

STANDARDS FOR COMMERCIAL SUPPORT:

Changes Have Been Adopted

- A Spring 2021 Update -



A NEW NAME now called:

Standards for Integrity and Independence in Accredited Continuing Education

First adopted in 1992 and last updated in 2004 (17 years ago)



Intent

- Since the standards were last revised in 2004, the health care ecosystem has changed considerably, creating new challenges for protecting CME from industry bias.
- The revisions made are intended to streamline, clarify and modernize the Standards and ensure that the accredited CME system delivers on its promise to facilitate quality and unbiased education to the profession in a changing health care environment.



Trust is Core to the Value of Accredited CME

Additionally, because health care professionals serve as the legally mandated prescribers of medications, are responsible for the use of many devices, and are trusted authorities when advising patients, educators must protect the learning environment from industry influence to ensure the profession remains true to its ethical commitments.

Excerpt from JAMA article by Graham McMahon, ACCME President; *JAMA*. April 15, 2021; 325(18):1833-1834

https://jamanetwork.com/journals/jama/article-abstract/2778925





Standards for Integrity and Independence in Accredited Continuing Education

Released December 2020

Information Package

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401 N. Michigan Ave., Suite 1850 | Chicago, IL 60611 | Phone; 312-527-9200 | www.accme.org

ACCME has published a downloadable Information Package

containing an introduction to the new Standards, a transition timeline, the Standards at a Glance noting changes, and full text of the Standards

The following link can be used to access this information.

https://accme.org/standards-resources



Let's go to that link and Listen to a Brief Introductory Video by Graham McMahon, ACCME President



https://accme.org/standards-resources



Changes in Structure



learn well

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.

New overview (Preamble)

explaining principles and purpose of the Standards



Changes in Structure (con't)

- Re-organization of Standards based on applicability (those applicable to all CME listed 1st, followed by standards applicable to programs that are commercially supported)
- Policies & definitions integrated into the Standards themselves (requirements all in one place now)
- Brief introductions to each Standard



Changes in Terminology

- Eligible/Ineligible Companies replaces term Commercial Interest
- Mitigate replaces term Resolve, in vetting relevant financial relationships
- Accredited Continuing Education replaces term Continuing Medical Education to be inclusive of all health professions



With the new term Accredited Continuing Education, will we refer to this as ACE or CE in lieu of CME?

Per ACCMF.....

This term is really for reference within the Standards, which are used by many accreditors.

- (ACCME) Accreditation Council for Continuing Medical Education
- (ACPE) Accreditation Council for Pharmacy Education

- (AAFP) American Academy of Family Physicians (ANCC) American Nurses Credentialing Center (COPE) Council on Optometric Practitioner Education
- (JAICE) Joint Accreditation for Interprofessional Continuing Education

No changes have been made to the Accreditation Statement or the Accreditation Statement Policy. The ACCME has chosen to use the term accredited continuing education in the new Standards to be inclusive of all health professions.

There is no expectation that providers will change their terminology. You may continue to use the terms "continuing medical education" or "CME" as appropriate. Providers should feel free to use any of the acronyms, depending on their mission and the target audience they are reaching.



Let's take a much closer look at the changes to the Standards





Providers can IMMEDIATELY stop complying with requirements that have been removed

This includes the following:

- Individuals no longer need to disclose the financial relationships of their spouse or partner
- A formal written policy on Honoraria & Expense Reimbursement is no longer required, though providers still want to have a process in place.
- Providers no longer need to identify, mitigate or disclose relevant financial relationships for CME activities that are nonclinical in nature (i.e., leadership development, physician burnout, financial wellness for physicians, etc.)



Eligibility Section

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



Eligible Organizations

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



- Rehabilitation centers
- Schools of medicine or health science universities
- Software or game developers



As the workplace of the pharmacist



Ineligible Companies

(formerly known as Commercial Interests)

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

Previous definition of a Commercial Interest:

Any entity producing, marketing, re-selling, or distributing health care goods or services, used on, or consumed by, patients.



Owners and Employees of Ineligible Companies

- Owners and employees of ineligible companies are still considered to have unresolvable financial relationships and must be excluded from participating as planners or faculty.
- Ineligible companies are still prohibited from engaging in Joint Providership with accredited providers.
- Subsidiaries of an ineligible company cannot be accredited regardless of steps taken to firewall the subsidiaries.



Standard 1: Ensure Content is Valid

Applies to all accredited CE

- Incorporates/Replaces the current CME Clinical Content Validation Policy.
- Clarifies that education is an appropriate place to discuss, debate and explore new and evolving topics, but these areas need to be clearly identified as such within the program and individual presentations.

Providers must 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. (i.e., CBD or legalized marijuana)



Standard 2: Prevent Commercial Bias and Marketing in Accredited CE

Applies to all accredited CE

- Updates and simplifies the guidance for independence.
- **New**: Prohibits faculty from promoting or selling products or services that serve their professional or financial interests during accredited education (i.e., book promotion; referral of patients).
 - A faculty member can reference a book they've written, but no overt promotion
 - Book sales would be allowed outside of the educational space; provider may also raffle off a book
- New: Accredited providers must receive explicit consent from learners before sharing their names or contact information with ineligible companies or their agents.
 - Accredited provider is expected to explain to learners that you intend to share their information with an ineligible company. You can do that at registration; however, the learner must have the ability to opt out and still register for your activity.



Applies to all accredited CE

Simplified guidance on identifying, mitigating, and disclosing relevant financial relationships, while at the same time adding more rigor to the process.

COLLECTION

- New: Accredited providers must collect disclosure information from those in control of content about <u>ALL</u> of their financial relationships with ineligible companies. It is the accredited provider's responsibility to determine which relationships are relevant.
 - Individuals (planners and speakers) must disclose regardless of their view of the relevance of the relationship to education.
 - Financial relationships are relevant if the educational content an individual can control is related to the *business lines or products* of the ineligible company.
 - Example: If faculty advise they will not be discussing a company's products, but they will be talking about a therapeutic area of interest for said company, providers must still disclose the relationships – they are considered relevant.



COLLECTION

- New: Individuals must disclose relationships with ineligible companies within the prior 24 months (changed from the current requirement of 12 months).
 - You can choose whether to collect disclosure information when planning each activity or on a periodic basis, such as annually. If you choose to collect the information periodically, it is important to ask the person to update the disclosure if anything changes.
 - You will not be changing the frequency of disclosure collection, but rather the "look-back" period.
 - A disclosure form is one mechanism that providers might use. Other examples could include:
 - Collecting the information verbally and recording it in a spreadsheet, table, or database
 - Collecting disclosure information electronically (i.e, via e-mail, webbased form, or database)



COLLECTION

- Removed: Individuals no longer need to disclose the financial relationships of their spouse or partner.
- Clarifies that research grants from ineligible companies are financial relationships that should be disclosed, even if the funds go to the researcher's institution and not to the individual researcher.
- Clarifies that owners or employees of ineligible companies must be excluded from controlling content. (Includes the 3 exceptions to this exclusion, which should only be allowed cautiously.
 - 1) When the content of the activity is not related to the business lines or products of their employer/company.
 - 2) 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.
 - 3) 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

- New: Accredited providers do not need to identify, mitigate, or disclose relevant financial relationships for education that is **non-clinical in nature**, or where the learner group is in control of content, such as **spontaneous case conversations among peers**.
 - Regularly scheduled series, case conferences, or tumor boards are not considered "spontaneous case conversations among peers." The exception does not apply to conferences or rounds that have set times and dates and have traditionally been planned as accredited CME.
 - The exception is meant to apply to spontaneous learning opportunities that previously might not have been considered CME, like team huddles and impromptu leadership discussions. In these cases, with the guidance of the CME Department, learners can describe the learning opportunity (problem-in-practice and change that resulted) by using the new Quick Tool, which provides a good framework for spontaneous learning opportunities.



