



Accreditation Council[™]
for Continuing Medical Education

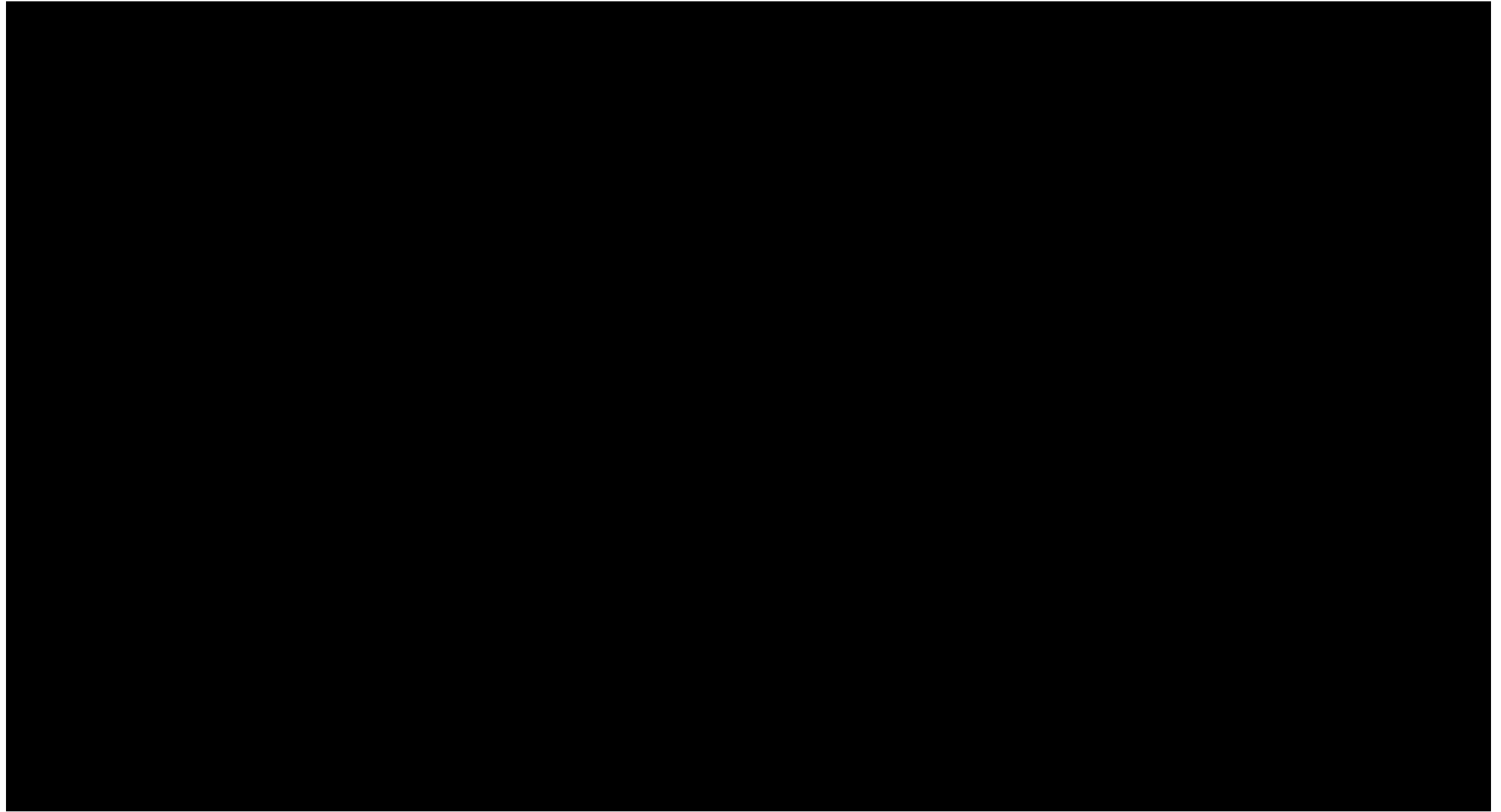
learn well

STANDARDS FOR COMMERCIAL SUPPORT

CHANGES ARE COMING
A Fall 2020 Update

First, a word from
Steve Singer, ACCME Vice President of
Education and Outreach

An Overview of the Current Standards



WHY ARE THEY CHANGING THEM?
WHAT DOES THAT MEAN, YOU ASK?



