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Call for Comment Survey Responses: Proposed Standards for Integrity and Independence in Accredited Continuing Education

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Call for Comment Survey Responses

Proposed Standards for Integrity and Independence in Accredited Continuing Education

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Eligibility

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	"whose primary business is…" Already unclear for certain diagnostic labs. Most diagnostic labs offer proprietary products, but it's not their primary business. Are you talking about only diagnostic labs whose primary business is these proprietary products, or all labs that market even one proprietary lab test?
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Two constructive comments and one question to consider are: • The description of ineligible entities could benefit from the added verbiage currently in Standard 1.5: "Organizations cannot be accredited if they advocate for unscientific modalities of diagnosis or therapy, or if their education promotes recommendations, treatment, or manners of practicing healthcare that are determined to have risks or dangers that outweigh the benefits or are known to be ineffective in the treatment of patients." • Including the word "primary" before "business" could cause confusion and potentially debate over the interpretation of "primary". It seems subjective. For example, if the individual feels that an organization's primary mission is to educate healthcare professionals and secondary (so to speak) business is distributing healthcare products, would that organization be eligible? • Currently the below-noted commercial interest clarification provided by the ACCME references "parent" and "sister" companies and advocating for commercial interests. The new definition doesn't account for these types of relationships and so does that mean that they are now acceptable for eligible entities to have? https://www.accme.org/faq/how-can-i-determine-if-my-organization-commercial-interest: "Structured Self-Assessment Related to ACCME's Definition of a Commercial Interest 1. … 2. Does your organization have a parent company that produces … 3. Does your organization have a sister co

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
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Accredited CE provider	ACCME	Hospital/healthcare delivery system	1. I would stick with the term commercial interest. It is clearer, especially as we work with faculty. You clarified employees/owners of commercial interests later and that clears up a big gap for accredited providers. Our faculty are going to understand "commercial interest" much better. 2. The word "primary" might create confusion. Can this be eliminated. How do we define "primary"? 3. "Diagnostic labs (that market or sell proprietary products)" does this mean that because a hospital may have a gene lab test that they market and sell to patients that they are ineligible? Or is it ok because it is not their "primary" business?
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Although I understand the eligible/ineligible terminology, the proposed terminology is too jargony. I have a hard-enough time conveying what a “commercial interest” is to my planners and speakers, but at least they understand what the “commercial” part means. The eligible/ineligible classification will be very difficult to explain. In addition, there is a discrepancy about nonprofits—on p7, it states that the new terms are to clarify that “eligibility for accreditation is not based on whether an organization is for-profit or nonprofit,” but on p12, under the definition for eligible entities, nonprofits are explicitly listed as eligible.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Clarify the definitions of primary business, owners, and employee. Reasons for confusion include the following: Primary business – What constitutes “primary”? Does this refer to someone who attains 51%+ income from a given business? Do we define primary business as the amount of effort /patient volume? In today’s market, companies often have various business lines and subsidiaries that could support its overall supply/service chain but are arguably not part of its primary business. Perhaps the focus needs to be more on the business’ vision or mission. The definition of primary business encompasses large ramification in the definition and our understanding of eligible/ineligible entities. Owners and employees - The definition of an owner and employee can vary depending on the state of operation for the business. For example, California defines certain freelancers (contract positions) as employees where other states do not. If each provider used its state laws to define business owner and employee, it could create inconsistencies across providers in identifying eligible/ineligible entities. The ACCME should provide further guidance on which employee/owner definition to use and clearly define both owners and employees, as they are pertinent in our understanding of eligible/ineligible entities.

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME		Clarity on how ACCME defines a “primary business” will be helpful for providers to make appropriate determinations of this.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Clarify the definitions of primary business, owners, and employee. Reasons for confusion include the following: Primary business – What constitutes “primary”? Does this refer to someone who attains 51%+ income from a given business? Do we define primary business as the amount of effort /patient volume? In today’s market, companies often have various business lines and subsidiaries that could support its overall supply/service chain but are arguably not part of its primary business. Perhaps the focus needs to be more on the business’ vision or mission. The definition of primary business encompasses large ramification in the definition and our understanding of eligible/ineligible entities. Owners and employees - The definition of an owner and employee can vary depending on the state of operation for the business. For example, California defines certain freelancers (contract positions) as employees where other states do not. If each provider used its state laws to define business owner and employee, it could create inconsistencies across providers in identifying eligible/ineligible entities. The ACCME should provide further guidance on which employee/owner definition to use and clearly define both owners and employees, as they are pertinent in our understanding of eligible/ineligible entities.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	clarity on "primary business" is defined
Accredited CE provider	ACCME	Hospital/healthcare delivery system	define "wearable product"; what about companies dedicated to financing medical device technologies (medical device/technology-based investment firms)?
Accredited CE provider	ACCME	Hospital/healthcare delivery system	For companies involved in genetic medicine, (genetic testing, diagnosis, treatment, etc.) where would they fall – eligible or ineligible? This type of company is the new reality of medicine. Restricting this type of presentation from a CME-certified activity would be detrimental to physicians and their patients.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	One clarification that I believe is required is the level of “ownership” that makes an individual ineligible to be part of a CME activity. Define Owner. Are you including stockholders/shareholders in this definition?

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Accredited CE provider	ACCME	Hospital/healthcare delivery system	Clarify the definitions of primary business, owners, and employee. Reasons for confusion include the following: Primary business – What constitutes “primary”? Does this refer to someone who attains 51%+ income from a given business? Do we define primary business as the amount of effort /patient volume? In today’s market, companies often have various business lines and subsidiaries that could support its overall supply/service chain but are arguably not part of its primary business. Perhaps the focus needs to be more on the business’ vision or mission. The definition of primary business encompasses large ramification in the definition and our understanding of eligible/ineligible entities. Owners and employees - The definition of an owner and employee can vary depending on the state of operation for the business. For example, California defines certain freelancers (contract positions) as employees where other states do not. If each provider used its state laws to define business owner and employee, it could create inconsistencies across providers in identifying eligible/ineligible entities. The ACCME should provide further guidance on which employee/owner definition to use and clearly define both owners and employees, as they are pertinent in our understanding of eligible/ineligible entities.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	It's clear to us but won't be clear to non-CME providers. Almost anywhere we use those proposed terms (on forms, esp disclosure form), we'll need to provide a definition and the list of organizations. Using a broader term to catch any conflicts of interest that aren't the typical ‘commercial interests,' drug or device companies seems reasonable. Because the proposed terms aren't descriptive, using them will be cumbersome. We might as well say "commercial interests and other entities such as etc. etc." rather than use a new term.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	We believe the terminology eligible and ineligible are not going to be clear to external bodies, organizations and healthcare professionals. In addition, there needs to be clarity on the eligible entities. For example, Technology or data management companies (non-health related) are eligible; does that in turn mean that health related technology and data management companies are ineligible. It appears that Electronic health records companies, which would be considered health data management are eligible entities.

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Accredited CE provider	ACCME	Hospital/healthcare delivery system	Regarding new terminology, “Ineligible entities” If the goal is to “simplify and clarify” it would be better to refrain from adding to “CME-ese” lexicon that already creates barriers for CME Department staff communications with physician planners and faculty. Better to continue with or more clearly integrate the term “Commercial Supporter.” Regarding use of the word, “primary” - Entities that are ineligible to be accredited in the ACCME System are organizations whose primary business is … Please contemplate if a health system will be considered an eligible entity in scenarios that are not uncommon strategies for healthcare systems to cut costs and increase revenue. 1-Enters into a collaborative partnership with other healthcare systems to manufacture and distribute generic medications in an effort to control their costs? 2-Has a subsidiary that supports its employees and medical staff members to become innovators in healthcare by developing a product that will improve patient safety and/or health care outcomes, and that subsidiary ultimately patents and sells technology in partnership with the inventor(s)?
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Under the Ineligible Entities: How do we know when a product has begun the FDA approval process? What happens if the product begins the FDA approval process during the educational activity? Also, please define a wearable product. Finally, please better define owners. What does “owners” include? Founders, private equity, etc.

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Accredited CE provider	ACCME	Hospital/healthcare delivery system	your definition for Eligible Entities, it is not clear what you mean by “Entities eligible to be accredited . . . serving as fiduciary to patients . . .). A clearer description of this aspect of your definition would be appreciated, as it is often difficult enough for those of us CME employees without advanced degrees to interpret exactly what the ACCME means and wants. The changing of the terminology from Standards for Commercial Support to Standards for Integrity and Independence in Accredited CE is not necessary or helpful to providers. If all of this language changes, that means that every provider has to rewrite every policy and form connected to SCS to accommodate the ACCME’s new language. More work, with no real benefit. We are still trying to achieve the same end, which is to limit the influence of industry on accredited CME. This is the ACCME creating more unnecessary work for providers. Under Types of Organizations That Cannot Be Accredited in the ACCME System Where you say “Joint providership enables accredited providers to work with some types of nonaccredited organizations to deliver accredited education.” – If an accredited provider is allowed to engage in a joint providership relationship with another accredited provider (like an accredited medical education company), while knowing that only one of the two will take full accreditation responsibility for the activity, then that should be stated.
Accredited CE provider	ACCME	Nonprofit (other)	Consider offering examples to help clarify the difference between pharmacies (eligible entities) and pharmaceutical companies (ineligible entities) (e.g., Walmart pharmacy, Walgreens pharmacy, PillPack by Amazon Pharmacy). Given AMA/ACCME alignment parameters suggesting the use of gamification, specify that “software or game developers” are eligible only if non-health related, like is the case for technology or data management companies. Consider explaining the difference between a software and technology company.
Accredited CE provider	ACCME	Nonprofit (other)	Need clarification regarding the definition of eligible and ineligible entities (e.g., are all nonprofit organizations eligible entities, even if they also produce healthcare products/services?). Please provide additional clarification for the term “primary business” as a differentiator to determine ineligible entities. How is “primary business” determined?

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Accredited CE provider	ACCME	Nonprofit (other)	Overall, while the classifications seem appropriate and primarily well-defined, we still see areas for which further clarification is needed. These include: relationships between eligible and ineligible entities; entities that could seemingly fit in either category; what constitutes an employee relationship; individuals or organizations that may have a legitimate role in both types of entities: • Can an ineligible entity own an eligible entity? (e.g. an advertising agency owning an education company) • If so, how is this resolved/mitigated? • Are there firewall requirements? • If so, what are they? • Likewise, can an eligible entity own an ineligible entity? (e.g. a group medical practice develops [owns] a proprietary device or diagnostic used for patient care? • If so, how is this resolved/mitigated? • Are there firewall requirements? • If so, what are they? • Are freelance contractors, such as medical writers or statisticians, able to provide services to both eligible and ineligible entities? • Other examples: Is a for-profit medical marijuana manufacturer or dispensary eligible? Is a for-profit pharmacy eligible? Can clinicians sell over-the-counter drugs or cosmeceuticals? Can an eligible entity (e.g. a patient advocate) receive funding by ineligible entities for non-certified efforts, (e.g. advisory boards)? Can a publishing company accept a paid advertorial?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	- Provide a definition of “primary,” and how “primary” will be measured in terms of an organization’s mission and function. -Define the beginning of an “approval process through the FDA,” and provide examples of how providers may demonstrate compliance.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	- Recommend more clearly spelling out how the new standards differ from the old—there are a few places where the differences are minute. - Terminology changes—if accredited continuing education is replacing continuing medical education will we need to change ‘CME’ to ‘ACE’? Would older activities be grandfathered in with ‘CME’ or would we need to go back and change everything to ‘ACE’?

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Accredited CE provider	ACCME	Nonprofit (physician membership organization)	"Growers, distributors, or sellers of medical FOODS and dietary supplements." I work with obesity clinicians. Diet is a major component of treatment. This definition doesn't tell me where to draw the line between medical and non-medical foods. "Manufacturers of health-related wearable products" In my area, this could mean Fitbits and athletic gear, because exercise is a major component of obesity treatment. I doubt that's your intent. I'm guessing you actually mean a brace or sling or something like that, but the wording is too broad to be clear to my situations. What's health-related vs. what's fitness- or fashion-related?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	“Ineligible entity” is confusing and will not mean anything to faculty, planners, learners who are not familiar with the ACCME. The term “commercial interest” is already misunderstood; this new term would be worse in terms of acquiring and disseminating accurate disclosures and would significantly interrupt compliance with disclosure guidelines. We suggest continuing to use the term “commercial interest”. “Manufacturers of health-related wearable products” should be more clearly defined to only include companies where their principle product line is a wearable product with health-related implications. “Owners” needs to be more clearly defined, i.e., is it a majority stock owner? Is a Board member defined as an owner? “Subsidiaries of an ineligible parent company cannot be accredited” is confusing. Suggest: "Subsidiaries cannot be accredited when a parent company has been deemed ineligible because of structure or function.” By changing the term “continuing medical education” to “accredited continuing education,” you no longer differentiate education for the health professions from other education i.e., legal, etc. Under ACCME we are providing continuing medical education and the credit type is AMA PRA Category 1 credits for physicians, known in the medical professional system as CME. State licensing, federal regulations, and others who regulate physician learning requirements rely on the specifics of the term CME. The revised term would be confusing in the medical profession.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	According to the definition on page 7, an ineligible status is based on primary mission. How is primary defined? 51% of overall business? This needs a more specific explanation.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Could ineligible entities also include 'Agents whose clients are ineligible entities'?

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Accredited CE provider	ACCME	Nonprofit (physician membership organization)	1. ACCME have outlined examples of what they consider "eligible" entities and "ineligible" entities. However, ACCME included "Technology or data management companies (non-health related)" as eligible and did not state the opposite, i.e. health-related tech companies were ineligible. This leaves us in a state of confusion. SAGES opines that technology and data management companies do not meet the definition of ineligible entity and therefore there should be no distinction of “non-health related” or “health related.” 2. There is no definition of the terms “owner” or “employee.” Questions regarding the term owner include: a) Is a stock ownership percentage threshold for compensation that should make an individual ineligible? b) Is there a threshold of income that might cause a person to be considered ineligible, regardless of the way it is earned, such as $100K or $200K? c) Does the position that a person holds in a company, such as CEO or Founder, regardless of the method of income earned (or lack of income) automatically make the individual ineligible? 3. There is no definition of “primary business” in the new definition of ineligible entities. This puts a great deal of burden on the provider. Are we supposed to look at the percentage of sales? The number of FTEs working on the products? The number of patients impacted by the products? 4. It is unclear which holds supremacy, the definition of ineligible entities or the examples. The advertising, marketing or co
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Numerous members of many professional organizations are involved in biomedical startups. it is this innovation by members that makes our societies so advanced and cutting edge. Due to such members interest in science and advancing medicine, they are usually the more active members of professional medical societies, are more knowledgeable on topics presented. It would be a disservice to the society and its members to restrict such entities from participating. Greater clarification is needed on healthcare related wearable products.

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	ASCP appreciates the further clarity of diagnostic labs as eligible and ineligible entities. (Eligible: Diagnostic Labs that do not sell proprietary products; Ineligible: Diagnostic Labs that market or sell proprietary products). Regarding Bio-Medical Startups proposed as being Ineligible entities if they have begun an approval process through the FDA, the CPD community may not have sufficient knowledge to understand the FDA approval process and when it actually begins for Bio-Medical Startups. The definition of “owners” is not clear. What defines an “owner?” To what degree of ownership does this relate (e.g. stocks, mutual funds, etc.). Greater clarity is needed. The use of the term, Ineligible Entities, is problematic as we believe it will cause confusion to the learners, individuals in control of content, commercial supporters and other stakeholders. For example, when seeking disclosure information from all those in control of content and we reference the term, Ineligible Entities, we do not believe that those in control of content providing disclosure information will understand what we are requesting. The term, Commercial Interests, is well understood by learners, those in control of content, and other stakeholders and thus recommend that we retain the term, Commercial Interests. For the Eligibility section of the Standards, we would suggest using the term, Commercial Interests (Types of Organizations that Cannot Be Accredited in the ACCME system).
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Diagnostic Laboratories (that market or sell proprietary products) and Compounding Pharmacies (that manufacture proprietary compounds) are ineligible entities. What about Pharmacies affiliated with an ineligible entity (e.g. Walgreens or Publix, etc.). We assume this type of pharmacy could not be accredited since the pharmacy is a division of an ineligible entity (e.g. Walgreens or Publix, etc.)? This means that pharmacists employed by a hospital pharmacy could control content which addresses healthcare goods or services used on or consumed by patients. But a pharmacist employed by an ineligible entity (e.g. Walgreens or Publix, etc.). could not control content which addresses healthcare goods or services used on or consumed by patients. It might be nice to make this clearer.

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Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Clarification on 'manufacturers of health-related wearables'. Would FitBit be a health-related wearable, but not Apple Watch which can run an ECG (as the primary business of Apple does not fit the definition of ineligible)? How is Apple any different from an ECG machine used at clinics/hospitals? For medical foods and dietary supplements, would suggest adding 'manufacturers'. These are not only grown but manufactured in labs. EHR companies and other health information tech companies should have significantly more scrutiny in light of the Practice Fusion lawsuit. Any entity that could influence medical/prescribing decisions (outside of clinical services providers) could receive financial incentive for influencing those decisions & should be ineligible entities. Please elaborate on 'insurance and managed care companies. Is this in relation to Is this in relation to individual health insurance or would it be inclusive of malpractice insurance companies? What would be an example of a "fiduciary to patients, the pubic or population health?" Please clarify where medical equipment manufacturers fall within the classification of eligible/ineligible (i.e. robotics, endoscope camera, ultrasound machine). Please provide further explanation on how pharmacies are considered eligible entities as their primary business is 'selling, re-selling, and distributing healthcare goods/services.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Ineligible entity is very clear for those of us used to CME, however, it would require additional explanation to leadership and commercial interests.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	It may be helpful to provide a broader set of examples or clarifying what ACCME defines as a healthcare product used by or on patients. For example, does ACCME consider over-the-counter products produced by entrepreneurs for their patients to be healthcare products (e.g. skin creams, suntan lotions, etc.). If so, these types of entities should be clearly identified to decrease ambiguity as entities creating these products clearly serve the "professional or financial interests" of owners. Further, it may be worth considering words other than "eligible and ineligible entities" as the naming has negative connotations that are not necessary.

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
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Accredited CE provider	ACCME	Nonprofit (physician membership organization)	• Be more explicit to providers that the examples of eligible and ineligible entities are not exhaustive lists; readers could misinterpret. • Be more explicit to providers that new definition of “ineligible entity” replaces the current definition of and terminology of “Commercial Interest”; readers could be confused. • Provide definitions of the words "primary", "products", "owner" as these words can be interpreted differently and therefore have different outcomes. • Provide definition of “wearable products” as it makes many companies ineligible. For example, Apple has a mobile app which can take your pulse while you hold your phone. Does that mean a cell phone is a wearable product and all phone companies are ineligible entities? • Not clear why “pharmacies” are listed as eligible. For example, it is our understanding that Walgreen pharmacy is currently allowed while CVS pharmacy is not allowed due to different corporate structures. • Need ACCME to assist providers determine if an organization is eligible or ineligible. This is a complicated and changing landscape. Researching companies, parent companies, and subsidiaries will be even more time consuming for providers. Can ACCME help providers decipher this landscape without having to do a Corporate Review Structure? Many providers are probably researching the same companies to determine if they are eligible. Can the ACCME create/share/update a list of companies?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Please define "Ownership" - is that majority shareholder? Or does any ownership, eg 25% apply? What about stocks I own in a public company? Private company? And the start-ups - what if they have been started to gain a patent but are still pre-clinical/ no FDA process?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	re: "Subsidiaries of an ineligible parent company cannot be accredited." This blanket statement is confusing. Please clarify further. Clarity on how ACCME defines a “primary business” would be helpful for providers to make appropriate determinations of this.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Recommend ACCME consider that the word “company” versus “ineligible entity” to ensure clarity for physicians and patients. ACCME should also more clearly define “primary business” and how the definition is to be used.

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Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Please see our full comments sent to communications@accme.org. We understand ACCME may interpret this to prohibit physicians who sell dietary supplements to their patients from presenting on any topic. Such a policy appears to turn on how ACCME intends to apply its definition of ineligible status for “sellers of medical foods and dietary supplements” to physicians. We ask that the statement defining ineligible entities be redrafted to make clear that while physicians selling products may have a relationship with an ineligible entity that needs to be addressed per Standards 2 and 3, they themselves are not. Except for highly unusual arrangements that should be disclosed and addressed pursuant to proposed Standards 2 and 3, physicians who sell supplements have no financial interest in sales made to any party other than their own direct patient sales. As stated in proposed Standard 3, “financial relationships of any dollar amount are defined as relevant if the educational content is related to the business lines or products of the ineligible entity.” Such relationships can best be addressed a proper assessment of the level of evidence and the use of disclosure and other requirements in the proposed standards. We are particularly concerned that speakers would be ineligible and banned from speaking at all, even on topics irrelevant to financial interests. The limitation in Proposed Standard 3 to an assessment of actual conflicts is sufficient and consistent with long-standing
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The term “owner” is vague and requires clarification in order for providers to be compliant. Is there a certain threshold of stock ownership, for example, that would categorize an individual as an owner? Or is any degree of personal financial investment considered ownership? Also, we have faced many instances of individuals performing research in an academic institution, in which the institution creates a start-up company based on the research. If the individual was the source of the research on which the start-up is based and is given a title with the start-up but financial control is maintained by the institution, is this individual an owner?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Recommend aligning with the CMSS Code for Interactions with Companies. Define "primary business" and "owner." Why would an EHR company be considered eligible?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The AUA would like to support the comments presented by CMSS and recommend the alignment of the definition of an "ineligible entity" with the CMSS Code for Interaction with Companies definition of "Company".

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Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Primary Business: How does ACCME define this? This will be help for providers to make appropriate determinations. Mitigate: requires explanation every time it's used. Healthcare delivery systems: Vague, provide definition and examples. Eligible Entities: Will not be understood by general healthcare provider, will need explanation each time we ask them to disclose. Ineligible Entities: Too broad, beyond the realm of products used on or by patients. Many listed products are not used in conjunction with any specific disease or condition. By this logic, all food, vitamins, water, exercise equipment, etc. are a healthcare product. Where would we get a list of companies that are ineligible? Not all companies list "manufacturer" or "Compounding Pharmacy" in their name. Limit to healthcare products PRIMARILY used by or on patients. Growers, distributors, etc. ACCME is overstepping here. These are routinely marketed to the general public and not at all limited to the patient population. Impossible to implement. Includes Advertising, Marketing or communication firms whose clients etc. All clients? Some clients? How would we know? Where would we get a client list? Impossible to implement. Mfr of health-related wearable products: Category is too broad. Wearable products are marketed to the general population, not solely to patients. These types of products should be clearly identified and limited to those used PRIMARILY by patients, NOT the general public. Would compression socks count?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The types of eligible/ineligible organizations in the expanded list are helpful; however, additional detail is needed to clarify ineligibility. Specifically, why would an organization be ineligible?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	There is now a distinction between diagnostic labs. More clarity needs to be provided on what will constitute as a product, will a consultation service count as a product. What about proprietary testing? Should the distinction be between whether the labs markets to patient's vs physicians? In the era of molecular diagnostic testing, the line between labs that sell proprietary products and those that do not will quickly blur.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Will there be a link (or additional resources) to decipher parent/subsidiaries of ineligible entities. Will ACCME define "primary business" for ineligible entities?

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Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The ACCME should more clearly define “primary business” and how the definition is to be used. As an example, would an organization be ineligible if 1) it does NOT meet the definition of an ineligible entity because its primary purpose is NOT producing, marketing, selling, re-selling or distributing healthcare products used by or on patients, but 2) DOES meet one of the examples of ineligible entities? An example would be an organization that provides clinical services directly to patients but also sells dietary supplements in their office. Diagnostic testing in genetics is highly specialized and outside the scope of typical in-house laboratories. However, a clarification should be added which indicates “any ineligible entity which is acquired by a commercial interest, but which maintains a firewall between the organizations will still be considered an eligible entity. The ineligible entity interest should provide documentation to the provider about this firewall to ensure independence.” This will enable experts in rare disease research and genetics to present work on assays and advances in diagnostic testing. It is not clear as to the exception of companies that are subsidiaries of ineligible companies with appropriate firewalls as to employees being eligible to provide content. ACMG recommends exempting “diagnostic labs (that market or sell proprietary products)” as an ineligible entity.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The terms “primary business” and “primary mission and function” leave excessive room for interpretation about the relative value of various product lines within a business. Sufficient detailed guidance on how to differentiate an entity’s “primary” business from its other lines of business will be greatly needed to remove abject subjectivity and ensure standardization. On the list of supplied eligible entities, pharmacies are noted as eligible, despite its central business of selling and distributing healthcare products. Ineligible entities include pharmacy benefits managers, but not pharmacies. Also included as eligible are electronic health record companies, some of which problematically provide treatment guidance. Therefore, the lists provided of eligible versus ineligible entities serves to blur objective lines, instead of clarifying the current proposed definition. In efforts to support improvements in clarity and alignment regarding ineligible entities, ACP does endorse the definition of “company” published by CMSS: “For-profit entities that develop, produce, market or distribute drugs, devices, services or therapies used to diagnose, treat, monitor, manage, and alleviate health conditions”.

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
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Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The proposed term “ineligible entities” reflects an ACCME-centric perspective that ignores the main use of the existing term, “commercial interest.” The majority of individuals who will apply the term will be the planners, faculty, authors, editors & staff of educational activities who are required to complete financial disclosures. For these thousands of individuals (for our organization alone), whether or not an entity is eligible for accreditation by ACCME will seem completely irrelevant. What is relevant is whether a relationship with the organization needs to be disclosed and requires a conflict of interest (COI) resolution or will preclude an individual from participating in a CME activity. For that purpose, the existing term of “commercial interest” makes sense. Providers will need to provide the long ACCME explanation of which relationships must be reported, and the new term will only create added confusion. Use of the “ineligible entities” terminology throughout the "proposed" standards makes it appear that the change is a fait accompli, which is regrettable. Similarly, changing the term CME to Accredited Continuing Education (ACE) is unnecessary. Except in the narrow world of accreditation, CME is thought to mean exactly what it says (not limited to physician education). Rather than trying to get millions of learners who are used to the term CME to change to ACE, it would seem easier to instruct educators to broaden their thinking re the CME terminology.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We applaud the ACCME for clarification on organizations that are ineligible such as diagnostic labs and biomedical startups. However, suggest including that in addition to the FDA, that international regulators be included. We do international activities, as well as have international speakers.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Trying to find eligibility for subsidiary companies produces additional administrative burden, particularly with startups where relationships aren’t clearly defined. We suggest that the eligibility of the parent company does not define or affect the eligibility of the subsidiary in terms of Standard 3. Clarity on how ACCME defines a “primary business” will be helpful for providers to make appropriate determinations of this.

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Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	This section is clear in regard to explaining who can and can't be a CME provider. However, the use of the term "ineligible" throughout the rest of the document in place of what used to be called "commercial interests" is problematic because the term ineligible is not intuitively understood in the way that the term commercial interest is. Even if someone did not know the exact meaning of commercial interest, they could understand the basic meaning. Untended consequences: the language of the Standards becomes inaccessible to anyone who is not steeped in the definitions. This makes it more difficult to share text from the standards with physicians and others (administrators and executive leaders) who do not have this level of understanding. Language used on disclosure forms would also have to change to be consistent with this change—again adding confusion. This might be especially confusing to non-English speaking faculty. Suggest using a term that better reflects the reason why these entities are ineligible such as: commercially conflicted, commercial interest, or financially conflicted. Not sure why the word "system" was added to ACCME.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	To ensure greater clarity & consistency when accredited providers implement the Standards, examples of companies that meet the definitions of eligible & ineligible entities will be needed to distinguish a) tech/data management companies/non-health related (eligible entities) from manufacturers of health-related wearable products (ineligible entities) & b) tech companies (e.g. Apple), that are non-health-related, but develop health-related wearable products. "Primary business" should be further defined, as it is subject to interpretation. "Commercial interest" is an established term within the CME enterprise that needs minimal clarification overall, whereas "eligible" & "ineligible" entities are terms that correlate with whether an organization may be accredited but are not descriptive enough to all who engage with accredited CE, including learners. Thus, we recommend that the term, "commercial interest," not change. Also, the ACCME may wish to collaborate with the CMSS to align the definition of an "ineligible entity" with that of "company," which is cited in the CMSS Code for Interactions with Companies (https://cmss.org/code-signers-pdf/) and includes the word "develops." We concur with the addition of "owners", along with employees, as those whose participation in accredited CE may occur in limited circumstances. To provide greater clarity, "owners" should be further defined, as to whether that includes someone who holds a patent and/or has stock options.

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Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We comment here on the ACCME's adoption of new terms in the revised Standards. We request that the ACCME reconsider including "Electronic health records companies" as "Eligible Entities." As with any company conducting commercial activity in the healthcare space, some degree of education on the use of their product is relevant and appropriate. However, given the risk of bias in the content or delivery of such education, it may not be suitable for continuing education credit. It is for this reason that the ACCME has determined that entities with a "commercial interest" should not be able to deliver CME to clinicians. For these reasons, the AMIA Board of Directors calls on the ACCME, and related entities concerned with continuing professional education, to recognize that companies that sell HIT systems and products, including EHR vendors, are a commercial interest. We encourage ACCME to work with all stakeholders to establish rules and processes by which they may support certified CME in a manner that is independent and unbiased. Just as pharmaceutical and medical device companies have developed experience with such rules since they were applied to such companies, so, too, should HIT companies incorporate similar structures & processes to support independent, unbiased continuing education. Doing so is critical to ensuring a safe, high-quality healthcare system that will benefit all parties including patients, healthcare professionals, health systems, & HIT companies.

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Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Would recommend removing all reference to “protecting” learners. As written, “ACCME is committed to ensuring that accredited continuing education … 2) protects leaners from promotion, marketing and commercial bias.” has a negative connotation to it. This is not only condescending to learners, but also positions financial supporters – who can be valuable partners within appropriate parameters – very negatively. It may be helpful to provide a broader set of examples or clarification on what ACCME defines as health-related wearable products. Are they ineligible because they are “healthcare products” used by patients, or just because they are any products used by the public that could have an impact on their health? The category is so broad, it’s hard to truly understand what falls within it, i.e. apple watch or newest prosthetic. As written, one can interpret all food, vitamins, water, exercise equipment, bicycles, etc. as a healthcare product. It is not clear what the ACCME is truly trying to regulate.
Accredited CE provider	ACCME	Other: Nonprofit, scientific research association	The definition of a bio-medical startup limits the designation to organizations that have begun an approval process through the FDA. That qualification seems to exclude international bio medical startups. Is that exclusion on purpose?
Accredited CE provider	ACCME	Other: Public/nonprofit/healthcare system/education/school of medicine	Pharmacies and insurance companies are eligible, but pharmacy benefit managers are not. It was clearer when "commercial interests" and "nonprofit interests" were separated completely.
Accredited CE provider	ACCME	Other: University - not a school of medicine	Clarification of "subsidiaries" and "primary business."

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Accredited CE provider	ACCME	Other: university	Having used ineligible/eligible to describe specific entities for many years, it is unclear why we would stop calling them commercial entities. Since the reason they are ineligible/eligible is based on their status as a commercial (or not) entity, why confuse the matter even further. We still have to clarify 'commercial entity' to those new to CME and changing it again makes very little sense. While the paperwork we use will have to be changed to reflect the new language, the conversations will remain the same. Please don't add more work to an already confusing topic. AND please don't add more work to those of us who have to change all the documents used in practice for yet another thing unrelated to the work-meaning if we err in how we manage commercial entities in any area of an activity, we expect a ding at reaccreditation but to get dinged because we used the wrong words is disheartening. Regarding the ineligible: Advertising etc. firms whose clients are ineligible: Need more info-will we need to get a list of all company clients? Diagnostic labs that market/sell proprietary products: How will we determine this? Manufacturers of health-related wearable products: Does this include all products like Fitbit which tracks things like heart rate etc. for the wearer or wearables wirelessly connected to a clinical office or lab, that is tracking data for a specific clinical purpose? Most APs are already have limited resources and staffing!
Accredited CE provider	ACCME	Publishing/education company	"Subsidiaries of an ineligible parent company cannot be accredited." While understanding that the determination of eligibility is all about structure and function, this blanket statement is confusing to many already. This is a case where more words would be helpful. Suggest: "Subsidiaries cannot be accredited when a parent company has been deemed ineligible because of structure or function, regardless of steps taken to firewall the subsidiaries." Clarity on how ACCME defines a “primary business” will be helpful for providers to make appropriate determinations of this.
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Accredited CE provider	ACCME	Publishing/education company	The Eligible Entities example: Technology or data management companies (non-health related) is unclear—specifically, what does "non-health related" entail? Conversely, would all technology/data management companies that ARE health related be ineligible? The ineligible examples only include wearable products, please elaborate. The grey area persists around downloadable clinical diagnosis/decision-support apps and programs which may or may not be used during the care of patients but are designed to improve care.

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Accredited CE provider	ACCME	Publishing/education company	Clarity on how ACCME defines a "primary business" will be helpful for providers to make appropriate determinations of this.
Accredited CE provider	ACCME	Publishing/education company	Clarity on how you view/consider a "primary business" will be help for providers to make appropriate determination of this that maintains the intended spirit.
Accredited CE provider	ACCME	Publishing/education company	For the most part, the info is clear and appropriate. Question: where would contract research organizations fall? They don't produce, market, sell, re-sell, or distribute anything...
Accredited CE provider	ACCME	Publishing/education company	RE: "Subsidiaries of an ineligible parent company cannot be accredited." While understanding that the determination of eligibility is all about structure and function, this blanket statement is confusing to many already. This is a case where more words would be helpful. Suggest: "Subsidiaries cannot be accredited when a parent company has been deemed ineligible because of structure or function, regardless of steps taken to firewall the subsidiaries." Clarity on how ACCME defines a "primary business" will be helpful for providers to make appropriate determinations of this.

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Accredited CE provider	ACCME	Publishing/education company	re: "The ACCME determines eligibility for accreditation based on the characteristics of the entity seeking accreditation and, if applicable, any parent company. Subsidiaries of an ineligible parent company cannot be accredited. If an eligible parent company has an ineligible subsidiary, the owners and employees of the ineligible subsidiary must be excluded from accredited continuing education except in the limited circumstances outlined in Standard 3.2." While understanding that the determination of eligibility is all about structure and function, this blanket statement is confusing to many already- as it sounds like even that appropriately firewalled subsidiaries of a non-operating holding company parent might be ineligible. This is a case where more words would be helpful. Suggest: "Subsidiaries cannot be accredited when a parent company has been deemed ineligible because of structure or function."
Accredited CE provider	ACCME	Publishing/education company	Regarding "Subsidiaries of an ineligible parent company cannot be accredited." While understanding that the determination of eligibility is all about structure and function, this blanket statement is confusing to many already. This is a case where more words would be helpful. Suggest: "Subsidiaries cannot be accredited when a parent company has been deemed ineligible because of structure or function, regardless of steps taken to firewall the subsidiaries." Clarity on how ACCME defines a “primary business” will be helpful for providers to make appropriate determinations of this.

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Accredited CE provider	ACCME	Publishing/education company	Technology or data management companies (non-health related) are listed as 'eligible entities'. Does this mean that a technology or data management company that is health related is 'ineligible'? How do you define a technology company? How do you define 'health related vs. non-health related? How is that different from an EHR or other type of software company? These companies collect and use patient level data, which is very much health related correct?
Accredited CE provider	ACCME	Publishing/education company	The first item relates to the terminology: "Eligible Entities" and "Ineligible Entities". Although these titles are clear, the application of the wording throughout the revised Standards may create unintended difficulties in application. Without context, "ineligible entities" sounds pejorative. We suggest "entities ineligible for accreditation" be used throughout the standards. In exploring this wording change with clinicians, there has been an appreciable difference in how the phrase “do you have any financial relationships with [ineligible entities] [commercial interests] or [entities ineligible for accreditation]” is received – with the latter being interpreted as less judgmental and overall neutral in tone. Secondly: Related to (eligible) tech companies/software companies and (ineligible) manufacturers of health-related wearable products: what about an app developer [software] meant to interface with 3rd part hardware? How would a diagnostic lab with laboratory-developed tests be classified? What about a pharma or device company that is commercialized outside of the US?
Accredited CE provider	ACCME	Publishing/education company	The overall classifications seem primarily well-defined, there are areas that require further clarification such as: relationships between eligible and ineligible entities where entities could potentially fit into either category, what firewall requirements are necessary for such an organization? Can an eligible entity own an ineligible entity? What about companies who make wearable devices, such as Fitbit? Would an employee be eligible to present data on a wearable or would they be considered a medical device company? If yes, would disclosures for stock in Nike, Apple, Fitbit, etc. now be necessary? Are freelance writers able to provide services to both eligible and ineligible entities?

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Accredited CE provider	ACCME	Publishing/education company	The word “influence” has been added, along with “control.” What is the intent of the word “influence” in this context? We presume the word “influence” in this context is related solely to ineligible entities not being allowed to control any aspect of the planning. Faculty and planners by definition “control and influence content” but it needs clarity. In addition, are “Call for Grants” from ineligible entities, that identify unmet educational needs of a target audience, and encourage the improvement of medicine and healthcare, considered to be “influence”? Since responsibility and control over the selection, content, faculty, educational methods, materials, and venue for an independent medical education activity belongs solely to the Accredited Provider, will “Call for Grants” continue to be permitted under the new standards? Ineligible entities. request as part of reconciliation, evaluation and outcomes data to be provided. Some examples of information requested by ineligible entities include: (1)descriptions of how each outcomes level was assessed, (2) learner responses and feedback, (3) identification of barriers to change, (4) identification of educational gaps that have been fulfilled, as well as (5) future needs of the audience. Is asking for outcomes reports to include this information considered “influence” even though the activity is developed independently of the ineligible entity?
Accredited CE provider	ACCME	School of medicine	(1) What does primary mean? (2) What does patient mean? If a person buys a wearable that is not prescribed does it count? It would seem like you would be better off limiting this to things that are prescribed, ingested, or used inside the body. (3) What is the difference between a smart scale and a wearable. (4) Strongly encourage you to eliminate the wearable piece.

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	Consider providing a limited exception (not for accreditation but for participation) for diagnostic laboratories that do genetic testing on human samples. AMC's doing work in Precision Medicine may be developing and performing genetic tests. The challenge is that there is diversity among the tests across laboratories (not all tests screen the same exons when testing for specific genes). Test developers are best positioned to distinguish the tests, indications, interpretations, and limitations. However, the physicians may be conflicted by having ownership or some type of employee status and thereby disqualified from participating. We are planning the steps for certifying a new molecular tumor board across a large health system. These are cases where patients have failed conventional therapy and have undergone genetic testing to identify potential mutations that may be amenable to application of therapies specific to the tumor's genome in contrast to therapies defined by tumor types. The genetic testing results are completed prior to the tumor board by the referring physicians. These patients are approaching the end of options and time is critical. Representatives of a genetic diagnostic laboratory have key insights in the board's review of testing reports (some from other diagnostic laboratories). The point of involvement is to assist with test interpretation to inform choice of agents for therapy (not to market genetic testing which will have already been conducted).

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	Eligible and Ineligible Entities are fine to categorize entities that can/cannot be accredited to provide CME content. However, replacing “commercial interest” with “ineligible entity” is problematic for conflict of interest (COI) identification and mitigation. COI forms will now change to this: “An ineligible entity is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.” Planners and faculty at CME activities might believe their financial relationships with “ineligible entities” in terms of grants, advisory boards, speakers bureau, etc., will make THEM ineligible to control the content of CME – even though the accredited provider will know that is not the case. Also, the term “ineligible” will cast an aspersion on the financial relationships people have that are, in fact, allowable and not inappropriate at accredited activities (as long as those conflicts are mitigated properly). It will be problematic for CME providers to explain to people, succinctly, that their own financial relationships with “ineligible entities” doesn’t make them “ineligible” to control content, nor that we, the accredited provider, deem those relationships to be less than sanguine. It is difficult to suggest a modification to remedy the type of confusion we believe will ensue in the process of identifying and mitigating conflicts of interest if “ineligible entity” replaces “commercial interest.”
Accredited CE provider	ACCME	School of medicine	In the last section, expand on this to say "subsidiaries cannot be accredited when a parent company has been deemed ineligible because of structure or function regardless of steps taken to firewall the subsidiaries" if that's what is intended. A toolbox and FAQ section with specific, common examples would be helpful to provide guidance.
Accredited CE provider	ACCME	School of medicine	my comments will be located under the comments for standard 3
Accredited CE provider	ACCME	School of medicine	If a faculty or planner has done either research for or serves on a board or has a relationship with an ineligible organization, does that make them an ineligible person? If so, then I assume if their relationship can be mitigated based upon the exceptions, then it is OK.

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	Eligible/ineligible are super confusing legalese – what does this mean? It's very close to HIPPA terminology of covered/non-covered entities which have been confusing people for years. It feels like the same old definition, just changing terminology to MORE confusing terminology. Say what we mean; an organization making money off patients in healthcare = promotional organization. An organization interested in teaching providers to provide better patient care = educational organization. There's always going to be so much gray & you're not going to be able to categorize every situation. Trust your providers to make the call & move on. (See obscenity legal history for examples or trying to legislate gray; "I shall not today attempt further to define the kinds of material I understand to be embraced within that shorthand description, and perhaps I could never succeed in intelligibly doing so. But I know it when I see it, and the motion picture involved in this case is not that." US Supreme Court Justice Potter Stewart, 1964 in Jacobellis v. Ohio.) Is this a good opportunity to clarify the difference between joint providership and Joint Accreditation and perhaps rename "joint providership"? I recognize ACCME primarily uses this definition as it decides who can be accredited, but we also must use it for relevant relationships so maybe some recognition of that use of the definitions and that these are guidelines for providers as we make our decisions would be useful.
Accredited CE provider	ACCME	School of medicine	re: "Subsidiaries of an ineligible parent company cannot be accredited." While understanding that the determination of eligibility is all about structure and function, this blanket statement is confusing to many already. This is a case where more words would be helpful. Suggest: "Subsidiaries cannot be accredited when a parent company has been deemed ineligible because of structure or function, regardless of steps taken to firewall the subsidiaries." Clarity on how ACCME defines a "primary business" will be help for providers to make appropriate determinations of this.

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	Recommend adding clarification on ineligible entities in regard to technology or data management companies that are healthcare related.
Accredited CE provider	ACCME	School of medicine	Tech non-health specified but no specifications in pharmacies and software/game developers.
Accredited CE provider	ACCME	School of medicine	If we are willing to accept FDA regulation as a line of demarcation for when an entity becomes ineligible (for start-ups), why not defer to the FDA's definitions for drug/medical device? No single definition will be perfect, but an already generally agreed upon standard will eliminate interpretation/guesswork. For example, "manufacturers of health-related wearable products" are considered ineligible, but where is the line? Does it include a Fitbit? The FDA says no (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices), but there is some room for interpretation within these guidelines. "Pharmacies" are included on the list of eligible entities, while "growers, distributors, or sellers of medical foods and dietary supplements," are ineligible. Nearly all retail pharmacies sell vitamins, so would that make them ineligible? If a health system forms a generic drug company to distribute drugs within system hospitals, is that now a commercial interest – as a distributor of pharmaceuticals? These are the questions that providers deal with on a daily basis, and the new categories do not add clarity. Also, per ACCME guidance, we have deferred to the IRS definition of employee to determine if a relationship should be categorized as such. Is that still the case under these definitions? If not, the threshold for owner/employee needs to be clearly defined.
Accredited CE provider	ACCME	School of medicine	The definition of an ineligible organization is unclear. What if someone is producing something with the intent that it will be used on patients, but it is not currently being used by patient? It sometimes seems as though clarification is needed regarding what a 'healthcare product' actually is. Is this only something prescribed, or is it over the counter? A question that frequently arises is whether drugstores and grocery chains/supermarkets that have pharmacies or sell all sorts of home healthcare items, nutritional supplements, etc. would be considered ineligible? For grocery stores it might not be their PRIMARY business, but depending on what is considered a healthcare product, it could be the primary business of a pharmacy (E.g. CVS, Walgreens...).

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	The terms ineligible and eligible are so broad and come with a meaning that could be misleading. When explaining to a clinician, that an organization is ineligible, but that 'yes' they can have an acceptable relationship with them, I can imagine confusion. The term 'ineligible' would lead most to believe that they're ineligible, in all respects. I also believe that the term commercial interest has meaning and there is a general understanding of it; I honestly think this term was clearer than ineligible/eligible. Also, for the tech or data management (non-health) companies-- are you envisioning Apple in this category? Or do you see them as a manufacturer of health-related wearable products? I have an Apple watch; it can do an EKG, but I use it to tell time and respond to texts. How do you make this distinction? I still don't think it's entirely clear. Lastly, (and I realize this word was in an ACCME note in the original standards, but I struggled with it then too), can you please define an owner of a company? What exactly does that mean?
Accredited CE provider	ACCME	School of medicine	They are clear, better than before, but still do not encompass all of the types of organizations that accredited providers are encountering in our work. What about Bio-medical start-up companies that have not yet begun the approval process with the FDA? What about data companies that collect health data for purposes of big data analysis? What about companies that provide patient coaching on lifestyle modifications? As soon as this list is published, there will be even more types of companies to evaluate for eligibility. Without wanting to stifle innovation and the important scientific exchange among clinicians and organizations advancing science, we need additional and on-going clarification here. This list would ideally be revised every six months based on questions that come in from providers. Also, What does the ACCME mean by “owner” in this statement: The owners and employees of ineligible entities are considered to have unresolvable financial relationships and must be excluded from participating as planners or faculty, and must not be allowed to influence or control any aspect of the planning, delivery, or evaluation of accredited continuing education. Is this distinct from ownership interest? What about a founder?

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	What is the rationale for the change in terminology? What is the intent of the ACCME? The term commercial support is clear- ineligible does not represent the situation that we are resolving.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	• Can you clarify what is an example of "primary business". For example, if a business has both eligible and ineligible divisions (not subsidiaries), is the determination dependent on the person presenting, and whether their role with the company is relevant to the content? • ASCO would encourage full alignment with the CMSS definition of company from the CMSS Code for Interaction with Companies o The word "company" may be clearer to both providers and patients than "ineligible entity" o The verb "develops" would more closely tie with the listing of bio-medical startups in your list of ineligible entities o Noting "for-profit" in the definition would be a clear descriptor to help providers and other distinguish companies from eligible entities. o Expand "healthcare products used by or on patients" with "drugs, devices, services or therapies used to diagnose, treat, monitor, manage, and alleviate health conditions". • Why are software or game developers considered eligible to be accredited, or should you specify that the software/games cannot be used by or on patients? • We looked for healthcare-related technology/data management companies in the ineligible list but didn't see anything – should that be added? • What is the ACCME opinion regarding eligibility of entities involved in supporting the research infrastructure? • Could you clarify why pharmacies are eligible entities, but pharmaceutical distributors are considered ineligible?
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	Based on the definitions, it appears that home care companies, where the focus is to provide clinical services to patients in the home setting would be classified as an eligible entity because the clinical care is being provided directly to the patients. If the ACCME agrees, please add to the eligible organizations list.

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	Subsidiaries of an ineligible parent company cannot be accredited." While understanding that the determination of eligibility is all about structure and function, this blanket statement is confusing to many already. This is a case where more words would be helpful. Suggest: "Subsidiaries cannot be accredited when a parent company has been deemed ineligible because of structure or function, regardless of steps taken to firewall the subsidiaries. “Ineligible entities” - Consider maintaining the term commercial interests and modify the definition to indicate that commercial interests are ineligible entities. Changing the language from commercial interests to ineligible entities would result in Providers having to update language on documents, forms, websites etc. which would be a tremendous burden.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Other: academic medical center	"If an eligible parent company has an ineligible subsidiary, the owners and employees of the ineligible subsidiary must be excluded from accredited continuing education..." What about the reverse? If Hospital A (an eligible entity) has a subsidiary that serves as a Pharmacy Benefits Manager (an ineligible entity), then is Hospital A suddenly ineligible? How do you define "ownership"? What is "medical food", especially in the age of lifestyle medicine? The problems also relate to Standard 3 revisions. Suggestions are difficult when it's unclear what you want to achieve.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	Please clarify what constitutes a ‘health-related wearable product’.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	The classifications are not as clear as could be. For example, group purchasing organizations are not listed.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	The introduction of the word “primary” into the proposed new definition would appear to suggest an increased flexibility by the ACCME in categorizing organizations as eligible or ineligible. Also, the determination of primary may vary between organizations depending on what metric is used to make the determination, thus leading to less consistency across the CME enterprise.

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	Better clarification regarding Biomedical Startups. What about companies that plan education for ineligible organizations, or are involved with marketing for them, whether or not they have a fire wall.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	In the definition of ineligible entities, clarification on “primary business” would be helpful. How should accredited providers determine what constitutes an entity’s “primary business”?
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	We appreciate the clarity added to this standard. Academic centers will continue to encourage faculty to protect their intellectual property, resulting in ownership/employment. We recommend that the providers be allowed to mitigate these relationships by doing the following: 1. Document the activity planner/author/speaker has a current primary appointment with a college or university 2. Require that the discloser attest, at the time of disclosure to the provider, that they are compliant with their campus COI management. 3. Provider follows the allowed steps to mitigate the relationship(s). Campuses ensure these faculty are eligible to teach medical students and residents via these plans, that should allow for accredited providers to mitigate their relationships. In any case, a solution to this issue is needed. As providers, we can't continue to make the case to leadership that CME matters when the some of the most successful researchers/innovators are not able to teach in accredited activities. 2. In general the level of expertise it will require of non-clinical providers to research and understand the growing complexity of business ownership line of disclosed entities, is overwhelming. We request the ACCME make available a list naming ineligible entities for providers to reference. 3. These closely sounding words "eligible and ineligible' may become a problem over time.
Accredited CE provider	Other: Accreditation Council for Pharmacy Education	Nonprofit (other)	Conflicting language: The eligibility section sates that owners/employees of ineligible entities have "unresolvable" relationships, yet the language and direction in Standard 3 is to "mitigate" financial relationships, not to "resolve" them. This could have unintended consequences (see notes in Standard 3 section).

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider		Nonprofit (physician membership organization)	I go to meetings to learn new things (methods, procedures, etc.). If credit is only given for teaching things which are generally accepted, then how are we going to make any progress? It would have taken about 100 years before credit would have been given for Semmelweis' antiseptic procedures. If only generally accepted things are taught for credit, then it is a waste of time to go to meetings except for new doctors who have not already learned those things!
Accredited CE provider	Other: ACPE	Hospital/healthcare delivery system	While I applaud the dedication to putting service of others above self-interest, employment by an organization in the "ineligible entities" list should never be a sole basis of who can and cannot be an accredited provider. As a part of a very large company that includes both eligible and ineligible segments of the business, the ownership has never been a determinant in the content of our educational activities. The content not the ownership should be basis of eligibility. Employment in one segment of the business should not mean that I cannot provide "scientifically justified and generally accepted" educational content. While I can see that you might need additional scrutiny in certain settings, employment alone should not qualify or disqualify anyone. We need more providers of quality, scientifically-sound education, not less.
Accredited CE provider	Other: ACPE	Publishing/education company	I'm wondering about potential for bias if eligible entities are not acting as a fiduciary to patients. For example, insurance companies and pharmacies are both listed as eligible entities. An insurance company could own a pharmacy (many own specialty pharmacies) and if they were engaged in CE, could there be an opportunity for bias by driving customers to their pharmacy business?
Accredited CE provider	Other: ANCC	Other: Professional Association	The term eligible vs ineligible may be confusing since ineligible organizations may be able to be a part of accredited continuing education for which the content is not related to the products or services of the "ineligible" organization. I agree that commercial interest is not the correct term because there is great confusion on what is a commercial interest.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Eligible entities are OK. I like the list. "Ineligible entities" does not change the meaning of "commercial Interests" which is a term everyone is used to. Do not change it. This is unnecessary word-smiting and confusing. Same for Mitigate. No change in meaning. Resolution has a clear meaning to surveyors and programs. Keep Resolution.

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Explain how ACCME views and classifies "providers of clinical service directly to patients".
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	I find the terms "eligible" and "ineligible" confusing, and there does not seem to be as clear a distinction between the two as there was previously when we used the term "commercial interest." For example, pharmacies sell healthcare products used by patients. Why does that not make them ineligible?
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	I understand software developers as eligible but 'game' developers. What is game referred to
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Please clarify where medical equipment manufacturers fall within the classification of eligible/ineligible (i.e. robotics, endoscope camera, ultrasound machine). Please provide further explanation on how pharmacies are considered eligible entities as their primary business is 'selling, re-selling, and distributing healthcare products used by patients'. Does the term 'products' encompass the prior language of 'goods and services'? Please define.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	School of medicine	Is a dispensary of medical cannabis considered an ineligible organization? I believe the answer is "yes" based on the following bullet, "Growers, distributors, or sellers of medical foods and dietary supplements."
Accredited CE provider			I believe the concept of commercial interests is acceptable; seems like a change is being made here for the sake of change. Adding "eligible" and "ineligible" entities doesn't seem like a simplification, rather an extension of complications. As a provider, I would welcome simplification as promised as the premise of this entire project.

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Advocacy organization			• Please provide clarification about publishing companies, as there is a distinction between professional organizations that publish their own materials and large publishing houses. Is it possible to separate publishing companies from education companies in this list? • It would be helpful to have examples of nonaccredited organizations that can engage in joint providership educational activities with accredited providers. • For companies involved in genetic medicine, (genetic testing, diagnosis, treatment, etc.) where would they fall – eligible or ineligible? This type of company is the new reality of medicine. Restricting this type of presentation from a CME-certified activity would be detrimental to physicians and their patients.
Advocacy organization			Definitions of primary business, owners, and employees is unclear. It would be helpful if there were clearer definitions added to the list of new terms. Reasons for confusion include: Primary business Does this refer to someone who attains 51%+ income from a given business? Do we define primary business as the amount of effort /patient volume? The definition of primary business encompasses large ramification in the definition and our understanding of eligible/ineligible entities. Owners and employees The definition of an owner and employee can vary; for example, California defines certain freelancers as employees where other states do not. ACCME should provide further guidance on which employee/owner definition to use. Again, these terms should be clearly defined as they are pertinent in our understanding of eligible/ineligible entities.

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Advocacy organization			Overall, while the classifications seem appropriate and primarily well-defined, NAMEC sees areas for which further clarification is needed. These include: relationships between eligible and ineligible entities; entities that could seemingly fit in either category; what constitutes an employee relationship; individuals or organizations that may have a legitimate role in both types of entities: • Can an ineligible entity own an eligible entity? (e.g. an advertising agency owning an education company) • If so, how is this resolved/mitigated? • Are there firewall requirements? • If so, what are they? • Likewise, can an eligible entity own an ineligible entity? (e.g. a group medical practice develops [owns] a proprietary device or diagnostic used for patient care? • If so, how is this resolved/mitigated? • Are there firewall requirements? • If so, what are they? • Are freelance contractors, such as medical writers or statisticians, able to provide services to both eligible and ineligible entities? • Other examples: • Is a for-profit medical marijuana manufacturer or dispensary eligible? • Is a for-profit pharmacy eligible? • Can clinicians sell over-the-counter drugs or cosmeceuticals? • Can an eligible entity (e.g. a patient advocate) receive funding by ineligible entities for non-certified efforts, (e.g. advisory boards)? • Can a publishing company accept a paid advertorial?
Clinician/healthcare professional			If one can teach about a disease state it should follow, they should be able to teach how and why to do so. Medicine only progresses through thoughtful and discerning trial and error and must be allow this leeway to advance.
Clinician/healthcare professional			MAYBE: Healthcare is changing rapidly. In the past, it was easier to identify commercial interests by whether they marketed or sold proprietary items used in healthcare. However, as venture capital is moving into purchasing clinical practices, the lines of commercial bias are more challenging. I am concerned that areas of patient selection and overriding individual clinical judgment may be at greater risk in some educational scenarios. What protections will be in place?

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Clinician/healthcare professional			The explanations are clear. However, using the term 'ineligible' is not intuitive. The previous term "ACCME-Defined Commercial Interest" was better and more intuitive as it implied from the get-go that we are concerned with commercial interests.
Clinician/healthcare professional			The list is good. However, there may be two organizations with a common parent where one is an ineligible subsidiary and the other is not. Currently ANCC states that the second organization may be eligible for accredited continuing education if there is an adequate corporate firewall that shields it from influence by the other organization and maintains its independence. Please address this. Thank you!
Clinician/healthcare professional			They are clear but not appropriate. There is no reason to dictate what can be taught as a protocol, just because it's not backed by science or in randomized trials. The use of parachutes has never been tested in a randomized trial, but we teach the use of that to our military every day.
Continuing education accrediting body			ACPE advises differentiation and clarification on compounding pharmacies. Pharmacies that compound according to a prescription specific to a particular patient would qualify as eligible entities (i.e., pharmacies) as they are engaging in established pharmacy practice. These “traditional” compounding pharmacies are required to comply with the United States Pharmacopeia and state regulations. Compounding pharmacies that possess the ability to compound large batches with or without prescriptions would be ineligible. Such compounding pharmacies are required to comply with Current Good Manufacturing Practices and register under Section 503B of the Federal Food, Drug, and Cosmetic Act; they are referred to as outsourcing facilities by FDA. While recognizing the use of new terminology to clarify eligibility, “ineligible entities” may present challenges in comprehension for those outside of accreditation involved in CE (e.g. planners, speakers). Given that the introduction to the Eligibility section addresses protection of learners from promotion, marketing, and commercial bias, it may be worthwhile to incorporate these aspects into the description of ineligibility. Suggest additional definition/guidance on “primary business”. Given the complexity and scope of many healthcare-related businesses, determination of the primary business can be challenging. Suggest removing parentheses used in examples as the enclosures are specific to the determination rather than incidental.

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Continuing education accrediting body			Concern: While the terms “eligible” and “ineligible” make sense in the context of ACCME, other accreditors, and those wishing to be accredited the term will fail to resonate with faculty who will be asked to disclose their financial relationships to “ineligible entities.” In the current context, a full definition of a “commercial interest” is still required, but it at least orients the respondent in the general direction of what they are required to disclose. While we appreciate ACCME’s desire to find a broader term, we also think that “commercial interest” remains relevant and useful. Perhaps a term like “ineligible commercial entity” might be more appropriate. Laboratories: While we appreciate that ACCME is attempting to address what we felt was an unwarranted loophole, the proposed solution is not ideal and may have unintended consequences.
Ineligible Entity (commercial interest, such as pharmaceutical, device, life-science company)			"Subsidiaries of an ineligible parent company cannot be accredited." While understanding that the determination of eligibility is all about structure and function, this blanket statement is confusing and does not consider appropriately firewalled entities. In addition, clarity on how ACCME defines a “primary business” will be helpful to make appropriate determinations.
Medical/healthcare association			Addition of a glossary with clear definitions in this context for at least following terms: primary business, owner, health related wearable devices. Under ineligible entities, add “manufacturers” to the example of “Growers, distributors and sellers of medical foods and supplements,” as many supplements and some foods are manufactured, not grown. While the Alliance agrees that clear separation and freedom from commercial influence are critical, the references to protecting the learning environment in the 2nd and 4th paragraphs come across as paternalistic and negative, as if accusing our industry members of an active assault on the independence of accredited CE. We suggest using terminology such as “maintaining” or “establishing” instead.

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Medical/healthcare association			Our concern is the mis-categorization of pharmacy benefit managers (PBMs) as ineligible entities. PBMs do not produce, market, sell/re-sell or distribute health care products and therefore, do not fit within the proposed definition of ineligible entities and should not be classified as such. PBMs provide population care management through an evidence-based approach and provide access to medications to millions of patients through the pharmacy benefit. PBMs are an integral part of pharmacy practice and provide a vital service to many health plans. PBM pharmacists are an important component of our membership and other pharmacy associations, so their categorization as an ineligible entity poses significant concerns for pharmacists who serve on planning committees and as faculty. Their continued participation is vital to the quality of our program. Our education program has maintained several steps to ensure our activities are not biased or promotional. Our last two national meetings have had an average of 99.5% of participants indicate “no bias detected.” In addition, because insurance companies are considered eligible entities, there is concern as to how PBMs owned by a health insurance organization will be classified. We strongly recommend that ACCME remove PBMs from the list of ineligible entities. Identifying these practitioners as ineligible will impact professional associations who have a mission to serve and educate those who practice managed care pharmacy.
Medical/healthcare association			re: "Subsidiaries of an ineligible parent company cannot be accredited." While understanding that the determination of eligibility is all about structure and function, this blanket statement is confusing to many already. This is a case where more words would be helpful. Suggest: "Subsidiaries cannot be accredited when a parent company has been deemed ineligible because of structure or function, regardless of steps taken to firewall the subsidiaries.” Clarity on how ACCME defines a “primary business” will be help for providers to make appropriate determinations of this.

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Medical/healthcare association			The AMA Council on Medical Education strongly recommends providing clarity regarding the meaning of the term "primary business" as it relates to the new proposed definition for Ineligible Entities. This phrasing needs clarification because there are many commercial and for-profit entities that have not historically been subject to ACCME or accredited provider scrutiny that now produce, market, sell or distribute health care products to patients. For example, Apple Inc. has become heavily invested in health care technology that is directly marketed to physicians and consumers. If a planner/faculty member of an educational event, or their spouse, consults or is employed by Apple, does this need to be disclosed and then mitigated? Who determines what is Apple's primary business? The Council believes that this determination should not be the responsibility of the accredited provider and requests the ACCME to clarify and provide guidance with regards to the intent of this definition. Additionally, the Council encourages the ACCME to provide guidance to accredited providers and other educational entities that may have legacy relationships (e.g., endowments, naming rights) with what will be classified as an ineligible entity.
Medical/healthcare association			To add needed clarity, elaborate on subsidiaries as it relates to ineligibility. As subsidiaries ineligible even if firewalls in place? What about large corporate pharmacies-if they own a PBM division, are all employees ineligible? If so, state that. Are pharmacies that sell dietary supplements ineligible? Define primary business. Are health-related technology/data management companies ineligible-not specified on list, if so, why? Define what non-health-related means as in non-health related data management companies.

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Nonaccredited CE provider			The word “influence” has been added, along with “control.” What is the intent of the word “influence” in this context? We presume the word “influence” in this context is related solely to ineligible entities not being allowed to control any aspect of activity planning. Faculty and planners by definition “control and influence content” but it needs clarity. In addition, are “Call for Grants” / “RFPs” from ineligible entities that identify unmet educational needs of a target audience and encourage the improvement of medicine and healthcare considered to be “influence”? Since responsibility and control over the selection of content, faculty, educational methods, materials, and venue for an independent medical education activity belongs solely to the Accredited Provider, will “Call for Grants” / “RFPs” continue to be permitted under the proposed new standards? Ineligible entities currently request as part of grant reconciliation requirements that evaluation and outcomes data be provided. Some examples of information currently requested by ineligible entities include: (1) descriptions of how each outcomes level was assessed, (2) learner responses and feedback, (3) identification of barriers to change, (4) identification of educational gaps that have been fulfilled, and (5) future needs of the audience. Is asking specific outcomes measures, such as these items considered “influence”, even though the Accredited Provider maintains control of the evaluation methods?
Other: Accredited CE provider, Continuing education accrediting body, and medical/healthcare association			re: "Subsidiaries of an ineligible parent company cannot be accredited." While understanding that the determination of eligibility is all about structure and function, this blanket statement is confusing to many already. This is a case where more words would be helpful. As an example, would an organization be ineligible if it does not meet the definition of an ineligible entity because its primary purpose is not producing marketing, selling, reselling or distributing healthcare products used by or on patients, but does meet one of the examples of ineligible entities? Examples of this would be a provider of clinical services directly to patients that also sells dietary supplements in their office, or a technology company whose primary business is not healthcare but does make a health-related wearable device. Clarity on how ACCME defines a “primary business” will be helpful for providers to make appropriate determinations of this.

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: Answering both as accreditor and accredited provider.			The WSMA finds the updated definitions useful. However, the terms “eligible” and “ineligible” are confusing. The term “commercial interest” is more easily understood on the surface because the term itself communicates why there is cause for concern. To say someone has a “relevant financial relationship with an ineligible organization” is not clear at face value. Another example: If we ask on an evaluation whether there was bias toward an ineligible organization, the attendees will have no idea what we’re talking about. It is also confusing to talk about getting a grant from an ineligible organization (i.e. we’ll get questions about whether their ‘ineligibility’ extends to their ability to provide an educational grant.) Please consider creating an FAQ about “software or game developers,” “manufacturers of health-related wearable products,” and how to tell when those lines cross. The ACCME should include a reference link to the questions to determine eligibility.
Other: CME/CE Consulting Services Company			Overall, the definitions of eligible and ineligible organizations are clear and appropriate. However, additional clarification about where artificial intelligence (AI) software fits would be helpful. Additionally, more clarity around manufacturers of health-related wearable products that, themselves, have various utilities (e.g. iWatch) would be beneficial. Is a wearable product that includes an application to help monitor health, though that is not the sole purpose of the product, ineligible? Proceeding with the term “eligible entities” makes sense, however, we don’t necessarily find it all that useful/helpful to juxtapose this with the “ineligible entities,” given it’s clear which entities are eligible for accreditation. In our opinion, the term does not lend greater clarity and could serve to alienate professionals and organizations that have long been supporters in the CPD enterprise. Would it not be okay to stick with the term “commercial interests” given the definition, though slightly modified, remains largely consistent? Further, “commercial interest” is a term that is long-standing in the CPD enterprise and one that is familiar to all stakeholders (CPD professionals, faculty, etc.). Last, the language clarifying parent companies and subsidiaries is beneficial.

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: Consulting company; licensed clinician			Please be as specific as possible regarding eligible and ineligible organizations. For example, are the following eligible: practice management organizations, manufacturers/distributors/sellers (MDS) of over-the-counter drugs, MDS of cosmeceuticals? What about organizations such as patient advocacy organizations and publishing companies who do occasional projects funding by pharma companies that support marketing efforts (e.g. advisory boards)? What about publishing companies who solicit/produce “advertorials”?
Other: I am a faculty member/CME content provider/CME course director and my views do not necessary represent the views of my institution, the Medical College of Wisconsin			Good attempt at differentiating eligible from ineligible entities. Unfortunately, there remains some gray areas where for-profit healthcare delivery systems and nursing homes would be eligible entities. Care would be needed to ensure that their activities don't indirectly promote their services. I am not sure how to best limit the marketing aspects of their activities. How would these concerns be subsumed under the proposed Standards?
Other: Independent software vendor			The rationale used does not mention how to address potential conflicts of interest for for-profit company’s business relationships. What should be done, for example, when a game developer that has external funding or ownership from private equity or a venture capitalist be eligible, if the investors also own or have interest in non-eligible companies, such as a biomed start up? How do conflicts get addressed when eligibility is the question, rather than content?

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: Joint Provider			Provide examples of this new wording. Some could interpret that any sale of vitamins, etc. would cause ineligibility. We suggest to specifically state that clinicians whose primary business is to provide clinical services would NOT fall under this new exclusion, if the selling of these items is not their primary business. If the intention of ACCME IS to exclude these providers, then the new policy should also be applied without discrimination to all eligible entities, including hospitals or health care delivery systems. Example: all employees at a hospital like Kaiser, who require patients to purchase pharmaceuticals by Kaiser doctors in their own Kaiser pharmacies would also be ineligible. Applying this policy only to one type of entity is discriminatory. Clarification is needed as this is already being interpreted and applied inconsistently. Example: in 2017, an ANCC Nursing Accreditation training specifically instructed nurse planners to not allow speakers who sold products in their clinics, using naturopathic doctors and dermatologists as examples. When we asked for a written policy on this, the instructor stated due to their joint providership relationship with ACCME, ACCME had verbally advised ANCC to inform nurse planners of this change. As a joint provider, we proactively asked primary CME accreditors for clarification. There was inconsistent understanding of how to handle this.
Other: MedChi is both an Accredited Provider and a Recognized Accreditor			There is confusion in the appearance of cross-over which seems to indicate that some organization can be eligible and ineligible at the same time. Providers will struggle with this. It needs more clarity.
Other: Publishing/education company			Subsidiaries of an ineligible parent company cannot be accredited." While understanding that the determination of eligibility is all about structure and function, this blanket statement is confusing to many already. This is a case where more words would be helpful. Suggest: "Subsidiaries cannot be accredited when a parent company has been deemed ineligible because of structure or function, regardless of steps taken to firewall the subsidiaries."

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: Recognized accreditor and Accredited CE provider			One potential unforeseen issue I can imagine with the phrase “(that market or seen proprietary products)” that qualifies diagnostic labs as being ineligible is around molecular tests. For instance, most academic institutions have their own molecular panels for solid and/or hematologic tumors that are at least named if not “proprietary” whereas a reference lab or other company might have a similar (in terms of methodology if not actual genes assayed) “proprietary” panel and could argue to some extent that the system is unfair. I’ve been trying to think of a better/more fair qualifying distinction and the best I can come up with is diagnostic labs (that market directly to consumers). That language may present challenges (and extra work) for providers in trying to decide which entities do this, even doing their due diligence with internet searches (e.g., in my opinion, a statement such as "ask your doctor about …" is direct to consumer marketing, but that may be challenging for folks to tease out.
Other: State Medical Society/Publisher/Accredited Provider/Recognized Accreditor			Relative to the terms "eligible entities" and "ineligible entities", several comments were received that the terms are not intuitive and there is no shared understanding of these terms, which will require additional education to CME stakeholders. Physicians expressed concern with allowing infusion centers, ambulatory care centers and other physician-owned organizations that are designated as eligible entities be allowed to accredit CME when they have witnessed that individuals representing these organizations have tried to drive referrals at CME activities. What are the criteria to determine the difference between an education company and a communication company? Are technology or data management companies that are health-related considered to be ineligible entities? Will the ACCME provide guidance in the future on eligibility for organization types that are not currently on either list?
Patient, caregiver, member of the public			"Eligible" and "ineligible" have such broad interpretation that organizations may not know which they fall under, and faculty/planners will NEVER understand the distinction.

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Recognized Accreditor (state/territory medical society)			• There will be some providers who may jump to the conclusion that if something is not ineligible then it is immediately eligible just due to the semantics of the words. There will be some grey areas (insurers, technology, even EHR or foundations) that need clear and easy decision-making pathways, a flowchart may be helpful. • Good addition of corporate structure and clarity for employees and owners. • Regarding parent companies, including a flowchart or additional resource for determining this would be helpful.
Recognized Accreditor (state/territory medical society)			1. We at PRMA feel health law firms should be further clarifying. 2. We suggest that where it says "joint providership enables ..... ", be expressed in a way that the nonaccredited organizations be the focus of the sentence. This will allow that an unquestionable meaning of noneligible for joint providership, avoiding challenges.
Recognized Accreditor (state/territory medical society)			Considering recent events concerning EHR vendor Practice Fusion, I do not think that EHR vendors should be eligible for accreditation: Practice Fusion admitted to implementing clinical decision support alerts in its software to increase opioid prescriptions. The company received "sponsorship payments" from pharmaceutical companies, which influenced the CDS alert development and implementation.
Recognized Accreditor (state/territory medical society)			Eligible: Diagnostic labs (that do not sell proprietary products); Ineligible: Diagnostic labs (that market or sell proprietary products); Should "eligible" include the work "market"? "Do not market or sell"?
Recognized Accreditor (state/territory medical society)			I feel like this may just cause confusion as everyone understand commercial interests. However, I do like how they list eligible and ineligible entities so people can more easily determine what is what.
Recognized Accreditor (state/territory medical society)			In the past, pharmacies were considered a "CI" and ineligible. Suggest the wording "as workplace of the pharmacist" in the language, as it was explained in a conference call. Clarify "owners and employees", stock or shareholders.

Are the explanations and classifications for organizations that are eligible and ineligible for accreditation clear and appropriate? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Recognized Accreditor (state/territory medical society)			There needs to be clearer explanation of both due to the fact there is overlap provided. The explanation provided will need explanation of the overlap and how it should be used.
Recognized Accreditor (state/territory medical society)			Top of p.12: Remove "The ACCME is committed to ensuring that accredited continuing education (1) presents learners with only accurate, balanced, scientifically justified recommendations, and (2) protects learners from promotion, marketing, and commercial bias. To that end," These are also addressed in Standard 1, 2, and 4 so it is repetitive. Revise to: The ACCME has established the following guidance on the types of entities that may be eligible and ineligible to be accredited in the ACCME System. The ACCME, in its sole discretion, determines which entities are awarded ACCME accreditation. For format consistency, on the list of Eligibility Entities, next to Pharmacies, add (that do not manufacture proprietary compounds). Bottom of p. 12: Remove "The owners and employees of ineligible entities are considered to have unresolvable financial relationships and must be excluded from participating as planners or faculty, and must not be allowed to influence or control any aspect of the planning, delivery, or evaluation of accredited continuing education, except in the limited circumstances outlined in Standard 3.2." This is addressed in Standard 2.1, so it is repetitive. Revise last two sentences to: Ineligible entities are also prohibited from engaging in joint providership with accredited providers. Joint providership enables accredited providers to work with some types of nonaccredited, eligible entities to deliver accredited education.

Standard 1: Ensure Content is Valid

Is Standard 1 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME		rewording 1.4 to: "Accredited education may inform learners about approaches to diagnosis or treatment that are controversial or not supported by evidence that meets the requirements in 1.3 above but must not include advocacy for these approaches or teach healthcare professionals how or when to use the them." Rationale for change: Inclusion of the wording “not generally accepted” is redundant- as already stated in 1.1.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	1) As it is currently written, Standard 1.5 refers to criteria for accrediting organizations versus referring to validating content. • As mentioned above, consider including the verbiage from 1.5 in the explanation of ineligible entities. • Consider still keeping the general verbiage section 1.5 but revising it to refer to the content versus organization eligibility. Perhaps something such as: “Accredited education cannot advocate for unscientific modalities of diagnosis or therapy, nor promote 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.” 2) In support of Standard 5.2c it would be helpful to also include the language from it or something similar with Standard 1: “Educational materials that are part of accredited education (such as slides, abstracts, handouts, evaluation mechanisms, or disclosure information) must not contain any marketing produced by or for an ineligible entity, including corporate or product logos, trade names, or product group messages.”
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Would like to learn how the ACCME community comments on Standard 1 #4. How are accreditors to know all “controversial” approaches?

Is Standard 1 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Standard 1 Item 5 - What does the ACCME mean by “unscientific modalities?” In CE, teachers often inform learners about treatments (drugs, etc.) in clinical trials, but not yet approved for use. This does not mean they are advocating the use of these things, but it would be negligent not to mention innovations or treatments on the horizon. Please be more specific about what you mean by “advocating” for such modalities and where you draw the line between informing learners about coming innovations and “advocating” for those prospective innovations, so providers can clearly describe the parameters to our educators.
Accredited CE provider	ACCME	Nonprofit (other)	Consider further addressing the responsibility of the accredited provider. In order to fulfill the responsibility of being an accredited provider, when new therapies are found to be viable, evidence based and safe, they should be made available by accredited CE free of commercial influence. It is the responsibility of accredited providers to assess the overall quality of the research, not merely the source, to identify safe and effective approaches, faculty who can teach them well and to ensure the education is made accessible to practitioners. Consider replacing the term “controversial” with “unproven” or “experimental”. “Controversial” is defined as disagreement rather than experimental and/or unproven as described on the ACCME website. Provided these experimental therapies are requested by the patient, safe and free of commercial interest, accredited education is the most reliable means for receiving this relevant information. Consider providing a link to the ACCME webpage highlighting presentation best practices for these topics, including the design for the activity and clear communication of the objectives of the material. Consider incorporating the descriptions of “balanced view” currently available in ACCME FAQs. Consider removing 1.5. This standard describes the characteristics of an organization that cannot be accredited based on certain practices, practices that are contrary to the oath taken by a physician. This seems obvious and oddly placed.

Is Standard 1 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (other)	We suggest that the standard provide a stronger clarification of what is considered “an approach to diagnosis or treatment that is controversial or not generally accepted.”
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	- See 1.3 – Please include examples of “generally accepted standards.” - See 1.4 – Please include a definition of the term advocacy. - See 1.4 – Please do not conflate “controversial” with “not generally accepted.” We agree that teaching about the latter should generally be circumscribed, but teaching about controversies, including how and when to use therapies labeled as such, is one clear way to resolve their status for health care professionals. Additionally, it should be noted that not teaching about “how or when” the use of “controversial” therapies might result in patient harm be appropriate could be detrimental to patients for whom “generally accepted” therapies have been unsuccessful.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	1.1 Define “scientifically justified” so that a provider is able to make the determination that content is scientifically justified. Consider replacing “scientifically justified” with other wording that is appropriately defined and understood.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	1.4 Accredited providers can effectively teach about how to consider use of emerging approaches to diagnosis, technology, surgical procedures, treatment options that are controversial or not generally accepted without advocating for them. Recommend the deletion of [or teach healthcare professionals how or when to use them.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Accredited education may inform learners about approaches to diagnosis or treatment that are controversial or not supported by evidence that meets the requirements in 1.3 above but must not include advocacy for these approaches or teach healthcare professionals how or when to use the them.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Delete in 1.4 "or teach healthcare professionals how or when to use them."

Is Standard 1 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	For full comments please see submission to communications@accme.org. Both standards– "scientifically justified" and "generally accepted"– are ill-defined and vague. They allow for widely disparate and subjective interpretations and do not a set a meaning that gives a clear direction. In the context of federal action, such a general standard has been expressly rejected by the courts as unenforceable as it is too vague and ill-defined to give adequate notice as a standard. Pearson v. Shalala, 130 F. Supp. 2d 105 (D.D.C. 2001); Pearson v. Shalala, 164 F.3d 650, 660 (D.C. 1999) (The Pearson cases considered whether FDA had properly promulgated a standard of "significant scientific agreement" as applied to the threshold for making health claims on dietary supplements.) The use of criteria that could be imposed arbitrarily does not appear to us to benefit ACCME's valid interest in the quality of professional education. Such a vague standard allows interpretation to be based upon point of view rather than a fair reading of the evidence. This is particularly true when there are multiple points of view or paradigms of care. We believe ACCME would be served by also adopting standards that encourage, rather than discourage, diversity of viewpoint. This would not conflict with our mutual mission of teaching methods that are supported by evidence, but it is inconsistent with a requirement that concepts be "generally accepted." That standard is highly restrictive.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	HRS sometimes uses a debate format to allow participants to hear different perspectives about treatments that may be considered controversial or for which data are limited. A debate format that counterbalances any potential advocacy toward untested approaches should be allowed to promote discussion.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	In Section 4, how does one define "Controversial" and who gets to decide what is controversial? To innovate in medicine, it is important to teach how and when to use controversial methods.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Item four allows for a description of unproven modalities but does not allow for a more nuanced presentation of technique, risks and benefits.

Is Standard 1 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	In 1.3 the phrase “in support or justification of a patient care recommendation” unnecessarily limits the scope of the standard. Our organization holds meetings where the scientific content may not be directly related to patient care (Phase I trials) but it should nevertheless conform to accepted standards of research. 1.5, “unscientific” will need to be defined. Also, note that the focus of the statement is on who can/can’t be accredited whereas this section relates to validity. Suggest rewriting this statement to emphasize what you would like to see or the principles that should be applied.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	It is unclear where the line is between “cutting edge” science that will move the field forward and “controversial or not generally accepted” science. Laparoscopic cholecystectomy, a surgery with tremendous benefit to patients, would never have been perpetuated if SAGES had not implemented a vast number of trainings to teach something that many were skeptical about. SAGES opines that there must be some leeway for discussions about how and when controversial approaches could be used ethically.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Standard 1.4 Broaden the language to suggest that it may be beneficial to discuss when and how it might be appropriate to use new techniques that may not have an evidence base yet. Standard 1.5 Clarify the term 'unscientific' - for example, would alternative and integrative medicine, which many patients ask about, be unscientific?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Standard 1.4 indicates that accredited CE must not address “how or when to use” controversial or other approaches in medicine. Accredited CE provides a framework to ensure that content is valid and free of promotion and commercial bias. Accredited providers effectively develop education that can describe controversial and other methods not generally accepted without advocating for those approaches. Furthermore, physicians and health care professionals need to be aware of a variety of treatments and methods that patients use, including those that may be too new or cutting edge for significant research or are off-label, since patients ask about them. If accredited providers cannot educate about these approaches, industry will. How much evidence would be needed to validate content?

Is Standard 1 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Standard 1.4 is very limiting for education on “cutting-edge” or emerging techniques and technologies. We would suggest modifying the language to state “Accredited education may inform learners about approaches to diagnosis or treatment that are controversial, emerging or not generally accepted, including how or when to use them in the context of currently available evidence. They must not include advocacy for approaches that do not yet have a sufficient evidence base.”
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Standard 1.5 is confusing as it seems to blend current Clinical Content Validation Policy clause #3 with the eligibility rules to be an accredited provider. Since this Standard is about content, it should say “content” instead of “organizations”.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Suggest rewording 1.4 to: "Accredited education may inform learners about approaches to diagnosis or treatment that are controversial or not supported by evidence that meets the requirements in 1.3 above but must not include advocacy for these approaches or teach healthcare professionals how or when to use the them." Alternatively: “Accredited education may inform learners about approaches to diagnosis or treatment that are controversial but in clinical practice and / or undergoing empiric trials. Presenters must not include advocacy for any specific approaches that would represent a conflict of interest.” Rationale for change: Inclusion of the wording “not generally accepted” is redundant- as already stated in 1.1. With respect to "generally not accepted" - does this mean not FDA approved or something else? There are many instances of "off label use" in the management and treatment of painful disorders. To pick an example - the use of biologic products in regenerative therapies. Many if not most regenerative treatments have not been approved by the FDA but are widely taught in courses and in conferences by respected medical organizations. Is the disclosure "off-label use" adequate for accreditation?

Is Standard 1 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Suggest rewording 1.4 to: "Accredited education may inform learners about approaches to diagnosis or treatment that are controversial or not supported by evidence that meets the requirements in 1.3 above, but must not include promotion of these approaches or teach healthcare professionals how or when to use the them; off-label use content that includes patient care recommendations, when supported by evidence, is allowed."
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Suggest rewording to: "Accredited education may inform learners about approaches to diagnosis or treatment that are controversial or not supported by evidence that meets the requirements in 1.3 above, but must not include advocacy for these approaches or teach healthcare professionals how or when to use the them; off-label use content that includes patient care recommendation, when supported by evidence, is allowed."
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The general principles outlined for content validity are clear, although item 1.4, regarding “controversial” diagnosis and treatment approaches raises a question that should be answered. If a presenter is teaching about one of these practices in a clinical context, how could that be accomplished without in some way referencing how and when the controversial practice might be undertaken? It seems that learners would need to understand the “how” and “when” of these controversial procedures to acquire a full understanding of them, and that these aspects of the controversial content could be described without advocating for their use or making a claim of their superiority or effectiveness when compared to the accepted alternatives.

Is Standard 1 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The general principles outlined for content validity are clear, although item 1.4, regarding “controversial” diagnosis and treatment approaches raises a question that should be answered. If a presenter is teaching about one of these practices in a clinical context, how could that be accomplished without in some way referencing how and when the controversial practice might be undertaken? Is it impossible to do this without specifically advocating for others to adopt the practice? It seems that learners would need to understand the “how” and “when” of these controversial procedures to acquire a full understanding of them, and that these aspects of the controversial content could be described without advocating for their use or making a claim of their superiority or effectiveness when compared to the accepted alternatives.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The standard appears to imply that accredited education cannot advocate for clinical trials (in general) or specific clinical trials as they are not 'generally accepted' approaches. The same appears true for integrative medicine or any off-label use. Who determines which approaches to diagnosis or treatment are not controversial or generally accepted? If this will be the accredited provider, what resources will be available to accredited providers to make these decisions? How will this be evaluated at reaccreditation? Performance-in-practice activities? What additional resources will volunteer surveyors need to accomplish this review?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We would suggest a modification to Standard 1.4: Add the following sentence: “Excluded from this restriction are approaches to diagnosis or treatment that have been developed utilizing accepted scientific rigor but that have yet to be incorporated into day-to-day practice.”

Is Standard 1 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Other: Public/nonprofit/healthcare system/education/school of medicine	The first and fourth points seem to be in conflict. Given the long turn-around between scientific discovery and clinical implementation, hence a whole NIH initiative (and many others) focused on D&I (Dissemination & Implementation) and "clinical translation"... how do we expect to change clinical practice via accredited education if "1. All recommendations involving clinical medicine in accredited education must be scientifically justified AND generally accepted within the profession of medicine as appropriate for the care of patients." Please consider striking "AND generally accepted within the profession of medicine as appropriate for the care of patients." from #1 #4 also has some similar issues. "4. Accredited education may inform learners about approaches to diagnosis or treatment that are controversial or not generally accepted but must not include advocacy for these approaches or teach healthcare professionals how or when to use them." Recommendation to strike the words "or not generally accepted" from #4.
Accredited CE provider	ACCME	Other: Teleconferencing Medical Education Company	It's unclear if there are any exceptions at all to this standard.
Accredited CE provider	ACCME	Other: University - not a school of medicine	Additional clarifications to "generally accepted".
Accredited CE provider	ACCME	Publishing/education company	Accredited education may inform learners about approaches to diagnosis or treatment that are controversial or not supported by evidence that meets the requirements in 1.3 above but must not include advocacy for these approaches or teach healthcare professionals how or when to use the them." Rationale for change: Inclusion of the wording “not generally accepted” is redundant- as already stated in 1.1.

Is Standard 1 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	Accredited education may inform learners about approaches to diagnosis or treatment that are controversial or not supported by evidence that meets the requirements in 1.3 above but must not include advocacy for these approaches or teach healthcare professionals how or when to use the them. Rationale for change: Inclusion of the wording “not generally accepted” is redundant- as already stated in 1.1.
Accredited CE provider	ACCME	Publishing/education company	Accredited education may inform learners about approaches to diagnosis or treatment that are controversial or not supported by evidence that meets the requirements in 1.3 above but must not include advocacy for these approaches or teach healthcare professionals how or when to use the them.
Accredited CE provider	ACCME	Publishing/education company	Accredited education may inform learners about approaches to diagnosis or treatment that are controversial or not supported by evidence that meets the requirements in 1.3 above but must not include advocacy for these approaches or teach healthcare professionals how or when to use them
Accredited CE provider	ACCME	Publishing/education company	Additional clarification is needed as to what is considered "an approach to diagnosis or treatment that is controversial or not generally accepted." Does this include all off-label uses of a treatment when there are strong opinions for and against it? Or for types of patient care such as chiropractic, acupuncture, or even vitamin supplements? What standard criteria should be followed for "not generally accepted?"
Accredited CE provider	ACCME	Publishing/education company	I suggest rewording 1.4 to: "Accredited education may inform learners about approaches to diagnosis or treatment that are controversial or not supported by evidence that meets the requirements in 1.3 above but must not include advocacy for these approaches or teach healthcare professionals how or when to use the them."
Accredited CE provider	ACCME	Publishing/education company	Rationale for change: Inclusion of the wording “not generally accepted” is redundant- as already stated in 1.1.