For more information, visit accme.org/standards

What is your name and email? Name: Email: When will the education take place? Date: Do you have a title or brief description for the Title/Brief Description: education? If yes, please note it to the right; if no, leave blank. Examples: Emergency Department team huddle; Leadership in a time of crisis; Well-being check-In What practice-based problem (gap) will this education Practice-based problem (gap): Examples: Improve care coordination; Better communication with patients and families; Want to give better feedback to students What is/are the reason(s) for the gap? Reason(s) for the gap: How are your learners involved? Examples: We need strategies to discuss difficult topics with family members; Don't know best ways to improve team collaboration Review the three statements to the right. The education will... (check all that apply) If you can check any of these boxes, you do not need to identify, only address a non-clinical topic (e.g., leadership or mitigate, and disclose relevant financial relationships. communication skills training). If you unable to check any boxes, please contact your CE be for a learner group that is in control of the content (e.g., program administrator to implement processes for ensuring the spontaneous case conversation among peers). integrity and independence of this education. be a self-directed educational activity where the learner will control their educational goals and report on changes that resulted (e.g., learning from teaching, remediation, or a personal development plan). What change(s) in strategy, performance, or patient Desired change(s) in strategy, performance, or patient care: care would you like this education to help learners accomplish? Examples: Eliminate stigmatizing language from communications with patients; Improve my management skills In order to award CME/CE credit, please indicate the Education duration: hours and minutes duration of the education. Please report time in 15-minute increments. Discuss with learners the changes they intend to make Changes learners intend to make to strategies, performance, or patient to their strategies, performance, or patient care that will result from this activity and list that information to the right. Example: I will use the evidence-based checklist we discussed to improve screening my patients for past military service. After the activity, please collect attendance and learner change information for the activity and send it to the continuing education department in order for credit to be awarded. You can also list the attendees on the back of this form.

No

Note for Continuing Education Staff

This completed form provides the necessary information to demonstrate the professional practice gap and underlying needs, expected results, appropriate format, changes in learners, independence, and administrative information needed to award credit to learners. Please enter this activity in ACCME PARS following your usual process, and provide to learners your accreditation statement, the credit designation statement, and any applicable MOC statements. If you have awarded MOC credit, please report learners in PARS within 30 days of the education. For questions or assistance, contact ACCME at info@accme.oru.

Excerpted from the Toolkit for the Standards for Integrity and Independence in Accredited Continuing Education © 2020 by the Accreditation Council for Continuing Medical Education (ACCME®)

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Quick Tool – Part of the ACCME's new Toolbox

This completed form provides the necessary information to demonstrate the professional practice gap and underlying needs, expected results, appropriate format, changes in learners, independence, and administrative information needed to award credit to learners.



MITIGATION – Point of Clarification

- For a journal-based CME activity, providers do not need to identify, mitigate and disclose to learners the relevant financial relationships for the authors and editors of the article.
 - ACCME advises that process is handled by the journal editors.
 Disclosure by authors is a standard component of published articles, and the editorial review process manages that mitigation.
 - The accredited provider **does**, however, need to identify, mitigate, and disclose relevant financial relationships for those involved in planning the journal-based CME activity (i.e., the person(s) choosing the article(s) and/or writing the evaluation mechanism.)



MITIGATION

- Reminder: It is important to mitigate relationships prior to the individuals assuming their roles and take steps appropriate to that role (steps vary between planners and speakers).
 - Planners and other content experts can help determine relevance of relationships, if necessary.
 - Keep in mind that simply monitoring the CME content for commercial bias at the time of presentation is not an acceptable mitigation mechanism. (When providers identify relevant relationships, they must direct authors/teachers to take actions to assist in the mitigation.)
- Clarifies that providers should document the steps taken to mitigate relevant financial relationships.
 - A COI mitigation (resolution) form is one mechanism that providers might use.

Other examples could include:

- Recording the steps you took in a spreadsheet, table, or database.
- Saving your conversation and steps you took in an email to planners of faculty

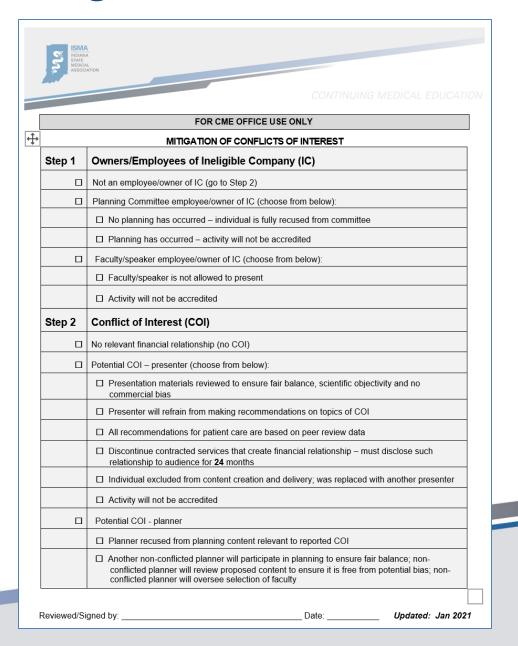


COI Mitigation (Resolution) Spreadsheet for Use with Individual Activities

Name of Individual	Individual's Role(s) in Activity	Name of Commercial Interest(s)	Nature of Relationship(s)	Mechanism(s) implemented to resolve conflict of interest appropriate to role(s) in the activity



COI Mitigation (Resolution) Form





DISCLOSURE

- New: When disclosing relevant financial relationships to learners, accredited providers must include a statement that "all relevant financial relationships have been mitigated."
- **Reminder**: Accredited providers must also still disclose the absence of relevant financial relationships when there are none.

Learners must receive disclosure information, in a format that can be verified at the time of reaccreditation, before engaging with the accredited education.



Standard 4: Manage Commercial Support Appropriately

Applies only to accredited CE that receives financial or in-kind support

- **Simplified** guidance about decision-making and disbursement, agreements, accountability, and disclosure to learners.
- Clarifies that an accredited provider can sign onto an existing commercial support 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.
 - Reminder: The accredited provider must disclose to the learners the name(s) of the ineligible company(ies) that gave commercial support.
 - It is best practice to disclose/acknowledge non-commercial support as well, but not mandated.
 - Reminder: A formal written policy on Honoraria & Expense Reimbursement is no longer required.

NOTE:

 ACCME removed the proposed requirement prohibiting joint providers from paying or reimbursing expenses to individuals such as faculty.



Standard 5:

Manage Ancillary Activities Offered in Conjunction with Accredited Continuing Education

Applies only when there is marketing by ineligible companies or non-accredited education associated with the accredited CE

- Simplified, updated guidance about the separation of accredited and non-accredited education
- Clarifies that learners must be able to easily distinguish between accredited education and other activities, such as non-accredited CE and marketing by ineligible companies.



Standard 5 (Con't): Manage Ancillary Activities Offered in Conjunction with Accredited Continuing Education

- New: Defined how much time (30-minute interval) must separate accredited activities from non-accredited activities if they are held in the same educational space.
 - What is the definition of educational space? Where the learner is engaging with content, material and faculty.
 - You do not need to wait 30 minutes after an accredited CE session before opening exhibits in another room. The key with this window of time is 'within the same educational space.'
 - Marketing and non-accredited education can take place at the same time as accredited education as long as it is in a different room and is clearly communicated to learners.
 - There does not need to be a 30-minute interval between accredited education and sessions that fit the exceptions listed in Standard 3 (ie, legislative briefing or awards ceremony).