GOAL

The ACCME's has communicated their goal is to:

- 1) Streamline, clarify, and modernize the Standards**
- 2) Ensure the Standards continued relevance and effectiveness in the changing healthcare environment**

The initiative supports the ACCME's strategic goal to assure the quality of accreditation.

FIRST CHANGE:

RENAMING
THE
STANDARDS

ACCME Standards for Integrity
and Independence in
Accredited Continuing Education

BACKGROUND AND PURPOSE

The ACCME acts as the steward of the Standards.

- First adopted in 1992
- Last updated in 2004 (15 yrs ago)

BACKGROUND AND PURPOSE

Over the past 15 years, the Standards have become a national and international model, adopted by accreditors across the health professions.

Joint Accreditation for Interprofessional Continuing Education[™] adopted the Standards in its accreditation process for multiple health professions.

(simultaneous accreditation to provide [medical](#), [nursing](#), [pharmacy](#), and [optometry](#) CE activities through a single, unified application process, fee structure, and set of accreditation standards, offered only to ACCME directly-accredited organizations at this time.)

TASK FORCE CREATED

ACCME created and convened the **Task Force on Protecting the Integrity of Accredited Continuing Education**

- It represented diverse perspectives, including accredited CE providers and the public
- They identified new and existing challenges related to managing complex issues of:
 - Disclosure
 - Conflicts of interest
 - Commercial support

REVIEW PROCESS

- Call for feedback open to all (2019)
- Focus groups with accredited CE providers
- Discussion sessions with volunteers from ACCME Accreditation Review Committee and Committee for Recognition and Review
- Webinars with ACCME's Recognized Accreditors (SMS)
- Day-long meeting with accreditor colleagues in the health professions
- Conference call with FDA staff

REVIEW PROCESS

- Additional call for feedback from State Medical Societies (Feb 2020 – just prior to pandemic)
- Review by ACCME Board of Directors (Summer 2020)

INFORMATION
PACKAGE
AVAILABLE

Call For Comment Standards for Integrity and Independence in Accredited Continuing Education

Information Package

<https://www.accme.org/publications/call-for-comment-information-package-standards-for-integrity-and-independence>

APPROACH TO REVISIONS

In preparing proposed revisions to the Standards, the ACCME and Task Force agreed it was essential to:

- Consider potential effect of revisions on stakeholders, including accredited education providers, colleague accreditors in the health professions and international organizations
- **Minimize unintended consequences**

APPROACH TO REVISIONS

The revised Standards should:

- Modernize policy language and concepts
- Express expectations clearly
- Remain criterion-based, with objective rather than subjective statements, to allow for consistent accreditation decision-making.

OVERVIEW OF REVISIONS

STRUCTURE

- **New name** to reflect the scope and intent of the Standards
- **New overview section** to explain the principles and purpose of the Standards
- **Re-organization** beginning with Standards applicable to all accredited CE, followed by the Standards applicable to education that is commercially supported

OVERVIEW OF REVISIONS

STRUCTURE

- **Policies and definitions** are integrated into the Standards to provide all relevant requirements in ONE DOCUMENT
- **Brief introductions** to each Standard, describing its overall purpose and when it is applicable

OVERVIEW OF REVISIONS

NEW TERMS

- **Eligible entities:** Organizations that are eligible for accreditation in the ACCME system
- **Ineligible entities:** Organizations that are not eligible for accreditation, formerly called ***commercial interests***. The new term is intended to clarify that eligibility for accreditation is not based on whether an organization is for-profit or non-profit, but based on its primary mission and function.

OVERVIEW OF REVISIONS

NEW TERMS

- **Mitigate:** The term *mitigate* replaces *resolve*, in guidance related to relevant financial relationships, to clarify that accredited providers are expected to mitigate the potential effect of these relationships on accredited CE.
- **Accredited continuing education:** The term *accredited continuing education* replaces *continuing medical education* to be inclusive of all health professions. They include accredited to explicitly differentiate between accredited and non-accredited CE providers and education.