Is Standard 1 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	Standard 1.4 is not clear. You can inform learners ABOUT controversial approaches but can't TEACH them how or when to use them. How much info does "inform about" include? Just the name? A description? Background info? What do you mean by "teach"? If the intent is to not have an entire activity focused on the controversial approach, then that needs to be clearly stated. Specific examples of "inform about" and "teach...how or when" would be helpful--compliant vs non-compliant examples.
Accredited CE provider	ACCME	Publishing/education company	Standard 1.4: How are you defining “controversial and not generally accepted”? In our content, we discuss emerging and promising approaches to care which may be controversial and not generally accepted because data to support their use may be limited. These treatments are new and, as such, have not yet been widely adopted, but have some evidence to support use. It can take up to 17 years to close the gap between when research shows a benefit and when clinicians are generally accepting this and changing their practice (http://www.nationalacademies.org/hmd/Reports/2001/Crossing-the-Quality-Chasm-A-New-Health-System-for-the-21st-Century.aspx).
Accredited CE provider	ACCME	Publishing/education company	Suggest rewording 1.4 to: "Accredited education may inform learners about approaches to diagnosis or treatment that are controversial or not supported by evidence that meets the requirements in 1.3 above, but must not include advocacy for these approaches or teach healthcare professionals how or when to use the them; off-label use content that includes patient care recommendation, when supported by evidence, is allowed."
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Accredited CE provider	ACCME	Publishing/education company	There may be some confusion between the term "generally accepted within..." by the ACCME and "standard of care" used in other settings such as malpractice claims. It would be important to clarify this. Also, see below.
Accredited CE provider	ACCME	Publishing/education company	With an “approach to revisions” being to “remain criterion-based, with objective rather than subjective statements, to allow for consistent accreditation decision making” – what standards of objectivity will be used to determine compliance or noncompliance with 1.4? Specifically: how are “controversial” and “not generally accepted” classified?

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Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	“Controversial” and “Generally accepted” in Standard 1.4 need further clarification. We interpret “generally accepted” to mean supported by evidence from studies conforming to "generally accepted standards of experimental design, data collection, and analysis." However, other physicians and CME providers we have spoken with are interpreting it to mean that “a majority of physicians generally practice or accept those same methods.” There are many ways to diagnose or treat certain patients, which are supported by peer-reviewed medical evidence. We assume ACCME means that if certain practitioners adopt, for example, complementary and alternative practices that might not be practiced “in general” by physicians at large, as long as those practices are based on evidence from studies conforming to "generally accepted standards of experimental design, data collection, and analysis," then those diagnostic and therapeutic recommendation ARE acceptable to approve for CME. But that is not clear to us at present.
Accredited CE provider	ACCME	School of medicine	No one wants CME to be for advocating snake oil solutions. With that said, discussions on controversial topics should be encouraged if done in a thoughtful way.
Accredited CE provider	ACCME	School of medicine	Recommend adding clarification on medical cannabis and aesthetics regarding scientific justification and appropriateness as accredited education.
Accredited CE provider	ACCME	School of medicine	Regarding standard 1.4, more guidance is needed on where the “line” is and how this will be enforced. We are unclear on how a faculty member would discuss controversial or unapproved diagnosis/treatments without at least touching on its application. As a provider we are likely to just prohibit this content to avoid potential compliance issues. I do not think this is the intended effect but is likely the path of least resistance.
Accredited CE provider	ACCME	School of medicine	Standard 1. 4. There needs to be clear differentiation between what it means to teach "about" controversial or generally non accepted diagnosis or treatment vs. "advocacy". There should also be guidance about how to document this resolution process.
Accredited CE provider	ACCME	School of medicine	Standard 1.4 – Clarify how to address questions from learners who question controversial/not generally accepted approaches to diagnosis or treatment

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Accredited CE provider	ACCME	School of medicine	Under 1. amend "medical" to read "health care" or "health"
Accredited CE provider	ACCME	School of medicine	What is the rationale for the change in terminology? What is the intent of the ACCME? The term commercial support is clear- ineligible does not represent the situation that we are resolving.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Hospital/healthcare delivery system	1.4 "Accredited education may inform learners about approaches to diagnosis or treatment that are controversial or not generally accepted but must not include advocacy for these approaches or teach healthcare professionals how or when to use them." needs to include some exception for evidence-based research that has not yet been FDA approved.

Is Standard 1 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	• Neither the ACCME nor providers can ensure that accredited education presents learners with only clinically valid content and is free from promotion, marketing and commercial bias. What the ACCME and providers can do is to set expectations and implement processes that minimize any risk of learners receiving content that is not clinically valid or is biased or promotional in any way. • Change introductory sentence to “Accredited providers are responsible for facilitating education that supports safe, effective patient care.” • Standard 1.4 may be difficult for disciplines like oncology where the science is evolving rapidly, leading to many areas where there is significant controversy and no clear-cut standard, and approaches are often debated. Accredited providers (eligible entities) can effectively teach about how to consider use of emerging approaches to diagnosis and/or treatment modalities that are controversial or not generally accepted. Learners benefit from accessing this information in a non-biased manner through accredited CE, following ACCME and other requirements for balance and scientific evidence. This is an important alternative to learning about new technologies and treatments solely from their commercial sponsors. Please clarify that “controversial and not generally accepted” will not limit providers to content about on-label/approved uses.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	Suggest consideration be given to ensuring that current wording of 1.4 does not create unintended consequence of limiting discussion of diagnostic and treatment options in development and for which evidence may be in process of being generated and published.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	Suggest rewording 1.4 to: "Accredited education may inform learners about approaches to diagnosis or treatment that are controversial or not supported by evidence that meets the requirements in 1.3 above but must not include advocacy for these approaches or teach healthcare professionals how or when to use the them."

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Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	The following wording is suggested instead of current wording: Providers must obey all applicable laws governing privacy and sharing of personal information of learners, attendees or registrants, including disclosure of such information when required by law
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	Examples, and how to determine what is controversial?
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	Standard 1.4 - What is the difference between “controversial” and “not generally accepted”? Who determines what is “controversial”?
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	How will scientifically justified be defined? Will we continue to expect programs to recognize a content validity policy? The word "justified" will create more consternation in some psychiatric programs. Will justified include acupuncture, chiropractic, functional medicine, original but unvetted scientific articles? The words "scientifically valid" have a current meaning with programs and surveyors that has worked. Please use that.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	I think more clarification could be given for standard (1.4). For example, I recently attended a review of novel FDA-approved drugs to inform clinicians of the indications and cost of these new drugs. Since these have not been on the market for more than a year, it may not be known yet whether they are "controversial or not generally accepted". Using these revised criteria, would it be appropriate to inform how or when to use these drugs? Clarification on how to determine general acceptance or resources for determining "general acceptance" may be helpful for staff who do not have a clinical or legal background.

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Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Regarding number 4, add some examples of what may be deemed as 'controversial'. For example, the topic of abortion may be controversial. Or is this not what is meant as controversial. Our CME Committee is reviewing an application at the moment. If it is considered as controversial and the talk is about mifepristone, and there are slides that explain how to use the drug for an abortion - then this application would be denied if #4 will be agreed upon in the Standards. There may be misunderstandings with #4. I suggest that it be further detailed.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	The standard appears to imply that accredited education cannot advocate for clinical trials (in general) or specific clinical trials as they are not 'generally accepted' approaches. The same appears true for integrative medicine or any off-label use. Who determines approaches to diagnosis or treatment that are not controversial or generally accepted?
Advocacy organization			• Please provide clarification about publishing companies, as there is a distinction between professional organizations that publish their own materials and large publishing houses. Is it possible to separate publishing companies from education companies in this list? • It would be helpful to have examples of nonaccredited organizations that can engage in joint providership educational activities with accredited providers.
Advocacy organization			NAMEC suggests that the standard provide a stronger clarification of what is considered “an approach to diagnosis or treatment that is controversial or not generally accepted.” For example, there are very strong opinions on the value of several types of on-traditional patient care, such as chiropractic or acupuncture. They generally do not have clinical trials designed, data collected, and analysis done. Are these controversial or not generally accepted? Is there a standard criteria/criterion for “not generally accepted?”

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Organization Type	**Accreditor**	**Provider Type**	**Comments**
Clinician/healthcare professional			As a Family Medicine and Integrative Medicine physician, my concern is that "generally accepted" terminology will discriminate against a lot of the therapeutics that I offer my patients. Currently, many areas of health care, (including the VA system) are encourage transformation of medicine and push whole person care, that is patient centered. Many are looking to find approaches that are not standard pharmaceuticals taught in medical school. With this Standard proposed, the ACCME is encouraging status quo rather than finding new ways to promote health transformation and help patients achieve health. For example, invasive back surgery, epidural steroid injections are "generally accepted" but they do not necessarily improve patient outcomes the way that acupuncture, mindfulness meditation, yoga and other less studies therapies could help patients in a lot lower cost, lower risk to them. In addition, we know that pharmaceutical and device manufacturers have more financial incentive and ability to pay for studies to demonstrate evidence. Integrative practitioners do not have the same financial power to fund studies. We also know that it's not as easy to study Integrative modalities compared with pharmaceuticals.
Clinician/healthcare professional			CME is designed to bring light to important medical information sometimes before it is presented in peer-reviewed journals and textbooks. Often, the CME content may be an over-view of multiple sources of information, providing a comprehensive presentation of a topic. Equally important is a synthesis of information and a unique approach and or treatment for a medical problem begging to be solved. I have taught courses approved for CME for more than 20 years and have on peer-reviewed research to substantiate the content. I have never dictated when and how the recipient should utilize the information. Restrictions to the licensed practitioner could be interpreted as an insult.
Clinician/healthcare professional			Delete "and generally accepted within the profession of medicine as appropriate for the care of patients". That returns the ACCME to accepting subjective information. Medicine is a varied career, and there is, in general, no "generally accepted within the profession as appropriate for the care of patients", and, in addition, patients are highly variable as well.

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Continuing education accrediting body			#1: The use of the word “medicine” in #1 is problematic and may limit the usefulness of these Standards in fields such as nursing, pharmacy, physical therapy, dentistry, and others. Consider “treatment of patients” as an alternative to “clinical medicine.” #4: We are concerned that the terms “controversial” or “not generally accepted” are vague and judgements about what might fall into this category will be subjective. We are also concerned that the distinction between “informing” and “advocating” may be subjective. We are concerned that we may be doing learners a disservice by not providing a wider context for potential treatments out of concern that we would be perceived as “advocating” for the treatment. There are widely used treatments such as plasma rich platelet infusions (PRP) that are used for multiple conditions even though the evidence to support these interventions rely on clinician experience and anecdote because of the lack of large-scale clinical trials. Regardless of whether one regards the current evidence sufficient to support PRP, the practice has become widespread and there is a need to ensure that it is performed safely. Would providers be prohibited from teaching safe methods of performing PRP in accredited CE?
Ineligible Entity (commercial interest, such as pharmaceutical, device, life-science company)			Not sure.
Ineligible Entity (commercial interest, such as pharmaceutical, device, life-science company)			Standard 1.1. All recommendations involving clinical medicine in accredited education must be scientifically justified within the profession of medicine as appropriate for the care of patients. Standard 1.4. Accredited education may inform learners about approaches to diagnosis or treatment that are controversial or not generally accepted but based on available scientific evidence; however, must not include advocacy for these approaches.

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Organization Type	**Accreditor**	**Provider Type**	**Comments**
Medical/healthcare association			"Generally accepted" is vague and not specific. Wording needs to be clear that generally accepted is not linked to FDA approval, but to the valid scientific evidence of efficacy and safety.
Medical/healthcare association			Change "…and generally accepted within the practice of medicine…." To "…and generally accepted within the profession of the intended audience…" Rationale: if the intent is to make these standards less physician-centric, as they are used by many in healthcare that do not practice medicine, per se, then the language should support that intent.
Medical/healthcare association			Standard 1.4 will be very difficult for accredited providers to monitor and enforce because the nuance between 'learning about' and 'advocating for' is very fine. When looking to advance a field of medicine, physicians must be able to effectively learn about new approaches because teaching how to use a novel technology or new technique is integral to learning. If strictly enforced, accredited providers may not be able to sponsor educational initiatives that are looking to improve the diagnosis or treatment of patient care. To ensure physicians can adequately learn and apply new information, the AMA Council on Medical Education recommends providing clarity to this standard regarding the meaning and definition of "advocating for".
Medical/healthcare association			Suggest rewording 1.4 to: "Accredited education may inform learners about approaches to diagnosis or treatment that are controversial or not supported by evidence that meets the requirements in 1.3 above but must not include advocacy for these approaches or teach healthcare professionals how or when to use the them." Rationale for change: Inclusion of the wording "not generally accepted" is redundant- as already stated in 1.1.

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Organization Type	**Accreditor**	**Provider Type**	**Comments**
Nonaccredited CE provider			Standard 1. Content Validity 1. “Generally accepted within the field of medicine” - implicit here is allopathic medicine. Many modalities are “generally accepted” within the fields of integrative medicine. Are these going to be given equal weight under these new guidelines? Every medical advance was, at one time, “not generally accepted”, leaps forward strain or break current paradigms. This provision puts a constraint on out-of-the-box medical thinking and approaches. How does the ACCME plan to balance scientific and medical innovation with “generally accepted?” This appears to be the path to enshrine mediocrity 2. “Fair and balanced diagnostic and therapeutic options” Does this mean that allopathic physicians must present integrative options in presenting their CME topics? EX: non-pharmacologic treatments for Chronic pain… HHS guidelines support a biopsychosocial model. Will this be supported for other pathologic entities under these guidelines? 4. “Taught about, as long as there is no when or why” What is the point of teaching about a diagnostic or therapeutic modality if not to teach appropriate clinical use? 5. “Unscientific modalities and risk of harm” Who decides what is “unscientific”? Many allopath’s are ignorant of the vast body of data supporting integrative and functional approaches.
Other: Accredited CE provider, Continuing education accrediting body, and medical/healthcare association			Suggest rewording 1.4 to: "Accredited education may inform learners about approaches to diagnosis or treatment that are controversial or not supported by evidence that meets the requirements in 1.3 above but must not include advocacy for these approaches or teach healthcare professionals how or when to use the them." Rationale for change: Inclusion of the wording “not generally accepted” is redundant- as already stated in 1.1.

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Other: CME/CE Consulting Services Company			In most respects, Standard 1 is very clear. However, item #4 could benefit from more detail and clarification. More information is needed to qualify to what degree inclusion of information "about approaches to diagnosis or treatment that are controversial or not generally accepted" is appropriate. Added clarity regarding the following statement would be helpful: "Accredited education may inform learners ABOUT approaches to diagnosis or treatment that are controversial or not generally accepted." For example, "Informing learners refers to a brief reference that alternative, controversial diagnosis or treatment methods exist," "Informing learners includes/encompasses…" Further, added clarity for the following statement would also be helpful: "MUST NOT include advocacy for these approaches or teach healthcare professionals how or when to use them." For example, "Examples of advocacy include…" or "Advocacy refers to…" Addressing the following question might also be a means to providing more clarity: What situations would warrant an accredited provider to appropriately "inform learners about approaches to diagnosis or treatment that are controversial or not generally accepted?" E.g. Communicating to learners that they may have a patient that comes into their practice referring to a controversial treatment called X and current literature indicates Y about that treatment…."
Other: Currently independent consultant; previously Director of CME for large subspecialty society			I have concern over Item #4 as it is currently written in two areas. First, what is the threshold for controversial? Innovation oftentimes is controversial when first introduced but can become standard of care. What level of research etc. must be met for an approach not to fall within the label of controversial and therefore subject to these limitations? Additionally, I am not clear how faculty would inform learners about an approach to diagnostics or treatment which did not in some include information on how or when to use the approach. I would suggest this should have more clarification.

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Other: I am a clinician-educator, board member of APPS, member of the Academic Consortium of Integrative Medicine and Health, and faculty provider for integrative medicine CME			Standard 1.1. Clarify what constitutes scientific justification. Provide very clear and detailed guidelines on the types of studies, journals and resources acceptable for review. Standard 1.1. Define "generally accepted." Guidelines typically lag research and clinical practice. Standard 1.3. Include research and publications beyond DBPCT that may not apply to more whole-system approaches to care. provide resources that allow for varied study designs with explanations of levels of evidence. Standard 1.4. Define controversial / generally accepted. Physicians do not learn much if any nutrition or integrative medicine during training, and therefore will not consider use standard of care or generally accepted. Inadequacies in training should not define whether something is generally accepted or not. Standard 1.5. Accreditation should not be withheld for recommendations that are generally safe but may differ from the most prevalent treatment approach. For example, while Mediterranean diets have the greatest quantity of supporting evidence, that should not negate the ability to provide content discussing plant-based diets, ketogenic diets or intermittent fasting. Massage and mind-body approaches are very low risk interventions, so where the evidence is mixed evolving, it should not be considered definitely ineffective. Standard
Other: Joint Provider			Define generally accepted. This is simply too vague and prone to bias and subjectivity. We need a rubric that clearly guides and allows for the changes and advancement in medicine. Likewise, while a gold standard of research is the double-blind study, there are advanced in evidence based research models that warrant ACCME's attention. While there is a massive body of research available, the limitation of the current gold standard application to all CME would drastically limit the ability of progress in medicine. The delay between what is discovered, implemented and practiced by clinicians and the actual publication or implementation of policies and clinical guidelines that would be then considered "generally accepted" would severely limit the ability to train clinicians in any useful manner.

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Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: Publishing/education company			Suggest rewording 1.4 to: "Accredited education may inform learners about approaches to diagnosis or treatment that are controversial or not supported by evidence that meets the requirements in 1.3 above but must not include advocacy for these approaches or teach healthcare professionals how or when to use the them."
Other: Standard setting organization for 24 specialty member boards			Standard 1.4 - Perhaps the framing should be about clarifying the level of evidence for approaches to diagnosis or treatment. If something is “expert opinion”, then that should be clear that it is not supported by multiple RCTs or other studies.
Recognized Accreditor (state/territory medical society)			Some providers are unclear if this is an absolute rule or if exceptions are allowed. Providers suggested defining the exceptions if applicable.
Recognized Accreditor (state/territory medical society)			• Standard 1.4: Good addition, though there will need to be further clarification of what is considered controversial or not generally accepted. Who will determine this information and how is it easily accessed by the providers? Possibly include clarification of “advocacy”. Possibly an addendum of definitions could be included. • Standard 1.5: It seems that “organizations” that cannot be accredited belongs, and should be added in the eligibility section, and this word in this section be changed to activity or education.

Do you foresee challenges or unintended consequences implementing Standard 1? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME		In light of the wording associated with start-up entities under ineligibility discussion, and the term “generally accepted” in this standard, providers and supporters may need some guidance/education on 1.1 and 1.4 to ensure that inclusion of content is not linked to FDA approval, but rather to the valid scientific evidence of efficacy and safety. There will also be times when the best opinions of appropriate government authorities will suffice, such as in managing novel infectious diseases like Covid19. If providers over-interpret the requirements in Standard 3, then the unintended consequences to patients could be huge, especially in areas like oncology and infectious diseases, where the evidence is evolving faster than the FDA approval processes. Likewise, too generous an interpretation could lead to inclusion of content not currently supported by sufficient evidence, such as is the case with some uses of cannabis in medical treatment.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	4.Accredited education may inform learners about approaches to diagnosis or treatment that are controversial or not generally accepted but must not include advocacy for these approaches or teach healthcare professionals how or when to use them. In pediatrics, we sometimes have to teach off label uses of drugs, especially in behavioral health and other subspecialties. This will severely limit faculty. The type of patient you would need to consider is covered and sometimes doses are reviewed as well - i.e. "the how or when" is definitely covered. These are the reasons providers are coming to the educational session.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Accredited providers do not have nearly enough time to be responsible to “ensure” that all research quoted in every event is scientifically sound in every way, and that all recommendations are non-controversial and are “generally accepted.” This would require a specialty-specific expert panel to review every talk ahead of time and would preclude any talk that is on the cutting edge of science and medicine.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Define "generally accepted" parameters.

Do you foresee challenges or unintended consequences implementing Standard 1? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	There are always challenges to implementing ACCME standards because we never know specifically how to comply with the ACCME's standards. We are attempting to interpret the law, as written by the ACCME, but we can never be quite clear on whether we are fully complying with the law when it is newly written and the ACCME does not provide any templates for implementing the law.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Would like to learn how the ACCME community comments on Standard 1 #4.
Accredited CE provider	ACCME	Nonprofit (other)	Continuing the seventeen-year implementation gap and forcing learners to find education from non-accredited and potentially biased providers. Healthcare providers preferentially seek accredited continuing education to learn how to safely apply emerging evidence-based therapies rather than those that are already well established. In this context, we, as providers can only meet our directive if we offer educational activities that teach how to safely apply such therapies. It is incumbent upon us to shorten the seventeen-year implementation gap from established research to clinical practice and ensure healthcare practitioners are not forced to seek medical education from non-accredited and commercially biased providers. In order to adequately fulfill the responsibility of being an accredited provider, when new therapies are found to be viable, evidence based and safe approaches for the patient, they should be made available by accredited continuing education free of commercial influence regardless of the venue of research. It is the responsibility of CME providers to assess the overall quality of the research, not merely the source, to identify safe and effective approaches, faculty who can teach them well and to ensure the education is made accessible to practitioners.
Accredited CE provider	ACCME	Nonprofit (other)	Suggest rewording 1.2 to include preventative options (in addition to diagnostic and therapeutic)

Do you foresee challenges or unintended consequences implementing Standard 1? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (other)	We would suggest that it seems to be extremely difficult to raise the issue of a controversial treatment without providing learners with some context for how or when it is used. This would be especially true in cases where a treatment is generally accepted in certain therapeutic situations, but not others.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The identification of bio-medical startup (that have begun an approval process through the FDA) employees and owners would be operationally burdensome and unrealistic for ACCME accredited providers with sizeable activities and programs to implement. For instance, the time and resources required to verify a bio-medical startup's FDA approval status would be onerous, time consuming, and may not yield the accurate information required to determine participation as a planner or presenter.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	- 1.4 is very restrictive and might impact education on treatment of pediatric patients. Many standard practices are off-label in pediatrics and the limitation on teaching healthcare professionals how or when to use them may create an unintended consequence on designing education for pediatricians. Suggest additional clarification. - 1.4 – how will this impact emerging fields/breakthroughs? To provide a forum for scientific debate, debates about emerging knowledge require advocates for both sides. For instance, trans medicine is relatively new and evolving; 5 years ago, what is now considered best practice was considered controversial, and forums to discuss how and when to use different approaches and methods are important.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Accredited providers (eligible entities) can effectively teach about how to consider use of emerging approaches to diagnosis and/or treatment modalities that are controversial or not generally accepted. Our accredited providers know how to present and discuss these innovative practices without advocacy for their use.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Content can be controversial, and evidence based. If we cannot teach how or when to use a "controversial" intervention, the risk is that we leave that education to industry or non-accredited education.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Could limit the scope of content discussed during accredited education resulting in gaps in health care professions competence and performance.

Do you foresee challenges or unintended consequences implementing Standard 1? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	1.4 doesn't leave room to promote "cutting-edge" education that's not yet incorporated into everyday practice. Suggest modifying language so it includes "education may teach healthcare professionals how or when to use controversial or not generally accepted approaches to diagnosis or treatment that have been developed utilizing accepted scientific rigor." Without modifications to 1.4 cutting-edge education related to diagnosis and treatment options could be considered unacceptable. Some forms of education relay on this type of education to keep our members up to date on the newest innovations in their field of medicine. Allowing this information to be disseminated through accredited continuing education could help ensure Ineligible Entities are not solely educating medical professionals on late-breaking/specialty impacting techniques and tools rather than "eligible entities." Providers will require some guidance/education on 1.1 and 1.4 to ensure that inclusion of content is not linked to FDA approval, but rather to the valid scientific evidence of efficacy and safety. Sometimes the best opinions of appropriate government authorities will suffice, such as in managing novel infectious diseases like Covid19.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	1.4 Who determines what is "controversial or not generally accepted"? As new advances come out in surgery, some techniques or treatments are accepted by many surgeons but not all. What percentage need to disagree with them in order to define them as controversial or not generally accepted? Some devices or techniques are seen as being appropriate in certain patient populations or for some diagnoses, but not others. Are those "generally accepted" or not? Shouldn't there be a responsibility to teach when to use those if they are generally considered appropriate for certain situations but not all?

Do you foresee challenges or unintended consequences implementing Standard 1? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	It is felt that Standard 1.4 will generally be difficult to enforce for several reasons. Further defining what is meant by “controversial” or “not generally accepted” will likely create contested debates among medical educators and accreditors. In particular, because clinicians need to know about the effects of new or emerging technologies that patients are adopting -- including a balanced understanding how they might be used, medical educators have an obligation to help clinicians appropriately respond to the rapidly evolving therapeutic and digital health landscape. For example, some clinicians report needing help on how to practically incorporate continuous glucose monitoring data into their workflows - even if this is not currently recommended by clinical guidelines. If accredited providers are prohibited from addressing issues like this, clinicians will be forced to learn directly from industry.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	It limits discussion to sanctioned topics, and as such is disrespectful of adult learning styles.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Loss of patient care quality and opportunities; could curtail professional development; impact maintenance of certification requirements. The mere fact that a therapy is controversial is not a basis to restrict teaching its methods. Such a standard would repress the development of new ideas, especially in controversial areas where professional interaction may be most needed. This standard would have made it improper to teach a considerable number of therapeutic methods that were once highly controversial but now widely accepted as good medicine. Stating that controversial methods may not be taught, in fact, takes a serious leap beyond standard 1.1 and 1.3. Methods may be evidence-based yet controversial. By conflating the two, ACCME appears to demonstrate an intent is to bar CE content providers from teaching any therapy that is controversial even if there is reasonable evidence for the position. Standards 1.1 and 1.3 are inconsistent with Standards 1.4 and 1.5. These latter standards would be dangerous for the development of medicine and inconsistent with the history of clinical development and ever-changing growth that are frequently accompanied by controversy.

Do you foresee challenges or unintended consequences implementing Standard 1? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Providers and supporters may need some guidance/education on 1.1 and 1.4 to ensure that inclusion of content is not linked to FDA approval, but rather to the valid scientific evidence of efficacy and safety. There will also be times when the best opinions of appropriate government authorities will suffice.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Some legal reviewers have already assumed that this includes banning education about so-called "off label" or rapidly evolving science. If that is the case, then the unintended consequences to patients could be huge, especially in areas like oncology and infectious diseases, where the evidence is evolving faster than the FDA approval processes.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Standard 1, Point 4. The ACCME has established a system whereby its accredited CE providers design education for adult learners. These adult learners are able to determine what they need to learn and make decisions weighing the facts before them in their unbiased education. Point 4 is too prescriptive in using the phrase, “or teach healthcare professionals how or when to use them.” Today we are seeing new infections like coronavirus. The decades of experience that underlie guideline development or evidence-based medicine do not always exist. Point 4 does not consider that ours is an era characterized by new diseases and new uses of once-banned medicines. The elimination of the phrase beginning “or teach…” would demonstrate the ACCME’s acknowledgement that healthcare providers do not always have the kind of evidence that exists in other therapeutic areas and that CE providers can deliver education that includes “how or when to use” approaches to dx or tx that are less established.

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Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Taken literally, there can be no more advances in medicine. This is absurd. There never is a "consensus," or "generally accepted science or practice" for any new or novel treatment or therapy by your definition. Without advocacy, there can be no new enlightenment. In fact, it is a complete misnomer to call it, "continuing education," when, as proposed, it would be re-education of existing dogma. That, I already know. I want to learn what is just coming into awareness and cutting-edge practice. If I wanted just that, I could read a textbook. For me, the whole purpose, in fact, the only purpose for continuing education, is to learn what was left out of the textbook or what has been discovered since the book was published. I vote that you scrape all but paragraph five and the first bullet.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The requirement that “Accredited education may inform learners about approaches to diagnosis or treatment that are controversial or not generally accepted but must not include advocacy for these approaches or teach healthcare professionals how or when to use them” could hinder use of the debate format in which faculty are assigned to take a side, especially with regard to controversial topics, so that different perspectives may be presented. With appropriate oversight, these types of debates can be especially thought-provoking.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The term “generally accepted” may need some guidance/education on 1.1 and 1.4 to ensure that inclusion of content is not linked to FDA approval, but rather to the valid scientific evidence of efficacy and safety. There will also be times when the best opinions of appropriate government authorities will suffice. If providers over-interpret the requirements in Standard 3, then the unintended consequences to patients could be significant, especially where the evidence is evolving faster than the FDA approval. Likewise, too generous an interpretation could lead to inclusion of content not currently supported by sufficient evidence.

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Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The term “not generally accepted” is not a clear definition. Without potential modifications to Standard 1.4, cutting-edge education related to diagnosis and treatment options could be considered unacceptable. This education is critical for keeping clinicians up to date on the newest innovations in their field of medicine. Empowering accredited providers to disseminate this information through accredited continuing education could help ensure Ineligible Entities do not step in to fill the void as the sole educators of medical professionals on late-breaking/specialty impacting techniques and tools rather than “eligible entities.”
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	There is a real possibility of stifling research and new ideas if they first must be scientifically justified and generally accepted by the profession in order to be presented in an accredited setting. How do new ideas emerge? There is possibility of less new research and developments within the field.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	There might be issues when a medication/therapy/device is being used off-label.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	This could include off-label use of numerous devices and products and in most medical practices, much of what we do is off-label. Restricting this will inhibit members from learning and providing the best care for patients.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We have presentation on topics that could be considered "controversial" but are evidence based.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	What's the line between controversial practices that are being researched and advocating controversial practices? We do a lot of research presentations. Sometimes, research is into controversial practices, to debunk or learn more about efficacy, and sometimes the findings are positive. We have basic science and pre-clinical presentations that might fall into this.

Do you foresee challenges or unintended consequences implementing Standard 1? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Without a clear standard for what level of evidence is required for a diagnosis or treatment to be considered valid, it will be difficult to ensure that a fair and balanced discussion is being presented to learners. For example, if a presenter discusses a therapy that is not discussed in a clinical guideline, would that therapy be considered controversial? And how would excluding discussion of that therapy not result in an unbalanced discussion of available treatment options? Providers need a better understanding of the standard of evidence that would allow content to be considered “valid” in order to ensure compliance with the Standard while meeting the educational needs of their learners.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Without the above referenced addition, we are concerned that cutting edge diagnosis and treatment information will be considered invalid. This would have a negative impact on the medical profession remaining up-to-date and having this information communicated through accredited medical education. A major concern would be that this could lead to “Ineligible Entities” educating the health care team on late-breaking/specialty impacting techniques and tools rather than “eligible entities.”
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	I am not sure that presenters will understand that they can inform about the approach but not explain how or when to use the approach. I anticipate that learners will ask these questions during the presentations. How are the faculty supposed to respond to questions?? I see the learners being frustrated an angry at the organization for talking about these things without more explanation.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	If, for example, you develop a new surgical procedure that saves lives. How is it going to become generally accepted if you cannot teach how or when to use it. Standard 1 puts medicine back in the middle ages or worse! It stands in the way of progress!
Accredited CE provider	ACCME	Other: Public/nonprofit/healthcare system/education/school of medicine	Yes, if #1 of Standard 1 is not changed (by striking "AND generally accepted within the profession of medicine as appropriate for the care of patients.") and #4 is not changed (by striking the words "or not generally accepted"), no new scientifically justified practices will be able to BECOME generally accepted as the NEW standards within the profession as medicine.

Do you foresee challenges or unintended consequences implementing Standard 1? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Other: Teleconferencing Medical Education Company	Some wording is very vague, e.g. generally accepted. yet also extremely limiting/absolute, e.g. "applies to all accredited continuing education".
Accredited CE provider	ACCME	Other: University - not a school of medicine	In the race to maintain accreditation, some providers may over-interpret and therefore make things more difficult than necessary
Accredited CE provider	ACCME	Publishing/education company	1.2 is a timebomb. While on the surface it appears similar to the current 5.2, “fair” will be used by dogmatic groups to undermine the proposed 1.4 and 1.5 with claims of being providers being “fair and balanced” instead of the current standard of scientifically validated. In the existing 5.2, context of generic names and impartiality clarifies what is intended. In the new 1.2, the insertion of “fair” https://en.wikipedia.org/wiki/False_balance https://blog.blackswanltd.com/the-edge/how-to-find-fairness-in-a-negotiation If content is compliant with the new 1.3, shouldn’t that cover issues of 1.4? – In other words, if a new concept/approach/treatment is scientifically validated, but not yet “generally accepted”, should it not be taught? Put more simply: if it’s probably right, but not widely understood, should that not be a component of CME?
Accredited CE provider	ACCME	Publishing/education company	Given the wording associated with start-up entities under ineligibility discussion, and the term “generally accepted” in this standard, providers and supporters may need some guidance/education on 1.1 and 1.4 to ensure that inclusion of content is not linked to FDA approval, but rather to the valid scientific evidence of efficacy and safety. There will also be times when the best opinions of appropriate government authorities will suffice, such as in managing novel infectious diseases like Covid19. If providers over-interpret the requirements in Standard 3, then the unintended consequences to patients could be huge, especially in areas like oncology and infectious diseases, where the evidence is evolving faster than the FDA approval processes. Likewise, too generous an interpretation could lead to inclusion of content not currently supported by sufficient evidence, such as is the case with some uses of cannabis in medical treatment.

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Accredited CE provider	ACCME	Publishing/education company	In light of the wording associated with start-up entities under ineligibility discussion, and the term “generally accepted” in this standard, providers and supporters may need some guidance/education on 1.1 and 1.4 to ensure that inclusion of content is not linked to FDA approval, but rather to the valid scientific evidence of efficacy and safety. There will also be times when the best opinions of appropriate government authorities will suffice, such as in managing novel infectious diseases like Covid19. If providers over-interpret the requirements in Standard 3, then the unintended consequences to patients could be huge, especially in areas like oncology and infectious diseases, where the evidence is evolving faster than the FDA approval processes. Likewise, too generous an interpretation could lead to inclusion of content not currently supported by sufficient evidence, such as is the case with some uses of cannabis in medical treatment.
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Accredited CE provider	ACCME	Publishing/education company	In light of the wording associated with start-up entities under ineligibility discussion, and the term “generally accepted” in this standard, providers and supporters may need some guidance/education on 1.1 and 1.4 to ensure that inclusion of content is not linked to FDA approval, but rather to the valid scientific evidence of efficacy and safety. There will also be times when the best opinions of appropriate government authorities will suffice, such as in managing novel infectious diseases like Covid19. If providers over-interpret the requirements in Standard 3, then the unintended consequences to patients could be huge, especially in areas like oncology and infectious diseases, where the evidence is evolving faster than the FDA approval processes. Likewise, too generous an interpretation could lead to inclusion of content not currently supported by sufficient evidence, such as is the case with some uses of cannabis in medical treatment.
Accredited CE provider	ACCME	Publishing/education company	It would be incredibly difficult to raise an issue of a controversial treatment without providing learners with some context for how, why, or when it is used - particularly for times when something is accepted for one area but may be off-label in another - or available as a treatment in one country, but not yet in the US. When there is legitimate scientific debate, are faculty required to teach to the side that is more popular since the other may be "not generally accepted?"

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Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	Rationale for change: Inclusion of the wording “not generally accepted” is redundant- as already stated in 1.1.
Accredited CE provider	ACCME	Publishing/education company	Some legal reviewers have already assumed that this includes banning education about so-called "off label" or rapidly evolving science. If that is the case, then the unintended consequences to patients could be huge, especially in areas like oncology and infectious diseases, where the evidence is evolving faster than the FDA approval processes.
Accredited CE provider	ACCME	Publishing/education company	Standard 1.4: Providers might withhold content in activities about approaches to care which are new and innovative but considered controversial and not generally accepted by many. This will further slow the translation of research to practice.
Accredited CE provider	ACCME	Publishing/education company	This might be interpreted that "off label" education is not permitted. I don’t think that is the intent, so consider explicitly noting that this is permissible in accredited education.
Accredited CE provider	ACCME	Publishing/education company	When emerging* pharmacological agents, devices, therapies, and/ or technologies first become available there is often a significant gap between "generally accepted within the profession of medicine as appropriate care for the care of patients" and the new care options. This gap tends to be larger in community-based care settings than in academic centers due to inertia and the slowness with which community based physicians are able to absorb and apply new information. Your definition of "generally accepted." appears to promote status quo! It needs clarification re the critical role of CME to shorten the gap between evidence based scientifically validated new and improved care options. The field of medicine moves too fast for CME providers to be encouraged to keep things as they are.
Accredited CE provider	ACCME	Publishing/education company	While I agree with the Standard in general, I find it limiting. There are many areas in medicine where there may be not data or evidence to support a best approach. In these instances, clinicians may share best practices in the absence of data. However, without the context of when and how to make those decisions in a setting of uncertain is not helpful to clinicians. The is particularly important for experts to share their knowledge and when and how they make certain treatment or diagnostic decisions. As an accredited provider, we should not limit best practices sharing and intellectual exchange.
Do you foresee challenges or unintended consequences implementing Standard 1? If yes, please explain.			

Organization Type	Accreditor	Provider Type	Comments
Accredited CE provider	ACCME	School of medicine	I have a concern that in Standard 1.1- the term "profession of medicine" is appropriate for the care of patients. I would submit that since these standards are being used by joint accreditation as well as other accrediting bodies, that a more appropriate term would read as follows: all recommendations involving quality clinical care must be scientifically justified and generally accepted within healthcare professions (eg. medicine, nursing, pharmacy, etc.) as appropriate and focused on the optimum care of patients.
Accredited CE provider	ACCME	School of medicine	I think there is often a question as to how one 'ensures that content is valid'. While at times it might be easy from a program description to determine when content might be questionable, this might not always be the case. Ensuring that something is so, could be problematic.
Accredited CE provider	ACCME	School of medicine	If “generally accepted” refers to "generally accepted standards of experimental design, data collection, and analysis," then we can collect those citations as part of our content validation process. If “generally accepted” means a majority of physicians don’t agree with those diagnostic and therapeutic methods (even if they are supported by scientific evidence), then we would have no idea how to ascertain that general agreement. Thus we might not approve certain CME activities that we should do because they are supported by “generally accepted” scientific evidence.
Accredited CE provider	ACCME	School of medicine	In light of the wording associated with start-up entities under ineligibility discussion, and the term “generally accepted” in this standard, providers and supporters may need some guidance/education on 1.1 and 1.4 to ensure that inclusion of content is not linked to FDA approval, but rather to the valid scientific evidence of efficacy and safety. There will also be times when the best opinions of appropriate government authorities will suffice, such as in managing novel infectious diseases like Covid19. If providers over-interpret the requirements in Standard 3, then the unintended consequences to patients could be huge, especially in areas like oncology and infectious diseases, where the evidence is evolving faster than the FDA approval processes. Likewise, too generous an interpretation could lead to inclusion of content not currently supported by sufficient evidence, such as is the case with some uses of cannabis in medical treatment.

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Accredited CE provider	ACCME	School of medicine	In light of the wording associated with start-up entities under ineligibility discussion, and the term “generally accepted” in this standard, providers and supporters may need some guidance/education on 1.1 and 1.4 to ensure that inclusion of content is not linked to FDA approval, but rather to the valid scientific evidence of efficacy and safety. There will also be times when the best opinions of appropriate government authorities will suffice, such as in managing novel infectious diseases like Covid19. If providers over-interpret the requirements in Standard 3, then the unintended consequences to patients could be huge, especially in areas like oncology and infectious diseases, where the evidence is evolving faster than the FDA approval processes. Likewise, too generous an interpretation could lead to inclusion of content not currently supported by sufficient evidence, such as is the case with some uses of cannabis in medical treatment.
Accredited CE provider	ACCME	School of medicine	See note above. Given the ambiguity, we are likely to just say "no" to any potential discussion of a controversial topic rather than risk a compliance issue.
Accredited CE provider	ACCME	School of medicine	Standard 1.4 – since learners may be informed about controversial/not generally accepted approaches to diagnosis or treatment, what would be the appropriate response if a learner has questions about the controversial/not generally accepted approach since learners cannot be taught how or when to use them?
Accredited CE provider	ACCME	School of medicine	Terminology is less clear with revised terms of eligible and ineligible.
Accredited CE provider	ACCME	School of medicine	There are several areas that would be difficult to define. 1) What is "generally accepted" is not always clear.... especially with new therapies. 2) At what point when "describing" an approach would it be considered to include "how to" information.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Hospital/healthcare delivery system	In pediatrics, a lot of treatment recommendations are considered "off label" because they are not part of the standard manufacturer and/or FDA recommendations.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Hospital/healthcare delivery system	Standard 1: #4 may be difficult to manage from the accrediting office. With the words "must not", any help you can provide on how to ensure this happens 100% of the time would be beneficial.

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Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	• It may be to the provider's benefit to consider standard disclaimers that highlight measures that have been put in place to provide clinically valid educational content, but ultimately the content is owned by the speakers and presenters and any opinions are their own. • It may be worth clarifying expectations from the ACCME related to ensuring that education conforms to content validity standards. For example, it is unrealistic to expect providers who develop large annual meetings to review the slides of every single speaker prior to presentation (ASCO has over 1000 unique presentations in its Annual Meeting, for example). Or will the expectations for this new standard with regard to documentation in the Self-Study and Performance-in-Practice files be similar to what is required now?
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	In light of the wording associated with start-up entities under ineligibility discussion, and the term "generally accepted" in this standard, providers and supporters may need some guidance/education on 1.1 and 1.4 to ensure that inclusion of content is not linked to FDA approval, but rather to the valid scientific evidence of efficacy and safety.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	Item #4 is very restrictive and might impact education on treatment for pediatric patients. Many standard practices are off-label in pediatric patients and the limitation on educating healthcare professional how or when to use them may create an unintended consequence in designing education for those who provide care for pediatric patients. Suggest additional clarification.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Other: School of Nursing	The use of integrative therapies are often discussed in live activities and enduring materials. Standard 1.4 makes it seem like we cannot provide contact hours for any sessions, or even a full activity, that offers presentations from practitioners that use/teach about integrative therapies.

Do you foresee challenges or unintended consequences implementing Standard 1? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	Standard 2.3 Currently, the overall attendee list for large educational conferences or annual meetings, is shared with exhibitors, some of whom may be ineligible entities; it is common practice under current privacy laws and policies to allow the attendee to opt out of this sharing. Exhibit space sales could decrease significantly if no pre-invites or follow-up could be made without tasking the attendee with giving permission each and every time. The use of the word “Each time” is both restrictive and burdensome for the accredited provider and the learner. We consider that the use of the wording as it stands could have severe financial impact on some educational activities resulting in them no longer being financially viable.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	An issue may be controversial to some and not to others depending on what side of the issue you are. In NJ, we have a medicinal marijuana program and have legalized medical aid in dying for the terminally ill. Both topics could be considered controversial, but they are legal in NJ. More detailed clarification on what will be permitted within accredited continuing education when a “controversial” topic is legal within the state would be helpful.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	Many topics are controversial (e.g., hormone therapy for transgender kids), vehemently opposed by some, or accepted by some/many but may not have the most rigorous science behind them (e.g., acupuncture). This may lead to unintended consequences with exclusion of education about important topics related to vulnerable populations because of fear of being determined to be out of compliance with this standard.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	We will need assistance from the ACCME to easily identify ineligible entities in a timely manner. The complexity and swiftly changing nature of business ownership may be too much for providers to manage in the short time we often have between a receiving a completed disclosure and the launch of an activity.
Accredited CE provider	Other: Academy of General Denistry	School of medicine	Number 4 may be difficult to manage on-site. Faculty may be tempted to speak "off the record" or make a casual comment that can be misconstrued. Number 5 may be easily challenged. It may need to be more specific.

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Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Other: Accreditation Council for Pharmacy Education	Nonprofit (other)	In Standard 1.4, what is the definition of "controversial?" For example, medical cannabis may be considered controversial, but it is legal at the state level in some jurisdictions and practitioners need to be educated in order to appropriately care for patients, which may include when or how to use it.
Accredited CE provider	Other: ACPE	Hospital/healthcare delivery system	Our organization owns both eligible and ineligible subsidiaries, and I believe that the proposed standard as written would disqualify us from any longer being a provider of accredited continuing education. Regardless of who is responsible for an individual's payroll, the content is either valid and unbiased or it is not. When you ask attendees if the content is free of bias, those responses should be the cause for additional scrutiny by the accrediting organization, not simply the name or makeup of the provider's business.
Accredited CE provider	Other: CMS	Hospital/healthcare delivery system	Education and information should be presented by experts in the field of information, most likely if a speaker is an expert in specific topics, they have made a career out of knowing this information and therefore probably have some sort of financial relationship in their background. More stipulations will make it more difficult to get the most informed and expert speaker.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Standard 1.4 states we can't teach how or when to use approaches that are not generally accepted. We will need to proactively educate our CME leaders and speakers that it is not enough to say a treatment is controversial or not the usual standard treatment. If they get a question that directly addresses how or when it's appropriate to use alternate treatments the speakers will need to defer the answer, so that it is not answered during accredited continuing education. Some speakers may not remember or may want to elaborate instead if they have had success using that treatment in some cases. We can bring this to the speaker's attention, but we can't guarantee they won't speak out of turn. We cannot invite that speaker in the future, but the damage would already be done.

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Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Standard one 1. "Generally accepted" is an indeterminate description, I suggest "supported by data whose biases are considered". To learn about includes how and when. Recommendations made in accredited continuing education must "strive to" be accurate, balanced, and scientifically justified. Knowledge is always changing. 4.5 Advocacy is too subjective and easily implied and limits free speech. Opinions are opinions, discussion as to the source of the opinion can be encouraged.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	We have this statement on our Conflict of Interest Form: First, please go to https://openpaymentsdata.cms.gov/ and review anything on the list within the past 12 months. We also have the following attestations: q I do not have any relevant financial relationships with any commercial interests q I reviewed my OpenPayments data and have found no other conflicts other than listed above
Advocacy organization			For companies involved in genetic medicine, (genetic testing, diagnosis, treatment, etc.) where would they fall – eligible or ineligible? This type of company is the new reality of medicine. Restricting this type of presentation from a CME-certified activity would be detrimental to physicians and their patients.
Advocacy organization			While they may be uncommon, there are likely to be situations of legitimate scientific debate on an approach to diagnosis or care. Does one or the other option in such instances automatically fall into the category of controversial or not generally accepted if it is the choice preferred by fewer clinicians? NAMEC would also suggest that it is extremely difficult to raise the issue of a controversial treatment without providing learners with some context for how or when it is used. This would be especially true in cases where a treatment is generally accepted in certain therapeutic situations, but not others.

Do you foresee challenges or unintended consequences implementing Standard 1? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Clinician/healthcare professional			All recommendations involving clinical medicine in accredited education must be scientifically justified and generally accepted within the profession of medicine as appropriate for the care of patients. This is not appropriate; medicine is still an art and a science. We still can work off clinical experience of our own or others. This is also leaving "generally accepted" to someone's opinion, who might disagree with others, especially someone conventionally trained vs. someone trained in integrative medicine. Accredited education must give 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, and analysis. Conforming to standards is dangerous, 40% of the patients are not served by the conventional standards of care and need personalized, individualized therapies to get well.
Clinician/healthcare professional			CME is a golden opportunity to introduce practices not (yet) used by the general medical community. An approach must start somewhere, raising awareness and offering the opportunity for open discussion within the scientific community. I imagine many topics presented to the ACGME might seem "too novel," and yet later, the practice becomes mainstream. (i. e. certain allergy testing by otolaryngologists). The purpose of CME is not to censure, but to allow scientific discovery that is backed by science, and the references submitted to support the content should reflect scientific support for the topic.
Clinician/healthcare professional			Controversial products and treatments cited in steps 4 and 5 continue to be developed and used with limited ongoing research. This may cause difficulties in implementation.

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Organization Type	**Accreditor**	**Provider Type**	**Comments**
Clinician/healthcare professional			If this proposed change stands, only ACCME and the AMA will be able to determine what is valid content. To truly "give a fair and balanced view of diagnostic and therapeutic options" you must be able to include those therapies that are not necessarily "scientifically justified and generally accepted within the profession of medicine as appropriate for the care of patients" which include the use of food as medicine as well as traditional therapies from long-standing traditions such as Traditional Chinese Medicine and Ayurveda which as whole-system approaches are not well studied within the drug-protocol paradigm. In addition, the "generally accepted standards of experimental design, data collection, and analysis" are now being challenged as we learn about genetic variability and individuality of responses. "4. Accredited education may inform learners about approaches to diagnosis or treatment that are controversial or not generally accepted but must not include advocacy for these approaches or teach healthcare professionals how or when to use them." This does not make sense that you would specifically forbid teaching healthcare professionals WHEN or HOW TO USE these approaches to diagnosis or treatment.
Clinician/healthcare professional			It is clear that the standard as written is vague. One physician's science is another physicians quackery. True evidence-based medicine cannot and does not exist due to it primarily never having been studied on every person who a treatment may be warranted. Thus, science still becomes a part, an art.
Clinician/healthcare professional			It may be difficult for some providers to identify, in (4), the line between "informing" learners about controversial topics and "advocating".
Clinician/healthcare professional			It will lead to arbitrary application.
Clinician/healthcare professional			Standard 1.4 appears to disqualify the discussion of off-label use of pharmaceuticals in circumstances that currently occur on a nearly daily basis in pediatric practice. I am very concerned about this new limitation.

Do you foresee challenges or unintended consequences implementing Standard 1? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Clinician/healthcare professional			New: Standard 1: 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. I see a bit of a challenge in the wording of this standard. There is work that we do in the field of allergies that we use to help identify what the allergy is, and then advise the patient to avoid the allergen. This can be what is ingested, breathed or touched. If the patient is exposed, they can become ill. This is a very important field and relatively poorly understood. The testing that is used for this is very important, and it is important to teach how and when to do this type of testing. This field should have advanced farther by now, but it has not, generally likely due to other commercial interests which have tried to discredit this field. It would be a shame to not allow teachings in this area in regard to what type of testing is available and when and where to apply the teachings.
Clinician/healthcare professional			Standard 1 is vague and open to interpretation about what is considered standard of care. It does not allow for innovation to be taught as it is almost never the standard of care. It negates the clinical benefits of case studies, clinical observation or therapies that may have limited clinical data. Different organizations may disagree on what is considered standard of care. Promoting specific devices, brands, etc. should be eliminated from presentations, but to discourage teaching other physicians about novel, new therapies goes against our principles as doctors and educators.
Clinician/healthcare professional			There are many research and evidence-based treatments that are not uniformly accepted, perhaps fitting into cutting-edge therapies, that would not be able to be discussed and thoroughly reviewed with this new standard. A perfect example is fish oil- in the 1990's and early 2000's omega3 fish oil would not have been eligible to discuss under these new guidelines. Today we have vacepa. Also, I have treated and helped many patients with the techniques and procedures taught by the American Academy of Environmental Medicine, which under these new guidelines, would no longer be approved for ACCME credit.

Do you foresee challenges or unintended consequences implementing Standard 1? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Clinician/healthcare professional			There will be repeated arguments as to what is, or is not, "generally accepted". In addition, it will deter new discoveries. Evidence requires a hierarchy- a physician or other health care professional observes a beneficial or harmful effect of a diagnostic or treatment strategy on a patient, and reports it! He or she, and others, will keep looking, and release a case series. Then, hopefully funding will ensue for a case-control study, and then a cohort study, and then trials of treatments.
Clinician/healthcare professional			What is considered 'controversial' may be difficult to determine and may include some level of subjectivity.
Clinician/healthcare professional			You are increasing health disparity by pushing forward a two tiered system. One for individuals who can pay for integrative or alternative health care out of pocket and one group of individuals who cannot afford to and must rely on care reimbursable by health plans and limited to "generally acceptable" therapies such as surgery, medical devices and pharmaceuticals. This has all sorts of ethical implications.
Continuing education accrediting body			We are not sure how we could define “generally accepted” or “controversial” for our providers.
Continuing education accrediting body			While incorporating content validation into the revised Standards is welcome, there exists potential for over-interpretation of Standard 1 that could limit education on emerging/novel disease states and therapies. Additional guidance on what constitutes “scientifically justified” and “generally accepted” may be warranted. And Standard 1.4 may be subject to varied interpretation on the distinction between “informing about approaches to diagnosis or treatment” versus “teaching…how/when to use them.”
Ineligible Entity (commercial interest, such as pharmaceutical, device, life-science company)			If "controversial" and "not generally accepted" are not defined by an objective, clinical standard, this seems difficult to implement.

Do you foresee challenges or unintended consequences implementing Standard 1? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Ineligible Entity (commercial interest, such as pharmaceutical, device, life-science company)			Since new/emerging diagnostic and treatment strategies may be interpreted as “not generally accepted,” because of their status as new or emerging strategies/agents, and to preserve compliant discourse regarding potential clinical application (ie, the how and when), please consider the removal of the term “not generally accepted.” For example, clinical trial data may include scientific information regarding pathophysiology, but may also include important information regarding clinical implications, risk/benefit profiles, and tailoring therapeutic approaches based on data. New considerations in the diagnosis and treatment of disease is an important part of the educational exchange, and often in advance of guideline update cycles, FDA approvals, etc. A comprehensive approach is appropriate, including the disclosure of the level of scientific evidence to support the approach, within the context of how or when to apply that information. For this reason, please consider the removal of “or teach healthcare professionals how or when to use them” as this may also be similarly misinterpreted.
Medical/healthcare association			For topics that are not supported by evidence-providing this type of information may still be required including dosing and common indication/types of patients using-this can be done without advocating use. If providers over-interpret requirements, then unit needed consequences to patients could be significant where evidence evolves faster than FDA approval. What about “off-label” use?
Medical/healthcare association			In light of the wording associated with start-up entities under ineligibility discussion, and the term “generally accepted” in this standard, providers and supporters may need some guidance/education on 1.1 and 1.4 to ensure that inclusion of content is not linked to FDA approval, but rather to the valid scientific evidence of efficacy and safety. There will also be times when the best opinions of appropriate government authorities will suffice, such as in managing novel infectious diseases like Covid19. If providers over-interpret the requirements in Standard 3, then the unintended consequences to patients could be huge, especially in areas like oncology and infectious diseases, where the evidence is evolving faster than the FDA approval processes. Likewise, too generous an interpretation could lead to inclusion of content not currently supported by sufficient evidence, such as is the case with some uses of cannabis in medical treatment.

Do you foresee challenges or unintended consequences implementing Standard 1? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Medical/healthcare association			In Standard 1.4, the use of the phrase “advocating for” might inadvertently preclude eligible entities, in particular academic institutions, from responding to, or clarifying inappropriate or proprietary claims, made by ineligible entities or others.
Medical/healthcare association			Standard 1 is biased and basically prevents any organization from teaching/advocating treatment methods that are not necessarily "universally" accepted in the medical field. This is skewed towards anything but well-worn traditional treatments that may be far behind the times of innovation. The only way physicians change is to learn about new and different changes in the field. This is how medicine progresses, not necessarily by towing the line. This rule will eventually lose any innovative treatments that develop and likely lose medical groups who are innovative. ACCME will very likely become extinct if these rules are enforced. "All recommendations involving clinical medicine in accredited education must be scientifically justified and generally accepted within the profession of medicine as appropriate for the care of patients". NOT ACCEPTABLE.
Medical/healthcare association			The Alliance supports the greater clarity provided in how to deal with controversial topics, but more guidance is needed and can be offered in supplemental documents, rather than the standards themselves. Standard 1.4 does not appear to take into consideration new discoveries that are evidence-based, such as first-in-kind diagnostic tools or treatments, rare diseases, therapeutic areas with rapidly evolving scientific options, such as oncology or underrepresented populations in clinical trials, such as pediatrics. The inability to address these fully in accredited CE could result in patient harm. How does one assess when enough evidence exists to allow discussion of how and when to use a therapy or diagnostic method? For example, in cannabis medicine rigorous research on currently available strains is now going to be possible within the US and is being actively pursued and published elsewhere. The scientific evidence for and against indications and about dosing will evolve, yet the topic is likely to remain controversial because it is both scientific and political in nature. Shouldn’t accredited CE be concerned only with the evidence?

Do you foresee challenges or unintended consequences implementing Standard 1? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Nonaccredited CE provider			I foresee that these guidelines will cause a stifling of the conferences that are promoting therapeutic modalities that are designed to be coupled with allopathic medicine but are not allopathic. CME is a MAJOR draw for conferences to be able to appeal to wider audiences and increase exposure and education. Without being able to attract a wide audience to conferences and activities that challenge the status quo, ACCME will hamstring efforts to truly advance the field of medicine toward better patient care for less money. These provisions will not serve to do anything to challenge our current ineffective and unsustainable medical system.
Nonaccredited CE provider			Suggest rewording 1.4 to: "Accredited education may inform learners about approaches to diagnosis or treatment that are controversial or not supported by evidence that meets the requirements in 1.3 above, but must not include advocacy for these approaches or teach healthcare professionals how or when to use the them; off-label use content that includes patient care recommendations, when supported by evidence, is allowed."
Other: Accredited CE provider, Continuing education accrediting body, and medical/healthcare association			In light of the wording associated with start-up entities under ineligibility discussion, and the term “generally accepted” in this standard, providers and supporters may need some guidance/education on 1.1 and 1.4 to ensure that inclusion of content is not linked to FDA approval, but rather to the valid scientific evidence of efficacy and safety. There will also be times when the best opinions of appropriate government authorities will suffice, such as in managing novel infectious diseases like Covid19. If providers over-interpret the requirements in Standard 3, then the unintended consequences to patients could be huge, especially in areas like oncology and infectious diseases, where the evidence is evolving faster than the FDA approval processes. Likewise, too generous an interpretation could lead to inclusion of content not currently supported by sufficient evidence, such as is the case with some uses of cannabis in medical treatment.

Do you foresee challenges or unintended consequences implementing Standard 1? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: CME/CE Consulting Services Company			Given that item #4 currently lacks needed clarity in terms of what would make providers compliant, a potential challenge occurs when planners/managers and/or faculty, authors and content developers seek to include information “about approaches to diagnosis or treatment that are controversial or not generally accepted” in the absence of clear parameters regarding what is and is not appropriate. In short, what crosses the line into non-compliance? Item #4 has some parallel to the carve-out for utilization of employees of commercial interests in CME. The carve-out is often misinterpreted as accredited providers mistakenly think that they “make it work” to fit an employee of a commercial interest into one of the special-use cases. The language, as currently written, for item #4 may open the door to an increased inclusion of information about “approaches to diagnosis or treatment that are controversial or not generally accepted.”
Other: Consultant			I think it will be difficult to enforce compliance when it comes to be allowed to education about controversial practices, but not being allowed to educate clinicians how to carry them out. However, I think it's a good compromise because if you don't even acknowledge that controversial, off-beat practices exist, you risk being perceived as out of touch with reality.
Other: Consultant - own my own company			It may be hard for some providers to manage the line with content and faculty with ONLY presenting ABOUT the controversial approaches and having no recommendations. I imagine learners asking that very question- when has this been used and why? But I do see the value in keeping clinicians up to date on what is out there, and that it should be accredited.

Do you foresee challenges or unintended consequences implementing Standard 1? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: Currently independent consultant; previously Director of CME for large subspecialty society			I have concerns that if this is followed too strictly, it could lead to stifling of reporting on innovative approaches at the early stages. My experience in more than 20 years working with surgeons in CPD has been that reporting on their new thoughts and insights into particular clinical problems at conferences leads to discussion, sharing of ideas and perspectives, research, and ultimately changes in standard of care. But in the early stages of reporting on a new approach, controversy seems inevitable, as many are happy with the status quo. As currently written, I have concerns that the policy leaves room for it be too broadly applied.
Other: I am a clinician-educator, board member of APPS, member of the Academic Consortium of Integrative Medicine and Health, and faculty provider for integrative medicine CME			The lack of clarity is problematic. Clear resources should be provided, as well as a channel for support from ACCME to ask questions and clarify issues. Doing so will help CME providers provide content that meets the guidelines and create a bridge that ultimately benefits providers and patients.

Do you foresee challenges or unintended consequences implementing Standard 1? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: Joint Provider			Yes. Unless ACCME is willing to take a deep look at what "generally accepted" means and / or define it explicitly as you interpret it internally, this will be highly problematic. There is no transparency in saying that there is no definitive list, when clearly there is. Example: At the 2019 ACCME Annual Conference, during the session, "Bringing Educational Leadership to Controversial Topics: Managing CME About Medical Marijuana", when asked if there was a definitive list of topics that ACCME deems controversial, Dr. Graham McMahon replied that there is not a definitive list available, but then said quote “Go with your gut.” McMahon and co-presenters then listed the following topics as being controversial or not evidence based: Medical marijuana, Stem cells, Alternative medicine, Chiropractic care, Homeopathy, Naturopathy and Psychedelics. ACCME recommends consulting with someone from “conventional” medicine who is unbiased. First this is simply not true and a dangerous precedent is being set within ACCME to broadly label entire professions that in many cases not only have ample research, but also clinical guidelines that are generally accepted. Ex: Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline from the American College of Physicians. This clearly demonstrates the internal lack of understanding of the integrative health research.
Other: MedChi is both an Accredited Provider and a Recognized Accreditor			Regardless of ACCME's opinion regarding Medical Cannabis, it is becoming part of clinical care. The ability of providers to address and provide clinical education regarding what might be termed emerging therapies should be defined and a clear process outlined that allows providers to address these without fear of falling into noncompliance. The current approach will lead to accredited CME not being relevant in areas where it should be.
Other: physician, patient, member of certifying board, member of educational academy			content is "valid". valid means founded on evidence or fact. to be generally accepted within the practice of medicine is not a guarantee of validity. not all safe, effective or necessary care is known by the majority of doctors. I personally went to 12 board-certified, well-trained, respected, scientific, mainstream physicians who could not diagnose and treat my neuro-immunotoxic disease. (I had a 70% recovery.) 5-15% of the patient population are not "normal". Does everybody get sleepy on diphenhydramine? No, some become agitated. sometimes "N" = 1.

Do you foresee challenges or unintended consequences implementing Standard 1? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: Publishing/education company			In light of the wording associated with start-up entities under ineligibility discussion, and the term “generally accepted” in this standard, providers and supporters may need some guidance/education on 1.1 and 1.4 to ensure that inclusion of content is not linked to FDA approval, but rather to the valid scientific evidence of efficacy and safety. There will also be times when the best opinions of appropriate government authorities will suffice, such as in managing novel infectious diseases like Covid19. If providers over-interpret the requirements in Standard 3, then the unintended consequences to patients could be huge, especially in areas like oncology and infectious diseases, where the evidence is evolving faster than the FDA approval processes. Likewise, too generous an interpretation could lead to inclusion of content not currently supported by sufficient evidence, such as is the case with some uses of cannabis in medical treatment.
Other: Standard setting organization for 24 specialty member boards			There should be clarity regarding assurance to high-value CME across the accreditation system. That accredited CME programs who be free of commercial bias by 'ineligible entities'.
Patient, caregiver, member of the public			I believe that this standard is the best approach, although medical marijuana use will be impacted.
Recognized Accreditor (state/territory medical society)			It appears logical and it makes sense.
Recognized Accreditor (state/territory medical society)			Number 4 - the way it is expressed leaves the door open addressing the CME with an approach that will camouflage the approach to teach professionals how and when to use. I suggest that the second part of the sentence after the "but" should be at the beginning of the sentence.
Recognized Accreditor (state/territory medical society)			Research medical schools and universities push faculty into bring products to market (and being a financial partner in that process). As soon as there appears to be potential, an on-paper-only company gets established for the purpose of attracting venture capital, which ultimately may not be successful. I think there needs to be further sharpening of what it takes to be a bio-medical start-up.

Do you foresee challenges or unintended consequences implementing Standard 1? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Recognized Accreditor (state/territory medical society)			Might discourage encouraging participation in clinical trials which by definition are experiment of sorts. 1.4 & 1.5: There are therapies that are evidence based but not generally accepted. Practice gaps can be defined around these many times. Also there may be legitimate guidance or opinion on how or when to use therapies that are not generally accepted and do not have a lot of evidence but have some value in certain situations. Speaker's clinical experience about how and when to use such therapies when standard or traditional therapies are not working may be very valuable. Examples that come to mind are in Integrative Medicine, defined as holistic or natural therapies (such as nutrition, supplements, meditation, acupuncture, etc) that are INTEGRATED WITH traditional and standard approaches. This is different than simply complementary therapies (used in parallel with standard treatment) or alternative therapies (used as alternatives to standard treatments). Many of these therapies do have evidence but it may be overlooked in favor of pharmaceutical or surgical therapies. With regard to this particular example, we actually may be biasing education in favor of pharmaceutical therapies instead of holistic therapies as outlined above, which would be an unintended consequence of this Standard. This new aspect of the standard seems to restrict a subject matter expert from relating their clinical experience, especially as related to cases that don't respond to standard therapy.
Recognized Accreditor (state/territory medical society)			The term "scientifically justified" has always needed clarification. This standard goes a long way towards that. I like the concept of being able to talk of controversial or generally not accepted treatments or diagnoses as long as they are not advocated. Accredited education should not stymie creativity. I think there are still going to be misunderstandings about this and hope that we can in the future further refine our stance here. One area that has been an issue for our program is the introduction of Functional Medicine into our community. This centers more on patient needs than literature. Although more of a holistic approach it is still grounded in science.

What comments or questions do you have about Standard 1?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider		Nonprofit (physician membership organization)	As above. Are faculty to respond "Due to ACCME rules, I can't explain this further." If they do answer about how or when, will the organization be held accountable for the faculty violating the rule if someone reports the issue to ACCME?
Accredited CE provider	ACCME		We applaud the effort by ACCME to have all of the requirements for independence and integrity in one document.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	As mentioned above, this will greatly hinder and frustrate faculty, learners and providers in the pediatric world. Learners are sincerely trying to ascertain how they can best help patients with the resources available to them as providers. Time is an extremely valuable variable to providers and this standard adds another step in the process of finding out what is needed as providers will have to seek more information outside the activity.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	I recommend changing the language to: Accredited providers are responsible to “inform speakers and planners that….” followed by the requirements (rather than ENSURE). We rely on the professional integrity of our speakers and planners, and there is no way we would have the resources to convene a specialty-specific expert panel to review every talk to ensure validity, general acceptance, and the sound methodology of every study in every reference.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	One of our biggest frustrations is that the ACCME makes rules, but does not give providers a simple template, that if implemented, would help the provider to comply satisfactorily with the rule. Too much is left to interpretation and guesswork.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Please clarify 1.4. Perhaps an example can be communicated using a compliant/non-compliant definition as the word "controversial" can be subjective
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Standard 1 is clear and concise.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Would like to learn how the ACCME community comments on Standard 1 #4.
Accredited CE provider	ACCME	Nonprofit (other)	Suggest rewording 1.2 to include preventative options (in addition to diagnostic and therapeutic)

What comments or questions do you have about Standard 1?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (other)	The overall intention of Standard 1 is to promote safe, effective patient care content without commercial influence. However, the language of the new proposed Standards, while effective in refraining from serving industry, goes too far in restricting the scope of high quality, evidence based, and generally accepted interventions that could serve healthcare professionals. The stated purpose of ACCME is to prepare Clinicians to deliver safe, effective, cost-effective, compassionate care, based on best practice and evidence. It is meant to expand beyond what is taught in Medical School. Therefore, this standard above all others must support this. In the era of personalized medicine, “generally accepted” is an outdated and restrictive term, as a one-size-fits-all approach to therapeutic intervention is rapidly becoming obsolete. “Generally accepted” therefore, in the sphere of Accredited Continuing Education, must also allow for contextual evidence that determines what is best for individual patients. Moreover, “generally accepted” should not be defined by insurance interests nor cost-effectiveness, neither of which can adequately account for a personalized approach to therapeutic intervention. Finally, consider replacing the term Valid with “Safe and Effective” in the title of the Standard as it is not utilized throughout the standard and is a subjective term.

What comments or questions do you have about Standard 1?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Suggest removing the following text from Standard 1.4. “or teach healthcare professionals how or when to use them.” ACOEM postulates that Standard 1.4 as currently written will result in drastically limiting an accredited provider’s ability to present cutting-edge science that has not moved out of research trials. This can result in stifling scientific inquiry and reduce the benefits that researchers achieve during collaborative discussion of theoretic treatments among a large and diverse group of learners. While we appreciate that the proposed Standard allows for discussion about approaches to diagnosis or treatment that are controversial or not generally accepted, discussion about how or when to use these approaches is integral to the peer group discussion that contributes to, and inspires, rigorous testing methods. Suggest removing the following text from Standard 1.4. "or teach healthcare professionals how or when to use them."
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	1.1 Need to define “scientifically justified” – when is that threshold achieved? 1.4 When does teaching about something become “advocating” for something?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	1.4-Education/guidance with examples of limitations would be helpful-where to draw the line on content, for example on cannabis, functional medicine, supplements?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Add a requirement to include (say on the PowerPoint slide) a reminder that a particular modality is not FDA, AMA, ACOG, etc. approved; or that literature supportive of the modality is not described in the peer reviewed medical literature.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Comments noted above.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	For full comments please see submission to communications@accme.org.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Good to fold in content validation policy into this.

What comments or questions do you have about Standard 1?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Growers, distributors, or sellers of medical food and dietary supplements; ACCME is overstepping their purview. These items are routinely marketed to the general public and not at all limited to the patient population. Impossible to implement. Includes Advertising, Marketing or communication firms whose clients are ineligible entities. All clients? Some clients? Any clients? How would we know? Where would we get a client list? This is impossible to actualize. Healthcare products used on or by patients: Limit healthcare products to healthcare products PRIMARILY used by or on patients.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	How are we to address off-label use?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	I believe that standards 1.1 through 1.3 and 1.5 are adequate to ensure valid education based on scientific justification without getting into the weeds and forcing providers to try to determine whether something is "controversial and not generally accepted" or whether a speaker might veer off the path and talk about when to use such a diagnosis or treatment instead of just talking about it. This just makes our jobs harder without adding that much value.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	I was at the meeting in SF where the reasons for using ineligible were discussed and I nevertheless feel strongly that the fact that they could not come up with a better word is not a sufficient reason to use a word that is likely to create more confusion.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	In Section 4, how does one define "Controversial" and who gets to decide what is controversial? To innovate in medicine it is important to teach how and when to use controversial methods. This is clearly a response to medical marijuana based research
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	It would be helpful to include best practices regarding when and how an eligible entity can develop educational content about the appropriate use of new techniques that may not have an evidence base yet.

What comments or questions do you have about Standard 1?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Overall the content of Standard 1 is clearly stated and describes the requirements for content validity effectively. Will there be a process for addressing claims against activities that are accused of violating the requirements of 1.5, regarding the teaching of ineffective or risky approaches to patient care? What will be the burden of proof to make an argument either for or against the validity of an activity's content in the case of new or experimental concepts on which there may not yet be consensus?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Related to above, you seem to assume that someone taking a continuing education course is completely unaware of the actual practice of medicine and has no skills in judging the veracity of a presentation that has already been vetted or the basic tenants of science. Continuing education is only for those who have demonstrably shown that they have mastered the basic practice of medicine. Most of #1 is actually an insult to anyone who has earned their doctorate and assumes that they must be protected from all evils and bias in the world and that, in spite of their educational accomplishments, they need to be treated like a high school biology class. Please just scrap it.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Statement 5 seems out of place under 'Standard 1: Ensure Content is Valid'. Wouldn't these organizations be considered ineligible entities? Suggest moving this language to the 'Eligibility' section.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We support the intent of this Standard with the caveat noted above.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We support this new standard.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	What evidence would be required to determine the content is valid if, upon audit, content is determined to be controversial?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Will there be a process for addressing claims against activities that are accused of violating the requirements of 1.5, regarding the teaching of ineffective or risky approaches to patient care? What will be the burden of proof to make an argument either for or against the validity of an activity's content in the case of new or experimental concepts on which there may not yet be consensus?

What comments or questions do you have about Standard 1?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Other: Public/nonprofit/healthcare system/education/school of medicine	Institutions should be allowed, and encouraged, to teach cutting edge, evidence-based medicine, even before it has become generally accepted practice, in order to advance the standards of practice.
Accredited CE provider	ACCME	Publishing/education company	Accredited education may inform learners about approaches to diagnosis or treatment that are controversial or not generally accepted but must not include advocacy for these approaches or teach healthcare professionals how or when to use them. While CME programs should not be designed to promote or advocate strategies that are not generally accepted. However, it also should not prohibit best practice sharing and expert advice especially in areas where there is no evidence to support specific decision making. I can foresee that if some discussions occur where an expert faculty may share their best practices and it would be construed as a provider breaking this standard.
Accredited CE provider	ACCME	Publishing/education company	Are faculty still allowed to speak “off-label” if they identify this to the learners?
Accredited CE provider	ACCME	Publishing/education company	Delete 1.4 from the standard or provide definitions and examples for “controversial” and “not generally accepted.” Clarify the difference, with examples, between informing learners about a controversial approach vs teaching them how or when to use the approach. One person’s inform could be another person’s teach how, easy to get this wrong and then be in conflict with this standard.
Accredited CE provider	ACCME	Publishing/education company	I applaud the effort by ACCME to have all of the requirements for independence and integrity in one document.

What comments or questions do you have about Standard 1?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	In light of the wording associated with start-up entities under ineligibility discussion, and the term “generally accepted” in this standard, providers and supporters may need some guidance/education on 1.1 and 1.4 to ensure that inclusion of content is not linked to FDA approval, but rather to the valid scientific evidence of efficacy and safety. There will also be times when the best opinions of appropriate government authorities will suffice, such as in managing novel infectious diseases like Covid19. If providers over-interpret the requirements in Standard 3, then the unintended consequences to patients could be huge, especially in areas like oncology and infectious diseases, where the evidence is evolving faster than the FDA approval processes. Likewise, too generous an interpretation could lead to inclusion of content not currently supported by sufficient evidence, such as is the case with some uses of cannabis in medical treatment
Accredited CE provider	ACCME	Publishing/education company	It is commendable that ACCME is making a concerted effort to have all of the requirements for independence and integrity in one document.
Accredited CE provider	ACCME	Publishing/education company	It's nice to see "content validity" as the first priority
Accredited CE provider	ACCME	Publishing/education company	We applaud the effort by ACCME to have all of the requirements for independence and integrity in one document
Accredited CE provider	ACCME	Publishing/education company	We applaud the effort by ACCME to have all of the requirements for independence and integrity in one document - thank you! 1.4-Education/guidance with examples of limitations would be helpful-where to draw the line on content, for example on cannabis, functional medicine, supplements?
Accredited CE provider	ACCME	Publishing/education company	We applaud the effort by ACCME to have all of the requirements for independence and integrity in one document.
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Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	We applaud the effort by ACCME to have all of the requirements for independence and integrity in one document.
Accredited CE provider	ACCME	School of medicine	Having all requirements for independence and integrity in one document is helpful.
Accredited CE provider	ACCME	School of medicine	i don't really foresee any challenges with this Standard.
Accredited CE provider	ACCME	School of medicine	I think it's clear and it seems like you combined C10 with Standard 1, which is helpful.
Accredited CE provider	ACCME	School of medicine	I'm sure there are some things that are "way out there" but there are many gray areas that providers may avoid in order to be safe. We may lose education in novel therapies due to a very strict interpretation of "not generally accepted."
Accredited CE provider	ACCME	School of medicine	It is always difficult when a criterion allows for interpretation. I would also recommend generalizing #4 when it says teach healthcare professionals to instead be learners. Attendance can range from patients to administrators, down to the providers offering the care and those just interested in the topics. Also, i am not sure #5 should be within this section. It should be moved up to the section of ineligible entities. Then instead have #5 say "Education should not promote recommendations, treatment..."
Accredited CE provider	ACCME	School of medicine	It's helpful to know the difference between an eligible and ineligible organization, but I was surprised some entities that could potentially profit from promoting their products are included as eligible: electronic health records and software/game developers.
Accredited CE provider	ACCME	School of medicine	Make the pathway for providing CME on controversial topics as clear as possible.
Accredited CE provider	ACCME	School of medicine	See above-- we need to be careful that the ACCME and related regulatory bodies use language that reflects not only profession specific expectations but interprofessional collaboration and CE expectations as well
Accredited CE provider	ACCME	School of medicine	Since the standards have become a national and international model, I prefer this simplicity of the language of the COI.
Accredited CE provider	ACCME	School of medicine	The addition of number 4 is helpful.

What comments or questions do you have about Standard 1?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	No one should have issues here, right? It's the Content Validity policy just moved into the Standards, so we should all be here already. It is sometimes difficult when new/emerging health treatments issues (ex. Medical marijuana), but ACCME does a great job of supporting us as those come up and helping guide us. As long as that continues, this is helpful and a good, clear boundary that makes common sense. I like the inclusion of content validity in the Standards, so that's nice. Could #5 say "Organizations cannot be accredited, and accredited education does not…." to help make the point what invalid content is and how it applies to providers who are applying these rules to specific activities?
Accredited CE provider	ACCME	School of medicine	We will utilize the "types of organizations" that may be accredited as eligible entities as well as define ineligible entities on some of our forms. These clarifications are important and the ACCME defines them very well. We will update our current CME Content Development and Validation Policy to reflect the new terminology.
Accredited CE provider	ACCME	School of medicine	When you have over 100 different RSS events, so many going on each day, how do you insure content validation at each activity? We know the topic ahead of time but do not know the details and count on the course director to be the local authority. We can audit a few of these programs but cannot attend all of them in person as we do not have the resources as many are over the lunch time or early morning at the same time. We appreciate the ability to mention alternative approaches without giving much detail other than recognizing the existence of alternatives. Thank you for providing that new piece of clarity.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Hospital/healthcare delivery system	Having the definition for valid content is very important. I do wonder if bullet 4 and 5 have been enough an issue where these statements are warranted.

What comments or questions do you have about Standard 1?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Hospital/healthcare delivery system	Providers will need guidance on how to address situations where a treatment is not FDA recommended for pediatric patients but are supported through scientific research and evidence.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (other)	item 5, which talks about "organizations that cannot be accredited" might be better placed in the eligibility section. Like the note "Standard 1 applies to all accredited continuing education." Should help remove any confusion among organizations that don't accept commercial support that this standard applies to them as well.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	We applaud the effort by ACCME to have all of the requirements for independence and integrity in one document.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Other: Electronic health record company	We agree with the standard and have no further comments or questions.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Other: School of Nursing	Standard 1.4 - how does a practitioner of an integrative therapy not advocate for its use?
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	For standard 1.4 it would be very helpful if the ACCME provide some education/guidance with examples of limitations. Would help to allow providers some insight into where to draw the line on content, for example on cannabis, functional medicine, supplements?

What comments or questions do you have about Standard 1?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	In light of the wording associated with start-up entities under ineligibility discussion, and the term “generally accepted” in this standard, providers and supporters may need some guidance/education on 1.1 and 1.4 to ensure that inclusion of content is not linked to FDA approval, but rather to the valid scientific evidence of efficacy and safety. There will also be times when the best opinions of appropriate government authorities will suffice, such as in managing novel infectious diseases like Covid19. If providers over-interpret the requirements in Standard 3, then the unintended consequences to patients could be huge, especially in areas like oncology and infectious diseases, where the evidence is evolving faster than the FDA approval processes. Likewise, too generous an interpretation could lead to inclusion of content not currently supported by sufficient evidence, such as is the case with some uses of cannabis in medical treatment. I applaud the effort by ACCME to have all of the requirements for independence and integrity in one document.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	There should be clarification on 1.1 and 1.4 as it may create some confusion on whether generally accepted means that it is linked to FDA approval or to the validity of its scientific evidence and safety.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	We appreciate that content validity has been moved to the front. If providers give careful consideration to this standard, compliance with the remainder of the standards should not be difficult.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	Who would determine what is controversial? One organization may fee a topic is fine, while another may find it controversial (e.g., Medical Marijuana)
Accredited CE provider	Other: Academy of General Dentistry	School of medicine	I appreciate the inclusion of number 5.

What comments or questions do you have about Standard 1?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Other: ACPE	Hospital/healthcare delivery system	I believe narrow, cut and dry listing of who can and cannot be accredited will disqualify otherwise exemplary providers. If there are truly concerns, I would rather see more frequent reviews of our continuing educational program to ensure we are providing "accurate, balanced, scientifically justified recommendations". We have undergone scheduled reviews without concerns about our integrity or independence, but this appears to be set aside by these proposed changes. Although I see how increased concern or oversight may be warranted, quality education can and is being provided by individuals within your proposed ineligible list. I would be greatly disappointed to see your revised standards drive quality providers out of this process without some means of proving themselves as being unbiased and upright in their educational work.
Accredited CE provider	Other: ACPE	Publishing/education company	An example would be helpful about how speakers can teach about an approach but not advocate for it. For example, does including a reference imply advocating since the learner could learn more information on their own?
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	I think that one of the unintended consequences implementing Standard 1 is why is this suddenly an issue. I personally have had a lot of education on Standard 1 since 2008 and do not feel that it is confusing at all. I think it is important request faculty to look themselves up on OpenPayments and disclose as appropriate.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	pls see above
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Standard 1 explicitly explains accredited education, which is scientifically justified educational information accepted for patient care. Learners of accredited programs should be given a fair and balanced view of diagnostic and therapeutic options informing of approaches to care, and not influencing advocacy for a type of care. For me, this is the summary for Standard 1 which I feel is well written and an appropriate explanation for the expected standards for accredited educational programs.

What comments or questions do you have about Standard 1?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	The standard is clear and relatively unchanged except for the substituted terminology (accredited education.)
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Thought and speech control is not a good goal. Freedom of speech, free debate and consideration of the options and their sources of support is more consistent with the scientific method.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	What are the ways in which providers may document content validity? Will tools be developed and made available?
Advocacy organization			Item 4: Would this apply to complementary and alternative medical treatments?
Advocacy organization			Please see our comments above.
Clinician/healthcare professional			"Generally accepted" will not work Medicine is too compartmentalized. Most doctors have no idea about the fine points of Parkinson's medication, for example. Those details are not generally accepted, due to ignorance outside Movement Disorders Neurology. I practice environmental medicine (which has departments at NYU, Harvard, U N Carolina, and several dozen others, and a clinic at UCSF Mt Zion. UCSF has instructed all departments to apply the principles of environmental medicine (defined by CDC in 2000 as "virtually all chronic human illness results from the interaction between genetic vulnerability and modifiable environmental exposure) but most doctors are unaware of those principles. They are not "generally accepted" despite multiple med school environmental medicine departments and clinics. I am the author of 28 peer-reviewed papers in general medicine, surgery and environmental medicine and hold two board certifications. I have learned more clinically useful science at the American Academy of Environmental Medicine than at most other CME-generating organizations, but fear ignorance of the above cited principles might endanger their mission.

What comments or questions do you have about Standard 1?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Clinician/healthcare professional			Accredited education may inform learners about approaches to diagnosis or treatment that are controversial or not generally accepted but must not include advocacy for these approaches or teach healthcare professionals how or when to use them. Again, you can't tell people what they can advocate for and not. This is sounding like we live in a communist country. Organizations cannot be accredited if they advocate for unscientific modalities of diagnosis or therapy, or if their education promotes recommendations, treatment, or manners of practicing healthcare that are determined to have risks or dangers that outweigh the benefits or are known to be ineffective in the treatment of patients. - In who's opinion? Again, dangerous, sounding akin to a dictatorship
Clinician/healthcare professional			I would add "accredited continuing education in healthcare." That makes it clearer. I like this standard.
Clinician/healthcare professional			Perhaps there could be some circumstances in which it is okay to advocate for the benefit of an approach that has been used for 50 years and has saved many lives, and to allow the lecturer to explain when and how to use this approach with allergies. As long as the limitations to this approach are explained to the learners.
Clinician/healthcare professional			Repression of innovative medical concepts.
Clinician/healthcare professional			See above. This Standard restricts medical education to a narrow world view which is on the verge of changing as we look at 1. new models of evaluating effectiveness of treatments for the individual versus holding tight to a one-size-fits-all approach that does not account for individuality and 2. whole-systems based approaches that are not able to be evaluated by the paradigm of the double-blind placebo-controlled study paradigm. These modes are outdated and should not be looked at as the ONLY way to evaluate validity of diagnosis and treatment. They are not.
Clinician/healthcare professional			There continues to be a large gray area of education about healthcare that is "ineffective". Not everyone always agrees on where acceptable moves into unacceptable. But that is not a new challenge and it will continue to be there. The current standard, as written, is excellent.

What comments or questions do you have about Standard 1?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Clinician/healthcare professional			This standard is onerous and unacceptable to those physicians want to learn about modalities and therapies for those patients who fail the "standard of accepted care."
Clinician/healthcare professional			Unfortunately, funding for the higher standards of research studies (case- control through to cohort through to trials) is rare in coming. corporate entities fund such studies to determine if their products/techniques are ok
Clinician/healthcare professional			What is generally accepted mean? Is it conventionally accepted or is it accepted by good science in a complementary paradigm? Too vague. Again, the definition is way to confining to allow for many therapies to grow from the research that is only conventionally accepted. Not every new finding can be centered about double blinded placebo-controlled studies that some believe to be the epitome of scientific validation.
Clinician/healthcare professional			Who decides standard of care? How is it defined? If there are several studies showing a therapy is beneficial, but may not be considered the standard of care, why can this not be taught?
Ineligible Entity (commercial interest, such as pharmaceutical, device, life-science company)			In 1.4, the term "controversial" seems to leave vulnerable education on approaches that may be clinically sound but costly or politically unpopular. "Not generally accepted" is a difficult standard to determine, as novel but promising approaches do take time to become established.
Ineligible Entity (commercial interest, such as pharmaceutical, device, life-science company)			Perhaps the intent or spirit of this standard could be conveyed by adjusting the language to communicate a positive statement that reflects that faculty shall present clinical applications of new and emerging strategies by referencing the best available evidence to support balanced consideration of therapeutic options.
Medical/healthcare association			(1) Related to standard 1, point #4: Will use non-FDA approved approaches that are generally used in accredited education by way of case studies be acceptable? Typically, case studies do not advocate for these approaches but teaches how and what patient populations could be considered for such a technique used in diagnostic or therapeutic approaches. Is this consider still acceptable? (2) Related to standard 1, point #5: When there is scientific work/research, usually in poster or oral abstracts based upon clinical trial or other types of research data that is accredited education, is this still permissible given that effectiveness being studied is still under investigation?