Standard 5 (Con't): Manage Ancillary Activities Offered in Conjunction with Accredited Continuing Education

QUESTION: Does there need to be a 30-minute interval between accredited and non-accredited education in **virtual activities**?

ANSWER: For live, online activities, if the learner will remain in the same "virtual space" for a non-accredited session, then the provider must ensure that there is a 30-minute interval before or after accredited education.

If the learner is required to leave the virtual space to transition between accredited and non-accredited activities, and will need to take an action, such as clicking a link that clearly communicates that they are leaving the accredited education, then there is no time-interval requirement.



Tools and Forms

Tools have been developed to support providers with the implementation of the new Standards.

We'll go over those shortly.



Toolkit for the Standards for Integrity and Independence in Accredited Continuing Education



Reorganization of ACCME Accreditation Criteria

With the update to the Standards, ACCME decided to simplify the organization and naming of the Accreditation Criteria.

AT A GLANCE

• Eliminated Accreditation Criteria 7-10: These criteria referred to the Standards for Commercial Support. To simplify, they removed the redundancy of embedding the Standards in the Accreditation Criteria.

C7: The provider develops activities independent of commercial interests

- Avoiding use of employees/owners of commercial interests (ineligible entities)
- Conflict of interest resolution (mitigation)
- Conflict of interest disclosure to learners

C8: The provider appropriately manages commercial support

C9: The provider maintains a separation of promotion from education

C10: The provider activity promotes improvements in health care and NOT proprietary interests of a commercial interest (ineligible entity)



Reorganization of ACCME Accreditation Criteria (continued)

- New structure: The Core Accreditation Criteria (formerly Criteria 1–13) are reorganized and grouped into topic areas to better reflect the Plan Do Study Act (PDSA) cycle, which is the foundation of the criteria. ACCME refers to these as the core criteria to differentiate them from the commendation criteria.
- Keywords, not numbers: ACCME replaced the numbering system with keywords to more clearly identify the purpose of each criterion. This change applies to the Core Accreditation Criteria and the Menu of Criteria for Accreditation with Commendation.



New Look and Feel of the Core Criteria

Accreditation Criteria

Initial applicants seeking to achieve Provisional Accreditation, a two-year term, must comply with the following Core Accreditation Criteria: Mission, Program Analysis, Educational Needs, Designed to Change, and Analyzes Change.

Providers seeking Accreditation, a four year-year term, must comply with all the Core Accreditation Criteria. Accredited providers also have the option to seek Accreditation with Commendation, a six-year term. See the explanation below.

All providers must comply with the applicable Standards for Integrity and Independence in Accredited Continuing Education and applicable policies.

Core Accreditation Criteria			
CME Mission and Program Improvement			
Mission	The provider has a CME mission statement that includes expected results articulated in terms of changes in competence, performance, or patient outcomes that will be the result of the program. (formerly Criterion 1)		
Program Analysis	The provider gathers data or information and conducts a program-based analysis on the degree to which the CME mission of the provider has been met through the conduct of CME activities/educational interventions. (formerly Criterion 12)		
Program Improvements	The provider identifies, plans and implements the needed or desired changes in the overall program (eg, planners, teachers, infrastructure, methods, resources, facilities, interventions) that are required to improve on ability to meet the CME mission. (formerly Criterion 13)		

Educational Planning and Evaluation		
Educational Needs	The provider incorporates into CME activities the educational needs (knowledge, competence, or performance) that underlie the professional practice gaps of their own learners. (formerly Criterion 2)	
Designed to Change	The provider generates activities/educational interventions that are designed to change competence, performance, or patient outcomes as described in its mission statement. (formerly Criterion 3)	
Appropriate Formats	The provider chooses educational formats for activities/interventions that are appropriate for the setting, objectives, and desired results of the activity. (formerly Criterion 5)	
Competencies	The provider develops activities/educational interventions in the context of desirable physician attributes (competencies). (formerly Criterion 6)	
Analyzes Change	The provider analyzes changes in learners (competence, performance, or patient outcomes) achieved as a result of the overall program's activities/educational interventions. (formerly Criterion 11)	

You'll notice the crosswalk between the old numbering system and the new topic areas.



Reorganization of ACCME Accreditation Criteria (continued)

- No changes to the Core Accreditation Criteria: There are no changes to the wording or expectations of the Core Accreditation Criteria (formerly Criteria 1–13), except for the removal of Criteria 7-10 and replacement of numbers with keywords, as described above.
- Menu of Criteria for Accreditation with Commendation: There are *no* changes to the commendation criteria, except that the numbers have been replaced with keywords, as described above. As before, compliance with the menu is an *option*, not a requirement.



Reorganization of ACCME Accreditation Criteria (continued)

- Compliance expectations: Providers will be evaluated for compliance with the Core Accreditation Criteria, applicable Standards for Integrity and Independence in Accredited Continuing Education, and applicable policies.
- Data entry: ACCME plans to update the Program and Activity Reporting System (PARS) and accreditation management system in Summer 2021 to reflect these changes.

We'll be talking about THIS later in the day.



New Look and Feel of the Commendation Criteria

Menu of Criteria for Accreditation with Commendation (optional)

Improves Patient/Community

Health

To be eligible for Accreditation with Commendation, CME providers must demonstrate compliance with all of the Core Accreditation Criteria, in addition to eight criteria from the commendation menu. Choosing from the menu, providers need to demonstrate compliance with any seven criteria of their choice, from any category, plus one criterion from the "Achieves Outcomes" category, for a total of eight criteria.

All providers must demonstrate compliance with the applicable Standards for Integrity and Independence in Accredited Continuing Education and applicable policies.

Promotes Team-based Educa	tion
Engages Teams	Members of interprofessional teams are engaged in the planning and delivery of interprofessional continuing education (IPCE). (formerly Criterion 23)
Engages Patients/Public	Patient/public representatives are engaged in the planning and delivery of CME. (formerly Criterion 24)
Engages Students	Students of the health professions are engaged in the planning and delivery of CME. (formerly Criterion 25)
Addresses Public Health Prior	rities
Advances Data Use	The provider advances the use of health and practice data for healthcare improvement. (formerly Criterion 26)
Addresses Population Health	The provider addresses factors beyond clinical care that affect the health of populations. (formerly Criterion 27)
Collaborates Effectively	The provider collaborates with other organizations to more effectively address population health issues. (formerly Criterion 28)
Enhances Skills	
Optimizes Communication Skills	The provider designs CME to optimize communication skills of learners. (formerly Criterion 29)
Optimizes Technical/Procedural Skills	The provider designs CME to optimize technical and procedural skills of learners. (formerly Criterion 30)
Creates Individualized Learning Plans	The provider creates individualized learning plans for learners. (formerly Criterion 31)
Utilizes Support Strategies	The provider utilizes support strategies to enhance changes as an adjunct to its CME. (formerly Criterion 32)
Demonstrates Educational Le	adership
Engages in Research/Scholarship	The provider engages in CME research and scholarship. (formerly Criterion 33)
Supports CPD for CME Team	The provider supports the continuous professional development of its CME team. (formerly Criterion 34)
Demonstrates Creativity/Innovation	The provider demonstrates creativity and innovation in the evolution of its CME program. (formerly Criterion 35)
Achieves Outcomes	
Improves Performance	The provider demonstrates improvement in the performance of learners. (formerly Criterion 36)
Improves Healthcare Quality	The provider demonstrates healthcare quality improvement. (formerly Criterion 37)