PROPOSED STANDARDS AT-A-GLANCE

NEW OVERVIEW SECTION

- Describes purpose and principles of the Standards
- Describes role of accredited CE providers in ensuring that accredited education serves the needs of patients.

PROPOSED STANDARDS AT-A-GLANCE

ELIGIBILITY SECTION

- Updated definitions of organizations that are eligible and ineligible for accreditation
- Updated lists of organizations that are eligible and ineligible
- Clarification about how corporate structure affects eligibility (parent/subsidiary companies)

PROPOSED STANDARDS AT-A-GLANCE

STANDARD 1:

ENSURE CONTENT IS VALID

- Incorporates the current CME Clinical Content Validation Policy
- **New:** Clarifies that education may inform learners *about* approaches that are not generally accepted but must not advocate for those approaches or teach *how* or *when* to use them.

PROPOSED STANDARDS AT-A-GLANCE

STANDARD 2:

PREVENT MARKETING OR SALES IN ACCREDITED CONTINUING EDUCATION

- Updates and simplifies the guidance for independence
- **New:** Prohibits faculty from marketing or selling their products or services during accredited CE.
- **New:** Accredited providers must receive consent from learners before sharing their names/contact information with ineligible entities.

PROPOSED STANDARDS AT-A-GLANCE

STANDARD 3:

IDENTIFY, MITIGATE AND DISCLOSE RELEVANT FINANCIAL RELATIONSHIPS WITH INELIGIBLE ENTITIES

- **New:** Accredited providers must collect disclosure information from those in control of content about all of their financial relationships with ineligible entities.

It is the accredited provider's responsibility to determine which relationships are relevant. Individuals must disclose regardless of their view of the relevance of the relationship to education.

- Simplified definition of *relevant financial relationships*

PROPOSED STANDARDS AT-A-GLANCE

STANDARD 3: (continued)

- Clarification that owners or employees of ineligible entities (formerly *commercial interests*) must be excluded from controlling content or participating as planners or faculty.
- Simplified guidance on identifying, mitigating, and disclosing relevant financial relationships.
- **New:** When disclosing relevant financial relationships to learners, accredited providers must include a statement that all relevant financial relationships have been mitigated.
- **New:** Exception for self-directed (POC) education, where learner is in control of content and there are no planners/faculty. In these cases, accredited providers do not need to identify, mitigate, or disclose relevant financial relationships.

PROPOSED STANDARDS AT-A-GLANCE

STANDARD 4: MANAGE COMMERCIAL SUPPORT APPROPRIATELY

- Simplified guidance about decision-making and disbursement, agreements, accountability, and disclosure to learners.
- **New:** Accredited providers must pay or reimburse expenses to individuals such as faculty; joint providers cannot make these payments.
(BIG CHANGE)

PROPOSED STANDARDS AT-A-GLANCE

STANDARD 5:

MANAGE ANCILLARY MARKETING AROUND ACCREDITED CE

- Simplified, updated guidance about the separation of accredited education and marketing by ineligible entities.
- Clarifies that learners must be able to easily distinguish between accredited CE and other activities, such as non-accredited CE and marketing. These other activities must not be interleaved (interspersed) within the accredited education.

A DEEPER DIVE

Types of Organizations That May Be Accredited in the ACCME System

Eligible Entities: Entities eligible to be accredited in the ACCME System are organizations whose primary 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
- Nonprofit organizations
- Nursing homes
- Pharmacies As workplace of pharmacist
- Publishing or education companies
- Software or game developers
- Rehabilitation centers
- Schools of medicine or health science universities
- Technology or data management companies (non-health related)

A DEEPER DIVE

Types of Organizations That *Cannot* Be Accredited in the ACCME System

Ineligible Entities: Entities that are ineligible to be accredited in the ACCME System are organizations 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 entities)
- Bio-medical startups (that have begun an approval process through the FDA)
- **Compounding pharmacies (that manufacture proprietary compounds)**
- Device manufacturers or distributors
- **Diagnostic labs (that market or sell proprietary products)**
- **Growers, distributors, or sellers of medical foods and dietary supplements**
- Pharmaceutical companies or distributors
- Pharmacy benefit managers
- Reagent manufacturers/sellers
- Manufacturers of health-related wearable products

A DEEPER DIVE

RE-ORGANIZATION

Applies to all accredited continuing education.