What comments or questions do you have about Standard 1?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Medical/healthcare association			We applaud the effort by ACCME to have all of the requirements for independence and integrity in one document.
Medical/healthcare association			Would you require a disclaimer similar to “off-label use” disclaimer when a provider has an activity simply intended to "inform"?
Nonaccredited CE provider			Many providers and supporters of independent continuing medical education could or will assume that this includes banning education about "off-label" or rapidly evolving science. If that is the case, then the unintended consequences to patients could be huge, especially in areas like oncology and infectious diseases, where the evidence is evolving faster than the FDA approval processes.
Other: Accredited CE provider, Continuing education accrediting body, and medical/healthcare association			We applaud the effort by ACCME to have all of the requirements for independence and integrity in one document.
Other: Answering both as accreditor and accredited provider.			The WSMA supports content validation being at the beginning of the standards. This sets the stage for the rest of the standards clearly. 1.4: WSMA appreciates the clarification that faculty/presenters can “teach about, but not how.”
Other: CME/CE Consulting Services Company			The statement at the top, “Standard 1 applies to all accredited continuing education,” is helpful. Further, pulling the CME Clinical Content Validation Policy into the Standards for Commercial Support helps to streamline the standards and policies.
Other: I am a clinician-educator, board member of APPS, member of the Academic Consortium of Integrative Medicine and Health, and faculty provider for integrative medicine CME			As above. I appreciate and support the need for raising the standard across the board for continuing education. However, the current practices of the ACCME has alienated organizations and creating divisiveness. I would prefer to see integrative, lifestyle and preventive medicine and the ACCME working in partnership to achieve this goal.

What comments or questions do you have about Standard 1?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: Joint Provider			Clarify what you mean. Consult and work with experts in areas that ACCME is defining as "controversial" so that misstatements about research and bias can be mitigated. Create a pathway for joint providers to have a voice and relationship with ACCME. The current model unintentionally puts joint providers who are trying like to comply with ACCME's current unclear polices at risk. ACCME should be aware that is currently a drastic difference in how primary providers already interpret many of the polices. The new changes to Standard 1 would only amplify this situation. Is there any formal way for joint providers for formally work with ACCME, other than through their Primary Provider? We would ask that a pathway be created to at least include the voice of joint providers more directly in some meaningful way, as there are discrepancies in the intention of how these policies get written and developed versus how they get delivered and applied. interpreted.
Other: MedChi is both an Accredited Provider and a Recognized Accreditor			I appreciate the inclusion of content validation into the standards. This will help address providers having to refer to a separate policy.
Other: physician, patient, member of certifying board, member of educational academy			"controversial"–it was once controversial to wash one's hands, to radiate the thymus gland, to use cimetidine for stomach ulcers, to suggest that stomach ulcers were often an infectious disease, to use high doses of radiation to get an X-ray picture, to depend on the TSH as an index of hypothyroidism when the body might not be converting free T4 over to free T3. my own Academy, the American Academy of environmental medicine, teaches safe effective means to diagnose and treat many patients who do not fit the usual pattern. Thank God, they helped me.
Other: Publishing/education company			We applaud the effort by ACCME to have all of the requirements for independence and integrity in one document.
Other: Recognized accreditor and Accredited CE provider			Thank you for clarification and guidance on controversial approaches to diagnosis or treatment.

What comments or questions do you have about Standard 1?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: State Medical Society/Publisher/Accredited Provider/Recognized Accreditor			A suggestion is made to maintain Standard 5.1 - the content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest. While similar language is included in Standard 2 - #2, This would continue to serve as a written reminder to individuals of the intent of CME and focuses more on the content of the activity.
Recognized Accreditor (state/territory medical society)			Some providers are unclear if this is an absolute rule or if exceptions are allowed. Providers suggested defining the exceptions if applicable.
Recognized Accreditor (state/territory medical society)			At PRMA all of those involved in the CME Councils are physicians. We insist that CME must be always of clinical and/or scientific value so we can have peace of mind when caring for patients.
Recognized Accreditor (state/territory medical society)			Don't agree with deleting Medical from the title and referring generically to "" Accredited Continuing Education"". If the move is toward interdisciplinary education in the healthcare professions, we are healthcare professionals involved in medicine, so why not refer to it as Accredited Medical Education?
Recognized Accreditor (state/territory medical society)			I do anticipate questions in relation to education on medical marijuana and Standard 1.
Recognized Accreditor (state/territory medical society)			What is the definition/marker for a bio-medical startup that is beginning an approval process through the FDA, and how is an accredited CME provider going to make that determination? Is it being in the form 510k pre-market database (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm)? What if the company exists only on paper, which will be the frequent case for many start-ups by faculty at research universities?
Recognized Accreditor (state/territory medical society)			Will ACCME offer guidance on best methods to ensure content is valid? I foresee that providers that offer RSS may have questions with regard to series such as tumor board and M & M, where content is not developed far in advance.

Standard 2: Prevent Marketing or Sales in Accredited Continuing Education

Is Standard 2 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider		Nonprofit (physician membership organization)	I assume that this does not include scanners in the exhibit hall since by allowing the badge to be scanned the attendee is consenting. Does this mean that we can no longer supply a list of all the attendees at the meeting unless they check a box saying that we can release their contact information to the ineligible entity? I assume this means we can't say that by attending the meeting you automatically consent to providing your name. I think more clarification is needed in this area.
Accredited CE provider	ACCME		2.3-Suggested wording change:" Providers must obey all applicable laws governing privacy and sharing of personal information of learners, attendees or registrants, including disclosure of such information when required by law." Comment: In the past, the ACCME has tried to stay out of the legal space. We suggest that they take that approach here. Privacy laws are evolving, and not yet universally agreed upon.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	"The accredited provider must not share the names and contact information of learners with any ineligible entities or their agents without the explicit consent of the individual learners each time the data is to be shared. This consent must include the name of the ineligible entity receiving the learner information and describe how the entity intends to use the information." - REMOVE THIS or modify to be more specific about what contact information means. When asked, I will provide an attendee list that includes the city and state to exhibitors so they can have an idea of the audience that is participating in our activity in order for them to determine if they should attend.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	“whose primary business is…” Needs clarification. Most diagnostic labs offer proprietary products, but it’s not their primary business. Are you talking about only diagnostic labs whose primary business is these proprietary products, or all labs that market even one proprietary lab test?

Is Standard 2 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	2.2 - Distinguished national speakers/faculty may have published their research that may be relevant to the content for educational purposes. By default, this may look like they're promoting themselves and/or research books. This standard limits faculty who can bring value to the educational content in order to be leaders in healthcare. Modification: take out "promote"
Accredited CE provider	ACCME	Hospital/healthcare delivery system	2.2 “faculty must not promote or sell products or services that serve their professional or financial interests during accredited education” – I’d like a better definition of “products or services” (i.e., are textbooks included in this? is this referencing only clinical products or services? What about non-clinical products or services?)
Accredited CE provider	ACCME	Hospital/healthcare delivery system	In reference to ACE must protect… #2: Please clearly define or provide examples of “faculty must not promote or sell products or services that serve their professional or financial interests during accredited education.” In some cases, faculty will put their contact information, including office location, phone and email address up at the conclusion of their presentations – is this considered “promotion”? If faculty uses the organizational logo for their employer on their slide design, is this considered “promotion” and should it be disallowed? Given that company logos of ineligible entities are excluded, is it expected that a similar approach be utilized with faculty in an effort to minimize the appearance of promotion.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	In reference to ACE must protect… #2: Please clearly define or provide examples of “faculty must not promote or sell products or services that serve their professional or financial interests during accredited education.” In some cases, faculty will put their contact information, including office location, phone and email address up at the conclusion of their presentations – is this considered “promotion”? If faculty uses the organizational logo for their employer on their slide design, is this considered “promotion,” and should it be disallowed? Given the that company logos of ineligible entities are excluded, is it expected that a similar approach be utilized with faculty in an effort to minimize the appearance of promotion.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	It would be helpful to have clarification on products/services for professional or financial interest. Many items can fall under this category: textbooks, referrals, Honorarium, etc.

Is Standard 2 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Not sure of the modifications, more a general statement that for 2.3: The accredited provider must not share the names and contact information of learners with any ineligible entities or their agents without the explicit consent of the individual learners each time the data is to be shared. This consent must include the name of the ineligible entity receiving the learner information and describe how the entity intends to use the information. The last sentence seems very specific and would be likely to change due to the ever-evolving privacy laws and regulations.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	On #2. I would strike the sentence., "Faculty must not promote or sell products or services". I think this will confuse providers and they may not be thinking about how to address this standard directly when mitigating the conflict of interest. Also, it does not make sense to me as a provider to have this sentence there although the directive makes sense.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Standard 2 #2: Better define products and services. Does this include books, leadership organizations, etc.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	The use of the term "protect" with respect to "protecting learners from marketing and commercial bias," makes it sound like our learners are either children or fools. We can inform learners of potential conflicts and do our best to mitigate that, but it is presumptuous to tell a learner, "I am protecting you from information that you may not have enough sense to realize is biased." It risks insulting our learners and teachers. I suggest a less "parental" term - perhaps "inform" learners of the potential for marketing and commercial bias. For 2.2, Please be more specific about how providers are supposed to make the distinction between a faculty member or content contributor in the field talking about a therapeutic area in which he/she is a recognized expert and in which he/she most likely has related industry relationships (consultants, speaker's bureau, patents) and what constitutes a faculty member promoting and/or selling products or services ? Isn't any faculty member who shows him or herself to be knowledgeable about diagnostic, treatment or therapeutic areas ostensibly selling him or herself as a potential consultant or referral option to the learner? We need examples of what would constitute a violation of this policy because it is open to interpretation due to lack of specificity.

Is Standard 2 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	This Standard is prohibiting healthcare professionals who author published scientific, peer-reviewed information from delivering their expertise in other formats outside of the realm of the CME activity.
Accredited CE provider	ACCME	Nonprofit (other)	Consider defining the word “promote” in Standard 2.2. For instance, if a protocol, book, software or other product is the only one of its kind on the market is saying the name considered promotion? Is discussion of a trademarked protocol any different than discussing a guideline or NIH protocol? Please provide clarity.
Accredited CE provider	ACCME	Nonprofit (other)	It would be helpful for accredited and joint providers if ACCME would explicitly state that supporters can or cannot dictate in their RFPs, grant portals, LOAs, or other any other means what type of outcomes the provider will assess. Most supporters have different expectations as to what kind of outcomes will be delivered based on what is written in a grant. This is not something that we feel is a compliance issue but more so an issue on not all funders being on the same page with regards to outcomes.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	# 3 specifies that providers may not share the names and contact information of learners with ineligible entities without explicit consent of learners each time the data is shared. Clearly this would include commercial supporters of CME. This is appropriate and easily managed because CME staff would likely play a role in securing and managing these funds. But what about exhibitors at large meetings/conferences, members of corporate affairs boards, etc.? CME staff often play no role in the recruitment and management of these companies (some of whom might be eligible and some of whom might be ineligible). It could prove very difficult for CME staff to ensure that learners are notified about all such vendors and their intentions, with explicit permission given by each learner. Why not just require each accredited provider to have a privacy policy in place that protects its learners from the unwanted sharing of personal data with any entity?

Is Standard 2 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	• 2.0 - Define the terms owner and employee. 2.0 - Develop a threshold for a relevant financial relationship. For instance, how can a financial relationship of $1 be construed as relevant? 2.1 – Include “Subject to the exceptions in Standard 3.2…” at the beginning of this section. 2.1 – Define “influence” and “involvement” and explain how “mitigation” applies, if at all. 2.2 - Recognize the nature of specialization in lab testing (both commercial and academic) or therapy development (personalized CAR T cells, for example) where only one lab in the nation might conduct a test and have the expertise to educate physicians about it. 2.3 – Define the term learner. In this instance, does the term learner include all activity registrants?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	2.2 – Clarification is needed as to whether this would apply to a) the marketing/sales of eligible entities’ own products/services (ie, can an eligible entity/medical specialty society promote its own publications & educational activities to learners of its accredited CE activities?), b) products, services, and/or publications that are developed by & directly benefit faculty & others who affect content (ie, a faculty member wrote a book on a topic & receives royalties) and/or c) only those products/services used by/on patients. Also, “faculty” should be further defined to encompass other roles (eg, authors, subject matter experts), as many associate “faculty” as those who teach in live activities. 2.3 – We concur with the intent to protect learners’ personal information & believe it can be achieved without added administrative burden to accredited providers by editing it to reflect the following: “The accredited provider must not share the names and contact information of learners with any ineligible entities or their agents without the explicit consent of the individual learners”. The term, “learners,” also needs further clarification, such as whether it would encompass any attendee of an annual meeting or only someone who participates in a specific activity or educational session. This requirement should not apply to anyone who visits an exhibitor & chooses to provide his/her contact information. Also, “explicit consent” should be defined.

Is Standard 2 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	2.2 The second sentence of 2.2 must include more specifics associated with "products or services that serve their professional or financial interests." While no one wants to hear a speaker be promotional, there is a difference between promoting a book or teaching app versus a new surgical device. Recommendation - Faculty must not promote or sell products or services directly related to clinical services or patient care that serve their professional or financial interests..]
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	2.2, as written, prevents faculty from promoting products that serve their professional or financial interests, many of which could be beyond what they are required to disclose in standard 3. For example, faculty could promote a book they wrote, from which they receive royalties, but those royalties would not need to be disclosed since the publisher is not an “ineligible entity”. How could the accreditor enforce this without being inconsistent with the disclosure policy? We suggest either that 2.2 be limited to promotion of ineligible entities/commercial interests, or, our preference, that 2.2 expand on what needs to be disclosed. In our opinion, if someone is receiving royalties from a publication, that should be disclosed, and they should not promote the book in the CME activity. 2.3-Suggested wording change:" Providers must obey all applicable laws governing privacy and sharing of personal information of learners, attendees or registrants, including disclosure of such information when required by law." Comment: In the past, the ACCME has tried to stay out of the legal space. We suggest that they take that approach here. Privacy laws are evolving, and not yet universally agreed upon.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	2.3 Would recommend including a statement that accredited providers must obey all applicable laws governing privacy and sharing of personal information.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	2.3 Providers must obey all applicable laws governing privacy and sharing of personal information of learners, attendees or registrants, including disclosure of such information when required by law." Comment: In the past, the ACCME has tried to stay out of the legal space. We suggest that they take that approach here. Privacy laws are evolving, and not yet universally agreed upon.

Is Standard 2 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	2.3: Suggest: Providers must obey all applicable laws governing privacy and sharing of personal information of learners, attendees or registrants, including disclosure of such information when required by law." In the past, the ACCME has tried to stay out of the legal space. We suggest that they take that approach here. Privacy laws are evolving, and not yet universally agreed upon. As written, ACCME's Standard 2.3 is overreaching its authority by dictating how eligible entities communicate their data sharing policies with their members. As more eligible entities are figure out better wats to use their data, this standard could negatively impact them if the ACCME doesn't deem their processes adequate. Eligible entities already have these types of policies in place, so the ACCME doesn't need to police this. The standard is also too vague, which too much variability with how the ACCME can judge each eligible entity.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	2.3-Suggested wording change:" Providers must obey all applicable laws governing privacy and sharing of personal information of learners, attendees or registrants, including disclosure of such information when required by law." Comment: Privacy laws are evolving, and not yet universally agreed upon.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Although Standard 2 is somewhat clear, we suggest that names and academic or professional affiliations should be allowed to be shared with attendees for identification purposes, but not specific contact information such as mailing addresses, email addresses, telephone numbers, etc without the consent of individual learners.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Defer to CMSS response.

Is Standard 2 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Item 2.3 requires that the name of the ineligible entity/ies receiving learner data be disclosed to the learner at the time that consent is given. This should be modified to specify that consent be received from each learner to share the individual's data with any ineligible entities directly associated with the activity prior to learner data being shared. This consent should also specify that the data sharing will be done only within the context of the specific activity in question. This would be in alignment with the demands of the GDPR rules with which many providers have already created compliance mechanisms. In addition, item 2.2 should clarify the types of "products and services" that faculty are not allowed to promote. Does this include only products and services used on patients (similar to an ineligible entity), or could it be anything the faculty member may have a financial interest in, such as a book or other educational resource?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Item 2.3 requires that the name of the ineligible entity/ies receiving learner data be disclosed to the learner at the time that consent is given. This should be modified to specify that consent be received from each learner to share the individual's data with any ineligible entities directly associated with the activity prior to learner data being shared. This consent should also specify that the data sharing will be done only within the context of the specific activity in question. This would be in alignment with the demands of the GDPR rules with which many providers have already created compliance mechanisms.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	o In Standard 2.2, need definition of "promote". Many speakers are also authors in their subject matter on which they speak. For example, if a faculty speaker mentions their book (as content reference) but does not tell the audience to go buy it, is that considered promotion? o In Standard 2.3, need definition of "learner". Is it only those who completed an activity or everyone who started the activity?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We are concerned that the level and nature of scientific evidence and of eligible individuals is not clear as noted in our full comments.

Is Standard 2 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Prevent/eliminate Note that the first sentence uses the phrase marketing and commercial bias whereas the title says marketing and sales. Suggest using consistent language-sales seems more consistent with the rest of the language. b. Researcher: provide a definition. Is this the PI or would it apply to anyone who is on a grant?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Provide examples to clarify what products or services are of concern. Please consider a rewrite of this point, such as “During accredited education faculty must not promote or sell products or services that serve their professional or financial interests – such as books they have authored, or patents or laboratories they own.”
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Suggest ACCME specify its intent with this standard and clarify whether it relates to faculty who develop products/services that are used by or on patients (which aligns with the definition of “ineligible entity”) and write/publish books. ACCME should provide examples related to this Standard to aid in compliance. Suggested wording change: "Providers must obey all applicable laws governing privacy and sharing of personal information of learners, attendees or registrants, including disclosure of such information when required by law.”
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Suggested wording change:" Providers must obey all applicable laws governing privacy and sharing of personal information of learners, attendees or registrants, including disclosure of such information when required by law." Comment: In the past, the ACCME has tried to stay out of the legal space. We suggest that they take that approach here. Privacy laws are evolving, and not yet universally agreed upon.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The accredited provider must not share the names and contact information of learners with any ineligible entities or their agents without the explicit consent of the individual learners. (delete remainder)

Is Standard 2 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The standard language implies that an author/editor of a textbook could not promote that book in accredited education. However, that book may be a support strategy (C32) to enhance change as an adjunct to the education. Could an activity still be accredited education if the faculty is from a specialty practice, the audience is primary care, and the content includes recommendations on when to refer patients to a specialist?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We are extremely concerned with the wording of Standard 2.3. This appears to be over-reach by ACCME. We strongly recommend that “each time the data is to be shared” be stricken from the first sentence of 2.3. Further, we would replace the stricken language with “prior to the educational activity taking place.” Finally, we recommend that the Standard include language that identifies potential reasons for which “ineligible entities” might communicate with learners.
Accredited CE provider	ACCME	Other: Teleconferencing Medical Education Company	Clear definitions are needed for the wording as too much is left to interpretation.
Accredited CE provider	ACCME	Other: university	Accredited providers must receive consent from learners before sharing their names or contact information with ineligible entities. See Standard 2.3 In this instance, what is a learner? Does this include all registrants at an activity or just those requesting CME credits?
Accredited CE provider	ACCME	Other: University - not a school of medicine	further definition of the term "learner" AND include "opportunity to opt-out" rather than require specific permission every time
Accredited CE provider	ACCME	Publishing/education company	2.3 - Suggested wording change: "Providers must obey all applicable laws governing privacy and sharing of personal information of learners, attendees or registrants, including disclosure of such information when required by law." Comment: In the past, the ACCME has tried to stay out of the legal space. We suggest that they take that approach here. Privacy laws are evolving and not yet universally agreed upon.

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Organization Type	**Accreditor**	**Provider Type**	**Comments**
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Accredited CE provider	ACCME	Publishing/education company	2.3-Suggested wording change:" Providers must obey all applicable laws governing privacy and sharing of personal information of learners, attendees or registrants, including disclosure of such information."

Is Standard 2 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	Additional clarification is requested on subset 3: Should notification be on a 1:1 basis with the participant or can consent be obtained by participants “opting in” with specifics outlined as to who and why info sharing is proposed.
Accredited CE provider	ACCME	Publishing/education company	In the past, the ACCME has tried to stay out of the legal space. We suggest that they take that approach here. Privacy laws are evolving, and not yet universally agreed upon.
Accredited CE provider	ACCME	Publishing/education company	In the proposed 2.2 - what is to be the objective standard for "promotion"? What if that promotion is for products or services that are still acceptable for "eligible entities"? For example - if a speaker mentions a clinical textbook for which they receive royalties - is that a "promotion" of a "product" that will serve their financial interest? Example 2 - in a coordination of care discussion, if any provider engages in tips that would allow for better patient referrals, would this not directly or indirectly have the potential to promote their "services" that "server their professional or financial interest", even though clinical care is not grounds for ineligibility? Can a practicing pharmacist discuss dispensing of naloxone under the surgeon general's standing order? Where is the line to be drawn on this new standard? - Is it meant to only pertain to financial gain with regards to ineligible entities? The standard, as written, is unclear. In 2.3 - in discussions with many providers, there is concern about the intended meaning of "and" in "the names and contact information". If this were a legal contract, unless the context otherwise requires: “A or B” means “A or B or both”; “either A or B” means “A or B, but not both”; and “A and B” means “both A and B”; - does this truly mean “BOTH the names and contact information”? Through discussion with providers, it is heavily preferred that this be the case as names are often distributed without contact information.

Is Standard 2 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	It would be helpful for accredited and joint providers if ACCME would explicitly state that supporters cannot dictate in their RFPs, grant portals, LOAs, or other any other means what type of outcomes the provider will assess, nor which statistical tests will be used, nor how they will be reported (such as dictating the use of a template slide). It should be noted that some supporters are still trying to control what outcomes will be measured and reported for activities they fund. Providers then feel they must ask outcomes questions specifically about the supporters' product.
Accredited CE provider	ACCME	Publishing/education company	Providers must obey all applicable laws governing privacy and sharing of personal information of learners, attendees or registrants, including disclosure of such information when required by law
Accredited CE provider	ACCME	Publishing/education company	Providers must obey all applicable laws governing privacy and sharing of personal information of learners, attendees or registrants, including disclosure of such information when required by law." Comment: In the past, the ACCME has tried to stay out of the legal space. We suggest that they take that approach here. Privacy laws are evolving, and not yet universally agreed upon.
Accredited CE provider	ACCME	Publishing/education company	Providers must obey all applicable laws governing privacy and sharing of personal information of learners, attendees or registrants, including disclosure of such information when required by law." Comment: In the past, the ACCME has tried to stay out of the legal space. We suggest that they take that approach here. Privacy laws are evolving, and not yet universally agreed upon.
Accredited CE provider	ACCME	Publishing/education company	Standard 2.2 Suggest adding "personal" to the 2nd sentence. "Faculty must not promote or sell products or services that serve their PERSONAL, professional, or financial interest during accredited education." Also, not sure it's clear this would include websites.
Accredited CE provider	ACCME	Publishing/education company	Standard 2.2: How are you defining “promotion” and “marketing” in Standard 2.2? If a faculty member has a financial relationship with a commercial interest for their role on a speaker’s bureau and discusses use of the commercial interest’s product (using a generic name) in the activity, is this automatically considered promotion or marketing? Or would it be acceptable to discuss the product if the provider completed the process developed for COI mitigation?

Is Standard 2 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	Suggested wording change:" Providers must obey all applicable laws governing privacy and sharing of personal information of learners, attendees or registrants, including disclosure of such information when required by law." Comment: In the past, the ACCME has tried to stay out of the legal space. We suggest that they take that approach here. Privacy laws are evolving, and not yet universally agreed upon.
Accredited CE provider	ACCME	Publishing/education company	Suggested wording change:" Providers must obey all applicable laws governing privacy and sharing of personal information of learners, attendees or registrants, including disclosure of such information when required by law." Comment: In the past, the ACCME has tried to stay out of the legal space. We suggest that they take that approach here. Privacy laws are evolving, and not yet universally agreed upon.
Accredited CE provider	ACCME	Publishing/education company	The term learner should be defined, in order to determine whose information can and cannot be shared with ineligible entities or their agents.
Accredited CE provider	ACCME	School of medicine	#1 should say owners and/or employees I would recommend #2 to be changed to say that faculty must not promote or sell products or services for any ineligible company. Unless you are saying that if faculty don't have a relationship then they are allowed to promote or sell products or services of an ineligible company. #3. Is this specifically when the company is wanting an attendee list? My concern is when funds are received to support the educational offering from an ineligible entity would the organization be required to notify attendees or faculty if their names are submitted when providing the reconciliation paperwork (usually only applicable if less than 50 attendees, not buffet style, etc) and doesn't usually include their entire contact information. Also, there are times where the sign-in sheets are visible to ineligible entity agents as they are present at the offering and walking by the registration table, how will organizations mitigate those agents from looking at the attendee list (or is that still allowed)?
Accredited CE provider	ACCME	School of medicine	2.3-Suggested wording change:" Providers must obey all applicable laws governing privacy and sharing of personal information of learners, attendees or registrants, including disclosure of such information when required by law."

Is Standard 2 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	Please consider allowing the accredited provider to obtain global consent in contrast to consent by each ineligible supporter. Suggested language could be “I consent to share my name and contact information with the exhibitors or their agents of this activity to contact me by email, mail, or phone.”
Accredited CE provider	ACCME	School of medicine	Suggested wording change:" Providers must obey all applicable laws governing privacy and sharing of personal information of learners, attendees or registrants, including disclosure of such information when required by law." In the past, the ACCME has tried to stay out of the legal space. We suggest that they take that approach here. Privacy laws are evolving, and not yet universally agreed upon.
Accredited CE provider	ACCME	School of medicine	The new Standard 2.2 “Faculty must not promote or sell products or services that serve their professional or financial interests during accredited education” needs clarification. Would this apply to only ineligible entities or eligible entities as well.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	• In bullet 1. of the introduction, in order to remove the word “ensure”: “The accredited provider must make all decisions related to the planning, delivery and evaluation of accredited education without any influence or involvement from the owners and employees of an ineligible entity.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Other: academic medical center	Make 2.2 less broad and allow for flexibility.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	We suggest the following wording for Standard 2.3: Providers must obey all applicable laws governing privacy and sharing of personal information of learners, attendees or registrants, including disclosure of such information when required by law.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	#2 examples of what is and isn't okay- does it include books, talking about new techniques that they/their institution may have been involved with developing?
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Does 2.2 mean that if faculty go so far as to reference say, a book they've written, they've violated this standard? While "marketing or selling" seems like a no brainer, a little more explanation around this would be helpful.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Somewhat! "Professional" interests can be viewed broadly and suggest removing or providing a definition of professional interest in the context of accredited CME. ACCME FAQ that include scenarios for compliance and non-compliance would also be helpful.

Is Standard 2 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Recognized Accreditor (state/territory medical society)	School of medicine	Regarding #3 - The accredited provider must not share the names and contact information of learners with any ineligible entities or their agents without the explicit consent of the individual learners each time the data is to be shared. This consent must include the name of the ineligible entity receiving the learner information and describe how the entity intends to use the information. Question 1 - Clarification regarding "contact information." The assumption is this includes direct means of communication including email address, mailing address, and phone number. The question is, does this include city, state, and/or hospital/clinic? Question 2 - Does the same consent process apply to eligible entities? My recommendation is to have the same consent process apply for both entities.
Advocacy organization			supporters cannot dictate in their RFPs, grant portals, LOAs, or other any other means what type of outcomes the provider will assess, nor which statistical tests will be used, nor how they will be reported. It should be noted that some supporters are still trying to control what outcomes will be measured and reported for activities they fund.
Continuing education accrediting body			In #1, add “agents” to read as follows: “. . .without any influence or involvement from the owners, employees, or agents . . .”
Ineligible Entity (commercial interest, such as pharmaceutical, device, life-science company)			Standard 2.1. The accredited provider must ensure that all decisions related to the planning, delivery, and evaluation of accredited education are made without any influence from the owners and employees of an ineligible entity.
Medical/healthcare association			2.3-Suggested wording change:" Providers must obey all applicable laws governing privacy and sharing of personal information of learners, attendees or registrants, including disclosure of such information when required by law." Comment: In the past, the ACCME has tried to stay out of the legal space. We suggest that they take that approach here. Privacy laws are evolving, and not yet universally agreed upon.

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Organization Type	**Accreditor**	**Provider Type**	**Comments**
Medical/healthcare association			2.3-Suggested wording change:" Providers must obey all applicable laws governing privacy and sharing of personal information of learners, attendees or registrants, including disclosure of such information when required by law." Comment: In the past, the ACCME has tried to stay out of the legal space. We suggest that they take that approach here. Privacy laws are evolving, and not yet universally agreed upon.
Medical/healthcare association			Our comments assume that “pharmacy benefit managers” are removed from the list of ineligible entities. Specific to 2.1: We believe that this section should note that there may be exceptions, as listed in the “Eligibility” section and section 3.2. There are instances when faculty from an ineligible entity would be an appropriate faculty (e.g., regulatory/policy issues, health outcomes research not tied to any specific drug). Specific to 2.3: It is common practice for organizations to offer an opportunity for exhibitors, including those that may be ineligible entities, to acquire the overall attendee list for a convention or meeting for the purpose of providing pre-invites or follow-up information that may be interest to participants. Under current privacy laws and policies, attendees are offered the opportunity to opt-out of this sharing. The restriction as proposed would place undue burden on learners and organizations if permission was required every time these lists were shared. Further, the term "learner" may be interpreted by legal teams as any attendee, including those who did not attend accredited sessions. This could impact information exchange and the overall experience of event participants.

Is Standard 2 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Medical/healthcare association			The enforcement and practical implementation of Standard 2.2 is problematic because in all practicality, any time an academic faculty member presents at a local, regional or national meeting, they by definition, are promoting themselves to “further professional interests.” Most academic institutions place emphasis on these types of activities as part of their academic promotion guidelines and some even require academic promotion as a condition of employment. As written, only a tenured full professor, who is no longer concerned with promotion, could fulfill this standard. Furthermore, if strictly enforced, presenters would no longer be able to include the name of their institution as part of their educational presentation. The AMA Council on Medical Education does not believe this was the intent of the standard and encourages its revision to provide clarity.
Medical/healthcare association			What is “each time”? Word so that privacy laws are maintained, or that sharing information within legal requirements.
Other: Accredited CE provider, Continuing education accrediting body, and medical/healthcare association			The American Osteopathic Association (AOA) agrees that accredited providers should not share learner data without their consent. Further, the AOA believes understanding and complying with the details of applicable data sharing law/regulations is a standard business practice and expectation of a CME provider organization that does not need oversight or regulation by accreditors. As written, the AOA believes Standard 2.3 puts undue burden on the accreditor determining compliance and on the provider to comply with an additional standard that may not align with other requirements to which they must comply. When a learner grants permission for their data to be shared, the onus should be on them to understand what will be shared, with whom it will be shared, and how it will be used. As such, the AOA strongly recommends the following revision to Standard 2.3: "The accredited provider must not share the names and contact information of learners with any ineligible entities or their agents without the explicit consent of the individual learners.”

Is Standard 2 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: Answering both as accreditor and accredited provider.			2.2 Further clarification is needed: Does this Standard also exclude services provided by eligible organizations? E.g., Can a specialist not talk about the services they provide if a primary care physician were to refer their patient to that type of specialist for care? 2.3 Clarification is needed of what is meant by “each time” data is shared. Otherwise, WSMA supports this change.
Other: CME/CE Consulting Services Company			It would be helpful if the definition of promotion could be more clearly defined, or a list of non-commercial products that could be considered promotional, be included. For example, if a faculty member’s book is mentioned, is that considered promotion? Currently, publishing companies who provide book royalties do not meet the ACCME’s definition of a commercial interest (e.g. ineligible entity). As well, as it pertains to Standard 2.3 and the challenges we highlight below, would it not be sufficient for the ACCME to simply request that consent be obtained from learners to share contact information with exhibitors, sponsors and other attendees, without the inclusion of entity name and how they intend to use the information?
Other: Consultant			I think it would be a good idea to add the word "assessment of need" in addition to planning and delivery (in the first sentence.) I will say more about this at the end of this survey, but in general I think there now exists a great deal of commercial bias introduced very early into many commercially supported programs, especially those that begin with an RFP from industry. In my experience, accredited providers do precious little to actually make sure that commercial bias is not present in the needs assessments that are written to justify funding for a program, and on which the learning objectives are often based.
Other: Consulting company; licensed clinician			2.1. It would be helpful for accredited and joint providers if ACCME would explicitly state that supporters cannot dictate in their RFPs, grant portals, LOAs, or other any other means what type of outcomes the provider will assess, nor which statistical tests will be used, nor how they will be reported. It should be noted that some supporters are still trying to control what outcomes will be measured and reported for activities they fund. 2.3. How does this relate to the Sunshine Act? Some supporters request names of participants in live events that include a buffet meal, even though this is an exempted from reporting requirements.

Is Standard 2 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: I am a clinician-educator, board member of APPS, member of the Academic Consortium of Integrative Medicine and Health, and faculty provider for integrative medicine CME			Clarification of employees of ineligible entities. Does this mean consultants for companies such as pharmaceutical companies cannot be involved in planning, delivery or valuation of accredited education?
Other: I am a faculty member/CME content provider/CME course director and my views do not necessary represent the views of my institution, the Medical College of Wisconsin			I would suggest an exemption for educational materials.
Other: MedChi is both an Accredited Provider and a Recognized Accreditor			2.3: This standard is not clear and will be problematic. Does this standard allow for a general opt-out by the learner at the time of registration? or will the accredited provider be required to contact each learner for opt-out separately and repeatedly as sponsors/exhibitors are added? This needs clarity, given that sponsors and exhibitors are added all throughout the pre-meeting process. I would suggest allowing this to be done via general opt-out as part of the registration process.
Other: Publishing/education company			2.3-Suggested wording change:" Providers must obey all applicable laws governing privacy and sharing of personal information of learners, attendees or registrants, including disclosure of such information when required by law." Comment: In the past, the ACCME has tried to stay out of the legal space. We suggest that they take that approach here. Privacy laws are evolving, and not yet universally agreed upon.

Is Standard 2 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: State Medical Society/Publisher/Accredited Provider/Recognized Accreditor			In Item #1 - please define if founders of an ineligible entity are included with owners and employees.
Patient, caregiver, member of the public			I would include that faculty members should not solicit information from companies.
Recognized Accreditor (state/territory medical society)			Clarification regarding whether exhibitors are included in this standard. Can the consent be an opt out vs. obtaining written consent from each learner?
Recognized Accreditor (state/territory medical society)			Please include a definition of definition of “products or services” (i.e., are textbooks included in this? What about non-clinical products or services?) Remove the requirement that the consent must include the name of the ineligible entity receiving the learner information and describe how the entity intends to use the information.
Recognized Accreditor (state/territory medical society)			Standard 2.1 – Revise to: “The accredited provider must ensure that all decisions related to the planning, delivery, and evaluation of accredited education are made without any influence or involvement from the owners and employees of an ineligible entity, unless they fall within the three exceptions outlined in 3.2.
Recognized Accreditor (state/territory medical society)			Use a different term for " ineligible entities" Be more concrete in the language in Standard number 4. List specific examples.

Do you foresee challenges or unintended consequences implementing Standard 2? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME		2.1 Broad interpretation of the current wording may result in an impact on industry's compliant right to issue Requests for Proposals (RFPs), the ability to publish general information included on grant portals, industry's ability to ask for and/or recommend the reporting of outcomes as a result of awarding substantial monetary funds, none of which impart industry's involvement in content development and implementation. 2.3. Currently, the overall attendee list for large convention or annual meeting, in some form, is shared with exhibitors, some of whom may be ineligible entities; it is common practice under current privacy laws and policies to allow the attendee to opt out of this sharing. The restriction as proposed here would go far beyond that if the term "learner" is interpreted by legal teams as any attendee. Exhibit space sales could decrease significantly if no pre-invites or follow-up could be made without tasking the attendee with giving permission each and every time. Granted, privacy laws are evolving- so why codify one such set of restrictions here?
Accredited CE provider	ACCME	Hospital/healthcare delivery system	2.2 will limit working with distinguished speakers who might be published or successful in their specialty.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	2.3 – I agree with the requirement that the accredited provider must not share the names and contact information of learners with 'ineligible entities' without the explicit consent of the learner [this is already our policy]; however, I am concerned about the remaining requirement that "the consent must include the name of the ineligible entity receiving the learner information and describe how the entity intends to use the information." Often grants and exhibit support is still being confirmed up to a few days prior to an event; consent is often gathered at the time the learner registers for an event. It will be difficult to wait until all support is known before obtaining consent; time constraints will make this difficult to complete.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Are faculty still allowed to sell their own books in the exhibit space? Are faculty allowed to give their own books away as prizes in drawings at live activities?
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Speakers often reference published books they have written in their teachings. Without clarification, Standard 2 seems to devalue their research as an educational reference. It will be a challenge to get high regarded physicians, etc., to re-research all their material to steer away from citing their own work.

Do you foresee challenges or unintended consequences implementing Standard 2? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	2.3. Exhibitors pay for the opportunity to market their products (appropriately) at accredited CE activities. Physicians are free to interact with these exhibitors. They do not have to be "protected" from them. Similarly, allowing our exhibitors to look over our registration list (which does not have phone numbers or email addresses) gives them an opportunity to target specific people for potential sales. From the exhibitor's perspective, connecting with potential customers is the whole point of supporting an accredited activity with exhibit fees. If this new rule is enacted, there is the possibility that industry will curtail its purchasing of exhibit space because the benefit to them will be limited and we rely on this exhibit funding to help defray costs of running our meetings.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	In the past we have never shared this information. However, there has been a move in our institution to provide it with permission. We receive this permission per activity during registration, but at the time, we wouldn't be able to provide the learners a list of who and how the data will be used by any exhibitors. This policy would just force others to no longer be able to share any of this information again.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Standard 2 #2: There could be confusion on what products and services are included, resulting in non-compliancy.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	We rely on support from our exhibitors to offset financial costs for our activities. If we cannot provide basic attendee lists to them, this will cause fewer to be able to attend.
Accredited CE provider	ACCME	Insurance company/managed-care company	I am concerned that this would prohibit speakers from being able to talk about the content of their books (product) and then offer to sign them. There are many great speakers for conferences that do this and it would be a shame to not be able to offer CME for appropriate content because of this.

Do you foresee challenges or unintended consequences implementing Standard 2? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (other)	Clarify language in 2.2 to include specific types of products or services to be avoided (e.g., presume the intent is not to prohibit speakers from discussing books they have authored that may provide value to learners) Standard 2.3 would prohibit organizations from sharing learners' information with ineligible entities without explicit consent. This would be impossible to implement as learners may include representative of ineligible employees. Since attendee contact information is shared with all learners to facilitate networking and information sharing, will not be able to predict in advance who will have access to the information, nor how it will be used, as long as registrations are accepted from ineligible entity representatives!
Accredited CE provider	ACCME	Nonprofit (other)	In the absence of the clear definition for "promote" educators could unknowingly violate the standard or hold back and not share safe, effective patient care techniques.
Accredited CE provider	ACCME	Nonprofit (other)	Our accredited organization has seen faculty presenters mention their own books as part of CME presentations. It will take education on the part of the CME provider to ensure that faculty presenters know that this promotion of professional or financial interest is not appropriate in a CME activity.
Accredited CE provider	ACCME	Nonprofit (other)	We ask for further consideration and clarification as to how Standard 2.3 relates to the Sunshine Act. Some supporters request names of participants in live events that include a buffet meal, even though this is exempted from reporting requirements. Would providing that information be a violation of compliance for accreditation even thought the CI is attempting to interpret federal legislation?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	- Requires explicit consent from the learner each time the data is shared. For a large annual meeting with multiple supporters, could we use one consent form that covers all of the supporters or would we need individual consent forms tied to each supporter? The administrative burden could be significant if an automated system is not used in the creation of this, and this management system may be a financial burden.

Do you foresee challenges or unintended consequences implementing Standard 2? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	"Each time the data is shared...the name of the ineligible entity". When you are talking about a conference of thousands of attendees, this is difficult to imagine. Is it acceptable to get one-time attendee permission during registration to share their data with a bonded mail/email house that sends advertising on behalf of advertisers (including ineligible entities) as long as the data is never shared DIRECTLY with the ineligible entity? (Following CAN-SPAM opt out regulations, of course.) Is your purpose to keep the data out of the ineligible entity's database, or is it to make it nearly impossible to sell advertising to ineligible entities? What about attendees who personally consent to have their badges scanned in the exhibit hall (which is defined as a commercial space)?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	• Standard 2.1. should include references to the exclusions detailed in Standard 3.2.a-c.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	2.1 Broad interpretation of the current wording may result in an impact on industry's compliant right to issue Requests for Proposals (RFPs), the ability to publish general information included on grant portals, industry's ability to ask for and/or recommend the reporting of outcomes as a result of awarding substantial monetary funds, none of which impart industry's involvement in content development and implementation. 2.3. Currently, the overall attendee list for large convention or annual meeting, in some form, is shared with exhibitors, some of whom may be ineligible entities; it is common practice under current privacy laws and policies to allow the attendee to opt out of this sharing. The restriction as proposed here would go far beyond that if the term "learner" is interpreted by legal teams as any attendee. Exhibit space sales could decrease significantly if no pre-invites or follow-up could be made without tasking the attendee with giving permission each and every time.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	2.1 – ACCME will assess providers as non-compliant as a consequence of ACCME's lack of clarity and transparency concerning the definitions of "owner" and "employee." 2.2 – Presentation of weak and outdated science during accredited continuing education thereby diminishing or adversely impacting patient care. 2.3 – Operational burdens and negative outcomes to the marketing and exhibit business lines of accredited organizations.

Do you foresee challenges or unintended consequences implementing Standard 2? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	2.1 Broad interpretation of the current wording may result in an impact on industry's compliant right to issue Requests for Proposals (RFPs), the ability to publish general information included on grant portals, industry's ability to ask for and/or recommend the reporting of outcomes as a result of awarding substantial monetary funds, none of which impart industry's involvement in content development and implementation. 2.3 Currently, the overall attendee list for large convention or annual meeting, in some form, is shared with exhibitors, some of whom may be ineligible entities; it is common practice under current privacy laws and policies to allow the attendee to opt out of this sharing. The restriction as proposed here would go far beyond that if the term "learner" is interpreted by legal teams as any attendee. Exhibit space sales could decrease significantly if no pre-invites or follow-up could be made without tasking the attendee with giving permission each and every time. Granted, privacy laws are evolving- so why codify one such set of restrictions here? This could impact organizations in the future about what they do with their mailing lists and how they share them. The comment "Each time the data is shared" within Standard 2.3 could lead to significant process changes for many eligible entities and could directly impact some organizations' members. This change would significantly and negatively impact the already high administrative burden.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	2.2 – While we concur with ensuring accredited CE is free of marketing/sales of products/services, prohibiting this by eligible entities that develop education and resources to enhance learning and patient care would have a detrimental effect.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	2.2 Would this include books or publications? Authors can benefit financially from promoting books. 2.3 During the registration process, our learners are able to opt out of having their information shared. Seeking permission for every individual request for data would be burdensome to the learner as well as the provider.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	2.3 Sharing of data each time? Does that mean each time you sell a list? That would be very cumbersome and disruptive to marketing of exhibit space. Suggest that the consent be for each activity. This could be done as part of registration. What is a learner? Suggest this be defined as the professional or scientific attendee, not all registrants.

Do you foresee challenges or unintended consequences implementing Standard 2? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	2.3 Requiring providers to describe how an entity intends to use information and specifically who will receive it is an unreasonable burden. We give strict guidelines to corporate supporters that limits how they may use a list of attendees and, per GDPR, already receive permission from any learners before sharing their information but it is unrealistic to believe we can go through and tell those learners specifically who will receive the information and how they will use it.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	2.3. Currently, the overall attendee list for large convention or annual meeting, in some form, is shared with exhibitors, some of whom may be ineligible entities; it is common practice under current privacy laws and policies to allow the attendee to opt out of this sharing. The restriction as proposed here would go far beyond that if the term "learner" is interpreted by legal teams as any attendee. Exhibit space sales could decrease significantly if no pre-invites or follow-up could be made without tasking the attendee with giving permission each and every time. Granted, privacy laws are evolving- so why codify one such set of restrictions here?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	As written, ACCME's Standard 2.3 is overreaching its authority with dictating how eligible entities communicate their data sharing policies with their members. As more eligible entities are figuring out better ways to use their data, this standard could negatively impact them if the ACCME doesn't deem their processes adequate. Eligible entities must already comply with privacy laws, so the ACCME doesn't need to police this. Including this standard only adds burden and redundancy for accredited providers.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Clarification by example would assist CME providers in complying with this proposed change.

Do you foresee challenges or unintended consequences implementing Standard 2? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Currently, the International Society for Magnetic Resonance in Medicine organizes up to 8 live events a year. For each event, we ask attendees when registering to opt-out if they do not wish to have our corporate sponsors contact them. We are able to adjust our registration documents to have an opt-in option, meeting the requirement of explicit consent from attendees; however, our main concern is the explicit consent including the name of the ineligible entity (corporate sponsor). Our smaller workshops often have sponsors that do not sign and return the Letter of Agreement until immediately before the event. In addition, our early registration deadlines are at least a month before the event. As a result, many of our attendees will have already registered before we have discussed funding with an ineligible entity. Furthermore, for a single event, we could have up to five entities offering commercial support. An attendee would need to acknowledge their acceptance five times. While the intention is likely to reduce the information that is offered to ineligible entities, this is burdensome on the individuals registering.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Currently, the overall attendee list for annual meetings are, in some form, shared with exhibitors, some of whom may be ineligible entities; it is common practice under current privacy laws and policies to allow the attendee to opt out of this sharing. The restriction as proposed here would go far beyond that if the term "learner" is interpreted by legal teams as any attendee. Exhibit space sales could decrease significantly if no pre-invites or follow-up could be made without asking the attendee, or having to seek permission, each and every time.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	If item 2.3 stays as it is currently written it could create significant challenges for ensuring compliance for accredited providers who host large annual meetings or other similar live courses. In the case of a large conference, for example, it is possible that some ineligible entities participating as exhibitors may not be confirmed when a learner registers to attend the event and provides her consent to have her information shared. In its current format item 2.3 suggests that a new consent would be required from each learner every time a new ineligible entity becomes associated with the activity. This would not be a manageable process when handling enrollments of several thousand learners at a large conference. A single learner consent that can address data sharing with any and all ineligible entities directly associated with the activity seems to satisfy the intent of this item.

Do you foresee challenges or unintended consequences implementing Standard 2? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	If this language stays as it is currently written it could create significant challenges for ensuring compliance for accredited providers who host large annual meetings or other similar live courses. In the case of a large conference, for example, it is possible that some ineligible entities participating as exhibitors may not be confirmed when a learner registers to the event and provides her consent to have her information shared. In its current format item 2.3 suggests that a new consent would be required from each learner every time a new ineligible entity becomes involved in the activity. This would not be a manageable process when handling enrollments of several thousand learners at a large conference. A single learner consent that can address data sharing with any and all potential ineligible entities seems to satisfy this goal.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	In section 3, this is beyond GDPR requirements. Our Corporate support is not totally worked out before we open registration so we would not be able to list every ineligible entity that the data would be shared with
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Like #1, this is enormous overkill. We all know to "follow the money" and disclosure should be made. But, in reality, medicine does not advance without a great deal of money. We all know to see who paid for the study, paper, grant, whatever. Again, you give no credit to the ability of highly educated individuals to be reasonably skeptical about the motivations of any presenter and ask the appropriate questions. Is that not implicit in the very definition of "continuing education?"
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Many of the active members of societies are authors of book chapters. although they may not be promoting their textbook or entities it may be difficult for them to educate members without referencing their own hard work that has produced valuable scientific information. I do agree they should not promote their product for purchase but use of the product or text information should be allowed.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	o In Standard 2.2, limitations on faculty will present challenges to planners and providers. o In Standard 2.3, having to get consent of the individual learners “each time” the data is to be shared could be problematic. Suggest a one-time consent.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Please see our full comments submitted to communications@accme.org.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Problems implementing a process and platform to get all individual consent each time IT expenses.

Do you foresee challenges or unintended consequences implementing Standard 2? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Regarding Standard 2.3: We believe it to be outside the purview of ACCME and accreditation in general to govern how learner info is managed. What is pertinent to accredited medical education is whether the education is independent, unbiased, evidence-based, and impactful. Providers should be able to establish their own terms with their learners on how learner info is used and shared with outside entities. For example- a registration agreement could be a tool to ensure the learners have full understanding on how their info will be used and also provide an opportunity for the learners to opt out. Requiring the description from each entity on how learner information will be used and to elicit permission for each instance of learner info being shared is out of the scope of accreditation and should be up to the provider and related entities to navigate per already established laws and standards.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The ACCME is proposing a standard that does not, in any way, impact the content of the educational activity. Rather, ACCME is proposing a requirement that would be an administrative nightmare to implement. In a worse-case scenario, 1-200 or more “ineligible entities” could request a mailing list and accredited providers would be required to go back to the learners each time for consent. Besides being administratively overwhelming, learners could easily become frustrated with the accredited body which would naturally lead to accredited bodies directing their frustration back to ACCME.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The ACMG agrees that accredited providers should not share learner data without their consent. Beyond this, the ACMG believes that understanding and complying with the details of applicable data sharing laws/regulations is a standard business practice and expectation of a CME provider organization. Thus, this does not need additional oversight or regulation by accreditors. As written, the ACMG believes Standard 2.3 puts undue burden on the accreditor determining compliance and the provider to comply with additional standards that may not align exactly with other requirements. The onus should be on the learner, when granting permission for their data to be used, to understand what will be shared, with whom and how it will be used. As such, the ACMG strongly recommends the following revision to Standard 2.3: The accredited provider must not share the names and contact information of learners with any ineligible entities or their agents without the explicit consent of the individual learners. each time the data is to be shared. This consent must include the name of the ineligible entity receiving the learner information and describe how the entity intends to use the information.

Do you foresee challenges or unintended consequences implementing Standard 2? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The restriction as proposed here goes far beyond what is required by law, even under the GDPR. As each organization strives to comply with the still evolving laws and regulations regarding privacy and data management that apply to them, it seems unnecessary and unduly burdensome to codify a separate, more onerous set of restrictions here. The new requirements would increase staff time and technology requirements and would impact the very business model, free market and exchange of information all parties have come to expect.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	While an opt-out message seems appropriate to mandate for all ineligible entities who send messages, requiring an opt-in with each marketing effort could affect business relationships with companies who help to support our meetings as well as be an administrative nightmare for a provider.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Will it be the role of the accredited provider to determine if a product or service 'serves their professional and financial interests'? If so, what resources will be available to accredited providers to make these decisions? How will this be evaluated at reaccreditation? Performance-in-practice activities? What additional resources will volunteer surveyors need to accomplish this review? Standard 2.3: The consent requirement adds administrative burden to accredited providers and does not allow for efficiencies in process. May also lead to loss of revenue as exhibitors may not commit. As an alternative, suggest that accredited providers still requires learners consent and knowledge of the ineligible entities, but reduces burden of accredited providers by the following: The accredited provider must not share the names and contact information of learners with any ineligible entities or their agents without the explicit consent of the individual learners each time the data is to be shared. The accredited provider must inform learners of all ineligible entities receiving the learner information prior to the start of the activity. Accredited providers must allow and inform learners they can revoke consent at any time.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	You state "This consent must include the name of the ineligible entity receiving the learner information and describe how the entity intends to use the information". While we can easily list who will be receiving this information not entirely sure that the ineligible entity will tell us what they are planning to do with this information.
Accredited CE provider	ACCME	Other: not-for-profit CME provider	What about providers or speakers promoting a particular textbook. Entities publishing textbooks are eligible entities, but is it OK for a speaker to promote their specific textbook? It is in the Speaker's financial benefit if purchased.

Do you foresee challenges or unintended consequences implementing Standard 2? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Other: Teleconferencing Medical Education Company	The wording leaves a lot to interpretation, e.g. what are considered as "products" and "services", no clear definitions are provided. I fear that the lack of clarity will lead to confusion and uncertainty.
Accredited CE provider	ACCME	Other: university	Could this be disruptive to the marketing of exhibit space - would exhibitors have to get written permission to get/use someone's contact information and provide it to the AP?
Accredited CE provider	ACCME	Publishing/education company	2.1 Broad interpretation of the current wording may result in an impact on industry's compliant right to issue Requests for Proposals (RFPs), the ability to publish general information included on grant portals, industry's ability to ask for and/or recommend the reporting of outcomes as a result of awarding substantial monetary funds, none of which impart industry's involvement in content development and implementation. 2.3. Currently, the overall attendee list for large convention or annual meeting, in some form, is shared with exhibitors, some of whom may be ineligible entities; it is common practice under current privacy laws and policies to allow the attendee to opt out of this sharing. The restriction as proposed here would go far beyond that if the term "learner" is interpreted by legal teams as any attendee. Exhibit space sales could decrease significantly if no pre-invites or follow-up could be made without tasking the attendee with giving permission each and every time. Granted, privacy laws are evolving- so why codify one such set of restrictions here?

Do you foresee challenges or unintended consequences implementing Standard 2? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	2.1 Broad interpretation of the current wording may result in an impact on industry's compliant right to issue Requests for Proposals (RFPs), the ability to publish general information included on grant portals, industry's ability to ask for and/or recommend the reporting of outcomes as a result of awarding substantial monetary funds, none of which impart industry's involvement in content development and implementation. 2.3. Currently, the overall attendee list for large convention or annual meeting, in some form, is shared with exhibitors, some of whom may be ineligible entities; it is common practice under current privacy laws and policies to allow the attendee to opt out of this sharing. The restriction as proposed here would go far beyond that if the term "learner" is interpreted by legal teams as any attendee. Exhibit space sales could decrease significantly if no pre-invites or follow-up could be made without tasking the attendee with giving permission each and every time. Granted, privacy laws are evolving- so why codify one such set of restrictions here?
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Do you foresee challenges or unintended consequences implementing Standard 2? If yes, please explain.			
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Accredited CE provider	ACCME	Publishing/education company	2.1 Broad interpretation of the current wording may result in an impact on industry's compliant right to issue Requests for Proposals (RFPs), the ability to publish general information included on grant portals, industry's ability to ask for and/or recommend the reporting of outcomes as a result of awarding substantial monetary funds, none of which impart industry's involvement in content development and implementation. 2.3. Currently, the overall attendee list for large convention or annual meeting, in some form, is shared with exhibitors, some of whom may be ineligible entities; it is common practice under current privacy laws and policies to allow the attendee to opt out of this sharing. The restriction as proposed here would go far beyond that if the term "learner" is interpreted by legal teams as any attendee. Exhibit space sales could decrease significantly if no pre-invites or follow-up could be made without tasking the attendee with giving permission each and every time. Granted, privacy laws are evolving- so why codify one such set of restrictions here?
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Accredited CE provider	ACCME	Publishing/education company	2.3 - The majority of life CME activities seem to provide an attendee list, often without contact information. In many cases, representatives of entities ineligible for accreditation would be present and receive a copy. Would this violate 2.3? It is typical in live, regional CME activities with exhibit halls for the provider to furnish a list of registered attendees with name only (not including contact information) prior to the activity. This list is typically used by ineligible entities to determine which staff and how many will attend the event, based upon their preexisting knowledge of the providers in attendance. This appears to be common practice for association meetings with attendance in the hundreds to the thousands and is a common process. There is not breakdown of the existing or proposed SCS with this practice, but disarray and disruption will result unless the standard is applied as “BOTH the names and contact information”.
Accredited CE provider	ACCME	Publishing/education company	2.3. Currently, the overall attendee list for large convention or annual meeting, in some form, is shared with exhibitors, some of whom may be ineligible entities; it is common practice under current privacy laws and policies to allow the attendee to opt out of this sharing. The restriction as proposed here would go far beyond that if the term "learner" is interpreted by legal teams as any attendee. Exhibit space sales could decrease significantly if no pre-invites or follow-up could be made without tasking the attendee with giving permission each and every time. Granted, privacy laws are evolving- so why codify one such set of restrictions here?
Accredited CE provider	ACCME	Publishing/education company	Broad interpretation of the current wording may result in an impact on industry’s compliant right to issue Requests for Proposals (RFPs), the ability to publish general information included on grant portals, industry’s ability to ask for and/or recommend the reporting of outcomes as a result of awarding substantial monetary funds, none of which impart industry’s involvement in content development and implementation. 2.3. Currently, the overall attendee list for large convention or annual meeting, in some form, is shared with exhibitors, some of whom may be ineligible entities; it is common practice under current privacy laws and policies to allow the attendee to opt out of this sharing. The restriction as proposed here would go far beyond that if the term "learner" is interpreted by legal teams as any attendee. Exhibit space sales could decrease significantly if no pre-invites or follow-up could be made without tasking the attendee with giving permission each and every time. Granted, privacy laws are evolving- so why codify one such set of restrictions here?

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Accredited CE provider	ACCME	Publishing/education company	Further consideration and clarification is needed as to how Standard 2.3 relates to the Open Payments/Sunshine Act. Some supporters request names of participants in live events that include a buffet meal, even though this is exempted from reporting requirements. Would providing that information be a violation? If you do serve a plated meal and must provide a list to the supporter and a learner has a meal but will not give permission to have their name provided - you would be in violation of the open payments act while being in compliance with the ACCME. How would that work?
Accredited CE provider	ACCME	Publishing/education company	In 2.3, if we have an exhibit hall where exhibitors can scan name badges, would a sign at the entrance saying basically "if you enter the exhibit hall you are consenting to receive information from any company you allow to scan your badge" meet this requirement? Or do we have to give them something at each booth? Would we have to list each company on that sign, or would the fact they choose whom they allow to scan them cover that?
Accredited CE provider	ACCME	Publishing/education company	Standard 2.2: Providers need to be clear about what is considered promotional to make sure content presented is independent.
Accredited CE provider	ACCME	Publishing/education company	Without a clear definition of learner, it is difficult to know when and from whom consent must be obtained. This term can be interpreted differently by different organizations in different situations.
Accredited CE provider	ACCME	School of medicine	2.1 Broad interpretation of the current wording may result in an impact on industry's compliant right to issue Requests for Proposals (RFPs), the ability to publish general information included on grant portals, industry's ability to ask for and/or recommend the reporting of outcomes as a result of awarding substantial monetary funds, none of which impart industry's involvement in content development and implementation. 2.3. Currently, the overall attendee list for large convention or annual meeting, in some form, is shared with exhibitors, some of whom may be ineligible entities; it is common practice under current privacy laws and policies to allow the attendee to opt out of this sharing. The restriction as proposed here would go far beyond that if the term "learner" is interpreted by legal teams as any attendee. Exhibit space sales could decrease significantly if no pre-invites or follow-up could be made without tasking the attendee with giving permission each and every time. Granted, privacy laws are evolving- so why codify one such set of restrictions here?

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Accredited CE provider	ACCME	School of medicine	2.1 Broad interpretation of the current wording may result in an impact on industry's compliant right to issue Requests for Proposals (RFPs), the ability to publish general information included on grant portals, industry's ability to ask for and/or recommend the reporting of outcomes as a result of awarding substantial monetary funds, none of which impart industry's involvement in content development and implementation. 2.3. Currently, the overall attendee list for large convention or annual meeting, in some form, is shared with exhibitors, some of whom may be ineligible entities; it is common practice under current privacy laws and policies to allow the attendee to opt out of this sharing. The restriction as proposed here would go far beyond that if the term "learner" is interpreted by legal teams as any attendee. Exhibit space sales could decrease significantly if no pre-invites or follow-up could be made without tasking the attendee with giving permission each and every time. Granted, privacy laws are evolving- so why codify one such set of restrictions here?
Accredited CE provider	ACCME	School of medicine	2.2 We have many of our university faculty who provide education on novel treatments and therapies that they have developed. In many cases we may be the only clinical center that is providing these treatments and services. This could be considered "marketing" since it could generate referrals.
Accredited CE provider	ACCME	School of medicine	Accredited Continuing Ed offices are required to provide excellent education as well as compete with the many other agencies that offer CME - and in order to do so we need to have a rather large budget (get the best speakers, find the best locations, have the best price for the learners, etc). I know that our office tries to offset these costs by inviting exhibitors to attend our events in order to keep the cost down for our attendees. The biggest question i get from these exhibitors is if they can have a list of the attendees - with only name, city, and state on them. Never with contact information. I am concerned that if we are no longer able to permit them to have even this most basic of information - which is easily available online anyways - it will cause them to no longer bother attending these events. This would be disastrous for our office and our learners.
Accredited CE provider	ACCME	School of medicine	clarify 2.3 for contact information to not be shared. Are geographic locations, summary of credentials or specialties, etc okay?

Do you foresee challenges or unintended consequences implementing Standard 2? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	I think what's happening here is a broadening with #2, right? So now we're saying that faculty cannot promote anything that serves their interests, even if it's not related to the content? So, if a faculty member has a book on liver treatments and is speaking on professional development, they couldn't mention their book? That kind-of makes sense, unless they were saying writing books helps you develop professionally… and I'm not sure what limiting them from talking about it or ignoring a part of them that is based in reality gets us in terms of better education or better informed learners, but if that's what we have to do, we can do it. Also, will this raise a concern with book publishers who might have an exhibit table not bringing the book of any speaker who also happens to be an author of their book? That might be limiting for several of our larger conferences.
Accredited CE provider	ACCME	School of medicine	If faculty are an author of a book that is referenced during their talk and the book is not given out with registration but is sold separately from the accredited education in a separate location after the conference or over lunch, is that acceptable. As long as the faculty are not promoting the book sale during the talk, is this acceptable? Could you provide more clarification or examples of this Standard? We have this occurrence a few times each year and the author will sign their book and speak to the attendees individually. They do benefit of course, from the sale of the book, so I know this is an area of caution, but it is not something that is used in patient care, other than possibility a reference document.
Accredited CE provider	ACCME	School of medicine	If healthcare professionals must not promote services that serve their professional interests, would this have a negative impact in regards to educating/informing healthcare providers about services that are available to patients.
Accredited CE provider	ACCME	School of medicine	Law laws deal with privacy concerns. This is not your lane. Stay out of it.

Do you foresee challenges or unintended consequences implementing Standard 2? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	Per the standard 2.2 there is no mention of products or services from "ineligible entities." Consequently, if a speaker has written a book, any mention of that book can be construed as "promote or sell products or services that serve their professional or financial interests" so at no point can the existence of said book be acknowledged which could be seen as "promoted". That seems irrational. Currently at SACME and speakers have mentioned their books - so now that is in question, have we mixed accredited talks with that which cannot be accredited?
Accredited CE provider	ACCME	School of medicine	Please consider allowing the accredited provider to obtain global consent in contrast to consent by each ineligible supporter. Suggested language could be “I consent to share my name and contact information with the exhibitors or their agents of this activity to contact me by email, mail, or phone.”
Accredited CE provider	ACCME	School of medicine	So, for Standard 2, #1, it does not address the exceptions that are then made in Standard 3, # 2, or indicate that there are any exceptions to this. I think this should be indicated else it seems that there are none. If there are none, I think that also needs to be stated (the exceptions of Standard 3, #2 do not apply). For #2, I want to clarify a scenario; an orthopedic surgeon is speaking at one of our accredited courses. He has helped to design a device (as a consultant) that has proven improved outcomes when utilized on a patient for knee surgery. He wants to compare outcomes when utilized this device vs. other devices. Due to the improved outcomes, he has a preference toward the device that he did happen to help to design. Is this considered promoting a product that serves his professional or financial interest? His relationship would be considered relevant and disclosed to all learners.
Accredited CE provider	ACCME	School of medicine	What is the intent of the ACCME in changing the name to Accredited Continuing Education. Accredited CE could be any type of higher education.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Hospital/healthcare delivery system	I can see potential confusion related to 2.2, including: 1) defining what constitutes "promotion of products/services that serve professional interests" especially when there are no relevant financial relationships (if faculty has a book, for example, is any mention of this promotional or can it be mentioned in a resource context?), and 2) the full extent of faculty's professional/financial relationships may not always be known since traditional disclosure processes would only identify relationships with ineligible entities.

Do you foresee challenges or unintended consequences implementing Standard 2? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Hospital/healthcare delivery system	Standard 2.3 is a concern. We currently share attendee lists with exhibitors for large conferences. Changing the process from an "opt-out" to an "opt-in" will likely cause a significant decrease in exhibitor participation in our conferences.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Hospital/healthcare delivery system	Standard 2: #2 we currently allow for the sale of books, usually at a reduced rate. As written, it would prohibit the sale of books too. Standard 2: #3 we don't share unless the learner has opted in. The new language would make us the communicator and create a lot of processing back and forth between the company and learners. The first time use when provided might be feasible but what if the company decides 2 months after a course to make contact again, do they need to contact us, then we contact all learners to tell them they will now receive another poke from the company and how, then let the company know that we have contacted the learners, etc. etc. When do we get out of the cycle of communication between the ineligible entity and the learner?
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (other)	2.3 - "each time the data is to be shared". This seems like it could result in a significant burden not only for providers but also learners. Maybe consider a single opt-in or out as sufficient.

Do you foresee challenges or unintended consequences implementing Standard 2? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	• Standard 2.2 should be clarified to note whether it relates to faculty who develop products/services that are used by or on patients (which aligns with the definition of “ineligible entity”), or if it encompasses all marketing or sales of all products and services, such as those who write/publish books. Additionally, would this standard apply to individuals who hold patents relevant to the content being discussed and collect royalties on those patents? The ACCME should provide examples related to this Standard. • Standard 2.3 will likely introduce significant burdens, particularly for providers who hold activities for large number of attendees, due to the requirement to get consent from each individual for each time data are shared. Although there are alternatives to implementation such as offering an opt-out opportunity versus an explicit individual consent, ASCO would instead encourage that the ACCME let go of this suggested update all together because it is already addressed in GDPR and other privacy regulations. If there needs to be any mention at all, maybe it is a statement simply noting that the ACCME intends for accredited providers to confirm to all relevant privacy regulations, such as GDPR.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	Item #3 requires explicit consent from the learner EACH time their data is shared. For a large annual meeting with multiple supporters, is it possible to obtain consent that covers all of the supporters or would the individual consent need to be tied to each supporter? The administrative burden could be significant if an automated system is not used and the creation of this management system may be a financial burden for many organizations.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	We request clarification and guidance be provided that would allow for attendee lists to continue to be provided to participants in an activity that may include name and institution or city, state, but not personal contact information such as, email, mailing address, or phone number.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Other: academic medical center	Providers must not allow faculty to "promote or sell products or services that serve their professional or financial interests during accredited education." Does that include my speaker who is a long-time contributor to the standard textbook in her field? Does it include my faculty who is speaking about a new, specialized procedure available only at a few centers at one of which he practices?

Do you foresee challenges or unintended consequences implementing Standard 2? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	2.3 - Many exhibitors request attendee lists for large annual meetings and conferences, many who are ineligible entities. If attendees are given the options to opt out of this sharing, we do not feel this further limitation is necessary. For the number of attendees at any given conference or large meeting, having to require each to consent to this each time would be difficult.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	Standard 2.3: Currently, the overall attendee list for large educational conferences or annual meetings, is shared with exhibitors, some of whom may be ineligible entities; it is common practice under current privacy laws and policies to allow the attendee to opt out of this sharing. Exhibit space sales could decrease significantly if no pre-invites or follow-up could be made without tasking the attendee with giving permission each and every time. The use of the word “Each time” is both restrictive and burdensome for the accredited provider and the learner. We consider that the use of the wording as it stands could have severe financial impact on some educational activities resulting in them no longer being financially viable.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	In the past we have allowed discussion of non-pharma or non-device products such as an author’s book or consulting services. If this is now totally eliminated as being eligible for accreditation, it will limit what non-clinical content we can qualify as accredited.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	Our program will likely adopt a policy that does not allow for sharing of information with ineligible entities, rather than managing permissions. In this case, we may lose support from ineligible entities who currently pay to exhibit at our meetings/conference. This will results in increased charges to learners to attend and limiting access to high quality CE for under-resourced learners.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	Would take more research into each speaker's history, if the intent is stricter than what is currently being done to evaluate financial relationships
Accredited CE provider	Other: ACPE	Hospital/healthcare delivery system	The definition of marketing may need to be clearer, as showing a picture or a weblink of a readily available educational resource could potentially be considered a violation, even though the intent is to provide additional opportunities for gaining a better understanding of the subject.

Do you foresee challenges or unintended consequences implementing Standard 2? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Other: ACPE	Publishing/education company	We appreciate, and agree with, the intent of this standard but do anticipate logistical challenges with capturing explicit consent when the list of ineligible entities changes frequently up until the program. A database will be needed to track how the entity intends to use the information to know which leaners information has been shared with which entities. This will be an administrative burden.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	2.2 may be an issue
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Faculty must not promote services etc. Faculty may be invited to provide an update on XXX which includes use of new YYY laser, so technically that could be viewed as promotional, when in fact CME purpose is to get learners current on eval & mgmt of ZZZ pts.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	I think it is important request faculty to look themselves up on OpenPayments and disclose as appropriate.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Oftentimes subject matter experts write and publish books. These individuals are then invited to present in accredited education. This provides a forum to educate on their professional interests and possibly financial interests. Oftentimes, education will include statements that further the presenter both professional and financially as they wrote book(s) on the topics being presented. While publishers and individuals themselves are not ACCME-defined commercial interests, this is often viewed by learners as a commercial bias. ACCME FAQ that include scenarios for compliance and non-compliance would be helpful.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	What about our faculty who have authored chapters in textbooks and receive royalties, when the text is the recognized go-to "bible" (E.g. Pathology's standard reference as basis for current recommendations)
Advocacy organization			NAMEC asks for further consideration and clarification as to how Standard 2.3 relates to the Sunshine Act. Some supporters request names of participants in live events that include a buffet meal, even though this is exempted from reporting requirements. Would providing that information be a violation?

Do you foresee challenges or unintended consequences implementing Standard 2? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Advocacy organization			This Standard is prohibiting healthcare professionals who author published scientific, peer-reviewed information from delivering their expertise in other formats outside of the realm of the CME activity.
Clinician/healthcare professional			I do not see why I cannot have an ACCME accredited lecture by someone who authored a book on the subject.
Clinician/healthcare professional			Need a better definition as the what prevention and sales of accredited CME is.
Clinician/healthcare professional			Please explain "Faculty must not promote or sell products or services that serve their professional or financial interests during accredited education." in (2). What are professional interests and how does that impact academic medicine? Commercial interests have always wanted access to individuals for later marketing. This standard should stop that.
Clinician/healthcare professional			Repression of innovative medical concepts.
Clinician/healthcare professional			Standard 2.1 is becoming an increasing challenge for academic faculty as an increasing number of academic faculty are involved in small technological ventures typically deigned to enhance the care of patients. Using the same rules for the CEO of a major pharmaceutical company and a faculty member with a small side venture (often encouraged by the academic health centers) will result in excluding faculty with a high level of expertise from ever speaking in accredited CME, an unfortunate consequence. It would be good to find a way to be able to mitigate the conflict for the academic faculty rather than considering the conflict not resolvable. Standard 2.2. Many medical educators may refer to their book (for example a book on leadership, student assessment, etc.) in their talk, in the same way that they may refer to an article they may have published. It is why often they are considered expert and invited to speak. Standard 2.2 would not allow them to do so, yet medical education companies are not considered ineligible entities. Consider being consistent by using the same restriction as ineligible entities, that is if used by or on patients. Standard 2.3 Conference planners sometime ask if names can be shared with the 'exhibitors'. Requesting that the name of the ineligible entity be also shared may cause a challenge to conference planners who may then not be able to open registration until all exhibitors are fully confirmed and no new exhibitors can be added.
Do you foresee challenges or unintended consequences implementing Standard 2? If yes, please explain.			

Organization Type	Accreditor	Provider Type	Comments
Clinician/healthcare professional			This is good judgement and protects the learners.
Continuing education accrediting body			Our organization does not share the information about who participated in a specific educational activity or session. However, large events such as our Annual Conference include promotional events such as Product Theaters (promotional presentations) and exhibits. Companies sponsoring Product Theaters currently receive a pre-registration list and a post conference list of attendees which is subject to an “opt out” provision. While the product theater is a promotional event, the data comes from registering for the Annual Conference as a whole, of which CME is a primary activity and draw. We are unsure of how this Standard would apply to this scenario. If it does, we have the following concerns: • The “opt in” vs “opt out” requirement coupled with the requirement that we inform participants of how the data would be used would be burdensome and perhaps entirely impractical to implement • If we no longer provide the pre-registration list to product theater sponsors, they will not be able to promote them, and we will lose a substantial revenue stream that supports our Annual Conference
Ineligible Entity (commercial interest, such as pharmaceutical, device, life-science company)			We firmly support that “all decisions…are made without any influence…” The concern is that the inclusion of the term “involvement,” which is broad, may be misinterpreted allowing for confusion on industry’s current, compliant practices of issuing Requests for Proposals, publishing general information currently included on grant portals, and/or requesting verification of the fulfillment of grant obligations as agreed to in executed Letter of Agreements including outcomes as a measure of impact and verification of program completion. For these reasons, we suggest removal of the word “involvement.”

Do you foresee challenges or unintended consequences implementing Standard 2? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Medical/healthcare association			2.1 Broad interpretation of the current wording may result in an impact on industry's compliant right to issue Requests for Proposals (RFPs), the ability to publish general information included on grant portals, industry's ability to ask for and/or recommend the reporting of outcomes as a result of awarding substantial monetary funds, none of which impart industry's involvement in content development and implementation. 2.3. Currently, the overall attendee list for large convention or annual meeting, in some form, is shared with exhibitors, some of whom may be ineligible entities; it is common practice under current privacy laws and policies to allow the attendee to opt out of this sharing. The restriction as proposed here would go far beyond that if the term "learner" is interpreted by legal teams as any attendee. Exhibit space sales could decrease significantly if no pre-invites or follow-up could be made without tasking the attendee with giving permission each and every time. Granted, privacy laws are evolving- so why codify one such set of restrictions here?
Medical/healthcare association			Associations with exhibit programs need the ability to sell registrant mailing lists; Otherwise this could be disruptive to the marketing of exhibit space. What about ineligible entities with access to mobile event app with attendee information which is generally an opt-in for attendees to share their info with other attendees.
Medical/healthcare association			In general, the Council supports Standard 2.3 and the intent for needing to obtain learner permission prior to sharing names and contact information with ineligible entities; however, doing so each and every time that information is to be shared may not practical. Many ACCME accredited entities are also organizations who generate income streams from selling contact information to various entities for purposes that may have little to do with the original educational event. An unintended consequence may be the severe impact that this standard would have on those entities. Furthermore, we believe that while this regulation may work for attendees at educational events such as annual meetings, it may be harder for those participating in a webinar series or enduring materials, for example. Finally, it is plausible for a physician to begin receiving more notifications seeking permission to share information than they would have otherwise received if the information had been shared under the previous arrangement. The Council recommends to delete the stipulation, "…each time the data is to be shared…" from the proposed standard.

Do you foresee challenges or unintended consequences implementing Standard 2? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Medical/healthcare association			Specific to 2.3: The term “learner” should be clarified, especially as used in the proposed standards. This should be differentiated from a meeting “attendee.” If they are considered the same, this could cause a significant shift in current business practices for many professional associations.
Medical/healthcare association			Standard 2.3: Our organization already has policies in place to address/control communication from industry. While there are only a few opportunities for industry to obtain learners contact information, placing a requirement that we contact them every time something is going to be sent would create additional and unnecessary administrative work for staff and increased frustration on the part of our members with the additional e-mail contact.
Medical/healthcare association			The universal response to 2.3 in our survey of Alliance members was negative, as all raised confusion over the definition of learner vs attendee vs participant. And most addressed the issues of logistics of implementation, as most exhibit halls are still booking space right up to the opening of the show and some commercial support grants are not fully executed until just before the activity starts, thus obtaining permission from persons and including information on all ineligible entities and their intended use would be difficult to pull off in time to have a list available for distribution to attendees, as well as exhibitors , (some of whom might be healthcare professionals working in industry). The current usual process is to include an opt in or opt out of sharing information during the attendee registration process, which may take place months before the activity. Many also indicated the potential that this could negatively impact their exhibit space and sponsorship sales, a necessary source of revenue for many ACE programs.
Nonaccredited CE provider			2.1 Broad interpretation of the current wording may result in an impact on industry’s standard procedure to issue Requests for Proposals (RFPs), the ability to publish general information included on grant portals, none of which constitute industry involvement in content development and implementation.

Do you foresee challenges or unintended consequences implementing Standard 2? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: Accredited CE provider, Continuing education accrediting body, and medical/healthcare association			2.1 Broad interpretation of the current wording may result in an impact on industry's compliant right to issue Requests for Proposals (RFPs), the ability to publish general information included on grant portals, industry's ability to ask for and/or recommend the reporting of outcomes as a result of awarding substantial monetary funds, none of which impart industry's involvement in content development and implementation. 2.3. At times, an overall attendee list for large convention may be shared with exhibitors, some of whom may be ineligible entities; it is common practice under current privacy laws and policies to allow the attendee to opt out of this sharing. The restriction as proposed here would go far beyond that if the term "learner" is interpreted by legal teams as any attendee. Exhibit space sales could decrease significantly if no pre-invites or follow-up could be made without tasking the attendee with giving permission each and every time. As stated above, the AOA believes understanding and compliance with the details of applicable data sharing laws and regulations is a standard business practice and expectation of a CME provider. Furthermore, privacy laws are evolving – we do not believe that the ACCME should codify one such set of restrictions.
Other: CME/CE Consulting Services Company			As Standard 2.3 is currently proposed, "names and contact information of learners cannot be shared with ineligible entities or their agents without individual consent. The consent must include the name of the ineligible entity and how they intend to use the information." Often at annual meetings a CME attendee list is distributed to all learners for networking purposes, etc., which we believe this proposed standard is seeking to prevent from automatically happening. That said, the accredited provider would need to vet every CME-registered attendee of the conference to ensure the list of attendees is not shared with another attendee who may be an agent of an ineligible entity. This would be quite burdensome to the accredited provider.
Other: Consultant			If this standard is stiffened and strengthened the way I think it should be, there will indeed be major challenges, because the way needs assessments are written today will have to change. This will be especially true for assessments of need that are written in response to RFPs from industry. For example, if someone actually holds the accredited providers' feet to the fire here, I can expect the accredited providers will start to protest and complain quite loudly.

Do you foresee challenges or unintended consequences implementing Standard 2? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: Consultant - own my own company			I am unclear as what to do with the situation that a faculty may have used their own textbook as the basis for the activity content (I have experienced this directly) or even used as a reference along with other content. Maybe final version of this standard can give some guidance on that. I agree that faculty should not be promoting ANYTHING they will benefit from in their course contents.
Other: I am a faculty member/CME content provider/CME course director and my views do not necessary represent the views of my institution, the Medical College of Wisconsin			Registrants frequently attend a specific presentation because of the speaker's expertise and may wish to purchase a book by the speaker. Didactic presentations seldom capture all the information available in a book. If sales aren't permitted, I foresee complaints by attendees.
Other: Joint Provider			Many times, the most published authors who have clinically relevant information are who clinicians ask to hear as speakers. If CME excludes these subject matter experts solely due to the fact that they have published books, it may limit great speakers from speaking as well as unintentionally create pathways outside of the CME model that will in the end devalue CME.
Other: MedChi is both an Accredited Provider and a Recognized Accreditor			2.3 Has ACCME regulations moving into legal areas that are governed in many cases by regulations that can vary by state and region. Reword to be related to applicable privacy laws.
Other: physician, patient, member of certifying board, member of educational academy			By the way, this machine ate my words carefully crafted over the past 15 minutes. "Marketing" -- a free market of ideas allows the clinician to be educated and decide for himself. Do you need to baby sit professionals?

Do you foresee challenges or unintended consequences implementing Standard 2? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: Publishing/education company			2.1 Broad interpretation of the current wording may result in an impact on industry's compliant right to issue Requests for Proposals (RFPs), the ability to publish general information included on grant portals, industry's ability to ask for and/or recommend the reporting of outcomes as a result of awarding substantial monetary funds, none of which impart industry's involvement in content development and implementation. 2.3. Currently, the overall attendee list for large convention or annual meeting, in some form, is shared with exhibitors, some of whom may be ineligible entities; it is common practice under current privacy laws and policies to allow the attendee to opt out of this sharing. The restriction as proposed here would go far beyond that if the term "learner" is interpreted by legal teams as any attendee. Exhibit space sales could decrease significantly if no pre-invites or follow-up could be made without tasking the attendee with giving permission each and every time. Granted, privacy laws are evolving- so why codify one such set of restrictions here?
Patient, caregiver, member of the public			Number 3 should be clarified as there will be confusion related to the Physician Payment Sunshine Act.
Recognized Accreditor (state/territory medical society)			If accredited providers must not share the names and contact information of learners with any ineligible entities or their agents without the explicit consent of the individual learners, then simplify the requirement to stating that we can't share information without a learners permission but allow accredited providers to ask just one time specific to the activity (not the ineligible entity) so that we can collect permission or refusal simply, perhaps at the time of registration. In reality supporters are acquired sporadically up until the time of an event, so we don't want to have to send numerous emails to learners every time a new sponsor/exhibitor comes on board.
Recognized Accreditor (state/territory medical society)			It's possible that not sharing names with exhibitors will be a deterrent and reduce funding.

Do you foresee challenges or unintended consequences implementing Standard 2? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Recognized Accreditor (state/territory medical society)			Please include a definition of definition of “products or services” (i.e., are textbooks included in this? What about non-clinical products or services?) Remove the requirement that the consent must include the name of the ineligible entity receiving the learner information and describe how the entity intends to use the information. Although we agree with the requirement that the accredited provider must not share the names and contact information of learners with ‘ineligible entities’ without the explicit consent of the learner, we are concerned about the remaining requirement that “the consent must include the name of the ineligible entity receiving the learner information and describe how the entity intends to use the information.” Often grants and exhibit support is still being confirmed up to a few days prior to an event; consent is often gathered at the time the learner registers for an event. It will be difficult to wait until all support is known before obtaining consent.
Recognized Accreditor (state/territory medical society)			Possibly challenges with the last portion "describe how the entity intends to use the information." While I believe that the entity can give a general description, the extent as to how they use the information cannot be controlled once the information is released. I understand the authorization of releasing names, just uneasy about having control over how they use the information in the future.
Recognized Accreditor (state/territory medical society)			The accredited provider must be aware that non accredited CME's may not be presented between accredited CME. I have participated in ACCME accredited activities (not PRMA providers) where apparently the CME provider in a joint providership allowed non accredited CME during lunch time of a hole day activity.
Recognized Accreditor (state/territory medical society)			There may be scenarios in which an eligible diagnostic lab becomes ineligible (becomes a diagnostic lab that markets/sells proprietary products) or a pharmacy that does not compound becoming a compounding pharmacy.
Recognized Accreditor (state/territory medical society)			Tracking down consent from all learners. How to accomplish this in an efficient way.

What comments or questions do you have about Standard 2?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME		There is a need to clarify the term “learner” as used in this document. Suggest that the ACCME consider efforts of the ACEHP and an associated task force, working on standardization of terminology in healthcare CPD. If the current wording is retained, would a blanket consent for a group of ineligible entities meet the spirit of this standard (consent to share with all exhibitors at XYZ conference), rather than consent to include every specific company name? This presents many operational challenges, without seeming to add clarity or value to the learner.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	2.2: Faculty must not promote or seek products or services that serve their professional or financial interests... we sometimes have faculty development speakers and speakers addressing professionalism or systems-based topics that will refer to their websites or their books. I’m assuming those types of plugs will no longer be allowed. What if we give away a speaker’s book and then have a book-signing? Will that be in compliance?
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Another downside of enactment of this rule is that the ACCME will be putting yet another burden on the provider to get consent from every learner to share his/her name with the exhibitor. In addition, it is ridiculous to require the provider to “describe how the entity intends to use the information,” when it is obvious the information will be used for sales purposes. This is a time-consuming managerial challenge, particularly for small CME staffs, who can barely keep their heads above water as it is. The ACCME is treating learners like children and, quite frankly, the learners and faculty we interact with resent, and often express anger at, the raft of restrictions the ACCME has put on accredited CE.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Do products/services include referrals? As publishing companies are considered eligible entities, would textbooks be considered eligible educational material? Can textbooks be used as supplemental resources for MOC and syllabi? If yes to these questions, can authors of the textbook also be faculty members?
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Standard 2 is clear and concise.

What comments or questions do you have about Standard 2?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Thank you adding #3. This has been an unspoken rule but can create confusion. It makes sense that it is unprofessional and unethical to give out our participants' information but having the standard in writing helps.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	We appreciate that the verbiage relays the expectation that the education is non-promotional, regardless of whether the products or services are of a commercial interest/non eligible entity.
Accredited CE provider	ACCME	Insurance company/managed-care company	Would this prohibit speakers from being able to talk about the content of their books and then have a book signing later?
Accredited CE provider	ACCME	Nonprofit (other)	2.3 clearly has unintended consequences and should be removed.
Accredited CE provider	ACCME	Nonprofit (other)	Appreciate the new Standard title. Very clear.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	- Because of the rapid pace of significant developments and advancements in hematology, which often are the result of collaboration between researchers and industry, ASH remains concerned that ACCME's interpretation of certain of its policies is inconsistent with ASH's ability to provide the optimal accredited continuing education and is more restrictive than necessary to "protect learners from marketing and commercial bias," which is the stated purpose of the Standard. - The proposed standards are built around an old framework, not one that recognizes that therapies can now be "home grown" in academic institutions (CAR T cells, gene therapies, etc.) and that expertise in doing so should be shared. Implementing Standard 2, as proposed, would continue to limit the inclusion of cutting-edge science from accredited continuing education.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	- Please provide examples of what would be required to demonstrate compliance
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	• Standard 2.1. should include references to the exclusions detailed in Standard 3.2.a-c.

What comments or questions do you have about Standard 2?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	2.1 - We concur with the addition of “owners”, along with employees, as those whose participation in accredited CE may occur in limited circumstances.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	2.3 If the current wording is retained, would a blanket consent for a group of ineligible entities meet the spirit of this standard (consent to share with all exhibitors at XYZ conference), rather than consent to include every specific company name? This presents many operational challenges, without seeming to add clarity or value to the learner. 2.3 By including requirement “each time the data is shared” within 2.3, will lead to significant process changes for many eligible entities. Throughout the year, multiple ineligible entities request mailing lists, which is conducted through very detailed process to ensure members aren’t negatively impacted and mandating this requirement would require a lot of unnecessary time to fulfil this requirement. Appears to be another area where ACCME is overstepping their role and specifically with “each time the data is shared” it will directly impact our members, which they could easily become frustrated with us asking them for permission multiple times. Processes should be managed/developed by the eligible entities as they know their members more than the ACCME and understand the administrative work it takes to complete certain tasks. The administrative burden as well as costly tech in order to accomplish this makes 2.3 unreasonable. Need to clarify the term “learner” as used in this document. Suggest that the ACCME consider efforts of the ACEHP and an associated task force, working on standardization of terminology in healthcare CPD.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Clear what the standard is about; will be easy to explain.