The provider demonstrates the impact of the CME program on patients or their

communities. (formerly Criterion 38)





New Look and Feel of Document for Menu of Commendation Criteria - Showing Critical Elements



learn well

	MENU OF CRITERIA FOR ACCREDITATION WITH COMMENDATION					
CRITER	ION	RATIONALE	CRITICAL ELEMENTS	STANDARD		
Promote	s Team-based Education					
Engages Teams	Members of interprofessional teams are engaged in the planning and delivery of interprofessional continuing education (IPCE). (formerly C23)	Interprofessional continuing education (IPCE) occurs when members from two or more professions learn with, from, and about each other to enable effective interprofessional collaborative practice and improve health outcomes. This criterion recognizes accredited providers that work collaboratively with multiple health professions to develop IPCE.	Includes planners from more thanoneprofession (representative of the target audience) AND Includes faculty from more than oneprofession (representative of the target audience) AND Activities are designed to changecompetence and/or performance of the healthcareteam.	Attest to meeting this criterion in at least 10% of activities (but no less than two) during the accreditation term. At review, submit evidence for this number of activities:* S=2; M=4; L=6; XL=8		
Engages Patients/ Public	Patient/public representatives are engaged in the planning and delivery of CME. (formerly C24)	Accredited continuing medical education (CME) is enhanced when it incorporates the interests of the people who are served by the healthcare system. This can be achieved when patients and/or public representatives are engaged in the planning and delivery of CME. This criterion recognizes providers that incorporate patient and/or public representatives as planners and faculty in the accredited program.	Includes planners who are patients and/orpublic representatives AND Includes faculty who are patients and/orpublic representatives	Attest to meeting this criterion in at least 10% of activities (but no less than two) during the accreditation term. At review, submit evidence for this number of activities:* S=2; M=4; L=6; XL=8		
Engages Students	Students of the health professions are engaged in the planning and delivery of CME. (formerly C25)	This criterion recognizes providers for building bridges across the healthcare education continuum and for creating an environment that encourages students of the health professions and practicing healthcare professionals to work together to fulfill their commitment to lifelong learning. For the purpose of this criterion, students refers to students of any of the health professions, across the continuum of healthcare education, including professional schools and graduate education.	Includes planners who are students ofthehealth professions AND Includes faculty who are students ofthehealth professions	Attest to meeting this criterion in at least 10% of activities (but no less than two) during the accreditation term. At review, submit evidence for this number of activities:* S=2; M=4; L=6; XL=8		

^{*}Program Size by Activities per Term: S=small <39; M=medium: 40-100; L=large: 101-250; XL=extra-large: >250



One Year Transition Phase



To facilitate the transition, ACCME has created the following timeline.

Requirements that have been removed:

Accredited providers can **immediately** stop complying with requirements that have been removed from the Standards.

Requirements that are new or changed:

Accredited providers will be expected to comply with new or changed requirements in the Standards by January 1, 2022.



The current Standards for Commercial Support will remain in place for existing and any newly accredited providers coming on board through





Reaccreditation Impact

- Fall 2021: New Structured Abstract and new Self Study Report forms will be published that begin to reflect the updated Standards & Reorganized Criteria (for June 2022 cohort).
 - Will have a key that includes crosswalk (i.e., Analyzes Change formerly known as C11)
- January 2022: Providers expected to demonstrate compliance with new Standards in <u>all</u> activities.
 - So if you are planning activities <u>now</u> for 2022, ensure you are incorporating the new Standards.
 - ACCME expects accredited providers to take reasonable steps to comply with the new Standards for activities tking place in 2021 that will continue to be available in 2022 and beyond.
 - For activities that were planned or released prior to 2021, ACCME does not expect you to make changes to or obtain new disclosure information from the individuals who were in control of content.
- January 2022: When providers come up for re-accreditation they
 will be held accountable for compliance with the old Standards only
 in the requirements that are the same.



2021 Interviews - Things You Might See

Requirements that have been eliminated in the new Standards are no longer going to be evaluated in decision-making, effective immediately.*

Standard	Stop doing NOW	Expect to change in the future (for activities after 1/1/2022)
3	Looking for Spouse or Partner on disclosure forms	
3		Looking for disclosure form that includes 24 months and revised definition of Ineligible Company
3		Must collect ALL (not just relevant) financial relationships
4	Looking for policy on honoraria and reimbursement	



ACCME WEBSITE RESOURCES

ACCME has now replaced the old Standards with the new on their website and has begun using the new terminology.

https://accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce

Standards for Integrity and Independence in Accredited Continuing Education

PREAMBLE

ELIGIBILITY

STANDARD 1: ENSURE CONTENT IS VALID STANDARD 2: PREVENT COMMERCIAL BIAS AND MARKETING IN ACCREDITED CONTINUING EDUCATION

STANDARD 3: IDENTIFY, MITIGATE, AND DISCLOSE RELEVANT FINANCIAL RELATIONSHIPS STANDARD 4: MANAGE COMMERCIAL SUPPORT APPROPRIATELY

STANDARD 5: MANAGE
ANCILLARY ACTIVITIES
OFFERED IN CONJUNCTION
WITH ACCREDITED CONTINUING
EDUCATION

The old Standards can be found in ACCME's archives.

Archived Resources: Standards for Commercial Support

- Standards for Commercial Support: Standards to Ensure Independence in CME Activities (PDF)
- Archived Examples of Compliance and Noncompliance with the ACCME Standards for Commercial Support (Criteria 7-10) (PDF)
- Archived Accreditation Requirements (PDF)

Tools have been developed to support providers with the implementation of the new Standards.

Toolkit for the Standards for Integrity and Independence

This toolkit includes templates, sample forms, and checklists in fillable PDF format for you to adapt and use as you choose. Use of these resources is completely optional.

- Download the full Toolkit (fillable PDF)
- Download the tools from the Toolkit as separate fillable PDFs:
 - o Tools for Identifying, Mitigating, and Disclosing Relevant Financial Relationships
 - o Tools to Ensure that Clinical Content is Valid
 - Quick Tool to Simplify Educational Planning when Identification, Mitigation, and Disclosure are Not Required

Now Back to Tools and Forms



Toolkit for the Standards for Integrity and Independence in Accredited Continuing Education

The ACCME has provided a Toolkit of resources to assist providers in transitioning to the new Standards.

The initial collection of tools focuses on:

- Standard 1: Ensuring Content is Valid
- Standard 3: Identifying, Mitigating, and Disclosing Relevant Financial Relationships.

These 2 standards are applicable to all accredited providers, whether or not commercial support is received. Use of these resources is completely **optional**.





Questions? E-mail info@accme.org



Note for Continuing Education Staff

If any of the following statements apply to the education, you **do not** need to identify, mitigate, or disclose relevant financial relationships for this accredited continuing education:

- ✓ It will only address a non-clinical topic (e.g., leadership or communication skills training).
- ✓ It is for a learner group that is in control of the content entirely (e.g., spontaneous case conversation among peers)
- It is a self-directed educational activity where the learner will control their educational goals and report on changes that resulted (e.g., 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.

STEP 1: Before you begin planning your education, collect information from all planners, faculty, and others who would be in positions to control content. Ask them to provide information about **all** their financial relationships with ineligible companies over the previous **24 months**.

Ensure you use this definition: Ineligible companies are those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

Hint: Use the Template for Collecting Information about All Financial Relationships from Planners, Faculty, and Others. There is no minimum financial threshold; individuals must disclose all financial relationships, regardless of the amount, with ineliable companies.