- Standard 1: Ensure Content is Valid
- Standard 2: Prevent Marketing or Sales in Accredited Continuing Education
- Standard 3: Identify, Mitigate, and Disclose Relevant Financial Relationships with Ineligible Entities

Applies only to accredited continuing education that receives financial or in-kind support from ineligible entities.

- Standard 4: Manage Commercial Support Appropriately

Applies only when there is marketing by ineligible entities associated with the accredited continuing education.

- Standard 5: Manage Ancillary Marketing around Accredited Continuing Education

SMS FEEDBACK/ CONCERNS IN CALL FOR RESPONSES



FEEDBACK RE: NEW TERMINOLOGY

- “Mitigate” – Is there a need for a new word for resolve? (Mitigate means to “make less severe.” Does mitigate send the message that CME providers only want to make financial relationships “less severe” or “resolve” them?)
- The new term – Accredited Continuing Education may cause confusion with CEs. Why not keep the term Accredited Continuing **Medical** Education, it helps differentiate (ie, CLE – continuing legal education)

SMS
FEEDBACK/
CONCERNS
IN CALL FOR
RESPONSES

FEEDBACK RE: STANDARD 1

- Seem fairly-well aligned with current content validation rules and do a good job of consolidating them into one place.

SMS
FEEDBACK/
CONCERNS
IN CALL FOR
RESPONSES

FEEDBACK RE: STANDARD 2

- Clarification regarding whether exhibitors are included in this standard. Can the consent be an opt out vs. obtaining written consent from learners to share names/contact information with ineligible entities (*commercial interests*)
- Does this mean that an author of a book could not promote that book in accredited CE? In the past, ACCME's response has been "this isn't prohibited."

SMS
FEEDBACK/
CONCERNS
IN CALL FOR
RESPONSES

FEEDBACK RE: STANDARD 3

- Will the current COI Flowchart be updated to reflect this new process?
- What resources will be available to CME providers to help determine relevancy of financial relationships?
- Shifts the burden from planners/faculty onto accredited CME providers for identifying all financial relationships with ineligible entities and then deciding if they are relevant/related to content. I don't see how it adds value to the integrity of CME to justify the increase in labor.

SMS
FEEDBACK/
CONCERNS
IN CALL FOR
RESPONSES

FEEDBACK RE: STANDARD 4

- With respect to requirement that accreditors in a joint-providership relationship control disbursement of funds, please note this will create a significant administrative burden on smaller organizations that rely on joint providership as a revenue stream.
- Currently the accredited provider is aware of commercial support received, as they sign all agreements and approve activities in joint providerships. They also ask for a detailed budget and summary of how funds were used. Why does this need to change? What problem is this change trying to solve?

SMS
FEEDBACK/
CONCERNS
IN CALL FOR
RESPONSES

FEEDBACK RE: STANDARD 5

- Providers have concerns about prohibition of non-accredited education being “interleafed” (interspersed) with accredited education. This would cause problems for many providers, because of the expense and logistics required for a separate room.
- This would make it impossible to have a session of non-accredited education scheduled immediately before or after a CME activity.

SMS FEEDBACK/ CONCERNS IN CALL FOR RESPONSES

FEEDBACK RE: IMPLEMENTATION PHASE

- “Crosswalk” will be needed between the old standards and the new.
- Resources must be practical and applicable and available at the beginning of the phased implementation.
- ACCME should allow ample time, recognizing the need to update forms, processes and policy language, as well as educating all individuals involved in planning and implementation.
- These changes have come at a time when there are so many changes to be made it is truly overwhelming for all of us.

ACCME
BOARD
ACTIONS

Board made modifications and has adopted a set of revised Standards.

We do not yet know what those modifications are.

ACCME plans to announce in Dec. 2020

NEXT STEPS

WHAT WE DO KNOW:

ACCME will release a transition plan for the accredited CE community.

Plan will include:

- Transition phase to give accreditors (SMS), accredited educational providers, faculty and stakeholders time to prepare to meet expectations of the revised Standards.

NEXT STEPS

The current
Standards for Commercial Support
will remain in place

AND

accredited CE providers should
continue to comply with them,
in addition to complying with other
accreditation requirements.



Stay
tuned