What comments or questions do you have about Standard 2?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Currently, it is common practice for some form of the overall attendee list at a large convention or meeting to be shared with exhibitors so they may provide attendees with information about activities at the meeting. Since exhibitors could be ineligible entities, there is no reasonable way to maintain this practice and satisfy the revised Standard 2.3 as currently written. For example, even if a learner provided explicit consent to the sharing of name and contact information with exhibitors during the registration process (the most logical place to obtain consent), the explicit consent would need to be updated and revised each time a new exhibitor registered which is time varied (?) for the convention or meeting. Even for learners who provided explicit consent to share their data with exhibitors, the additional step of updating their consent would hinder the flow of helpful information. Exhibit space sales and sponsorship could decrease significantly if no pre-invites or follow-up could be made without obtaining explicit consent from all learners.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Faculty must not promote or sell products or services that serve their professional or financial interests during accredited education. Does this include their books? I think many books are helpful to learners regardless of being written by a faculty member. Sometimes an organizations bookstore may take several books (boxes) to set-up a mini bookstore at a conference. Does that mean these books must be checked to may sure no one is presenting who might have a book in the mini bookstore?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	How does ACCME recommend we handle the new request of what information is provided to marketing entities? Can it be listed as general or does it have to be specific to each entity?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	I like that you have included any promotion as part of this one - so no book sales after the talk ;)
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	In section 3, this is beyond GDPR requirements. Our Corporate support is not totally worked out before we open registration so we would not be able to list every ineligible entity that the data would be shared with

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Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Many organizations sell mailing lists, how will this be affected? Will there be further guidance for organizations on managing the consent process with ineligible entities?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Please see our full comments submitted to communications@accme.org.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The new language does a good job of providing a succinct description of the basic requirements for separating promotional content from education in items 2.1 and 2.2 (with the clarification of “products and services” in item 2.2).
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The new language does a good job of providing a succinct description of the basic requirements for separating promotional content from education in items 2.1 and 2.2.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The processes for Standard 2.3 should be managed/developed by the eligible entities within already existing legal parameters.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	There is a need to clarify the term “learner” as used in this document.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	There is a need to clarify the term “learner” as used in this document. Suggest that the ACCME use of a associated task force to work on standardization of terminology. If the current wording is retained, would a blanket consent for a group of ineligible entities meet the spirit of this standard (consent to share with all exhibitors at XYZ conference), rather than consent to include every specific company name? This presents many operational challenges.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Under eligible/ineligible entities, only the term ‘products’ is used. Does the term 'products' encompass the current CI language of 'goods and services'? Or is the intent that 'products' are only tangible items? Standard 2.2 notes 'products or services' which may imply that the term 'products' is not inclusive of 'services'. Please clarify.

What comments or questions do you have about Standard 2?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We suggest that names and academic or professional affiliations should be allowed to be shared with attendees for identification purposes, but not specific contact information such as mailing addresses, email addresses, telephone numbers, etc. without the consent of individual. learners. Also, we think there could be more clarity around "learner." Is that someone who is claiming CME credit, or does it apply to all meeting attendees regardless of CME?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We support offering learners the opportunity to opt out of receiving mailings or other communications from “ineligible entities.” We believe this is most efficiently accomplished by asking participants prior to taking part in the educational activity if they are willing to receive these communications. Included in this communication could be potential goals “ineligible entities” may have in reaching out to them, including marketing, invitations to company events, engagement in focus groups, etc.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	While we understand this standard is attempting to remove a physician’s mis-knowledge to which they are agreeing, the specific instructions of adding individual entities in the consent will add an unnecessary layer of work for providers and physicians, harming the smaller, understaffed, and underfunded providers.
Accredited CE provider	ACCME	Publishing/education company	• Are registrants for a conference considered learners? • Are only those who request credit considered learners? • If a registrant list is to be shared with exhibitors as part of their fee for exhibit space, can a blanket consent for sharing with all exhibitors listed in the conference program be obtained at time of registration?
Accredited CE provider	ACCME	Publishing/education company	• Q: If an RFP for commercial support from an ineligible entity designates a disease state or focus on the RFP, is that considered “influence?”
Accredited CE provider	ACCME	Publishing/education company	Are ineligible entities permitted to disseminate Requests for Proposal, Calls for Grants, etc.? If so, do any limits or restrictions apply? Should it be limited to asking for grants on a general topic? Can it ask for grants focusing on a specific topic? Can it ask for a specific type of activity, such as a satellite symposium or an online monograph? Can it identify educational gaps and intended audiences?

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Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	Does this mean that we cannot have advertisements for other accredited education visible on the same screen as the education for a webinar?
Accredited CE provider	ACCME	Publishing/education company	In 2.2, does "products or services" include websites? If yes, might want to add that term specifically for those pushing memberships or such on their website.
Accredited CE provider	ACCME	Publishing/education company	In the proposed 2.3 - "this consent must include the name of the ineligible entity receiving the learner information and describe how the entity intends to use the information" places an undue deferred responsibility onto accredited providers - what if the ineligible entity lies to the provider as to their intended use? what if they "pull a Cambridge Analytica" and use the information later in ways exceeding those originally consented to? It is an undue standard to apply the potential future, unforeseen bad actions of a third party back to the accredited provider.
Accredited CE provider	ACCME	Publishing/education company	Standard 2.2: Provide clarification and examples about promotion and marketing.
Accredited CE provider	ACCME	Publishing/education company	The inclusion of 2.3 is interesting as global privacy laws are being developed that apply to all entities with regards to the distribution of marketing/sales materials particularly electronic. We have had this policy in place for more than 3 decades and if ineligible entities want to continue their interactions with learners, then they have to gain permission and the contact information directly. Partnering with lead retrieval organizations enables attendee-approved badge scanning on exhibit floors. Indirectly, this policy creates an environment where the booth representatives have to work and interact with interested learners rather than relying on the meeting organizers to provide the information.
Accredited CE provider	ACCME	Publishing/education company	There is a need to clarify the term “learner” as used in this document. Suggest that the ACCME consider efforts of the ACEHP and an associated task force, working on standardization of terminology in healthcare CPD, to help ensure providers implement standards with consistency.
Accredited CE provider	ACCME	Publishing/education company	There is a need to clarify the term “learner” as used in this document. Suggest that the ACCME consider efforts of the ACEHP and an associated task force, working on standardization of terminology in healthcare CPD.
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Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	"Accredited education must be free of marketing or sales of products or services. Faculty must not promote or sell products or services that serve their professional or financial interests during accredited education." Would this include products or services such as books/advocating for referrals to a center or hospital? Would patents and royalties be prohibited? There is a need to clarify the term “learner” as used in this document. Suggest that the ACCME consider efforts of the ACEHP and an associated task force, working on standardization of terminology in healthcare CPD. If the current wording is retained, would a blanket consent for a group of ineligible entities meet the spirit of this standard (consent to share with all exhibitors at XYZ conference), rather than consent to include every specific company name? This presents many operational challenges, without seeming to add clarity or value to the learner.
Accredited CE provider	ACCME	School of medicine	“Faculty must not promote or sell products or services that serve their professional or financial interests during accredited education.” – Is this standard limited to discussions related to relationships with ineligible entities, or would this include discussing procedures done at a faculty member’s hospital? For example, we have a few faculty members who are prominent in the field of immunotherapy. Would discussions of their hospital’s immunotherapy program be off-limits (since they could potentially benefit from more patients)?
Accredited CE provider	ACCME	School of medicine	2.3 will not affect us; our institution already requires that & it has not been an issue for us to enforce.
Accredited CE provider	ACCME	School of medicine	For #3, does that mean we cannot distribute a registration list (names, city, state) to learners if exhibitors are present, as they could take a copy of the list? Or does it mean that in order to distribute a registration list we have to get the permission of each learner to include their name on the list?
Accredited CE provider	ACCME	School of medicine	I particularly like the addition of Standard 2.3. Our institution does not provide that information as we work to comply with FCC standards and privacy considerations for our learners.

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Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	If an attendee list is provided in the packet and exhibitors register and get a packet with the attendees, would this need approval of each attendee before being placed on the list to be shared with all attendees. Many people enjoy receiving the list of attendees so they can see if there is someone they either know or want to meet during the presentation, however, if it gets into the hands of the vendors, I understand they may use this as a potential mailing or contact list.
Accredited CE provider	ACCME	School of medicine	In the past I have had several experiences with speakers "hawking" their book during their presentation and it never felt right to me. I'm glad to see this clarified. Also, it is good to have non-sharing of participant information with ineligible entities clarified. We don't do it, but the question gets asked occasionally. This gives more power to the denial other than that it is not our university's policy to share this information.
Accredited CE provider	ACCME	School of medicine	Nice to see the protection contact information of learners incorporated. This will give providers another source to reference when enforcing privacy policies already in place.
Accredited CE provider	ACCME	School of medicine	Standard 2.2 is very helpful. Our policy has been to carefully vet any situations that arise that might arise concerning “Faculty must not promote or sell products or services that serve their professional or financial interests during accredited education” it is helpful that this is spelled out in the standards. Does this include books that the faculty have authored? Could they be sold outside of the classroom? Standard 2.3 is excellent. We appreciate the intent to protect individual’s privacy.

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Accredited CE provider	ACCME	School of medicine	There is a need to clarify the term “learner” as used in this document. Suggest that the ACCME consider efforts of the ACEHP and an associated task force, working on standardization of terminology in healthcare CPD. If the current wording is retained, would a blanket consent for a group of ineligible entities meet the spirit of this standard (consent to share with all exhibitors at XYZ conference), rather than consent to include every specific company name? This presents many operational challenges and it would be a burden to the provider to constantly update the specific company name(s) as exhibitors are added through the course of planning and simultaneous registration activity.
Accredited CE provider	ACCME	School of medicine	This has come up in the past and so we are glad the guidelines are clearer now.
Accredited CE provider	ACCME	School of medicine	We had a few instances like this in the past. Thank you for making this clearer.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Hospital/healthcare delivery system	In regard to 2.1, a note referencing the exceptions noted in 3.2 for situations when employees of ineligible entities can influence content may be helpful.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (other)	Like 2.2 -- doesn't come up often but helps to have clarification. Like the note "Standard 2 applies to all accredited continuing education." Should help remove any confusion among organizations that don't accept commercial support that this standard applies to them as well.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	How do you define “owner” for an ineligible entity? Please provide an objective standard.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	ACC does not share learner contact information with commercial interests. We have always only provided attendee lists that includes name, city and state (only); therefore, I have no concerns with anything in Standard 2 as it states “The accredited provider must not share the names and contact information of learners”
What comments or questions do you have about Standard 2?			

Organization Type	Accreditor	Provider Type	Comments
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	Item #3, please provide examples of what would be required to demonstrate compliance.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Other: Electronic health record company	We agree with new language and currently support this by not allowing any sessions related to a sales or marketing opportunity to be accredited.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	I support the proposed changes to Standard 2. Please include the efforts of the ACEHP and an associated task force, working on standardization of terminology in healthcare CPD.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	In the past, the ACCME has tried to stay out of the legal space. We suggest that they take that approach here. Privacy laws are evolving, and not yet universally agreed upon, but laws already exist covering this issue which we have to adhere to.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	We have never (and would never) share non-aggregate learner information with supporters.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	Would this have an impact on those who might have to report for the Sunshine Act?
Accredited CE provider	Other: Academy of General Dentistry	School of medicine	I would assume the provider would need to demonstrate compliance with number 3?

What comments or questions do you have about Standard 2?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Other: Accreditation Council for Pharmacy Education	Nonprofit (other)	Add in Standard 2.1: "...except in the limited circumstances outlined in Standard 3.2."
Accredited CE provider	Other: ACPE	Hospital/healthcare delivery system	Overall, I think the term "free of marketing" will need to be more clearly described to prevent the unnecessary avoidance of conveying potential ancillary resources not specifically being endorsed by the educational activity.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Especially like and appreciate 2.3. I could see an issue as written though as 2.3 doesn't specify as to when the consent is to be obtained. Is it before the start of the education? Recommend that it before the start of the education.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Have concerns around Standard 2.2
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Not sure why you are taking the former information and remarketing as something new?
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Please clarify this statement: Faculty must not promote or sell products or services that serve their professional or financial interests during accredited education. Does this refer only to Ineligible entities? Sometimes faculty step right up to the line and appear to promote their private practices, books, etc. that do not fall under the auspices of ineligible entities but still "feel" like self-promotion.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	These are great changes!

What comments or questions do you have about Standard 2?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Advocacy organization			• Is the accredited provider required to receive consent for the learners for every individual activity or can consent be one time opt-in for all activities provided by the accredited provider? • Can an item (i.e. book published by faculty available for purchase online) be on display outside of the educational space, as long as not sold at the activity? • Are faculty still allowed to sell their own books in the exhibit space? Are faculty allowed to give their own books away as prizes in drawings at live activities? • Are faculty still allowed to sell their own books in the exhibit space? Are faculty allowed to give their own books away as prizes in drawings at live activities?
Advocacy organization			Are ineligible entities permitted to disseminate Requests for Proposal, Calls for Grants, etc.? If so, do any limits or restrictions apply? Should these be limited to asking for grants on a general topic? Can they ask for grants focusing on a specific topic? Can they ask for a specific type of activity to be proposed, such as a satellite symposium or an online monograph? Can they identify educational gaps and intended audiences?
Clinician/healthcare professional			Allow for teaching of innovative medical concepts.
Clinician/healthcare professional			I would add "in healthcare" here too. Step 3 is well done!
Clinician/healthcare professional			It is excellent.
Clinician/healthcare professional			The specificity of how an ineligible entity intends to use the information is absent. My presumption is that the intended use could be very broad.
Medical/healthcare association			Define learner in terms of meeting attendee versus just participating in an activity. What is explicit consent? opt in/opt out? The ACCME should not use broad definition of all meeting registrants when interpreting this standard.

What comments or questions do you have about Standard 2?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Medical/healthcare association			Since we already have policies in place that are acceptable to our members that basically address the concept the ACCME is proposing we don't believe this is a necessary addition to the current Standards.
Medical/healthcare association			There is a need to clarify the term “learner” as used in this document. Suggest that the ACCME consider efforts of the ACEHP and an associated task force, working on standardization of terminology in healthcare CPD. If the current wording is retained, would a blanket consent for a group of ineligible entities meet the spirit of this standard (consent to share with all exhibitors at XYZ conference), rather than consent to include every specific company name? This presents many operational challenges, without seeming to add clarity or value to the learner.
Other: Accredited CE provider, Continuing education accrediting body, and medical/healthcare association			There is a need to clarify the term “learner” as used in this document. If the current wording is retained, would a blanket consent for a group of ineligible entities meet the spirit of this standard (consent to share with all exhibitors at XYZ conference), rather than consent to include every specific company name? This presents many operational challenges, without seeming to add clarity or value to the learner.
Other: Answering both as accreditor and accredited provider.			WSMA generally supports the Standard, but requires more information in order to properly implement.
Other: CME/CE Consulting Services Company			Individuals register for a conference for various reasons: networking, exhibitor and sponsor communication, etc., not just solely to attend accredited CME sessions which can be a portion of the overall conference. Based on the standard, accredited provider units cannot share specific CME attendee information with ineligible entities without the required consent and documentation. Oftentimes, however, non-CME staff manage the selling of exhibits and sponsorships and are completely separate from the CME provider unit and therefore are completely firewalled from any of the CME components of the conference. As such, could those non-CME staff members provide an attendee list as part of the exhibitor package to those ineligible entities? Does the ACCME have any jurisdiction over this?

What comments or questions do you have about Standard 2?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: Consultant			Sometimes I feel like the little child in the fairy tale by Hans Christian Andersen who cries out how the emperor isn't wearing any clothes. It's clear to me that commercial bias is common in commercially supported CE today in the United States, especially when it comes to writing needs assessments. It's just that so many people are making so much money, it's really not in their interest to draw attention to it. The only reason I draw attention to it is that if I don't, the situation could get even worse. And that would not be good for patients.
Other: I am a faculty member/CME content provider/CME course director and my views do not necessary represent the views of my institution, the Medical College of Wisconsin			2.2 Does this mean that speakers who have authored books on their area of expertise cannot have those books available for sale before or after the presentation? Would it make a difference if the eligible entity made books available for sale rather than the speaker?
Other: Joint Provider			Would you clarify whether an author of a book can discuss research from that book without mentioning the book itself or title. That is unclear currently. While academic publications and research have always been a standard in medicine, more and more, clinical leaders are authoring their own books on the topic of their expertise.
Other: physician, patient, member of certifying board, member of educational academy			are we standing too close to the trees to see the forest? the whole structure of healthcare including medical research, primary health education, CME, Journal publications and marketing is saturated with commercial bias–the sale of drugs. My Academy teaches many non-pharmacological approaches we help patients, particularly those who are in the minority and may have idiosyncratic physiology.
Other: Publishing/education company			There is a need to clarify the term “learner” as used in this document. Suggest that the ACCME consider efforts of the ACEHP and an associated task force, working on standardization of terminology in healthcare CPD. If the current wording is retained, would a blanket consent for a group of ineligible entities meet the spirit of this standard (consent to share with all exhibitors at XYZ conference), rather than consent to include every specific company name? This presents many operational challenges, without seeming to add clarity or value to the learner.

What comments or questions do you have about Standard 2?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: Recognized accreditor and Accredited CE provider			If a provider uses learner nametags with barcodes that include learner contact information, then utilizes a barcode scanning system with vendors in an exhibit hall to obtain learner information, does that process meet the spirit of the standard? Is the provider obligated to (1) inform learners exactly which of their information (e.g., email, mailing address, etc.) is being shared with the barcode and/or (2) "require" exhibitors to ask learners to scan their badges (or, alternatively provide learners with an explanation that that is what the badge scanning system is for?)
Other: State Medical Society/Publisher/Accredited Provider/Recognized Accreditor			Relative to Item 2 - does the ACCME consider "house ads" in publications that promote education and other medical information resources to be "products and services"?
Patient, caregiver, member of the public			I think there could be further clarification about devices
Recognized Accreditor (state/territory medical society)			Although we agree with the requirement that the accredited provider must not share the names and contact information of learners with 'ineligible entities' without the explicit consent of the learner, we are concerned about the remaining requirement that "the consent must include the name of the ineligible entity receiving the learner information and describe how the entity intends to use the information." Often grants and exhibit support is still being confirmed up to a few days prior to an event; consent is often gathered at the time the learner registers for an event. It will be difficult to wait until all support is known before obtaining consent.
Recognized Accreditor (state/territory medical society)			Are exhibitors included in this?
Recognized Accreditor (state/territory medical society)			Clarification of educational books, products or services. Many speakers are published authors and may refer to their work. Also clarify referral to websites.
Recognized Accreditor (state/territory medical society)			Given the interest in proper disclosure, why do we not require this to include funding from federal, state, or event local institutional resources?
Recognized Accreditor (state/territory medical society)			Not sure how all pharmacies are not considered ineligible, since they sell prescription medication to patients, and that is their primary mission.

Standard 3: Identify, Mitigate, and Disclose Relevant Financial Relationships with Ineligible Entities

Is Standard 3 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	"Owner" needs to be better defined. If someone owns stock in a company, are they an "owner"? How much stock makes you an owner? "relevant to" and "related to" needs to be better defined. Is the content of the CME "related to" a certain medication if... - the class of medications is discussed but not the specific product of the financial interest? - the talk does not mention the class of medications but is about the same disease? - the talk is about a different disease in the same specialty?
Accredited CE provider	ACCME	Hospital/healthcare delivery system	3.4 The ACCME must be specific about how they expect providers to "mitigate relationships prior to the individual assuming their role."
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Glad to see the ineligible entities exceptions part of the Standards. Standard 3 #1b. Define financial relationships? Can you also define research relationship? Standard 3 #2b is unclear. Can you clarify this exception with examples or more detail? Standard 3 #3 How do we determine what is relevant? Can you define relevant?

Is Standard 3 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Item 1 - Please elaborate on the possible roles of individuals in control of content. 1-The ACCME considers “all persons in a position to control the content of an educational activity” to be individuals who have control of, influence over, or responsibility for, the development, management, presentation, approval or evaluation of the CME activity. These individuals are commonly referred to as presenters or planners, reviewers and approvers. a-Presenters include but are not limited to faculty, moderators, authors, teachers, medical writers. b-Planners, reviewers and approvers also include but are not limited to members of planning committees, advisory boards and/or CME/CE Committees, peer reviewers, and content reviewers. 2-The ACCME considers resolution mechanisms for Presenters to differ from those of Planners, Reviewers and Approvers. 3-To resolve conflicts of interest for Planners, Reviewers and Approvers and others with similar non-presenter roles who have relevant financial relationships, the ACCME expects providers to implement mechanisms that ensure independence in the planning, review and approval processes, prior to their involvement. Also include the following as this has been a common non-compliance finding. The ACCME expects providers to use the complete definition of a “commercial interest” in its communication requesting disclosure of relevant financial relationships to ensure the provider obtains the full range of commercial relationships.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	More guidance is needed to define how 'the provider' should determine 'relevance' of financial relationships. The Activity Director? An administrator? Someone else?
Accredited CE provider	ACCME	Hospital/healthcare delivery system	One small question on the exception for self-directed continuing education. Does that mean that case based regularly scheduled series like M & Ms or case discussions do not need to identify relevant financial relationships? That may be unclear to providers.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	We need clear definitions and examples of “basic science research” and “pre-clinical research”, “drug discovery”, etc. If the CME Provider staff does not have clinical backgrounds, how does the CME Provider determine compliance?

Is Standard 3 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (other)	Clarify Standard 3 2.b. – Is Standard 3.2b stating that a lecture can be provided by an employee of an ineligible entity if none of the lectures in the CE activity contain more than basic science research, or that the lecture provided by an owner/employee of an ineligible entity can't contain more than basic science research? Consider including a link to the COI Flowchart in Standard 3.4 (Mitigating relevant financial relationships)
Accredited CE provider	ACCME	Nonprofit (other)	Providers should not be required to use the term "ineligible entities" when collecting disclosures, as this will likely cause unnecessary confusion. The definition "organizations whose primary business is producing, marketing, selling, or distributing healthcare products used by or on patients" should be sufficient. Also suggest including a minimum dollar amount to define financial relationships, versus the current language 'any dollar amount' defined as relevant. Allow those with financial relationships to determine which are relevant for various activities.
Accredited CE provider	ACCME	Nonprofit (other)	Standard 3 states that "the accredited provider is responsible for identifying relevant financial relationships between individuals in control of educational content and ineligible entities and managing these to ensure they do not introduce commercial bias into the education." However, section 3.1 states that the provider must "collect information from all planners, faculty, and others in control of educational content about all their financial relationships with ineligible entities within the prior 12 months." Since many faculty members work in multiple fields or in fields for which there are a wide range of issues/topics/etc., why would a provider be required to identify an irrelevant relationship?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	- S3 contains conflicting statements. "Financial relationships of any dollar amount…ineligible entity" (first paragraph of S3) and 3.2a imply that not all financial relationships are relevant; 3.3 states that relationships are only relevant if related to the topic at hand—which we already collect and mitigate. These items stand in conflict with 3.1, which states that all relationships must be disclosed, irrelevant relationships. Please provide additional clarity or guidance on rationale for collecting all versus relevant.

Is Standard 3 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	#2 and #3 should be switched, especially if we are asking for all relationships - we need to first identify the relevant relationships before someone is excluded. Maybe I am interpreting incorrectly! #2 - should 'relevant' be with 'ineligible entities? #4 - 'mitigate' sounds like lawyers need to be involved...
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	3.0 and 3.1 – Establish a reasonable threshold for "relevant financial relationships." 3.1 – Define the term "executive role." 3.1 – Recognize that changes in relationships during 12-month disclosure collection period change approaches to mitigation. 3.1 – Define what "others in control of educational content" means in addition to "planners" and "faculty." 3.2 – Define owner and employee. 3.2 – Clarify if owners are also able to participate in planning or as faculty in the three specific exceptions. 3.2a – Refine this statement to address that an activity that involves many content areas, but an ownership or employment relationship would only impact a small part of the content. 3.2 b – Clarify "basic science" in the second of the special use exceptions for employees of ACCME-defined ineligible entities. For example, does "basic science" apply exclusively to research that takes place before human testing of a product? Consequently, once testing moves to the human or clinical stage, will these previously exempted employees of ACCME-defined ineligible entities be prohibited from accredited continuing education? 3.3 – Address the circumstance where the content of an educational activity is wide ranging (e.g., during a professional society's annual meeting) and a planner or speaker only has a financial relationship in one area of the activity. 3.4 – Define options for providers to mitigate the relevant financial relationships of planners.

Is Standard 3 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	3.1 Recently many faculties are “comprehensive” with their disclosure, by including both “relevant” and “all other” relationships. We agree with providing relationships to educate the attendees but find it a problem for the provider to determine relevancy. Recently the AACR leadership studied these issues and feels that only “researcher” can determine what is relevant, as they are the ones who have knowledge of their research. The provider may also not have sufficient staff members and other resources necessary to research on the presenters’ COI and determine relevance for every presentation. 3.4 Disclose all relevant financial relationships to learners- AACR recommends that the disclosure be made to include relevant financial relationships with ineligible organizations relevant to the education and then include all other relationships separately. Attached is a suggested template developed by the AACR COI Task Force. This will increase transparency and help the learner in understanding the speaker’s disclosure.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	3.1 Would recommend adding an exception that if an accredited activity does not include any clinical recommendations and/or the accredited provider determines that there is no potential for conflict of interest, then it is not necessary to collect all of the financial relationships of those in control of content.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	3.1: Collect Information: We suggest that the second sentence be revised as follows: There is no minimum financial threshold; individuals must disclose all financial relationships with ineligible entities. Although, “with ineligible entities” is included in the prior sentence it would be good to include it in the second sentence for reinforcement and clarity. 3.5: Second and third bullets: insert “relevant financial” prior to “relationships” for consistency and clarity. Additionally, we suggest adding the last sentence before 3.6, “Learners must receive this information before engaging with the accredited education” just after the fourth bullet in 2.5 so that it is clear that learners must receive the disclosure information not only for absence of relationships but also to the section, “Disclose all relevant financial relationships to learners.”

Is Standard 3 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	3.1: Retain current requirement to disclose relevant financial relationships with commercial interests. 3.2.c: Edit to "when they are participating as technicians to teach the safe and proper use of medical devices, do not recommend their purchase."
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Clarification on 5. d. as to where the statement that all relevant financial relationships have been mitigated should appear. Such as on the presentation's slides? As a part of the FI Index? Or all of them.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Defer to CMSS response
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Definitions (if any) required in the collection mechanism should be clearly articulated (e.g. who is in control of content, does partner refer to a personal relationship or a professional relationship or both, etc.). Modify the third sentence of the intro to Standard 3: "Speakers, planners, and any others in control of educational content must identify those relationships disclosed that are relevant to the talk/activity for which they are engaged." This should take the place of "The accredited provider is responsible for identifying" Are journal-based CME activities exempt from Standard 3 as noted in the current SCS FAQs? http://www.accme.org/faq/for-journal-based-cme-activity-do-i-need-collect-information-about-relevant-financial If you are creating a journal-based CME activity, the ACCME does not expect you to identify and disclose to learners the relevant financial relationships of the article's authors and editors or to resolve their conflicts of interest.

Is Standard 3 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Definitions of the terms "owner" and "employee" are needed to ensure compliance. Given the number of enduring activities, and the one to two year planning for large conferences, we recommend that the phasing in should be at least 18 months, preferably 24 months for full compliance. Education/guidance on means to obtain such disclosure in ways that will lesson burden on faculty and providers is requested. Would it be acceptable to ask planners/faculty to indicate which relationships they see as being relevant to the content of an activity (from the overall list they submit yearly)?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Does contracted research include 'principal investigators of research at academic institutions? Suggest clarification on the term 'contract research'; the term is not consistently used in the field. If the content of the accredited activity could in no way be related to products/business lines of ineligible entities (for example, a leadership course), do providers still need to collect info about ALL relationships with ineligible entities? 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 relationship 'less severe' versus 'resolve' them? Please define 'owner' of an ineligible entity. Clearly note if the exception for self-directed learner does NOT apply to case-based regularly schedule series (RSS).
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	For 3.5(d), we suggest the ACCME create a standard statement (like the accreditation statement) so that there is consistency across organizations. As a best practice, we also recommend that self-directed accredited continuing education also identify and mitigate relationships of staff CME planners involved.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	In statement about self-directed CE, it says “In these cases, accredited providers do not need to identify, mitigate, or disclose relevant financial relationships.” This needs to be further explained as it will create confusion for providers about their responsibilities.

Is Standard 3 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Please see our full comments submitted to communications@accme.org. We are concerned that the level and nature of scientific evidence and of eligible individuals is not clear as noted in our full comments.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	See our comments provided under eligibility. #4 was cut off due to space limitations. Please see the comment here: 4. It is unclear which holds supremacy, the definition of ineligible entities or the examples. The advertising, marketing or communication firms do not appear to meet the definition as we previously would have interpreted it (since their products are not prescribed or physically used on a patient). By including these organizations in the definition, SAGES opines that ACCME has placed a huge burden on providers as we attempt to determine which entities fall into this category, because ACCME has broadened the expectation of ineligible entities so far.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Standard 3.2 Ownership/Employee: Defining “ownership” is difficult here. Does that require a majority shareholding in the company to be considered an owner? What about an individual who owns a patent on a product and receives royalties the rest of their life? We have rejected many individuals because of their affiliations with ownership even though they are still able to provide unbiased scientific information for educational purposes with parameters in place. The three exclusions ACCME currently has in place are helpful to allow some of our top experts present, even though they have ownership/employment in a commercial interest but are within the rare exceptions. We are a small niche specialty so many of our faculty will have affiliations and don't want a red flag to be sent if we fall within those rare exceptions and review and resolve appropriately.

Is Standard 3 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The revisions to this standard with regard to identification of relevancy will be nearly impossible to administer for specialty societies. With over a thousand individuals providing disclosures for one activity alone, the onus is on the individual making the disclosure to identify what is relevant (per current ACCME standards and definitions). Only that individual knows exactly what content will be covered in their presentation AND knows the products/services of the organization with which the relationship exists (especially since many of these are small, obscure start-up companies). ACCME considers content about specific agents/devices, but not necessarily about the class of agents/devices, and not necessarily about the whole disease class in which those agents/devices are used, to be relevant – that is an incredible amount of detail for a COI reviewer to be able to discern. It would not be reasonable to ask staff or another volunteer to research all of the hundreds of companies (and their parent companies) to fully understand their offerings AND to know enough about the details of every presentation to be able to identify relevancy. Instead of requiring that the provider determine the relevancy of all relationships, specify that (1) all relationships should be disclosed; (2) the discloser would identify which relationships they believe are relevant to their presentation; and (3) the provider performs a high-level review of the relevancy assignments.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We recommend that ACCME incorporate the existing related Journal CME policy into this standard. We recommend that the responsibility for determining “relevant” relationships remain with the person disclosing. If the financial relationship is irrelevant to the CME activity, it shouldn’t be disclosed.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We see this as a significant change that requires time to properly interpret and implement particularly given staffing resources of smaller organizations such as ours which speaks to the roll-out phase duration. Given the number of enduring activities, and the one to two-year planning for large conferences, we recommend that the roll-out should be at least 18 months, preferably 24 months, to full compliance.

Is Standard 3 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We suggest more definition about how providers are supposed to assess relevance. We do not agree that disclosures are only relevant if the content is related to the business lines or products of “ineligible entities”. There are many instances when disclosures are relevant to the content, even if the related organization is not an “ineligible entity” and should be disclosed to the learner. Currently, when an ACCME provider conducts the self-study, the ACCME asks the provider to remove any disclosures that are not commercial interests. Based on these new standards, it appears that this would be the same process. We feel strongly that if a presenter discloses something, it is likely relevant, even if it is not a conflict related to a commercial interest/ineligible entity. None of these changes to the disclosure process should be approved until AAMC’s Harmonization of Financial Disclosure Reporting in Biomedical Journals initiative is complete and the final recommendations from the working groups, in which ACCME has participated as a member, are made available. Once is the final recommendations are clear, the CME community should have an opportunity to contemplate changes to the current requirements. It would benefit the continuing education community and the medical/research community as a whole to achieve harmonization of disclosure requirements.
Accredited CE provider	ACCME	Other: Accreditation Management, CME Consulting, and Joint Providing Company	Standard 3 says to collect disclose of all relevant financial relationships of planner and faculty. Currently, isn't it required to ask for RFR from faculty only as they relate to the topic? Am I wrong or is this a change? It says to mitigate relevant financial relationships. Shouldn't it say to mitigate conflicts of interest? We check to see if RFR are a COI, then we mitigate the COI, correct. If not a COI, we don't have to mitigate.
Accredited CE provider	ACCME	Other: malpractice insurer	For the requirement "Disclose absence of relevant financial relationships," please clarify if compliance can be met by a single statement. For example: No one involved in this accredited educational activity reported relevant financial relationships. Or if all individuals need to be listed, as when they disclose. Small point but a little confusing.

Is Standard 3 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Other: Teleconferencing Medical Education Company	Again, the wording needs to be more specific and defined. The added burden is astronomical.
Accredited CE provider	ACCME	Other: University - not a school of medicine	Relevant Financial Relationship is sufficient.
Accredited CE provider	ACCME	Publishing/education company	3.1 - "known financial relationships of their spouse or partner" - should this say "domestic partner" to clarify the ongoing issue under the current SCS with regards to "does that mean 'business partner'?" 3.1.b - Please clarify the objective standards for determination of "ownership interest" when "stocks and stock options" exist as separate and distinct descriptions. 3.1.b - Please clarify the objective standards for determination of "executive role" when "consultant", "employee", and "owner" are listed as separate and distinct descriptions
Accredited CE provider	ACCME	Publishing/education company	In 3.2: add "owners or" to the last sentence of the paragraph. "There are three exceptions to this exclusion--OWNERS OR employees of ineligible entities can..." In 3.4.b: what does "document the steps" require? Is a spreadsheet listing the steps enough or do I have to include copies of emails sent and received? In 3.5: define what "receive" this information "before engaging" with the activity mean. We have been told a CE info tab for an online activity is acceptable, but choosing to click a tab does not qualify as "receiving" the info, and allowing the participant to decide when they will open that tab, if at all, does not equal "before engaging". Need clear info on what is acceptable and what's not.
Accredited CE provider	ACCME	Publishing/education company	Its unclear which examples of financial relationship are resolvable vs those considered as “owners”, and thus must be excluded. Clarity specific to executive role and ownership interest, in particular would be helpful.

Is Standard 3 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	Standard 3.1 and 3.3: It would very challenging for us to collect all relationships and identify relevant ones as we have over 7,000 contributors. We spend a tremendous amount of time reviewing disclosures to determine if there is a COI, which we understand is necessary to ensure independence. However, we rely on the contributors to best determine relevancy. We believe the current system works well. Faculty understand the clinical area of their relationships and can make the determination as to what is relevant based on the subject matter of the content. If we were required to review all relationships for relevancy, the time spent on disclosure review would increase significantly due to the much larger number of relationships reported. ICMJE has recently proposed changing their form from 'relevant' to 'related' in order to address this issue, and even they are asking their contributors to categorize in order to assist journal editors in sorting through disclosures. Exception for self-directed activities: Why is this learning activity held to a different standard? There is as much of an opportunity, if not more, for commercial bias to be present. The learning taking place will be impromptu and will not allow for review of the content prior to the start of the activity. If this learning occurs as part of a group, no disclosure is required from those participating. In addition, there is not likely to be provider representation to take action if bias presents itself.
Accredited CE provider	ACCME	Publishing/education company	The revised standards commentary related to "Mitigate" states "The expectation hasn't changed, only the term used to describe it." This is confusing. If the expectation has not changed, what the is the intent of changing the word? Mitigate and Resolve are not synonymous.
Accredited CE provider	ACCME	Publishing/education company	What is ineligible?- How broadly or narrowly is this defined. Question- in radiology education would all professors and their spouses and partners be barred from teaching if they own for example shares in GE, Siemens or other large multinationals who make every type of imaging equipment? What if a spouse or partner inherits some of this stock. Would the professor be banned from teaching for 12 months? This cannot be fixed by a fine tuning of the standard.

Is Standard 3 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	While the CME Coalition supports the disclosure to the provider by planners and faculty of all relationships, we do see this as a significant change that requires time to properly interpret and implement. This speaks to the roll out phase duration. Given the number of enduring activities, and the one to two-year planning for large conferences, we recommend that phasing it should be at least 18 months, preferably 24 months to full compliance. Exception for Self-Directed: Need alternative wording for example (bedside, case conversation among peers). This is easily confused with case-based RSS activities. Perhaps: “spontaneous peer discussion of evidence and recommendations”
Accredited CE provider	ACCME	Publishing/education company	While we support the disclosure to the provider by planners and faculty of all relationships, we do see this as a significant change that requires time to properly interpret and implement. This speaks to the roll out phase duration. Given the number of enduring activities, and the one to two year planning for large conferences, we recommend that the phasing it should be at least 18 months. Preferable 24 months to full compliance. Exception for Self-Directed- Need alternative wording for example (bedside, case conversation among peers). This is easily confused with case-based RSS activities. Perhaps- “spontaneous peer discussion of evidence and recommendations"
Accredited CE provider	ACCME	Publishing/education company	Why would it be on the provider to identify irrelevant relationships when the faculty/planners are asked to provide all their financial relationships with ineligible entities within the prior 12 months? The standard should be limited to the provider identifying relevant financial relationships and taking action to mitigate them.
Accredited CE provider	ACCME	School of medicine	#.1 "prior to assuming the role" should be changed back to "prior to presenting". To get disclosure info requires they assumed the role of faculty for an activity.
Accredited CE provider	ACCME	School of medicine	#2 should say "owners and/or employees" and i would recommend also adding all the roles somebody can take in an accredited activity. This includes, authorship and reviewer.

Is Standard 3 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	2. A minor clarification would be helpful. Please provide clarification and/or examples to 'owners.' Does 'ownership' include intellectual property (e.g., patent rights, royalty payments)? One can imagine that aa faculty member may be an owner of intellectual property that is licensed to an ineligible entity but of course does not meet what commonly understood as the definition of "ownership" unless stock transfers have been involved. We anticipate that such faculty would be excluded from the definition of "owner". Also, does the transfer or purchase of any level of stock (e.g., one share) place one in the class of owners. Is that also true for stock that may be included in one's portfolio that are part of managed accounts and not a result of the individual's decision to purchase the stock? 3.4a. Re: Mitigate relationships prior to the individual assuming their role. Take steps appropriate to the role of the individual We are inquiring if the "prior to" represents a policy change – Please provide further clarification of the reference to 'prior'. Consider a faculty member who submits a disclosure during the planning process and a conflict is revealed, if the potential conflict is identified and a slide/content review by a non-conflicted member of the planning committee is performed prior to the start of the meeting, is that considered prior enough? If 'prior' mitigation is expected much earlier than this example, please provide examples of mitigation steps.
Accredited CE provider	ACCME	School of medicine	3.2 needs to be rewritten to allow for academic faculty who are strongly encouraged by their organization to create new companies while they remain active faculty and to allow local CME accrediting organizations to do the work we have agreed to do. I would ask the ACCME to reconsider the ability of these faculty to participate in CME and the local organizations ability to mitigate these conflicts. These will be the rules moving forward for many years, they should be written with consideration of the current and future landscape, not that of 20 years ago.

Is Standard 3 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	For Standard 3.2a and 3.3, “is not related to” and “is related to” are subject to individual interpretation. This ancillary guidance from the ACCME is much clearer: “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.” Misunderstandings would be clarified or at least decreased if “about specific agents/devices” were used in Standard 3 instead of “is related to.” “Is related to” is often interpreted to mean “about the general disease class,” when ACCME says in the ancillary guidance that that is not a problem as long as specific agents/devices of the commercial interest are not discussed/mentioned.
Accredited CE provider	ACCME	School of medicine	I am concerned about the exception for the self-directed continuing education. the language in that paragraph is not clear. I think that workplace learning that may be informal and/or spontaneous AND focused on clinical care and coordination does not require disclosure since planners and/or faculty may not be present -- is appropriate and low risk. The second exception- is not clear. When accredited providers serve as the source of information-- is unclear-- is this point of care CE or does this include web-based CE that can be accessed via mobile devices-- are the limitations for disclosure and resources just to ensure no links to ineligible entities?
Accredited CE provider	ACCME	School of medicine	I would like greater clarity in the definition of an owner and employee. If you are doing research for a company, what is that relationship? The whole area of spouse relationships is important but hard to get people to take that seriously when filling out disclosures. It feels like many overlook that response or minimize it like that would never impact their presentation as a faculty. We have to believe their responses and trust their integrity when filling out the disclosures.

Is Standard 3 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	Mitigate = legalese; resolve at least means something to the average person. I get where this is going with “mitigate” but really not common sense or common language. We can’t really “resolve” a bias or make it go away, so I like that we’re recognizing that. Mitigate is a better approach, to minimize the potential for biasing education, but I’m not sure it’s the right word. I imagine you’ll give us examples of possible “steps” to mitigate? Please include a clear, easy to find, definition of “financial relationship” (ex, 12 months, any amount, spouse or partner). Our institution really vets any relationships that providers have with any outside entity. Why can’t this be enough? So, if our institution has “signed off” on a research grant, why can’t we in accredited education be ok with that stamp of approval that the conflict is not biasing their job/work, when they are speaking or planning educational activities for our organization? It seems like we’re saying the lawyers and teams of people who handle and approve research grants aren’t good enough for CE, as if we’d know better somehow? Despite being inefficient, un-team-like, and pretty insulting, this contributes to faculty not understanding what CE is adding to their practice or value to the organization.
Accredited CE provider	ACCME	School of medicine	Please define the term 'owner'
Accredited CE provider	ACCME	School of medicine	This is a significant change that would require time to properly interpret and implement. Given the number of enduring activities, and the one to two-year planning for large conferences, we recommend that the phasing it should be at least 18 months, preferably 24 months to full compliance.

Is Standard 3 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	Was it intended to omit the current Standard 2.2 (An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity). Clarification is needed to address this matter. Was it intended to omit the current Standard 6.3 (The source of all support from a commercial interest must be disclosed to learners)
Accredited CE provider	ACCME	School of medicine	We see this as a significant change that requires time to properly interpret and implement. This speaks to the roll out phase duration. Given the number of enduring activities, and the one to two-year planning for large conferences, we concur that the phasing in should be at least 24 months to full compliance. Exception for Self-Directed- Need alternative wording for example (bedside, case conversation among peers). This is easily confused with case-based RSS activities. Perhaps- “spontaneous peer discussion of evidence and recommendations”
Accredited CE provider	ACCME	School of medicine	What is the intent of the ACCME in using the mitigate? Mitigate means "alleviate, reduce, diminish, lessen". Is this what we mean?
Accredited CE provider	ACCME	School of medicine	Would like a clear definition to determine who/what an ineligible entity is.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Hospital/healthcare delivery system	What is the definition or an example of ineligible entity?

Is Standard 3 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	• For item 3, it's unclear what documentation would be required to demonstrate that providers were identifying relevant financial relationships. Would the provider simply need to document the process in the Self-Study, or would there be additional requirement for each specific Performance-in-Practice file? • Similarly for item 4, would providers simply need to describe their processes in the Self-Study, or would there be additional requirements to document compliance with this requirement in each Performance-in-Practice file? • Standard 3.1b provides examples of disclosure categories but does not provide a strict categorization to follow. Society volunteers have provided consistent anecdotal feedback that it is a significant burden to ensure complete and accurate disclosures when categories vary across organizations. It would be a marked improvement if physicians and others participating in CME, journal publications and other activities that require disclosure could have a consistent approach to documenting relationships with companies. The AAMC Disclosure Harmonization Task Force has proposed a harmonized disclosure form and has been in discussions with the ICMJE as they are considering an update to their disclosure form as well. The CMSS Task Force on Disclosure Harmonization also supports a single source of disclosure. An ACCME endorsement of a harmonized disclosure form would greatly increase the likelihood of its wide adoption, to the ultimate benefit of learners.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	While ACC supports the disclosure to the provider by planners and faculty of all relationships, we see this as a significant change that requires time to properly interpret and implement. This speaks to the roll out phase duration. Given the number of enduring activities, and the one to two-year planning lead time for large conferences, we recommend that the phasing for implementation should be allow 24 months to full compliance.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Other: academic medical center	See "eligibility" above. If it were clear what problem you're trying to repair, then suggested modification might be possible.

Is Standard 3 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	3.3 - This may be burdensome for smaller CME programs (hospital based) as they often have a very limited staff and do not have the clinical expertise to know when a relationship is relevant or not. Hiring or consulting an expert could be costly and the resources may be limited. It is hard to get clinicians to fill roles to review content, so adding this in addition could deter clinicians from volunteering all together.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	ACCME should provide guidance to providers on how to ask about specific financial relationships that bring a benefit to the presenter (See 2.2)
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	1. Please add language regarding refusal to disclose, as it appears in the current SCS. We frequently cite this standard to our planners, faculty, etc. when they fail to submit their disclosure to us in a timely planner. Citing a standard that explicitly states that they will be disqualified carries more weight than someone from our office informing them of the consequence. 2. Standard 3.5 – Please clarify how disclosure of the absence of relevant financial relationships “either individually or as a group” will work. If the intent is to enable to the provider to state “All planners have no relevant financial relationships to disclose” then I think you need to include a requirement that the names of all of these individuals need to be provided to the learners.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	Does not mention that employment of a spouse/partner is not treated the same as employment of the planner/speaker No mention of industry techs helping/assisting with demonstration / trouble-shooting of equipment (not serving as faculty). List other examples of self-directed so it isn't left to provider to determine
Accredited CE provider	Other: Accreditation Council for Pharmacy Education	Nonprofit (other)	- Define appropriate mitigation strategies - Remove exceptions

Is Standard 3 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Does contracted research include 'principal investigators of research at academic institutions? Suggest clarification as the term 'contract research'; the term is not consistently used in the field. If the content of the accredited activity could in no way be related to products/business lines of ineligible entities (for example, a leadership course), do providers still need to collect info about ALL relationships with ineligible entities? Please define 'owner' of an ineligible entity. Could an employee of an ineligible entity participate as a planner, if the content of the education is not related to the products of an ineligible entity. Clearly note if the exception for self-directed learner does NOT apply to case-based regularly schedule series (RSS).
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Need to go back to the term "Commercial interests."
Accredited CE provider			Including the term "mitigate" is a stretch - resolve accomplishes the same concept. Again, I feel a change is being entertained for change sake.
Advocacy organization			3.2. Please provide clarification or examples to 'owners.' Does 'ownership' include intellectual property (e.g., patent rights, royalty payments)? 3.2c. Please provide definitions and examples of "basic science research" and "pre-clinical research", "drug discovery", etc. If the CME Provider staff does not have clinical backgrounds, how does the CME Provider determine compliance? 3.4a. Re: Mitigate relationships prior to the individual assuming their role. Take steps appropriate to the role of the individual. – Please provide further clarification to 'prior'. If the potential conflict is identified and a slide/content review by a non-conflicted member of the planning committee is performed prior to the start of the meeting, is that considered prior enough? If 'prior' mitigation is expected much earlier than this example, please provide examples of mitigation steps.

Is Standard 3 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Advocacy organization			Standard 3 states that “the accredited provider is responsible for identifying relevant financial relationships between individuals in control of educational content and ineligible entities and managing these to ensure they do not introduce commercial bias into the education.” However, section 3.1 states that the provider must “collect information from all planners, faculty, and others in control of educational content about all their financial relationships with ineligible entities within the prior 12 months.” Since many faculty members work in multiple fields or in fields for which there are a wide range of issues/topics/etc., why would a provider be required to identify an irrelevant relationship? NAMEC suggests that the standard be limited to identifying relevant financial relationships.
Continuing education accrediting body			The section, Exception for Self-Directed Continuing Education, needs further elaboration on what constitutes self-directed CE that is not part of accredited CE. Additional examples would be helpful.
Continuing education accrediting body			We are concerned that the “eligible” vs. “ineligible” entities language will not be meaningful to the faculty whose relationships we will be requiring them to disclose. We feel that “commercial interest” remains a more useful term in this context. An alternative might be “ineligible commercial entity.” We applaud the use of “mitigate” as a replacement for “resolve.” However, the Standard does not give any guidance as to what mitigation steps would comply with the Standard. Consider expanding this section with examples of compliant mitigation strategies. While the proposed standard requires that providers inform learners that conflicts have been mitigated, it does not require a disclosure of how the conflict was mitigated. We believe that this information would be useful to learners and we support requiring that providers disclose it.
Ineligible Entity (commercial interest, such as pharmaceutical, device, life-science company)			Under 3.2 please expand on the definition of an "owner". Physicians/faculty who own stock in a commercial interest (ineligible organization) should still be able to plan/teach activities. The employee part of this is clear. But "owner" needs to be defined. Thank you.

Is Standard 3 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Medical/healthcare association			3.4b - provide information on the mechanism's providers are expected to use to mitigate relevant financial relationships.
Medical/healthcare association			Exceptions to exclusion is clear for employees, not for owners-need to clarify owners.
Medical/healthcare association			The AMA Council on Medical Education is concerned with the continued stipulation that the "accredited provider is responsible for identifying all relevant financial relationships." On the surface, this makes sense but it does not reconcile where the source of the information originates. As it currently exists, information related to relevant financial relationships is produced by the planner/faculty directly to the accredited provider. As written, this proposed change would make it the responsibility of the accredited provider to double-check the accuracy of the planner/faculty member and ensure that they are not withholding other relevant financial relationships. The Council does not believe that the accredited provider should be investigating or auditing the potential financial relationships of the planner/faculty, as conducting this work would be practically impossible for all but the largest accredited providers. The Council does not believe this to be the full intent of this proposed change and recommends revision to provide further clarity and direction.
Medical/healthcare association			While disclosure of ALL relationships sounds reasonable at first, the shift in responsibility for sifting through the list to find relevant relationships was a bridge too far for those who completed the Alliance survey. They would support collecting this information if the planner/faculty member would also indicate which relationships were relevant to content. While the provider would still have to review the total list, this would give them a place to start to connect the dots. Re "Exception for Self-directed CE": change current wording in example to "…spontaneous peer discussion of evidence and recommendations" to differentiate from case-based RSS activities.

Is Standard 3 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Medical/healthcare association			While the CME Coalition supports the disclosure to the provider by planners and faculty of all relationships, we do see this as a significant change that requires time to properly interpret and implement. This speaks to the roll out phase duration. Given the number of enduring activities, and the one to two-year planning for large conferences, we recommend that the phasing it should be at least 18 months, preferably 24 months to full compliance. Exception for Self-Directed- Need alternative wording for example (bedside, case conversation among peers). This is easily confused with case-based RSS activities. Perhaps- “spontaneous peer discussion of evidence and recommendations”
Nonaccredited CE provider			Clarify/reconcile 3.2.c with Standard 1.4
Nonaccredited CE provider			The revised standards commentary related to “Mitigate” states “The expectation hasn’t changed, only the term used to describe it.” This is confusing. If the expectation has not changed, what the is the intent of changing the word? Mitigate and Resolve are not synonymous.
Other: Accredited CE provider, Continuing education accrediting body, and medical/healthcare association			While the AOA supports the disclosure to the provider by planners and faculty for all relationships, we do see this as a significant change that requires time to properly implement. This speaks to the roll out phase duration. Given the number of enduring activities, and the one to two-year planning for large conferences, we recommend that the rollout should be at least 18 months, preferably 24 months to full compliance.

Is Standard 3 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: CME/CE Consulting Services Company			Standard 3.3 - It would be beneficial if the ACCME could provide greater context around the ACCME's standard of being "related to" as it pertains to the business lines or products of the ineligible entities. We see this as a frequent area of non-compliance with providers, and more guidance would be useful. Standard 3.4 - Accredited providers must mitigate relationships prior to the individuals assuming their roles. What mitigation mechanisms are recommended for planners with this update? Currently many accredited providers utilize peer review of planning decisions by qualified, non-conflicted planning committee members. In this case, however, a planner would have already assumed his/her role. What would be appropriate action to take prior to the planner "assuming their role?" Attestation Forms have previously been deemed a non-compliant resolution mechanism for planners, though this is an action that can be taken prior to a planner assuming his/her role. In 2016, the ACCME announced that Spouse/Partner employee relationships could be treated as relevant financial relationship, implementing a resolution mechanism to document compliance. We note this language is not overtly included in Standard 3, nor is it located within any policy or FAQ on the ACCME website, currently. Can we assume this ruling will hold true moving forward? If so, it would be helpful to include this language in the Standard?
Other: Consulting company; licensed clinician			What, if any role, can joint providers play? 3.1 and 3.3. Having to vet each disclosed relationship to determine its relevance will be a burden to many providers. This function can be very labor intensive and costly. Can the requirement be narrowed so that faculty, planners, etc disclose all relationships that relate to the content of the activity they are working on? 3.3. Please explain "related to". If a speaker has a relationship with biotech company A regarding ovarian cancer, but the activity relates to endometrial cancer, is the relationship relevant? If an author has a relationship with pharma company B regarding heart failure (HF) with reduced ejection fraction (EF) but the activity relates to HF with preserved EF, is the relationship relevant? It would be helpful for providers to have more clarity regarding how specific requirements for disclosure should be (eg, by therapeutic area or drug class).

Is Standard 3 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: I am a clinician-educator, board member of APPS, member of the Academic Consortium of Integrative Medicine and Health, and faculty provider for integrative medicine CME			Standard 3.2 implies that clinicians/researchers who receive support or grants from pharmaceutical companies et al cannot speak or plan continuing education, even if they do not promote the product/practice in a lecture. Similarly- will this apply for example to dermatologists and plastic surgeons who sell products and procedures in their office, physicians selling dietary supplements, or travel medicine providers offering medications and travel kits for sale? This should be made very clear if that is the case.
Other: Joint Provider			Primary accreditors should have the ability to mitigate relevant financial relationships and prevent commercial bias even with employees of ineligible entities. Further clarify that a sponsored talk specifically from a company rep about a product, clearly does not get CME. Using specific examples of what ACCME means and how it interprets actual events would be helpful for all these standards. Cases or help databases give people clear examples and allow all of us to follow the guidelines as intended, rather than be told by different primary accreditors different interpretations.
Other: Publishing/education company			While the CME Coalition supports the disclosure to the provider by planners and faculty of all relationships, we do see this as a significant change that requires time to properly interpret and implement. This speaks to the roll out phase duration. Given the number of enduring activities, and the one to two-year planning for large conferences, we recommend that phasing it should be at least 18 months, preferably 24 months to full compliance. Exception for Self-Directed- Need alternative wording for example (bedside, case conversation among peers). This is easily confused with case-based RSS activities. Perhaps- “spontaneous peer discussion of evidence and recommendations”
Other: State Medical Society/Publisher/Accredited Provider/Recognized Accreditor			Please include whether a founder should be excluded from controlling content or participating as planners or faculty in accredited education.

Is Standard 3 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Recognized Accreditor (state/territory medical society)			• Include the clarification/examples of those in control of content in the Standard (https://www.accme.org/faq/what-are-examples-those-control-content-described-standard-for-commercial-support-scs-21) • Define “Mitigate” thoroughly, why mitigate is more meaningful than resolve. • Include example or flowchart of what the process of mitigating would be. • Possibly link to the updated flowchart from the standard.
Recognized Accreditor (state/territory medical society)			3.1: If it is the accredited provider’s responsibility to determine which relationships are relevant, then additional information to collect should be added to the Collect Information section. Add a 3.1 c., such as – “The specialty area(s) of the ineligible entity related to the financial relationship.” Or “The specialty area(s) and health care good(s) or service(s) of the ineligible entity related to the financial relationship.”
Recognized Accreditor (state/territory medical society)			Everything was very clear with the exception of the "self-directed learner". More clarification would be helpful as accredited providers plan RSS activities.
Recognized Accreditor (state/territory medical society)			foresee potential confusion related to the new information on self-directed learning. Other than that, language seems clear.
Recognized Accreditor (state/territory medical society)			I suggest item number 4 give more concrete examples for clarity. Also, the terminology "ineligible entities" need to be revised to a more user-friendly term.
Recognized Accreditor (state/territory medical society)			Is it still valid not to collect RFRs when the educational content does not relate to products or services of any ineligible entity? Will the ACCME flowchart change? Unclear from "Collect information from all planners, faculty, and others in control of educational content about all their financial relationships with ineligible entities within the prior 12 months."
Recognized Accreditor (state/territory medical society)			Just from the name given to the Standard 3, the word "mitigate" raised a red flag for the suggested meaning of the word is too soft. I suggest any time the word "mitigate" to be substituted by "settle" or even keep "resolve" which have a stronger meaning.

Is Standard 3 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Recognized Accreditor (state/territory medical society)			May need a better explanation of "owner."
Recognized Accreditor (state/territory medical society)			Should discuss financial relationships of spouse/partner in greater detail here, as they are resolvable if direct employee of "CI" (Standard 3.1 or 3.2)
Recognized Accreditor (state/territory medical society)			Strike the word mitigate as it is a poor substitute. It does not cut it to express the true meaning of what needs to be done in terms of resolving conflicts of interest.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider		Nonprofit (physician membership organization)	It is complicated for staff without medical knowledge to sift through all the data provided to determine relevancy. It will require greater reliance on the outside volunteers to identify what is relevant.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	3.1 requirement for accredited providers to collect ALL financial relationships vs. those that are directly relevant to the content – and then the accredited provider determines which relationships are relevant; I feel this will be a time resource burden and do not see the benefit; I think it should still be allowed that the individual involved identifies what they feel is relevant to their role. If this is adopted, I envision providers collecting all relationships and then developing a form/process to go back and ask the individual which relationships are relevant --- will this be acceptable and if so, why create an extra step in the process?
Accredited CE provider	ACCME	Hospital/healthcare delivery system	As written, the proposed change of soliciting ALL (not just relevant) financial relationship information from all planners, faculty, and others in control of educational content will result in an overwhelming burden on a program/department. Based on the 2009 IOM report titled, Conflict of Interest in Medical Research, Education, and Practice that states, “more than 3,100 physicians [were sampled], 94% reported that they had had some type of relationship with industry during the preceding year. These relationships were primarily the receipt of food in the workplace (83 percent) or drug samples (78 percent) (Campbell et al., 2007a).” While this data was published before the PhRMA guidelines were developed, knowing that such a large number of potential planners, faculty, and others who have control of educational content will likely have a disclosure requiring mitigation is a signal of more administrative work to come. Seeking all disclosures from spouses and partners in addition to planners and faculty will create an untenable situation that also has ethical implications. Will the spouse or partner report their own relationships, or will the planner or faculty report it on their behalf? Already stretched resources are likely to be shifted toward compliance tracking as opposed to developing innovative, just-in-time opportunities. Given that food (meals) an overwhelming majority of relationships, is it ideal to screen all people to find a few who may have a relationship con

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	As written, the proposed change of soliciting ALL (not just relevant) financial relationship information from all planners, faculty, and others in control of educational content will result in an overwhelming burden on staff. Seeking all disclosures from spouses and partners in addition to planners and faculty will create an untenable situation that also might have ethical implications. Will the spouse or partner report their own relationships, or will the planner or faculty report it on their behalf? Already stretched resources are likely to be shifted toward compliance tracking as opposed to developing innovative, just-in-time opportunities.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	At academic institutions, there is extensive medical research taking place, including clinical protocols and drug trials. Many of our faculty have invented products or treatments and are now considered 'owners'. This Standard would have a large impact on our institution's academic mission if we now exclude those faculty members with invention disclosures. In addition, this Standard will severely limit those faculty who are driving innovation from sharing cutting edge medicine in a CME event.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Having the accredited provider determine the relevance of financial relationships (3.3) could put an large administrative burden on the provider's staff. We are often not medical professionals, and I could see a lot of time spent on researching an individual's disclosure information to determine relevance. In 3.4a, mitigating financial relationships prior to the individual assuming their role is neither practical nor realistic. One main strategy we use to resolve (now mitigate) COI for speakers is to review their presentations to ensure that they are fairly balanced, and evidence based. We cannot do that before they assume their role as speaker (although we can have the strategy in place; perhaps that is what is meant)? Also, we sometimes have a difficult time getting financial disclosure information from our speakers/authors/planners as early as we'd like as it is now. Although it would be ideal to receive that information at the beginning of the planning process, sometimes is it simply not possible.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	How are we supposed to take steps to mitigate relationships of planners before planners even begin the planning process? That doesn't make any sense. If a planner is an expert in the field, but is conflicted, how can one demonstrate that a person has been restricted in what he/she can contribute before they have contributed anything? Our process for conflicted planners has been to pair that planner with a non-conflicted content manager who oversees content in the planning stages and attests to the lack of inappropriate influence. How can we know what conflicts will arise before any content is contributed? This requirement is unreasonable and untenable and will put an even heavier burden on already overtaxed CE providers. 3.5 Requiring providers to include in the disclosure process a statement that "all relevant financial relationships have been mitigated" is not necessary. This would be just one more time consuming, bureaucratic hoop providers must jump through to state what, if we have done our jobs well, has already been demonstrated. If relationships are disclosed, peer-review and non-conflicted content manager oversight has been employed, that is evidence enough that steps have been taken to mitigate bias. We are stating the obvious. What's more, our learners are encouraged in our evaluations to indicate if they detected bias and to name that bias specifically, so there are already multiple steps employed to "mitigate" influence of commercial interests.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	I think the standard is clearly written and makes a lot of sense. I think providers will need a lot of education about this standard. Sometimes we as providers do allow those in control of content to decide on the relevance of their relationship to their content and this is not really the right thing to do. Again, it is a great change but may cause some confusion for providers. Also, if you have the expectation that providers must use the definition of an eligible or ineligible entity in their mechanism for collecting information then please put this in the standards.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Implementing Standard 3 could possibly require CME departments to have at least one person on staff with clinical knowledge to determine relevant relationships. This would put a strain on CME departments that do not have staff with that background and small departments that do not have the budgets to add additional staff with a clinical background.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	It will be burdensome for Providers, particularly small ones to sift through all financial disclosures to select the relevant ones, Some faculty have a plethora of relationships!
Accredited CE provider	ACCME	Hospital/healthcare delivery system	It would be a monumental task for the CME office to determine the relevancy of ALL financial relationships faculty may have for an event. If the content of the presentation is not related to a service/ product of a commercial relationship, the faculty MUST identify that themselves. There is no point in making the CME office responsible to identify that relevancy, when the faculty knows this already. This does not seem logical, nor feasible for a CME office to manage ALL relationships.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Item 3 Putting the onus on the provider to determine relevance is an impossibility for most providers considering budget for CME FTEs and typical clinical knowledge of staff in most CME departments. One society that already does this has more than 1 FTE focusing solely on this responsibility.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Section 3.2 that addresses excluding owners or employees of ineligible entities and exceptions to that could cause confusion during the reaccreditation surveying process. It seems the exceptions are subjective and debatable.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	See above. Requiring all relationships to be disclosed, and then relevance determined by 'the provider' might be burdensome where contributors to activities have many relationships with commercial interests, but few are relevant to the activity in question. Where did I see that disclosures must be obtained by planners before planning commences. This is potentially problematic: there are times when the initial planners, as part of the planning process, decide to bring in additional planners. How can this be accommodated?

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Standard 3 #1b: Accreditors need clarification of financial relationships to make better informed decisions. Standard 3 #2b: Accreditors may not apply this exception and deny the activity because they do not understand what's allowed. Standard 3 #3 Accreditor unsure of relevancy and incorrectly evaluates a disclosure.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	The amount of time this will require of providers has the potential to be exorbitant. Office staffs are already as minimum as possible. Also, providers may not have staff with the clinical and science background needed to appropriately research and mitigate these relationships. Personally, I believe mitigation of all relationships should continue to rest on the proposed faculty. If an individual is capable of functioning as a faculty, he/she should be able to read definitions, interpret, ask questions of the provider and appropriately determine if the relationship is relevant and should be disclosed.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	The process of collecting every relationship and then having my staff identify which are relevant to the educational content related to the business lines or products of the ineligible entity, will be extremely time consuming and somewhat impossible to manage. We do not have content experts in all areas that know every company and entity out there. We imagine this would be someone's full time job looking up every relationship and researching every company to determine relevance. In addition, for our RSS, which are organized slightly decentralized from our department, the coordinators in this area will not able to do this. Therefore, this would fall back on my team and our limited resources.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Use of the term ineligible entities will entail extra attention to explaining what that term means on the disclosure form.
Accredited CE provider	ACCME	Insurance company/managed-care company	Most people do this anyway, but it is often difficult to identify all of the companies and determine if they are ineligible especially since most of them are not.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (other)	Currently, ACCME terminology and definition of a commercial interest (any entity producing, marketing, re-selling, or distributing healthcare goods or services consumed by, or used on, patients) is clear, succinct, and easy to include on a form used to collect disclosures. While the terminology ("ineligible entities") makes sense from an accreditation perspective, we anticipate confusion when collecting disclosures, due to the fact that "ineligible" refers to the ability of an organization to be accredited and not the ability of an individual with a relationship with that organization to control accredited continuing education. For example, some might interpret having a relationship with an "ineligible" entity would disallow them from participating in accredited continuing education, or others might have a relationship but assume it is not relevant to disclose because they do not identify having that relationship as making them "ineligible" from participating in accredited continuing education.
Accredited CE provider	ACCME	Nonprofit (other)	For Standard 3.5 consider defining "before engaging with accredited education" in Standard 3.5.d. Please clarify if disclosure needs to occur in advance of the course or can it be just prior to the speaker providing the lecture?
Accredited CE provider	ACCME	Nonprofit (other)	Regarding Sections 3.1 and 3.3, requiring providers to identify each disclosed relationship to determine its relevance will be a burden to many providers. This function is labor intensive and costly. Can the requirement be narrowed so that faculty, planners, etc. disclose all relationships that relate to the content of the activity on which they are working?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	- Collecting all disclosure information instead of relevant disclosures will result in staff having to determine relevancy and resolve accordingly. This adds another layer of staffing needs and energy expenditure on program managers, as well as requiring staff to make judgement calls on relevancy. While some programs are smaller and would be more manageable, our annual meeting has more than 600 faculty—this would be an undue burden. - The way S3 is written requires staff to have knowledge of the commercial supporters and enough subject matter expertise to make the determination of a relevant financial interest; this expertise is not always available to staff.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	"ALL financial relationships with ineligible entities." There are SO many entities that are not in either bucket of eligible or ineligible. I fear that I could be swamped with every book deal, every journal they edit, everything under the sun. Do you consider your list of ineligible entities complete? Or are we supposed to worry about other categories?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	3.0 – In the absence of "thresholds" for relevant financial relationships, all financial relationships will be relevant and require mitigation. Certainly, not all financial relationships should be considered equal. For example, a $1 share in Pharma X is not equivalent to a $1 million share in Pharma X. Coupled with the mandate to identify all biomedical company employees and owners, the potential strain on organizational resources could be debilitating and ultimately diminish the quality and quantity of accredited continuing education. 3.3 – The additional resources required to search, analyze, identify, and sort relevant financial relationships may overwhelm the resources of even the largest accredited providers. Given the additional burden of this Standard, providers will exclude all planners and presenters with financial relationships from accredited continuing education. If the ACCME's goal is to prohibit planners and presenters with financial relationships, they should so state explicitly.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	3.1 This change could place a much larger paperwork burden on planners, faculty and accredited providers. This could make it more difficult to recruit and work with faculty members. In addition, accredited provider staff may not have the scientific or medical knowledge sufficient to determine whether relationships are relevant. There is a risk that relevant relationships will be missed or inaccurately reported to learners if those disclosing the relationship do not indicate whether it is relevant.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	3.1: This requirement places a significant paperwork burden on planners/faculty if this information must be obtained, de novo, for each activity. Interest in being planner/faculty may decrease. 3.3: Many accredited providers currently lack staff with the type of clinical or scientific background needed to determine whether a relationship is relevant to the content of an activity when faced with a long list of relationships. The alternative of treating every relationship as relevant and taking universal steps to mitigate is also costly in time and effort, and disclosure of total lists of relationships to a learner without vetting may be seen as a breach of the privacy of the faculty/planner and is also less meaningful to learners.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Agree with the approach to collect all financial disclosure information and then list relevant relationships for each activity. My only concern is that for #3, the language should emphasize collaboration between the provider and speaker. Since the learners will be getting only the relevant relationships, the accuracy of this information is paramount, therefore the provider should not do it unilaterally. For 5 (d) concern that text that includes “ineligible entities” will not be understood by audiences. Define the term “Researcher.” Is it a PI or anyone who is even slightly funded on a grant?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	As proposed, Standard 3 presumes that accredited providers have an unlimited database to all potential “ineligible entities.” While there is no question that accredited providers have a wealth of information in this area, the administrative burden is excessive when those in control of content can share this information. If the goal is to truly police potential bias, having those in control of content sharing what they consider “relevant” and having accredited providers verify would be a more efficient approach.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Capturing ALL relationships will add significant administrative burden to accredited providers. Accredited providers may not have the staffing resources needed to take on this additional work. Accredited providers may lose faculty/subject matter experts based on this administrative burden as the faculty/SME do not have time to pull all the information together. This requirement will also enforce the outdated notion that accredited education is administrative and focused on what cannot be allowed. During reaccreditation, will surveyors need to review specific information in activity files to ensure compliance with this change? How much additional time will be required of surveyors to add this level of detail?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Collect information from all planners, faculty, and others in control of educational content about all their financial relationships with ineligible entities within the prior 12 months. There is no minimum financial threshold; individuals must disclose all financial relationships, regardless of the amount, with ineligible entities. Individuals must disclose regardless of their view of the relevance of the relationship to the education. If the faculty do not think something is relevant, they should not have to disclose it. If we allow learners to claim credit based on their honesty, why are we not trusting our faculty?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	If you force the determination of relevancy to be made by the provider, providers will have no choice but to provide blanket approvals or simple spot-checks – unless the ACCME is willing to foot the bill for the enormous amount of administrative oversight that would be required to research each company and their parent company and interview each faculty member to fully understand the depth and breadth of the topic to be covered.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Interpreting and explaining standards; making sure we update information in all places!!!

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	• In Standard 3.5d, a requirement to include a statement about mitigation creates more work for the provider and is more for the learner to read when providers are trying to streamline copy. What is the added value to the learner (versus what providers are currently doing)? • Need more information about self-directed CE. Description states "In these cases, accredited providers do not need to identify, mitigate, or disclose relevant financial relationships" which creates confusion for accredited providers about their responsibilities.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Oh boy, the burden on the provider is a lot. Investigating all of the information is a lot of work - great job security for providers. I hope it is acceptable for us to ask the submitter to provide details about how the content of their session/ talk, etc. is related to the relationships to use for this purpose.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Only in clarifying where the 5.d. statement should be present.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Please see our full comments submitted to communications@accme.org. We are concerned that the level and nature of scientific evidence and of eligible individuals is not clear as noted in our full comments.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Same as #2. It's also overkill. It's like trying to imagine every possible monetary situation and protect us from it.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Standard 3.1. Suggest ACCME maintains the status quo which requires those in a position to control the content of an educational activity to disclose relevant financial relationships. By requiring those in control of educational content to disclose all financial relationships with ineligible entities, ACCME risks creating an unreasonable burden on both the accredited provider and the individual making the disclosure. Given that modern professionals often have vast investment portfolios, the accredited provider would now be tasked with researching an exponential number of relationships to determine whether or not a conflict exists. The individual making the disclosure is better informed about whether the potential for conflict presents itself. The proposed changes will force eligible entities to dedicate increasing staff time to the investigation of these disclosures; staff time that many eligible entities are currently not suited for. This change also would seem to disproportionately affect those smaller accredited eligible entities who provide excellent quality activities but operate on a sometimes razor thin operating budget. ACOEM believes that there should be a level playing field for all eligible entities to participate. The proposed changes will also increase the work of the faculty and planners making disclosures because every accredited provider uses a proprietary tool to collect disclosures, there not currently being a central repository for disclosures, such
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Standard 3.3: Identify Relevant Financial Relationships: Does this standard change the way UHMS currently identifies and resolves (mitigated) relevant financial relationships? The proposed standard accredited provider must sort through and identify financial relationships to determine the ones that are relevant to the content or activity. This process may require resources not currently available to all providers, such as web searching skills. What about for the large meetings with 500-1,000 abstract presenters, etc to sort through. What additional steps will be required and how much trust can be put on the professional to understand and disclose accordingly.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The ACMG applauds replacing “resolve” with “mitigate” but we do not agree with the proposed new requirement for disclosure information from everyone in a position to control content about all of their financial relationships with ineligible entities. This would unduly put a burden on content providers and the ACCME accreditor as many subject matter experts are in academic practices focused on research and may have many pages of lists with eligible and ineligible companies and organizations listed that would need to be sorted to indicate those with eligible and ineligible entities against the relevance to the activity. The requirement that employees of ineligible entities cannot be planners or faculty is not new. The specific addition of “owners” is new, and the ACMG would like ACCME to define what constitutes ownership.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The burden of peer and staff review of all disclosures would be significantly increased especially with regard to knowledge about the large number of diverse ineligible entities and determining their relevance. The structure and format of documentation required to demonstrate determination of relevance and subsequent mitigation is requested at the time the standards are released.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The definition of owner needs to be clarified
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The identification and mitigation of ALL financial disclosures will definitely increase the workload of all providers and their volunteer committees. I question why the change is being made.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The provider may also not have sufficient staff members and other resources necessary to research on the presenters’ COI and determine relevance for every presentation.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The wording, “Financial relationships are relevant if the educational content is related to the business lines or products of the ineligible entity,” suggests that disclosures that are not relevant should be removed. In our experience, many speakers with financial relationships with ineligible entities disclose all relationships even if it is not directly related to the content as they want to make a full disclosure. This new wording would mean before we mitigate these disclosures, we would have to sort out which are relevant or not and in thinking of an Annual Meeting with over 1,000 speakers, this would be extraordinarily time consuming. As stated above, it is our view that if a presenter discloses something and deems it relevant, planners should also deem it relevant and mitigate all of those disclosures. This also increases the likelihood that speakers will have disparate disclosures across their work, which can lead to additional confusion for them and mistrust from learners and the community as a whole. Also, many accredited providers currently lack staff with the type of clinical or scientific background needed to determine whether a relationship is relevant to the content of an activity when faced with a long list of relationships. Treating every relationship as suspect and taking universal steps to mitigate is costly in time and effort, and disclosure of total lists of relationship to a learner without vetting may be seen as a breach of privacy of the faculty/planner.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	There will be a large burden placed on providers if the definition of an ineligible entity is expanded/unclear as is currently proposed. If people are now disclosing ALL relationships with ineligible entities and the definition is unclear, the provider will be required to do research into corporate and financial structures of organizations, which will take time and resources away from developing quality medical education content.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	This change could potentially have a huge impact for specialty societies. Currently, on the ACCME flowchart for disclosures, an individual discloses only relevant relationships. With this proposed change, the provider will then be expected to determine relevancy which means that the provider needs to understand the structure and products of each entity and their parent company, as well as have the proper knowledge of the content that will be covered in the presentation itself. For medical specialty societies that have hundreds or thousands of disclosures for any given scientific session, this would be challenging to administer and extremely difficult to implement.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	This requirement places a significant paperwork burden on planners/faculty. if this information must be obtained for each activity, interest in being planner/faculty may decrease. Many accredited providers currently lack staff with the type of clinical or scientific background needed to determine whether a relationship is relevant to the content of an activity when faced with a long list of relationships. Getting busy clinicians in practice to volunteer for this role will also be hard. The alternative of treating every relationship as suspect and taking universal steps to mitigate is also costly in time and effort, and disclosure of total lists of relationship to a learner without vetting may be seen as a breach of the privacy of the faculty/planner. Without defining the terms "owner" and "employee", it will continue to be difficult to ensure compliance with the requirements restricting the use of owners and employees
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We recommend that the determination of relevance remain with the discloser, because they are best poised to determine the relevance of the content they plan to develop. An additional approach would be for the ACCME to provide a regularly updated database of non-eligible entities and business lines that accredited entities could share with disclosers to help them determine relevance as they complete their CME applications. We feel this approach would help to ensure accountability and standardization among disclosers and providers.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We understand that some journals are now requiring authors to disclose ALL financial relationships with commercial interests, whether these relationships are relevant or not. As much as we believe in harmonization among organizations concerned with education of healthcare providers, the fact is that many CE providers simply don't have the staff to sift through 100s if not 1000s of disclosures to determine which are relevant. The ACCME's existing processes for identifying relevant financial relationships with commercial interests allow activity planners and faculty to dedicate their time to the creation of unbiased, meaningful CE content. Collecting additional disclosures would not contribute to the impartiality or relevance of an activity. The resolution/mitigation PROCESS is of greater importance when planning CE activities than the collection of more data on financial relationships. To increase harmonization with other healthcare educational entities, it may contribute more to the COI resolution process to require disclosure of relevant financial relationships in the prior 24 rather than 12 months. The incorporation into the Standards of the FAQ regarding participation of employees of commercial interests in the creation of CE activities is a good change. However, learning "whether or when" to use a device is part of learning its safe and proper use. Edit as suggested above.
Accredited CE provider	ACCME	Other: Accreditation Management, CME Consulting, and Joint Providing Company	If we try to mitigate the RFR vs the COI, it will be confusing.
Accredited CE provider	ACCME	Other: MEC	I believe no one is better than the speaker to determine if a financial relationship is relevant to the subject matter in their talk. I think many providers will list all financial relationships whether they relate to the topic at that particular course or not to err of the side of caution. This could be misleading and confusing to the learners.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Other: not-for-profit CME provider	The change from asking planner/speakers to disclose relevant to all financial relationships is likely to: 1. Discourage speakers who have relationships with ineligible entities unrelated to the program from agreeing to speak because of the added paperwork involved and just the idea that they are required to disclose the financial details of their lives that are not relevant. I would feel like I was not being trusted to Disclose properly. 2. Cause undue hardship on small organizations because of additional time and paperwork involved in reviewing materials and communicating with Faculty over relationships that are not relevant. 3. It is NOT clear what record keeping will be required by Accredited providers to make such decisions and how that may need to be provided to the ACCME
Accredited CE provider	ACCME	Other: State Medical Society	Amount of detail re: how resolution/mitigation was accomplished?
Accredited CE provider	ACCME	Other: Teleconferencing Medical Education Company	Within this standard, every aspect of all finances would need to be collected, organized and processed from all "planners, faculty and others in control of educational content". This task would be extremely daunting as this could end up being a huge undertaking and I believe many providers would have an extremely difficult time keeping up with this type of requirement. Also, this would cost providers even more time/money to fulfill as it's currently written.
Accredited CE provider	ACCME	Other: university	In addition to replacing “resolve” with “mitigate,” this requires APs to collect disclosure information from everyone in a position to control content about all of their financial relationships with ineligible entities for the prior 12 months. Historically, we only had to collect information about commercial interests related to the content of the CME/CE activity. The AP would have to sort through and identify financial relationships to find the ones relevant to the content or activity. This process may require human and other resources not currently available to all APs. When disclosing relevant financial relationships to learners, APs must include a statement that all RFRs have been mitigated. This will require a change to any area that has the disclosure statement listed. Once again, we would be required to change documents, web pages etc. all of which cost human resource and already stretched finances to achieve.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Other: University - not a school of medicine	Inclusion of ALL Financial Relationships is highly burdensome on the accredited provider. This requirement is still dependent on the cooperation of the planner/speaker.
Accredited CE provider	ACCME	Publishing/education company	1,500-character limit; about 250 words 3.1- This requirement places a significant paperwork burden on planners/faculty if this information must be obtained, de novo, for each activity. Interest in being planner/faculty may decrease. 3.3- Many accredited providers currently lack staff with the type of clinical or scientific background needed to determine whether a relationship is relevant to the content of an activity when faced with a long list of relationships. Hospital-based CME/CE offices are of particular concern- they may not have the current expertise nor the funding to hire clinical experts to do the web/Internet searching often needed to determine relevance. Getting busy clinicians in practice to volunteer for this role will also be hard. The alternative of treating every relationship as relevant and taking universal steps to mitigate is also costly in time and effort, and disclosure of total lists of relationship to a learner without vetting may be seen as a breach of the privacy of the faculty/planner, and is also less meaningful to learners
Accredited CE provider	ACCME	Publishing/education company	3.1.b - With "executive role" existing as a new description, when "consultant", "employee", and "owner" are listed as separate and distinct descriptions, and 3.2 applying to "owners or employees" - there appears to be enough ambiguity and inconsistency to create downstream confusion and compliance challenges.
Accredited CE provider	ACCME	Publishing/education company	3.4.b: depending on what is required to "document the steps", this could entail a lot more man-hours. Exception for Self-Directed Continuing Education: state this is less opportunity for commercial bias when the learner is in control of the content. I disagree. The learner does not have the vetting process that an accredited provider has for preventing commercial bias. Would suggest only Self-Directed Education that has the accredited provider serving as the source of information be eligible for CE credit.
Accredited CE provider	ACCME	Publishing/education company	If the expectation has not changed, what the is the intent of changing the word? Mitigate and Resolve are not synonymous.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	Regarding Sections 3.1 and 3.3, requiring providers to identify each disclosed relationship to determine its relevance will be a burden to many providers. This function is labor intensive and costly. Can the requirement be narrowed so that faculty, planners, etc. disclose all relationships that relate to the content of the activity on which they are working?
Accredited CE provider	ACCME	Publishing/education company	Standard 3.1 and 3.3: This will be extremely challenging for us to implement with 7,000 faculty members. Exception for self-directed continuing education: Lack of independence in self-directed continuing education activities.
Accredited CE provider	ACCME	Publishing/education company	The standard is a significant intrusion of privacy for both the educator and spouse/ partner by requiring them to list all their ownership shares in so called ineligible entities no matter how small. Ownership in a commercial interest should stay as before where the conflict can be resolved by for example an independent peer review. Unintended consequences may be an uprising among the academic community of educators and an attempt to create a better and less intrusive ACCME type organization (compare to reaction to MOC proposals and the backing off from these). Another one may be mass non-compliance due to how draconian this new standard is with no heed given to how small and immaterial an ownership may be.
Accredited CE provider	ACCME	School of medicine	3.2, why not report all instead of sorting to report to learners? Full disclosure is key. 3.5d, does each mitigation need to be specified or can there be a general disclosure of the options for mitigation and that appropriate steps were taken. Basically, do we need to identify exactly which option was used for each potential COI for each person?

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	3.4a. Re: Mitigate relationships prior to the individual assuming their role. Take steps appropriate to the role of the individual. – In practice, this is a process. However, mitigating prior to one's assuming a role is understandable. At the first planning meeting when a course is discussed, the planning committee is assembled, disclosure is collected. The requirement to have a pre-planning meeting just to talk about disclosure and conflict of interest can be burdensome to developing education. If mitigating as early as possible at the point or prior to assuming the role might meet the requirements for all concerned.
Accredited CE provider	ACCME	School of medicine	A challenge I foresee is that we have more pressure from the university for faculty to bring ideas to commercially benefit patients and be available to the marketplace. Much of this pressure is for the university to have a financial return on the research expenditures and of course there is a financial return for the creator. We understand this creates an area that has to be disclosed, but it is getting bigger all the time. If we want to hear about this topic area, let's say a new devise with artificial intelligence on the market and it is very exciting, then the speaker cannot be the PI and "owner" or part owner, or they cannot receive CME for that presentation due to the COI created. This will be a growing area of concern. It is more of a comment than a question.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	As noted above, the new definitions for “ineligible entities” raise some questions. For example, I attended a (non-CME) conference where a patient who suffers from anxiety and depression spoke. This is obviously impactful education (and encourage by the ACCME). This speaker was noteworthy for having developed an app that serves as a resource for patients dealing with mental health issues as well as their providers. Since there is a fee associated with the app, is this a relevant financial relationship? Given the risk faced by providers for misinterpreting the requirements, were this person to participate in a course sponsored through our office we would likely err on the side of caution and exclude their presentation from credit, lest we face compliance issues later on. The ACCME has made great strides to emphasize that their role is "more coach than cop," but no one gets in trouble for over-complying. Providers are risk averse, and ultimately those who are hurt by over-interpretation of requirements are faculty, who are excluded from speaking, and learners who are unable to earn credit for valuable, worthwhile education. Again, I know this is not the ACCME's intention, but this is the reality of those “in the trenches” of accredited CME.
Accredited CE provider	ACCME	School of medicine	big push back from faculty and activity directors for increased work for no real benefit.
Accredited CE provider	ACCME	School of medicine	CME staff do not have the content knowledge or time to vet the multiple thousands of relationships to determine relevancy. This is an inappropriate over-reach of the CME role.
Accredited CE provider	ACCME	School of medicine	Exception for self-directed continuing education is unclear to me.
Accredited CE provider	ACCME	School of medicine	Faculty and committee members are not accustomed to disclosing ALL relationships since they have not had to in the past, so this will require some retraining. Also, it might be difficult for us as accredited providers to determine whether a person has disclosed everything.
Accredited CE provider	ACCME	School of medicine	I am concerned by adding the additional requirement that a statement be made that all relationships have been mitigated is just having another area where accredited providers will not achieve 100% EVEN if the process has taken place. As the requirement is that all relationships be resolved prior having this statement be added seems like extra work. And would this statement need to be listed even if no disclosures were present?