STEP 2: Review the disclosed relationships and exclude owners and employees of ineligible companies from participating as planners, faculty, or other roles unless the educational activity meets one of the exceptions listed below.

There are only three exceptions that allow for owners and/or employees of ineligible companies to participate as planners or faculty in accredited continuing education.

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

STEP 3: Determine which financial relationships are **relevant** to the content of the continuing education activity, **mitigate** those relevant financial relationships to prevent commercial bias, and **disclose** the presence or absence of all relevant financial relationships to learners prior to the activity.



(A) Determine relevant financial relationships for all who will be in control of educational content.

Financial relationships are relevant if the following three conditions are met for the individual who will control content of the education:

- ✓ 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.



Mitigate relevant financial relationships prior to individuals assuming their roles in the education.

Hint: Use the Worksheet for the Identification and Mitigation of Relevant Financial Relationships of Planners, Faculty, and Others to implement mitigation strategies appropriate to their role(s) in the educational activity.



Before the learner engages in the education, **disclose** to learners the presence or absence of relevant financial relationship for all persons in control of content.

Hint: Use the Examples of Communicating Disclosure to Learners to share all of the appropriate information before the activity.

Key Steps for the Identification, Mitigation, and Disclosure of Relevant Financial Relationships

A *Checklist for CME Staff* providing an overview of the 3-step process and things that are important to consider.

STEP 1: Before you begin planning

STEP 2: Reviewing disclosures and excluding owners/employees of ineligible companies

STEP 3: Determining which relationships are relevant







Note for Continuing Education Staff

If any of the following statements apply to the education, you **do not** need to identify, mitigate, or disclose relevant financial relationships for this accredited continuing education:

- ✓ It will only address a non-clinical topic (e.g., leadership or communication skills training).
- ✓ It is for a learner group that is in control of the content entirely (e.g., spontaneous case conversation among peers).
- It is a self-directed educational activity where the learner will control their educational goals and report on changes that resulted (e.g., 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.

At the beginning of your planning process, use the sample language below to communicate with prospective planners, faculty, and others who may be in control of content for the education. It is important to identify financial relationships before activity planning begins so that relevant financial relationships can be mitigated in a manner that is appropriate to each person's role.

Dear Prospective Planner/Faculty Member:

We are looking forward to having the opportunity to include you as a roposed role for person—e.g.
planner, faculty, reviewer, etc...> in the accredited continuing education, <nre>Insert activity title or working title and date/location information, if appropriate>.

Why am I receiving this communication?

Insert Accredited Provider Name> is accredited by the Accredited Provider Name>" is accredited by the Accreditor. we appreciate your help in partnering with us to follow accreditation guidelines and help us create high-quality education that is independent of industry influence. In order to participate as a person who will be able to control the educational content of this accredited CE activity, we ask that you disclose all financial relationships with any ineligible companies that you have had over the past 24 months. We define ineligible companies as those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. There is no minimum financial threshold; you must disclose all financial relationships, regardless of the amount, with ineligible companies. We ask you to disclose regardless of whether you view the financial relationships as relevant to the education. For more information on the Standards for Integrity and Independence in Accredited Continuing Education, please visit accme.org/standards.

Why do we collect this information?

Since healthcare professionals serve as the trusted authorities when advising patients, they must protect their learning environment from industry influence to ensure they remain true to their ethical commitments. Many healthcare professionals have financial relationships with ineligible companies. By identifying and mitigating relevant financial relationships, we work together to create 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.

What are the next steps in this process?

After we receive your disclosure information, we will review it to determine whether your financial relationships are relevant to the education. Please note: the identification of relevant financial relationships does not necessarily mean that you are unable to participate in the planning and implementation of this educational activity. Rather, the accreditation standards require that relevant financial relationships are mitigated before you assume your role in this activity.

To help us meet these expectations, please use the form we have provided to share all financial relationships you have had with ineligible companies during the past 24 months. This information is necessary in order for us to be able to move to the next steps in planning this continuing education activity.

If you have questions about these expectations please contact us at rovider contact information>.

Sample Letter to Explain Why Financial Relationship Information is Collected

At beginning of planning process, sample language CME providers can use to communicate with prospective planners, faculty and reviewers.

- Why they are receiving the communication
- Why the CME Office is collecting this information
- What the next steps are in the process of mitigation





To be completed by education staff.		_	Individual's prospective ro	le(s) in education
Name of Individual:		©	Identify the prospective role(s) that this person may have in this education (choose all that
Title of Continuing Education:			Planner Examples: planning committee, staff involved Teacher, Instructor, Faculty	d in choosing topics, faculty, or content
Date and location of Education:			Author, Writer Reviewer Other	
As a prospective planner or faculty membe influence. Please complete the form below		isk for	your help in protecting our lean	ning environment from industry
The ACCME Standards for Integrity and Infrom involvement in the planning and imple assistance. If you have questions, please of	mentation of accred			
To be Completed by Planner, Faculty, or O	thers Who May Con	trol Fo	lucational Content	
Please disclose all financial relationships th For each financial relationship, enter the name financial threshold; we ask that you disclose al disclose all financial relationships regardless o	of the ineligible com I financial relationship	pany a os, rega	nd the nature of the financial related and the nature of the amount, with ineligit	tionship(s). There is no minimum ble companies. You should
Enter the Name of Ineligible Company	Enter the Nature	of Fin	ancial Relationship	Has the Relationship Ended?
An ineligible company is any entity whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. For specific examples of ineligible companies visit accme.org/standards.	researcher, consulta contractor (including patent beneficiary, e Individual stocks and diversified mutual fu Research funding fre disclosed by the prin	ent, advi contra executive d stock nds do om ineli ncipal of n receive	onships include employee, isor, speaker, independent cted research), royalties or e role, and ownership interest. options should be disclosed, not need to be disclosed, gible companies should be r named investigator even if that res the research grant and	If the financial relationship existeduring the last 24 months, but ha now ended, please check the box in this column. This will help the education staff determine if any mitigation steps need to be taken
Example: ABC Company	Consultant			X
				H
In the past 24 months, I have not have	d any financial relati	ionshir	s with any ineligible companies	S.
attest that the above information is co	-			
Who te for Continuing Educat Use this template to collect all relevant fina educational content before they assume the activity, if your planners and faculty are a s periodic basis and ask the individuals to up	ncial relationships o eir role in the educa et group of individua	tion. As	s an alternative to collecting dis might choose to collect this in	sclosure information for each

Template for Collecting Information about All Financial Relationships from Planners, Faculty and Others

Basically a sample Financial Disclosure Form that you may adopt, if desired.

Compare your process or forms to this sample template to collect the right information about financial relationships.



ISMA Financial Disclosure Form

ISMA did not adopt this form but did update ours to reflect changes in the new Standards.

