccredited activities

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

Standards

Preamble/Eligibility (all)

Standard 1: Ensure Content is Valid (all)

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

Standard 3: Identify, Mitigate, and Disclose Relevant Financial Relationships (all)

Standard 4: Manage Commercial Support Appropriately (only if applicable)

Standard 5: Manage Ancillary Activities Offered in Conjunction with Accredited Continuing Education (only if applicable)

No disclosures needed

Non-clinical activities

- ✓ leadership, communication skills etc.

Spontaneous case conversations among peers

- ✓ bedside rounds, overnight cases

Self-directed education

- ✓ learning from teaching, remediation, personal development plan

What Is The Process To Ensure Independence From Commercial Influence In Accredited Continuing Education?



Collect information about financial relationships

We ask those who may have a role in controlling the CE content to disclose all financial relationships they have had over the past 24 months with *ineligible companies* (drug, device, and other companies ineligible for accreditation; see page 2 for the full definition).



Exclude owners or employees of ineligible companies

With a few exceptions, we exclude owners or employees of ineligible companies because their opportunity to insert commercial bias cannot be mitigated.



Identify and mitigate relevant financial relationships

We determine which financial relationships might allow control of CE content related to the business lines or products of an ineligible company and take steps to prevent the insertion of bias towards commercial products or services.



Disclose all relevant financial relationships to learners

We provide transparency to learners by informing them—prior to the CE activity—of the presence or absence of relevant financial relationships for all who were in control of the CE content, and that those relevant financial relationships were mitigated.



One Year Transition Phase

- Providers can immediately stop complying with requirements *that have been removed*.
- Accredited providers are expected to comply with *new or changed* requirements by **January 1, 2022**. We expect to begin measuring compliance after the transition phase.

***Note:** *This transition phase applies to providers that are ACCME-accredited, state-accredited, or jointly accredited. Providers accredited by other accrediting bodies that have adopted the Standards should contact their accreditor for information about the timeline.*

WORKING TOGETHER TO SUCCESSFULLY TRANSITION TO THE STANDARDS

LET'S HEAR FROM YOUR COLLEAGUES

Panelists

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WORKING TOGETHER TO SUCCESSFULLY TRANSITION TO THE STANDARDS

NEW RESOURCES TO SUPPORT YOUR IMPLEMENTATION

NEW STANDARDS RESOURCES

Standards Toolkit – Now in an Editable Microsoft Word Version

- ✓ Tools for Identifying, Mitigating, and Disclosing Relevant Financial Relationships
- ✓ Tools for Ensuring Valid Clinical Content
- ✓ Quick Tool to Simplify Educational Planning When Identification, Mitigation, and Disclosure is Not Required



Available now at <http://www.accme.org/standards-resources>

NEW STANDARDS RESOURCES

Courses on ACCME Academy

Key Concepts in the Standards for Integrity and Independence

40% COMPLETE

- Introduction and Overview
- Eligibility for Accreditation
- Vali
- Com
- Coni

Match each concept on the left with its definition on the right by clicking and dragging items in the left column to their corresponding partner in the right column.

Owners and Employees of Ineligible Companies	Occurring Within Past 24 Months; No Minimum Amount
Financial Relationships with Ineligible Companies	Nonresolvable financial relationships that cannot be mitigated
Financial ships	Before Those In Control of Content Take Their Roles in the Education

Graham McMahon, MD, MMSc
President and CEO, ACCME

Building Learner Trust with Independent CE

Curriculum

★★★★★

Resume

Available now at <https://academy.accme.org>

NEW RESOURCE FROM THE 2021 ANNUAL MEETING

Applying Standards for Integrity & Independence in Academic CPD Working Group

Facilitators:

- Barbara Anderson
- Kim Denny
- Dimitra Travlos
- Elizabeth Ward

Group Members:

- Stacy Atkinson
- Nikki Berry
- Nicole Brenson
- Sandy Deeba
- Kim DuQue Urdialez
- Janet Harszlak
- Lynn Hawk
- Dorothy Lane
- TJ Moore
- Julie ReBeau
- Sarah Ryan
- Erin Schwarz
- Ashley Thibodeaux
- Michelle Yoder
- Andrea Zimmerman

ACCME 2022 MEETING – APRIL 26-28 – HYBRID MEETING IN CHICAGO

Call for Proposals

Share YOUR expertise with your colleagues too, submit a Proposal for the ACCME 2022 Meeting!