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	I do think the requirement to collect ALL relationships will pose a huge burden on us that will likely mean we need another full FTE to help us manage. And, that FTE will need to have some broad medical expertise (not what we have now on our team) so they can confidently identify relationships. I'm not sure this is the best use of time for someone who has that kind of medical expertise and I know it will be expensive. In training, I would love to hear from someone like us (a very large decentralized program at an academic medical center where MANY people have research grants) explain how they handle the volume efficiently. Costs are going to be significant to us when we already have HUGE problems getting our program funded. And there's not clear improvement that I can sell to my organization of how this will make our education or our program better. 3.5d is fine; I am not convinced learners read those, know what they mean, or what to do with it so I do not believe there will be an effect here at all; more verbiage for learners to more easily ignore, just like all the disclaimers in drug commercials.
Accredited CE provider	ACCME	School of medicine	In Standard 3, #3, we must disclose only those relevant financial relationships. But in #2a, we touch on the exceptions. So, say Dr. X is an employee of Company B and he is permitted to speak because he is not speaking about anything related to the business lines or products of Company B. Would nothing then be disclosed to the learners or is that relationship (employee) inherently relevant because it exists?
Accredited CE provider	ACCME	School of medicine	Is the staff that is collecting the disclosure form now determining if the financial relationship is relevant as opposed to asking the person with the relationship to determine if he/she has a relevant financial relationship?
Accredited CE provider	ACCME	School of medicine	It will be a learning curve for internal faculty and committee members to disclose ALL relationships, but doable. Also, I believe it will be difficult for us, as accredited providers, to determine if ALL relationships were disclosed as well. While many folks are honorable with their intentions to disclose information, there are those who are not.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	Most of Standard 3 is fine-- the section on Exception for self-directed continuing education is going to create confusion that could have negative implications for providers. In its current form, it will also be difficult to explain to non -CE providers.
Accredited CE provider	ACCME	School of medicine	Requiring the accredited provider to be responsible for identifying relevant financial relationships by collecting all financial relationships does not streamline the process
Accredited CE provider	ACCME	School of medicine	Some CME providers are not aware of the ancillary guidance regarding the definition of “about” meaning “content about the specific agents/devices of the ineligible entity.” They interpret it to mean any content “related to” the whole disease class, and therefore, interpret a conflict of interest to be present when one is not, or exclude an owner/employee when their participation is actually allowable (according to exception #1). CME providers should all understand what is and isn’t meant by each term used in the Standards and accompanying guidance documents. At present, relevant, related to, and about are all used in various Standards and guidance documents, and they don’t necessarily mean the same thing. This causes confusion among CME professionals, which prevents providers from making similar decisions.
Accredited CE provider	ACCME	School of medicine	Some providers may not have the human resources to sort through and identify financial relationships with someone who is in an academic setting that is a researcher.
Accredited CE provider	ACCME	School of medicine	The academic medicine environment has changed dramatically over the past few years and this policy is structured without consideration of the changes, essentially dated rules carried forward from a time past. Faculty at academic institution with significant accomplishments in research, leaders in their fields, are frequently involved in the creation of companies with eventual products in their area of expertise. These companies are encouraged and even supported by the academic institutions. In addition to their NEW role with start-ups, these faculty continue to be respected academic physicians providing excellent clinical care and educating trainees in that care. Under these new guidelines these faculty are forbidden from participating in CME. All learners are impacted as they are now not permitted to learn from these thought and care leaders.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	The issue of using mitigate. Why use mitigate?
Accredited CE provider	ACCME	School of medicine	The revised standards place the responsibility for determining the relevance of a financial relationship solely on the accredited provider. This is a logical change, and I support it. However, it will increase our workload, as we currently trust our faculty to honestly and correctly identify whether a financial relationship is relevant. We will immediately start developing a plan to accommodate this new rule, so that we will be ready when the new standards go into effect.
Accredited CE provider	ACCME	School of medicine	The standard is not completely unclear. However, how is relevance to be determined? Is it up to the accredited provider to determine whether or not a spouse/partner's financial interests are 'relevant'?
Accredited CE provider	ACCME	School of medicine	To flip the responsibility of identifying relevant financial relationships to the provider from the content professional (speakers, planner, faculty) is unrealistic. This would require CME staff to know every possible business line and product of every ineligible entity. It would also require that CME staff are now experts in all areas of medical content development. Otherwise, how else will a CME staff member - often an admin or coordinator - be able to make this determination. Regardless to say, to meet this new requirement, would require massive investment in qualified staff and countless hours of researching every possible company and it's product lines.
Accredited CE provider	ACCME	School of medicine	We appreciate and agree with the revisions to Standard 3. We have a question about 1b – please define “ownership interest”. Is this distinct from being an owner? We understood this to be the same category as Owner or Employee. Please clarify. Regarding self-directed education – specifically, case conversations among peers – is this different from hospital case conferences and tumor boards?

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	Yes, you just made CME harder -- not easier. The bigger question is, as a result of these changes will the quality of CME be better? I think not. A lot of effort is put into the collection and resolution of conflicts. Is there an easier way? Perhaps just require the disclosure and not the COI if the dollar amount is below a certain threshold in aggregate for the past 12 months. $10,000k or something. More energy and resources should be spent on creating programs to improve patient care instead of collecting disclosures. This change is going in the wrong direction. Finally, why not have a 4th option that would allow an owner or employee to speak if the provider takes some extraordinary steps to ensure there is no bias. At large academic health centers faculty are encouraged to innovate and become owners. Those lectures will happen with or without CME. It is better to be at the table than not!
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Hospital/healthcare delivery system	Our organization already asks for all financial relationships with ineligible entities in our disclosure process, but I can see this change creating challenges or confusion for providers that may only ask for relevant relationships as determined by planners/faculty themselves. They will need new processes to determine relevance, communicate this change in the disclosure process to planners/faculty, and clearly understand when/what/how information needs to be stated in disclosure to learners (like what to do if a relationship is disclosed but isn't relevant for a given activity).

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Hospital/healthcare delivery system	Standard 3: #1 is a huge shift in responsibility from the individual speaker to the back office. We will have a huge learning curve as well as addition of work to manage at this level. For example: right now, the individual knows if their relationship with a company is in relation to what they are speaking about and can identify when it is. If they simply send us a listing of all relationships our back-office staff will have to look up companies, see what they make/do, then contact the disclosing individual to discuss their talk to see if there is a conflict. Right now, we have to do this with a smaller percentage and in the future it will increase by the thousands. Standard 3: #5d we aren't sure how adding this statement is beneficial yet creates more work and another element to monitor for.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Hospital/healthcare delivery system	The provider being responsible for tracking all financial relationships for those have influence over educational content, as opposed to tracking relevant financial relationships, will add to the provider's workload.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Hospital/healthcare delivery system	Unclear or lack of definition.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (other)	Asking providers to collect all relationships and then asking them to independently verify which relationships are relevant can be a challenge. Leaders in a clinical area often have relationships with multiple organizations. Also, faculty/planners are not going to be savvy about what an "ineligible entity" is and this will likely result in them disclosing things like NIH grants, board/officer positions with professional associations (ACG, ADA, etc.). Also, providers are not privy to what an ineligible entity might be doing with products/devices/services that are not currently public knowledge so it is possible the provider might determine an entity as not relevant due to lack of info when it is in fact relevant. The planner/faculty themselves are in best position to know if relationship is relevant. Perhaps they can indicate what they think is relevant and provider confirms it independently.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	• Standard 3.1 notes that information should be collected about all relationships with ineligible entities from the past 12 months. The latest draft from the Disclosure Harmonization Task Force proposes a 24-month look-back period for collecting information on relationships with companies. Although the initial focus for the Disclosure Harmonization Task Force has been author disclosures in submissions to medical journals, uniform disclosure criteria extending to CME planners and faculty would be of great benefit to the research and education communities. • In reviewing item 5d, while ASCO does agree that a statement improving transparency regarding mitigation strategies could be very beneficial for learners, we would not want to unintentionally communicate that a mitigation strategy somehow eliminates completely the potential for bias & promotion. Learners will always need to critically evaluate the content provided in the activity.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	3.1- Education/Guidance is needed on means to obtain such disclosure in ways that will lesson burden on faculty and providers. Would it be acceptable to ask planners/faculty to indicate which relationships they see as being relevant to the content of an activity (from the overall list they submit yearly)?
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	The change to the accredited provider being responsible for the identification of relevant financial relationships will be an enormous challenge for the provider staff who are not clinicians. The way it is written, Item #3 requires staff to have knowledge of the commercial supporters/ineligible entities and substantial subject matter expertise to make the determination of relevant financial interest. This level of expertise, many times is not always part of the CME staff and the time commitment to have large faculty programs reviewed is not insignificant.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Other: academic medical center	Collecting ALL financial information is unrealistic, especially if it involves researching subsidiary relationships. If faculty do disclose all financial relationships, it is simply unrealistic to expect the provider to conduct the research into financial and subsidiary structures that are suggested. Then, if we do follow this trail, how can we mitigate some relationships? If Hospital A (an eligible entity) has a subsidiary that serves as a Pharmacy Benefits Manager (an ineligible entity), then does an employee of Hospital A now have an unresolvable conflict of interest?

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	Implementing these changes will take time since many programs have already started planning for the next year. Phasing this Standard out would be helpful to allow time to properly interpret, prepare and implement.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	Many accredited providers currently lack staff with the type of clinical or scientific background needed to determine whether a relationship is relevant to the content of an activity when faced with a long list of relationships. Hospital-based CME/CE offices are of particular concern- they may not have the current expertise nor the funding to hire clinical experts to do the web/Internet searching often needed to determine relevance. Getting busy clinicians in practice to volunteer for this role will also be hard. The alternative of treating every relationship as relevant and taking universal steps to mitigate is also costly in time and effort, and disclosure of total lists of relationship to a learner without vetting may be seen as a breach of the privacy of the faculty/planner and is also less meaningful to learners.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	Provider teams are not always clinical experts or expert in all areas of clinical care and need to be able to consult with non-conflicted members of planning teams about relevance of relationships to content of activities. We rely on planning committees to offer clarifying information about content/business lines in order to make a determination of relevance.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	This change will require significant re-training for staff to be qualified in researching entities and companies to determine which relationships are relevant. This will be a workflow shift and reallocation of time spent on this endeavor.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	Unless an accredited provider's office has staff with a clinical or scientific background, the accredited provider will not be able to accurately determine which relationships are relevant most of the time. Personally speaking, this will be a tremendous burden on our office, which has three FTEs who would be responsible for struggling to review the relevancy of financial relationships for planners and faculty across 200 activities annually and that is probably 1-2 FTEs more than many other offices. If this standard were adopted as is, we would have no choice than to treat every relationship as relevant.
Accredited CE provider	Other: Accreditation Council for Pharmacy Education	Nonprofit (other)	- The self-directed exception opens a door for ineligible entities to directly or indirectly control educational content. - Difficult for regulatory and nonprofit providers, who do not provide direct patient care, to offer education on new, innovative, and/or challenging technology and drugs if all employees of ineligible entities are automatically excluded from being faculty.
Accredited CE provider	Other: CMS	Hospital/healthcare delivery system	Mitigation will put a strain on small CME programs that do not have much staff. This will increase and require more monitoring from CME programs than before as the responsibility is shifting more to the provider to investigate information from planners/presenters.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	"Individual stocks and stock options should be disclosed; diversified mutual funds do not need to be disclosed". Arbitrary as to definition and outdated. What of large ETF's of healthcare sectors or tiny stock holdings? Potential financial impact of the event is the issue. "...ineligible entities can participate as planners or faculty in these specific situations: a. when the content of the activity is not related to the business lines or products of their employer/company; b. when the content of the accredited activity is limited to basic science research, such as pre-clinical research and drug discovery, or the methodologies of research, and they do not make care recommendations; or c. when they are participating as technicians to teach the safe and proper use of medical devices, and do not recommend whether or when a device is used." This section shows and fosters a significant bias. Very highly paid Surgeons and other procedure-based practitioners can have significant educational interactions with ineligible entities and others cannot! I wonder what discipline the author belongs to. The truth is that new information on healthcare products are poorly covered by non-ineligible entities. The result of which is a poorly educated provider and fosters ancient practices. We are not forcing this on the procedure specialties, so why keep everyone else in the dark?
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	I feel that having the responsibility fall on the accredited provider to determine what is relevant or not is not reasonable. The accredited provider does not have the in-depth information that the person in control of the education content has of their own financial relationships. Where is the accredited provider going to find out the information about the ineligible entities? My guess would be they are going to ask the person who disclosed it.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	I think it is a mistake to leave the door open for owners/employees of com interests to be part of planning process. Not all CME providers are as skilled at managing questionable relationships and ensuring activity isn't tainted or have the time.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	I think it is important request faculty to look themselves up on OpenPayments and disclose as appropriate.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Must a statement that all relevant financial relationships have been mitigated be included if there were no relevant financial relationships?
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Need to update all of our policies and forms with the new terms.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	The change in verbiage from "resolve" to "mitigate" implies that some degree of conflict of interest is acceptable. This is concerning and may lead less vigilance.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	The term “mitigate” should be defined. Mitigate is not defined the same as “resolve” in any source. If the intent is to alleviate, lessen, or ease, the insertion of commercial bias into the content, then a simple documented note to those involved in controlling content regarding unbiased, non-commercial content, should suffice to document steps taken to mitigate relevant financial relationships. This documentation is currently found on the conflict of interest disclosure forms utilized by providers. To require a provider to collect all financial relationship information from planners, faculty and those in control of content, when some relationships are not relevant to the content seems to be a step backward. Large lists of financial relationships will be received by providers who do not have the staff with clinical or scientific knowledge to determine which are relevant. To expect the provider to determine if the educational content is related to the business lines or products of an ineligible entity requires that the provider be aware of every business line and product of all ineligible entities. This is not only inconceivable but daunting in the amount of research time, personnel and/or resources that would be required to comply.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	With newly expanded list of ineligible entities, asking for ALL financial relationships will result in overwhelming onslaught of administrative work to determine relevance. Better to honor faculty integrity in disclosing relevance.
Accredited CE provider			Mitigate will incur another level of explanation/processes to constiuents who engage in the accredited CME process with our office and staff. We are not part of the legal system, mitigate is a term I associate with the legal and insurance industries. Adding the term "mitigate" has the potential to modernize the standard but doesn't change the concept that resolution must occur.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Advocacy organization			As written, the proposed change of soliciting information from all planners, faculty, and others in control of educational content about ALL their financial relationship puts a burden on the members of our association. The IOM published a report in 2009 titled, Conflict of Interest in Medical Research, Education, and Practice. They reference a survey in that report which states, “more than 3,100 physicians [were sampled], 94% reported that they had had some type of relationship with industry during the preceding year….” Granted, this survey was conducted in 2007 before PhRMA revisions but assume 94% as a ceiling. Asking about all financial relations puts a tremendous burden on already stretched CME departments, particularly those providers who have understaffed CME departments. Additionally, the new Standards also task providers with asking spouses or partners to report known financial relationships. The CME department staff will need to investigate many more companies than previously. This potentially shifts the priority of CME providers from delivering high quality evidence-based education to that of “CME Police.” Aside from administrative implications, consider the cultural/ethical ramifications of asking planners, faculty, others in control of educational content, and spouses/partners about all/known financial relationships. This change could result in people not being forthright in their disclosures leaving us as providers with no real recourse.
Advocacy organization			Regarding Sections 3.1 and 3.3, requiring providers to identify each disclosed relationship to determine its relevance will be a burden to many providers. This function is labor intensive and costly. Can the requirement be narrowed so that faculty, planners, etc. disclose all relationships that relate to the content of the activity on which they are working?

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Advocacy organization			At academic institutions, there is extensive medical research taking place, including clinical protocols and drug trials. Many of our faculty have invented products or treatments and are now considered 'owners'. This Standard would have a large impact on our institution's academic mission if we now exclude those faculty members with invention disclosures. In addition, this Standard will severely limit those faculty who are driving innovation from sharing cutting edge medicine in a CME event. 3.4a. Re: Mitigate relationships prior to the individual assuming their role. Take steps appropriate to the role of the individual. – If the standing process to manage identified conflicts of interest is to perform a slide/content review by a non-conflicted member of the planning committee, it is often a challenge to obtain the slides/content in great advance before the activity. Although this is not the ideal scenario, it is the reality of activity planning. Activity faculty often do not meet stated deadlines even when incentivized with an honorarium. Expectation to advance this timeline will be problematic for the accredited provider and its staff.
Clinician/healthcare professional			It sounds reasonable but the definition of relevant financial relationships with ineligible entities needs definition.
Clinician/healthcare professional			Mitigate' by definition is 'to make less severe, less serious'. It is not as strong a term as 'resolve' and may encourage partial conflict resolution.
Clinician/healthcare professional			Recommend education on each aspect to reinforce compliance. Content is clear but must be clearly understood.
Clinician/healthcare professional			Repression of innovative medical thinking and concepts
Clinician/healthcare professional			There will be some resistance to disclosing ALL financial relationships, but it is absolutely the correct approach. The provider is in a better position to assess relevance.
Clinician/healthcare professional			Too much paperwork and bureaucracy for no benefit to transparency. Impacts faculty and is an invasion of privacy. We need as a society to disclose relevant relationships, not all relationships.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Clinician/healthcare professional			With respect to spouse/partner: Many people hold individual stocks. Stock options may be more relevant. Unclear why diversified funds are exempt. E.g. one can have individual stocks in one company and have the same stocks represented in various mutual funds, unclear what the differentiation is on this matter.
Continuing education accrediting body			Collecting and reviewing all financial relationships for relevance may be perceived as overly burdensome by providers who have historically obtained disclosure of relevant financial relationships only. Adequate time for process changes by the provider prior to implementation is warranted.
Continuing education accrediting body			We believe that the current “eligible/ineligible” language will serve as a barrier to faculty understanding the information that we will need from them during the disclosure process. We are also concerned that providers may be confused about which mitigation procedures will comply with the Standard.
Medical/healthcare association			I feel that presenters will be confused on what information they are to disclose. Only that related to their profession or all conflicts, such as mutual funds that include a pharma company. Needs to be explained further. Please explain the mitigation of above example.
Medical/healthcare association			If owner is not clarified-specifically anyone that owns one share of stock, which may include many healthcare workers/partners severely limiting pool of eligible experts. Suggest using the SEC guideline of 5% for ownership of stocks. So, all employees would be ineligible, but an owner of a limited amount of stock (less than 5%) would not be ineligible. We may have staff that own stock; we cannot exclude them from doing their jobs if they are healthcare professionals that deal with content.
Medical/healthcare association			Is it anticipated that commercial support by "ineligible entities" would be listed under the term of "ineligible entity(s) support"? If yes, that might be confusing to learners when "commercial support term is widely known and understood.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Medical/healthcare association			Regarding Standard 3.2.C, the AMA Council on Medical Education is concerned with the practical realities of how an accredited provider or physician learner can ensure that a technician can only teach the use of a medical device without recommending the use of that device. Understanding the indications for and proper use of medical devices is critical to learning about the safe and proper use of such devices and logistically, separating these two related concepts would be practically impossible. The Council believes that inserting specific language that prohibits an employee of an ineligible entity from commenting on, "… whether or when a device should be used" is not advisable and may actually lead to unsafe patient care. The Council recommends deleting the last phrase of this sub-standard that starts with, "… and do not recommend whether or when a device is used."
Medical/healthcare association			The Alliance has believed that determining the relevance of a financial relationship has ultimately always been the responsibility of the provider, but we recognize a clear disconnect across a broad array of providers who disagree with this view based on discussions of these revisions. We urge the ACCME to plan education on this confusion. Current provider staff may not have the necessary clinical or scientific background to determine relevance, and busy clinicians may not be available to volunteer for this. Thus, more financial resources may be needed. The provider needs to understand the structure and products of each entity (and their parent company), plus have first-hand understanding of the content to be covered in the presentation. That might work for providers with small programs/faculty; however, for medical specialty societies with tens of thousands of disclosures for a annual meeting it will be nearly impossible to administer. If approved, this requirement will create a financial and staffing burden and would reinforce the outdated notion that CME is administrative and all about checking boxes. Providers will also need education on how to determine if an entity is eligible or ineligible, such as with start-up companies. Many provider staff members are not knowledgeable of the various paths to FDA clearance/approval, and do not know how to locate information on research and development pipelines.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Nonaccredited CE provider			Without clarification to the comments above, this will be challenging to implement.
Other: Accredited CE provider, Continuing education accrediting body, and medical/healthcare association			As stated above, this requirement places a significant paperwork burden on planners/faculty and providers if this information must be obtained, de novo, for each activity.
Other: CME/CE Consulting Services Company			Because this standard now requires ALL financial relationships be disclosed by an individual in control of content, we could envision all disclosures reported will be automatically disclosed out to learners, regardless of relevance. This happens to a degree currently. While we do not advocate for a penalty for over-disclosure (particularly, given some organizations require disclosure beyond what the ACCME requires), it may be useful if the ACCME's required performance-in-practice documentation function to discern that a provider really understands what is relevant per the ACCME's definition versus what is not, regardless of what they choose to disclose out to learners.
Other: Hospital			I understand the issue, however, am not a clinician. Once I hand it over to a peer reviewer, I have to take their word they actually looked at it and the relationship is 'mitigated'.
Other: Joint Provider			Take botanical medicine for example - a topic often taught in integrative medicine conferences. A speaker who is well versed in botanicals that also works for a supplement company can present on the clinical research around a particular botanical, for example black cohosh or saw palmetto, without speaking about a specific brand. In conventional medicine, for example, a generic pharmaceutical use, side effects, etc. can be discussed, without referring to brand name products, companies, etc.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: MedChi is both an Accredited Provider and a Recognized Accreditor			I think there may be issues here related to staffing qualifications. Will organizations be able to have staff with a skill set to determine what relevancy would be. It is questionable as to whether some staff are capable of making such judgments. The lack of volunteers with qualifications will make this further complicated as well as the lack of cooperation from presenters in providing timely compliance with disclosure, which complicates the process under the current standards, these additional requirements will create further issues, that will create further risk to providers falling into non-compliance. A workable strategy needs to be provided.
Other: State Medical Society/Publisher/Accredited Provider/Recognized Accreditor			Several comments from NEJM Group supported the collection of all financial relationships and that those relationships should also be disclosed to learners. On the other, physician committee members were highly vocal in expressing that they did not support that a provider must collect disclosures from all in control of content. They commented that this will create a heavy administrative burden on the CME staff. They also indicated that this change will require additional physician engagement for review of an individual's relevant financial relationships as compared to the clinical products or services of the ineligible entities. They also added that this would require more research on the ineligible entities and their products and services.
Patient, caregiver, member of the public			The amount of work that providers will face to change the terminology related to "eligible" and "ineligible" in disclosures will be staggering-costing time, money, and staff. Some providers may feel that it is too much work to stay accredited because of this terminology.
Recognized Accreditor (state/territory medical society)			Agree with the premise about collecting all financial relationships and then the accredited provider decides if the relationship is relevant. However, there are a number of accredited providers who currently only ask about relevant financial relationships and let the planner/faculty make that determination. These organizations will need time to adjust their practices and potentially identify and educate staff or committee members who will now decide if a relationship is relevant or not.
Recognized Accreditor (state/territory medical society)			Due to the name change from resolve to mitigate and also the three exceptions to the exclusion, this will possibly cause confusion to the Provider, but I am sure the ACCME will have a plan to mitigate that if that should happen.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Recognized Accreditor (state/territory medical society)			If the exact wording that all RFRs have been mitigated is required, there will be an increase in unreasonable noncompliance's here. I hope it is acceptable to paraphrase this. I.e. "No one influencing content has been found to have a relevant financial relationship with a commercial interest." Or some other non-use of the word "mitigated"
Recognized Accreditor (state/territory medical society)			Liability and extra work for the accredited provider.
Recognized Accreditor (state/territory medical society)			Mitigate as a verb does not go well with Standard 3 # 4 when one says mitigate relevant financial relationships as it can be confusing.
Recognized Accreditor (state/territory medical society)			Not enough concrete examples and steps in item number 4.
Recognized Accreditor (state/territory medical society)			One of our providers didn't understand what the change was for "all" financial relationships. That leads me to believe there may also be confusion as to what would be a conflict.
Recognized Accreditor (state/territory medical society)			Possibly a learning curve on the nature of "ineligible entity," since it's defined as entities that cannot be accredited providers, but for the purposes of the standard, they may not control content. Perhaps the definition should include language about not controlling educational content.
Recognized Accreditor (state/territory medical society)			PRMA is right now in a court decision because Provider 4006997 is in essence claiming misinterpretation of this kind of words.
Recognized Accreditor (state/territory medical society)			Some may not want to provide their financial relationships if it's not relevant to the activity.

Do you foresee challenges or unintended consequences implementing Standard 3? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Recognized Accreditor (state/territory medical society)			Standard 3 - #1 – the proposed change will require accredited providers to collect ALL financial relationships (currently we only collect those financial relationships that are directly relevant to the content that will be planned, developed, or presented) – and then the accredited provider will be required to determine which relationships are relevant; we feel this will be a time resource burden and do not see the benefit. We believe it should still be allowed that the individual involved identifies what they feel is relevant to their role. Standard 3 - #5d – new requirement that a statement indicating that "all relevant financial relationships have been mitigated [this is a new term to replace "resolve"]. Learners must receive this information before engaging with the accredited education."-----We question the value this would provide to the learner.
Recognized Accreditor (state/territory medical society)			What if the bio-medical start-up as a company exists only on paper (e.g. no venture capital investment has occurred, no method for production, perhaps only a prototype but nothing more in terms of an actual product)? Many such 'discoveries' never make it to an actual product that is marketed. Is there any time limit saying this discovery is never going to become a product, so is this faculty member disqualified forever and ever?
Recognized Accreditor (state/territory medical society)			While many individuals already disclose ALL relationships, many do not (they only disclose what they deem as relevant relationships.) This may create additional work/administrative burden on the coordinator/employee responsible for oversight of the day to day CME program.

What comments or questions do you have about Standard 3?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Advocacy organization			If the academic institution has contractual relationships with industry, are there allowable exceptions to this Standard for individual faculty members with 'ownership' relationships? It would seem that the ACCME could provide a method to mitigate relationships in these circumstances, as this will be an issue in all academic settings. These individuals are often the singular expert in these very specific fields of medicine (i.e. oncology). 3.2 CME Providers need a very clear and definite definition of 'Owner' and 'Employee'. Are patents and royalties considered 'Ownership'? What about clinical trial and protocol involvement? In addition, CME Providers need clear guidelines on how best to determine which faculty relationships are relevant.
Advocacy organization			Our association would suggest we continue to solicit relevant disclosures only. If it is the intent that all relationships are disclosed, then we need the ACCME to own part of this burden. We would suggest something akin to the physician sunshine act database to list eligible and ineligible entities.

What comments or questions do you have about Standard 3?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Advocacy organization			What role can the joint provider play in identifying relevant financial relationships? Joint providers are often the entity having the bulk of direct interaction with activity faculty, including requesting disclosure of financial relationships. Can this practice continue? For sections 3.2 and 3.3, what does the phrase “the content of the activity is not related to the business lines or products” of an employer, company, ineligible entity refer to? • For example, if a speaker has a relationship with a company regarding treatment for ovarian cancer, but the activity relates to prostate cancer, is the relationship relevant? • If an author has a relationship with a company regarding the use of a scanning device to diagnose a condition, but the activity relates to treatment of a condition, is the relationship relevant? • If a faculty member owns a company that would be considered an ineligible entity within a defined topic for discussion, is he or she ineligible to prepare content on any other topic of discussion? Or, is the “not related to the business lines or products” statement applicable? It would be helpful for providers to have ACCME offer more clarity regarding specific requirements for disclosure (eg, by therapeutic area or drug class). For section 3.4, how does “mitigate” differ from the current term “resolve?” If not at all, what is the reason for the change? If it does differ, what are the specific differences?
Accredited CE provider		Nonprofit (physician membership organization)	Just to clarify, we still only disclose what we determine are the relevant disclosures and do not need to list those we determine are not relevant.
Accredited CE provider		Nonprofit (physician membership organization)	What does exception for self-directed education mean?
Accredited CE provider	ACCME	Hospital/healthcare delivery system	1. Standard 3 contains the statement "application to all accredited continuing education." We request that the ACCME consider changing that statement to "application to all accredited activities that make recommendations for diagnosis and treatment, including but not limited to

			prescribing drugs and/or medical devices". For example, accredited CME activities focused on educator development, research skills, leadership development, and fundamental sciences do not include diagnostics or treatment recommendations. 2. We appreciate the "Exception for self-directed continuing education". The statement opens up an important opportunity for clinicians to obtain CME credit for meaningful learning in the working-learning environment. 3. We think it is important to disclose that an accredited CME activity did not receive commercial support and will continue to do so. Standard 3 was clear and concise.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	3.1b - define "independent contractor"; define "executive role"; 3.5d – new requirement that a statement indicating that “all relevant financial relationships have been mitigated. Learners must receive this information before engaging with the accredited education.” -----I don’t understand what value this would provide to the learner.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	As written, the proposed change of soliciting ALL (not just relevant) financial relationship information from all planners, faculty, and others in control of educational content along with that of their spouse/domestic partner/life partner could result in an overwhelming burden on a program/departments with little return on investment as it relates to improved independence in accredited continuing education. I appreciate the intention of the standard but have concerns as to the expectations as to how it is to be executed without some logistical logistic support from ACCME. As a possible solution, is to consider a database process similar to the Sunshine Act database accessed by all accredited providers as needed for mitigation purposes. Additionally, and perhaps more importantly, I have ethical and privacy concerns with not having boundaries as it relates to which, if any disclosures we're asking for and add to that, having to ask about their significant others about any potential disclosures. This seems above and beyond what would normally be expected, especially considering that many of the people who work with us do so on a pro bono basis.

What comments or questions do you have about Standard 3?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	If the academic institution has contractual relationships with industry, are there allowable exceptions to this Standard for individual faculty members with 'ownership' relationships? It would seem that the ACCME should provide a method to mitigate relationships in these circumstances, as this will be an issue in all academic settings. These individuals are often the singular expert in these very specific fields of medicine (i.e. oncology). 3.2 CME Providers need a very clear and definite definition of 'Owner' and 'Employee'. Are patents and royalties considered 'Ownership'? If so, what is the expiration timeframe for disclosing patents? What about clinical trial and protocol involvement? In addition, CME Providers need clear guidelines on how best to determine which faculty relationships are relevant.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Our CME Program believes the most effective course of action would be to collect relevant financial disclosures only. If the ACCME deems it significant enough that all relationships be disclosed then the ACCME must own some of the administrative and financial burden that it requires, as described above.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Retain "relevant" relationships on the disclosure requirement. Physicians are well aware of the requirement, and there is no need to change the Standard 3 as it is now. Better define "owners" (i.e., stockholders?) of ineligible entities to be able to identify those individuals clearly.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	The term 'mitigate' is a more accurate word for describing how conflicts of interest are addressed.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	These are great changes. Thank you for clarifying disclosure on the absence on the control of content can be made as a group (this is always a good example at the ACCME meeting/case studies on commercial support). I also really appreciate the exception for self-directed continuing education but thought there may need to be some more definition of "self-directed". My initial interpretation was for a PI CME project but then I saw mention of "case conversation among peers" and got a little confused but hopeful that maybe with our case based regularly scheduled series, we may not need to collect financial disclosures.

What comments or questions do you have about Standard 3?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	We appreciate the following text from 2.1: “Individuals must disclose regardless of their view of the relevance.” and think it will be beneficial to include on our financial disclosure form.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	We believe that planners and faculty should disclose all relationships, but it should be on the learner to determine the relevance and bias. We do not believe the above will lessen any bias (implicit or not) it will just add additional work and little value to the learners.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	We really have a “Catch 22” in CME now because the very people who have been involved in clinical trials of therapeutics or who have been on the front lines of using those therapeutics and reporting on their efficacy are the very people the ACCME is trying to keep from contributing content, content they know better than anyone else, to CE programs. Our faculty repeated express exasperation at the ACCME regulations that have obligated us to remove expert faculty from accredited CME because of their relationships with industry. The ACCME’s ever more stringent and unreasonable requirements are impeding education, rather than enhancing it.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	We should continue to ask individuals in control of content to disclose relevant financial relationships. The likelihood that an individual will not be forthcoming is minimal. the impact on the CME provider is minimal in the existing SCS compared to the prospect of shifting the responsibility of determining relevance to the provider which will be unmanageable. Item 4-Mitigate relevant financial relationships: To improve clarity, separate item a, so there is an item b and c, as below. a. Mitigate relationships prior to the individual assuming their role. b. Take steps appropriate to the role of the individual. For example, steps for planners will likely be different than for faculty and would occur before planning begins. c. Document the steps taken to mitigate relevant financial relationships
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Why does the word mitigate now replace resolve? Can ACCME detail how they expect accreditors to mitigate? The definition of "mitigate" versus "resolve" seems to lessen the resolution needed. Please define what documentation and information is needed to mitigate a relevant financial relationship?

What comments or questions do you have about Standard 3?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (other)	Appreciate the revision to disclose ALL financial relationships with ineligible entities. Appreciate the inclusion of exemptions around self-directed CE. Appreciate the inclusion of examples of financial relationships. In addition, appreciate confirmation that only owners or employees are automatically excluded. Supportive of replacing “resolve” with mitigate. Appreciate clear examples of mitigation.
Accredited CE provider	ACCME	Nonprofit (other)	Question: would the statement that all relevant financial relationships have been mitigated have to be added to each individual speaker's disclosure statement or can it be a general overarching statement for all speakers presenting?
Accredited CE provider	ACCME	Nonprofit (other)	Suggest adding that the following language be used to disclose the absence of relevant financial relationships: “All [other] individuals in a position to control the content of this activity have no relevant financial relationships to disclose.” The intent of “inform learners about” is unclear if something else is intended. Changes to current disclosure language will place an additional administrative burden on staff. Need to ensure that there is a grandfathering for those planners and speakers for whom current disclosures are already on file. In general, need to provide guidance on means to obtain appropriate disclosures to lessen the burden on providers and planners/speakers.
Accredited CE provider	ACCME	Nonprofit (other)	This expansion of the ACCME's expectations is well stated.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	- What is the rationale for switching the responsibility from the speaker to the staff? The speaker has a higher level of qualification to determine relevancy.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	#1 - do we not disclose what they received? do you care about non-financial benefits?

What comments or questions do you have about Standard 3?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	3.1. It would be helpful for the ACCME to provide clarification on what needs to be collected if the educational content provides no clinical recommendations (i.e., there couldn't be any conflicts per ACCME definition) – do we still need to gather all information? 3.1 It would be helpful if the ACCME could confirm that the current policies for Journal-Based CME Activities will not change with this update – http://www.accme.org/faq/for-journal-based-cme-activity-do-i-need-collect-information-about-relevant-financial (If you are creating a journal-based CME activity, the ACCME does not expect you to identify and disclose to learners the relevant financial relationships of the article's authors and editors or to resolve their conflicts of interest.) 3.2. Allowing owners or employees to participate as technicians to teach the safe and proper use of medical devices is very appreciated. This provides clear direction. 3.4 We support the change of language from "resolving" to "mitigating" potential conflicts of interest.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	3.2- Exclusion of experts in rapidly evolving fields because of ownership in startups may be inappropriately applied because providers do not know the various paths to FDA approval/clearance. Need for education on how to determine pipeline status of products.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	3.3 The exception for employees of ineligible organizations is working well for a research organization like the AACR and their participation is important in making progress with a difficult practice gap such as cancer.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Appreciate the clarity of including 2.C Recommend harmonization of look back and content of disclosures with journals.

What comments or questions do you have about Standard 3?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	As the U.S. government's Open Payments database. Thus, those who contribute to numerous accredited education activities every year may be forced to invest many hours regurgitating the same information into many collection vehicles. A potential outcome of the proposed change is that faculty and planners will find it distasteful to be forced to share information about every investment, every consulting opportunity, every grant, etc. with a wide community of accredited education planners, regardless of the relevance of those relationships to the topic on which they are being asked to contribute. Ultimately, ACOEM foresees this resulting in highly skilled faculty and planners declining to participate in activities due to the additional work these changes create. This could negatively impact the quality of accredited healthcare education. Standard 3.2. Suggest that language be modified to include both eligible and ineligible entities. ACOEM suggests that the language be revised to exclude owners or employees of both eligible and ineligible entities from controlling content in accredited education, with the noted three exceptions. Owners and employees of entities that are eligible for accreditation may be equally as susceptible to promoting the interests of their organizations as are owners and employees of entities that do not qualify for accreditation. We find it interesting that these new proposed standards focus solely on ineligible entities and are silent on the issue
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Comments noted above. In addition, the prohibition against use of employees and owners of commercial interests results in an inability for the provider to select the best, most knowledgeable speaker for many topics.

What comments or questions do you have about Standard 3?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Does ACCME expect providers to collect disclosures and mitigate potential COI on a rolling basis up until the day of the education activity? If so, the collection and mitigation process will continue to be cumbersome, labor intensive, and difficult to accomplish with finite resources. The ACCME should ask providers to collect disclosures within 12 months of the education activity only. Providers may wish to reach out to planners and speakers for updates within this timeframe; however, it should not be a requirement.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Exclusion of experts in rapidly evolving fields because of ownership in startups may be inappropriately applied because providers do not know the various paths to FDA approval/clearance. Need for education on how to determine pipeline status of products. Standard 3.1 notes that information should be collected about all relationships with ineligible entities from the past 12 months. The latest draft from the AAMC Working Group on Uniform Disclosure Criteria for submission to medical journals proposes a 24-month look-back period for collecting information on relationships with companies. There would be significant benefit to individual researchers and authors who submit to journals and serve as CME planners, faculty and abstract authors to have a consistent standard across required disclosures. Examples of disclosure categories are provided but ACCME does not provide a strict categorization to follow. Categories therefore vary across organizations which make it hard for faculty to ensure they are accurately interpreting the categories and providing the correct disclosure information. Similar to the benefits of harmonizing the look-back period, it would be a marked improvement if physicians and others participating in CME, journal publications and other activities that require disclosure could have a consistent approach to documenting relationships with companies.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	I applaud the inclusion of 'A statement that all relevant financial relationships have been mitigated'

What comments or questions do you have about Standard 3?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	If this stands as proposed, education/guidance is needed on how best to obtain such disclosures in ways that will not increase the burden on faculty and providers and the best way to determine a pipeline status of products.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	In 3.1 (Collect Information) We support removing "relevant" from the financial relationships. Also, to provide additional clarity, we suggest including language that individual retirement and/or other investment portfolios/accounts through one's employer is listed as not needing to be disclosed.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	In asking individuals about all of their relationships with ineligible entities, accredited providers will be challenged with managing through an increased amount of information being disclosed. Organizational staff will need to become experts in what more companies do to determine relevance and mitigate relationships. This will be an added burden for many accredited providers to determine relevance and may result in organizations considering all disclosed relationships as relevant. Also, “mitigate” relationships is a better word choice to use vs. “resolving” them. Although all financial relationships with ineligible entities would need to be disclosed and relevance subsequently determined, please clarify what documentation (in the self-study and performance in practice files) would be needed to validate accredited providers’ practices with this Standard. Would ACCME expect to see a list of all relationships that are disclosed and those specifically identified as relevant? In addition to providing greater clarity on expectations for documenting disclosures, clarification on what evidence would be needed for mitigating COIs would also be helpful. Please identify any other examples as exceptions for self-directed CE, besides education occurring at the bedside. Would an Internet Point of Care Search activity be another example, where learners are fully in control of content?

What comments or questions do you have about Standard 3?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Is there still the requirement to disclose funding if the PI on a grant?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	o Does "self-directed CE" replace "individualized learning" as described in C31? o How would “self-directed CE” be documented as an activity type? Is it internet searching and learning; learning from teaching; manuscript review?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Please provide clarification on the use of the new term "mitigate" which is now replacing "resolve."
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	See previous responses.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Standardizing the requirements for what information should be disclosed by individuals in control of content, and that the accredited provider is responsible for determining a relationship’s relevance rather than the individual disclosing their relationships, should help to create a more consistent environment for learners. It will help to alleviate the confusion that can result when an individual discloses different information in different activities when providers have different disclosure requirements. The change to the use of “mitigate” to describe the management of conflicts of interest is an improvement over the language in the current Standards.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Standardizing the requirements for what information should be disclosed by individuals in control of content, and that the accredited provider is responsible for determining a relationship’s relevance rather than the individual disclosing, should help to create a more consistent environment for learners. It will help to alleviate the confusion that can result when an individual has different information disclosed in different activities when providers have different standards for this requirement. The change to the use of “mitigate” to describe the management of conflicts of interest is an improvement over the language in the current Standards.

What comments or questions do you have about Standard 3?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Thank you for excluding mutual funds. That you for only having to disclose relevant financial relationships to learners.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The proposed Standards clarify that the accredited provider must sort through and identify financial relationships to determine the ones that are relevant to the content or activity. This process would require additional staff resources that are not currently available or viable for our organization.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The term “mitigate,” in Standard 3.4, is a far more accurate term than “resolve” for what providers do with conflicts. This is considered a welcome change.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We do not disagree that it is imperative that relevant financial relationships be mitigated. We simply believe that there is a more efficient method to accomplish this and that is the method already in force. We applaud ACCME in allowing owners/employees to participate as technicians to teach the safe and proper use of medical devices as noted in Standard 3.2.c. This allows for actual educators to provide the education while the owners/employees of “ineligible entities” provide technical support.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	While SAGES agrees with the concept of requiring providers to collect all financial relationships with ineligible entities, SAGES does not agree with the proposed definition of ineligible entities. SAGES opines that this does not necessarily help eliminate bias in our education but instead just adds to the burdens of provider and makes CME more “police-like” rather than meaningful.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	While this will require a process change it may allow us to centralize our disclosure process. Rather than having to collect for each CME activity, we can collect for the year and determine if the reported disclosure if relevant to the activity.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Will it be expected that providers have different mitigating processes for planners vs. faculty?

What comments or questions do you have about Standard 3?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Other: Accreditation Management, CME Consulting, and Joint Providing Company	Disclose to learners: If a RFR is not a COI, does it have to be disclosed to learners. If it is a COI, shouldn't that be what is disclosed and stated that it was mitigated?
Accredited CE provider	ACCME	Other: Teleconferencing Medical Education Company	The wording is vague, the term "others in control of educational content" could be better defined.
Accredited CE provider	ACCME	Other: university	If we are using a disclosure statement that indicates, we vet everyone and those with an RFR that cannot be resolved is not allowed to participate- will we then be required to change it to include the word 'mitigate'? If so, doesn't anyone involved realize the time and resources it takes to make these seemingly arbitrary changes? This seems to occur every few years but doesn't seem to have the impact described when first proposed (hello...providership!). I wonder if the people making these suggestions work in a CME Program because if they had to pay someone to change 1 word on all the paperwork and pay the IT provider to change 1 word on all the webpages they might think twice about return on investment.
Accredited CE provider	ACCME	Publishing/education company	• Q: For those with no relevant financial relationship with ineligible entities, is the Provider responsible to list all by name, or can a statement be made, e.g. that all planners of the activity have no relevant financial relationships with ineligible entities?

What comments or questions do you have about Standard 3?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	3.1- Education/Guidance is needed on means to obtain such disclosure in ways that will lesson burden on faculty and providers. Would it be acceptable to ask planners/faculty to indicate which relationships they see as being relevant to the content of an activity (from the overall list they submit yearly)? 3.2- Exclusion of experts in rapidly evolving fields because of ownership in startups may be inappropriately applied because providers do not know the various paths to FDA approval/clearance. Need for education on how to determine pipeline status of products. Exception for Self-directed- Would the published results of the ICMJE disclosure process be adequate for authors of content included in activity content compendium for reference at point of care? If not, then obtaining disclosure from all authors of a previously published article or other reference would require intense labor. That would not be likely to promote development this type of POC learning.
Accredited CE provider	ACCME	Publishing/education company	For sections 3.2 and 3.3, what does the phrase “the content of the activity is not related to the business lines or products” of an employer, company, ineligible entity refer to? • For example, if a speaker has a relationship with a company regarding treatment for ovarian cancer, but the activity relates to prostate cancer, is the relationship relevant? • If an author has a relationship with a company regarding the use of a scanning device to diagnose a condition, but the activity relates to treatment of a condition, is the relationship relevant? • If a faculty member owns a company that would be considered an ineligible entity within a defined topic for discussion, is he or she ineligible to prepare content on any other topic of discussion? Or, is the “not related to the business lines or products” statement applicable? It would be helpful for providers to have ACCME offer more clarity regarding specific requirements for disclosure (e.g. by therapeutic area or drug class).

What comments or questions do you have about Standard 3?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	I think the ACCME would be wise to withdraw the proposed Standard 3 as currently proposed. When university deans find out how many of their best educators can no longer serve as faculty due to conflicts that cannot be resolved, the ACCME may find its support in jeopardy.
Accredited CE provider	ACCME	Publishing/education company	It's fantastic to see that the onus shifts to the accredited provider to identify relevancy, as opposed to permitting those who would be conflicted to self-identify (as many providers currently operate).
Accredited CE provider	ACCME	Publishing/education company	Standard 3.1 and 3.3: Please continue to support the process by which faculty members determine their relevant financial relationships.
Accredited CE provider	ACCME	Publishing/education company	The exception for self-directed continuing education - does this mean we no longer have to collect, resolve or mitigate, and disclose to learners at all?
Accredited CE provider	ACCME	Publishing/education company	There could be a period of adjustment and confusion as we move to this new standard, but we welcome the clarity and it should lead to easier management of disclosures from faculty.
Accredited CE provider	ACCME	Publishing/education company	To clarify, if no one who was in a position to control/influence content disclosed a relevant financial relationship with a commercial interest (ineligible entity) then we can provide a statement about the group rather than list all the names? for example, "none of the planners, faculty or other individuals in a position to control content has disclosed a relevant financial relationship with a commercial interest (ineligible entity)?
Accredited CE provider	ACCME	School of medicine	Although this standard is clearly written, I do not like the term 'mitigate'. Mitigate is defined as to lessen in force or intensity, as wrath, grief, harshness, or pain; moderate; to make less severe. If the accredited provider is determining what is a relevant relationship, then we would still need to resolve any potential conflicts. Perhaps it should be "Identify, Mitigate, Resolve, and Disclose Relevant Financial Relationships with Ineligible Entities."

What comments or questions do you have about Standard 3?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	Biggest challenge we face is the growth of entrepreneurship and the encouragement academic institutions give faculty. These faculty and healthcare providers, in turn, are excluded from participating in accredited education. The problematic/unclear definition of an eligible/ineligible organization makes this more challenging. There needs to be more clear definitions/guidelines regarding healthcare products, and when someone is considered a producer or retailer of such goods. Perhaps some clarification is needed around stocks and stock options - should someone be required to own some minimum percentage of a company's stocks in order for that to be worth noting or for it to be considered relevant? How is relevance decided?
Accredited CE provider	ACCME	School of medicine	I am concerned with #1 where it says that individuals must disclose regardless of their view of the relevance of the relationship. Isn't that the purpose of disclosure process to allow the faculty member to identify their relevant disclosures? By having them document all disclosures, the CME staff or others involved in the planning may have to take additional steps to clarify the relationship before the resolution process can even occur. CME staff are not always aware of the clinical relationship and service line compared to the topic they have been requested or identified to present on. For self-directed education (case conferences specifically) we always have a course chair and planner whose disclosures would be relevant as they have control of the overarching content of the conference and help moderate and monitor the series. This makes it sound like disclosures would not have to be received or disclosed for anybody involved in those self-directed education. If that was the case, it would need to be made very clear.
Accredited CE provider	ACCME	School of medicine	I image if this is passed as is that most CME providers will simply list all financial disclosures and not try to determine which is relevant and it will be left to the learner to determine if something is relevant or not.
Accredited CE provider	ACCME	School of medicine	I was surprised by the use of the term "mitigate," which is just to lessen something. If we determine there is a relevant relationship, then we would still need to resolve. Perhaps it should be "Identify, Resolve, and Disclose Relevant Financial Relationships with Ineligible Entities."

What comments or questions do you have about Standard 3?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	It was difficult to get physicians to comply with this in the first place and at least made sense that they could determine whether their relationships were relevant to their topic. But they have finally gotten used to doing it. Now they will need to provide information that they "know" is not relevant and I expect we will experience some new unpleasantness as we attempt to comply with this requirement. In addition, the definition of "mitigate" is "to lessen in force or intensity; moderate; make less severe; to make milder; mollify; appease. I think that this term is fuzzy when it comes to a disclosure and resolution process. I think that "resolve" is firmer, more definitive term.
Accredited CE provider	ACCME	School of medicine	Provide examples for the new 3.4 (document the steps taken to mitigate relevant financial relationships)
Accredited CE provider	ACCME	School of medicine	This does nothing to address academic medical centers ongoing and increasing issues with employees of spun-off companies from development of new technologies, molecules, medications, devices. You may have tried to address this by adding “biomedical startups” as ineligible entities, but it’s not clear. I see we still have the same three “special circumstances” which means that things are just as confusing as ever. The revisions have missed the opportunity to help us navigate this issue within our organizations. Could you define “employee/owner” better – is it someone receiving a salary or paycheck? Is it a specific title you are looking for? What is the intent behind this, and can you explain how the exceptions meet that intent? I think we’re trying to say drug reps can’t sell during education (makes sense, so say that), but it’s the gray and details that make this so often confusing and convoluted. Self-directed learning, as I understand it, is great – thank you! A move towards more common sense…

What comments or questions do you have about Standard 3?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	This policy is surprising in its grounding in the past and lack of respect for those accrediting CME. Providing high quality CME free of industry influence is the responsibility of all of us, on that we all agree. However, a policy that prevents experts in the field from participating in CME as teachers and concurrently prohibits CME accreditation organizations from providing local oversight is misguided. With regard to lack of trust in CME accrediting organizations: the premise of this rule appears to be that the local organizations accrediting CME programs are incapable of policing these conflicts. In almost every other aspect of the guidelines for CME accreditation the local organization certifying the credit in charged with assuring quality, non-conflicted material is presented. Why are they incapable of assessing if a speaker is conflicted to a degree that mitigation is impossible? If the CME organizations are doing their job correctly, they identify and mitigate the conflict; if not upon reapplication the ACCME has the ability to review and evaluate.
Accredited CE provider	ACCME	School of medicine	We will prepare a new Disclosure Form.
Accredited CE provider	ACCME	School of medicine	Where would you expect us to document the steps taken to mitigate relevant financial relationships? We do this through different mechanisms, but do not have a standardized way to document the mitigation that occurs.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Hospital/healthcare delivery system	Overall, we like the concepts of where this is going.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Hospital/healthcare delivery system	Would learning from teaching fall within the exception for self-directed continuing education?

What comments or questions do you have about Standard 3?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (other)	While the exceptions in section 2 are important they create a possible avenue for non-compliance due to misinterpretation. Extensive FAQ guidance and examples of compliance/noncompliance would be helpful. Presently, many providers just say no owners/employees in ALL cases to avoid possible noncompliance/misinterpretation of these specific situations. Like the note "Standard 3 applies to all accredited continuing education." Should help remove any confusion among organizations that don't accept commercial support that this standard applies to them as well.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	• In item 4a, it notes that steps for planners would occur before planning begins. However, a common strategy is recusal, which by definition occurs during the planning conversations and not before. It may be helpful for the ACCME to clarify what types of strategies it considers will demonstrate compliance for each category of individuals in control of content.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	3.2- Exclusion of experts in rapidly evolving fields because of ownership in startups may be inappropriately applied because providers do not know the various paths to FDA approval/clearance. Education and guidance is needed on how to determine pipeline status of products. 3.4 – Re: mitigate relationships prior to the individual assuming their role – “assuming their role” means that one has accepted the role, however, the disclosure process does not occur until faculty has agreed to participate in the activity. Suggested Change: Mitigate relationships prior to the individual participating in the planning and development of accredited education. Take steps appropriate to the role of the individual.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	What was the rationale for shifting the responsibility from the speaker to the provider staff? The speaker has a higher level of qualification to identify the relevance of a given relationship as it relates to a presentation. What does the ACCME hope to accomplish with this change and what training will be provided to non-clinical staff who are expected to have enough content expertise to make this determination? It is requested that the ACCME clarify the vision on how this will work for the providers. Also, what tools and resources will be available?

What comments or questions do you have about Standard 3?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Other: academic medical center	Simply unworkable.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Other: Electronic health record company	We agree with full disclosure of all financial relationships and providing a statement to learners that they have been mitigated.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	3.1- Education/Guidance is needed on means to obtain such disclosure in ways that will lessen burden on faculty and providers. Would it be acceptable to ask planners/faculty to indicate which relationships they see as being relevant to the content of an activity (from the overall list they submit yearly)?
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	3.1- It would be very useful if the ACCME could supply some education/guidance on means to obtain such disclosure in ways that will lessen the burden on both faculty and providers. For example, would it be acceptable to ask planners/faculty to indicate which relationships they see as being relevant to the content of an activity when submitting their full list of disclosures? 3.2- We consider it would be useful to have some additional education/guidance to help with the determination to exclude experts in rapidly evolving fields because of ownership in startups. Without this education/guidance, determination may be inappropriately made because some providers may not know the various paths to FDA approval.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	My comment here is regarding the difficulty of engaging non-conflicted planners/reviewers in certain medical disciplines such as oncology. The standard around planners/reviewers could be further explained. Such as planning committees with planners/reviewers with conflicts must have adequate means to mitigate conflicted members' input. It is sometimes impossible to find a non-conflicted reviewer and/or planner so clear guidelines would be very welcomed.

What comments or questions do you have about Standard 3?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	Our clinical staff routinely screen disclosed conflicts for relevance to a given activity and employ a number of mitigation strategies. We look forward to guidance on compliance with 3.4 a/b. Can peer review still be used to help mitigate conflicts or should faculty with relevant conflicts no longer be speaking about treatments? This could be challenging in rapidly evolving fields (e.g. oncology) where many trials/investigators are pharma-supported.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	Many providers under the current standards have adopted a policy that requires disclosure 1 time per 12 months instead of asking for disclosure for the previous 12 months from the time of engagement in a specific activity. Will the ACCME still allow for annual disclosure under the revised standards? Provider teams often do not include clinical experts, under the current standards we rely on non-conflicted members of planning committees to consult with us in order to determine if a disclosed relationship is relevant to the content of the activity, with the provider team making the final decision. Will this process be allowed by the ACCME under the revised standards?
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	Standard 3.4a – Resources to support the revised standards should include examples of steps to mitigate relevant financial relationships for planners prior to the individual assuming their role.
Accredited CE provider	Other: Accreditation Council for Pharmacy Education	Nonprofit (other)	- If individuals must disclose all financial relationships regardless of perceived relevance, then the Standard's language should be changed to identify all, not just relevant, relationships - Could there be defined mitigation strategies for employees of ineligible entities?
Accredited CE provider	Other: ACPE	Government or military	Under Exception for self-directed CE (I interpret that as home study), I'm not sure why you conclude that there is less opportunity for bias. I think that there should still be a declaration of the presence or absence of relevant financial relationships. In other words, ALL activities should have this requirement.

What comments or questions do you have about Standard 3?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Other: ACPE	Hospital/healthcare delivery system	In relationship to my concerns with standard 1 (i.e., ineligible entities), I strongly agree with the exception specifically stating, "when the content of the activity is not related to the business lines or products of their employer/company". In providing education we are not seeking to increase the profitability of our employer, but rather to improve the understanding and skills of our healthcare colleagues. This should apply to standard 1 as well.
Accredited CE provider	Other: ACPE	Publishing/education company	We appreciate the distinction of individual stocks vs stock options as that is a common question. Regarding the last sentence about self-directed learners, some resources controlled by ineligible entities are accurate and may be helpful to learners (they often have useful graphics/videos). We would think that information could be vetted appropriately.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	1) Definition of mitigate? 2) If all who control content (planners, presenters, reviewers) attests to the provider to behaviors in their role in the activity that are in accordance with the ACCME Standards for Commercial Support would this suffice as mitigation?
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Consider adding to the time requirement for disclosure of financial relationship. "Within the prior 12 months" does not include the coming year for transactions or relationships in the making (i.e. payments to be made in the future for services).
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	I support the requirement to have accredited providers collect disclosure information about all financial relationships and to determine the relevance. This has been our standard procedure and we have discovered actual conflicts of interest the individual did not note as relevant.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	In the case where there are no commercial interest relationships, do we still need to provide a verbal/written disclosure to learners at the beginning of each session of an RSS, or are there ways to make this easier? For instance, a disclosure at the beginning of the year, or a disclosure in the email invitation?

What comments or questions do you have about Standard 3?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	It is a trust matter when we ask for the disclosure of relevant information, but learners can usually differentiate between a real educational session and a marketing session. This change puts a much greater burden on the accredited provider, making it almost impossible for smaller accredited providers to perform.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Recycled information in a different format.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Standard 3 emphasizes importance of information collection and disclosures surrounding all accredited education programs. I agree with the statements reviewed.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Thank you for the clear definitions with the new Standards. It makes our job easier, as we can send these on to those who have questions.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	We would like you to create an algorithm checklist so that if/when we have potential conflicts we can use the checklist as our tool to ensure we are asking all the right questions and then have evidence for re accreditation of our process and possible conflict of interest resolution. Thanks.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Why do we need to include statement about mitigation? Isn't it obvious that if the financial relationship was not mitigated, the activity should not be CME approved?
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Widespread banning of interactions with “non-eligible entities” has inhibited discussion and consideration as to the risks and benefits of all available treatments for our patients. I suggest that we stop such blatant discriminatory policies and instead foster that the Continuing Medical Education Committees have oversight over these activities and designate structure and a different credit system for education from these ineligible entities.

What comments or questions do you have about Standard 3?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Would we be expected to update the disclosure language on all of our IEM/EMs that were edited and published prior to the change? Is the ACCME flowchart still applicable? It is very helpful and should be updated.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	YES! So glad to see this change!
Accredited CE provider	Recognized Accreditor (state/territory medical society)	School of medicine	Suggest changing "faculty" to "speaker". Faculty in an academic institution refers to professors and instructors. Speakers is more inclusive of ACCME approved providers. Speaker is referenced here, "The nature of the financial relationship. Examples of financial relationships include employee, researcher, consultant, speaker, independent contractor (including contracted research), royalties or patent beneficiary, executive role, and ownership interest." To be consistent, speaker should be used instead of faculty.
Clinician/healthcare professional			allow for teaching of innovative medical concepts
Clinician/healthcare professional			Good to have a disclosure of all financial relationships rather than just 'relevant' ones. For standard 3.4. Suggest the ACCME prepares supplemental information on best practices to mitigate/ resolve conflicts of interests. Given the educational emphasis on active learning and best practices for PowerPoint slides, reviewing slides as way to mitigate/resolve conflict may no longer be sufficient.
Clinician/healthcare professional			Self-directed education is important. My only concern is whether there are risks for bias that cannot be reviewed.
Clinician/healthcare professional			What number of individual shares is considered a financial conflict? Is the spouse/partner, who may have acquired the shares long before the personal relationship expected to relinquish their shares?

What comments or questions do you have about Standard 3?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Continuing education accrediting body			When considering the potential effect of revisions to colleague accreditors, it's worth noting that Self-Directed Continuing Education is not a term used by all. ACPE refers to self-directed learning as Continuing Professional Development (CPD) and defines categories/examples of learning outside of accredited CE that could be considered acceptable/valuable for CPD. Examples include reading/reflecting on healthcare literature, consultation with peers to address practice problems/needs, peer coaching/mentoring, serving as a content reviewer, professional volunteerism (e.g., holding office, committees/SIGs, community service), etc.
Medical/healthcare association			Although agree with the intent of this standard and its update, this is where the use of eligible and ineligible terms to learners could become unintentionally confusing.
Medical/healthcare association			Regarding determining whether an entity is eligible or ineligible, we urge the ACCME to develop a rubric or other guidance to assist in gathering information to make that determination, starting with what is the parent company, what is the primary business of that entity, if eligible parent but ineligible sister companies- what firewalls are required. Then on to the relevance to content - how to web search for products and indications, find and interpret a research pipeline, determine if human trials have begun and/or other entry into an FDA process of clearance/approval, etc.
Medical/healthcare association			The AMA Council on Medical Education is also concerned that while financial relationships are one source of potential coercion as it relates to continuing medical education, we also realize that they are not the only sources of coercion and the Council recommends that this be commented on within these revised standards.
Medical/healthcare association			We currently collect all possible conflicts from our members for review and resolution.
Nonaccredited CE provider			3.1- Education/guidance would be helpful on means to obtain such disclosure in ways that will lesson burden on faculty and providers. Would it be acceptable to ask planners/faculty to indicate which relationships they see as being relevant to the content of an activity and then have providers verify and confirm?

What comments or questions do you have about Standard 3?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Nonaccredited CE provider			Section 3.2.c appears to directly contradict 1.4. 3.2.c allows an exemption for ineligible entities to teach the use of a specific medical device, where section 1.4 specifically forbids this the instruction of "how and when to use" devices, diagnostics, or procedures. Why this inconsistency? 1.4 "Accredited education may inform learners about approaches to diagnosis or treatment that are controversial or not generally accepted but must not include advocacy for these approaches or teach healthcare professionals how or when to use them." 3.2 Exclusion exemption "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."
Other: Answering both as accreditor and accredited provider.			WSMA supports the language changes. (COI = RFR and “resolve COI” = mitigate) 3.1b Clarification needed: for contracted research, are the named or principal investigators still the only researchers who need mitigation? 3.4 Will ACCME keep its guidance for mitigation (i.e., keep the flow chart but update to current language)? There should be a link to this guidance in the Standards. 3.5d WSMA supports the new standard that requires the disclosure that RFRs have been mitigated.
Other: Consultant - own my own company			I appreciate the clarity on disclosure (especially that those will no relationships can be disclosed as group).
Other: Joint Provider			The fact that an employee of an ineligible entity cannot ever present at CME and can add no value to a CME event limits the ability to provide the most current evidence-based content to our participants. We are adults. The speaker already has to disclose and have a disclosure slide in their presentations. There is a process in place to review and evaluate that content prior to any speaker getting on the stage. As long as that speaker does not directly promote or recommend a specific brand product, there should be the ability to resolve these disclosures.

What comments or questions do you have about Standard 3?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: State Medical Society/Publisher/Accredited Provider/Recognized Accreditor			For journal-based CME, how will disclosure for authors be managed? What is the definition of self-directed learning in this case? If this does not apply to case-based RSS, but is limited to point of care learning, then it is suggested that this be clearly stated in the Standard.
Recognized Accreditor (state/territory medical society)			3.1b: does this remove the need for disclosers to include what was/is being received (salary, honoraria, etc.)? Excellent changes and simplification.
Recognized Accreditor (state/territory medical society)			Don't agree with replacing the word resolve with mitigate. Mitigate is seen as "trying to" whereas Resolve gives a better perception of actually doing something. Does 'mitigate' send the message that CME providers only want to make financial relationship 'less severe' versus 'resolve' them?
Recognized Accreditor (state/territory medical society)			I suggest that the disclosure be expressed exactly as in number 5, with the a, b, c, and d answered in the presentation. That is, to be presented to the learners follow the outline.
Recognized Accreditor (state/territory medical society)			Is the statement about having mitigated all RFRs only required when there are RFRs to disclose? So that if there are none to disclose, a statement like "None of the planners or faculty have relevant financial relationships to disclose" would still be sufficient?
Recognized Accreditor (state/territory medical society)			It will be an adjustment to change the word resolve to mitigate but that will be expected. What is important is that we are preserving and protecting the value of Accredited CE.
Recognized Accreditor (state/territory medical society)			Making it clear that it is the accredited provider's responsibility to determine which relationships are relevant is excellent. Programs that leave the participant disclosure up to faculty should be made con compliant.
Recognized Accreditor (state/territory medical society)			One of our providers did not feel that the change to the word "mitigate" is worthwhile.
Recognized Accreditor (state/territory medical society)			Please keep current requirement to collect relevant financial relationships.
Recognized Accreditor (state/territory medical society)			Previously noted comment related to spouse/partner language clarification.

What comments or questions do you have about Standard 3?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Recognized Accreditor (state/territory medical society)			Seeing that non-clinicians are often involved in the planning of CME, while all financial relationships will be asked for, could it then be asked of the individual which they believe are relevant? Or will this task have to be completed by a clinician?
Recognized Accreditor (state/territory medical society)			Standard 3 # 4 : Keep - Take steps to prevent all those with relevant financial relationships from inserting commercial bias into content. I prefer the use of the words - establish and sort out - in place of mitigate for a and b respectively. a. Establish relationships prior to the individuals assuming their role. Take appropriate steps based on the individual's role. For example, the steps for planners will likely be different than for faculty and supersede the faculty and would occur before planning begins. b. Document the steps taken to sort out relevant financial relationships.
Recognized Accreditor (state/territory medical society)			The individual in control needs to specify specialty area(s) or specialty area(s) and health care good(s) or service(s) of the ineligible entity related to the financial relationship this because we would not know this without asking the individual in the first place. It should be part of the data gathering. Will decrease guess work, decrease extra work, and streamline the process.
Recognized Accreditor (state/territory medical society)			We have some concern about use of the word "mitigate" and what that will mean to providers (regardless of actual definition.)
Recognized Accreditor (state/territory medical society)			What is the marker for being an employee of a bio-medical startup that is beginning an approval process through the FDA, and how is an accredited CME provider going to make that determination? Is it simply the individual's name being listed in the FDA database for Form 510k pre-market notification (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm)? If the bio-medical start-up as a company exists only on paper (e.g. no venture capital investment nothing in production), is that faculty member still prevented from talking on the subject, and when is the stopping point?

Standard 4: Manage Commercial Support Appropriately

Is Standard 4 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider			Delete the NEW provision that accredited providers must pay or reimburse expenses to individuals such as faculty; joint providers cannot make these payments.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	"The accredited provider may use commercial support to fund honoraria or travel expenses of planners, faculty, and others in control of content for those roles only. These expenses must be paid or reimbursed to the individuals directly by the accredited provider, and not by the ineligible entity or by a joint provider." - REMOVE JOINT PROVIDER! This will cause numerous administrative issues. I do not have the staff or the time to distribute funds for our joint providers. It is time consuming to set up new vendors in our system.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	It appears the Standard is targeted to ineligible entities; yet it introduces Joint Providers in 4.1.b.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Standard 4 #1b: Are there other costs that commercial support can be used for, such as venue, AV costs, printing, marketing materials? Standard 4 #1d: Can commercial support cover the cost of tuition and registration for learners? Can you please define learners?
Accredited CE provider	ACCME	Hospital/healthcare delivery system	there seems to be a change that was not highlighted in the summary of changes regarding decision-making and disbursement. Reference item b and the exclusion of a joint provider in this role. I suggest omitting "...or by a joint provider." from the following phrase. "...and not by the ineligible entity or by a joint provider."
Accredited CE provider	ACCME	Nonprofit (other)	Consider providing examples to accompany Standard 4.1.a. – “expenses related to the education or learners” include: meals, AV equipment for the CE activity, CE venue expenses, etc. OR state “anything beyond payment for exhibit space, etc.”

Is Standard 4 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (other)	In many instances, it is the joint provider who manages the activity under the direction of the accredited provider. This includes contracting with vendors, identifying and communicating with faculty, working with medical writers, and many other aspects of activity development and dissemination. In Standard 4, it is unclear whether or not the joint provider is permitted to pay vendors, such as a hosting web site or an audience generation vendor, directly. We suggest making it clear that the joint provider is permitted to make payments for activity development as necessary, under the supervision and approval of the accredited provider.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	"Joint Provider" should be removed from Standard 4.1b. Within Standard 4.1b, joint providers should be excluded from this as the roles and responsibilities should be clearly documented between the eligible entity and whom they are partnering with. It is fine to say ineligible entities cannot directly pay these expenses, but we partner with many organizations that could be considered eligible entities and they help share responsibilities, which includes reimbursing faculty expenses.

Is Standard 4 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	4.1.a. – If commercial support (CS) for jointly provided (JP) activities must be received/paid by accredited providers (AP) & not any JPs/educational partners, that should be explicitly stated. Would it be acceptable for the AP to direct the JP to receive/disburse CS for an activity? Requiring APs to disburse CS for JP activities will require more resources/systems to manage & increase the time to receive/process disbursements; not all organizations are set-up to manage that for JPs. It may also have unintended consequences of fewer organizations collaborating on accredited CE, which would negatively impact learner knowledge/skills & patient care & may prompt some commercial supporters to reconsider providing CS for CE. Alternatively, improvements in CS accounting for JP activities should be identified to ensure appropriate management/oversight. Clarification is also needed on how this relates to in-kind support at JP activities and expected oversight required of APs. 4.1.b. – Would the AP only need to pay/reimburse faculty expenses if CS is used for that purpose? If used for other costs (eg, AV), could the JP reimburse faculty/author expenses? 4.1.c. – Would commercially supported scholarships to residents/fellows remain acceptable & not addressed under these Standards? 4.3 – Besides documentation reviewed during reaccreditation, please specify when the ACCME would request an accounting of CS for an activity. We recommend that the current SCS 3.13 be maintained.

Is Standard 4 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	4.1: We have great concern about the proposed requirement of the accredited provider (and not the joint provider) to pay or reimburse directly to the individuals in control of content honoraria or travel expenses. This is the one requirement that has the most potential for disruption to the CME community. The additional workload to the accredited provider would most likely result in significantly increased joint providership fees which, in turn, could deter non-accredited entities from pursuing joint providership which in turn could result in a reduction in the availability of accredited continuing education to healthcare professionals. If the intent of the ACCME is to ensure more control of the accredited provider with the payment of honoraria and travel expenses to those in control of content, we propose that there are many other ways to achieve this goal without adding an unnecessary administrative burden to accredited providers. For example, the accredited provider could require a timely, detailed accounting of all disbursements of joint providers to all those in control of content to the accredited provider. The accredited provider can hold the joint provider accountable. If this requirement were to remain, clarification will need to be provided as to whether it ONLY pertains to those CME activities for which commercial support is received or if the intent is that this would pertain to ALL joint provided CME activities regardless of commercial support.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	4.1a Accredited providers need the flexibility to work with educational partners who are not ineligible entities. Although the financial management is the responsibility of the provider, that does not necessarily mean that honorarium or expense payments cannot be managed from another source. Recommendation- The accredited provider in collaboration with any educational partners is responsible for dispersing the commercial support. OR The accredited provider is responsible for the management of the commercial support.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	4.1a. Remove the first sentence, or alter to say “The accredited provider – or their designated accredited and/or eligible partner – is responsible for dispersing the commercial support.” 4.1b. “Joint Provider” should be removed from the end of the last sentence. Alternatively, the language could be amended to say, “These expenses must be paid or reimbursed to the individuals directly by the accredited provider or their designated accredited and/or eligible partner.”

Is Standard 4 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	4.3 – Delete “must produce that accounting, upon request” from the standard. This is an intrusive request and an attempt to exert unnecessary control over accredited providers. The request of additional financial records should only be permitted if there is a formal complaint or when the accredited provider is undergoing reaccreditation.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Consider this edit to first paragraph: "The support does not establish AN INAPPROPRIATE financial relationship between the ineligible entity and planners..." 4.1.a. Delete. 4.3 Edit to “The accredited provider either in direct or joint sponsorship must ensure that commercial support is managed appropriately.”
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Defer to CMSS response.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	It would be helpful if the ACCME could be more specific regarding how detailed the accounting record needs to be when we receive general support. 4.1a -Suggested change: "The accredited provider is responsible for making all decisions and diligent oversight regarding use of commercial support." 4.1 4.1b -Suggested change: "The accredited provider is responsible for ensuring that all financial commitments to faculty and planners are met in a timely manner. Ineligible entities may not pay faculty or planners directly." 4.1c- Add “Commercial support may be used to fund travel expenses for students in the health professions providing that all decisions made regarding awarding such funding are made independent of any ineligible entity.”
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Rather than requiring that the accredited provider in the joint providership relationship process the payments to those in control of content (item 1b), require that the accredited provider maintain documentation of any honorarium or reimbursement payments being made either by the accredited provider or the education partner. This could be accomplished through the requirement of item 3 (Accountability) as part of the record of how commercial support was used.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Rather than requiring that the accredited provider in the joint providership relationship process the payments to those in control of content (item 1b), require that the accredited provider maintain documentation of any honorarium or reimbursement payments being made either by the accredited provider or the education partner. This could be accomplished through the requirement of item 3 (Accountability) as part of the record of how commercial support was used.

Is Standard 4 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Standards 4a and 4b seem redundant and could be combined (or reworded if something needs to be distinguished between them).
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Suggest that accredited providers, while still entrusted to ensure education remains independent, be allowed to delegate dispersing of commercial support as well as expenses paid to individuals to a joint provider of the activity. Agreements – if the activity is jointly provided, the agreement must include the joint provider.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Suggested change: "The accredited provider is responsible for making all decisions and diligent oversight regarding use of commercial support" Suggested change: "The accredited provider is responsible for ensuring that all financial commitments to faculty and planners are met in a timely manner. Ineligible entities may not pay faculty or planners directly." Add "Commercial support may be used to fund travel expenses for students in the health professions providing that all decisions made regarding awarding such funding are made independent of any ineligible entity."
Accredited CE provider	ACCME	Other: Teleconferencing Medical Education Company	Again, 'others in control of content' is too vague.
Accredited CE provider	ACCME	Other: University - not a school of medicine	4.1b - include "Ineligible entities may not pay faculty or planner honoraria directly" 4.1c - Include "all decisions regarding student travel to be made by accredited provider independently of any ineligible entity"
Accredited CE provider	ACCME	Publishing/education company	4.1a -Suggested change: "The accredited provide is responsible for making all decisions and diligent oversight regarding use of commercial support." 4.1 4.1b -Suggested change: "The accredited provider is responsible for ensuring that all financial commitments to faculty and planners are met in a timely manner. Ineligible entities may not pay faculty or planners directly." 4.1c- Add "Commercial support may be used to fund travel expenses for students in the health professions providing that all decisions made regarding awarding such funding are made independent of any ineligible entity."

Is Standard 4 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	4.1a -Suggested change: Delete first sentence. This responsibility has already been addressed in the stem statement of the standard. 4.1 4.1b -Suggested change: "Commercial support may be used to fund honoraria or travel expenses of planners, faculty, and others in control of content for those roles only. The accredited provider is responsible for ensuring and documenting that all financial commitments to faculty, planners, and others in control of content are met in a timely manner. Ineligible entities may not pay faculty or planners directly." 4.1c- Add “Commercial support may be used to fund travel expenses for students in the health professions providing that all decisions made regarding awarding such funding are made independent of any ineligible entity.”
Accredited CE provider	ACCME	Publishing/education company	4.1a Suggested change: Delete first sentence. This responsibility has already been addressed in the stem statement of the standard. 4.1 4.1b Suggested change: "Commercial support may be used to fund honoraria or travel expenses of planners, faculty, and others in control of content for those roles only. The accredited provider is responsible for ensuring and documenting that all financial commitments to faculty, planners, and others in control of content are met in a timely manner. Ineligible entities may not pay faculty or planners directly." 4.1c- Add “Commercial support may be used to fund travel expenses for students in the health professions providing that all decisions made regarding awarding such funding are made independent of any ineligible entity.”
Accredited CE provider	ACCME	Publishing/education company	4.4: not clear what qualifies as disclosure "prior to the learners engaging". Same issue with disclosure of relevant financial relationships in Standard 3.5

Is Standard 4 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	Although 4.1.a begins "the accredited provider is responsible for dispersing the commercial support." it is not clear that the following sentence applies only to the use of said commercial support. For example - if a learner is themselves employed by an ineligible entity - would "Ineligible entities must not pay directly for any of the expenses related to the education or the learners." prohibit that person from being reimbursed or covered by their employer if they attend and participate as a learner only? Adding "... in a manner associated with the grant of commercial support" may ameliorate this issue. 4.1.b - why not let a joint provider issue the payment? They're likely the ones managing the budget for the activity. The accredited provider, in their oversight role, is akin to an IRB. That would be like requiring the IRB itself to reimburse clinical study participants for their mileage instead of ensuring that the conductors of the clinical study are operating safely and ethically. As long as the payments are made in accordance with the honorarium and reimbursement policies of the accredited provider, shouldn't it be acceptable for the joint provider to issue the payment? It's already assured that the joint provider could not themselves be an entity ineligible for accreditation. 4.4 - please clarify "prior to the learners engaging in the education" . "Prior to the beginning of the educational activity" was so elegant.
Accredited CE provider	ACCME	Publishing/education company	In many instances, it is the joint provider who manages the activity under the direction of the accredited provider. This includes contracting with vendors, identifying and communicating with faculty, working with medical writers, and many other aspects of activity development and dissemination. In Standard 4, it is unclear whether or not the joint provider is permitted to pay vendors, such as a hosting web site or an audience generation vendor, directly. Make it clear that the joint provider is permitted to make payments for activity development as necessary, under the supervision and approval of the accredited provider. Joint providers should be able to pay their faculty. It would be labor intensive on the accredited provider to take this on.
Accredited CE provider	ACCME	Publishing/education company	The Standard does not specifically say a joint provider cannot make payments to faculty and expenses associated with the educational activity. However, it specifically states that in the explanation.

Is Standard 4 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	While the content of Standard 4 has been edited and formatted to align with the proposed update, the overall intent and rules have remained the same for accredited providers. However, when the accredited provider engages in a joint providership relationship, the proposed Standard would be implemented in such a manner that the accredited provider would be directly responsible for handling all of the transactions relating to commercial support rather than thorough oversight and auditing of the non-accredited party. If this is the intent of the ACCME, I have no text edits to the Standard, but believe the challenges described below should be considered.
Accredited CE provider	ACCME	School of medicine	4.1 4.1b -Suggested change: "Commercial support may be used to fund honoraria or travel expenses of planners, faculty, and others in control of content for those roles only. The accredited provider is responsible for ensuring and documenting that all financial commitments to faculty, planners, and others in control of content are met in a timely manner. Ineligible entities may not pay faculty or planners directly." 4.1c- Add “Commercial support may be used to fund travel expenses for students in the health professions providing that all decisions made regarding awarding such funding are made independent of any ineligible entity.”
Accredited CE provider	ACCME	School of medicine	4.1b. Please consider modifying this standard to read something like the following. “These expenses may not be paid or reimbursed to the individuals directly by the ineligible entity but must involve a process that documents oversight by the accredited provider. The accredited provider needs to document the payment or reimbursement to the individuals.” The accredited provider would also need to provide evidence of all payments to individuals (e.g., confirmation letter with stated honorarium, reimbursement request with receipts, copies of checks) to document appropriate payment regardless of direct or joint providership.

Is Standard 4 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	Could you define “commercial support”? I think we are talking grants and not exhibitors or vendors which are still outside the educational space & time and so remain a business arrangement not part of accredited education? It would nice if you could be clear about that somehow. “in kind” gets a bit lost in here and is a legalese term that CPD providers may not pick up on or understand. Could you highlight, define and/or say “commercial support includes in-kind donations from ineligible entities that might include things like equipment to use during hands-on demonstrations, supplies, durable goods, etc.”? These comments get addressed in Standard 5, but always nice to define the terms first – maybe flip Standard 4 and 5?
Accredited CE provider	ACCME	School of medicine	joint provider and ineligible entity are not the same thing. This sentence is very confusing - "These expenses must be paid or reimbursed to the individuals directly by the accredited provider, and not by the ineligible entity or by a joint provider" A joint provider is an eligible entity, often times a nonprofit, working with a provider to develop content. They are not the same as an ineligible entity.
Accredited CE provider	ACCME	School of medicine	Modification to allow joint providers to pay expenses of honorarium and travel directly as long as the accredited provider maintains control/oversight of funds. Also the ability for joint providers to directly accept commercial support funds.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Hospital/healthcare delivery system	Standard 4: #1a It is clear as written however we feel it leaves a question unanswered regarding if the Joint Provider is able to collect and disperse as long as we are in the loop and aware of all funding sources, amounts, etc.

Is Standard 4 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	4.1a – Suggested Change - The accredited provider or their joint provider is responsible for dispersing the commercial support. Ineligible entities must not pay directly for any of the expenses related to the education or the learners. 4.1b – Suggested Change - The accredited provider may use commercial support to fund honoraria or travel expenses of planners, faculty, and others in control of content for those roles only. These expenses must be paid or reimbursed to the individuals directly by the accredited provider or their joint provider, and not by the ineligible entity. 4.1c- Add "Commercial support may be used to fund travel expenses for students in the health professions providing that all decisions made regarding awarding such funding are made independent of any ineligible entity."
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	Does payment by the accredited provider only relate to faculty/planner honoraria/travel? What about all the other expenses? Venue? Printing? Why single out honoraria/travel? What is the intent here? If payment of honoraria has intent, why is it acceptable for the JP to pay other expenses? Suggest: The accredited provider is responsible for managing and approving disbursement of the commercial support. The accredited provided may give control of this disbursement of funds to a joint provider. Ineligible entities must not pay directly for any of the expenses related to the education or the learners.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	For Standard 4.1b, we would suggest the following wording: The accredited provider is responsible for ensuring that all financial commitments to faculty and planners are met in a timely and appropriate manner. Joint Providers may pay faculty or planners directly and submit proof of payment to the accredited provider.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	It mentions joint providers may not distribute funds, does it also include may not accept the funding? 1.b - It states expenses may not be paid by ineligible entity or by a joint provider. What if the joint provider is an eligible entity?
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	Standard 4.1 and 4.1a – "The accredited provider must make all decisions regarding the receipt and disbursement of the commercial support" and "The accredited provider is responsible for dispersing the commercial support" seem to contradict one another.

Is Standard 4 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Recognized Accreditor (state/territory medical society)	School of medicine	1.b. The accredited provider may use commercial support to fund honoraria or travel expenses of planners, faculty, and others in control of content for those roles only. These expenses must be paid or reimbursed to the individuals directly by the accredited provider, and not by the ineligible entity or by a joint provider. What is the reason behind this proposed change? It is not reasonable to have the accredited provider disperse funds when working with a joint provider. As the accredited provider, I review and sign the financial support letter of agreement to ensure the terms and conditions are in accordance with the ACCME Standards of Commercial Support AND I review and approve the activity budget which includes the collection and payment of expenses (e.g. speaker honorarium and travel). My accounting department does not pay the joint providers expenses - the joint provider has their own accounting process. It will be an accounting logistical nightmare if me (as the accredited provider) must pay the joint providers expenses. Joint provider relationships within my program will cease and my department will loose about $25,000 in revenue each year.
Advocacy organization			• 4.1b. Please consider modifying this standard to read something like the following. “These expenses may not be paid or reimbursed to the individuals directly by the ineligible entity. Document the payment or reimbursement to the individuals.” The accredited provider would also need to provide evidence of all payments to individuals (e.g., confirmation letter with stated honorarium, reimbursement request with receipts, copies of checks) to document appropriate payment regardless of direct or joint providership. • Our strong recommendation is to remove the Joint Providers from this Standard, specifically Standard 4.1.b. This Standard should be targeted to ineligible entities, as it has been in the past.

Is Standard 4 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Advocacy organization			In many instances, it is the joint provider who manages the activity under the direction of the accredited provider. This includes contracting with vendors, identifying and communicating with faculty, working with medical writers, and many other aspects of activity development and dissemination. In Standard 4, it is unclear whether or not the joint provider is permitted to pay vendors, such as a hosting web site or an audience generation vendor, directly. NAMEC suggests making it clear that the joint provider is permitted to make payments for activity development as necessary, under the supervision and approval of the accredited provider.
Clinician/healthcare professional			It focuses largely on financial support. Please elaborate on "in kind" support- materials, space, non-monetary resources or services.
Clinician/healthcare professional			It is clear unless research does not exist.
Ineligible Entity (commercial interest, such as pharmaceutical, device, life-science company)			Standard 4.1.a. The accredited provider or partner is responsible for ensuring appropriate disbursement of commercial support. Ineligible entities must not pay directly for any of the expenses related to the education or the learners." Standard 4.1.c. The accredited provider must not use commercial support to pay for travel, lodging, honoraria, or personal expenses for individuals or groups of learners in accredited education except in the case of conference scholarships to students, residents, or fellows.
Medical/healthcare association			General statement: It would be beneficial for the standards to specify what type of commercial support is acceptable. For example, should all commercial support be in the form of an unrestricted educational grant? Is there another type of funding for accredited programming that is acceptable? Section 4.3: For accountability, we believe clarifying the supporting sentences would be helpful. We propose the following language, "The accrediting provider must keep a record of the amount and type of commercial support received. The provider must also keep accounting records on how the commercial support was used and must be able to provide an accounting summary to [change accrediting body to ACCME] and the commercial supporter upon request." This section also needs to clarify whether the "accounting" (as used in the above sentence) is for each individual activity or whether it refers to the entire program.

Is Standard 4 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Nonaccredited CE provider			4.1 a Alternative Language: accredited provider is responsible for overseeing the disbursement of commercial support. 4.2 a Alternative Language: These expenses must be paid or reimbursed to the individuals directly by the CME provider or their designated education partner or joint provider and not by the ineligible entity. This responsibility should be clearly outlined in an agreement between each organization.
Nonaccredited CE provider			4.1a -Suggested change: "The accredited provider is responsible for making all decisions and for diligent oversight regarding use of commercial support." 4.1b -Suggested change: "The accredited provider is responsible for ensuring that all financial commitments to faculty and planners are met in a timely manner. Ineligible entities may not pay faculty or planners directly."
Other: Answering both as accreditor and accredited provider.			4.1a and 4.1b are very similarly worded and could create confusion. 4.3 Clarification needed. How detailed does accounting need to be? Do accredited providers need to do all of the accounting for commercially supported activities?
Other: CME/CE Consulting Services Company			Standard 4.1 - This standard seems to position the accredited provider as the sole entity that can control commercial support. Section 1-a reads as though the accredited provider must be solely “responsible” for commercial support, and 1-b specifically calls out that expenses paid or reimbursed to individuals must be made DIRECTLY by the accredited provider and not by an ineligible entity or a joint provider. The added specificity begs the question as to whether the accredited provider must control all commercial support funds, or just those paid to individuals. Lastly, does 1-d eliminate the possibility of a travel grant for trainees, where commercial support is involved? If so, making this explicit would be helpful, given it is currently a carve-out. Standard 4.2 - To confirm, no longer is it required that an education partner(s) be identified? If so, making this explicit would be helpful, given it is currently required.
Other: Consultant			You're using the word "dispersing" when you mean "disbursing."

Is Standard 4 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: I am a clinician-educator, board member of APPS, member of the Academic Consortium of Integrative Medicine and Health, and faculty provider for integrative medicine CME			My understanding of this standard is that commercial contributions cannot be used for scholarships but can be used to defray the cost of the education offering overall. Are non-profits/philanthropic donations/academic programs that fall under the category of eligible entities able to provide scholarships, even if they are not an accredited CME provider?
Other: I am both chair of an Accredited CE provider (WSMA CME Committee) and a member of the WSMA CME Accreditation Committee.			The explanations of how commercial support may be used (Standard 4.1.b and c) are not clear. the wording in b. suggests that commercial support may be used by the accredited provider for travel, honorarium, and incidentals. The wording in 4.1.c has almost the same sequence of wording and appears to say that commercial support cannot be used for travel, honorarium, or incidentals. The wording in 4.1.b needs to clarify how the accredited provider can use the money with an example. Similarly, there needs to be clarification of what commercial support or ineligible entities can and cannot do. My issue is not the concepts, but the similarity of the wording can lead to confusion.
Other: Joint Provider			Accredited providers must pay or reimburse expenses to individuals such as faculty; joint providers cannot make these payments. Our modifications is that joint providers continue to be able to make these payments and provide detailed reports as they do now to their primary providers prior to and after every event in the form of a pre-approved budget and final actual report of revenue and expenses.
Recognized Accreditor (state/territory medical society)			Clarification if this only pertains to the expenditure of commercial support funding. For example, could a joint provider pay or reimburse individuals directly (as current policy) if no commercial support was received for the activity?
Recognized Accreditor (state/territory medical society)			Clarification regarding 4.2. Does the joint provider have to sign the commercial support agreement as well?

Is Standard 4 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Recognized Accreditor (state/territory medical society)			Clarity and examples of the terms, conditions, and purposes of the agreement would be helpful to providers and surveyors.
Recognized Accreditor (state/territory medical society)			Comments in "challenges" section below.
Recognized Accreditor (state/territory medical society)			Explain more in depth who would be responsible for the transfer of money in a joint providership- would all money still have to go through the accredited provider and then given back to the joint provider?