- Did <u>not</u> change to term CE, but left CME (Continuing Medical Education)
- Removed mention of and request for disclosure of spouse/partner
- Removed columns in grid for Self vs. Spouse/Partner and added "Has relationship ended?"
- Changed look-back on relationships from 12 to 24 months
- Changed section on Relevant Financial Relationships to All Financial Relationships
- Changed term "commercial interest" to "ineligible company"
- Changed term "resolved" to "mitigated"
- Updated Statements/Rules of ISMA Content Validation on form to include:
 - 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 the accredited provider 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.
- Within Glossary of Terms, updated:
 - Definition of "Commercial Interest," now called "Ineligible Entity"
 - Definition of "Relevant Financial Relationships"



ISMA Financial Disclosure Form

ISMA INDIANA BTATE STATE ASSOCIATION	DISCLOSURE	OF FINANCIAL I	CONTINU	ING MEDICAL EDUCAT	
		OF FINANCIAE I	KELA HONSHIP PO	TXIVI	
Name/Credentials	Click here to enter text.				
Telephone Number:	Click here to enter text.	E-Mail Address:	Click here to enter	text.	
Activity Name:	Click here to enter text.		Date:	Click here to enter text.	
Please indicate your role in this CME activity: Presenter/Faculty Course Director Moderator Planning Committee (Please check all that apply)					

Purpose: It is the policy of the Indiana State Medical Association (ISMA) to ensure balance, independence, objectivity and scientific rigor in all of its sponsored educational activities. All participating faculty, course directors, and planning committee members are required to disclose to the program audience any financial relationships related to the subject matter of continuing medical education (CME) activities/programs. Disclosure information is reviewed in advance in order, to manage and resolve any possible conflicts of interest. This information is necessary in order, for us to be able to move to the next steps in planning this CME activity.

Persons who fail to provide this information in advance of the course (allowing for adequate time for review) are not eligible to be involved in this CME activity.

<u>Participation</u>: We are pleased that you are willing and able to participate in this CME activity, which is accredited by the ISMA. The ISMA is accredited by the Accreditation Council for Continuing Medical Education (ACCME). As such, we are required to meet the ACCME's expectations for our practice of continuing medical education.

Step 1: Disclosure of All Financial Relationships

Please disclose all financial relationships that you have had in the past 24 months with ineligible companies (see definition in Glossary of Terms). For each financial relationship, enter the name of the ineligible company and the nature of the financial relationship(s). There is no minimum financial threshold; we ask that you disclose all financial relationships, in any amount, with ineligible companies. You should disclose relationships regardless of the potential relevance of each relationship to the education.

Regarding your role in this CME activity (check one):

□ No	In the nact 24 months	I have not had any	financial relationships	with an ineligible company.

Yes, I do have a personal financial relationship with an ineligible company (Provide information below)

Nature of Financial Relationship	Name of Ineligible Company(s)	Has the relationship ended?
☐ Consultant	Click here to enter text.	
☐ Speaker's Bureau	Click here to enter text.	
☐ Grant/Research Support ☐ Principal Investigator	Click here to enter text.	
☐ Board Member	Click here to enter text.	
☐ Stock Shareholder (self-managed)	Click here to enter text.	
☐ Full-time/part-time Employee/Owner*	Click here to enter text.	
☐ Other (Describe):	Click here to enter text.	

^{*} The ISMA PROHIBITS <u>employees and owners</u> of Ineligible Companies from participating on any CME PLANNING COMMITTEE and serving as presenters.

Additional information may be requested to address any perceived conflict of interest. All identified conflicts of interest must be mitigated in advance of the activity and disclosure information will be shared with activity participants.



1 Step 2: Speaker Disclosure of Off-Label and/or Investigational Uses

If at any time during my educational activity, I discuss an off-label/investigative use of a commercial product/device, I understand that I must provide disclosure of that intent.

□ No, I do not intend to discuss an off-label/investigative use of a commercial product/device.

☐ Yes, I do intend to discuss off-label/investigative use(s) of the following commercial product(s)/device(s).

Click here to enter text.

Step 3: ISMA Statements & Rules to Ensure Content Validation

We would like to enlist your help to ensure that educational content is fair and balanced and that any clinical content presented supports safe, effective patient care. This includes the expectations that:

- 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.
- 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. Citations of the work are recommended.
- The content and/or presentation of the information with which I am involved will promote quality or improvements in healthcare and will not promote a specific business interest of a commercial interest.
- Recommendations involving diagnosis and treatment discussed in the presentation are based on evidence which is accepted within
 the profession of medicine as adequate justification for their indications and contraindication in the care of patient.
- 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 the
 accredited provider to facilitate engagement with these topics without advocating for, or promoting, practices that are not, or not
 well adequately based on current science, evidence and clinical reasoning.
- Content cannot be included in accredited education if it advocates for unscientific approaches to diagnosis or therapy, or if the
 education promotes recommendations, treatment, or manners or 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.
- a lunderstand that ISMA CME staff will need to review my presentation and/or content prior to the activity, and I will provide educational content and resources in advance, as requested.
- I understand that commercial entity corporate names or logos should not appear on my slides or handouts.
- I understand that ISMA CME staff may be attending the event to ensure that my presentation is educational, and not
 promotional, in nature.
- If I am discussing specific health care products or services, I will use generic names to the extent possible. If I need to use trade names, I will use trade names from several companies when available, and not just trade names from any individual company.
- If I have been trained or utilized by a commercial entity or its agent as a speaker (e.g., speaker's bureau for any ineligible
- company, the promotional aspects of the presentation will not be included in any way with this activity.

 If I am presenting research funded by a commercial company, the information presented will be based on generally accepted scientific principles and methods and will not promote the commercial interest of the funding company.
- If I am presenting research studies, I will include weaknesses and strengths of each study, in addition to harms and benefits of specific products. I will also discuss studies presenting different conclusions about the product, if available.

If you have any questions regarding your ability to comply, please contact Jessica Davis, CME Coordinator, at 317-261-2060, or by e-mail at idavis@ismanet.org.

Step 4: Declaration

I will uphold the ISMA CME standards to ensure balance, independence, objectivity, and scientific rigor in my role in the planning, development or presentation of this continuing education activity. I understand that CME accreditation guidelines prohibit me from accepting any reimbursement (financial, gifts, or in-kind exchange) for this presentation from any source other than the accredited CME provider or its educational partner (or fiscal agent).

		,	
Signature/Printed Name:	Click here to enter text.	Date:	Click here to enter text.

If sending this completed document electronically, please type your name above and check this box:

By checking this box, I attest that the completed information is accurate. Please accept this as my signature.

Thank you for providing us with this information.

RETURN TO: Jessica Davis, CME Coordinator, at <a href="mailto:jessica-pavis-augustus-jessica-jessica-pavis-augustus-jessica

ISMA Financial Disclosure Form



Glossary of Terms as Defined by the American Council on Continuing Medical Education (ACCME)

Ineligible Company (formerly known as "Commercial Interest")

The ACCME defines an "ineligible company" as those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

Financial Relationships

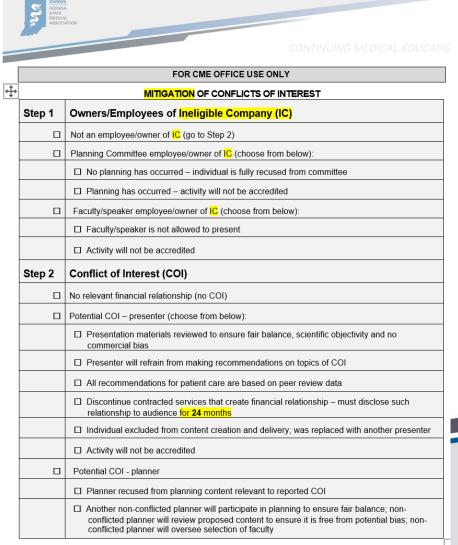
Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received, or expected.

Relevant Financial Relationships

ACCME focuses on collecting information about all 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. Inherent in any amount is the incentive to maintain or increase the value of the relationship. The ACCME classifies financial relationships as "relevant" if the educational content an individual can control is related to the business lines or products of the ineligible company.

Conflict of Interest

Circumstances create a conflict of interest when an individual has an opportunity to affect CME content about products or services of an ineligible company with which he/she has a financial relationship. The ACCME considers "content of CME about the products or services of that commercial interest" to include content about specific agents/devices, but not necessarily about the class of agents/devices, and not necessarily content about the whole disease class in which those agents/devices are used.