Participate through one of the following opportunities:

- Inspire and Teach! Sessions
- CME Effectiveness & Best Practices: Engaging in CME Research
- Better Together: Working Groups

The deadline for submissions is Friday, November 5, 2021, by 11:59 pm CT.

Visit the [Call for Proposals page](#) for more information.

NEW STANDARDS RESOURCES

Planning Guide for Independence in Accredited Continuing Education

Electronic (PDF) document and companion Microsoft PowerPoint slide presentation that accredited providers can use with planners and faculty to explain the process for collecting, mitigating, and disclosing relevant financial relationships.

Available now at <http://www.accme.org/standards-resources>



NEW STANDARDS RESOURCES

Planning Guide (cont.)

Overview of how CE providers use the Standards to ensure independence in accredited education.

Available now at <http://www.accme.org/standards-resources>



What Is The Process To Ensure Independence From Commercial Influence In Accredited Continuing Education?

As the stewards of the learning environment for healthcare professionals, accredited continuing education (CE) plays a critical role in navigating the complex interface between industry and the health professions. Through our accreditation, we ensure 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 document provides an overview of the process we use to protect the integrity and independence of accredited CE activities.



Collect information about financial relationships

We ask those who may have a role in controlling the content of CE to disclose all financial relationships they have had over the past 24 months with ineligible companies



Exclude owners or employees of ineligible companies

With a few exceptions, we exclude owners or employees of ineligible companies because their opportunity to insert commercial bias cannot be mitigated



Identify and mitigate relevant financial relationships

We determine which financial relationships might allow control of CE content related to the business lines or products of an ineligible company and take steps to prevent the insertion of bias towards commercial products or services



Disclose all relevant financial relationships to learners

We provide transparency to learners by informing them—prior to the CE activity—the presence or absence of relevant financial relationships for all who were in control of the CE content, and that those relevant financial relationships were mitigated



Want to simplify? Stop and ask these questions...

Accredited CE providers do not need to identify, mitigate, or disclose relevant financial relationships education that meets one or more of the following exceptions:

- Will the accredited education be non-clinical, such as leadership or communication skills training?
- Will a learner group be solely in control of content of the accredited education, such as a spontaneous case conversation among peers?
- Will this be 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?

The four-part process above is required when accredited CE content provides recommendations about care, including the use of products or devices that are used on or by patients. Talk to your CE staff about opportunities to simplify.

NEW STANDARDS RESOURCES

Planning Guide (cont.)

Helpful, non-technical explanations of what is required from those who wish to participate as planners, teachers, and reviewers in accredited CE.

Who needs to disclose?

You need to participate in disclosing financial relationships if you are to have any of these roles in accredited continuing education:

Planners



E.g. Planning Committees, CE Staff, Editors, Activity Director

Teachers



E.g. Speakers, Panelists, Instructors, Trainers, Coaches, Educational Consultants

Authors



E.g. Writers, Editors, Instructional Designers, Content Developers, Educational Researchers, CE Staff

Reviewers



E.g. Peer Reviewers, Editors, CE Staff

What needs to be disclosed?

You must disclose all your financial relationships over the past 24 months with ineligible companies on this list.

Disclose relationships whether or not they have already ended during the past 24 months.

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

These are companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

They are **ineligible** to be accredited in the ACCME System.

Available now at <http://www.accme.org/standards-resources>

NEW STANDARDS RESOURCES

Planning Guide (cont.)

Explains how mitigation of relevant financial relationships occurs using the Standards.