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider			The inclusion of the NEW language in Standard 4 stating joint providers cannot make payments relative to reimbursement of course faculty will have a direct effect on our business model. We are an academic medical center and we engage in joint providership of several activities with organizations who are then the educational partner. If we will be required to make payments for said expenses as a result of receiving commercial support for these activities, the model will no longer be sustainable for us. We incur a 7% Dean's tax at the point any funds are deposited to our accounts. We also have a procurement system that will require all of these faculty to be registered as "vendors" and this will be a monumental task in terms of manpower and time and timeliness. We would most likely have to end our relationship with approximately four joint providers, and this would affect us from a business function standpoint; several of these relationships have been in place for 15+ years.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	"The accredited provider may use commercial support to fund honoraria or travel expenses of planners, faculty, and others in control of content for those roles only. These expenses must be paid or reimbursed to the individuals directly by the accredited provider, and not by the ineligible entity or by a joint provider." - This will cause numerous administrative issues for our joint providers. I do not have the staff or the time to distribute funds for our joint providers. It is time consuming to set up new vendors in our system and this will cause lags in our process. I cannot stress enough how me cannot allow this to work efficiently with our joint providers.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	4.1a – “the accredited provider is responsible for disbursing the commercial support.” --- 4.1b “these expenses must be paid or reimbursed to the individuals directly by the accredited provider, and not by the ineligible entity or by a joint provider”------- I have major concerns with this proposed change as it relates to joint providers. I feel strongly that an accredited provider should be able to have the responsibility/authority to allow our joint providers to pay any/all expenses on our behalf. This proposed change would create a major hardship for my organization and I expect it would negatively impact our ability to work with joint providers.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	4:1. b. - We have a 3-4 jointly provided activities--Handling of funds and paying expenses is delegated to the non-accredited provider with accountability to us. It is extremely cumbersome and inefficient to take in grants, other funds, intended to support the non-accredited provider's education, then deposit them in our system and generate the paperwork and get approvals needed to pay speakers/others. We would discontinue joint providing if this requirement stands as it is.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Being responsible for all of the budget and expenses would limit our ability to collaborate with non-accredited institutions through joint providership. It would also be a challenge internally at the organizational level to change their structure to conform to this new standard.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Changing requirement for funding to go through the accredited provider will place significant burden on the provider. It will slow distribution of funds and place too many entities in the mix of payment handling. The legal department will be heavily involved, and this will place substantial burden on our institution as we do not have designated accounting support and the administrative load will be quite heavy. Smaller institutions, such as our, will be at greater risk for audit due to lack of dedicated accounting staff and placing unnecessary burden on legal, accounts payable, accounts receivable, vendor management, foundations, and financial responsibility will be placed on the provider. We will likely lose joint providers due to this change. This change WILL impact collaboration with joint providers which is the opposite of what we are being asked to promote.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Eliminating the role of Joint Providers in this area is yet am further demand on the time of accredited ones, particularly smaller ones. I suspect that some Joint Providers which are "single focused" may cease operations.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Expecting the accredited provider to pay honorarium and/or reimburse expenses associated with a joint providership could create an unintended barrier to supporting joint providerships and eliminate a significant revenue stream. This approach dissolves the line between verifying the disbursement and being responsible for the disbursement. Unexpected barriers to the success of this proposed standard include: 1) a content expert being on salary as opposed to receiving an honorarium; 2) required creation of new organizational financial and accounting processes to accommodate this new requirement; and 3) lack of the additional staff time to support the processing of additional payments. This standard is similar to the disclosure standard in that it seems to put more strain on an already overextended group
Accredited CE provider	ACCME	Hospital/healthcare delivery system	For those activities that are jointly provided the new addition of (a. The accredited provider is responsible for dispersing the commercial support. Ineligible entities must not pay directly for any of the expenses related to the education or the learners. and b. The accredited provider may use commercial support to fund honorarium or travel expenses of planners, faculty, and others in control of content for those roles only). These expenses must be paid or reimbursed to the individuals directly by the accredited provider, and not by the ineligible entity or by a joint provider) will cause additional work for my staff and have financial impacts on our budget. In an academic institution our accounts are subject to tithe and other withholding and collecting these funds will make it impossible to do jointly provided activities. In addition, one of the benefits of working with a trusted society or organization is that they manage these expenses. These changes will move away from that and add additional work to our team.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	I understand the intent of this and agree that the accredited provider needs to truly provide oversight for joint providership partners. My concern is, given that this isn't the current expectation, will organizations have the necessary financial institutional processes and administrative processes to "be allowed to do this".

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	If joint providers cannot continue to pay directly (with the oversight of the accredited provider) for activity expenses, including faculty honoraria and travel reimbursements, the ripple effect could be devastating to our CME program: 1) CME offices with limited staff, are not set up to manage the distribution of funds quickly to the many faculty and organizations involved in our jointly provided activities due to institutional bureaucracy. The Medical Education Companies with which we jointly provided activities are equipped to disburse payments to faculty quickly because they do not have to navigate the institutional bureaucracy of a hospital or university system. If we were responsible for paying faculty directly for every one of our jointly provided activities, we would have to set up new vendor accounts for every faculty person involved in every activity. The additional bureaucratic red tape involved would severely delay payments to faculty and put additional stress on an already stressed staff. 2) Some institutions charge a “dean’s tax” to process payments to faculty which would then decrease the funds available for running the CME activity. Medical education companies, who are often the ones securing grants, will not be happy with this. Not to mention the fact that grantors will not want to see dollars that were specifically allocated for CME costs, being skimmed off the top of the grant because of institutional “taxes.”
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Standard 4 #1b: Accreditors will not use commercial support in ACCME allowable ways in fear of being non-compliant. Standard 4 #1d: Need clarification to make informed decisions.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Standard 4, 1a, "The accredited provider is responsible for dispersing commercial support." This would create a challenge to accredited providers who work with international organizations (joint providers), where the joint provider receives the commercial funds in local currency and pays expenses related to the CE activity.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	The ACCME trusts the CME Provider to Joint Sponsor with a non-accredited, eligible entity; however, this Standard indicates a lack of trust in the CME Provider to ensure that compliance with all CME Standards has been met. How are the vast number of medical Societies of all sizes throughout the United States supposed to have CME-certified educational events? Many physicians count on those Society events to obtain pertinent and peer-to-peer information exchange. State institutions have specific financial guidelines and are not allowed to accept funding from medical Societies and reimburse speaker expenses.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	The new requirement that the accredited provider must pay all expenses using commercial support – eliminating the opportunity for joint providers to manage these responsibilities will create obstacles when dealing with certain JP.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	This may create an unintended barrier to supporting joint providerships and eliminate a significant revenue stream, however it is the appropriate process to meet criteria. This is an area of concern as we believe the non-accredited provider may be accepting commercial interest payments without our knowledge.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	We had difficulty understanding the statement “The support does not establish a financial relationship between the ineligible entity and planner, faculty, and others in control of the content of the education.” We think there might be a word missing that would connect the statement to the previous one. Does the statement mean (1) when an accredited CME activity receives commercial support, the commercial support does not create a financial relationship resulting in a conflict of interest that must be mitigated.” Or (2) planners, faculty, and others in control of content cannot have a financial relationship with a commercial supporter. Or (3) Joint providers or ineligible entities cannot create financial obligations for an accredited provider.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Insurance company/managed-care company	This will greatly change the nature of joint sponsorship (JS) relationships. There will need to be a very structured contract or agreement between the JS and the provider so that the accredited provider can receive and distribute the commercial support money and make the distributions. It also means additional accounting structures and support for the accredited provider. It is one thing to keep a spreadsheet of the commercial support and the distributions but a whole other thing to actually take the money in and then disperse it.
Accredited CE provider	ACCME	Nonprofit (other)	CE providers that rely on Joint Accreditation for delivery will need adequate lead time to navigate contracts for faculty members through the accredited providers. Commonly the organization seeking accreditation through a joint provider also contracts with learners. Joint providers may not be in a position to administer necessary contracts.
Accredited CE provider	ACCME	Nonprofit (other)	Section 1 (b) will add significant burden to CME providers that choose to work with joint providers. By not having the ability to contract out the reimbursement of honoraria and incidental travel expenses to the joint provider, there will be the unintended consequence that CME providers will need to shift resources from other "CME related duties" to accounting and administrative functions. Of course, having honoraria and expenses paid by the ineligible entity would jeopardize the integrity of the CME activity, but it does not seem that forcing the CME provider to accept an extra bookkeeping function does anything to either further separate education from marketing and sales, or make the CME content any more trusted by the healthcare individual or team.
Accredited CE provider	ACCME	Nonprofit (other)	This could force many providers who work exclusively in joint providership to create an additional finance division dedicated exclusively to individualized payments for activities when the non-accredited, eligible entity may already have the means to support such a task. We feel that it could discourage joint providership with some accredited entities.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (other)	We agree that the accredited provider should maintain oversight of all expenses and payment processes, as well as have documentation of all reimbursements/pay outs. Is it necessary that the accredited provider be the direct payer? The physician presenters involved in our CME activities are generally invited to speak by and have strong relationships with their membership associations and societies that we plan CME activities with. Our association/society partners work more closely with these physicians to collect needs assessment and gap analysis, and designing their presentation than with us, the accrediting body. We of course vet all presenters and are involved in content design, but they prefer to communicate with their physician members and staff that they know personally and see on a regular basis. We monitor all reimbursements/pay outs, but it would add additional labor and process changes for us to be the direct payer to each individual speaker.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	4.1c- As worded, this would prohibit so-called resident/fellow scholarships and travel funding that is provided through commercial support, with the recipients selected by the accredited provider and the student's academic institution- as this is a special set of learners. Is that the intent and if so, why?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	4.3 – ACCME should not have unrestricted access to the financial records and accounting of accredited providers with regards to accredited continuing education activities. This represents a significant overstep of its authorities. Accredited providers already provide ACCME with financial reports on an annual basis and during the 4-6-year reaccreditation process.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Although we generally do not accept commercial support, we believe 4.1 may end up being disruptive to staff, time consuming, and may have an impact on how budgets are prepared.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	As proposed, the changes risk introducing financial entanglements that are not in the interest of either the accredited provider or the joint provider. Given that the accredited provider is already tasked with overseeing the development of joint provider accredited education, it is reasonable to expect the accredited provider to monitor how the joint provider manages commercial support and for the accredited provider to require the joint provider to provide documentation that those monies are paid to planners, faculty and others for honoraria and travel expenses in accordance with the written policies and procedures of the accredited provider. Requiring the accredited provider to directly make the payments creates an additional level of bureaucracy that results in less – not more – transparency.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	As worded, this seems that it would prohibit so-called resident/fellow scholarships and travel funding that is provided through commercial support, with the recipients selected by the accredited provider and the student's academic institution- as this is a special set of learners. Is that the intent and if so, why? For jointly provided activities, the bulk of expenses for an activity are often incurred by the education partner, not the accredited provider. Funding entities often prefer to provide the funds directly to the entity spending the most, for their own accountability reasons. This wording is therefore confusing.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Consider inserting “inappropriate” in the main paragraph of Standard 4 so that it reads “The support does not establish an INAPPROPRIATE financial relationship between the ineligible entity and planners, faculty, and others in control of content of the education.” If there is commercial support, those funds are helping support the CE provider and that is an obvious and acceptable financial relationship. The goal is to prevent inappropriate payments to planners that will influence CE content. The recommendation in Standard 4, Point 1a, that the accredited provider be responsible for disbursing all commercial support, would pose a burden to CE providers engaged in joint providerships. Also, it could conflict with Criterion 28, “The provider collaborates with other organizations to more effectively address population health issues.” Perhaps a partner has a payment system that is superior to the CE provider’s and that was part of the reason for the joint providership. Adding a requirement that the CE provider must disburse commercial support funding does not seem to contribute to the planning and implementation of unbiased CE. Please consider a rewrite of the proposed 4.3 to “The accredited provider either in direct or joint sponsorship must ensure that commercial support is managed appropriately.”
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	For jointly provided programs, what is the benefit of having the commercial support paid to the provider and then reissued to the joint provider?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	If ACCME were to enact Standard 4, 1 a and b, it is likely that SAGES will no longer offer joint providerships as the accounting burden will be too great. This means that the small international non-profit that we currently joint provide with will likely no longer be able to offer accredited education to their members. This seems to be an extreme and unfortunate unintended consequence. Is there no other way to fix the underlying problems this proposed rule is trying to solve?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Making sure our accounting system support requirements for accountability; may incur additional costs

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Regarding standard 4.1.b requiring the accredited provider to handle the receiving and disbursement of funds, including faculty payment: Requiring the non-accredited entity to relinquish funds to and allow the joint provider to disburse and manage those funds is impractical. The non-accredited entity should provide the joint provider with a financial breakdown of income and expenses, as well as provide any LOAs for commercial support. However, organizations have their own finance departments, own systems and processes, and this revised standard hinders the efficiency and collaborative potential that joint providership opportunities provide.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Requiring the accredited provider to directly pay for these expenses as opposed to allowing the accredited provider to give permission to a joint provider to pay these expenses has the potential to disrupt staffing, costs and faculty satisfaction with the timing of reimbursement.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Some providers work with educational partners on activities supported only by registration fees, yet the same issues of payment for planners/faculty apply. This will impact their ability to meet any financial obligations that occur in advance of the activity. Rather than creating whole new systems within some provider organizations or augmenting accounting personnel resources, why not indicate how and when the provider is accountable and let them decide how best to address that accountability (direct payment or diligent oversight)? This would heavily add to the workload of the administration staff in the organization to process these checks leaving enormous room for error in payments being processed and sent to the correct person.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Standard 4 places fiscal responsibility on the accredited provider even in a joint providership. This will cause problems for joint providership relationships where the accredited provider does not receive nor distribute said funds and/or has no desire to do so.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Standard 4.1.B. This standard should distinguish between ineligible entities (who should be excluded from these roles and responsibilities as proposed) and other accredited and/or eligible partners. We partner with many organizations that are accredited and/or eligible entities, and in many cases, they are delegated to receive and disburse commercial support in accordance with a pre-determined budget and signed agreement of roles and responsibilities. While this may seem minor, it will make many eligible entities have to significantly change their processes and partnership structures for joint providership and add will require more staff and financial resources. This could limit the quantity and quality of education provided by many eligible entities, as well as discourage – rather than encourage - collaboration and partnership.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Standard 4: Manage Commercial Support Appropriately. The proposed change to require UHMS, as the accredited provider, to collect and disburse monies collected from Ineligible Entities (Commercial Interests) will create delays and additional workload that is not necessary in our view. Collecting sponsorship money from commercial supporters is labor intensive and distributing those monies to the appropriate social events and honorarium recipients is no simple task. Requiring us to collect all sponsorship money and then distribute that money can have a negative impact of receiving commercial support money in the future with the delays it may cause. UHMS already provides oversight of the collection and distribution of sponsorship money per the current standards. The new Standard 4 should simply require that oversight to continue.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The additional workload to the accredited provider would most likely result in significantly increased joint providership fees which, in turn, could deter non-accredited entities from pursuing joint providership which in turn could result in a reduction in the availability of accredited continuing education to healthcare professionals.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The requirement that the accredited provider disburse all commercial support could create barriers to the provision of some jointly provided activities. For example, some academic institutions have complicated payment systems that could significantly delay the processing of commercial support for a jointly provided activity. These organizations may also be required to deduct a “dean’s tax” from the funds, which would either reduce the funding available for the activity or significantly increase the amount of support needed for administrative costs, making education unnecessarily more expensive. The increased staffing and administrative costs may lead some accredited providers to stop participating in joint providership, which could result in a reduction in the availability of some education. This change may also impact the ability of some providers to receive commercial support necessary to produce an activity if the funders implement new rules or restrictions on the provision of support out of compliance concerns raised by their organizations.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The requirement that the accredited provider disburse all payments to those in control of content (item 4.1.b) could create barriers to the provision of some jointly provided activities. This would require increased staff time and costs for the accredited provider, which would lead to some providers electing to no longer participate in joint providership relationships, or to increase the fees they charge to educational partners to establish a joint providership. In either scenario, the potential end result is a decrease in access to accredited education for physicians because the availability of joint providership will reduce. We most often enter into these agreements with smaller state and local specialty societies that offer valuable educational opportunities to providers in their communities; reducing access to this education will not support the goal of improving patient care. These small societies operate on very tight budgets, and increasing the costs associated with joint providership could price this service out of their reach. It could also make it harder for them to receive the commercial support, often in small amounts, that is necessary for them to carry out these activities. Funders may not approve the grant requests for these activities because of the proportion of their costs that is allocated to administrative expenses. A separate but related question raised by this Standard is whether or not this new requirement would apply in the case of a jointly provide

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The resources required to track financials and disbursements would lead to our program possibly not continuing to joint sponsor. We have approximately 16 programs a year that we joint sponsor and we would jeopardize the ability to provide CME to their attendees. Some larger organizations already have this infrastructure but since we do not it would place a financial burden on our organization
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	These expenses must be paid or reimbursed to the individuals directly by the accredited provider, and not by a joint provider. CME providers are not being allowed to decide whether a joint provider can reimburse individuals takes away a provider's freedom to determine how to run their Program. I think as long as the provider has documentation from the joint provider, that should be enough.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	This would add significant administrative burden to smaller accredited providers that rely on joint providership as a revenue stream. This also has the potential to disrupt staffing, resources and faculty satisfaction with the timing of reimbursement. As an alternative, joint providers could be allowed to make these payments, but the accredited provider could be responsible to audit the activity revenues and expenses/payments in lieu of this? With respect to the requirement that providers in a joint providership relationship control the disbursement of funds, this will be administratively burdensome to those providers who work with joint providers. Is there an acceptable mechanism, such as detailed reporting of disbursements that could satisfy that these funds were appropriately disbursed, but allows the freedom of the grant funds being received and disbursed by the joint provider?

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We are concerned about how commercial support received in support of jointly provided conferences would have to be managed under this new language. It's not clear whether the joint partner would be prohibited from directly receiving commercial support (allowable currently) since the new language specifies that a joint partner may not pay or reimburse honoraria or travel expenses of planners, faculty and others in control of content using commercial support funds. Generally when an organization receives commercial support for a meeting, it is used to defray the overall costs associated with the meeting with no clear delineation as to which expenses will be paid using that commercial support since the provider must make all decisions as to how commercial support will be used. The commercial support is combined with the other income for the meeting (registration fees, exhibitor income, provider subsidies, etc.). The provider or the joint partner then pays all of the expenses using these combined funds. How could it be documented that a $15,000 in commercial support received to support as meeting with $150,000 in expenses was not explicitly used to pay or reimburse honoraria/travel expenses of planners, faculty, etc.? The requirement for accredited providers to explicitly pay all planner and speaker expenses when commercial support is received is overly complicated and onerous and could impact the ability of state specialty organizations to offer annual meetings for credit.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We do Joint Providership with organizations that are ANCC or ACPE accredited. If those organizations are the ones receiving commercial support, it does not make business sense for us as the ACCME accredited provider to manage the funds. A detailed accounting of the funds makes more sense than the ACCME accreditor needing to control all funds.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We strongly recommend that the current SCS 3.8 be maintained, such that the accredited provider may choose to have the joint provider/educational partner receive the commercial support and pay any/all activity expenses. Processing commercial support and individual bills (for faculty, vendors, etc.) through accredited providers (vs joint providers/educational partners) would create an extra and unnecessary step. It would add increased complexity to accredited providers' accounting practices and management processes, particularly when accredited providers are already working effectively with their joint providers/educational partners.
Accredited CE provider	ACCME	Other: Accreditation Management, CME Consulting, and Joint Providing Company	It is assumed from reading Standard 4 that since accredited provider is responsible for paying expenses etc., that Joint Provider cannot apply for, collect/deposit grants. If that is true, that should be stated. If it is not true and the Joint Provider can apply for, collect/deposit grants, and then give $$$ to accredited provider to pay honoraria, etc., that should also be documented.
Accredited CE provider	ACCME	Other: MEC	This may or may not require bylaw / protocol changes. eg: societies
Accredited CE provider	ACCME	Other: not-for-profit CME provider	Note: we do not accept Commercial support so do not have much experience here.
Accredited CE provider	ACCME	Other: State Medical Society	Possible confusion as to who is included in St.4 -1-C Does this pertain to CME staff, independent Learners not in control of content?
Accredited CE provider	ACCME	Other: Teleconferencing Medical Education Company	This entire standard would completely deter any provider from conducting a joint providership completely. This puts too large of a financial burden on the direct provider.
Accredited CE provider	ACCME	Other: university	Accredited providers must pay or reimburse expenses to individuals such as faculty; joint providers cannot make these payments. This burden would radically change the way APs manage a joint providership and will lead to APs being unwilling to jointly provide with anyone accepting commercial money. Our system would have to be changed so much so we decided we would not work with anyone taking commercial support.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Other: University - not a school of medicine	4.1a - Accredited provider should be allowed to decide how funds are dispersed, but not mandated. This causes an undue burden on the staff and could likely incur additional expenses imposed by parent group (ie. Offices of CME within University) Decisions should be made by accredited provider as in overall oversight, but then direct non-accredited partner to proceed with carrying out those decisions.
Accredited CE provider	ACCME	Publishing/education company	"These expenses must be paid or reimbursed to the individuals directly by the accredited provider, and not by the ineligible entity or by a joint provider." Bottom Line on Top: The new Standard 4.1.b could require accredited providers to create new Financial and Accounting functions in order to perform the direct collection and distribution of educational grant funds and to report on these activities to the non-accredited entity. This could prove costly in effort and expense. The solution is to require detailed financial reporting by the non-accredited entity. Accredited Entity Point of View From my point of view as the CEO of an accredited entity, I can see a number of unintended consequences from this new standard: 1. In the case of Joint Providership, requiring an accredited provider to reimburse faculty from grant funds would essentially force the accredited provider to create an Accounts Receivable, Accounts Payable, Financial Management and Accounting Function for the non-accredited entity. Through this function, grants would be received, managed, disbursed and reported on. Such a situation could create a difficult burden on the accredited provider. I would suggest that providing such a function for another entity may not be among the core competencies of the accredited provider.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	4.1a. Changing to a requirement that all funding actually go through the accredited provider may run afoul of legal teams as it breaks the chain of fiscal accountability. Also, it can slow the distribution of funds for development in joint providership situations. If the provider had knowledge of the grant budget & approved it, why cannot the funds be sent to the education partner & let them disperse, under the diligent supervision of the accredited provider? 4.1b. In addition, requiring that the accredited provider pay all planner/faculty honorarium & expense will also create a significant burden on some accredited providers who do not currently have the accounting staff to support this, thus increasing the cost of activities or decreasing the amount of actual funds for development. Education partners who partner with universities as their accredited provider may incur a so-called "dean's tax" of up to 70% on funds received directly by the university, thus raising the cost of an activity significantly. Overall, this change may result in a reduction in collaborations between organizations in the planning, implementation & evaluation of continuing education, which is the exact opposite of what is being promoted by ACCME & other accreditors. 4.1c. As worded, this would prohibit co-called resident/fellow scholarships & travel funding that is provided through commercial support, with the recipients selected by the accredited provider & the student's academic institution, why?

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	4.1a-Changing to a requirement that all funding go through the accredited provider may run afoul of legal teams as it breaks the chain of fiscal accountability. It can slow the distribution of funds for development in joint providership situations. If the provider had knowledge of and approved a grant budget, why cannot the funds be sent to the education partner to let them disperse, under the diligent supervision of the accredited provider? 4.1b-Requiring the accredited provider pay all planner/faculty honorarium and expense will create a significant burden on some accredited providers who do not currently have the accounting staff to support this, thus increasing the cost of activities or decreasing the amount of actual funds for development. Education partners who partner with universities as their accredited provider may incur a so-called "dean's tax" of up to 70% on funds received directly by the university, thus raising the cost of an activity greatly. Overall this change may result in a reduction in collaborations between organizations in the planning, implementation and evaluation of continuing education--the exact opposite of what is being promoted by ACCME and other accreditors. 4.1c-As worded, this would prohibit so-called resident/fellow scholarships and travel funding provided through commercial support, with the recipients selected by the accredited provider and the student's academic institution, as this is a special set of learners. Is that the intent and why?

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	4.1b- In addition, requiring that the accredited provider pay all planner/faculty honorarium and expense will also create a significant burden on some accredited providers who do not currently have the accounting staff to support this, thus increasing the cost of activities or decreasing the amount of actual funds for development. Education partners who partner with universities as their accredited provider may incur a so-called "dean's tax" of up to 70% on funds received directly by the university, thus raising the cost of an activity significantly. Overall, this change may result in a reduction in collaborations between organizations in the planning, implementation and evaluation of continuing education, which is the exact opposite of what is being promoted by ACCME and other accreditors. 4.1c- As worded, this would prohibit so-called resident/fellow scholarships and travel funding that is provided through commercial support, with the recipients selected by the accredited provider and the student's academic institution- as this is a special set of learners. Is that the intent and if so, why?
Accredited CE provider	ACCME	Publishing/education company	4.1b- Requiring that the accredited provider pay all planner/faculty honorarium and expense will create a significant additional burden on many accredited providers, to manage this process. 4.1c- As worded, this would prohibit so-called resident/fellow scholarships and travel funding that is provided through commercial support, with the recipients selected by the accredited provider and the student's academic institution- as this is a special set of learners. Is that the intent and if so, why?

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	As a non-accredited organization, we are defined as a joint provider. We collaborate with various CME providers such as associations, state medical societies and academic medical centers often with limited abilities to process payments to individual faculty. By moving the direct responsibility on to the CME providers we are concerned about the timing of payments and flexibility of booking flights and travel. Our courses are often delivered in rural areas where timing of payment and travel arrangements may be more than 30 days. We have dedicated travel staff who makes travel arrangements for faculty to our over 300+ activities and who ensures that the travel plans are made on-time and efficiently. We adherer to strict guidelines on the payment amounts that are being followed. We are concerned this change could force us to abandon many these joint provider relationships and have negative impact on collaborations as well as speakers' willingness to deliver valuable and much needed CME programs in the rural areas. Also, serval of the universities we work with have described if they pay the faculty directly that they would add a 30-70% deans' tax to those payments. We believe the proposed criteria as it is written will discourage collaborations.
Accredited CE provider	ACCME	Publishing/education company	By requiring accredited providers to disperse all commercial support under Standard 4, the role of the joint provider is limited and suggests that only the accredited provider can be the direct recipient of commercial support. Often, continuing education programs are done with multiple accredited providers working together. There are also practical payment processing issues, such as situations where the accredited provider (i.e., a smaller specialty or state medical society) does not have the staff to process payments to faculty and expenses or in the case of universities, which have to set up each speaker as a vendor in their systems and can take up to two years to secure authority to hire additional personnel. Perhaps a better alternative may be to require the accredited provider to keep records of faculty payments.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	By requiring accredited providers to disperse payments of honorarium and expenses to faculty, there are administrative concerns and payment processing issues. Often, continuing education programs are done with multiple accredited providers working together. Some accredited providers do not have the staff and resources to process payments to faculty. In these cases, payments will potentially be delayed, while staffing is secured, which will delay faculty receiving payments for participation and reimbursement for expenses incurred, in a timely manner. In addition, this may delay final reconciliations. A recommended alternative is for the Accredited Provider to keep a record of faculty payments made by a Joint Provider. The Accreditor Provider still retains control of the management of the overall funds, through this documentation, even when payment is made by a joint provider
Accredited CE provider	ACCME	Publishing/education company	It will cause a hardship on our CE Office if the joint provider is no longer allowed to directly receive the grants and disburse the funds.
Accredited CE provider	ACCME	Publishing/education company	Many accredited providers of all types do not have the resources to manage the collection of financial information and direct payment of expenses on behalf of their joint providers. They lack the staffing and sometimes systems to pay vendors, faculty, etc. Thus, they prefer that their joint providers manage these tasks. Problems that will arise include: • It may be difficult and costly for providers to revise their systems • Some providers will be forced to change their business models • Some providers will be forced to close their businesses/programs • It will cost more time for busy faculty to communicate with both providers and joint providers • Faculty may be confused over who to submit paperwork to or why they receive reimbursement from a different organization. Payments may take longer to process if handled between two different orgs.
Accredited CE provider	ACCME	Publishing/education company	Many accredited providers, particularly academic institutions, have cumbersome institutional financial processes that would result in long delays for the payment of honoraria and reimbursement of expenses to faculty. Such delays would discourage participation of knowledgeable and experienced clinicians as faculty in accredited education.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	Requiring that the accreditor be the sole payer of honoraria and travel expenses will be a nightmare as many projects with joint providers have the joint provider make those payments and the accreditor is not set up to do so. I think you'd accomplish your goal if payments were allowed from a joint provider or other eligible provider.
Accredited CE provider	ACCME	Publishing/education company	Separating the current 3.12 into 4.1 b and c is unnecessary and may create confusion. Additionally, the wording in 4.1.c "individuals or groups of learners" is likely to create confusion with respect to 4.1.b. It's likely intended for that statement to mean "individual learners or groups of learners" but the wording (specifically the use of "individuals") will be confused by some providers to contradict 4.1.b. In 4.4 - could it still say "prior to the beginning of the educational activity". What is the standard for "engaging in the education"? That sounds like "prior to registration" - which would be the point at which a learner commits or demonstrates active interest. Since registration is likely to take place before/concurrently to the approval of commercial support for many activities, the state of commercial support will change after some attendees have registered. Keeping the standard at "prior to the beginning of the educational activity" would keep what works in place, and provides a fixed, time-bound description aligned to the terms of 4.2 for when an agreement must be in place.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	The implementation of Standard 4, as proposed, in a joint providership situation is not only resource demanding but could result in educational programs being conducted without the provision for accreditation. Shifting the responsibility of being directly responsible for the Decision Making and Disbursement of all commercial support to the accredited provider will require an increase in staffing and thus, an increase in the joint providership fee being charged. Beyond that, at a corporate level, the reconciliation of these funds through ledgers and tax reporting requirements will not be insignificant and again, will result in an increase in the fee being charged for joint providership. At some point, the fees are going to reach a level where non-accredited parties will not be able to justify the expense and educational programs will proceed without accreditation. This resulting consequence seems counter-intuitive to what ACCME is trying to achieve.
Accredited CE provider	ACCME	Publishing/education company	The implementation of this standard will be burdensome for accredited providers. I would like to provide an explanation on why this will be so. Educational grant support has decreased for many of our joint providers. However, some of our joint providers continue to apply for grant support and the amounts they receive can be small in comparison to past years. For example, if a small amount of grant support (i.e. $5,000) is received, and the activity has several speakers (i.e. 20 or more) who receive honoraria and travel expenses, the onus will be on the accredited provider to collect the W9s, pay the speakers' honoraria and travel expenses (often requiring dialogue after the program ends) and submit 1099s at year's end. All of these tasks have previously been done by the joint provider, who already has a relationship with the speakers from arranging their travel/hotel accommodations and coordinating the logistics of the meeting. I fail to understand how this change will improve the quality of accreditation. Instead, I am concerned that an unintended consequence may be confusion on the part of the speakers as to who to communicate with regarding travel, other logistical questions, and honoraria payments. This change may also require us as the accredited provider to increase our fees to account for the additional accounting time this will require. This increase in fees has the potential to be passed on to the learner in the form of increased registration fees.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	We foresee a problem with implementing 1b. If we as the accredited provider were to be responsible for the actual payments to faculty, instead of the Joint Provider, it will impact us in several ways, increasing our workload and costs. 1. We would need to contract with the faculty directly in order to pay them (UK/EU accountancy practices). 2. We would then be an additional point of contact for the faculty member, with a different email address/organisation for them to become familiar with, which could lead to confusion. 3. If payment is in a different currency, then the bank charges would escalate. Certainly, for us in Europe. We in the UK saved 100s of Euros on one project because we moved to asking the Joint Provider to do the payments in Euro, in the UK we were being charged $10-15 per transaction, the Joint Provider in Euro-zone could do the transfer immediately for about 15 cents each. We also have a joint provider in Ukraine, and for us to pay in Ukrainian Hryvna would be even more expensive, take longer and may require security/compliance/money laundering checks as well.
Accredited CE provider	ACCME	Publishing/education company	We sometimes partner with other organizations (all of whom are eligible entities that have chosen for other reasons not to become accredited providers) to jointly provide education. The other organization may receive and manage commercial support. I think that if the joint provider is an eligible entity, they should be allowed to physically manage and disburse the commercial support funds as long as they account to the accredited provider and the use of the funds is agreed upon in advance.
Accredited CE provider	ACCME	Publishing/education company	While we are an accredited provider, there are times where we are not the primary coordinator of the educational activity. In these instances, it would create undo stress and workload for the accredited provider may not be intimately involved in the logistics of the educational activity. It also communicates that there is a distrust of the joint provider where there should not be if they are allowed by the Standards to be a joint provider in the first place.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	1 B. It would be extremely difficult to manage the payment of faculty for honoraria and travel/course related expenses for programs with joint sponsors. We do not have the staff to support this at this at this time and will not for the foreseeable future due to budget constraints. I believe it would be manageable to have a signed and documented agreement with a joint provider that outlines acceptable payment policies and collect all payment information to be included in the accreditation file. Joint sponsors are vetted carefully and an agreement between the parties that meets ACCME standards should be able to suffice for documentation of payments to faculty.
Accredited CE provider	ACCME	School of medicine	1b. would be very problematic for us. We do a lot of joint providership and we do allow the joint provider to pay or reimburse the expenses associated with the activity with our approval. This change would essentially mean that we would no longer be able to engage in joint providership as we do not have enough staff to oversee this process. Paying expenses in the university system is extremely cumbersome. It would simply not be possible for us to pay every expense associated with every activity we accredit.
Accredited CE provider	ACCME	School of medicine	4.1.b-potential burden placed on accredited providers when they could oversee funds and verify. Some smaller accredited providers may not have the systems or infrastructure to manage these disbursements. Additionally, some may need to shift the management fee to the provider for paying these costs and the financial management. Potential issues between joint providers or third-party conference planning organizations.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	4.1a- Requiring that all funding must go through the accredited provider will likely be challenging for most accredited providers. It can slow the distribution of funds for development in joint providership situations. If the provider had knowledge of the grant budget and approved it, why cannot the funds be sent to the education partner and let them disperse, under the diligent supervision of the accredited provider? 4.1b- In addition, requiring that the accredited provider pay all planner/faculty honorarium and expenses will create a significant burden on some accredited providers who do not have the accounting staff to support this, thus increasing the cost of activities or decreasing the amount of actual funds for development. Education partners who partner with universities as their accredited provider may incur a so-called "dean's tax" of up to 70% on funds received directly by the university, thus raising the cost of an activity significantly. Overall, this change may result in a reduction in collaborations between organizations in the planning, implementation and evaluation of continuing education, which is the exact opposite of what is being promoted by ACCME and other accreditors. 4.1c- As worded, this would prohibit so-called resident/fellow scholarships and travel funding that is provided through commercial support, with the recipients selected by the accredited provider and the student's
Accredited CE provider	ACCME	School of medicine	4.1b Are you saying no joint provider can pay or reimburse expenses even if they are not an ineligible entity? For a large meeting with a joint provider, this could add a lot of work for our Financial Administrator to pay all of the honorarium and travel.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	4.1b will mean that we either have to hire a FTE that focuses solely on finance and processing payments (not developing excellent education or independence or showing our value, but moving money around) or limit our joint providerships. Unfortunately, joint providerships are one of the things keeping our program financial afloat, so as we will likely have to opt to limit those, we'll be shooting ourselves in the foot. How does moving the payment process help us provide excellent education or keep things more independent? Our partnerships are built on trust; can't you trust your providers to police joint providerships appropriately? And if you can't trust them with money, are you sure you can trust us with professional practice gaps or evaluation? Why is it just the finance parts that are suspect? Ultimately, I will have to find another revenue generating mechanism for our program and we will likely shrink.
Accredited CE provider	ACCME	School of medicine	A HUGE challenge for medical schools and others that are doing a great deal of joint sponsorship is that, in many cases, the accredited provider does not have the resources to pay large numbers of speakers in a timely manner. The relationship between the accredited provider and the joint sponsor is one in which the joint sponsor has an efficient system to process payments and the accredited provider depends on the joint provider for that exact service. At our university, it might take months to process faculty honoraria checks and would require a great deal more paperwork.
Accredited CE provider	ACCME	School of medicine	As a Medical School we are simply unable to pay the honoraria and travel expenses of planners, faculty and others. We fully document this process with our joint providers to ensure there are no conflicts. Requiring this change of us would require structural changes to our institution that we are not in a position to make. Thus this changes threatens our core ability to carry out even the most basic understanding of CME programming and our mission.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	By requiring the accredited provider to pay for the expenses as opposed to allowing the joint provider to pay the expenses has many challenges and consequences. As a medical university it would impact us in the following ways: Disruption of current workflow for the already lean staff in place; Our university accounting department has indicated that they will not be able to withstand the additional work that this will create; The process of creating a new vendor in the system to requesting required documents is time consuming; and there will be a percentage taken by the College of Medicine (some refer to this as a Dean's Tax, we do not have a formal name for it) which could potentially impact the budget for the program.
Accredited CE provider	ACCME	School of medicine	If, as the accredited provider, I control and dictate who gets paid and what they get paid and I have the documentation to match, then it should not matter if I ask a partner in the activity such as a joint provider or using an old phrase a co provider to pay. Many SOM and health system rules around payment disadvantage the faculty and thus having an outside source pay, a source controlled by accredited provider, should be more than fine.
Accredited CE provider	ACCME	School of medicine	Many academic institutions CPD departments are very limited on staff and resources. The responsibility of accepting all commercial support funds and making expense payments and reimbursements may be cumbersome for CPD departments to support. In a university environment, many academic accredited providers must use a university-based foundation to serve as their payee. In those circumstances the foundation may retain up to 30% of the grant amount in return for serving as the payee. That is not consistent with the terms of the grant, and the grantor may not be inclined to give the funds under those circumstance. Allowing the joint provider (who is an eligible organization) to receive funds and pay faculty expenses/honorariums eliminates this problem.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	Not a major challenge, but how would we demonstrate that the accredited provider paid or reimbursed expenses to the faculty of a jointly provided program? What type of evidence is the ACCME looking for? Why did you make this change that expenses must be paid or reimbursed to individuals directly by accredited provider, and not by the ineligible entity or by a joint provider? We work with several professional societies to credit their CME activities and a couple time a year, the society will reimburse a faculty directly. I know we will have to change that methodology but wondering why that is a problem. Is it control? I think it sounds nice, but is it really necessary to control that much? We require accurate accounting of the payments; does it really matter if we pay them. It is going to add more regulation to the process and for what end?
Accredited CE provider	ACCME	School of medicine	Not allowing joint providers to pay speakers directly would create a major and unfunded administrative burden on CME staff, and result in a lot of unnecessary paperwork. Joint providers are often delegated responsibilities for collecting registration fees and therefore have the program funds to cover speaker expenses, while the accredited sponsor may not.
Accredited CE provider	ACCME	School of medicine	Our own office staff would struggle to process all the financial paperwork related to this standard, as would our institution's accounting and purchasing departments. Over the long term, the requirement that we, as the accredited provider, disperse all commercial support could put us out of business!

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	The 4.1.b proposed change poses a major challenge for universities as described, such as ours, and creates unnecessary inefficiencies and increased administrative burden on the accredited provider. This will not improve accountability as providers are already the responsible gatekeeper of all commercial funding received, disbursed, and reconciled for our accredited activities. The administrative assistance of a joint provider in performing these logistical tasks allows the accredited provider to focus on the educational methodology, design and content development of the educational activities for learners. This increased administrative burden will lessen the time available to focus on the intention of the educational activity to increase the knowledge, competency, performance of healthcare providers, as well as, potential patient outcomes. Increased administrative burden will eliminate our ability to manage large educational initiatives due to limited staff time and availability. Other factors that will result is faculty dissatisfaction with the timing of reimbursement, state income tax withholdings, additional document requirements for payments, the potential for increased administrative budget line items for the accredited provider and delays for our accounting department to establish new vendors into the university system. This change would effectively remove universities from the CE landscape.
Accredited CE provider	ACCME	School of medicine	The proposal that providers be the ones to manage all funds, including payment of honorarium and expenses will wreak havoc with many medical school organizations. Our university's finance and accounting section is unwieldy and slow, and adding additional payment processing will be awful, probably requiring additional staff, space, and equipment which our unit cannot afford to fund. In addition, educational partners will be horrified and embarrassed by how long it will take for bills to be paid. I can see us losing long time educational partners because their financial departments are nimble and ours are not.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	There are a number of ramifications to this new requirement. 1. Accredited providers have historically stated that many of their operations are short-staffed. The bookkeeping requirements will overwhelm an already resource-limited department/organization and require more staff support. If additional staffing is even possible, the focus needs to be more towards CPD professionals and not allotted towards administrative staff time. Additionally, our means for expanding staff for short-term needs is limited. We cannot hire someone just to handle reimbursement as this will not be a full FTE. Implementation and scaling on variable time frames can be extremely challenging and burdensome. 2. The transfer of the payment function to the accredited provider will then mean that the activity to the accredited provider's policies and procedures causing confusion and conflict that penalizes the payee. Examples: a. Honorarium and reimbursement limits including travel policies of the accredited provider may be contradictory to that of the joint provider. b. The joint provider's accounting policy does not require a W-9 to pay reimbursements. The accredited provider's accounting policy requires a W-9 in order to set up the individual in the accounting system. The planner or faculty member now has to provide a personal ID number to an organization that is one-step removed from the activity when they are dealing directly with the joint provider.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	There are notable changes in the proposed Standard 4. Although "the accredited provider must make all decisions regarding the receipt and disbursement of commercial support", the proposed Standard states that "the accredited provider is responsible for dispersing the commercial support". The proposed changes also state that the commercial support used for honoraria or travel expenses of planners, faculty, and others in control of content must be paid by the accredited provider and not by an ineligible entity or by a joint provider. By requiring the accredited provider to directly disperse commercial support as opposed to allowing the accredited provider to give permission to an educational partner (e.g., School of Medicine) to pay these expenses, it has major consequences for academic CME units (i.e., changes in budgetary requirements, increased staffing, costs, and faculty dissatisfaction with the timing of reimbursement). Besides these unintended consequences, many universities are not equipped for faculty payments and expenses. They also have a "dean's tax" or General Administrative Recharge that would reduce the educational funds by at least 7% to recover common infrastructure costs such as grounds, lighting, etc. In addition, there may be Stark or Anti-kickback legal considerations for certain entities. What is the intent of the ACCME? Can other ways achieve the intent in which the proposed requirement might not result in unintended consequences?
Accredited CE provider	ACCME	School of medicine	These expenses must be paid or reimbursed to the individuals directly by the accredited provider, and not by the ineligible entity or by a joint provider. What is the reason for including the joint provider? What concern/business is that to ACCME? When not concerning industry, this seems to be an overstep. There are all kinds of reasons that have nothing to do with bias that may result in partners handling funds. Stay in your lane.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	To ask providers to pay all honorarium and travel expenses on behalf of joint providers is simply not possible given the many systemic barriers in place at most academic medical centers and universities. This requirement is impractical and unrealistic for so many reasons. Including the lack of staff, resources, and institutional financial policies and procedures. It's also quite surprising that the ACCME is dictating operations for providers which would require staffing and resources we do not have and will not receive in this current healthcare environment.
Accredited CE provider	ACCME	School of medicine	We are a small office with a large volume of collaborated activities with external partners that receive commercial funding. This new Standard would cause a hardship and the viability of our program is at risk with this change. 1. We do not have the infrastructure to acquire this Standard for our small office. We have several annual courses that have anywhere from 200-300 speakers. With limited financial support from our institution, we would not be able to hire additional staff to support this change. 2. Our institution's financial infrastructure could not handle the additional volume or be able to 'promptly' pay honorariums or travel expenses. This alone would cause our external partners choosing to work with other providers. Not in favor of Standard 4.1(a-d). This would greatly impact our organization.
Accredited CE provider	ACCME	School of medicine	We do not agree with Standard 4 b specifically – “The accredited provider may use commercial support to fund honoraria or travel expenses of planners, faculty, and others in control of content for those roles only. These expenses must be paid or reimbursed to the individuals directly by the accredited provider, and not by the ineligible entity or by a joint provider.” We would never have ineligible entities paying faculty. However, we do not understand why this potential rule is being put in place with regard to joint providers. This would be extremely burdensome for our program and would necessitate significant additional expense. We do not understand or agree with this suggested change. We maintain close oversight and tight controls around payments being made by joint providers and we see this potential new requirement as potentially detrimental to our operations.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	We have allowed our joint providership organizations the opportunity to receive commercial support directly and pay the expenses associated with the activity. Our organization takes off a large percentage on any income that comes into the organization, and if we had to begin receiving that income it would reduce the overall income available to offset expenses. It would also require our office to be involved in the payment of expenses and since we are a public institution, we have lengthy requirements that other organizations may not have.
Accredited CE provider	ACCME	School of medicine	We would not be able to provide CME for joint providers who receive commercial support of any kind. Our University deducts up to 53% of all grants received from external entities, which would reduce the joint provider's revenue by that amount, and to which they would never agree. Additionally, we would not be able to absorb the additional time it would take to route and account for incoming and outgoing expenses related to the joint provider's commercial support. In short, we would need to decline providing CME for any joint providers receiving commercial support for their activities. We would lose important existing joint provider clients, which would severely affect our revenue in a negative manner.
Accredited CE provider	ACCME	School of medicine	When working with a joint provider, it isn't unreasonable of them to NOT want another entity to handle their money. Plus, as a University, the standards that our accounting office holds us to are much more stringent than other businesses, as far as the rules for honorarium payments, what travel expenses can be paid, etc. I could see how this would cause some issues with disbursements coming from our office, rather than the joint provider's office.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Hospital/healthcare delivery system	That depends on the answer to the above situation with Joint Providers.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Hospital/healthcare delivery system	The accreditor is responsible for dispersing all commercial support. We do this this internally but for joint providership we work with external institutions and make sure all commercial support agreements are accurate and signed and reconciliation is done properly but we do not disperse the funds. This will add a lot of extra work for our department. We feel we will not have the resources to complete this
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Hospital/healthcare delivery system	We frequently partner with other organizations to plan accredited activities. Many times, the partner will handle finances such as collecting registration fees, paying speaker travel and honorarium, etc. If one of these activities received commercial support and all funds needed to be channeled through the accredited provider, it could be very problematic and would limit our ability to partner with other organizations.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (other)	Requiring that commercial support can only be paid to the provider will create challenges when the provider is not able to process funds in a timely manner. If a provider (with a centralized accounting department at their institution) requires weeks to release funds, this would result in a significant financial burden on a joint provider who would need to front expenses until funds were released, and would lengthen the lead time for developing commercially supported accredited continuing education. Requiring providers to be the only ones who can pay expenses and honoraria could also have negative impacts. First, there is timely payment (see previous comment) of these items, which could mean that faculty are not only delayed in receiving honoraria after completing their role but they may also have the burden of waiting to be reimbursed for costs they put out in order to participate as faculty in the education. This new requirement may also lead to providers diverting resources from their primary mission -- educating HCPs -- to tangential tasks -- paying and tracking honoraria and expense payments. Providers work with joint providers in ways that match their organizations and their organizations' resources. It would be better to ask providers to have a system in place for oversight of such payments and leave it to them to develop a system that works for their organization rather than adding a significant administrative burden to provider units.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	It may be problematic to assert that commercial support does not establish a financial relationship between the ineligible entity and those in control of educational content, when reporting under the Sunshine Act does still happen for accredited CE activities. Because providers have no control over what companies choose to report, it may be better to eliminate this sentence in the introduction.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	Item 1b requires that the accredited provider and not the joint provider must pay all expenses. This has the potential to substantially increase the workload for the accredited provider. For example, a non-profit organization that is accredited may provide CME for their independent chapters who are not accredited. If burden for paying speaker expenses would now shift to the accredited provider, new accounting procedures will be required and documented. This has previously been a hands-off transaction. The chapter pays the program expenses including speaker reimbursement and provides the accredited provider documentation of what was paid.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Other: academic medical center	Some of our programs have dozens, at times hundreds, of faculty from across the world. These are individuals selected because they are thought leaders in their respective fields. To reimburse all of these individuals through our institution would be prohibitively expensive due to the complex administrative systems under which university medical centers operate. We have joint providers because they can more easily make legitimate payments to individuals. There are health systems with which we have institutional level affiliations including agreements with clauses that prohibit direct payments to affiliated employees. While we jointly provide educational activities with these health systems, we can in no way dictate their internal reimbursement processes.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	Standard 4.1b Requiring that the accredited provider pay all planner/faculty honorarium and expenses will create a significant burden on some accredited providers who do not currently have the staff to support this. For undertaken as a joint provider, the bulk of expenses for an activity are often incurred by the education partner, not the accredited provider. Thus, it may result in making joint providership less attractive for both parties (and even supporters) due to the increased burden for all parties involved. This would result in a reduction of the overall number of accredited educational programs available through joint providership.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	The requirement that all funds for an activity go through the accredited provider may substantially slow the distribution of funds for development, faculty payments, etc in joint providership situations. Many accredited providers do not have the staff in their CME/CE departments to handle the management of these large sums of money. In addition, many education partners who partner with Universities as an accredited provider could potentially incur additional costs associated with the dean's tax. This could reduce the collaboration between organizations significantly which goes against what the ACCME consistently promotes.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	4:1. b - The question of who pays honoraria and expenses of speakers is dictated by our institution. This will change will negatively impact our relationships with joint providers. We anticipate that this business model will limit our ability to develop relationships with smaller community-based organizations. Some joint providers may no longer accredit activities resulting decreased access to accredited continuing education for learners of multiple professions and lost revenue for accredited providers.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	If a joint provider is an eligible entity and they are not allowed to do any of the finances, we would imagine this would be a shift in workload for many providers

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	It has been our practice to allow joint providers to be payee on commercial support. Implementing a stipulation for our office to be payee (which will enable us to comply with paying expenses) may cause us to lose clients and partners such as Crohn's & Colitis Foundation. For a unit like ours being semi-cost recovery this will result in a drop-in business (joint providership) and therefore decreased revenue.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	Standard 4.1b – Requiring accredited providers to pay honoraria or reimburse travel expenses will (1) create a tremendous burden on our medical school CE office, (2) cause frustration among planners and faculty due to the cumbersome payment process employed by our university (e.g., planners and faculty need to register themselves as a vendor, submit a fair amount of paperwork beyond receipts, etc.), and (3) lead to a breakdown of relationships with joint providers due to inadequate accredited provider staffing to timely process honoraria and reimbursements and planner/faculty frustration with our university's policies. Our office has a hard-enough time paying our faculty/planners for our directly provided activities.
Accredited CE provider	Other: Academy of General Denistry	School of medicine	Number 1. a. and b. may be problematic if the joint educational provider is the one who applies for commercial support and is managing the budget for the activity. The accredited provider would have to receive commercial support from the joint provider to pay honoraria and make other disbursements? What if the accredited provider has decided not to apply for commercial support, but allows their joint education providers to apply if they wish? The accredited provider would continue to monitor the spending of the commercial support, sign the agreements, and review the budget at the end of the activity. I feel this process is still valid. Especially with relationships that have endured and been compliant in the past.
Accredited CE provider	Other: Accreditation Council for Pharmacy Education	Nonprofit (other)	- Would the ineligible entity providing support to defray/eliminate costs for all learners have a gained interest in doing so? Would a bias be assumed? If so, how could that be mitigated. For example, an ineligible entity's support used to eliminate costs for an activity that discusses the entity's product. - Consider adding language from Standard 5.1.a. to Standard 4.1.d.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Other: ACPE	Publishing/education company	This may shift work to the accredited provider in joint providership agreements. Commercial supporters often restrict the use of their funds for honoraria/travel expenses, so these are often paid from registration fees, which are collected by the joint provider, when there is one. The end result is the same - the faculty/planners are paid/reimbursed, and the accredited provider ensures there is no bias as a result of overall commercial support. From whom sends the actual check seems irrelevant.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	1. b-all expenses fall on the accredited provider. This could be an issue for some organizations when organizing larger events.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	It will be difficult and burdensome on the already low-staffed accredited provider offices to accommodate this change with changes to the responsibilities of joint providers.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	It would be nearly impossible for an accredited provider to disburse funds directly to a joint providers' planners or faculty. The logistics would be a nightmare for a system like ours (Ascension Health.)
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Some joint providerships may not occur under this proposed standard. There are accredited providers who currently joint-provide, but their continuing professional development department/organization is not in the business of handling financial transactions for non-accredited providers. In the joint-providership, an accredited providers counsels and apprises the non-accredited provider of ACCME Standards for Commercial Support and obtains an accounting of income and payment of expenditures in accordance with SCS 3.13.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	The accredited provider should not be responsible for for expenses when entered into a joint providership. Would be better to just require the JP to follow same rules and still manage expenses. We don't need yet another thing to do when we barely have enough resources as it is.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Advocacy organization			Many accredited providers of all types have not been designed to manage the collection of financial information and direct payment of expenses. They lack the staffing and systems to pay vendors, faculty, etc. Thus, they prefer that their joint providers manage these tasks. Problems that will arise include: • It may be difficult and costly for providers to revise their systems • Some providers will be forced to change their business models • Some providers will be forced to close their businesses/programs • It will cost more time for busy faculty to communicate with both providers and joint providers
Advocacy organization			Our constituents are concerned with the unintended consequences on joint providerships. Particularly, the section referencing expenses needing to be paid or reimbursed directly by accredited providers and not, among others, joint providers. What does this mean for providers who do not pay out honoraria, but instead pay their content experts a salary? There is a shift from providers making decisions regarding disbursement of commercial support to providers becoming responsible for that disbursement. Because of the burdents of the additional financial tracking requirements, many of SCMEC providers indicated they would likely discontinue to offer joint providerships. This will effectively reduce the amount of accredited education available to physicians, which we believe is not upholding the ACCME's mission.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Advocacy organization			There are a number of ramifications to this new requirement. 1. Accredited providers have historically stated that many of their operations are short-staffed. The bookkeeping requirements will overwhelm an already resource-limited department/organization and require more staff support. If additional staffing is even possible, the focus needs to be more towards CPD professionals and not allotted towards administrative staff time. 2. The transfer of the payment function to the accredited provider will beholden the activity to the accredited provider's policies and procedures causing confusion and conflict that penalizes the payee. Examples: a. Honorarium and reimbursement limits of the accredited provider may be contradictory to that of the joint provider. b. The joint provider's accounting policy does not require a W-9 in order to pay reimbursements. The accredited provider's accounting policy requires a W-9 in order to set up the individual in the accounting system. The planner or faculty member now has to provide a personal ID number to an organization that is one-step removed from the activity when they are dealing directly with the joint provider.
Clinician/healthcare professional			CME is expensive. By limiting commercial support, access of health care providers to knowledge that will help their patients is being limited.
Clinician/healthcare professional			If evidence exists of the benefit or harm of a practice, it can be stated the type of evidence that exists, and the strength/level of that evidence. As long as the level of evidence is quoted, then the accrediting body can explain how or when to use that evidence, with a reminder that the strength of evidence is weak, and requires more research. Medicine will continue developing- however slowly, because of shortage of funds.
Clinician/healthcare professional			Most of this is already established in the current standards for commercial support. That will not necessarily prevent people from complaining. "I personally think we developed language because of our deep inner need to complain" --Jane Wagner
Clinician/healthcare professional			Repression of progress in medicine.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Clinician/healthcare professional			There may be concerns with 1.b. if a joint provider is accountable for financial expenses.
Clinician/healthcare professional			This is quite an increase in workload for the accredited provider when the joint provider is prohibited from simple disbursement.
Continuing education accrediting body			Some providers may experience challenges in serving as the entity required to make payments/reimbursements. If the accredited provider holds the responsibility and accountability for decision-making, which is the expectation in all aspects of a joint providership relationship, what prohibits the joint provider from making payments with provider oversight of disbursement? Provider policies, agreements, budgetary information, and records of payment/accounting can serve as evidence of appropriate management of commercial support.
Continuing education accrediting body			We oppose the proposed prohibition on providers delegating the responsibility to pay faculty to a joint provider. Many providers enter into joint provider and other partnerships in order to extend what they are able to produce with their own staff. There are many ways for a provider to exercise control over delegated responsibilities beyond having to do this themselves. This rule would add an administrative burden on providers without providing a meaningful safeguard on potential abuse. Examples of how this delegation could be effectively controlled include the following: • Specifying honoraria and reimbursement policies in an agreement between the provider the joint provider to whom making payments has been delegated including requirements that must be met before a payment could be made • Requiring approval by the accredited provider before payments are made • Requiring a full reconciliation of how funds were used by the joint provider • Including the right to audit in the overall agreement between the accredited provider and the joint provider Please reconsider this requirement.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Ineligible Entity (commercial interest, such as pharmaceutical, device, life-science company)			For 4.1.a, many accredited providers do not have the capacity and resources to efficiently manage the receipt and disbursement of funds as outlined in the standard but instead rely on their educational partners (e.g. a medical education communication company with established administrative resources) to process support in a timely manner, without any added administrative burden or cost to the accreditor. For 4.1.c, as written this proposal does not allow for commercial support of scholarships and travel funding to students, residents, and fellows who otherwise could not afford to attend national meetings and, therefore, would not have the opportunity to be exposed to useful educational content and peer opportunities. We recommend providing additional language excluding this population from the standard, allowing compliant support of such educational opportunities to this group.
Medical/healthcare association			Excluding the joint provider from dispersing funds and paying planners and faculty will create a significant disruption in the accredited CE space as many accredited providers are not currently prepared to execute this change and implementing it will be both costly and difficult in some settings. Changing to a requirement that all funding actually go through the accredited provider may run afoul of legal teams as it breaks the chain of fiscal accountability. If the provider had knowledge of the grant budget and approved it, why cannot the funds be sent to the education partner and let them disperse, under the diligent supervision of the accredited provider? Specific comments on challenges: My organization office of general counsel takes 9-12 months to approve agreements, so this would end any commercial support for our activities; Delays in payment might result in professionals refusing to be planners/faculty for accredited education; 25% -70% overhead charges added by my university; To even begin to address this standard would require staff and resource expansion that is impossible to justify, especially in a climate of intense external political and economic pressures on healthcare systems; We foresee possible Stark and/or anti-kickback implications.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Medical/healthcare association			It would be beneficial for ACCME to specify what type of commercial support is acceptable for accredited activities, especially if there are other options outside of an unrestricted educational grant. If this is not specified, it may allow other types of commercial support, including funding through other departments within an ineligible entity that may are more closely tied to marketing (with the caveat that the contracts indicate that the entity cannot provide any content assistance).
Medical/healthcare association			Many continuing education programs utilize unrestricted grants from ineligible providers in partnership with a third-party education company that arranges for and manages the logistics of the educational program with oversight from the accredited provider. Standard 4.1.B requires that, “These expenses must be paid or reimbursed to the individuals (i.e., planner/faculty) directly by the accredited provider and not by the ineligible entity or joint provider.” This stipulation would be extremely burdensome to large academic providers, especially public universities who must often work within government regulated and inflexible business and finance guidelines. While the need to avoid having ineligible entities provide direct reimbursement to the planner/faculty is understood, the same should not be true for joint providers as there is still continued oversight and auditing by the accredited provider. The AMA Council on Medical Education is concerned about the unintended consequence on these larger providers that may suffer greatly from the ability to work with joint providers in hosting large educational initiatives.
Medical/healthcare association			Requiring eligible entities to manage commercial support funds for joint providers will result in a new level of oversight for providers. This new oversight will result in additional financial and resource burden. Eligible entities may move aware from joint providership; therefore reducing the number of CME opportunities to physicians.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Medical/healthcare association			While we understand and appreciate the intent of the new standard, we are concerned that it will create an unnecessary administrative burden for accredited providers who provide CME credit for professional societies or other non-profit organizations. Typically, reimbursement of travel expenses and honoraria for speakers are provided from the professional society, not the accredited provider. We are also concerned that the new standard may reduce the number of joint provider programs reducing CME offerings. We would advocate for a reporting system that requires the joint provider to complete a report detailing any faculty payments prior to any payment. Assuming the intent here is to improve transparency and reporting of commercial involvement in funding CME, ACCME might consider distinguishing between reimbursement provided by a non-profit organization using grants from other non-profit or government sources, and CME activities in which commercial sponsorship is providing funds for such reimbursement.
Medical/healthcare association			With respect to joint providers not being allowed to pay expenses directly, what can be done to allow but ensure control by the provider?
Medical/healthcare association			Within Standard 4.1.B, joint providers should be excluded from this as the roles and responsibilities should be clearly documented between the eligible entity and whom they are partnering with. It is fine to say ineligible entities cannot directly pay these expenses, but we partner with many organizations that could be considered eligible entities and they help share the responsibilities, which includes reimbursing faculty expenses. While this may seem minor, it will require many eligible entities to have to change their processes for joint providership unnecessarily and add more administrative and fiduciary responsibilities to their workload. we would be interested in hearing more about why the change is necessary.
Nonaccredited CE provider			4.1 a. Alternative Language: accredited provider is responsible for overseeing the disbursement of commercial support. 4.2a Alternative Language: These expenses must be paid or reimbursed to the individuals directly by the CME provider or their designated education partner or joint provider and not by the ineligible entity. This responsibility should be clearly outlined in an agreement between each organization. As a non-accredited organization, we are defined as a joint provider. We

			collaborate with various CME providers such as associations, state medical societies & academic medical centers with limited administrative abilities. By moving direct responsibility to the CME providers, we are concerned about the timing of payments & flexibility of booking flights & travel. Our courses are often delivered in rural areas where timing of payment & travel arrangements are made more than 30 days in advance. We have dedicated travel staff who make arrangements for faculty for 300+ activities & we adhere to strict guidelines on payment amounts. Several universities have stated if they pay faculty directly, they would add a 30-70% dean's tax to payments. We are concerned this change could force us to abandon many of these joint provider relationships & have a negative impact on collaborations as well as on speaker willingness to deliver valuable CME programs in rural areas. We believe the proposed criteria as it is written will discourage collaborations.
Nonaccredited CE provider			As a non-accredited organization, we are defined as a joint provider. We collaborate with CME providers such as associations, state medical societies, and academic medical centers who often have limited abilities to process individual faculty payments. By moving the direct responsibility to the CME providers, we are concerned about payment timing and flexibility of booking travel. Our courses are often delivered in rural areas. We have dedicated travel staff who arrange travel plans for faculty for our over 300+ activities. We adhere to strict guidelines on the payment amounts and pay in a timely manner. We are concerned this change could force us to abandon many joint provider relationships and have negative impact on collaborations and speakers' willingness to deliver valuable and much needed CME programs in rural areas. Several of the universities we work with have noted if they pay the faculty directly that they would add a 30-70% deans' tax. We believe the proposed criteria as it is written will discourage collaborations.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Nonaccredited CE provider			As a non-accredited organization, we are defined as a joint provider. We collaborate with various CME providers such as associations, state medical societies and academic medical centers often with limited abilities to process payments to individual faculty. By moving the direct responsibility on to the CME providers we are concerned about the timing of payments and flexibility of booking flights and travel. Our courses are often delivered in rural areas where timing of payment and travel arrangements may be more than 30 days. We have dedicated travel staff who makes travel arrangements for faculty to our over 300+ activities and who ensures that the travel plans are made on-time and efficiently. We adhere to strict guidelines on the payment amounts that are being followed. We are concerned this change could force us to abandon many these joint provider relationships and have negative impact on collaborations as well as speakers' willingness to deliver valuable and much needed CME programs in the rural areas. Also, several of the universities we work with have described if they pay the faculty directly that they would add a 30-70% deans' tax to those payments.
Nonaccredited CE provider			By requiring Accredited Providers to disperse payments of honorarium and expenses to faculty when commercial support is received creates administrative concerns and payment processing issues. Some accredited providers do not have the staff and resources to process payments to faculty. In these cases, faculty payments will potentially be delayed, thereby, likely frustrating faculty. In addition, this requirement will also likely delay final reconciliations. A recommended alternative is for the Accredited Provider to keep a record of faculty payments made by a Joint Provider. The Accredited Provider still retains control of the management of the overall funds, through this documentation, even when payment is made by a joint provider.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: Accredited CE provider, Continuing education accrediting body, and medical/healthcare association			4.1a - Changing to a requirement that all funding go through the accredited provider may run afoul of legal teams as it breaks the chain of fiscal accountability. It may slow the distribution of funds for development in joint providership situations. The accredited provider must have knowledge of the grant budget and must approve; thus, we believe that the funds should be able to be sent to the education partner and let them disperse, under the diligent supervision of the accredited provider. 4.1b - Joint providers should be excluded from this as the roles and responsibilities should be clearly documented between the eligible entity and whom they are partnering with. While this may seem minor, it will make many eligible entities have to change their processes for joint providership and add more administrative responsibilities to their workload. In addition, requiring that the accredited provider pay all planner/faculty honoraria and expense will also create a significant burden on some accredited providers who do not currently have the accounting staff to support this, thus increasing the cost of activities or decreasing the amount of actual funds for development. 4.1c- As worded, this would prohibit resident/fellow scholarships and travel funding provided through commercial support, with the recipients selected by the accredited provider and the student's academic institution - as this is a special set of learners. Is that the intent and if so, why?
Other: Answering both as accreditor and accredited provider.			Our understanding of 4.1 is that joint providers cannot touch any commercial support money at all. If this is true, WSMA does not support this change and has serious concerns. If joint providers can't receive and disburse commercial support, this will be a large added administrative burden on accredited providers. It will drive away joint providers and increase the cost of CME because of the aforementioned administrative burden on the accredited providers. This change will also potentially create barriers for joint providers to create accredited education for their own learners. Can joint providers pay for any CME expenses themselves?

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: CME/CE Consulting Services Company			Depending upon the ACCME's intent in Standard 4.1, this could impact a number of joint provider partnerships, if the accredited provider must disperse all commercial support funds. Currently, many joint providers are charged with disbursement of commercial support, with oversight by the accredited provider, as it's the joint provider that often takes a lead as a logistics organization in managing contractors and vendors.
Other: Consultant			I have talked to two friends who are accredited providers since these standards were published for public comment, and both have told me the new requirement to have the accredited provider be responsible for disbursing all commercial support is going to cause problems. I will leave my friends to spell out why in detail.
Other: Consulting company; licensed clinician			4.1. Some accredited providers do not have the systems or resources to receive grants and pay vendors, faculty, etc. and thus prefer that their joint providers manage these tasks. It may be difficult and costly for some providers to revise their systems to comply with this.
Other: Hospital			As a department of 2 this will be impossible.
Other: I am a faculty member/CME content provider/CME course director and my views do not necessary represent the views of my institution, the Medical College of Wisconsin			The budget and funding for educational activities from some eligible entities come from the marketing department rather than an educational division. In the interests of full disclosure and transparency, the source of institutional funding ought to be identified. .
Other: Joint Provider			For every primary provider there are 10s to 100s of joint providers that have been managing these expenses such as faculty honorarium, etc. for decades. This creates an undue burden for both parties. For example - just looking at speaker management - in particular for small CME offices that may currently manage large conferences with joint providers. They would have to take on 1099ing 100s of speakers, managing payments, etc. for every large conference that they jointly accredit. Long standing relationship with professional associations would likely not be able to continue due to this unnecessary administrative burden?

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: MedChi is both an Accredited Provider and a Recognized Accreditor			4.1 This standard will create a number of issues for joint providerships. If this is such an issue with non-compliance, I would suggest creating an auditing method that accredited providers could use to monitor the distribution of funds when the option of distrubution/disbursement is granted to the non-accredited joint provider. Regular funding useage reports, copying/including the accredited provider in communications and distribution/disbursement in real time or through periodic reporting could be used in lieu of placing the burden soley on the accredited provider.
Other: Medical Education Company			As a non-accredited organization, we are defined as a joint provider. We collaborate with various CME providers such as associations, state medical societies and academic medical centers, often with limited abilities to process payments to individual faculty. By moving the direct responsibility on to the CME providers we are concerned about the timing of payments and flexibility of booking flights and travel. Our courses are often delivered in rural areas where timing of payment and travel arrangements may be more than 30 days. We have dedicated travel staff who makes travel arrangements for faculty to our over 300+ activities and who ensures that the travel plans are made on-time and efficiently. We adhere to strict guidelines on the payment amounts that are being followed. We are concerned this change could force us to abandon many of these joint provider relationships and have negative impact on collaborations as well as speakers' willingness to deliver valuable and much needed CME programs in the rural areas. Also, serval of the universities we work with have described if they pay the faculty directly that they would add a 30-70% deans' tax to those payments. We believe the proposed criteria as it is written will discourage collaborations.
Other: State Medical Society/Publisher/Accredited Provider/Recognized Accreditor			Physician members anticipate that this change will delay payments to faculty and other individuals due to time needed for processing; that it will create administrative burden for both the CME staff and finance department of the accredited provider; and would raise costs to the CME programs as accredited providers try to cover costs for processing payments. In addition, we heard from one of our members who is affiliated with a state-funded, state-accredited organization that the state prohibits this type of payment structure.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Patient, caregiver, member of the public			I think the accredited provider managing the funds will be challenging but is a step in the right direction.
Recognized Accreditor (state/territory medical society)			"Why? If a program is expensive and joint provider is willing not share cost, then that should be allowed."
Recognized Accreditor (state/territory medical society)			4.1 and 4.2 There is substantial concern about the accredited provider being responsible for disbursement of funds. Currently, the accredited provider is aware of commercial support as they sign the agreement and approve activities in joint providerships. They also ask for a detailed budget and summary of how funds were used. If this all falls to the accredited provider, this again places additional responsibility and work on the provider including the involvement of a provider's accounting department.
Recognized Accreditor (state/territory medical society)			4.b regarding expenses must be paid or reimbursed to the individuals directly by the accredited provider will seem unmanageable by some. Education for surveyors what to look for during reaccreditation will be helpful.
Recognized Accreditor (state/territory medical society)			Currently, we are able to have the joint provider make all honoraria payments, travel reimbursement, etc. on our behalf. If this change is approved, this will create hardship for many accredited providers (especially given an accredited provider's financial policies and processes) and will likely negatively impact many of our provider's ability to work with external organizations/societies. We feel strongly that as an accredited provider, it should be our responsibility and choice to determine when we want to allow our joint provider to pay expenses and should not be dictated by the Standards of Commercial Support.
Recognized Accreditor (state/territory medical society)			Funding is given to support an organization, not to pay the organization providing the accredited education. Funders may not be able to justify paying a different type of organization (accredited provider), etc. There are certain types of funds set aside for certain reasons and certain types of organizations (the joint provider).

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Recognized Accreditor (state/territory medical society)			I am very perturbed that for the proposed new Standards for Integrity and Independence in Accredited Continuing Education, Standard 4.1b that a joint provider cannot manage commercial funding to pay for honoraria or travel expenses of planners and faculty. These will create several huge problems. First, our joint providers have the staff and time and resources to plan joint conferences and can pay for these many details of expenses incurred by planners and faculty that accredited provider staff do not have the staff, time and resources to manage. That is, after all, one of the reasons we even collaborate together in a joint providership relationship. Second, a number of the commercial support grants that I have received from pharma companies go directly to the joint provider and not to me as the accredited provider. As the accredited provider I would not even have direct access to the funds received by the joint provider. It would be tough for me as the accredited provider to pay for these expensed in turn. Remember in the ACCME Accreditation Requirements document (dated January 2020) on page 15 under " Joint Providership" and subsection "Compliance and Noncompliance Issues" the ACCME that compliance with accreditation requirements may be in documents submitted by the accredited provider or in files submitted by the nonacccredited (joint) provider. This implies that the joint provider is managing many responsibilities already in the planning and management of CME
Recognized Accreditor (state/territory medical society)			It would make accounting difficult since the money would have to pass through the accredited provider before it is transfered for other uses.
Recognized Accreditor (state/territory medical society)			Our company require a rigourous background check and a signed contract in order to pay a physician money of any sort. This would make it impossible for me as a provider to have any joint providerships and therefore eliminating many of the relationships that have been formed over the past several years. I believe that instead ask for a more detailed breakdown of expenses paid for activities to show the compliance of Standard 4.

Do you foresee challenges or unintended consequences implementing Standard 4? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Recognized Accreditor (state/territory medical society)			Per our CME Planning Committee, we find it impossible to have to do the finances and write checks for all Joint Providers. We are limited in staff and that would entail too much for one person. It would be nice to change this Standard to allow the Joint Provider to write their own checks but submit all proof of payment to all entities with their activity and explanation of each one.
Recognized Accreditor (state/territory medical society)			Possible push-back from joint providers who were previously able to pay speakers directly and will no longer be able to do so. (Or is this only in the event commercial report is received?) This will greatly affect existing relationships, budgets, partnerships.
Recognized Accreditor (state/territory medical society)			Possibly not unforeseen, but providers will have to update their processes if they have allowed joint provider to make payments/reimburse from grants.
Recognized Accreditor (state/territory medical society)			Those providers who have many joint provided activities and depend on fees they charge for jointly providing may not have the resources for managing the funds internally.
Recognized Accreditor (state/territory medical society)			With respect to the requirement that providers in a joint providership relationship control the disbursement of funds, this will be administratively burdensome to those providers who work with joint providers. Currently, the accredited provider is aware of commercial support as they sign the agreement and approve activities in joint providerships

What comments or questions do you have about Standard 4?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider			Is the goal to push educational partners to apply for ACCME accreditation in their own right? What is the impetus for this "rule" to be included in the standard. I trust our educational partners to follow our policy that aligns with the ACCME Standards for Commercial Support. The only providers I envison that would benefit from this rule are medical education companies. The inclusion of this language "feels" punitive.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Allow JP to pay expenses using funds from commercial support.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Clarification needed - would a joint provider be able to pay for speaker/faculty expenses directly if they only received exhibit/registration revenue and no Commercial Support funding? What if the joint provider received both exhibit funding and commercial support. Could they use the exhibit funds to pay speakers and the commercial support to pay for other expenses? Would accredited providers also have to pay on behalf of our joint providers for speakers/faculty expenses/honorarium when no commercial support was received? 4.1b language change to "The accredited provider may use commercial support to fund honoraria or travel expenses of planners, faculty, and others in control of content for those roles only. These expenses must be paid or reimbursed to the individuals directly by the accredited provider or their joint provider; these expenses must never be paid or reimbursed to the individuals directly by an ineligible entity."
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Clarification needed on the above
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Currently, accredited providers are responsible for the oversight and management of commercial support , which is accomplished with appropriate check and balance of accounting along with a joint provider policy. We believe this is an appropriate method that has been successfully demonstrated with accredited providers.

What comments or questions do you have about Standard 4?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Our institution delegates to the Joint Provider the reimbursement of speaker expenses; if the speakers are being reimbursed with registration or exhibit funds, rather than commercial support, can the Joint Provider still handle the reimbursement process? Will the CME Provider still be able to delegate the Joint Provider to be the recipient of the commercial support? This new Standard will significantly increase the workload of the already-burdened CME Provider if this Standard passes as proposed. Our strong recommendation is to remove the Joint Providers from this Standard, specifically Standard 4.1.b. This Standard should be targeted to ineligible entities, as it has been in the past. If this Standard is not rescinded, specifically regarding Joint Providers, how will ACCME police this requirement?
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Standard 4.1b This is a bad idea and would impede our ability to maintain our relationships with medical education companies, who we rely on, not only for valuable accreditation income, but for developing education that serves our therapeutic areas and reaches a much wider audience than we could ever reach on our own. The reason we partner with Medical Education Companies is because they have resources (expertise and manpower) that allows them to develop and manage many more aspects of complicated, broad-based educational activities aimed at our target audiences than our 2 person CME enterprise can handle. We run the risk of losing this relationship if we are unable to manage the work involved in generating payments for our many jointly provided activities from our institution. This would mean a loss in the number of activities accredited by our program, a loss in the reach of our CME program and a loss in accreditation income, which could be devastating to our CME enterprise.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	We are just unclear of why the change to only allow payments be directly from the provider in the case of joint providership. We are curious to know why the need for that change?
Accredited CE provider	ACCME	Hospital/healthcare delivery system	We recommend that the ACCME does not go forward with requiring accredited providers to pay expenses in the case of joint providerships.

What comments or questions do you have about Standard 4?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Would you reconsider allowing the accredited provider to delegate handling of income/paying expenses to the non-accredited provider as long as proper accountability occurs.
Accredited CE provider	ACCME	Insurance company/managed-care company	Is there a way for the accredited provider to not have to receive the money and disperse it but perhaps be the one to direct where the money is dispersed as a part of the written agreement with the JS?
Accredited CE provider	ACCME	Nonprofit (other)	Appreciate the clarity in Standard 4.1.d. that CE providers can use commercial support funds to defray costs of the education for ALL learners.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	4.1c. Currently, the ACCME has carved out an exception to this statement for resident/fellow scholarship (https://www.accme.org/faq/based-expectations-scs-312-can-we-provide-scholarships-residents-and-fellows). Can this exception be included in the guidelines for clarity?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	4.3 – If a complaint is lodged against an accredited provider, specific to Standard 4.3, only then should the accredited provider disclose financial information regarding the activity in question.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	How will surveyors audit that the accredited provider is making these payments vs. the joint provider? If attestation, then truly how meaningful is this new requirement? Must the 'nature of support' only be disclosed if the contribution is in kind? Suggest keeping the current SCS 3.7 (The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.) as part of the new standard 4.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	I cannot really tell what changed aside from the joint provider thing so I guess I'm good here

What comments or questions do you have about Standard 4?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	In regard to what was formally allowed under 3.12 (and defined within ACCME's FAQ https://www.accme.org/faq/based-expectations-scs-312-can-we-provide-scholarships-residents-and-fellows) "Based on the expectations of SCS 3.12, can we provide scholarships to residents and fellows? Yes. Scholarships for Residents and Fellows fall under the purview of other organizations' guidelines and standards (e.g., See the Ethical Opinion 9.6.2 (d) of the Council of Ethical and Judicial Affairs of the AMA). It is not a topic addressed by the ACCME in the Standards for Commercial Support. The existence of such scholarships and/or the compliance by the provider in the administration of such scholarships will not be reviewed by the ACCME's accreditation process. ACCME does not find providers out of compliance with SCS 3 for providing scholarships to Residents and Fellows through their academic institutions, residency or fellowship programs as part of their medical training." Are providers permitted to provide resident travel scholarships to attend meetings? and/or if a meeting attendee does not claim credit for a meeting (i.e. residents/staff) are they also excluded from receiving travel scholarships to attend an accredited education event?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Suggest ACCME maintains current Standard: “The provider, the joint provider, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of–pocket expenses in compliance with the provider's written policies and procedures.”
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The accredited provider currently controls the letter of agreement with a commercial entity when working with a joint provider. The current oversight has worked flawlessly, and the proposed changes would unduly create a larger burden for the accredited provider by taxing additional staffing resources. This new proposal could result in loss of educational grants or educational opportunities for learners as the ACMG would not desire to add this additional administrative burden. This would also pit the provider and joint provider in awkward situations with potential grantors. What is the ACCME trying to accomplish with this change? If we understood the problem, we can suggestions for correction that would maintain our current efficiencies working with our joint providers.

What comments or questions do you have about Standard 4?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The basic premise that the accredited provider should maintain more direct control over the use of commercial support is a reasonable one, but the implementation as currently described may create unintended negative consequences. The other elements of this Standard are in alignment with the current requirements and are not questioned.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The basic premise that the accredited provider should maintain more direct control over the use of commercial support is a reasonable one, but the implementation as currently described may create unintended negative consequences. The other elements of this Standard are in alignment with the current requirements and are not questioned.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	This change would greatly impact our organization's administrative staff across various departments. We want to know why ACCME thinks that this change is needed. 4.1a Changing to a requirement that all funding actually go through the accredited provider may run afoul of legal teams as it breaks the chain of fiscal accountability. Also, it can slow the distribution of funds for development in joint providership. If the provider had knowledge of the grant budget and approved it, why cannot the funds be sent to the education partner and let them disperse, under the diligent supervision of the accredited provider? 4.1b In addition, requiring that the accredited provider pay all planner/faculty honorarium and expense will also create a significant burden on some accredited providers who do not currently have the accounting staff to support this, thus increasing the cost of activities or decreasing the number of actual funds for development. Overall, this may result in a reduction in collaborations between organizations in the planning, implementation, and evaluation of continuing education, which is the exact opposite of what is being promoted by ACCME and other accreditors.4.1c- As worded, this would prohibit so-called resident/fellow scholarships and travel funding that is provided through commercial support, with the recipients selected by the accredited provider and the student's academic institution- as this is a special set of learners. Is that the intent and if so, why?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We strongly recommend that the current SCS 3.8 be maintained, such that the accredited provider may choose to have the joint provider/educational partner receive the commercial support and pay any/all activity expenses. We have established processes/mechanisms to ensure appropriate oversight of our joint providers/educational partners and compliance with the Standards.

What comments or questions do you have about Standard 4?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We support Standard 4
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	What is the current concern that ACCME is trying to mitigate with the proposed requirement that the accredited provider?
Accredited CE provider	ACCME	Other: Accreditation Management, CME Consulting, and Joint Providing Company	If accredited provider enters into a signed agreement with Joint Provider on how money (grants/exhibits) is collected, handled, etc. can the Joint Provider be allowed to apply for and collect grant money?
Accredited CE provider	ACCME	Other: Teleconferencing Medical Education Company	This is a dissolution of the joint providership.
Accredited CE provider	ACCME	Publishing/education company	- There seems to be an inherent disconnect between the stem statement for this section (The accredited provider must make all decisions regarding the receipt and disbursement of the commercial support.) and the requirements for 4.1a (The accredited provider is responsible for dispersing the commercial support ...). Is the intent that the provider should receive all funds? Or, to make all decisions about how dispersed? For jointly provided activities, the bulk of expenses for an activity are often incurred by the education partner, not the accredited provider. Funding entities sometimes prefer to provide the funds directly to the entity spending the most, for their own accountability reasons. This wording is therefore confusing. Regarding payment of faculty and planners, it would seem more realistic, given the limitations of many providers to currently handle the revised standard requirements, to establish the requirements for clear policies on timely oversite of such payments, no matter who makes them (except by an ineligible entity, of course) and for documentation of payments (beyond the current one of an activity budget reconciliation). Some providers work with educational partners on activities supported only by registration fees, yet the same issues of payment for planners/faculty apply. Rather than creating whole new systems within some provider organizations or augmenting accounting personnel resources, why not indicate how and when the provider is accountable and

What comments or questions do you have about Standard 4?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	2. The expenses incurred for the accredited provider and then passed on to the non-accredited entity could make the situation too expensive for the non-accredited entity. Many non-accredited entities are smaller associations or boards and are not accredited because the financial and human resources burden of acquiring accreditation are too great. For the same reason, making the cost of joint providership too expensive could force non-accredited providers to stop doing accredited education. There are many non-accredited entities that do valuable education and research, and their work could become lost to the medical community. 3. Accredited providers could be forced to refuse joint providership that includes grants, with the same result as in #2 above. 4. Having to coordinate 2 separate accounting systems could also be a burden. While the accredited provider would keep account of grant income and expenses, the non-accredited entity would still have legal responsibilities (IRS and other agencies). Syncing the information between the 2 accounting systems could be a problem. 5. Many non-accredited entities rely on management companies for their business operations, including the development and management of education. There is the possibility that 3 accounting systems would now be involved.
Accredited CE provider	ACCME	Publishing/education company	4.1a- If the provider has knowledge of an activity budget and approves it, why cannot the funds be sent to the education partner and let them disperse, under the supervision of the accredited provider? Can the ACCME's concern be addressed by providing different financial documents/tracking of disbursements?

What comments or questions do you have about Standard 4?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	4.1a-There is an inherent disconnect between the stem statement for this section (The accredited provider must make all decisions regarding the receipt and disbursement of the commercial support.) and the requirements for 4.1a (The accredited provider is responsible for dispersing the commercial support....). Is the intent that the provider should receive all funds or to make all decisions about how dispersed? For jointly provided activities, the bulk of expenses are often incurred by the education partner, not the accredited provider. Funding entities often prefer to provide the funds directly to the entity spending the most, for their own accountability reasons. This wording is therefore confusing. Regarding payment of faculty/planners, it would be more realistic, given the limitations of many providers to currently handle the revised standard requirements, to establish the requirements for clear policies on timely oversight of such payments, no matter who makes them (except by an ineligible entity) and for documentation of payments (beyond the current one of an activity budget reconciliation). Some providers work with educational partners on activities supported only by registration fees, yet the same issues of payment for planners/faculty apply. Rather than creating new systems within some provider organizations or augmenting accounting personnel resources, why not indicate how/when the provider is accountable and let them decide how best to address that accountability.
Accredited CE provider	ACCME	Publishing/education company	An accredited provider is not necessarily a meeting manager and should not be directly involved in such a manner. The thorough oversight and auditing of joint providers is resource demanding as is and increasing this responsibility to include all transactions involving commercial support could potentially negatively impact the conduct of accredited continuing education.
Accredited CE provider	ACCME	Publishing/education company	Giving accredited providers the responsibility of decision-making and disbursement of funds should also include the freedom to decide the processes by which they accomplish that responsibility in alignment with the other standards including independence from ineligible entities. We suggest that all decision-making and disbursement decisions be the responsibility of the accredited provider, including whether or not a joint provider or educational partner can be responsible for the payment of honoraria and expense reimbursements to faculty. The accredited provider can put in place any accountability measures they deem necessary to ensure funds are disbursed properly.

What comments or questions do you have about Standard 4?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	It is critical to our business that providers be allowed to make payments through their joint providers. As we already oversee the work our joint providers do and require a budget be provided, it is critical that joint providers be able to pay faculty honoraria, travel expenses, etc. in order to avoid disruption to a system that currently works well and compliantly. If this changes, we will not be able to offer as many joint providers the ability to accredit their activities less we bring on additional full-time staff.
Accredited CE provider	ACCME	Publishing/education company	It is good to have further clarity that the ineligible entity cannot have any kind of financial relationship with faculty or planners. I wonder if 1d. falls foul of pharma company compliance when it comes to supporting CME through independent grants. We have seen several contracts that stipulate that this is not allowed. Perhaps the wording can be amended to read that the funds can be used to reduce the registration rate for the delegates. I don't know if it is problem, a grant officer in a pharma company would be able to advise better.
Accredited CE provider	ACCME	Publishing/education company	Please change the language as described above.
Accredited CE provider	ACCME	Publishing/education company	There seems to be an inherent disconnect between the stem statement for this section (The accredited provider must make all decisions regarding the receipt and disbursement of the commercial support.) and the requirements for 4.1a (The accredited provider is responsible for dispersing the commercial support ...). Is the intent that the provider should receive all funds? Or, to make all decisions about how dispersed? For jointly provided activities, the bulk of expenses for an activity are often incurred by the education partner, not the accredited provider. Funding entities sometimes prefer to provide the funds directly to the entity spending the most, for their own accountability reasons. This wording is therefore confusing. Regarding payment of faculty & planners, it would seem more realistic, given the limitations of many providers to currently handle the revised standard requirements, to establish the requirements for clear policies on timely oversite of such payments, no matter who makes them (except by an ineligible entity, of course) & for documentation of payments (beyond the current one of an activity budget reconciliation). Some providers work with educational partners on activities supported only by registration fees, yet the same issues of pymnt for planners/faculty apply. Rather than creating whole new systems within some provider organizations or augmenting accounting personnel resources, why not indicate how & when the provider is accountable. Let them decide.