Reviewed/Signed by: Date: Updated: May 2021





Note for Continuing Education Staff

Use this sample worksheet to identify and mitigate relevant financial relationships that you have identified for planners, faculty, and others who will control educational content for your education activity. Please make sure that (1) the mitigation strategy is appropriate to the person's role in the activity, and (2) that mitigation is implemented before each person takes on their role.

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

After collecting all financial relationships from prospective planners, faculty, and others, exclude any persons who are owners or employees of ineligible companies. 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.

Review the information for all persons whom you did not exclude in Step 1 and determine whether each person's financial relationships with ineligible companies are relevant to the content of the education you are planning. Financial relationships are relevant if the following three conditions are met for the prospective person who will control content of the education:

- √ 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 and **implement** that strategy before the person assumes their role.

Using the lists below, identify which mitigation strategy(ies) will be used for all persons with relevant financial relationships who control the educational content of the educational activity. You may select multiple strategies but be sure to use strategies appropriate to the role(s) that each person has. You can also identify your own strategies for mitigation.

Mitigation steps for planners (choose at least one)

- ✓ Divest the financial relationship
- √ Recusal from controlling aspects of planning and content
 with which there is a financial relationship
- √ Peer review of planning decisions by persons without relevant financial relationships
- √ Use other methods (please describe):

Mitigation steps for faculty and others (choose at least one)

- ✓ Divest the 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)
- ✓ Use other methods (please describe):

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

Α	В	С	D
NAME OF PERSON	ROLE(S) IN ACTIVITY	STEP(S) TAKEN TO MITIGATE RELEVANT FINANCIAL RELATIONSHIP	DATE IMPLEMENTED
Example: Dr. Jones	Planner	Recusal from topic/faculty selection	10/28/21

Worksheet for the Identification and Mitigation of Relevant Financial Relationships of Planners, Faculty and Others

Takes the place of the Flowchart for Resolution of Personal Conflicts of Interest

You may adopt this form to record/document how you mitigated individual relationships, if you desire.







Note for Continuing Education Staff

If any of the following statements apply to the education, you **do not** need to identify, mitigate, or disclose relevant financial relationships for this accredited continuing education:

- ✓ It will only address a non-clinical topic (e.g., leadership or communication skills training).
- ✓ It is for a learner group that is in control of the content entirely (e.g., spontaneous case conversation among peers).
- It is a self-directed educational activity where the learner will control their educational goals and report on changes that resulted (e.g., 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.

Use the sample language below to provide disclosure to learners in a format that can be verified at the time of accreditation. Disclosure must be provided to learners **before** engaging with the accredited education.

What gets disclosed to learners before the education?

If there are NO relevant financial relationships:

Inform learners that planners, faculty, and others in control of content (either individually or as a group) have no relevant financial relationships with ineligible companies.

EXAMPLES:

"Dr. Xin Lee, faculty for this educational event, has no relevant financial relationship(s) with ineligible companies to disclose."

"Ruth Hopkins, Dr. Maryam Elbaz, and Ken Sanders, authors of this educational activity, have no relevant financial relationship(s) with ineligible companies to disclose."

"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."

If there ARE relevant financial relationships:

Disclose name(s) of the individuals, name of the ineligible company(ies) with which they have a relevant financial relationship(s), the nature of the relationship(s), and a statement that all relevant financial relationships have been mitigated.

EXAMPLES:

Nicolas Garcia, faculty for this educational event, is on the speakers' bureau for XYZ Device Company.

Dr. Yvonne Gbeho, planner for this educational event, has received a research grant from ABC Pharmaceuticals.

All of the relevant financial relationships listed for these individuals have been mitigated.

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.
- ✓ It may be helpful to include definitions of terms to learners to support their understanding of your processes (e.g., ineligible companies, relevant financial relationships, etc...)

Examples of Communicating Disclosure to Learners

Uses sample terminology for disclosure statements when there are <u>no</u> relevant relationships

AND

when there <u>are</u> relevant financial relationships, in a format that can be verified at the time of reaccreditation.

Remember that disclosure must be provided to learners **before** engaging with accredited education.





Note for Continuing Education Staff

Use this sample template to communicate expectations to planners, authors, and faculty about ensuring valid clinical content for accredited education. For more information about these expectations, see Standard 1 of the Standards for Integrity and Independence at accme.org/standards.

Dear Prospective Planner/Faculty Member:

As an important contributor to our accredited education, we would like to enlist your help to ensure that educational content is fair and balanced, and that any clinical content presented supports safe, effective patient care. This includes the expectations that:

- 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.
- 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.
- 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.
- Content cannot be included in accredited education if it advocates for unscientific approaches to diagnosis or therapy, or if the 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.

These expectations are drawn from **Standard 1** of the ACCME Standards for Integrity and Independence in Accredited Continuing Education. For more information, see **accme.org/standards**. If we can help you to understand and/or apply these strategies to your education, please contact us at forwider-contact-information.



Please consider using these strategies to help us support the development of valid, high quality education.

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

- 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.

Although accredited CE is an appropriate place to discuss, debate, and explore new and evolving topics, presenting topics or treatments with a lower (or absent) evidence base should include the following strategies:

- 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
- Construct the activity as a debate or dialogue. Identify other faculty who represent a range of opinions and perspectives; presentations should include a balanced, objective view of research and treatment options.
- Teach about the merits and limitations of a therapeutic or diagnostic approach rather than how to use it.
- Identify content that has not been accepted as scientifically meritorious by regulatory and other authorities, or when the material has not been included in scientifically accepted guidelines or published in journals with national or international stature.
- Clearly communicate the learning goals for the activity to learners (e.g., "This activity will teach you about how your patients may be using XX therapy and how to answer their questions. It will not teach you how to administer XX therapy").

Guidance for Planners, Authors and Faculty: Ensuring Clinical Content is Valid

A sample template to communicate expectations to planners, authors and faculty in the planning stage to ensure valid clinical content for the accredited education they will be developing.

ISMA communicates the majority of this information within the Statements/Rules of ISMA Content Validation on pg. 2 of our Financial Disclosure Form.



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 Yes giving a fair and balanced view of diagnostic and therapeutic options? [Standards for Integrity and O No Independence 1.11 Comments: Does all scientific research referred to, reported, or used in this educational activity in support or O Yes justification of a patient care recommendation conform to the generally accepted standards of O No experimental design, data collection, analysis, and interpretation? [Standards for Integrity and Independence 1.2] Comments: O Yes 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] O No Comments: Does the educational activity avoid advocating for, or promoting, practices that are not, or not yet, Yes adequately based on current science, evidence, and clinical reasoning? [Standards for Integrity and O No Independence 1.31 Comments: Does the activity exclude any advocacy for, or promotion of, unscientific approaches to diagnosis or Yes therapy, or recommendations, treatment, or manners of practicing healthcare that are determined to have O No 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] Comments:

Note for Continuing Education Staff

One strategy to ensure the clinical content validity of accredited continuing education is to allow external (peer) review by persons with appropriate clinical expertise and no relevant financial relationships with ineligible companies, defined as those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. The questions above direct reviewers to share feedback about each of the requirements that comprise Standard 1 in the Standards for Integrity and Independence. For more information, see accme.org/standards.

Toolkit for the Standards for Integrity and Independence in Accredited Continuing Education © 2020 by the Accreditation Council for Continuing Medical Education (ACCME®)

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Template for Peer Review: Ensuring that Clinical Content is Valid

An example of a tool to facilitate peer review to ensure that clinical content is valid.