Mitigate relevant financial relationships

Before the person assumes their role in the CE activity, take steps to mitigate by preventing all those with relevant financial relationships from inserting commercial bias into content

Planners, reviewers



Making decisions related to the scope and direction of the content, educational goals, identification of practice gaps and needs, selecting speakers, authors, reviewers

Teachers, authors



Teaching, writing, producing and delivering education

End the financial relationship

(including having ended the relationship within 24 months)

Recuse individual from controlling aspects of planning and content with which there is a financial relationship

Peer review planning decisions and review determinations by persons without relevant financial relationships

End the financial relationship

(including having ended the relationship within 24 months)

Recuse individual from controlling aspects of planning and content with which there is a financial relationship

Peer review of content 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)

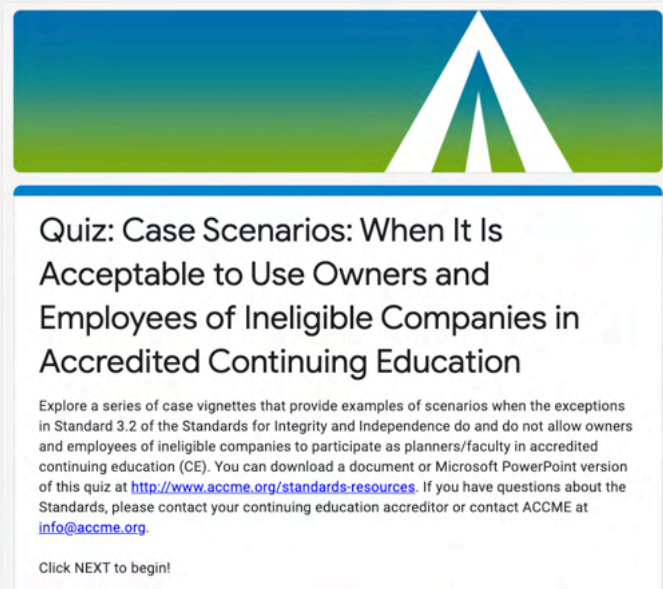
Available now at <http://www.accme.org/standards-resources>

NEW STANDARDS RESOURCES

Case Scenarios: When It Is Acceptable to Use Owners and Employees of Ineligible Companies in Accredited Continuing Education

- Document with multiple case vignettes
- Microsoft PowerPoint slides
- Online quiz

Available now at <http://www.accme.org/standards-resources>



ACCREDITATION PROCESS

Excel Spreadsheet for Documenting Financial Relationships

- Already part of ACCME's accreditation process
- Required for all performance in practice not under Standard 3 exceptions
- Efficient way to track management of financial relationships
- Where to find the template:
 - ✓ ACCME Website > Publications > Accreditation Requirements and Fees > Reaccreditation
 - ✓ <http://www.accme.org/standards-resources>

USING CASES TO THINK THROUGH MITIGATION OF RELEVANT FINANCIAL RELATIONSHIPS

Case 1: Standard 3 – Stockholder and Speakers' Bureau

A plastic surgeon has disclosed that she serves on a speakers' bureau for the manufacturer of an acne drug. She is facilitating a meet-the-professor discussion on challenging cases in managing scar revision for acne vulgaris.

What process, if any, is necessary to ensure that her discussions are balanced and evidence-based?

Mitigation approaches – for faculty

Teachers, authors



Teaching, writing, producing and delivering education

End the financial relationship

(including having ended the relationship within 24 months).

Recuse individual from controlling aspects of planning and content with which there is a financial relationship.

Peer review of content 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).

Case 2: Standard 3 – Abstract Reviewer

A dermatologist has been assigned to review and grade scientific abstracts for an upcoming annual meeting at which selected abstracts will be presented as part of the accredited CME. He is a compensated researcher for a company that has products in many areas of dermatology, which will likely be related to the abstract content.

How can this relationship be mitigated?

Mitigation approaches –for planners

Planners, reviewers



Making decisions related to the scope and direction of the content, educational goals, identification of practice gaps and needs, selecting speakers, authors, reviewers

End the financial relationship

(including having ended the relationship within 24 months).

Recuse individual from controlling aspects of planning and content with which there is a financial relationship.

Peer review planning decisions and review determinations by persons without relevant financial relationships.

Case 3: Standard 3- Patent holder

An orthopedic surgeon has obtained a patent for a new type of pedicle screw. She is receiving royalties from a device company that is commercializing the product.

Is she able to participate as a speaker in a CME activity presenting on spinal surgery, and if so, what are some steps that would mitigate this relationship?

Financial Relationships for Owners/Employees

Planners/Faculty	Disclosed and Mitigated	Excluded from CME
... has patents that result in royalties	X	
... consults for a biomedical startup or industry	X	
... is employed by a biomedical startup with no products yet	X	
... has stock or stock options in a medical company	X	
... is <u>employed</u> by or <u>owns</u> a biomedical enterprise AND has initiated approval at FDA or similar AND CME content is related to product(s) or business lines		X

The three exceptions for owners/employees...