What comments or questions do you have about Standard 4?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	There seems to be an inherent disconnect between the stem statement for this section (The accredited provider must make all decisions regarding the receipt and disbursement of the commercial support.) and the requirements for 4.1a (The accredited provider is responsible for dispersing the commercial support ...). Is the intent that the provider should receive all funds? Or, to make all decisions about how dispersed? For jointly provided activities, the bulk of expenses for an activity are often incurred by the education partner, not the accredited provider. Funding entities sometimes prefer to provide the funds directly to the entity spending the most, for their own accountability reasons. This wording is therefore confusing. Regarding payment of faculty and planners, it would seem more realistic, given the limitations of many providers to currently handle the revised standard requirements, to establish the requirements for clear policies on timely oversite of such payments, no matter who makes them (except by an ineligible entity, of course) and for documentation of payments (beyond the current one of an activity budget reconciliation). Some providers work with educational partners on activities supported only by registration fees, yet the same issues of payment for planners/faculty apply. Rather than creating whole new systems within some provider organizations or augmenting accounting personnel resources, why not indicate how and when the provider is accountable and l
Accredited CE provider	ACCME	School of medicine	4.1b. Questions 1. What prompted the change? 2. What data can be shared to support the need for this change? 3. Were there alternative versions of this standard that were considered before electing for this change? 4.1b. Comment - Professional or specialty societies, most or all of which are non-profit organizations, rely on partnerships with academic accredited providers to jointly provide education will struggle with their education mission for it is certain the cost burden will be shifted to them. 4.1c. Can commercial support be used for travel grants to support students to attend meetings? Documentation would include application, selection criteria, review, selection, and disbursement.

What comments or questions do you have about Standard 4?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	As an accredited provider within a University setting, and a state funded institution with restrictions on business practices and limited means to widely disseminate new practice information. Ineligible funding is an imperative resource that helps meet dissemination of educational needs.
Accredited CE provider	ACCME	School of medicine	Clarification is required around what kind of agreement is required; what does 'execute' mean? We have received so many questions regarding whether there has to be a penned or electronic signature - some companies insist that a letter from then, that the accredited provider signs, (electronic or other) is sufficient; the company does not need to 'sign'.
Accredited CE provider	ACCME	School of medicine	I can see this standard putting our office out of business. Our university funds only about 1/7 of our annual budget and we earn the remainder through fees that we must charge. To deal with this requirement, we will have to raise our fees so much higher that our educational partners will no longer want to work with us. This requirement will have disastrous impact on university CE offices. Our financial units are not set up to manage these kinds of payments, will no doubt require additional "taxes" to do so, and even then will do it badly.
Accredited CE provider	ACCME	School of medicine	I do not understand what problem this change is designed to correct. I would be willing to discuss solutions to whatever problem currently exists in order to not shift this burden to medical schools and other providers who may not be able to adjust.
Accredited CE provider	ACCME	School of medicine	I think that that the financial consideration in Standard 4.1.c that requires that the accredited provider must pay for all expenses for honoraria, travel expenses could be problemsome for some providers. I think that this is an approach to require/mandate provider oversight of the commercial support funds -- which is fine for our office but may be a challenge for some.
Accredited CE provider	ACCME	School of medicine	In Standard 4.1b, you note that accredited providers must pay or reimburse expenses to individuals such as faculty; joint providers cannot make these payments. I am unclear on the problem that this is attempting to address. The standards already require that all commercial support be given with the full knowledge of the accredited provider, who must be included on and sign all LOAs. Additionally, ineligible entities are already prohibited from being the non-accredited partner in joint providerships. So if an ineligible entity cannot be a joint provider, and if all commercial support must be given with the accredited provider's consent (and they must document the expenditure of all commercial support) what does this provision seek to address?

What comments or questions do you have about Standard 4?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	Most joint providers are nonprofit, patient advocates, small hospitals which aren't accredited but want to produce valuable accredited education. This will force many to abandon their accredited educational efforts since most don't have the budget or staff to become accredited on their own. And since most CME offices are fee for service, this will have a huge and negative impact on our bottom lines and potentially result in the laying off of personnel.
Accredited CE provider	ACCME	School of medicine	Our internal processes would struggle to handle this new influx of processing, resulting in delays in payment, which could in turn cause our external educational partners to eventually seek another accredited provider.
Accredited CE provider	ACCME	School of medicine	Perhaps a way to navigate would be for the accrediting provider to "sign-off" on any payment requests for the support, such as honorarium or travel expenses. There could be a standard template provided by the ACCME that captures all of the necessary information. This would eliminate any confusion as well as capture the information required.
Accredited CE provider	ACCME	School of medicine	Please do not implement Standard 4b
Accredited CE provider	ACCME	School of medicine	Recommend allowing joint providers to pay expenses. In this case the joint providers must provide to the accredited provider an estimated, itemized budget prior to the activity so the accredited provider ensures use of funds is appropriate. Following the activity, the joint provider must provide a reconciled, itemized budget of actual expenses to the accredited provider.
Accredited CE provider	ACCME	School of medicine	The standard 4 revision is VERY problematic! What is the intent of the ACCME? Can other ways achieve the intent in which the proposed requirement might not result in unintended consequences?
Accredited CE provider	ACCME	School of medicine	The words "a joint provider" should be removed from 1b. There was no explanation in the information packet as to why joint providers were included in the statement.
Accredited CE provider	ACCME	School of medicine	Would the change outlined in 1b only apply to activities that receive commercial support or all activities?
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Hospital/healthcare delivery system	Would all providers still be expected to have a written honoraria policy?

What comments or questions do you have about Standard 4?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Other: academic medical center	WHAT ARE YOU TRYING TO FIX?!? This revision suggests that existing financial oversight is inadequate. Fine. Then oblige us to better demonstrate our oversight. If your goal is to drive academic providers, small health systems, mid-sized hospital systems, and most MECs out of CME, then mission accomplished.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Other: Electronic health record company	We have no additional comments for this standard.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	I support the proposed changes.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	It is our responsibility as accredited providers to be fiscally conscientious with grant funds. To ensure independence and compliance, we make all disbursements and appreciate the clarity of this standard.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	Standard 4.1b With regard to the requirement for payment of faculty and planners, it would seem more realistic, given the limitations of many providers to currently handle the revised standard requirements, to establish the requirements for clear policies on timely payment over site and documentation of such payments. Rather than creating the need for new systems, increased burden, as well as additional resource requirements, within some provider organizations, would it not be more consistent to indicate how and when the provider is accountable and let them decide how best to address that accountability (direct payment or diligent oversight)?
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	When working with a joint provider, I see no reason why the accredited provider (AP) must pay all honoraria/travel. If an accredited provider has a relationship with a reputable joint provider (JP) and sound agreements are in place where the AP gives control to the JP for payments, why must the accredited provider take on this extra process? This will cause added and unnecessary work in the finance department. Has ACCME confirmed that ineligible entities will now only provide payment to accredited providers? That is currently not the case. This seems to be a great deal of back and forth with dollars.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	This change may encourage non-accredited partners to become accredited providers themselves (if eligible. Is this the goal of ACCME? To increase the number of eligible accredited providers?

What comments or questions do you have about Standard 4?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	Will the ACCME limit enforcement of this activity to only those activities that involve commercial support?
Accredited CE provider	Other: Accreditation Council for Pharmacy Education	Nonprofit (other)	Good addition to allow for all learner costs to be defrayed/eliminated as long as it doesn't imply bias of the educational content.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Good move forward but could be better. I still am of the opinion that commercial support, no matter how it is managed, can lead to unintended and possibly unconscious bias. The following link is a scholarly article that explains the reasoning and data support for this opinion. I do not believe that disclosure of commercial support is enough. Research shows that physicians tend to believe their sophistication protects them from influence of bias. This article provides evidence that level of education or experience does not necessarily disqualify an individual from flawed thinking. https://heinonline.org/HOL/LandingPage?handle=hein.journals/indana94&div=26&id=&page=
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	No comments. Standard 4 is again well written and an appropriate guideline for commercial bias free accredited education.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Our policy is no commercial support, and that simplifies things for us.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Please correct diction: change disperse to disburse in 1a: "The accredited provider is responsible for disbursing the commercial support."
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	remove the new clause. (Accredited providers must pay or reimburse expenses to individuals such as faculty; joint providers cannot make these payments. See Standard 4.1b.)

What comments or questions do you have about Standard 4?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	I disagree with 4.1b.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	We do not accept commercial support.
Advocacy organization			Please see the above comments. It is critical that providers be allowed to make payments through their joint providers. We suggest that joint providers, serving as an agent of the accredited provider, continue to be permitted to pay faculty honoraria, travel expenses, etc. in order to avoid disruption of a system that currently works effectively and compliantly.

What comments or questions do you have about Standard 4?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Advocacy organization			Questions 1. What prompted the change? 2. If the accredited provider explicitly states in the educational grant application that the money will not be used for faculty reimbursement/honorarium, is the accredited provider still responsible for reimbursement and honorarium payments? 3. If the joint provider/educational partner is able to pay faculty expenses directly rather than the faculty paying and submitting for reimbursement, is that okay? 4. Do funds used for travel for pre-planning meetings also need to be controlled by the accredited provider? 5. Are travel grants for individuals not in control of the activity content okay to be managed by joint provider/educational partner? 6. If speakers are being reimbursed with registration or exhibit funds, rather than commercial support, can the joint provider still handle the reimbursement process? Will the CME Provider still be able to delegate the joint provider to be the recipient of the commercial support? 7. How does the ACCME plan to oversee this requirement? Comments 1. Professional or specialty societies, most or all of which are non-profit organizations, rely on partnerships with academic accredited providers to jointly provide education will struggle with their education mission for it is certain the cost burden will be shifted to them. 2. State institutions have specific financial guidelines and are not allowed to accept funding from medical Societies and reimburse speaker expenses.
Advocacy organization			We recommend that we retain the status quo.
Clinician/healthcare professional			allow for teaching of innovative medical concepts
Clinician/healthcare professional			Please see above.
Clinician/healthcare professional			Well written and precise.

What comments or questions do you have about Standard 4?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Clinician/healthcare professional			What percentage of discrepancies were found with joint providers disbursing the funds vs the accredited provider? Were there sanctions or criminal charges in any of the cases?
Medical/healthcare association			4.1a- There seems to be a disconnect between the stem statement for this section (The accredited provider must make all decisions regarding the receipt and disbursement of the commercial support) and the requirements for 4.1a (The accredited provider is responsible for dispersing the commercial support). Is the intent that the provider should receive all funds or make all decisions about how dispersed? For jointly provided activities, most expenses for an activity are often incurred by the education partner, not the accredited provider. Funding entities often prefer to provide the funds directly to the entity spending the most, for their own accountability. This wording is therefore confusing. Regarding payment of faculty and planners, it is more realistic, given the limitations of many providers to currently handle the revised standard requirements, to establish the requirements for clear policies on timely oversight of such payments, no matter who makes them (except by an ineligible entity) and for documentation of payments (beyond the current one of an activity budget reconciliation). Some providers work with educational partners on activities supported only by registration fees, yet the same issues of payment for planners/faculty apply. Rather than creating new systems within some provider organizations or augmenting accounting personnel resources, why not indicate how and when the provider is accountable and let them decide how best to address that accountability.
Medical/healthcare association			Some providers work with joint providers on activities supported only by registration fees, yet the same issues of payment for planners/faculty would apply. Rather than creating whole new systems within some provider organizations or augmenting accounting personnel resources, why not indicate how and when the provider is accountable and how they must be able to demonstrate fulfillment of that requirement? Then the provider can best decide how best to address that accountability (direct payment or diligent oversight)?
Nonaccredited CE provider			4.1 a. Alternative Language: accredited provider is responsible for overseeing the disbursement of commercial support. 4.2a. Alternative Language: These expenses must be paid or reimbursed to the individuals directly by the CME provider or their designated education partner or joint provider and not by the ineligible entity. This responsibility should be clearly outlined in an agreement between each organization.

What comments or questions do you have about Standard 4?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Nonaccredited CE provider			We believe the proposed criteria as it is written will discourage collaborations between accredited and nonaccredited organizations and accredited organizations between each other.
Other: Answering both as accreditor and accredited provider.			The WSMA does not support the change that only accredited providers receive and disburse commercial support, as this will adversely impact both accredited and joint providers. It will add administrative burden on accredited providers; because of this, the cost of accredited education will rise, driving away joint providers, which in turn creates barriers for non-accredited providers to create accredited education for their own learners.
Other: CME/CE Consulting Services Company			Can a joint provider manage commercial support funds, outside of direct payments to individuals, so long as the accredited provider is ultimately responsible and overseeing budgetary expenditures?
Other: Consultant			How can an accredited provider ensure that education remains independent of an ineligible entity when the money for the education comes in response to an RFP from the ineligible entity? And the RFP spells out in great detail exactly what type of education industry wants to support? And what types of formats industry wants to see? And what types of outcomes industry would like to see? It flies in the face of common sense. And it certainly throws open wide the doors to commercial influence of education. This is a contradiction that would be difficult to explain to outsiders, or newcomers to the industry who have been told that there is this great firewall between industry and clinician learners.
Other: Joint Provider			What is the rationale behind this change? Could other ways be explored to achieve the unclear goal of this change that would not place the financial burden of needing additional staff for example on small CME offices. Any clarification on why this is needed would be helpful.
Other: MedChi is both an Accredited Provider and a Recognized Accreditor			Regarding 4.1 Here is a serious issue that has to be resolved. The requirement that only the accredited provider can disperse funds will affect a pool of providers who are challenged by staff, infrastructure, and policy and procedures, that would create issues with disbursement of funds and the charging of fees. Some accredited providers are not built to do this. This will create a lot of issues and seems to be addressing a problem that doesn't exist. Has there been a lot of issues in this area? This will affect provider decisions regarding doing funded joint providerships, ultimately reducing the pool of providers available to work in joint providerships.

What comments or questions do you have about Standard 4?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: Medical Education Company			As a non-accredited organization, we are defined as a joint provider. We collaborate with various CME providers such as associations, state medical societies and academic medical centers, often with limited abilities to process payments to individual faculty. By moving the direct responsibility on to the CME providers we are concerned about the timing of payments and flexibility of booking flights and travel. Our courses are often delivered in rural areas where timing of payment and travel arrangements may be more than 30 days. We have dedicated travel staff who makes travel arrangements for faculty to our over 300+ activities and who ensures that the travel plans are made on-time and efficiently. We adhere to strict guidelines on the payment amounts that are being followed. We are concerned this change could force us to abandon many of these joint provider relationships and have negative impact on collaborations as well as speakers' willingness to deliver valuable and much needed CME programs in the rural areas. Also, serval of the universities we work with have described if they pay the faculty directly that they would add a 30-70% deans' tax to those payments. We believe the proposed criteria as it is written will discourage collaborations.
Other: physician, patient, member of certifying board, member of educational academy			I must say I got bogged down in some of the technical language.
Other: Recognized accreditor and Accredited CE provider			If a provider maintains a "foundation" separate from the parent organization and that foundation is used to offer travel grants for residents, etc., can commercial support be deposited into the foundation coffers (dare I say laundered?) and then used to provide travel grants?

What comments or questions do you have about Standard 4?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: State Medical Society/Publisher/Accredited Provider/Recognized Accreditor			Physician members are strongly opposed to requiring that the accredited provider be required to make payments to individuals in lieu of the joint provider. It is unclear whether the commercial supporter is required to provide the payment for commercial support to the accredited provider, even though it states that the accredited provider is required to make all the decisions regarding receipt and disbursement of commercial support. Please clarify. Under decision making and reimbursement, it states that payment for individuals' honoraria or travel expenses must be paid only by the accredited provider. Does this apply only to activities that accept commercial support? Does this apply only to individual's expenses or does it apply to all expense for the activity including AV, facility, administrative, food and beverage, etc.?
Patient, caregiver, member of the public			Providers STILL continue to disclose grant support for CME with a logo. I would also add something that disclosure of support to the audience cannot be documented without a signed agreement.
Recognized Accreditor (state/territory medical society)			• Should the accredited provider provide a specific level of support for “in-kind” such as attending the meetings to confirm the appropriate in-kind support was provided, etc.? • If a joint provider is an eligible entity, why can’t they pay or reimburse the expenses?
Recognized Accreditor (state/territory medical society)			How does this effect commercial support given to a hospital's educational "foundation"?
Recognized Accreditor (state/territory medical society)			Must a provider still have written policies & procedures re: honoraria / speaker expense reimbursement? (Was the only required policy; will no longer be read.) It appears joint providers can no longer directly receive commercial support and would no longer be involved in signing a written agreement.
Recognized Accreditor (state/territory medical society)			Per our CME Planning Committee, we find it impossible to have to do the finances and write checks for all Joint Providers. We are limited in staff and that would entail too much for one person. It would be nice to change this Standard to allow the Joint Provider to write their own checks but submit all proof of payment to all entities with their activity and explanation of each one.
Recognized Accreditor (state/territory medical society)			Please keep currently policy which allows JP to pay for direct expenses related to the activity.

What comments or questions do you have about Standard 4?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Recognized Accreditor (state/territory medical society)			Please reconsider this change.
Recognized Accreditor (state/territory medical society)			Providers are very concerned about the proposed prohibition against joint providers disbursing funds for honoraria or travel expenses. This would create new administrative burdens, and several providers anticipate that this would cause them to stop entering into joint providership agreements where commercial support is accepted. The joint provider should continue to be allowed to make payments and reimbursements to planners, faculty and other content controllers, and show the movement of these moneys in a manner agreed to by the accredited provider and the joint provider.
Recognized Accreditor (state/territory medical society)			This really starts a movement in the direction of not trusting the joint provider with managing money and managing commercial support funding – funding that the Pharma companies are perfectly aware is being sent to the joint provider. This sound like a lack of trust issue and I will lose the support or collaboration of some of my joint providers if they feel that they cannot be trusted. Whoever came up with this idea should re-examine this idea and also not equate joint providers with the “ineligible entities” mentioned earlier in these Standards all in the same sentence. We are talking about two totally different entities with different goals, responsibilities, reporting requirements etc. I am going to encourage resistance to this idea with everyone I possibly can and I will be willing to debate this with anyone at any time.
Recognized Accreditor (state/territory medical society)			Typo in standard 4.1.a (p. 15): "dispersing" should be "disbursing."

Standard 5: Manage Ancillary Marketing around Accredited Continuing Education

Is Standard 5 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider		Nonprofit (physician membership organization)	It should be made clear in 2 d that if the material includes disclosures - this makes something educational content. The definition of educational content should be made clear by ACCME. Normal understanding would not assume including disclosures makes something educational content. If in the material, you say this session was sponsored by an unrestricted educational grant turn the material into educational content???
Accredited CE provider	ACCME	Hospital/healthcare delivery system	"Live continuing education activities: Marketing, exhibits, and nonaccredited education must not occur in the physical space immediately before or after an accredited education activity, and must not be interleafed within the accredited education. Learners must not be presented with product promotion or product-specific advertisement while engaged in accredited education and must not be required to interact with representatives of ineligible entities." - This needs to be more specific. What does "Immediately" mean. What does "interleafed" mean.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	1. In 2a., add “where accredited education takes place” after “in the physical space”. It might be necessary to be more specific about “before” and “after” or provide guidance for providers to create their own specifics. 2. We believe 2a does not allow the display of banners containing the logos of ineligible entities as a way of disclosing commercial supporters in the physical space where accredited education takes place. 3. We believe that company logos are permissible on training materials produced by the company when health care professionals from the health care facility that has already purchased a device and/or system are being trained on the device and/or system. 4. We believe the correct word is “interleaved”.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	2.a With respect to live teaching, please clarify what you mean by “immediately before or after?” Please define what kind of time separation could be approved so a non-accredited session or activity could take place in the same room. If one has a 15-minute break between accredited and non-accredited activities, can they be held in the same room?
Accredited CE provider	ACCME	Hospital/healthcare delivery system	5.2a. The term “immediately” requires some further definition or explanation. “Interleafed” requires some further definition or explanation.

Is Standard 5 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Accredited education differs from “ineligible non-accredited education” please provide a crossover as to how. Some non-accredited education is designed by ineligible entities and thus ineligible for accredited education status so how would this standard apply to education that is non-accredited, but could be accredited? Secondly, in regards to Standard 5.2.a an operationalized definition of “…immediately before or after an accredited education activity” is necessary. Is “immediate” a specific amount of time? If participants move from one room for accredited education to an adjacent room for non-accredited education, is this still the same physical space because they are in such close proximity to each other? For example, during a break in the accredited education a participant leaves the main room to visit the foyer, where ineligible entities have purchased advertising space and speaks with them and then returns to the main room when the accredited education begins – has this standard been violated in this example? Finally, is the reference to “interleafed” specific to paper marketing copy or could it have implications for digital marketing and how live activities are designed?
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Clarification needed for "Marketing, exhibits and non-accredited education must not occur in the physical space immediately before or after an accredited education activity, and must not be interleafed within the accredited education." More specifically, why can't our programs be planned with both accredited education and non-accredited education if necessary?
Accredited CE provider	ACCME	Hospital/healthcare delivery system	For 5.2a, consider including social events sponsored by a ineligible entities (e.g. a dinner) or a similar descriptor in addition to the “Marketing, exhibits, and nonaccredited education…” verbiage.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	It is very expensive to manage a CME activity and having to pay for the conference space to be able to accommodate the CME activity and the Exhibit Hall. If the Exhibit Hall (marketing), as stated in the proposed Standard 5 “must not occur in the physical space immediately before or after an accredited education activity…” then as I understand it, we would need to have a space for breakfast/breaks for the attendees, separate from the Exhibit Hall. Must clearly define "physical space," "immediately before and after."

Is Standard 5 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	It would be useful to have clarification on "interleaved" and "immediately." What would be considered immediately and is there a time frame that is an acceptable standard between accredited and nonaccredited education (for example, nonaccredited education begins following an hour break at the completion of the accredited education)?
Accredited CE provider	ACCME	Hospital/healthcare delivery system	More clarity on what constitutes "interleafed." As a surveyor I have seen instances of credit being withdrawn from a particular session (say session 2 out of a series of contiguous sessions 1, 2 & 3) because - for instance - material was found at the last minute to include product logos; or a speaker had a previously undisclosed / unresolved relationship with a relevant commercial interest. Does this standard mean that the session cannot take place, even if learners are told in advance that the session carries no credit?
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Please clarify the definition of “non-accredited education” as it relates to Standard 5.2.a. If non-accredited education differs from “ineligible non-accredited education” please provide a crossover as to how.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Please clarify the definition of “non-accredited education” as it relates to Standard 5.2.a. If non-accredited education differs from “ineligible non-accredited education” please provide a crossover as to how. Some non-accredited education is designed by ineligible entities and thus ineligible for accredited education status so how would this standard apply to education that is non-accredited, but could be accredited? Secondly, in regards to Standard 5.2.a an operationalized definition of “…immediately before or after an accredited education activity” is necessary. Is “immediate” a specific amount of time? If participants move from one room for accredited education to an adjacent room for non-accredited education, is this still the same physical space because they are in such close proximity to each other? For example, during a break in the accredited education a participant leaves the main room to visit the foyer, where ineligible entities have purchased advertising space and speaks with them and then returns to the main room when the accredited education begins – has this standard been violated in this example? Finally, is the reference to “interleafed” specific to paper marketing copy or could it have implications for digital marketing and how live activities are designed?

Is Standard 5 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Standard 5 2a. What does "physical space immediately before or after" mean? What time lapse is allowed? Are exhibitors allowed during lunchtime, etc.? What does ACCME mean by "must not be interleafed within the accredited education"? Can ACCME please provide examples of compliancy and non-compliancy for this standard section
Accredited CE provider	ACCME	Hospital/healthcare delivery system	There needs to be a clear definition of “interleafed”. Does this term apply to a live activity?
Accredited CE provider	ACCME	Hospital/healthcare delivery system	We need clarification on the term interleafing. In addition, please clarify what is meant by preferential access in this statement: Ineligible entities may not provide preferential access to or distribute accredited education to learners.
Accredited CE provider	ACCME	Nonprofit (other)	Consider defining “immediately before/after” and “interleafed” using specific and quantitative time and space parameters.
Accredited CE provider	ACCME	Nonprofit (other)	Need to clarify what is meant by the terms 'immediately before or after' and 'interleafed' in Standard 5.2a.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Please provide additional guidance on approaches for smaller events vs larger, and what constitutes a separate space. Are there other ways to ensure learners can clearly distinguish?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	2a - physical space - have always received questions about this...is there a distance or measurement of what entails physical space before/after?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	1b. add “accredited before education. 2a. change interleafed (refers to paper) to interspersed.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	2a stating that non-accredited education "must not be interleafed within the accredited education" is not entirely clear. Does that just mean that non-accredited talks can't be included in a set of accredited talks or is it going further to say that non-accredited workshops or activities are not allowed during lunch breaks? Also, does "immediately before or after" mean within five minutes? 10 minutes? If non-accredited sessions are held in a small room from 7:00-7:50 AM and an accredited breakout session starts in that same room at 8:00 AM, is that okay or still considered "immediately after?"

Is Standard 5 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	5.0 – Include language that acknowledges that non-accredited continuing education does not always mean promotional content is being delivered, even in cases where the content is being delivered by an ineligible entity. There is an underlying paternalistic assumption that accredited providers must “protect” highly educated health care professionals and assist them with distinguishing between promotional and educational content (non-accredited). 5.2a – Define “immediately” for live events. As providers consider what activities to accredit, it may be logistically impossible to accommodate “promotional” activities in a separate place. For example, even the largest convention centers may only have one space in which to accommodate 10,000 meeting participants once other space is allocated for additional sessions. 5.2d – Provide specific and relevant examples. For instance, mobile meeting apps that include logistics information and schedules as well as links to education content have replaced paper programs. Can mobile apps include marketing for or by an ineligible entity?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	5.2 sounds reasonable but isn't completely clear. What is meant by "interleafed”? How long must exhibits and non-accredited education be separated from accredited education? Define "immediately." Should there be a break in-between sessions?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	5.2(a): The term “immediately” requires some further definition or explanation. Is the intent to make sure that learners clearly know of that the nature of the presentation is changing between accredited and non-accredited and that the learner has time to leave if desired? If so, then using words to that effect would be better than “immediately.” We believe this statement is unclear: “must not be interleafed within the accredited education.” We suggest the following statement instead: “must not occur immediately before or after accredited education without a break in the program.” • 5.2(b): We find the new language more ambiguous than what was previously stated. For an online continuing education activity, when does the education activity begin? Is it when the learner launches the course? Is it when (s)he first sees the accreditation statement? Is it (s)he they are on the home page of the LMS? We are trying to determine if an ad on the home page is acceptable if the learner doesn’t have to click on the ad to get to the educational activity. For print materials, is an advertisement on the back cover okay if it’s not interleafed within the pages of the CME content?

Is Standard 5 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	5.2a Further clarification is needed with some terms used in this Standard related to live CE activities: • Physical space: would this encompass a specific meeting room, a hall, and/or convention center? • Immediately: how much time would need to lapse between sessions? • Interleafed: This term is more synonymous with journals; preferred terms for live activities would include sequential or concurrent.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	5.2a. We recommend that term 'physical space' and "immediately" be defined and the ACCME provides guidance regarding exactly how an accredited provider would be responsible for distinguishing between accredited education and other activities. Consider Marketing, exhibits, and nonaccredited education that takes place during an accredited educational conference must clearly be identified as non-accredited education.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	5.5a. Regarding the language, "Marketing, exhibits and non-accredited continuing education must not occur in the physical space immediately before or after an accredited education activity, and must not be interleafed within the accredited education" there are a few issues that cause concern. First, what defines, "immediately?" How long of a break/amount of time in between the non-accredited and accredited education activity must there be to fulfill the definition of "immediately?" Second, the use of the term, "non-accredited education" by the ACCME assumes that it is somehow commercial or promotional in nature. There are many activities that occur within live events (especially those at annual meetings of the medical specialty societies) such as town halls, award presentations, poster viewing sessions, etc that are not at all commercial or promotional but are not part of accredited CME. Clarity is needed around these types of non-accredited activities and non-accredited activities such as those presented by industry. Lastly, what is the definition of "interleafed" in a live continuing education activity? The term, "interleafed" may be suitable for print/enduring continuing education activities but it does not seem to make sense for live continuing education activities.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	ACCME should clarify 2a. What does "nonaccredited education" mean? Does this include things like our opening ceremonies? What about our award ceremony? What does "immediately before or after" mean? ACCME should also define the term "interleafed" since that is not commonly used in a live setting.

Is Standard 5 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Additional clarification is needed regarding the term interleafing, as well as further define "immediate" and "physical" space.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Can you clarify what is meant by immediately before or after the education by ineligible entities and define "interleafed."
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Define "immediately." Interleafed does not make sense in the context of a live activity. Consider concurrent or sequential. 5.2.a. Live continuing education activities: Marketing, exhibits, and nonaccredited education developed by or with influence from an ineligible entity must not occur in the...
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Delete “and nonaccredited education” from the sentence: “Marketing, exhibits, and nonaccredited education must not occur in the physical space immediately before or after an accredited education activity, and must not be interleafed within the accredited education.”
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Modify 5.2.a: “Marketing, exhibits, and nonaccredited education must clearly be identified as such in any physical space that is also utilized for an accredited educational activity."
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	In Standard 5.2a, need definition of "nonaccredited education". Does it mean education from an ineligible entity or from any entity? In Standard 5.2a, need clarity on "…immediately before or after an accredited education activity…" In Standard 5.2a, the word "interleafed" indicates print and is not the correct word to use in reference to a live event.

Is Standard 5 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Section 2, Part A states that Marketing, exhibits, and non-accredited education must not occur in the physical space immediately before or after an accredited event. What would the appropriate time period be for a space break so that it is not counted as “immediately”? 10 minutes, 1 hour, 1 day? Section 2, Part A states that Marketing, exhibits, and non-accredited education must not occur in the physical space immediately before or after an accredited event. What would the appropriate time period be for a space break so that it is not counted as “immediately”? 10 minutes, 1 hour, 1 day? This section also states that Marketing, Exhibits, and non-accredited education …must not be interleafed within the accredited education. The term “interleafed” makes no sense in a live activity context. Does that mean that we can’t have company sponsored workshops at lunch? Is a non-accredited session between two accredited sessions no longer allowed, or would it be allowed with a break between the sessions? Or is this more specific to non-accredited and accredited talks taking place in one session?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	See CMSS response.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Standard 5.2: this proposal requires rewording to clarify what constitutes “immediately before or after”, and “interleafed”. Although the terms seem more appropriate in reference to journal-based or enduring materials, many questions are raised in reference to producing and managing live educational activities.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The language as written implies that a CME and non-CME activity can't immediately follow each other in the same room. What about large meetings where rooms are repurposed all the time to accommodate a variety of events? Additional clarification as to what immediately before or after would be helpful. If left as is the ACCME will receive question on this, is it 15 minutes or 30 minutes, etc.? I also think this kind of detail is not really the purview of the standards.

Is Standard 5 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The term “immediately” requires some further definition or explanation. Is the intent to make sure that learners clearly know of that the nature of the presentation is changing between accredited and non-accredited and that the learner have time to leave if desired? If so then using words to that effect would be better than “immediately”. “Interleaved” also is not clear. Suggest replacing “preferential access” with “selectively allow/provide direct access to….”
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The term “immediately” requires some further definition or explanation. Is the intent to make sure that learners clearly know of that the nature of the presentation is changing between accredited and non-accredited and that the learner have time to leave if desired? If so then using words to that effect would be better than “immediately”. Also,currently providers can exclude presentations from the accredited CME program to permit the free flow of information.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The term “interleafed” is not meaningful in the context of live activities (item 2a). Events can take place either sequentially of concurrently, and if sequential in time they can be in the same or different physical spaces. Providers need to know: 1) if accredited education and non-accredited events can take place concurrently, in separate spaces, during a live activity; 2) if accredited education and non-accredited events can take place sequentially in the same physical space, and if so what is the necessary time between these to avoid one following the other “immediately”; 3) if accredited education and non-accredited events can take place sequentially in different physical spaces, and if so what is the necessary time between these to avoid one following the other “immediately”.

Is Standard 5 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The term “interleafed” is not meaningful in the context of live activities (item 5.2.a). Events can take place either sequentially or concurrently, and if sequential in time they can be in the same or different physical spaces. Providers need to know: 1) if accredited education and non-accredited events can take place concurrently, in separate spaces, during a live activity; 2) if accredited education and non-accredited events can take place sequentially in the same physical space, and if so what is the necessary time between these to avoid one following the other “immediately”; 3) if accredited education and non-accredited events can take place sequentially in different physical spaces, and if so what is the necessary time between these to avoid one following the other “immediately”. Also, non-accredited education does not automatically equal promotional content provided by an ineligible entity. An accredited provider may have a variety of reasons to include non-accredited events within the program of a live activity. It is important to distinguish promotional educational offered by ineligible entities from evidence-based non-accredited education offered by an accredited provider; in its current form the Standard does not recognize this distinction.

Is Standard 5 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	This defines non-accredited education (N-AE) broadly (eg, sales/promo content by ineligible entities & N-AE by eligible entities) and presumes all N-AE is problematic; there are different purposes/benefits to each (eg, specialty societies provide membership updates, educate trainees on financial management). These have a place in CE. To achieve what may be ACCME's intent, this should be revised to: "a. Live continuing education activities: Marketing, exhibits, and nonaccredited education 'developed by or with influence from an ineligible entity' must not occur…" 5.2.a. – Clarification is needed on: a) "Physical space" – Is that the same meeting room, hallway, or building? It is not feasible to rent more/separate meeting space. b) "Immediately" – how long of a break is acceptable? c) "Interleafing" –this is closely associated with journals; preferred terms would be "sequential" & "concurrent." More guidance/examples are needed on how this relates to large annual meetings. Would it be acceptable to have 1 meeting room, in which accredited & N-AE/non-promo sessions take place sequentially, ie, in Meeting Room 100, sessions are held sequentially as CME, Non-CME, and CME? Also, would it be acceptable to have CME & Non-CME sessions occurring concurrently, ie, CME in Room 102 at 10am, Non-CME in Room 202 at 10am? The expectation should be on accredited providers distinguishing accredited education from N-AE without a need to specify time/space differences.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	This Standard assumes that all nonaccredited education is commercially supported. Please rewrite to differentiate between nonaccredited education that is/isn't commercially supported.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Would recommend: "Marketing, exhibits, and nonaccredited education that takes place during an accredited educational conference must clearly be identified as non-accredited education. The accredited provider must have practices in place to clearly distinguish accredited education from non-accredited education for learners."

Is Standard 5 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Other: Nonprofit, scientific research association	This sentence is not clear: “Marketing, exhibits, and nonaccredited education must not occur in the physical space immediately before or after an accredited education activity, and must not be interleafed within the accredited education.” We suggest modifying it to read. “Attendees should not encounter marketing, exhibits, and promotional education just before they enter or immediately after they exit an accredited education activity or interleafed within the accredited activity.” Nonaccredited education includes non-promotional education that does not fit the definition of CME such as sessions focused on helping globally diverse students navigate US research institutions and locate academic or research appointments. The term promotional education would be more appropriate as nonaccredited does not solely mean promotional.
Accredited CE provider	ACCME	Other: Teleconferencing Medical Education Company	Again, the wording is vague. What is the definition of "immediately before or after an accredited education activity"? Is that considered 5 minutes, 30 minutes, 5 hours?
Accredited CE provider	ACCME	Other: University - not a school of medicine	define/clarify "immediately" as in both time and proximity. define "preferential access" - would this include group rates negotiated or partially paid for by employers for attendance or enduring learning.
Accredited CE provider	ACCME	Publishing/education company	• A definition of the term immediately before or after an accredited education activity (standard A definition of the term immediately before or after an accredited education activity (standard 5-2a)—does this mean that an accredited activity ending at 5pm and a non-accredited or industry event starting at 5:01pm is not considered compliant with Standard 5? --If it is not compliant, how can these types of events be planned that would demonstrate compliance? Regarding print enduring activities and 2b: does this exclude medical journals where participants may leaf through pages up to the article which include promotional materials, but the activity is free from any promotion?

Is Standard 5 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	5.2.a: define "immediately" before or after. If it is clearly announced that the CE activity has ended and there is time for learners to leave before the non-accredited activity starts, is that sufficient? Also, what does "product-specific advertisement" include? Is it ok to announce a non-accredited product theater that is happening in another room or is that considered advertising in the educational space?
Accredited CE provider	ACCME	Publishing/education company	5.2 a- The term “immediately” requires some further definition or explanation. Is the intent to make sure that learners clearly know of that the nature of the presentation is changing between accredited and non-accredited and that the learner have time to leave if desired? If so then using words to that effect would be better than “immediately”. “Interleafed” is not a familiar term in healthcare CE. Please use other wording (perhaps “interspersed”) to explain what you mean here. 5.3 – Suggest replacing “preferential access” with “selectively allow/provide direct access to….”
Accredited CE provider	ACCME	Publishing/education company	5.2 a The term “immediately” requires some further definition or explanation. Is the intent to make sure that learners clearly know of that the nature of the presentation is changing between accredited and non-accredited and that the learner have time to leave if desired? If so then using words to that effect would be better than “immediately.” “Interleafed” is not a familiar term in healthcare CE. Please use other wording (perhaps “interspersed”) to explain what you mean here. 5.3 Suggest replacing “preferential access” with “selectively allow/provide direct access to….”

Is Standard 5 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	5.2a- The term “immediately” requires some further definition or explanation. What defines “immediately”? 5 minutes? 10 minutes? Is the intent to make sure that learners clearly know of that the nature of the presentation is changing between accredited and non-accredited and that the learner have time to leave if desired? If so then using words to that effect would be better than “immediately”. 5.2a - “Interleaved” is not a familiar term in healthcare CE. And the dictionary definitions available do not relate to CE. Please use other wording (perhaps more than one word) to explain what you mean here. 5.2 c – Suggest making an exception for medical devices, when specificity is needed. 5.3 – Suggest replacing “preferential access” with “selectively allow/provide direct access to….”
Accredited CE provider	ACCME	Publishing/education company	5.2a- While I appreciate the need to allow for some interpretation of the word “immediately”, it would be helpful to include guidance on what is intended with this Standard. This will help providers determine what is appropriate in various settings and situations. The term “Interleafed” doesn’t resonate with a live activity setting. Perhaps “alternate between accredited and promotional non-accredited education” works? 5.2 – Not all non-accredited education is marketing or promotional. Please consider distinguishing between these different types of education, rather than putting them all in the same bucket (as marketing). Offering an independent non-educational lecture such as a motivational keynote related to healthcare, immediately followed by accredited education is very different from a promotional, sponsored lecture followed by accredited education. 5.3 – Not sure the intent of the statement about “preferential access”?

Is Standard 5 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	5.2a. The term “immediately” requires some further definition or explanation. Is the intent to make sure that learners clearly know of that the nature of the presentation is changing between accredited and non-accredited and that the learner have time to leave if desired? If so then using words to that effect would be better than “immediately”. “Interleafed” is not a familiar term in healthcare CE. Please use other wording (perhaps “interspersed”) to explain what you mean here. 5.3. Suggest replacing “preferential access” with “selectively allow/provide direct access to….”
Accredited CE provider	ACCME	Publishing/education company	Define "interleafing" and provide more detail on 2.d. ("information distributed...")
Accredited CE provider	ACCME	Publishing/education company	Section 2.a. - "interleafed" should be replaced with "interspersed" and perhaps the sentence should be revised to "Marketing, exhibits, and nonaccredited education must not occur in the physical space of an accredited education activity." Section 3 should be clarified through examples.
Accredited CE provider	ACCME	Publishing/education company	The statement “Ineligible entities may not provide preferential access to or distribute accredited education to learners” needs to be further clarified. Currently, some providers request that supporter representatives help improve activity registration and participation by distributing information cards about the activity. It is specified that in these circumstances the information is to be distributed only during non-sales/promotional interactions with prospective learners. Will this practice still be permitted?

Is Standard 5 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	What does 5.3 even mean? "Ineligible entities may not provide preferential access to or distribute accredited education to learners." - Is this meant to replace the existing 4.5? If so, a key difference between the existing 4.5 and proposed 5.3 is that the current 4.5 holds accredited providers accountable for their actions and methods. It is clear in the existing 4.5 that the accredited provider cannot proactively solicit or otherwise engage a commercial interest to deliver CME activities to learners. But the proposed 5.3 is too ambiguous. - If a CME provider creates a textbook that a representative of an ineligible entity distributes to a learner on their own volition (PhRMA and AdvaMed permit distribution of educational materials) could that be deemed a violation? Regarding "preferential access" - if, at a live CME activity, a representative of a commercial interest was to drive a learner to the activity - would this be "preferential access"? - Enforcement standards must focus on the actions of the accredited provider, not on the untold actions of third parties. Stating that "ineligible entities may not..." - the ACCME does not accredit "ineligible entities" and neither they, nor the accredited providers, are in a position to police or control improper behavior by those groups. - (SCS4.5) "A provider cannot use a commercial interest as..." works perfectly as an example of enforcing the actions of that are in the control of an accredited provider.
Accredited CE provider	ACCME	School of medicine	5.2.a-need to specify how long a break is...what is "immediate". Is space or time the issue? What does it mean by "interleafed"...clarity is needed.
Accredited CE provider	ACCME	School of medicine	5.2a. Please provide further clarification for the terms “interleafed”, “immediately before” and “immediately after”.
Accredited CE provider	ACCME	School of medicine	Do not understand what is meant by physical space. ..same room, same square feet inside a room, same conference building, etc.????
Accredited CE provider	ACCME	School of medicine	I'm not sure what "preferential access" means in #3.
Accredited CE provider	ACCME	School of medicine	Problems again with terminology that don't represent reality of CME providers.
Accredited CE provider	ACCME	School of medicine	This is confusing - please clarify 5.2a – Live continuing education activities: Marketing, exhibits, and nonaccredited education must not occur in the physical space immediately before or after an accredited education activity, is “before or after” a question of place or time? In other words, is this saying that marketing, etc. must not be close to the physical space or in the same physical space that an accredited activity takes place?

Is Standard 5 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	This is fine, but “interleafed” doesn’t have any common sense meaning. Education should be separate, but we need clear, understandable guidelines about what that means. For live, does that mean you shouldn’t have a lunch break in the exhibit hall, or does it mean session by session? Also, what counts as “required to interact” – branded hotel keys? A Wi-Fi password that’s the name of a company or a company slogan? Have to walk through logos to get to the educational space?
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Hospital/healthcare delivery system	I'm confused about what the terms immediately and interleafed mean in standard 5.2a: Live continuing education activities: Marketing, exhibits, and nonaccredited education must not occur in the physical space immediately before or after an accredited education activity and must not be interleafed within the accredited education. Does immediately mean that you need a break before and/or after a non-accredited session of an accredited activity? If so, how long of a break is required? Does interleafed mean that you can't have non-accredited sessions in-between accredited sessions, even if there is a break? Would non-accredited sessions need to be moved to the end of the day with a break before of some specific amount of time?
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (other)	item 2c includes the clarification "including corporate or product logos, trade names, or product group messages." in item 2d, if the intention of "may include marketing by or for an ineligible entity, please consider adding the same clarification as with 2c. in the past, different providers have interpreted whether, for example, logos of commercial interests that are part of a conference exhibit hall, could be included in a handout containing schedules and logistical information differently. the additional clarification on 2d would address that.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	Further clarification is needed with some terms used in this Standard related to live CE activities: • Physical space: would this encompass a specific meeting room, a hall, and/or convention center? • Immediately: how much time would need to elapse between sessions? For example, would having a break before/after the nonaccredited education suffice? • Interleafed: This term is more synonymous with journals; a preferred term for live activities would be sequential or concurrent. How much of a time/space gap is the ACCME looking to have so that the education is not considered to be “interleafed”?

Is Standard 5 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	5.2a- The term “immediately” requires some further definition or explanation. Is the intent to make sure that learners clearly know of that the nature of the presentation is changing between accredited and non-accredited and that the learner have time to leave if desired? If so then using words to that effect would be better than “immediately”. What is the intent of “interleafed”? Does this mean non-certified education may only take place before or after a day-long face-to-face activity, for example?
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	Standard 5.2a: The term “immediately” requires some further definition or explanation. Isn’t the intent here to make sure that learners clearly know that the nature of the presentation is changing between accredited and non-accredited and that the learner have time to leave if desired? If so then using words to that effect would be better than “immediately”.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	Clarify what cannot be interspersed with CME. What if the non-accredited education has nothing to with industry, but is simply not appropriate for CME (E.G., something dealing with the business end of the organization)? The room where CME is being delivered cannot be used for non-CME before, during or after the CME activity. Does this mean that we cannot parse out lunch-time talks that may not be credited, or that the room cannot be used after the course completes for non-CME demonstrations, even if it is clearly indicated that it is non-accredited? Is the 'obligatory pathway' verbiage no longer relevant?
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	What does “interleafed” mean? If the intent is to prohibit independently organized industry sponsored programs, then state that.

Is Standard 5 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Other: ACPE	Publishing/education company	In 2A, recommend clarifying if marketing, exhibits, or nonaccredited education can occur in the same physical space immediately before or after an accredited activity if those time slots immediately before or after were before or after the official start/end of the accredited program. For example, if the accredited program has ended and there is a post-conference symposium, this language implies it could not occur in the same room, despite the accredited program having officially concluded.
Accredited CE provider	Other: CMA	Hospital/healthcare delivery system	clarify when such an activity can take place: separate room with breaks before and after?
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	"Ineligible entities may not provide preferential access to or distribute accredited education to learners" - I don't understand what this means or what it is intended to prevent. Concrete examples would be very helpful.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	What about Joint providers. They cannot be commercial interest. The prologue indicates that in Standard 4 they would not be allowed to pay directly for faculty etc. Why could they not pay directly at the direction of the accredited provider? Makes no sense and will likely often be done unwittingly.
Accredited CE provider			What is accredited medical education - what's wrong with continuing medical education. It's acceptable for some words to stand the test of time. I've mentioned previously that I'm not a proponent of change just for change sake.
Advocacy organization			5.2a. Please provide further clarification for the terms “interleafed,” “immediately before” and “immediately after”.
Advocacy organization			NAMEC suggests that the statement “Ineligible entities may not provide preferential access to or distribute accredited education to learners” be further clarified. Currently, some providers request that supporter representatives help improve activity registration and participation by distributing information cards about the activity. It is specified that in these circumstances the information is to be distributed only during non-sales/promotional interactions with prospective learners. Will this practice still be permitted?

Is Standard 5 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Advocacy organization			We would like to see clarification on the following statement, "…nonaccredited education must not occur in the physical space immediately before or after an accredited education activity…" Does ACCME mean to say ineligible nonaccredited education rather than just non accredited education? The second part of this is statement also needs clarification. How much time constitutes "before or after?" Can we have clarification on seconds, minutes, or hours? There needs to be clarification on what is meant by "interleafed." Does the ACCME mean to say that nonaccredited education cannot occur between accredited education sessions?
Continuing education accrediting body			• "eligible/ineligible" terms are problematic. Consider an alternative term that will have more meaning for faculty such as "ineligible commercial entity" or "commercial interest." • "immediately before" and "immediately after" requires more definition • The term "interleafed" is confusing in a live context and we are therefore unsure of what ACCME intends to prohibit • In #5 the term "distribute" is vague. Is the issue sole distribution, or distribution itself? Would distributing a brochure with the URL of an online activity be considered "distributing" the activity if it is otherwise publicly available?
Continuing education accrediting body			Suggest further defining or changing terminology from "preferential access."
Ineligible Entity (commercial interest, such as pharmaceutical, device, life-science company)			Standard 5.2. Consider the use of "promotional" education throughout instead of the term "nonaccredited."
Medical/healthcare association			5.2d - what is meant by "logistical information"?
Medical/healthcare association			As written, Standard 5.2.A is still too vague and in some regards unachievable. When hosting our Annual Meeting and CME courses, we often must repurpose rooms to accommodate many of the activities we offer, both accredited and non-accredited. We would ask that it be restated as "Marketing, exhibits, and non-accredited education that takes place during an accredited educational activity must be clearly identified as a non-accredited activity"

Is Standard 5 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Medical/healthcare association			Define “immediately”, need more specificity/explanation. How to notify leaner, need specificity. Define “physical space” –room, hallway, and building? Give examples Define “interleafed” give examples, use a different word that is clearer. Define “click through” –give examples What is allowed or not allowed to be included in conference bags?
Medical/healthcare association			Please explain the use of the term "interleafed."
Medical/healthcare association			Section, Explanation of Standard 5: As written, implies that the ineligible entity is marketing the accredited activity. This statement should clarify that the ineligible entity is conducting marketing activities in proximity to accredited education. Section 5.2.a: We agree that marketing and exhibit space should not occur in the same physical space at the same time as accredited activity. However, we disagree with the statement that non-accredited education could not occur in the space “immediately before or after” an accredited session. First, non-accredited education is a very broad term and in the current context, suggests that it is overtly biased. Types of non-accredited education vary but can certainly be non-promotional and provide opportunities to build knowledge and skills that are not clinical or product specific. Second, with large, national meetings, space can be limited, and therefore, it may be necessary to re-use space for various session types. There needs to be clarity on what “immediately before or after” means. Most conferences provide breaks between sessions – is this considered “immediately before or after?” We feel that organizations, accredited providers, and/or education teams are and should be responsible for ensuring that participants are aware of the accreditation status of each program. Lastly, the term “interleafed” is not one that is commonly used in health care education, so more explanation on this terminology is requested.

Is Standard 5 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Medical/healthcare association			The Alliance is agreement with the need to separate accredited CE and nonaccredited CE. Regardless, there is a need to better define “immediately”. This could be done by explaining the intent (e.g. clear notice to participants that the nature of education in a space is changing and allowing enough time for those who wish to enter or leave to do so). Thus, the provider could determine if perhaps 5 minutes are needed for a small group to exit a conference room or maybe 20 minutes for a large crowd to exit a ballroom. We suggest avoiding arbitrary selection of a minimum time, as it may not apply to all situations and the decision should be up to the provider to make and defend.
Medical/healthcare association			The Council on Medical Education is aware that the American Academy of Family Physicians (AAFP) has provided comment regarding Standard 5.2.A and we support this proposed language that states, “Marketing, exhibits and non-accredited education developed by or with influence from an ineligible entity, must not occur in the physical space…” The reason for this suggested edit is that non-accredited education such as business meetings, legislative or advocacy updates, town halls and other events frequently coincide with accredited education but are not influenced by commercial industry or an ineligible entity. The Council agrees the proposed language will help to provide clarity regarding the intent of this standard.
Medical/healthcare association			This might include a sentence to clarify that activities such as society member meetings, committee meetings, and group exercise programs are not considered “nonaccredited education.” In addition, this might include clarification of what is adequate separation from nonaccredited education, for example, that a break of at least 10 minutes between activities is not considered “immediately before or after” an accredited activity.
Other: Accredited CE provider, Continuing education accrediting body, and medical/healthcare association			The AOA believes that if quality, independent, non-promotional, non-accredited education is clearly identified as non-accredited CME to learners, it should not have to be separated. The AOA views this as a very critical issue and strongly recommends modifying Standard 5.2.a as follows: a. Live continuing education activities: Marketing, exhibits, and nonaccredited education developed by or with influence from an ineligible entity must not occur in the physical space immediately before or after an accredited education activity, and must not be interleafed within the accredited education. 5.3 – Suggest replacing “preferential access” with “provide direct access to…” which will clarify the intent.

Is Standard 5 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: CME/CE Consulting Services Company			While it is clear accredited CME should not be intermingled with marketing or promotion, there are occasional instances whereby a session is simply not accredited for reasons that have nothing to do with promotion or marketing. So long as such sessions are clearly marked in an agenda and made clear to learners, it is our belief that independence would not be compromised. In addition, added clarifications within 5.2 would be helpful, based on the questions we have outlined below.
Other: Consultant			The word choice is problematic where you say that marketing and promotional messages "must not be interleafed" within the accredited education. This terminology makes sense for printed materials, where it's easy to see how the leaves might refer to pages in a magazine or booklet. But it makes no sense in the context of a live meeting. Try a different verb, like "intermingled" or "interspersed."
Other: Consultant - own my own company			I think more clarity needs to happen treated to what 'immediately' means... what is the definition of an adequate amount of time before or after a session that would be considered not immediate? Especially in the case of a session where credit may have been removed due to inability to resolve COI before the activity, would it no longer be OK for that session to stay in the same location? would it need to just be cancelled instead? or would the typical break of 10 - 15 minutes be adequate? I have always wanted clarity from the ACCME on this.
Other: Joint Provider			Clarify specifically what you mean by interleafed, using both time and space clarifications. Again, we are adults and disclosing properly should allow for adult learners to make the choice themselves as whether or not they want to attend an event. Require that rooms that offer non-CME be clearly marked and/or that slides state NON-CME offering. Otherwise, state clearly how many minutes between sessions and / or how much distance is needed between rooms. It seems like this is already a current policy, that is inconsistently implemented or applied depending on how primary providers interpret what is meant by it. The new language does nothing to change or clarify this issue.
Other: State Medical Society/Publisher/Accredited Provider/Recognized Accreditor			Relative to Item 2a - could the ACCME define the time that meets the requirement for "immediately before or after" when exhibits or nonaccredited education may be offered in the physical space?

Is Standard 5 clear as written? If no, what modifications do you suggest?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Recognized Accreditor (state/territory medical society)			• Revise Standard 5.1 to: The accredited provider must ensure that learners can easily distinguish between accredited education and other activities, such as ineligible entity education and marketing. • Revise Standard 5.2 a. to: Live continuing education activities: Marketing, exhibits, and ineligible entity education must not occur in the physical space immediately before or after an accredited education activity, and must not be included within the accredited education. Learners must not be presented with product promotion or product-specific advertisement while engaged in accredited education and must not be required to interact with representatives of ineligible entities.
Recognized Accreditor (state/territory medical society)			Explained below in "unintended consequences"
Recognized Accreditor (state/territory medical society)			Item number two, letter d, needs clarification. It indicates marketing material with schedules and logistical information that it is okay to advertise the "ineligible entity." It still should remain independent from the accrediting education's schedules and logistical data. Does this mean an agenda that lists the title and schedule of the speakers can market the "ineligible entity?" Not clear.
Recognized Accreditor (state/territory medical society)			May need better wording for part 2a - "immediately before of after". What does that mean? If there is a break in between is that still considered immediately before or after?
Recognized Accreditor (state/territory medical society)			Please clarify Standard 5, #2 what is meant by “space immediately before or after an accredited education activity.” We would like better guidance on what qualifies as a sufficient break in time between accredited and nonaccredited education (i.e., is 5 minutes sufficient? 15 minutes?)

Do you foresee challenges or unintended consequences implementing Standard 5? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider			Confusion - so now we will have confusion with the terms ineligible entites, mitigate and accredited medical education.
Accredited CE provider		Nonprofit (other)	THIS CONDITION IS NEVER SATISFIED - IMPLICITLY THIS IS ALWAYS THERE Arrangements to allow ineligible entities to market or exhibit in association with accredited education must not: c. Be a condition of the provision of financial or in-kind support from ineligible entities for the education THE ONLY SOLUTION IS TO BAN ALL ANCILLARY MARKETING
Accredited CE provider		Nonprofit (other)	This creates very large restrictions on venues for activities. It would force providers to spend significantly more on hotel space, and make some venues unusable. It creates increased difficulty in scheduling as well and could require eliminating networking events, meals, etc...
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Given the lack of clarity with some of the key terms, I am concerned that non-compliance could occur because the intention and expectations are unclear.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	How can we plan for an agenda that require accredited and non-accredited education?
Accredited CE provider	ACCME	Hospital/healthcare delivery system	If one presentation in the middle of a day-long CME event is not certified for credit (because of reasons of non-compliance), and this omission of credit is indicated in the final program agenda provided to the learner, but that presentation is held in the same meeting space as the CME activity, does this situation comply with the new Standards? Or must we have a separate space for the non-CME portion of the activity? Is it acceptable to hold a promotional satellite program during lunch, clearly indicated as such to the learner, in the same meeting space as the day-long CME activity (noting that a separate lunch is offered in a room where the promotional presentation is occurring?

Do you foresee challenges or unintended consequences implementing Standard 5? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Is Standard 5 truly only applicable for activities that have advertising/exhibits? At first reading, I was very concerned about 5.2a, because it looks like it would no longer be an option to have any talk that does not count toward credit between two talks that do count toward credit, even if it is marked clearly in the program materials. One of our last-resort strategies for non-resolvable conflicts as well as speakers who do not submit financial disclosure information is to pull CME credit from that particular talk (we provide mainly live activities). We also sometimes have demos/talks at our live events that just don't meet the definition for CME, but that also aren't promotional (a demo by our music therapist, for example). None of these are promotional or marketing in nature. However, we rarely have exhibitors or marketing, so it may not apply.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Oftentimes it is difficult to control what speakers use on their slides, handouts and collateral materials as far as corporate logos, photos etc. It is becoming exceedingly difficult to change a presenter's slides and even more difficult with already printed collaterals without some sort of backlash.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Please provide clarification on what is immediately before or after the CME activity. How long a time is necessary? Also, what is the "physical space?" is that within the same CME activity room? Adjacent room, or another conference space within the same hotel/conference hall? Can breakfast and break food for the attendees be offered in the same space where exhibitors have their booths? Exhibitors offer marketing, and breakfast/break are "immediately before and after the CME activity."
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Prohibiting nonaccredited activities or sessions from taking place in the same space as the accredited activity AFTER the accredited activity is done is not practical or even possible in most venues. If on campus, we only have 1 conference room, so we would not have another space option. At an outside venue, renting additional rooms costs more money. If we clearly delineate between the close of the accredited activity and the commencement of the non-accredited activity, having the nonaccredited activity in the space in which the accredited activity took place should not matter.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Space limitations and financial burden are among the factors that contribute to the difficulty implementing this standard. Not all institutions have the resources necessary to comply.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	The standard section is not clear so accreditors could mistakenly approve a physical space, time lapse, marketing piece or exhibit that is non-compliant.

Do you foresee challenges or unintended consequences implementing Standard 5? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	We would want more information on interleafing. There are times that we don't provide credit for certain sessions, but we still want to be able to offer the education. These updates don't appear to accommodate for that, especially if you have limited space and time.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	While the general intention of this standard seems to be that accredited and non-accredited education along with advertising should not intermingle concurrently, I think the ability to operationalize the standard is limited due to lack of clarity in many of the terms used throughout the standard. Many definitions are need to better express intentions of the standard. Terms that need to be clarified/operationalized include: 1) non-accredited education vs. ineligible non-accredited education; 2) physical space; 3) "… immediately before or after…." 4) interleafed; and 5) corporate logos (as referenced above should this also include those of faculty and planners who are presenting content in some form? There is an unintended consequence in requesting that learners engage with accredited education without having to click through, watch listen to, or be presented with product promotion or product-specific advertisement. Providers would be barred from using the complimentary platforms like Facebook, YouTube, Audible, PodBean as cost effective options to deliver digital education. It would require providers to look at alterative options to deliver online content. These options may be cost prohibitive.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Will we be able to have product theater's at lunch? Is that "interleafing"?
Accredited CE provider	ACCME	Nonprofit (other)	In 2.a. - What does "physical space" mean? The same room in which the education is held? Or the general area? For example, if there is an exhibit table outside the room where the program is held, would that count?
Accredited CE provider	ACCME	Nonprofit (other)	Restrictions on event space and budget limitations make it impractical to reserve completely separate physical spaces for CE and non-CE content for a live activity. It is much more practical to allow a scheduled break between CE and non-CE content, and to clearly delineate through signage and announcements so that all learners are aware of the distinction between CE and non-CE content and have the opportunity to leave one or the other as desired.

Do you foresee challenges or unintended consequences implementing Standard 5? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (other)	Section 2 (a) distinguishing that non accredited education not being in the same physical space (room) before or after accredited education clears up some ambiguity in the previous version of the SCS. While this change may cause some burden for smaller live meetings, it is a welcome clarification of the ACCME's intent, and it is much appreciated.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	• For our smaller programs that do not have as much space or as many options, we would have to locate an entirely different room with size accommodations and ensure A/V is provided—this would be at great cost and limit our budgets severely, as well as limit where we can rent space—this would be a significant burden both financially and programmatically. • Define physical space – would a barrier in the room be enough? Would a time buffer between CME and non-CME be enough? If we are unable to financially and practically secure different rooms, how can we comply? • We would have to re-design how our live programs run to ensure ineligible sessions are kept very separate—are there other ways to ensure learners can easily distinguish?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	" Must not be interleafed within the accredited education." I'm not sure I'm clear on this - do you intend for the same rule that no non accredited -CE sessions can occur in the same building / on the same day as accredited CE?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	5.0 – By deeming all content presented by noneligible entities promotional, ACCME opens the door to a dilution of the quality of accredited continuing education and a shift toward industry becoming more visible in the provision of state-of-the-art continuing education to physicians. 5.0 – For academic practices with a significant focus on research, this restrictive definition is symptomatic of the broader campaign by ACCME to diminish the role of basic science in accredited education for physicians. 5.2a – There are logistical and financial constraints involved with separating accredited continuing education and promotional sessions (as currently defined by ACCME), particularly at large scale events like the ASH Annual Meeting. Depending upon ACCME's interpretation of "immediately," some providers may not be able to demonstrate compliance.

Do you foresee challenges or unintended consequences implementing Standard 5? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	5.2 Nonaccredited education should not be associated or confused with marketing or promotional activities. An example of nonaccredited education is education developed for international audiences who do not need US based CME credits and is presented outside of the US but is developed within the same structure as accredited education.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	5.2(b): We find the new language more ambiguous than what was previously stated. For an online continuing education activity, when does the education activity begin? Is it when the learner launches the course? Is it when (s)he first sees the accreditation statement? Is it (s)he they are on the home page of the LMS? We are trying to determine if an ad on the home page is acceptable if the learner doesn't have to click on the ad to get to the educational activity. For print materials, is an advertisement on the back cover okay if it's not interleafed within the pages of the CME content?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	5.2.a is too vague and in some regards unachievable. When hosting our Annual Assembly, we often must repurpose our rooms to accommodate many of the activities we offer, both accredited and non-accredited. There is a significant financial impact with this standard, which requires eligible entities to spend more money or limit their access to certain venues because of space restrictions. Historically, the ACCME has not been so prescriptive in how accredited providers should meet an expectation. The ACCME should take a similar approach in this case, setting an expectation of clearly distinguishing between accredited and nonaccredited activities, but not micromanage how accredited providers meet that expectation. This standard also does not distinguish between "promotional" activities and "nonaccredited education." Many non-accredited activities are not promotional (for example, poster presentations) and should not be restricted in the same way as promotional activities.

Do you foresee challenges or unintended consequences implementing Standard 5? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	5.2a Currently providers can exclude presentations from the accredited CME program to permit the free flow of information. However, with the proposed changes this is not permitted. For the AACR, some speakers request that their talks not be accredited, for example commercial interest employees. The content is teaching about the scientific or discovery process, never promotional. The content covers research discovery process and not about treatment or diagnostics. Target learners are scientists who are participating in the discovery process. Further, we have sessions such as poster highlights, that are not CME, that are done right after an education session. Not promotional, but it is not worth the effort to accredit.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	5.2a- The challenge for providers is: what determines the amount of separation needed- or is all such promotional content off limits in the educational space 24/7 during the duration of the activity/conference? This is an issue for all conferences but is especially significant for local or regional meetings with limited choices of affordable meeting space and the need for exhibit/promotional revenue to offset indirect costs for the organizations providing the activity.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	5.2d: We question whether it is prudent to have marketing with a schedule of the CME activity or even logistical information. We see that as part of the whole CME activity, in particular the schedule. It seems like a slippery slope to allow marketing with the announcement of CME. In addition, the challenge is: what determines the amount of separation needed or is all such promotional content off limits in the educational space 24/7 during the run of the activity/conference? This is an issue for all conferences but is especially significant for smaller meetings with limited choices of affordable meeting space and the need for exhibit/promotional revenue to offset indirect costs for the activity.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	As currently written, I can see issues upholding this when trying to effectively use meeting space at larger meetings or when trying to use limited space.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Challenges = space constraints and resources to accommodate new requirements.

Do you foresee challenges or unintended consequences implementing Standard 5? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Currently, while we have all educational sessions separate from exhibits during our Annual Meeting, our smaller workshops do not have the means to rent out two conference rooms for, at times, 40 people, at a hotel. Additionally, we often have events at institutes with limited space availability. Our current practice when we have nonaccredited education at our workshops is to push all nonaccredited sessions to the end of the day, on the last day (when applicable), after a 20-30-minute break. We mark the session as optional and make it very obvious there is nothing keeping the attendee in the room unless they wish.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Depending on the interpretations of "interleafed" and "immediately before or after" this could have further impact on the ability of non-profit associations to continue to provide quality medical education, given the increasing costs and decreasing budgets of many institutions. We make sure to include signs and descriptions that make it very clear which sessions/activities are accredited and which are not. We also find that most of the companies that pay for and offer workshops at our meetings are actually providing education that the attendees find valuable as it is rarely focused just on their products. Those who do that don't get many attendees.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	For this proposed standard we note that accredited CE providers have experience with separating certified education from non-accredited education. If a non-certified session, e.g. “State of the Association” or Keynote Speaker, is taking place immediately before or after the live certified activity, it is enough to tell participants via an announcement or notation in the schedule handout that the session does not offer credit. Also, “non-accredited” does not always mean that the session is commercially supported or biased. e.g. CE providers generally plan webinars and poster halls using the same processes as planning a certified activity, while not offering learners credit for these offerings. The ACCME’s proposed changes do not take these processes or circumstances into account. By requiring that non-certified education not occur in the same “physical space immediately before or after an accredited education activity,” another question comes to mind. Does this mean that “physical space” is the entire conference center, or just a particular room? Would, say, an exhibit hall or non-certified session have to take place in a completely different center/hotel? Also, “interleaf” is a better descriptor for an enduring material but is less clear when describing an annual meeting which has several concurrent sessions.

Do you foresee challenges or unintended consequences implementing Standard 5? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	In Standard 5.2b, reference to “click through” could pose a problem when CME content is posted on a site like YouTube which may contain promotion and clicking through such promotion to get to the content is out of the control of the accredited provider.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	It’s challenging for providers to determine the proper amount of separation that is needed for a live activity to take place in the same “space” after marketing, exhibits, and nonaccredited education has occurred and vice versa. This is an issue for all conferences but is especially significant for the local or regional meetings with limited choices of affordable meeting space and the need for exhibit/promotional revenue to offset indirect costs for the organizations providing the activity that are planned by our joint providers.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Need specifics on 'physical space.'
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Per the above comments, addressing these will provide further clarification and alleviate concerns regarding "immediately" and "interleafed."
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Term “immediately” needs clarification. What is an ample break time between sessions if the venue space does not allow for a different room to be used? Term “interleafed” needs clarification. Can the meeting have both CME and non-CME sessions?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The ACMG agrees learners should be able to easily distinguish between accredited education and all other activities, both educational and promotional. The ACMG also agrees that marketing, sales or other promotion should not occur in the physical space immediately before or after accredited education in order to further emphasize this distinction. The ACMG does not agree that independent, non-promotional, yet non-accredited education must be separate from accredited education. Education that is not accredited cannot be assumed to be inherently bad, just because it was not explicitly designed to meet the accreditors requirements. An example of this would be committee meetings, legislative updates, membership updates.

Do you foresee challenges or unintended consequences implementing Standard 5? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The challenge for providers is: what determines the amount of separation needed- or is all such promotional content off limits in the educational space 24/7 during the run of the activity/conference? This is an issue for all conferences but is especially significant for local or regional meetings with limited choices of affordable meeting space and the need for exhibit/promotional revenue to offset indirect costs for the organizations providing the activity. Further clarification is needed with some terms used in this Standard related to live activities: • Physical space: would this encompass a specific meeting room, a hall, and/or convention center? • Immediately: how much time would need to lapse between sessions? • Interleafed: This term is more synonymous with journals; preferred terms for live activities would include sequential or concurrent. As referenced in Standard 5, “nonaccredited education” does not necessarily mean that the content is promotional or that it is being delivered by an ineligible entity. Rather, there are times when accredited providers choose to develop and deliver clearly identified quality, independent nonaccredited education, such as posters or town halls, in conjunction with accredited content. These nonaccredited activities should not have to be separated. If ACCME’s intent is to better distinguish accredited education from promotional content developed and delivered by ineligible entities, that should be clearly specified.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The phrase “nonaccredited education” encompasses more than promotional content and will cause logistical issues with non-promotional live activities. For example, while live events are generally composed of CME sessions, many events have the occasional poster session, town hall, or other independent but important sessions that are not designated for CME credit for administrative reasons.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The unclear language of item 2a described above makes the planning of large live activities, such as a multi-day conference, extremely challenging. A more clearly stated description of what is and is not compliant in this context is needed.

Do you foresee challenges or unintended consequences implementing Standard 5? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The unclear language of item 5.2.a described above makes the planning of large live activities, such as a multi-day conference, extremely challenging. A more clearly stated description of what is and is not compliant in this context is needed.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	This standard makes an assumption that any sessions that are not CME accredited are promotional and this is not accurate. For example, at large meetings we have sessions that are for patient advocates and "Highlights of the Day" sessions (which are very popular) and we do not provide credit for various reasons (target audience not physicians, avoiding "double dipping"). In both cases, the reasons for not giving credit have nothing to do with the sessions being "promotional". All CME sessions are clearly labelled, and I do not think physicians who attend these non-accredited sessions would expect them to be for CME. Since they are not promotional there is no need to have a break between sessions. The unintended consequence of this standard is that it would make it more difficult to schedule our sessions because it would impose a requirement to have a break between CME and non-CME sessions. It also reduces flexibility for scheduling –which is a big issue with large meetings where you often have limited rooms. Suggest rewording the standard so it applies to promotional sessions (or so that non-promotional sessions are excluded).
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	To meet ACCME requirements (especially with regard to use of employees and owners of commercial interests), it is sometimes necessary to remove credit from specific presentations. Now that ACCME intends to include startups that are not yet providing products or services used on or by patients in the definition of "ineligible entities," even more faculty will be excluded from participation in accredited education. We clearly communicate using many methods when credit is not available for a presentation or session. With this proposed revision, we would need to completely remove important content from our meeting or move it to the exhibit hall. That change would be inconvenient for learners and removes their ability to determine for themselves whether they wish to participate in nonaccredited education.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We have industry sponsored workshops during the lunch hour. A strict interpretation of "interleafed" would not allow this and we would lose a great amount of monetary support.

Do you foresee challenges or unintended consequences implementing Standard 5? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We will need a clearer distinction/separation between accredited and non-accredited sessions. For instance, we've started using "tracks" in our programming, each "track" runs 90 mins and consists of 3-30 minute shorter and more concise related topics within in each, no break in-between. One or two of the topics may be CME related while the other is not.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	When given appropriate information, learners can easily discern between promotional and non-promotional content. In blended learning, it may be completely appropriate to intersperse accredited and non-accredited content (e.g. provide research and recommendations (accredited) followed by presentations on drugs/devices available or in development for use presented by “ineligible entities” (not accredited) Further, 5.2.a presumes that accredited providers have unlimited access to as much space as they want – which simply is not accurate – especially for smaller live activities. As written, this standard could cost accredited providers more money or, keep them from contracting with some locations based on lack of available space.
Accredited CE provider	ACCME	Other: Accreditation Management, CME Consulting, and Joint Providing Company	If a 6-hour activity has 5 hours/credits and 1 hour/non-credit, how long does the accredited provider have to wait between credit sessions to have non-credit session in the same conference room? If lunch is held in the same room where accredited education is held, can there be a non-credit lunch activity in the same room?
Accredited CE provider	ACCME	Other: Nonprofit, scientific research association	Is the intent of this standard to prevent attendees from encountering advertisements and vendors as they enter and immediately after they exit the learning space or does this mean that a large meeting/conference with multiple sessions cannot use a specific room for an accredited session than schedule a nonaccredited (i.e. non-promotional) session in the same room but in the next session time slot? If the intent is to prevent a single session room from offering accredited and nonaccredited activities within the same day or meeting, the impact would greatly increase costs and the workload of our volunteer program committee members. It may also prevent accredited providers from offering valuable but nonaccredited (non-promotional) education at their meetings. I’m referring to education that is not accredited because the content does not fit the definition of CME. For example, we may use the same session room to have a scientific session in the morning time slot than in the mid-day timeslot we offer a workshop for students to learn more about career paths for clinician-scientists.

Do you foresee challenges or unintended consequences implementing Standard 5? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Other: not-for-profit CME provider	Again, my experience is limited.
Accredited CE provider	ACCME	Other: Teleconferencing Medical Education Company	Education event attendance will decrease, and a financial burden will be put on the education providers. One simple example would be if a sponsored lunch is considered "immediately before or after an accredited education activity". If so, then it's no longer allowed, and those lunches are no longer paid for. This means more money will be required of the provider who may decide to remove the paid-for lunch completely. All day/multiple day events where no lunch/dinner is provided means the learner has to leave the venue, buy their own meal and then come back. This increases safety concerns, especially if it's a large event, and could be enough reason for learners to decide to not attend at all.
Accredited CE provider	ACCME	Other: university	Standard 5.2a. clarifies that learners must be able to easily distinguish between accredited education and other activities, such as nonaccredited continuing education and marketing. These other activities must not be interleaved within the accredited education. This means non-accredited education must not occur in the physical space immediately before or after an accredited education activity and must not be interleafed within the accredited education. This would disallow an AP from having a non-accredited session during the accredited day of education without having the non-accredited session in a separate room. In our case for example we do a 2-day conference with one plenary each day offering credits. These sessions would have to be separated causing addition cost, planning, staffing etc. You would no longer be allowed to make an announcement saying 'the next session will (or will not) be offering CE credits.

Do you foresee challenges or unintended consequences implementing Standard 5? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	3. Ineligible entities may not provide preferential access to or distribute accredited education to learners. While I agree 100% with not providing preferential access to ineligible entities. I do see the potential downside to not allowing ineligible entities to distributed accredited education. I think not allowing ineligible entities to distributed accredited education that is support with commercial support from that specific ineligible entity make sense. However, I don't think it makes sense for ineligible entities help increase awareness of educational conferences. Clinicians are increasing busy in their practices and may not aware of valuable medical conferences in their community that may be beneficial to them and to the care of their patients. With the marketing and promotion of CME activities increasingly more expensive on providers, I believe that increasing awareness of medical conferences by ineligible entities excluding entities that may have provided commercial support for the educational conference (i.e., sales professionals) can be a benefit to clinicians and to accredited providers. It would be a disservice to clinicians and their patients for them to not know about a conference that can be a benefit to them and their patients. Also, it would be a disservice to accredited providers if there is a lack of attendance at a medical conference and increased promotion costs.
Accredited CE provider	ACCME	Publishing/education company	5.2a The challenge for providers is: what determines the amount of separation needed - or is all such promotional content off limits in the educational space 24/7 during the run of the activity/conference? This is an issue for all conferences but is especially significant for local or regional meetings with limited choices of affordable meeting space and the need for exhibit/promotional revenue to offset indirect costs for the organizations providing the activity.
Accredited CE provider	ACCME	Publishing/education company	5.2a- The challenge for providers is: what determines the amount of separation needed- or is all such promotional content off limits in the educational space 24/7 during the run of the activity/conference? This is an issue for all conferences but is especially significant for local or regional meetings with limited choices of affordable meeting space and the need for exhibit/promotional revenue to offset indirect costs for the organizations providing the activity.

Do you foresee challenges or unintended consequences implementing Standard 5? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	5.2a- The challenge for providers is: what determines the amount of separation needed- or is all such promotional content off limits in the educational space 24/7 during the run of the activity/conference? This is an issue for all conferences but is especially significant for local or regional meetings with limited choices of affordable meeting space and the need for exhibit/promotional revenue to offset indirect costs for the organizations providing the activity.
Accredited CE provider	ACCME	Publishing/education company	5.2 a- The term "immediately" requires some further definition or explanation. Is the intent to make sure that learners clearly know of that the nature of the presentation is changing between accredited and non-accredited and that the learner have time to leave if desired? If so then using words to that effect would be better than "immediately". "Interleafed" is not a familiar term in healthcare CE. Please use other wording (perhaps "interspersed") to explain what you mean here. 5.3 – Suggest replacing "preferential access" with "selectively allow/provide direct access to…."
Accredited CE provider	ACCME	Publishing/education company	5.2a. The challenge for providers is: what determines the amount of separation needed- or is all such promotional content off limits in the educational space 24/7 during the run of the activity/conference? This is an issue for all conferences but is especially significant for local or regional meetings with limited choices of affordable meeting space and the need for exhibit/promotional revenue to offset indirect costs for the organizations providing the activity.
Accredited CE provider	ACCME	Publishing/education company	Most university, conference center and hotel venues for educational spaces represent millions, if not billions, of hard infrastructure investments that cannot be altered as far as the physical configuration as to where the classroom is located relative to the exhibit space. In most cases, the exhibit space is located right near or next to the classroom with no other options for relocation. Also, many universities, associations and other CME providers have signed contracts for many future years for event space. These typically come with severe cancellation penalties. There may simply not be adequate supply of suitable venues even if the existing contracts where grandfathered.
Accredited CE provider	ACCME	Publishing/education company	Potentially if methods to be compliant are not clear as often times physical space is limited as well as time and use of available space while mandating compliance may be challenging.

Do you foresee challenges or unintended consequences implementing Standard 5? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	Requiring accredited providers to police whatever may be done with the CME materials that they create (proposed 5.3) is an impossible standard. 5.2.a - please clarify "must not be required to interact with representatives of ineligible entities." to specify that this does not mean *in a standard educational capacity*. Meaning, if a representative of an ineligible entities is themselves a learner in a CME activity, and not operating or engaging in any promotional or marketing behavior, would they have to be sequestered in a special part of the room where no other learners will potentially ask them to move their chair so that they can get past? If it is a group activity, would these other learners be prohibited from speaking with or engaging in the activity with non-industry learners, even as both groups operate as simple learners of the course?
Accredited CE provider	ACCME	Publishing/education company	Since the meanings aren't clear, I can see many, many potential problems.
Accredited CE provider	ACCME	Publishing/education company	While we understand the sentiment of the new proposed rule that non-accredited education cannot be interwoven with/held in the same room immediately before or after accredited education, we feel it will pose a challenge for providers and their target audiences. Non-accredited education is not always promotional education, and explicitly prohibiting non-accredited education from occurring in the same physical space immediately before or after an accredited activity will devalue non-accredited education and could ultimately hurt learners' ability to participate in important educational programs. (For example, when unaccredited hospital systems organize one-day conference where none of the sessions are promotional, but some sessions are not accredited.) Furthermore, the accredited provider often is not the conference organizer and does not have control over the entire agenda. (For example, when an education provider is providing one of many sessions at a full day conference organized by an advocacy group.) Smaller conferences, while they still provide much value to learners, may not have a robust enough agenda or the financial support to completely separate non-accredited, non-promotional education from accredited education. It may be advantageous to exclude non-accredited, non-promotional education from this rule.

Do you foresee challenges or unintended consequences implementing Standard 5? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	5.2a- The challenge for providers is: what determines the amount of separation needed- or is all such promotional content off limits in the educational space 24/7 during the run of the activity/conference? This is an issue for all conferences but is especially significant for local or regional meetings with limited choices of affordable meeting space and the need for exhibit/promotional revenue to offset indirect costs for the organizations providing the activity. If we use a meeting room with only a lobby or hallway outside the door that's available for exhibits, must there be a side door or back door to enter to avoid exhibits? This isn't always feasible. Do we need to allow a 5 or a 15-minute break to switch gears from a CME session to a clearly identified non-CME session? These are the types of specific questions I hear often.
Accredited CE provider	ACCME	School of medicine	5.2a- The challenge for providers is: what determines the amount of separation needed- or is all such promotional content off limits in the educational space 24/7 during the run of the activity/conference? This is an issue for all conferences but is especially significant for local or regional meetings with limited choices of affordable meeting space and the need for exhibit/promotional revenue to offset indirect costs for the organizations providing the activity.
Accredited CE provider	ACCME	School of medicine	5.2a. This could be prohibitive for organizations or venues that have a limited amount adequate meeting space. Examples: 1. Meeting venue with only one large conference space (e.g., classroom style for 100). Breakfast and lunch are eaten at one's seat. There are times that there is a non-accredited talk during lunch. 2. If a venue has sufficient meeting space (e.g., hotel or conference center), additional meeting space adds to the cost of the event.
Accredited CE provider	ACCME	School of medicine	A separate space needed for non-accredited education may not be feasible for some locations or providers. In these instances, adequate break would be necessary and providing clear information to learners through brochure, on-site materials, verbal information, loop slides, etc.
Accredited CE provider	ACCME	School of medicine	Consider allowing non accredited portions of education to take place in same room as accredited education however still keeping promotional/marketing portions distinctly separated. For live meetings this could potentially cause the activity to incur additional costs for space when budgets are limited.

Do you foresee challenges or unintended consequences implementing Standard 5? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	For nonaccredited education, what is the definition of immediately before or after accredited education in the physical space? What is a reasonable amount of time? In order to be evaluated on compliance for this, we need clarity of this kind of detail, even though it sounds like it may be perceived as overly dictating, if we are at the mercy of a committee looking at this and making a judgement, we should know the guidelines they will determine are adequate for compliance or a best practice. For example, faculty who have unresolvable conflicts of interest might still give an educational talk that is not accredited at the end of the day and there is not enough space for the talk to be in a different room. What do you suggest for those of us with space constraints? Attendees may not want to stick around for a 20-minute break at the end of the day for a nonaccredited break, followed by the presentation.
Accredited CE provider	ACCME	School of medicine	Problems with terminology.
Accredited CE provider	ACCME	School of medicine	Some worthy things could happen at a CME invent that are not promotional. Make it clear that only the promotion stuff needs to be separate.
Accredited CE provider	ACCME	School of medicine	Without a clear definition this will be very problematic.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Hospital/healthcare delivery system	Not being able to have non-accredited sessions in the same meeting space as accredited sessions will cause logistical challenges with meeting space, which is often limited and expensive.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	As referenced in Standard 5, “nonaccredited education” does not necessarily mean that the content is promotional or that it is being delivered by an ineligible entity. Rather, there are times when accredited providers choose to develop and deliver clearly identified high quality, independent nonaccredited education, such as posters or town halls, in conjunction with accredited content. These nonaccredited activities should not have to be separated. If ACCME’s intent is to better distinguish accredited education from promotional content developed and delivered by ineligible entities, that should be clearly specified.

Do you foresee challenges or unintended consequences implementing Standard 5? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	5.2a- The challenge for providers is: what determines the amount of separation needed- or is all such promotional content off limits in the educational space 24/7 during the run of the activity/conference? This is an issue for all conferences but is especially significant for local or regional meetings with limited choices of affordable meeting space and the need for exhibit/promotional revenue to offset indirect costs for the organizations providing the activity.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	5.2a- The challenge for providers is: what determines the amount of separation needed- or is all such promotional content off limits in the educational space 24/7 during the run of the activity/conference? This is an issue for all conferences but is especially significant for local or regional meetings with limited choices of affordable meeting space and the need for exhibit/promotional revenue to offset indirect costs for the organizations providing the activity.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	Standard 5.2a: As written, a challenge for providers is how to determine the amount of separation needed to comply with the guidelines? Is all nonaccredited content off limits in the accredited educational space 24/7 during the run of the activity/conference? This may not be an issue for all educational activities but is especially significant for local or regional meetings where there are limited choices of affordable meeting space and the need for exhibit/promotional revenue to offset indirect costs for the organizations providing the activity. Therefore, this change could lead to a number of accredited activities no longer being financially viable and thus cancelled.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	Will there be any exceptions to “nonaccredited education”? For example, we run a full day conference with eight speakers. One speaker fails to submit his disclosure form prior to the event, but still shows up to the event prepared to speak. Rather than penalizing the learners who have paid a registration fee and expect to learn about the topic that the speaker will present on, we make it clear to the learners that this one particular talk will not provide CE credit, as the speaker did not submit his disclosure form in a timely manner.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	Would potentially eliminate activities from utilizing their time efficiently if they want to conduct some form of business or discussion that does not meet CME criteria.

Do you foresee challenges or unintended consequences implementing Standard 5? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Other: Academy of General Dentistry	School of medicine	Number 2.a. may cause problems if the provider is restricted to meeting space that has only two areas, one for education and one for exhibits. It may be difficult to keep from using the same educational space for accredited and non-accredited education. Providers would have to have a way to explain their space restrictions.
Accredited CE provider	Other: Accreditation Council for Pharmacy Education	Nonprofit (other)	A final conference/meeting schedule should contain a schedule for all activities, which includes educational activities. Therefore, marketing/promotional content by ineligible entities will always be alongside educational content. By allowing promotional materials on the schedule, it could potential imply bias.
Accredited CE provider	Other: ACPE	Hospital/healthcare delivery system	Many conferences I have attended will have extreme difficulty in clearly segregating accredited from unaccredited activities. If appropriate disclosure is made, I don't think shared space in a matter of consecutive time or on pages of a brochure should limit an accredited provider. This standard may unintentionally limit educational opportunities that are so desperately needed.
Accredited CE provider	Other: ACPE	Publishing/education company	This could be a challenge with smaller programs with limited space.
Accredited CE provider	Other: CMA	Hospital/healthcare delivery system	Can non-CME activity take place during the symposium in a NEW room with a break before and after the session? Is that compliant?
Accredited CE provider	Other: CMA	Hospital/healthcare delivery system	Teach procedures with new technologies.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	2a states: "Marketing, exhibits, and nonaccredited education must not occur in the physical space immediately before or after an accredited education activity, and must not be interleafed within the accredited education." The requirement to separate types of education would present a hardship for those conferences where both accredited and nonaccredited education occurs. In hospitals with limited space, it is simply not possible to provide both in two separate rooms. Also,

Do you foresee challenges or unintended consequences implementing Standard 5? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Advocacy organization			5.2a. This could be prohibitive for organizations or venues that have a limited amount adequate meeting space. Examples: 1. Meeting venue with only one large conference space (e.g., classroom style for 100). Breakfast and lunch are eaten at one's seat. There are times that there is a non-accredited talk during lunch. 2. If a venue has sufficient meeting space (e.g., hotel or conference center), additional meeting space adds to the cost of the event. If the CME Provider is required to have a separate venue/room for the non-CME presentation, it will result in excessive cost additions to the live conference budget. In addition, in many venues and/or on the institution's campus, space for separate presentations is often unavailable.
Advocacy organization			A fair amount of nonaccredited education occurs before or after a meeting in the same physical space. An example from the hospital setting are business meetings before or after case discussion or any other regularly scheduled series. Not allowing nonaccredited education before or after an accredited meeting would disrupt business practices and/or jeopardize a fair amount of accredited activities. There needs to be clarification on what is meant by the term "before or after." A clearer definition would help ameliorate financial ramifications when developing accredited education. This could help save thousands of dollars in expenses when planning a large conference. Clarification of "before and after" would help clarify the term interleaved. There is an unintended consequence is requesting that learners engage with accredited education without having to click through, watch listen to, or be presented with product promotion or product-specific advertisement. Providers would be barred from using platforms like Facebook or YouTube as cost effective options to deliver education. It would require providers to look at alterative options to deliver online content. These options may be cost prohibitive.
Clinician/healthcare professional			(3) prohibits distributing accredited education from being distributed to learners. YES! Does this include at any time, during or after an event?
Clinician/healthcare professional			Ineligible entities at times have medical journals on their table (that include studies supporting their line of work). If the journal includes CME, could that be interpreted or overlooked as a problem with standard 5.3?