The questions direct reviewers to share feedback about each of the requirements that comprise Standard 1.

ISMA will continue to use our own existing Content Review Form.





What is your name and email?	Name:	
	Email:	
When will the education take place?	Date:	
Do you have a title or brief description for the education? If yes, please note it to the right; if no, leave blank.	Title/Brief Description:	
Examples: Emergency Department team huddle; Leadership in a time of crisis; Well-being check-In		
What practice-based problem (gap) will this education address?	Practice-based problem (gap):	
Examples: Improve care coordination; Better communication with patients and families; Want to give better feedback to students		
What is/are the reason(s) for the gap? How are your learners involved?	Reason(s) for the gap:	
Examples: We need strategies to discuss difficult topics with family members; Don't know best ways to improve team collaboration		
Review the three statements to the right.	The education will (check all that apply)	
If you can check <u>any</u> of these boxes, you do not need to identify, mitigate, and disclose relevant financial relationships.	 only address a non-clinical topic (e.g., leadership or communication skills training). 	
If you unable to check any boxes, please contact your CE program administrator to implement processes for ensuring the integrity and independence of this education.	be for a learner group that is in control of the content (e.g., spontaneous case conversation among peers).	
	 be a self-directed educational activity where the learner will control their educational goals and report on changes that resulted (e.g., learning from teaching, remediation, or a personal development plan). 	
What change(s) in strategy, performance, or patient care would you like this education to help learners accomplish?	Desired change(s) in strategy, performance, or patient care:	
Examples: Eliminate stigmatizing language from communications with patients; Improve my management skills		
In order to award CME/CE credit, please indicate the	Education duration:hours and minutes	
duration of the education.	Please report time in 15-minute increments.	
Discuss with learners the changes they intend to make to their strategies, performance, or patient care that will result from this activity and list that information to the right.	Changes learners intend to make to strategies, performance, or process.	atient
Example: I will use the evidence-based checklist we discussed to improve screening my patients for past military service.		
After the activity, please collect attendance and learner change department in order for credit to be awarded. You can also list	e information for the activity and send it to the continuing education the attendees on the back of this form.	
Note for Continuing Education Staff		
appropriate format, changes in learners, independence, and admi in ACCME PARS following your usual process, and provide to lea	nstrate the professional practice gap and underlying needs, expected result nistrative information needed to award credit to learners. Please enter this a mers your accorditation statement, the credit designation statement, and are ase report learners in PARS within 30 days of the education. For questions	activity ny
assistance, contact ACCINE at info@accme.org. rpted from the Toolkit for the Standards for Integrity and Independence in Accre-	rited Continuing Education	Page
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Quick Tool for Planning Accredited Continuing Education

You can adopt this tool to simplify educational planning when identification, mitigation, and disclosure are not required.

(Non-Clinical or Spontaneous CME)

ISMA is adopting this form!

After the activity, please collect attendance and learner change information for the activity and send it to the continuing education department in order for credit to be awarded. You can also list the attendees on the back of this form.





learn well

Standards for Integrity and Independence in Accredited Continuing Education

Transition Checklist

We want to do everything we can to support the continuing education community's successful implementation of the new Standards. We encourage you to review the <u>Standards</u> and <u>resources</u> and begin working on your transition plan now, so that you are in compliance by January 1, 2022. Here's a checklist to help you get started.

Standard 1: Ensure Content is Valid

While there is nothing new in our approach to content validity, we suggest that you take the following steps to confirm that your processes meet our expectations.

- ✓ Check out the tips and strategies in the clinical content validation tool from the Standards Toolkit.
- ✓ Review your process for ensuring that education is fair and balanced, and supports safe, effective patient care.
- ✓ Review your process for communicating your expectations to planners, authors, and faculty.

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

- Communicate to faculty that they cannot actively promote or sell products or services during accredited education
- If you intend to share learners' names or contact information with an ineligible company, determine how you will obtain the explicit consent of individual learners.
 - If you ask for consent at registration, the learner must have the ability to opt out and still register for your activity.
 - The consent statement must be clearly visible—not hidden in a long list of terms and conditions.

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

- ✓ Check out the <u>Tools for Identifying, Mitigating, and Disclosing Relevant Financial Relationships</u> from the Standards Toolkit.
- Change your process as needed to make sure that you collect information from all planners, faculty, and others in control of educational content about:
 - o all their financial relationships with ineligible companies
 - within the 24 months prior to their involvement with an accredited CE activity
- Use the correct and complete definition of ineligible company: Those whose primary business is producing, marketing, selling, reselling, or distributing healthcare products used by or on patients.

Transition Checklist

ACCME and ISMA encourage you to begin working on your transition plan now.

There is a checklist to help you get started.

https://accme.org/publications/standa rds-for-integrity-and-independencetransition-checklist-pdf

It contains all the factors for you to consider:

- Review your processes......
- Change your forms.....
- Communicate to faculty......

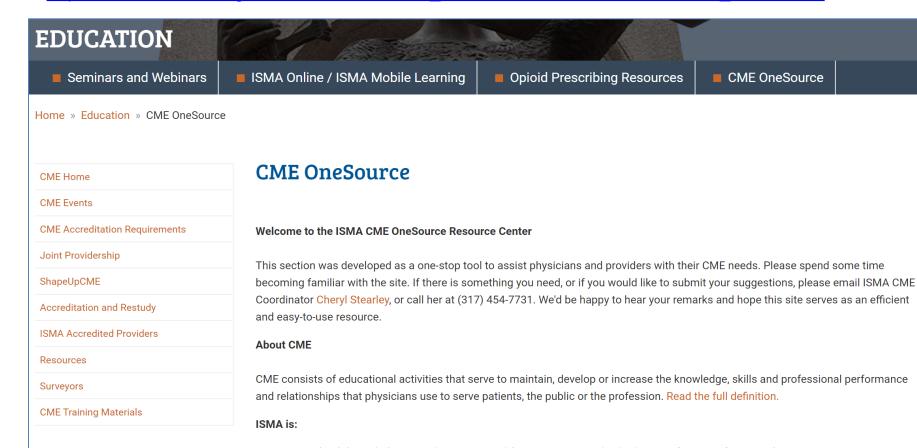


ISMA WEBSITE RESOURCES

ISMA's CME OneSource contains updated forms and other documents.

Providers may adopt and adapt them for their own use if so desired.

https://www.ismanet.org/ISMA/Education/CME OneSource/ISMA/Education/CME OneSource



- Accredited through the Accreditation Council for Continuing Medical Education (ACCME®) to provide CME activities.
- Allowed to provide joint providership programs.
- A recognized provider through the ACCME® to accredited organizations in Indiana to offer CME programs.

Here's What ISMA Updated

- CME Intake Form (used with JP's or internal departments)
- Financial Disclosure Form
- CME Application & Planning Worksheet
- Marketing Guidelines
- Financial Disclosure Grid
- Joint Provider Activity Guide & Checklist

CME OneSource

https://www.ismanet.org/ISMA/Education/CME OneSource/ISMA/Education/CME OneSource

Joint Providership Documents

https://www.ismanet.org/ISMA/Education/CME_OneSource/Joint_Providership

Accreditation Requirements

https://www.ismanet.org/ISMA/Education/CME OneSource/CME Accreditation Requirements

ShapeUpCME

https://www.ismanet.org/ISMA/Education/CME OneSource/ShapeUpCME/

ShapeUp CME was a 2014 project, in collaboration with Indiana's CME providers, to produce a streamlined set of ACCME-compliant forms which could be quickly accessed and utilized for CME activities within any hospital or healthcare organization.

Many of these will be outdated with implementation of the new Standards.