Owners and employees of ineligible companies (such as pharma or a startup) can participate as presenters and planners in CME if...

the content of the activity is not related to the business lines or products of their employer/company.

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.

if 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.

Case 4: Working with an Owner

Dr. Potash is presenting on a new smoking cessation product, which she invented, that recently received FDA approval. She also owns the company that will be marketing the product. This medication is given using an implantable dispensing device. She will discuss different approaches to smoking cessation (without mentioning her product) and demonstrate the safe and proper implantation of the device on a volunteer.

Answer – Working with an Owner

Dr. Potash is presenting on a new smoking cessation product, which she invented, that recently received FDA approval. She also owns the company that will be marketing the product. This medication is given using an implantable dispensing device. She will discuss different approaches to smoking cessation (without mentioning her product) and demonstrate the safe and proper implantation of the device on a volunteer.

No, this scenario does not meet the exception.

Rationale: The presenter is going beyond teaching the safe and proper use of the device to include information about ways to help patients stop smoking cessation. This could create a reasonable opportunity to market smoking cessation products (including hers) to the learners.

Case 5: Working with an Employee

Dr. Jones is an employee of a company that produces and markets vaccines. She has been asked to speak on the logistics of supply chains as she previously worked for a company that pioneered global supply chains for vaccines requiring extremely low temperature storage.

Answer-Working with an Employee

Dr. Jones is an employee of a company that produces and markets vaccines. She has been asked to speak on the logistics of supply chains as she previously worked for a company that pioneered global supply chains for vaccines requiring extremely low temperature storage.

Yes, this scenario meets the first exception: not related.

Rationale: The logistics of supply chains (even if those are used for vaccines) is sufficiently separated from the clinical use of vaccines to make it unlikely the speaker would introduce bias about her company's vaccines.

QUESTION & ANSWER

Q&A

Q: When do we need to implement the 30-minute separation between accredited continuing education and another activity?

Q&A

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A: Implement separation if next activity is in the same space AND

a) is controlled by ineligible company OR

b) includes any clinical education OR

c) contains any marketing/promotion

Q&A

Q: Why would we ask “...has the relationship ended” on our disclosure form and how should we manage responses?

Q: Are we to use the term “relevant” financial relationship per the new standards?

Q&A

Q: Why would we ask “...has the relationship ended” on our disclosure form and how should we manage responses?

A: If the financial relationship is relevant and it has ended, then no other mitigation steps are necessary. That relevant relationship must still be disclosed to learners.

Q: Are we to use the term “relevant” financial relationship per the new standards?

A: The Standards have replaced the term “conflict of interest” with “relevant financial relationship” because of the negative connotation that some planners/faculty have with the concept of COI...it is up to you to decide what terminology you want to use.

Q&A

Q: Please confirm that once a relationship has been mitigated, the mitigation strategy does not have to be shared with learners.

Q&A

Q: Please confirm that once a relationship has been mitigated, the mitigation strategy does not have to be shared with learners.

A: The mitigation strategy does not need to be shared, but Standard 3 does require the provider to inform the learners that relevant financial relationships have been mitigated.

Q&A

Q: What record retention expectations have been affected by the New Standards?

Q&A

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A: Our abstract for performance-in-practice has been updated to reflect the new Standards. That's an easy way to ensure you're capturing the information needed.

Q&A

Q: We ask our learners whether they detected commercial bias. Should we continue to do that?

Q&A

Q: We ask our learners whether they detected commercial bias. Should we continue to do that?

A: ACCME's requirements have never required the use of a question for learners about commercial bias. We know some providers have chosen to include that as part of your own monitoring processes. Up to you if you want to continue...if it adds value.

Q&A

Q: Please clarify company logos from an ineligible company when they are being acknowledged as a commercial supporter. What's appropriate and what's not?

Q&A

Q: Please clarify company logos from an ineligible company when they are being acknowledged as a commercial supporter. What's appropriate and what's not?

A: No logos are ever allowed in the disclosure to learners of the source of commercial support.

THANK YOU

E-mail your questions to: info@accme.org