Do you foresee challenges or unintended consequences implementing Standard 5? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Clinician/healthcare professional			Mobile apps may be an issue and accredited providers must evaluate those for any marketing materials.
Clinician/healthcare professional			Repression of innovation in medicine
Clinician/healthcare professional			There is a happy medium. The pendulum was too far in support of companies in the past, but now it has swung too far to the other side. Many non-profit CME venues have simply ceased to exist due to the bureaucracy and admin hassle of the new rules. This hurts the public, since small meetings in out of the way locations simply aren't available anymore the way they used to be.
Continuing education accrediting body			As exists with the current Standards for Commercial Support, providers are challenged (and challenge accreditors) to define an appropriate amount of separation (in space and time – e.g., how long is “immediately”?).
Continuing education accrediting body			Many of our smaller constituent organizations hold meetings on a very modest budget and have the resources to rent only a single meeting room. Commercial support, including hosting promotional activities is an important source of revenue for these activities. Without further clarification of “immediate before” and “immediately after” this could negatively affect their ability to present education. At the end of a CME conference if the conference were to formally adjourn, take a 10 minute break, and then invite those who want to stay to return to the same room for a promotional presentation (that is explicitly labeled as promotional and non-CME), would this be in compliance?
Ineligible Entity (commercial interest, such as pharmaceutical, device, life-science company)			An important distinction that should be further reviewed is the difference between promotional education and independent education that is not accredited. Nonaccredited, independent education is developed in alignment with all the same guidance’s set forth by the ACCME for accredited education, with the exception that credit cannot be earned. This is an important category of professional education and should not be lumped together with promotional education by unintended oversimplification of education types. This is increasingly the case when, for example, an association does not allow accredited satellite symposia in conjunction with an annual meeting but will allow nonaccredited live IME adjacent to general sessions, which is then endured by accredited educational material.

Do you foresee challenges or unintended consequences implementing Standard 5? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Medical/healthcare association			5.2a- The challenge for providers is: what determines the amount of separation needed- or is all such non- accredited and promotional content off limits in the educational space 24/7 during the run of the activity/conference? This is an issue for all conferences but is especially significant for local or regional meetings with limited choices of affordable meeting space and the need for exhibit/promotional revenue to offset indirect costs for the organizations providing the activity.
Medical/healthcare association			5.2a- The challenge for providers is: what determines the amount of separation needed- or is all such promotional content off limits in the educational space 24/7 during the run of the activity/conference? This is an issue for all conferences but is especially significant for local or regional meetings with limited choices of affordable meeting space and the need for exhibit/promotional revenue to offset indirect costs for the organizations providing the activity.
Medical/healthcare association			Additionally, the Council also recommends further revision of Standard 5.2.A specifically regarding the stipulation that states, "… must not occur in the physical space immediately before or after an accredited education activity…" This guideline will undoubtedly hamper location availability for many accredited providers and potentially increase the costs for hosting and attending continuing education events. In all practicality, many conferences, especially small to-medium sized conferences, utilize a foyer or anteroom for promotional purposes in lieu of purchasing another separate room which adds to the costs of the conference. Attendees can still clearly determine what is sponsored and what is educational in these arrangements. The Council believes that forcing sponsorships into a separate nearby room would unnecessarily add to the expense of continuing medical education and we recommend elimination of this phrase from the standard.
Medical/healthcare association			Define -- "completely separate from," does this mean not in the same room or during a CME activity. Can the non-accredited education occur during lunch when no other accredited education is occurring?
Medical/healthcare association			Poster sessions at annual meetings continues to be in a state of ambiguity on whether or not to offer as part of the accredited education as they are typically adjacent but with separation from exhibit hall area. Some providers have elected not to offer CME because of the lack of clarity from ACCME. Not sure if the updated language really helps in clarification and still see this as a challenge.

Do you foresee challenges or unintended consequences implementing Standard 5? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Medical/healthcare association			Should the standards be adopted as written, I think many national organizations would not have clear guidance on how to handle their conference content if they provide both accredited and non-accredited activities. Terminology such as “immediately before and after” and “interleafed” are very vague and require further explanation.
Medical/healthcare association			Small conferences with limited space. What determines the amount of separation needed? What can be in conference bag? Can promotional materials with logos and product images be included as long as it is not included in documents transferring educational content or on the exterior of the bag? Lanyards?
Medical/healthcare association			There is a possible significant financial impact with this standard, which will require eligible entities to spend additional funds and/or limit their access to certain venues because of space restrictions.
Medical/healthcare association			We agree that learners must be able to easily distinguish between accredited education and other activities. We believe the intent of this clause is to prevent commercial entities from placing marketing efforts adjacent to CME activities in a way that is difficult to distinguish marketing from CME. However, we are concerned that the new language is non-specific and could make it challenging to program important aspects of live activities that have nothing to do with this aim. Activities such as society member meetings, committee meetings, journal editorial board meetings, and even group exercise programs might now be prohibited if they held are in the same space before or after a CME activity. This is a common practice at conferences sponsored by professional societies, and efforts to avoid such a juxtaposition could create scheduling nightmares or require otherwise unnecessary additional space to segregate rooms by CME or non-CME purposes throughout a meeting We would advocate for a specific and clear statement and written notice through a presentation slide or signage that indicates explicitly the program is a nonaccredited activity

Do you foresee challenges or unintended consequences implementing Standard 5? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: Accredited CE provider, Continuing education accrediting body, and medical/healthcare association			The AOA does not agree that independent, non-promotional, yet non-accredited education must be separate from accredited education. Enactment of this standard will require significant changes to program planning of the AOA's live meetings which have regular non-accredited yet non-promotional sessions on membership updates, legislative updates, etc. that are included within a program that is accredited. Furthermore, for local and regional meetings that have limited choices of affordable and accessible meeting space, this will cause an issue to create such separation of these types of non-accredited, yet non-promotional education.
Other: CME/CE Consulting Services Company			Depending upon the ACCME's intent with 5.2, added expense/work could be involved in preventing an obligate path in and around promotional spaces. While preventing an obligate path has always been deemed a best practice, frequently, many providers conducting a conference with an exhibit hall will hold breaks within this promotional space, and not manage a separate break area external to it.
Other: Consultant			Just a general observation: it will be very difficult for the people who want CME to remain fair, balanced, and unbiased (the men in the white hats) to keep up in the technology race with the people who want CME to drive sales (the men in the black hats). Don't get me wrong: I want the white hats to win. But when it comes to technology, the more money you have, the trickier ways you can come up with to use digital media savvy to get around the latest restrictions meant to level the playing field. And, the more money is at stake, the more money the men in the black hats will be willing to spend to gain access to the people (clinician learners) who can help them achieve their sales targets.
Other: Joint Provider			Sometimes spacing for small events is not conducive to multiple rooms. Instead, timing is used to clearly demarcate CME from non-CME. Example - a CME activity in a 1 room retreat ends at lunch. A non-CME yoga session is offered in the same space during the break. Everyone knows that the activity is Non-CME and learners are able to opt out without any consequence or negative impact to either the learner or the program. This does not in any way diminish the quality of validity of CME, in fact, it elevates and modernizes CME offerings.

Do you foresee challenges or unintended consequences implementing Standard 5? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: MedChi is both an Accredited Provider and a Recognized Accreditor			Regarding 5.2a: This will be problematic and will create un-necessary economic issues requiring having additional rooms, etc., which may be impossible in some smaller venues. Some non-CME sessions may not be so due to promotional issues, but more related to other issues. I would suggest creating a time-based alternative with clear language to be shared with the learner regarding the fact that a session will not be CME.
Other: Publishing/education company			5.2a- The challenge for providers is: what determines the amount of separation needed- or is all such promotional content off limits in the educational space 24/7 during the run of the activity/conference? This is an issue for all conferences but is especially significant for local or regional meetings with limited choices of affordable meeting space and the need for exhibit/promotional revenue to offset indirect costs for the organizations providing the activity.
Other: State Medical Society/Publisher/Accredited Provider/Recognized Accreditor			In the circumstance when a faculty member's presentation is in the middle of an accredited activity, and the faculty member transitions to a new job as an employee of an ineligible entity after their original disclosure was submitted and does not update the accredited provider until it's too late to select another faculty member, how does the ACCME wish for providers to manage this situation?
Patient, caregiver, member of the public			The immediately before and after will create a lot of confusion. I would say that there should be adequate break and clear acknowledgement that the session is non-accredited. An industry symposium can generate revenue for an accredited provider with limited space, and this will reduce that revenue.
Recognized Accreditor (state/territory medical society)			Standard 5.1a. If you use the term non-accredited education then that potentially eliminates CME for Committee Learning, holding a medical staff business meeting that follows with a CME offering, etc. Standard 5.2b. Organizations can't necessarily control ads that pop up on Facebook, YouTube, etc. which are becoming more popular as mediums for education; and we will probably see an increase in innovative, online, general platforms, that are supported by various advertising.
Recognized Accreditor (state/territory medical society)			5.2a. Would make it impossible to have a session of "non-accredited education" scheduled before or after a CME activity. Potential unintended consequence may be if something that is not eligible for CME by a state legislature, but would not be ACCME defined ineligible entity, such as leadership education that may include a portion of hospital business.

Do you foresee challenges or unintended consequences implementing Standard 5? If yes, please explain.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Recognized Accreditor (state/territory medical society)			Agenda items listing a schedule of speakers for the educational event can inadvertently market the ineligible entity. Not clear.
Recognized Accreditor (state/territory medical society)			Providers with limited meeting space may be challenged with this standard without clarification on the specific timing before or after an accredited education activity.
Recognized Accreditor (state/territory medical society)			Seems to actually allow commercial promotion. (5.5.2 D seems contradictory to 5.5.C)

What comments or questions do you have about Standard 5?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider		Nonprofit (other)	There are many types of nonaccredited education do not, and should not, be so strictly separated from accredited education. Chiefly, this creates massive challenges for interdisciplinary events. A live educational interdisciplinary event will often have some sessions that are not ACCME accredited. Under the proposed standard, an event could not have a session accredited only for pharmacists immediately follow a session accredited for pharmacists, physicians and nurses. The scheduling difficulties for this would be immense. Other boards similarly adopting this standard would make interdisciplinary events all but impossible. Furthermore, non-accredited education can also be quite valuable. A session may be devoted to cutting-edge, yet controversial content, that a provider may not wish to accredit, but still wants to have at their meeting. Networking events provide benefits without being accredited. This can be avoided simply by making the standard only the first sentence "The accredited provider must ensure that learners can easily distinguish between accredited education and other activities, such as nonaccredited education and marketing." Which providers can do in ways that don't create scheduling and content nightmares?
Accredited CE provider		Nonprofit (physician membership organization)	It would be helpful to understand was immediately before and after means to ACCME. Sometimes, space is limited in the hotel... if there is 15 minutes between the non-CME and CME activity is that enough distance? What does interleafed mean in ACCME's mind??
Accredited CE provider	ACCME	Hospital/healthcare delivery system	5.2a - I'd like there to be better guidance on what qualifies as a sufficient break in time between accredited and non-accredited education (i.e., is 5 minutes sufficient? 15 minutes?)
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Clarification please.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	For this standard, bold/italicize/otherwise emphasize that this standard only applies when there's advertising/exhibits by ineligible entities associated with the activity. I can see a lot of confusion, especially with 5.2, which appears to lump in all nonaccredited education with marketing/promotion.

What comments or questions do you have about Standard 5?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	If the CME Provider is required to have a separate venue/room for the non-CME presentation, it will result in excessive cost additions to the live conference budget. In addition, in many venues and/or on the institution's campus, space for separate presentations is often unavailable.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	It should be noted, that the only reason we have non-accredited sessions these days is because the ACCME has forced us to do so because of its restrictions on the use of some of our faculty in accredited activities. The ACCME is assuming that because a physician is the owner or paid employee of a commercial interest, that the person is absolutely going to be biased and try to sell his/her product. We have physicians on our staff who are innovators and inventors in their fields and yet the ACCME prohibits them from teaching what they know in accredited activities. This infuriates our senior administration because they consider the rule an impediment to sharing the knowledge these innovators have to impart. So we now have non- accredited sessions to accommodate these faculty but now the ACCME is throwing up more roadblocks for the voices of these innovators to be heard. You are not trusting that our learners have enough maturity and sense to distinguish between promotional and non-promotional education. Furthermore, this over regulation on content is impeding education rather than enhancing it.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Please clarify the standard.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.
Accredited CE provider	ACCME	Nonprofit (other)	Appreciate the clear new title of Standard 5.

What comments or questions do you have about Standard 5?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (other)	Need to clarify that it is sufficient to have breaks between CE and non-CE sessions, and to clearly indicate those sessions which are accredited continuing education through program materials, signage, and verbal announcements. Need to provide guidance regarding inclusion of corporate or product logos, trade names, or product group messages on sponsored materials which may be visible in the physical space of live accredited education but are not part of the education (e.g., can a logo be displayed on the login page for sponsored wireless internet access that is available during the accredited continuing education activity?)
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	• Are there other ways to ensure CME programs are not unduly influenced by commercial interests? • Are there exceptions for smaller events that may not have the capability to have separate rooms for accredited vs. non-accredited?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	"Nonaccredited education must not occur in the physical space IMMEDIATELY before or after an accredited education activity..." What is IMMEDIATELY? If there is a 5-minute break, is that sufficient? 15 minutes? What is "the physical space"? The inside of the same session room? The same building? What is "interleafing" to you? I think it means no break between in a live event. Or does that mean I can't list non-CME education in the same list of conference events as CME sessions (like on the app or website)?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	5.2 Currently providers can exclude presentations from the accredited CME program to permit the free flow of information. With the proposed changes this is not permitted. For the AACR, some speakers request that their talks not be accredited, for example commercial interest employees. The content is teaching about the scientific or discovery process, never promotional. The content covers research discovery process and not about treatment or diagnostics. Target learners are scientists who are participating in the discovery process. Further, we have sessions such as poster highlights, that are not CME, that are done right after an education session. Not promotional, but it is not worth the effort to accredit.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	5.2.D is confusing and may need to be reworded.

What comments or questions do you have about Standard 5?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	5.2a: The challenge for providers is: what determines the amount of separation needed, or is all such promotional content off limits in the educational space 24/7 during the run of the activity/conference? This is an issue for all conferences but is especially significant for local or regional meetings with limited choices of affordable meeting space and the need for exhibit/promotional revenue to offset indirect costs for the organizations providing the activity.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	ACCME should appreciate that blended learning can easily incorporate accredited and non-accredited programming. To preclude the ability to offer this content interchangeably presumes that valid adult learning theory does not support this as an appropriate instructional design – which is simply not true. Further, standard 5.2.a places an undue financial burden on the accredited provider, potentially requiring them to contract for more space than might be needed if the same space can be used for multiple purposes. Indeed, this standard invokes the long eschewed myth of the "obligate pathway" which has haunted CME providers new and old for years and is not supported by any reliable data that would suggest a negative impact on learners. Clarification on how to manage advertising in scientific journals when journal-based CME is provided should be included in these standards.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Agree that marketing, sales, and promotion should not occur in the physical space before, during, or after accredited education. Do not agree that independent, non-promotional, non-accredited education must be separate from accredited education. If quality, non-accredited education is clearly identified as non-accredited to learners, it should not need to be separated.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Comments noted above.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	How will this affect web programs and mobile apps for ACE activities which have both ACE and non-accredited education that are within the same ACE activity. What is expected?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	It is suggested that "nonaccredited education" be rephrased as "promotional education."

What comments or questions do you have about Standard 5?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	It will be helpful to be able to point to 'Ineligible entities may not provide preferential access to or distribute accredited education to learners' when discussing commercial support
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Please clarify if the a) current SCS 3.11 (social events/meals not competing or taking precedence over education) and b) current SCS 5.2 (use of generic names and multiple trade names, where available) would remain requirements. 5.2 .b. – Clarification is needed as to how this Standard is different from the current SCS 4.2 and whether ads and promotional materials would now be able to face the first or last pages of print materials. 5.3 – To ensure greater clarity, “preferential access” should be defined.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Re live activities: If we are to make it very clear that it is not accredited CE, is it ok to have one room be for CE and another for non-CE on the same day/ in the same building?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Section 2, Part A states that Marketing, exhibits, and non-accredited education must not occur in the physical space immediately before or after an accredited event. What would the appropriate time period be for a space break so that it is not counted as “immediately”? 10 minutes, 1 hour, 1 day? Section 2, Part A states that Marketing, exhibits, and non-accredited education must not occur in the physical space immediately before or after an accredited event. What would the appropriate time period be for a space break so that it is not counted as “immediately”? 10 minutes, 1 hour, 1 day? This section also states that Marketing, Exhibits, and non-accredited education …must not be interleafed within the accredited education. The term “interleafed” makes no sense in a live activity context. Does that mean that we can’t have company sponsored workshops at lunch? Is a non-accredited session between two accredited sessions no longer allowed, or would it be allowed with a break between the sessions? Or is this more specific to non-accredited and accredited talks taking place in one session?

What comments or questions do you have about Standard 5?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Standard 5.2.A assumes participants of an accredited educational activity cannot differentiate between promotional and non-promotional content, even when eligible entities have clear processes in place to distinguish these activities. Overall, this standard will prohibit eligible entities from pursuing innovative and forward-thinking education, limit valuable content for learners, as well as unnecessarily add to the financial and planning burden for accredited providers.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Standard 5.2a states "…nonaccredited education must not occur in the physical space immediately before or after an accredited education activity…". If a physician group conducts a business meeting (nonaccredited ed) which is "immediately" followed by a CME session, would that be non-compliant?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Term "immediately" needs clarification. What is an ample break time between sessions if the venue space does not allow for a different room to be used? Term "interleafed" needs clarification. Can the meeting have both CME and non-CME sessions?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The accredited provider must ensure that learners can easily distinguish between accredited education and other activities, such as nonaccredited education and marketing. a. Live continuing education activities: Marketing, exhibits, and nonaccredited education developed by or with influence from an ineligible entity must not occur in the physical space immediately before or after an accredited education activity. Learners must not be presented with product promotion or product-specific advertisement while engaged in accredited education and must not be required to interact with representatives of ineligible entities.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The physical segregation of accredited and nonaccredited content may leave learners with the perception that nonaccredited education is inherently bad and that adult learners cannot distinguish between educational value and marketing/sales. This is a particularly paternalistic viewpoint given the target audiences of ACCME accredited providers.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The remaining elements of Standard 5 are clearly stated and in line with the current Standards. These parts of the Standard do not raise any questions or concerns.

What comments or questions do you have about Standard 5?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The remaining elements of Standard 5 are clearly stated and in line with the current Standards. These parts of the Standard do not raise any questions or concerns.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	What is the definition of “immediately before and after?” If there is a solid break between the sessions, does that meet the requirements of this standard? We also are concerned with the definition of “nonaccredited education.” Sometimes we are required to remove credit from sessions that do not meet other standards (i.e. did not receive a disclosure from a speaker). Would we not meet the requirements of this standard because a single talk is not accredited due to a lack of disclosure? Would this therefore become a nonaccredited education interleafed in accredited education?
Accredited CE provider	ACCME	Other: university	in this case we have 2 full day seminars with one session offering CME. Everyone stays in 1 room for the entire day Would we then have to book an additional room, move everyone into that room for 1 hour and then move everyone back to the original room? Regardless of the notice that that one session offers CME, even if it was scheduled first or last? We already have to book additional space for vendors, now this? the financial impact would be a tremendous burden. This would definitely result in us losing this activity (and the revenue) if we could not offer CME. Without knowing why this proposal was important, it seems to make offering CME much harder than it has to be.
Accredited CE provider	ACCME	Publishing/education company	• Again, can the RFP from an ineligible entity identify a disease state on the RFP or is this considered influence? • If an ineligible entity is commercially supporting an educational activity such as a conference, can they be given exhibit space as a “perk”, or must they enter into a financial agreement for the exhibit space as well as an LOA for Commercial Support? • If a break is provided before and after the nonaccredited education, can accredited education be given in the same room? Or does all nonaccredited education take place before or after all accredited education?

What comments or questions do you have about Standard 5?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	Between sessions, i.e. at the start of a break or lunch or at the end of the day (but not the end of the conference), is it ok to announce a non-accredited product theater that is going to happen in another room, or is that considered advertising in the educational space? Or does it depend on what is announced? just the topic? the actual title? the speaker?
Accredited CE provider	ACCME	Publishing/education company	Revise title to include: "…for the Health Professions"
Accredited CE provider	ACCME	Publishing/education company	Will ACCME be responsible for the financial damage to its members for the economic losses caused by its new standards?
Accredited CE provider	ACCME	School of medicine	I appreciate the clarification that corporate logos are not permitted in any educational materials that are part of the activity, the current wording is a bit vague as to when it applies.
Accredited CE provider	ACCME	School of medicine	Interleafed could use greater definition and clarity with examples.
Accredited CE provider	ACCME	School of medicine	It is not clear from this if you are also removing the silly rules, including AMA, about what language to use on save the date vs more extensive materials. Please remove. Simply require entities to disclose who they are and that they are accrediting. Extra verbiage does not add value and again simply waste resources.
Accredited CE provider	ACCME	School of medicine	Looks fine.
Accredited CE provider	ACCME	School of medicine	Sometimes the space in educational venues is very limited and we must make some space do "double duty." We have occasionally had to use the same space for education and then a later promotional activity. We clearly delineate on the agenda what is education, what is not certified, and use signage, announcements, and slides as reminders. Will there be clearer guidance provided about this kind of situation?
Accredited CE provider	ACCME	School of medicine	The one comment I have is the fact that non-accredited education can occur surrounding (if in a different room and not marketed in any relation or time of the CME content) an accredited activity seems confusing.
Accredited CE provider	ACCME	School of medicine	There could still be questions about what is/is not acceptable. Are postcards advertisements included in handouts but not interleafed with educational materials, acceptable?
Accredited CE provider	ACCME	School of medicine	Whatever way this goes, specific examples in a toolkit or FAQs is sorely needed.

What comments or questions do you have about Standard 5?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	While this doesn't seem to cause significant changes, it seems like a missed opportunity to provide more clarity than is currently offered. Will PARS still ask us for exhibitor revenue? If so, should something here alert to the fact that providers need to collect financial information about that revenue?
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (other)	with regard to 2a, thank you for providing guidance on live activities, but leaving it to providers to interpret "immediately before or after an accredited education activity" as this allows for the provider some flexibility in cases where, for ex, a small venue is used and it's not possible to use only room only for accredited education, and another for non-accredited. The spirit of what providers are being asked -- to keep accredited education and marketing separate -- comes through. Some examples in FAQ of various acceptable strategies that providers have used to keep the two separate would be helpful.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Other: Electronic health record company	We have no additional comments for this standard.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	Ineligible entities may not provide preferential access to or distribute accredited education to learners. I also think this standard needs an expansion. Currently reps from ineligible entities are permitted to distribute a pos card or flyer as long as the postcard/flyer is "creating awareness," and not offering direct access with a key or code. I think this is inappropriate. A rep from an eligible entity should not be distributing anything related to accredited education - not even an awareness postcard.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	Question for clarification on 5.3: Some pharma companies have developed "educational websites" or public pages where they feature or list enduring activities they have supported. How do we respond if they request a thumbnail graphic and link to our activities (which are housed on other sites or servers)? Is this considered "preferential access" or "distribution of accredited education"?

What comments or questions do you have about Standard 5?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	Standard 5.2a: It is not clear if this guideline only relates to supported non-accredited activities or does the same apply, even if the non-accredited activity is not commercially supported? In addition, there is no guidance given as to a permissible amount of separation between and accredited and non-accredited activity at a live event, would 5-minute separation suffice? This wording makes sense for print materials but needs to be better articulated in the live meeting setting.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	Can 'sponsorship opportunities' be defined. We occasionally get requests from groups (such as medical societies) about offering sponsorship opportunities because they have done so elsewhere. It would be good to have guidance as to what is allowable and what is not. They generally ask about things such as a company 'sponsoring' internet usage, a certain meal function, etc.
Accredited CE provider	Other: Accreditation Council for Pharmacy Education	Nonprofit (other)	Should Standard 5.2.d. be more specific to ensure logos and other promotional content is not shown on, for example, schedule pages that list the times/locations of educational content?
Accredited CE provider	Other: ACPE	Publishing/education company	Are there additional descriptors that could be added to accommodate limited space availability? Perhaps that there must be a certain amount of time in between these types of programs?
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Kudos on replacing "continuing medical education" with "accredited continuing education". This change is VERY supportive of our interprofessional team and reflects how the majority of our education is provided.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Please correct the diction for 2a: you mean "interspersed" rather than "interleafed."
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Standard 5 spells out limitations to marketing restrictions for programs that are accredited. I agree with what is stated.

What comments or questions do you have about Standard 5?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	This has been needed for a long time.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	We do not use ancillary marketing. In my opinion, we should do something much more innovative and beneficial, such as working with and educating our State Government Leaders and Health Departments to increase immunizations and decrease infant mortality and support eating right and exercising.
Advocacy organization			1. Provide clarification on how long of a break needs to occur in the same space between exhibit/marketing and the educational activity (i.e. Would it be acceptable for exhibits/marketing to occur in a space, followed by a 15 minute break where the room is reorganized and all marketing removed, and then followed by an educational activity in the same space?). 2. Can events that are not accredited be included in the same promotional material (i.e. brochure) as accredited activities? 3. I would also appreciate clarification on what is considered the educational space (i.e. is a curtain or makeshift wall considered enough separation between marketing/exhibits and educational activity)? 4. Is coffee provided outside of the educational space in the exhibit area, allowed to be brought into the educational space by the learners? 5. If one presentation in the middle of a day-long CME event is not certified for credit (because of reasons of non-compliance), and this omission of credit is indicated in the final program agenda provided to the learner, but that presentation is held in the same meeting space as the CME activity, does this comply with the new Standards? Or must we have a separate space for the non-CME portion of the activity? 6. Is it acceptable to hold a promotional satellite program during lunch, clearly indicated as such to the learner, in a separate meeting space from the day-long CME activity?
Advocacy organization			A bit more clarity of this standard would be appreciated

What comments or questions do you have about Standard 5?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Advocacy organization			In addition to the question asked above, for printed CME activities, can an advertisement occur immediately prior to or immediately following an activity so that it is visible when the learner first encounters or completes the activity? If so, what restrictions exist? For example, is it permitted as long as the advertisement is not connected to the activity content? What if the supporter is the advertiser, but it is for a product or service not related to the content?
Clinician/healthcare professional			Allow for teaching of innovative medical concepts.
Clinician/healthcare professional			I would love if you added "product placement" to the list in (2.c)
Continuing education accrediting body			While establishing the means by which accredited CE is to be separate from promotional/marketing opportunities, consideration should be given to guiding providers to take steps to avoid perceptions of bias.
Medical/healthcare association			Exhibits and promotional materials help provider offset indirect costs. Need clarification on whether a separation is "time," and/or "space," or "time and space."
Medical/healthcare association			Standard 5.2.A assumes participants of an accredited educational activity cannot differentiate between promotional and non-promotional content, especially given the amount of information eligible entities provide to them. Additionally, this standard also assumes that participants do not like having these types of activities at their meeting. As busy medical professionals, many appreciate the opportunity to view new and innovative product presentations conducted during the time away from their practice that they have devoted to enhancing their medical education.

What comments or questions do you have about Standard 5?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Medical/healthcare association			The lumping of independent non-accredited education with promotional/marketing education, under the single term of “non-accredited’ education casts aspersions on the former that that are not correct. There are many reasons why an educational activity or effort is not accredited including lack of easy access to an accredited provider, financial cost of credit issuing, time and resources of staff to complete required processes/paperwork, and lack of credit claim by past attendees, or topics that do not appear to fit within the AMA PRA definition of CME (such as a legislative update, membership update, or wellbeing exercise presented in between accredited presentations) none of which devalue the legitimacy of the content. The entire Alliance Annual Meeting is non-accredited because the number of credit claims was not worth the financial cost to the organization. While we recognize that the ACCME is concerned and responsible for maintaining the integrity of accredited CE, we would urge insertion of wording in the introduction to the Standards to describe two types of education that fit into the non-accredited bucket: “independent non-accredited education and marketing/promotional presentations.” We do agree that there needs to be a clear indication to the learner of which type of education is being presented and that separation of these from accredited education is prudent.

What comments or questions do you have about Standard 5?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: Accredited CE provider, Continuing education accrediting body, and medical/healthcare association			The AOA understands that the ACCME intends to define non-accredited education as all education that is not accredited. This could include marketing, sales, or other promotional activities developed by or with influence from ineligible entities as well as non-accredited educational information and resources developed independently by an accredited provider or eligible entity. The AOA agrees learners should be able to easily distinguish between accredited education and all other activities, both educational and promotional. The AOA also agrees that marketing, sales, or other promotion should not occur in the physical space immediately before or after accredited education in order to further emphasize this distinction. The AOA does not agree that independent, non-promotional, yet non-accredited education must be separated from accredited education. Education that is not accredited cannot be assumed to be inherently bad; it simply means it was not explicitly designed to meet the accreditor's requirements. An example of this would be a legislative update, membership update, or wellbeing exercise presented in between accredited presentations. This type of important non-accredited education should not have to be artificially segregated from accredited CME. Learners benefit from all types of accredited and non-accredited activities at live events and as long as the learner can clearly distinguish between these types of activities, it should be left to the learner to make these in
Other: Answering both as accreditor and accredited provider.			WSMA supports Standard 5. Will the updated standards change an accredited provider's ability to give an ineligible entity an exhibit space at no cost, as long as it is not a "condition of the provision of commercial support?"

What comments or questions do you have about Standard 5?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: CME/CE Consulting Services Company			5.2 – Several related questions: 1. Can the ACCME clarify what is meant by no exhibits (and other promotional activity) immediately before/after a CME activity? As an example, if exhibits are set up in a foyer outside the doors of a meeting space, is this permissible? 2. Also related to this standard, when the ACCME states learners, "must not be required to interact with representatives of ineligible entities," does this now mean the ACCME would hold providers responsible for ensuring an obligate path is not created between learners and ineligible entities (e.g. breaks/meals in the exhibit hall only)? 3. If the accredited provider ensures that learners can easily distinguish between accredited education and nonaccredited education, is independence compromised if a provider has a non-accredited and non-promotional education that follows an accredited education session, if this were clearly marked in the agenda and there was a break separating the two sessions? 4. Can the ACCME provide clarification on the sponsorship of meeting apps and whether or not this is permissible, so long as no logos appear on pages containing CME content and information?
Other: Consultant - own my own company			This standard has always needed some more clarity, and now is time to get it in there. "What does 'interleafed' in alive activity actual describe?
Other: I am a faculty member/CME content provider/CME course director and my views do not necessary represent the views of my institution, the Medical College of Wisconsin			5.2.c. Clarification: does this mean that educational materials such as slides CAN be produced by an ineligible entity provided that it is NOT branded?

What comments or questions do you have about Standard 5?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: Joint Provider			Again, why the change? What specific issues have you found that is keeping adults from understanding what offerings CME vs Non-CME are. Making learners walk down a hall to a non-CME event or wait for an evening session is not necessary. Clearly defining CME and NON-CME spaces would better allow mixed learning.
Other: MedChi is both an Accredited Provider and a Recognized Accreditor			• 5.2a: Essentially would make it impossible to have a session of non-accredited education scheduled before or after a CME activity. Effectively making rooms during a conference CME only unless broken up by a meal or other activity. This will create additional, and perhaps unnecessary, expenses for conferences.
Other: State Medical Society/Publisher/Accredited Provider/Recognized Accreditor			Please provide the definition of "click through". Please specify the intent/definition of "while engaged in the accredited education activity." If an online journal has a range of ads on its webpages, and a learner clicks on the landing page for an educational activity and sees no advertising once they are in the education space, is this acceptable to the ACCME? Can "house ads" for educational activities and other medical information resources be included in the right or left rail or banner of an educational activity?
Patient, caregiver, member of the public			Where logos can go should be addressed (such as meeting bags- it looks like a sea of one logo in a room), as well as conditions surrounding exhibiting and doing a satellite symposium. Some providers will require CME credit for their ancillary symposia, but only exhibitors may be supporters for those symposia, even when planned and presented by an independent entity.
Recognized Accreditor (state/territory medical society)			Further . . . does this now allow for advertising by CI on a syllabus, schedule, flyer, web page? As long as no educational content is included? What about if it includes learning objectives/program description?
Recognized Accreditor (state/territory medical society)			I will suggest that all providers must be fully aware that the non-accredited activities must be held at breakfast or dinner, not between accredited CME's, that is - lunch. Are non-accredited CME 's accepted between accredited CME 's?

What comments or questions do you have about Standard 5?			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Recognized Accreditor (state/territory medical society)			Maybe some guidance on large meetings that offer special "sponsorship" packages, like paying for Wi-Fi, key cards, name badges, and the like. Should this be prohibited because these services/items cross into the educational space?
Recognized Accreditor (state/territory medical society)			Standard 5, 2c, some providers have the perception that previously, trade names had to be used in conjunction with generic names and all agents in a class had to be referenced, unless there were specific differences between agents in a class. Many learners may not be familiar with generic names but recognize agents by trade name. Removing all trade names may result in confusion that should have been adequately addressed in the previous requirements.
Recognized Accreditor (state/territory medical society)			There are likely providers who are currently allowing non-accredited education to occur in a meeting room, followed by a CME session in that same meeting room. If by the wording "in the physical space" you are referring to meeting rooms, you will have to clarify to providers that non-accredited education must be delivered in a separate room from where the CME session will be held. Providers will groan a little but will eventually be able to adjust. If by the words 'in the physical space" you are referring to a hotel or facility overall, this will be seen as unreasonable because most providers and learners will say that they can differentiate between the end of an accredited program and the start of non-accredited education.
Recognized Accreditor (state/territory medical society)			What is meant by "presented" in 5.2.a? Can a provider devote time in the program agenda to visit the exhibitors/vendors?

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Advocacy organization			Many of the proposed changes are wonderful and work in theory; however, from anecdotal conversations, our jobs would become substantially more difficult. Proposed changes would require a more involved accredited provider in the joint providership process. This would undoubtedly require joint providership prices to go up or eliminate these relationships. The elimination of interleaved education also puts funding streams at risk. Providers could be looking at additional incurred cost in acquiring event space due to the ambiguity in the way the proposed change is written. Furthermore, we are then tasked with heavier workloads. The expectation to ask everyone in the control of educational content and their spouses/partners to disclose all financial relationships is really an unnecessary burden. Conflicts of interest can arise in the form of political, religious, and cultural biases that are impossible to document. Consider the OBGYN physician who does not favor the idea of abortions. We would argue that this is a more significant conflict and impossible to mitigate. Again, already overburdened and understaffed departments would be inundated with disclosures to review. This assumes that people are forthright in their disclosure. It may be easier to say, “I don’t have any.” Deceitful disclosures jeopardize the sanctity of accredited education. This doesn’t even address the cultural and ethical implications of asking someone to report all their financial relationships.
Accredited CE provider		Nonprofit (physician membership organization)	I think the changes to Standard 1 are not wise as far as making progress in medicine goes.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME		Revise title to include: "…for the Health Professions" We are concerned that the use of the term to "non-accredited" education throughout the document sends a message that only accredited CE is of value. Independent non-accredited CE may exist without credit for a variety of reasons including lack of easy access to an accredited provider, financial cost of credit issuing, time and resources of staff to complete required processes/paperwork, none of which devalue the legitimacy of the content. While we recognize that ACCME is concerned and responsible for maintaining the integrity of accredited CE, we would urge insertion of wording in the introduction to the Standards to describe two types of education that fit into the non-accredited bucket: "independent non-accredited education and marketing/promotional presentations." We do agree that there needs to be a clear indication to the learner of which type of education is being presented and that separation of these from accredited education is prudent. We support the change from CME to CE. However, many of our members envisage this change will cause confusion. Outside of the current independent healthcare educational environment, this change may make adherence to internal company compliance regulations problematic. For example, government and journalists will struggle with using the terms correctly and likely not make the proper distinctions necessary to accurately communicate the independence and value of "accredited CE

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	1. We recommend that ACCME consider adding EHR companies the ineligible entities category. As EHRs become ubiquitous in health care facilities, it is in the realm of possibility that any EHR company could embed algorithms into diagnostic or treatment processes that benefit the EHR company or some ineligible entity and not the patient. 2. We appreciate the inclusion of the term “employee” in the definition of ineligible entities. We have had ongoing push-back from ineligible entities who insist the Medical Science Liaisons (MSLs) should be permitted to attend accredited CME activities or which they have provided commercial support and or purchased exhibit space. 3.We appreciate the efforts of the ACCME and its task force to consolidate existing SCS and related policies, etc., to create actionable new Standards for Integrity and Independence in Accredited Continuing Education that are extremely well-written.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Algorithms, examples of compliancy and non-compliancy for each of the standards and sections would be extremely helpful. Also, a webinar and/or workshop about the revised standards would also be helpful. Tools on education for the accreditors would also be extremely useful. Accreditors will have to educate staff and their organizations on the changes.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	As previously described, these new Standards seem contrary to moving the field of medicine forward. In addition, they will add to the already burdened CME Providers’ workload. CME Providers are currently considered by the institution as a service department; adding these draconian restrictions will put the CME Provider in an adversarial and punitive role with the institution’s faculty and leadership. If these Standards are an attempt to protect the learning environment from industry influence to CME participants and keep healthcare professionals true to their ethical commitments, the outcome will be unsuccessful. Instead, the outcome of these Standards will be detrimental to the CME Provider, program chairs, faculty, and the medical community as a whole, ultimately having a negative impact on patients when physicians do not have knowledge of cutting-edge medical information.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	I noted the language change from "Accredited Continuing Medical Education" to "Accredited Continuing Education". Does that have implications for the language of criterion 6, the accreditation statement, and even the name of the Council, etc.?
Accredited CE provider	ACCME	Hospital/healthcare delivery system	In the end, the intention of improving independence and decreasing the likelihood of commercial bias with these new standards has missed the mark. While some definitions (eligible v. non-eligible entities) have provided some clarity, most standards functionally act to increase our workload, decrease our revenue sources and not improve our ability to ensure independence.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	In the end, the intention of improving independence and decreasing the likelihood of commercial bias with these new standards is the obvious intention of these standards. While some definitions (eligible v. non-eligible entities) have provided some clarity, there are other clear terms and concepts need clarification that would make me more comfortable with implementing these proposed standards.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Several of these updated standards will cause a significant burden on my staff and department, specifically the changes in Standard 3. These do not consider the changing marketplace and the that fact that many academic institutions, like ours, are hiring faculty who are experts in certain areas and have start-ups and other relationships where they are owners/and or employees of "ineligible entities". This makes it impossible for these department chairs and key faculty in the organization to organize or participate in the planning of any CME. We live in a capitalist society and companies and academic institutions want experts for a reason. Our hope was that these new standards might address this and provide us some solutions. It appears that they won't, and it will make for difficult conversations moving forward and for novel education not to be offered to our learners.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Thank you for simplifying and also for incorporating content validity into the SCS.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	Thank you, no additional comments. Look forward to the results. The Sharp CME Team.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Hospital/healthcare delivery system	The examples and clarifications are appreciated and, if approved, will provide accreditors a better tool for communicating expectations. Thank you!
Accredited CE provider	ACCME	Hospital/healthcare delivery system	The name change from continuing medical education to accredited continuing education will be confusing for learners at institutions that are not joint accredited. Many institutions have different departments based on professional education (CME, nurse education, pharmacy education), and medical in the name indicates the type of accreditation being provided. The title Accredited Continuing Education also may be confused with other types of CE such as law or real estate as there is no reference to healthcare in the phrase with the "medical" removed.
Accredited CE provider	ACCME	Hospital/healthcare delivery system	The people who are developing these ever more restrictive rules for CE are not in the trenches with those of us who interact with teachers and learners on a regular basis and are battered by their frustration and anger at being over-regulated. It is a shame really that education in the medical field is being regulated in such a way as to be detrimental to the original intent of education, which was to share knowledge and advance the profession.
Accredited CE provider	ACCME	Insurance company/managed-care company	I like the new terms of eligible and ineligible entities and mitigate instead of resolve, but I am reluctant about the change of CME to ACE. That will take a lot of getting used to. As an accredited ACCME and ANCC provider, please work together with ANCC to align the requirements not only for joint accreditation but also for those of us who are not joint accredited but have both.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (other)	In healthcare, generally accepted medicine relies on siloed concepts that, in the best of circumstances, are linked to provide optimal healthcare for patients. Safe treatments and therapies are comprised of evolving techniques derived from the latest research. Some research is conducted by academic institutions. Other is conducted by commercial entities. Regardless when new therapies are found to be viable and safe therapeutics for the patient, education consisting of both learning about as well as patient application must be made available in academic high-quality education free of commercial influence. Given this, new approaches to healthcare are being researched. Safe and more expeditious “bench to bedside” approaches provide more opportunities for effective treatment and ultimately optimal care – shortening the seventeen-year implementation gap. It is the responsibility of Accredited CE providers to identify safe and effective approaches, faculty who can teach them well and to ensure the education is made accessible to practitioners. As stated by ACCME directly, it is not possible for ACCME staff and personnel to research and approve all that is to be taught. They must rely on high quality CE providers to utilize approved processes.
Accredited CE provider	ACCME	Nonprofit (other)	Suggest clearly labeling all standards with sequential numbering and using the same numbering system to clearly relate all guidance, education, and FAQs developed, as well as the date of each update. Need to ensure that all accredited providers are informed in a timely manner of all updates to standards and interpretive guidance.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (other)	We do not understand the reason for the term accredited continuing education. Please clarify what you mean by this term. We find it to be an exceptionally confusing term. • It does not indicate that the education that it is in any related to medicine or health care; this term can be used for any industry • Do you mean education developed by accredited providers? If so, it should be noted that providers are accredited to certify activities for credit; activities are certified for credit by providers accredited to do so; with a few notable exceptions, there are no accredited activities in the US • Clinicians will be confused by this change in terminology; they have been accustomed to terms such as “continuing medical education,” “CME,” “continuing nurse education,”’ “continuing pharmacy education,” etc. • If ACCME and other accrediting bodies wish to provide a single term that would be applicable for all learners within the medical community, why not maintain “Continuing Medical Education (CME)” which clearly communicates that it is intended to assist medical and health care professionals improve their professional knowledge and practices. Further, please clarify this language to ensure accuracy and alignment with standard terminology. Many providers work hard to have their staff and colleagues use correct terminology, and ACCME’s ongoing use of “accredited continuing education” is confusing and not helpful.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	• "Continuing education" appears in revised title and throughout the proposed standards. It is evident that the word "medical" has been removed. However, the ACCME is still a national accreditation body for continuing physician education. Please explain the purpose of the omission. • How does this change to CE impact the relationship and alignment with the AMA PRA Credit System which is focused on physician education/CME? • Current Standards of Commercial Support (SCS) 2.2, 3.2, 3.9, 3.10, and 3.11 do not explicitly appear in the proposed new standards. Are we to assume those requirements are deleted? • Currently, the SCS are crucial elements of the Criteria 7-10. Will the Criteria be revised as a result of revising the Standards? If so, will revised Standards and revised Criteria happen in tandem?
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	A clearer definition of where Artificial Intelligence falls into this standards update would be appreciated.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	ACOEM has reservations about replacing the term "continuing medical education" with "accredited continuing education." We posit that "accredited continuing education" is overly general and does not serve to differentiate the specialized education that doctors, and other healthcare professionals consume from the wide world of adult education. While we applaud the efforts of the ACCME to use language intended to include the spectrum of healthcare professionals, we encourage the ACCME to consider that the label of "continuing medical education" is instantly recognizable among the many licensing bodies and institutions in which our constituents serve. If the task force, having reviewed feedback from stakeholders, remains convinced that a new term is vital to the cause of inclusion, we suggest "accredited healthcare education" be considered.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	ASCP appreciates the further clarity of diagnostic labs as eligible and ineligible entities. (Eligible: Diagnostic Labs that do not sell proprietary products; Ineligible: Diagnostic Labs that market or sell proprietary products) but feel that further clarity is needed regarding the definition of "products" related to Diagnostic Labs. We suggest the following: Products include physical items that are sold to external entities, such as manufactured test kits, reagents, or instrumentation. It also includes physical items provided to patients in the context of direct-to-consumer testing. The goal of the above proposed definition is to: • Ensure laboratory testing services and activities are not considered products • Exclude utilization management programs or IT solutions • Not include facilities that make physical products (e.g. reagents), but only distribute them internally • Address direct-to-consumer testing (since there is no physician intermediary on the ordering side)
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	I appreciate the evaluation of the current criteria and call for comment. Overall, I think there are positive changes with more clearly identifying the criteria so it is not open to interpretation, which may lead to potential non-compliance. I believe there is a way to manage the integrity of educational CME with oversight, as we are professionals, but do not need to micromanage entirely with managing commercial support on behalf of joint providers or looking further into disclosures outside of the current disclosure paperwork we require. I think there will be some pushback with the term CME moving to "accredited continuing education," but feel it is an appropriate change if adopted. Thank you for allowing my feedback on the proposal and I look forward to more information.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	I think the revised Standards are written in a clear and comprehensive manner.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	I would ask that we not apply extreme restrictions to our presenters, active members, innovators in these medical societies. the physicians speaking on the podium are the experts and as the experts they are usually involved with product development, research, consulting etc. As long as these conflicts are disclosed, there should be no issue.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Implementation should be phased in similar to the new commendation criteria (at least 2 years). It would be helpful to have a sample disclosure form or simply draft language to use when requesting new disclosure information Also, the current COI flowchart should be revised to reflect new processes. Case scenarios (even hypothetical) should be available upon implementation to help providers familiarize themselves with the new standards. Please develop a one-pager on what has changed within standards (simply succinct summary). Make it easy for providers (specifically primary CME staff) to explain the changes and new requirements to all stakeholders (leadership, planners, faculty, etc.) It will be critical for ACCME to work WITH the entire community and utilize the expertise that each provider type (including recognized accreditors and their providers) bring to the system. Resources cannot be developed in isolation from CME providers. Specifically, front line CME personnel (not only managers/directors) as they will be the ones responsible for implementing any changes. Resources must be practical and applicable and available at the beginning of the phased implementation.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Integrating all policies and definitions into the revised Standards is a helpful change. While the proposed Standards are conceptually the same as the current ones, there are new terms to integrate, and some will require further organizational review before operationalizing. We plan educational activities up to 18 months in advance of delivery. An implementation timeline for the new Standards will need to account for providers' own planning timelines and the system and process changes that many will also need to make to comply. A rollout timeline of 24 months would be sufficient.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	-Move away from the paternalism inherent in the requirements, particularly the mindset about needing the "protect" learners and addressing how a $1 stake in a company creates an "unbridgeable" COI. Allow for "mitigation" short of elimination. -Recognize the rapid pace of change in medicine. The standards are built around an old framework, not one in which only one lab in the nation can run a specialized diagnostic test or any institution with a good manufacturing practices facility can "grow" individualized therapies. -Define terms in the standards so as to ensure transparency throughout the processes of implementation and reaccreditation. Gaps in definitions remain, including "owner" and "employee." -Stop using the term "mitigate". If the only steps that ACCME will accept to "mitigate" relevant financial interests are steps that eliminate holders of such interests entirely from the accredited CE process (subject only to the exclusions in 3.2). The complete elimination of these experts does not bode well for the future of accredited CE. -Take note of the feedback from the January 2019 Call for Feedback. The Standards proposed in the 2020 Call for Comment are inconsistent with the 2019 feedback. There are specific issues that need to be addressed before these requirements be operationalizable, we recommend an additional round of public comment before finalizing these standards. Not doing so will result in years of negotiation over how to comply with the requirements.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Once the final version is written, I would recommend that someone go through and makes sure the same terms have been used consistently throughout.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	Thank you for the significant step forward in the proposed standards and the efforts to address the complexities that have evolved. We are grateful for the opportunity to comment.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The AAMA supports efforts to assure content is appropriate for accredited activities. There is a real concern that we don't unduly limit discussions of new ideas and innovations.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The changes make a lot of sense and I can tell that this was a massive undertaking - thank you to the task force!
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The proposed Standards are in general an improvement over the current Standards in that they more directly and concisely describe the requirements in most cases.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	The proposed Standards are in general an improvement over the current Standards in that they more directly and concisely describe the requirements. As stated above, though, there are specific items that require clarification in order for the Standards to support providers and result in quality education.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	This is great and look forward to results and changes!! It would be great if ACCME offered resources about changes to share with staff and healthcare professionals that don't always understand 'CME' speak.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We applaud the ACCME in their efforts to strengthen and consolidate the Standards for Commercial Support. Thank you for the opportunity to comment.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We appreciate ACCME's efforts to elevate the quality of ACE course and the opportunity to comment and hope for a dialogue with ACCME

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We are very disappointed with the timing of these new Standards and the ongoing efforts of the AAMC's Harmonization of Financial Disclosure Reporting in Biomedical Journals initiative. It makes that work seem irrelevant. We strongly suggest that the ACCME wait to approve any changes until that project is complete so as not to have providers make two sets of changes. Our understanding from Dr. McMahon is that he is supportive of the harmonizing project, however these Standards are not consistent with its stated goals. In addition, given the breadth of the feedback that our organization has on these new standards alone, we strongly suggest that the ACCME make revisions and put out a second call for comment before anything is finalized.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We believe there is more work to do with the definition of what constitutes an ineligible entity, especially when referring to a diagnostic laboratory. We plan on continuing our talks with ACCME regarding this fast-changing landscape and strive to ensure that professionals receive appropriate education regarding best practices and resources for patient care.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We don't like the term "accredited continuing education" because that could be inclusive of other continuing education that is non-medical. For instance, the first thing to populate in a Google search of the term is in reference to graduate programs and universities. We like continuing the term "accredited continuing medical education." The use of the term does not preclude different credit types being issued under this umbrella. Furthermore, we believe this will add further confusion. Outside of the current independent healthcare educational environment, this change may make adherence to internal company compliance regulations problematic. For example, government and journalists will struggle with using the terms correctly and likely not make the proper distinctions necessary to accurately communicate the independence and value of "accredited CE."

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We thank the ACCME for the opportunity to respond to their call for comments regarding the proposed changes to the Standards for Commercial Support. We are hopeful our suggestions and recommendations will be carefully considered as the ACCME updates their guidelines. We would strongly encourage the ACCME to invite a second round of comments prior to finalization, after initial feedback has been integrated.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We urge insertion of wording in the introduction to the Standards to describe two types of education that fit into the non-accredited bucket: “independent non-accredited education and marketing/promotional presentations.” We do agree that there needs to be a clear indication to the learner of which type of education is being presented and that separation of these from accredited education is prudent. We support the change from CME to CE. However, many of our members may foresee this change as confusing. Outside of the current independent healthcare educational environment, this change may make adherence to internal company compliance regulations problematic. For example, we anecdotally observe a consistent struggle with using the terms correctly and likely not make the proper distinctions necessary to accurately communicate the independence and value of “accredited CE.” In the future when ACCME issues FAQs on the standards or any of their policies, we recommend that they number the FAQs – one number per question – and they include the date when the FAQ was issued.
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	We welcome the replacement of the word “resolve” with “mitigate” since “mitigate” accurately reflects what ACCME has aimed for through the years. This will make the process more understandable to individuals involved in the development and presentation of accredited activities.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Nonprofit (physician membership organization)	While I continue to applaud ACCME efforts to improve medical education and make certain it is non-biased, I believe at some point the regulations begin to have less impact and just become burdensome. In surgical fields, the relationship between device manufacturers and surgeons is important as one needs the expertise of the other to continue to improve products. Surgeons also need to stay up to date with new devices and the pros and cons of each. It seems to me that getting that information during a well-run, accredited medical meeting where there is more opportunity to compare different products is a good option.
Accredited CE provider	ACCME	Other: Accreditation Management, CME Consulting, and Joint Providing Company	SIIACE?
Accredited CE provider	ACCME	Other: malpractice insurer	Good job in addressing problems with current Standards.
Accredited CE provider	ACCME	Other: Nonprofit, scientific research association	The form did not allow me to opt-out of responding to a specific section. Please allow that option for future items. For example, Standard 4 was not reviewed by us because we do not accept commercial support. However, I had to click Yes it was clear because I didn't have any comments.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Other: not-for-profit CME provider	Reducing the number of Standards was a good thing, but what was really lacking in the presentation of some of the changes is WHY? Were there examples of where problems arose in programs sponsored by ACCME accredited providers that would not have happened if the new standards were in place? That would have been very informative and would make me feel differently about what for us will be the biggest change - collecting ALL vs. only RELEVANT financial information. We have few Faculty/Planners that have any relevant associations to report. All of our information gathering forms will have to be redone. More importantly, I am very concerned that many of our Faculty will decide it is not worth the effort to teach for a few hours if they are required to spend time reporting ALL of their financial information. They also may resent having to do so if not related to their presentations. It may work for large institutions or Academies that have sway over their members but for us, it will just be burdensome with no known benefit. It was not even made clear what records we will need to create and retain regarding how we decide what is and what is not RELEVANT. What will we need to show to the ACCME at reaccreditation? Can we be punished if we didn't do our job thoroughly enough?
Accredited CE provider	ACCME	Other: State Medical Society	Well written.
Accredited CE provider	ACCME	Other: Teleconferencing Medical Education Company	I urge you to please reconsider making any of these new standards go into permanence.
Accredited CE provider	ACCME	Other: university	You didn't mention changing CME to ACE in this survey. I found this confusing. Would we have to change everything 'CME' to 'ACE'? We are accredited for CME, CNE, CHES and CPH - would it now be ACE, CNE, CHES and CPH? Would your name become ACACE? We need a lot more information on this change. I don't want to be snarky, but it feels like we are being asked to do more and more with way less every year. ACCME is a monopoly; we have no other option. Now that our fees have skyrocketed by 150%, these additional changes feel like a double whammy. Jobs may be lost, accreditations given up etc. - is it worth it?

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Other: University - not a school of medicine	While appreciating the goal to consolidate the SCS into one document, additional definition and guidance will be required as well as a fully defined timeframe for implementation.
Accredited CE provider	ACCME	Publishing/education company	My strong recommendation would be that that Standard 4.1.b. should be modified to allow the non-accredited entity to reimburse expenses to faculty and others as is stipulated in the Standard. The Standard should also be modified to say that the Accredited provider is responsible for having a process in place that verifies payments are done properly and that the process must go beyond a simple post-event budget report. The revised standard could include some criteria around the type of reporting that should be available for review as is necessary. I would suggest that a proper accounting report would be appropriate. For example, the non-accredited entity could be required to have a distinct accounting code or codes for the disbursement of grant funds. That would allow reports to be created, if need be, at an item level in order to review and ensure compliance. I would be happy to discuss this further with the appropriate ACCME staff.
Accredited CE provider	ACCME	Publishing/education company	Overall, we think this is a good evolution of the standards. We particularly like the term accredited continuing education. We hope that this is something that will also gain traction internationally.
Accredited CE provider	ACCME	Publishing/education company	Overall, the proposed changes are helpful, as they add clarity to some areas that were ambiguous/open to interpretation.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	Providers are “Accredited,” and Activities are “Certified.” The intent of changing “Continuing medical education” to “accredited continuing education (ACE)” may have been to be inclusive of disciplines other than physicians and to clearly distinguish "CME/CE" from non-accredited activities. Perhaps an alternative, is using the terms “Certified Continuing Education” and “Non-Certified Continuing Education.” 1. Q: Many conferences and activities with accredited education still provide one program book to the learners inclusive of all information. Can these program books contain advertising if there is a separate section in the book clearly identified as “non accredited information” or do two separate books need to be created?
Accredited CE provider	ACCME	Publishing/education company	Regarding dropping the "M" in CME: when we only call it CE, it no longer is clear what type of credit we are offering plus it no longer matches what the AMA calls it. It makes sense for the Joint Accreditation group to call it CE, but not the ACCME. The type of CE that ACCME-accredited providers offer is CME, for MDs/DOs. Although several other groups accept this type of credit (ANCC, NCCPA, etc.), to not include the M in CME will cause confusion for our participants who aren't MDs.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	Revise title to include: "…for the Health Professions." We are concerned that the use of the term to "non-accredited" education throughout the document sends a message that only accredited CE is of value. Independent non-accredited CE may exist without credit for a variety of reasons including lack of easy access to an accredited provider, financial cost of credit issuing, time and resources of staff to complete required processes/paperwork, none of which devalue the legitimacy of the content. While we recognize that ACCME is concerned and responsible for maintaining the integrity of accredited CE, we would urge insertion of wording in the introduction to the Standards to describe two types of education that fit into the non-accredited bucket: "independent non-accredited education and marketing/promotional presentations." We do agree that there needs to be a clear indication to the learner of which type of education is being presented and that separation of these from accredited education is prudent. We support the change from CME to CE. However, many of our members envisage this change will cause confusion. Outside of the current independent healthcare educational environment, this change may make adherence to internal company compliance regulations problematic. For example, government and journalists will struggle with using the terms correctly and likely not make the proper distinctions necessary to accurately communicate the independence and value of "accredited CE."

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Accredited CE provider	ACCME	Publishing/education company	Thank you for all your hard work on this!
Accredited CE provider	ACCME	Publishing/education company	Thank you for the opportunity to participate in this process, and the thoughtful review of feedback!
Accredited CE provider	ACCME	Publishing/education company	Thank you for the opportunity to review and make comments/provide feedback!

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	The newly proposed standards do not serve its members. I would ask the ACCME to consider the broader consequences for educators and learners. Many talented dedicated educators will be disqualified from teaching due to the new rules re ownership. Why is the ACCME so set on alienating commercial interests who support CME with almost 1 billion per year? It seems there should be a way to build for more support with a different approach that still provides for a separation of learning from marketing.
Accredited CE provider	ACCME	Publishing/education company	This is a great start, with a good intention, but work needs to be done to clarify, and mitigate some issues. Thank you for opening this call for feedback to receive perspectives of the CE community. We hope that you listen to, consider, and act upon the feedback provided.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	We applaud the ACCME in their efforts to strengthen and consolidate the Standards for Commercial Support. We believe with our suggested changes that the ACCME will be able to accomplish their mission and help the overall CME community gain a better understanding on how to implement the new Standards. Revise title to include: "…for the Health Professions". We are concerned that the use of the term to "non-accredited" education throughout the document sends a message that only accredited CE is of value. Independent non-accredited CE may exist without credit for a variety of reasons including lack of easy access to an accredited provider, financial cost of credit issuing, time and resources of staff to complete required processes/paperwork, none of which devalue the legitimacy of the content. While we recognize that ACCME is concerned and responsible for maintaining the integrity of accredited CE, we would urge insertion of wording in the introduction to the Standards to describe two types of education that fit into the non-accredited bucket: "independent non-accredited education and marketing/promotional presentations." We do agree that there needs to be a clear indication to the learner of which type of education is being presented and that separation of these from accredited education is prudent. We support the change from CME to CE. However, many of our members envisage this change will cause confusion.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	We are concerned that the use of the term to "non-accredited" education throughout the document to encompass sends a message that only accredited CE is of value. Independent non-accredited CE may exist without credit for a variety of reasons including lack of easy access to an accredited provider, financial cost of credit issuing, time and resources of staff to complete required processes/paperwork. While we recognize that ACCME is concerned and responsible for maintaining the integrity of accredited CE, we would urge adoption of a change in wording to be less pejorative to describe two types of education that fit into the non-accredited bucket: “independent non-accredited education and promotional presentations.” We do agree that there needs to be a clear indication to the learner of which type of education is being presented and that separation of these is prudent. We support the change from CME to CE. However, many of our members envisage this change will cause confusion. Outside of the current independent healthcare educational environment, this change may make adherence to internal company compliance regulations problematic. For example, government and reporters will struggle with using the terms correctly and likely not make the proper distinctions necessary to accurately communicate the "independence" of this type of education.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	Publishing/education company	We do not understand the reason for the term accredited continuing education. Please clarify what you mean by this term. We find it to be an exceptionally confusing term. • It does not indicate that the education is in any way related to medicine or health care; this term can be used for any industry • Do you mean education developed by accredited providers? If so, it should be noted that providers are accredited to certify activities for credit; activities are certified for credit by providers accredited to do so; with a few notable exceptions, there are no accredited activities in the US • Clinicians will be confused by this change in terminology; they have been accustomed to terms such as “continuing medical education,” “CME,” “continuing nurse education,”’ “continuing pharmacy education,” etc. • If ACCME and other accrediting bodies wish to provide a single term that would be applicable for all learners within the medical community, why not maintain “Continuing Medical Education (CME)” which clearly communicates that it is intended to assist medical and health care professionals improve their professional knowledge and practices. Further, please clarify this language to ensure accuracy and alignment with standard terminology. Many providers work hard to have their staff and colleagues use correct terminology, and ACCME’s ongoing use of “accredited continuing education” is confusing and not helpful.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	Baylor College of Medicine is appreciative for the opportunity to provide feedback to the Standards for Integrity and Independence of Accredited Continuing Education. The integration of policies into the standards is a great improvement in support of the accredited provider to access one document. Much of the proposed changes to the standards are improvements to furthering the integrity of continuing education. There are particular concerns as posed in our responses that reflect the perspective of a medical school and academic medical center. Regardless of organizational types, CME/CPD departments are asked to do more (e.g., MOC and interprofessional education) with existing or less resources. We ask that the ACCME consider the burden shift that the changes will put on accredited providers. Obtaining additional staffing resources is a hard-won battle. It is important that the resource is put towards developing and providing relevant and necessary quality education rather than tasks or functions that do not add value to our work. In making changes it would be helpful to the community for the ACCME to share aggregated data for the significant changes to be addressed. For example, what is the segment of the audience that is at risk? This is particularly important when the impact is a financial one.
Accredited CE provider	ACCME	School of medicine	Excellent revisions. An evolutionary, rather than revolutionary, change, keeping the spirit of the current Standards while clarifying and consolidating the rules.
Accredited CE provider	ACCME	School of medicine	I think the most difficult will be to appropriately define "mitigate" for our direct and joint providers -- although most won't really care.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	I understand that the term ineligible entities is proposed because the term commercial interest is considered to apply only to private vs. non-profit organizations. However, when we talk about a conflict of interest with a commercial entity, everyone understands what we are talking about and why it would be inappropriate for speakers to have such an interest. When we will use the term "ineligibles," practically no one outside of the CME enterprise will know what we are talking about and a great deal of time will have to be spent explaining this type of "CME speech." I think that it would be preferable to keep the term commercial interest and add in parenthesis whatever else ACCME wants to exclude, e.g. non-profits with a business interest.
Accredited CE provider	ACCME	School of medicine	I was disappointed in the final product. I was really hoping that you were going to make things easier, not harder. Examples eliminate COIs but have a more extensive disclosure. Add a threshold dollar amount for disclosures. Refer people to the open payment portal -- why are we collecting disclosures when there is a national database already? Allow owners/employees to talk if steps are taken to prevent bias.
Accredited CE provider	ACCME	School of medicine	In addition, thank you for clarifying what defines the difference between an eligible and ineligible organizations. However, I am surprised at a few eligible entities listed – Electronic health records and software or game developers. These two entities would profit from promoting their products.
Accredited CE provider	ACCME	School of medicine	It would be helpful to understand the rationale behind the multiple terminology changes. The proposed terminology changes do not represent the functions of CME units. Standard 4 revisions will be devastating to our CME unit in terms of cost, staffing, and requirements of the medical school.
Accredited CE provider	ACCME	School of medicine	Most of the revisions here are welcome and much appreciate. Thank you for listening to your community.
Accredited CE provider	ACCME	School of medicine	Overall, we appreciate the work the ACCME has done over the past few years towards more transparency/partnership, and for adapting to the changing healthcare landscape. We think these new standards are a good starting point but hope for further clarification and conversation with the community before they are finalized and adopted.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	Overall, I think that they look fine and are much clearer and more concise that the previous standards and policies. My major concern is that the ACCME as a lead regulator and charter member of Joint Accreditation use inclusive interprofessional language that reflects a commitment to the multiple professions of health care that are not part of the delivery of comprehensive and quality health care.
Accredited CE provider	ACCME	School of medicine	Overall, you need to be a lawyer to understand the language and intent of the Standards; the average CPD professional struggles, not to mention learners, who this is meant to "protect". Also, we haven't seen any evidence that these rules & SIGNIFICANT amounts of work do anything to make education better or keep our education independent. Has anyone ever asked learners if they read the disclosures? Much less take them into account how we hope they do? It doesn't seem as though any of our previous feedback was considered in this version. If we hoped to focus on instructional design, building a home for our learners, explaining our value and connecting our work to improved patient care, this new revision will completely pull us away from that. We, as a CPD community, are about to get wrapped up in these Standards for probably a few years; is that where we should be funneling our energy? What problem is this solution trying to solve? How are these standards helping healthcare providers care for patients better when their reality is filled with interdependence with commercial organizations? Finally, I wish you could have timed this better – you have our activity data & know our PARS data is due soon – you must recognize that January-February are ridiculously busy times for us to provide thought on this incredibly important topic.
Accredited CE provider	ACCME	School of medicine	Recommend modifying term accredited continuing education to accredited continuing healthcare education. This allows the term to remain inclusive of different healthcare professions while also remaining specific to healthcare since other professions outside of healthcare have their own accredited continuing education requirements.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	Thank you for updating these standards. We hope that the definition of ineligible entity will continue to be updated as new situations are likely to arise. Please do not include the provision that joint providers cannot pay faculty expenses. Overall, these proposed Standards are an improvement. Thank you!
Accredited CE provider	ACCME	School of medicine	Thank you for your efforts to strengthen and consolidate the Standards for Commercial Support.
Accredited CE provider	ACCME	School of medicine	Thank you for your work on these. Our CME team appreciates updating and clarifying the standards. This is great work.
Accredited CE provider	ACCME	School of medicine	There are some excellent changes being proposed but some that cause us great concern, primarily the requirement of direct financial management by accredited providers who may not have the organizational mechanism to do this work, although they are completely capable of reviewing and overseeing the manner in which a designated educational partner can do so easily and nimbly. This causes us great concern.
Accredited CE provider	ACCME	School of medicine	Transition phrase – how much time will be given to prepare and meet the expectation of the revised Standards.
Accredited CE provider	ACCME	School of medicine	very worried about the new terminology for continuing medical education. Accredited continuing education sounds like and will be confused with standard CEUs. To avoid singular terms like medical and nursing and to embrace in part interdisciplinary, please consider accredited healthcare education (AHE)or accredited healthcare continuing education (AHCE)
Accredited CE provider	ACCME	School of medicine	We assume that if ACE is to be used instead of CME, then ACCME will soon change its organizational name to ACACE. We also believe there will be a lot confusion among physicians, our most important constituent group, who will continue to use the term “continuing medical education” and not understand why “their” continuing education moniker has been altered to something they don’t understand and with which they don’t agree. We are confident this will not be a popular decision, nor one that will be easy to implement on all our guidance documents and CME application forms.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	ACCME	School of medicine	We think the change from CME to CE will cause confusion and create a lot of work changing forms, documents, etc. for not much advantage. There is also the connotation that CE isn't medical education but is the verbiage for nursing or other professional development in any field such as accounting. CME is clear to the learner. Outside of the current independent healthcare educational environment, this change may make adherence to internal company compliance regulations problematic. For example, government and journalists will struggle with using the terms correctly and likely not make the proper distinctions necessary to accurately communicate the independence and value of “accredited CE.” In the future when ACCME issues FAQs on the standards or any of their policies, we recommend that they number the FAQs one number per question and they include the date when the FAQ was issued.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Hospital/healthcare delivery system	In the eligibility section, last paragraph, the word unresolvable is used. Since this resolve was changed to mitigate in the standards, perhaps this should be re-phrased to reflect the mitigate verbiage.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Hospital/healthcare delivery system	The task force did an excellent job! Glad to see there will be a transition phase and education/resources as part of the implementation process.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Hospital/healthcare delivery system	We like the new language and distinction between the eligible and ineligible entities. Nice job and we feel that the communication previously provided was considered. Thank you.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (other)	Appreciate that ACCME initiated this process to address challenges not met by the current SCS. Also appreciate that this was a process that involved other accrediting bodies so that everyone can be on the same page and providers involved in interprofessional education do not have to worry about following different guidance/standards depending on the profession for which the education is being developed.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	ASCO strongly encourages the ACCME to take this opportunity to align these Standards with the CMSS Code for Interaction with Companies and the proposals from the Disclosure Harmonization Task Force, led by AAMC, ASCO, JAMA and CMSS. There would be significant benefit to individual researchers and authors who submit to journals and serve as CME planners, faculty and abstract authors to have a consistent standard across required disclosures. Learners would benefit from consistent disclosure standards as well.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	Overall the Proposed Standards are clear in intent but how the ACCME will use them in documenting compliance is not as clear. Strategies and tools will be needed to help providers with the more challenging aspects of the new standards, specifically, Standard 3, Item 3 and Standard 4, Item 1b which, as written will change the workload for most CME departments which are often understaffed. It is critical that the ACCME balance the purpose of the new requirements with the efforts required for a CME department to comply.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Nonprofit (physician membership organization)	We applaud the ACCME in their efforts to strengthen and consolidate the Standards for Commercial Support. We believe with suggested changes that the ACCME will be able to accomplish their mission and help the overall CME community gain a better understanding on how to implement the new Standards. We would like to see a detailed FAQ document released simultaneously with the new Standards to ensure questions around practical application are addressed immediately to support the consistent interpretation and implementation of the Standards.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Other: academic medical center	We always appreciate clear definitions and standards. Unfortunately, many of these are muddled. When they are not, they're simply unworkable for many of us.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Other: Electronic health record company	The Eligibility section is clearly written, and we agree with the updated language. We also vigorously support the underlying premise that the standards should be "designed to create a clear, unbridgeable separation between accredited education and industry marketing and to ensure that accredited continuing Education serves the needs of patients and the public." Thank you for the opportunity to comment on the proposed ACCME Standards for Integrity and Independence in Accredited Continuing Education.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	Revise title to include: "…for the Health Professions" In the future when ACCME issues FAQs on the standards or any of their policies, we recommend that they number the FAQs one number per question and they include the date when the FAQ was issued. I believe with these suggested changes that the ACCME will be able to accomplish their mission and help the overall CME community gain a better understanding on how to implement the new Standards.
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	Publishing/education company	Thank you for this relevant, timely, and succinct revision. These are more intuitive to us than the previous SCS and we are ready to begin implementing them!
Accredited CE provider	Joint Accreditation for Interprofessional Continuing Education	School of medicine	We appreciate the additional clarity of the new standards. We recommend that a standard be added to reflect the leaner's responsibility in managing/reporting bias. Providers will work hard to ensure activities are free of commercial bias, but there are multiple factors outside of our control that could result in multiple forms of bias in a presentation. Learners should be informed that they need to speak up when the see/experience bias. They should not be passive in this process.
Accredited CE provider	Other: ACPE	Hospital/healthcare delivery system	The educational content should be the sole determinant of appropriateness. There should be no standard that automatically disqualifies a provider simply because of their employment. We need more qualified educators not fewer. Thank you for your consideration of this matter, but please do not adversely affect longstanding educational providers simply because of ownership.

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Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Other: ACPE	Nonprofit (physician membership organization)	The Standards still seem to be in line with what our organization is doing. Thanks for allowing feedback.
Accredited CE provider	Other: ACPE	Publishing/education company	Thank you for the opportunity to review and comment on these proposed changes!
Accredited CE provider	Other: CMA	Hospital/healthcare delivery system	interweaving of CME and non-CME can be accommodated in the same space. just clearly identify non-CME session.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	General comment - great changes. Much clearer and more direct.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	I find the term "accredited continuing education" to be uninformative because it doesn't state that this is education for physicians. Please insert "medical" so that it's "accredited continuing medical education." Otherwise the target audience is unclear.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	I support the current Standards for Integrity and Independence of Accredited Continuing Education as stated and reviewed.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	Implementation should be phased in similar to the new commendation criteria (at least 2 years). It would be helpful to have a sample disclosure form or simply draft language to use when requesting new disclosure information. Also, the current ACCME COI flowchart should be revised to reflect new processes. Case scenarios (even hypothetical) should be available upon implementation to help providers familiarize themselves with the new standards. Please develop a one-pager on what has changed within standards (simply succinct summary). Make it easy for providers (specifically primary CME staff) to explain the changes and new requirements to all stakeholders (leadership, planners, faculty, etc.)
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	providing participant lists without contact information is a standard when allowing exhibits from ineligible entities. We have not in the past provided email or other contact information.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	These are my personal opinions as a CME Director for more years than I could count. These are not the views of the organization that I am employed by. Such policies as this one has created an environ that stops all industry supported information/education. Our patients obtain information in real time and we need a system of continuing education that fulfills our ability to cogently discuss and consider present and near future trends. Thank you.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	We do not use ancillary marketing.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	We need to be clear if it is 'Continuing Medical Education (CME)' to differentiate for just 'Continuing Education (CE)' as we are educating the medical community (that includes all members of healthcare team). Education is the first step to improve patient care and all our activities are for healthcare providers and from which patients benefit. If the ACCME is so intent on changing CME to CE, then it also need to change its name from ACCME to ACCE.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	Hospital/healthcare delivery system	We need to make disclosures (especially when there are no conflicts of interest) easier for RSS's.
Accredited CE provider	Recognized Accreditor (state/territory medical society)	School of medicine	Many offices are named, "Continuing Medical Education Department" or something similar. Is it the ACCME's expectation to have programs update their office name to eliminate the word "Medical" and include the word, "Accredited?" Example Old: Continuing Medical Education Department New: Accredited Continuing Education Department Preference would be to not include "accredited."

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Advocacy organization			NAMEC does not understand the reason for the term accredited continuing education. Please clarify what you mean by this term. We find it to be an exceptionally confusing term. • It does not indicate that the education that it is in any related to medicine or health care; this term can be used for any industry • Do you mean education developed by accredited providers? If so, it should be noted that providers are accredited to certify activities for credit; activities are certified for credit by providers accredited to do so; with a few notable exceptions, there are no accredited activities in the US • Clinicians will be confused by this change in terminology; they have been accustomed to terms such as “continuing medical education,” “CME,” “continuing nurse education,”’ “continuing pharmacy education,” etc. • If ACCME and other accrediting bodies wish to provide a single term that would be applicable for all learners within the medical community, why not maintain “Continuing Medical Education (CME)” which clearly communicates that it is intended to assist medical and health care professionals improve their professional knowledge and practices. Further, please clarify this language to ensure accuracy and alignment with standard terminology. Many providers work hard to have their staff and colleagues use correct terminology, and ACCME’s ongoing use of “accredited continuing education” is confusing and not helpful.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Advocacy organization			The Texas Alliance for Continuing Medical Education is appreciative for the opportunity to provide feedback to the Standards for Integrity and Independence of Accredited Continuing Education. The integration of policies into the standards is a great improvement in support of the accredited provider to access one document. As an organization that represents several types of accredited providers, we ask that the ACCME consider the burden shift that the changes will put on accredited providers. CME/CPD departments are asked to do more (e.g., MOC and interprofessional education) with existing or less resources. It is important that those resources are put towards developing and providing quality education rather than tasks or functions that do not add value. Recommend: • 24 months for implementation of Standard 4 to allow time to set up new processes and to hire personnel for managing faculty reimbursement and payments. • 18 months for implementation Standard 5 as most annual activities have already booked their event spaces and may need time to look into different spaces for the following year in order to remain in compliance • 12 months for implementation of cleaning up eligible entities – specifically exclusion of Diagnostic labs (that sell proprietary products). Some activities may have already approved content by diagnostic labs for the coming year and will need to construct language for declining their involvement the following year and recruitment of other eligible entities.
Clinician/healthcare professional			I am board certified in Integrative Medicine (ABOIM) and these new guidelines would prevent me from obtaining the ACCME credits to maintain this board certification.
Clinician/healthcare professional			I applaud you for the work you have done on the accreditation process. Thank you.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Clinician/healthcare professional			I appreciate the effort to get independent comments. However, I would caution about using subjective evaluations about the "general acceptability" of practices within the practice of health care. New ideas are based on observation and reporting, and evidence gradually accumulates as researchers and funding are available. Practices may be worthwhile, even when the strength of evidence is not very strong. As long as practitioners are cautioned about the strength of evidence, they can use their own judgment with regard to the needs of particular patients. That way, "health care professionals and teams can be reassured that they can trust effective, cost-effective, compassionate care that is based on best practice and evidence.".
Clinician/healthcare professional			I have enjoyed two rewarding careers: Education for 12 years with a Masters Degree in Education, and Physician (M. D.) for 30 years. I still get excited when I learn new information about a topic and am able to teach my patients how to care for themselves. The more formal structure of CME courses provides for a concentrated flow of information that might take days or weeks to assemble and analyze. This input broadens and strengthens the physician's knowledge base and gives the licensed medical practitioner the opportunity to utilize those parts he/she feels are important to patient care. I did not note any education credentials from those on your Committee. I think it would be a good idea to include someone experience in learning to help the Committee better understand the higher levels of evaluation that physicians have honed in determining what to include in their medical practices.
Clinician/healthcare professional			I like your use of 'mitigate' rather than resolve. The term 'ineligible entity' may be off-putting to some folks, but I can't think of a better term. Thank you for your diligence on this revision. I like it much better that the previous version.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Clinician/healthcare professional			I thank the Task Force for an amazing amount of good work done on the behalf of all interested in quality, compliant, accredited continuing education. I appreciate the opportunity to review and comment on the draft revisions.
Clinician/healthcare professional			Organizations should be free to teach cutting edge therapies and those which may be observed clinically or have solid case studies behind them. Especially if the therapy is known to be safe. There are no double-blind studies on most surgical techniques, there are no double-blind studies on vaccinations and there are no double-blind studies on chemotherapy, yet these are all standard of care. Please keep commercial bias out of presentations but allow organizations to present material that is practical and relevant to those of us the field trying to help patients.
Clinician/healthcare professional			Overall well written. I am concerned however that the new standards do not take into consideration the growing number of academic faculty who are involved in small biomedical start-ups in their line of expertise and who are forever unable to plan/ speak in their line of expertise. Disclosing and resolving their conflict could better serve the field and advance science.
Clinician/healthcare professional			Please do not make such decisions on limiting what we as dedicated and experienced physicians can teach one another. This would be a very backward decision to make and suppress forward thinking in medicine. We are intelligent human beings and accomplished professionals that are solely here to improve the health of our patients, as well as, to help our colleagues to be more knowledgeable.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Clinician/healthcare professional			Regarding Standard 1: Ensure Content is Valid- denying CME will deter some or many physicians from attending activities that may impart medical innovation and delivery of potentially lifesaving treatment because that treatment is not generally accepted by the medical community currently - but may be acceptable as conventions change (which is why we call it conventional medicine). The info is scientifically valid, it is merely ahead of its time - but nonetheless true. I'm uncomfortable with letting ACCME and AMA determine what is valid content, since this may well be driven by biased or even corrupt, self-serving motives (political, financial, or otherwise). As a physician, I am fully capable of judging the content of a lecture or an article or series of articles or a treatment/intervention for its usefulness to me and my patients.
Clinician/healthcare professional			Strike a reasonable balance to protect the public, both from overzealous dishonest marketing, but also access to information. Many MDs sense that the CME bureaucracy has become self-serving, rather than existing to support the public,
Clinician/healthcare professional			This adds clarity to areas that have become opaquer with changes in healthcare. It hopefully will allow continued fine-tuning to accommodate standards to the changes that will continue to occur.
Clinician/healthcare professional			Too little time was given for feedback. Shorting physician feedback appears contrived.
Continuing education accrediting body			Define what constitutes high quality evidence. There is a reference made to CME/CPD being cost-effective, is being cost-effective a value of accredited CPD?
Ineligible Entity (commercial interest, such as pharmaceutical, device, life-science company)			As our community advances our goals to close healthcare gaps and improve patient care, industry recognizes that it is incumbent on us as part of the CE/CME community, for the benefit of learners, health care systems, and our respective organizations to not only comply with relevant guidelines (e.g. ACCME, OIG, and PhRMA) but also to proactively assess our practices, to promote continuous improvement. We appreciate the opportunity to be a part of this evolution.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Ineligible Entity (commercial interest, such as pharmaceutical, device, life-science company)			Integrity is the quality of being honest and having strong moral principles; moral uprightness. I view the addition of the word "integrity" to the title of the Standards as indication that the ACE community may lack honesty, strong moral principles and uprightness in assuring that clinicians and teams have a protected space to learn, teach, and engage in scientific discourse free from commercial influence. I believe it should be removed from the title but discussed in the Standards as part of the expectations for ACE providers.
Medical/healthcare association			Completely agree with introductory statement: "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". Learners expect this from accredited education. However, the use of "eligible" and "ineligible" entities and "accredited organizations" are both used throughout the proposed update. Would it be clearer to the learners with the use of terms "accredited entity" and "non-accredited entity"? Confident there are opinions on both sides but trying to put myself into what is most clear to the learner and accredited versus non-accredited seems more understandable.
Medical/healthcare association			I strongly advise changing Standard 2 to accept most all valid educational activities, not necessarily just those "accepted within the profession of medicine". "All recommendations involving clinical medicine in accredited education must be scientifically justified and generally accepted within the profession of medicine as appropriate for the care of patients."

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Medical/healthcare association			Our organization, the Academy of Managed Care Pharmacy (AMCP), is a professional membership association that serves health care professionals who implement and support the pharmacy benefit for millions of Americans. While our organization is not currently ACCME-accredited, we recognize that adoption of these standards would likely encourage other accrediting bodies to consider these or similar standards. Our organization, like many accredited providers, take these standards seriously and applaud ACCME for taking the initiative to update their standards. Our greatest concern is the categorization of pharmacy benefit managers as ineligible entities, specifically to serve as faculty and planners for educational programming. Within our organization, we have PBM pharmacists who contribute greatly to our educational programming by serving on education planning committees and faculty. We have no evidence to suggest that they contribute to any bias within our programming. As you may be aware, many insurance organizations have their own PBMs, so this further complicates the fact that an eligible entity has an ineligible subsidiary as part of their organization. For our internal purposes, this needs clarification. Our recommendation is to remove “Pharmacy Benefit Managers” from the list of ineligible entities. Similar to other associations, there are specific concerns about mailing lists and session schedules at our conferences. We appreciate the opportunity to submit comments.
Medical/healthcare association			Thank you for the opportunity to provide feedback.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Medical/healthcare association			The Alliance suggests the addition of the words “in the Health Professions” to the title of the standards. Regarding determining whether an entity is eligible or ineligible, we urge the ACCME to develop a rubric or other guidance to assist in gathering information to make that determination. Regarding relevance to content, education on how to web search for products and indications, find and interpret a research pipeline, determine if human trials have begun and/or other entry into an FDA process of clearance/approval, etc. The Alliance asks for consideration of a change in the use of the term “accredited continuing education” to “certified continuing education”. Organizations are accredited as providers or approved as sponsors (APA); activities are certified by accredited providers. There are very few directly accredited activities offered in any profession within the US. The Alliance recommends a phase in period of 2 years, many activities have a planning horizon of 18 months or more and this would allow for development of processes and education needed to effectively implement the changes included in the revised standards. There should also be clarity on whether or not already launched activities that bridge the date of final implementation need to be retro fitted to comply with these requirements. If substantive changes are made by the ACCME as a result of comments received, a second short comment period prior to final approval might be wise.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Medical/healthcare association			The AMA Council on Medical Education recommends the ACCME reconsider its intent to change the naming of these regulations to "Standards for Integrity and Independence in Accredited Continuing Education." Specifically, we are concerned about the complete removal of the word 'Medical' from what may be considered the ACCME's most important document. Accredited education is not unique to physicians, or even to the health professions, and are concerned that removing a clear focus on this word dilutes the critical role of education in our profession. After all, "Continuing Medical Education" are the three most important words that comprise "ACCME." The Council understands the need to be inclusive of all health professions and actively supports the ongoing efforts to optimize health professions continuing education through Joint Accreditation (JA). We recognize that these standards form the backbone for JA and that calling out "Medical Education" is not inclusive of other professions. However, the Council believes that many accredited providers will never pursue JA and thus still work to advance medical education. Thus, the ACCME must not lose sight of its accountability to the medical profession and include Medical in standards. The Council appreciates the opportunity to provide comment and suggestions regarding the revised Standards. This is a difficult area to navigate and the hard work and effort of the ACCME Board and staff is apparent in these revisions.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Medical/healthcare association			We applaud the ACCME in its efforts to strengthen the SCS. We believe with our suggested changes that the ACCME will be able to accomplish its mission and help the overall CME community gain a better understanding on how to implement the new Standards. Revise title to include: "…for the Health Professions" We are concerned that the use of the term "non-accredited" education sends a message that only accredited CE is of value. Independent non-accredited CE may exist without credit for a variety of reasons including lack of easy access to an accredited provider, financial cost of credit issuing, time and resources of staff to complete required processes/paperwork, none of which devalue the legitimacy of the content. While we recognize that ACCME is responsible for maintaining the integrity of accredited CE, we would urge insertion of wording in the introduction to the Standards to describe two types of education that fit into the non-accredited bucket: "independent non-accredited education and marketing/promotional presentations." We agree that there needs to be an indication to the learner of which type of education is being presented and that separation of these from accredited education is prudent. We support the change from CME to CE. However, many of our members envisage this change will cause confusion. Finally, when ACCME issues future FAQs on its Standards policies, we recommend that they number the FAQs one number per question, and include the date issued.
Medical/healthcare association			We support the intent of the new standards. We have concerns as stated above related to logistics of time/space and mailing lists that do not need to impact the spirit of the standards. We have questions about wording that needs to be clarified or there will be continued confusion and the need for FAQs for clarification.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Nonaccredited CE provider			Not having seen any of the previous guidelines, I think that the committee has done some good work to ensure that commercial influences are not taking over the realm of CME. I would urge that the committee NOT change the language from "CME" to "ACE" in order to preserve emphasis on Medical education at the center of the activity. I think that the language regarding "Validity of content" is troubling on many fronts as mentioned in my comments. My belief is that the ACCME's responsibility is to ensure that continuing education remains untethered from commercial interests, and that it allows emerging groups conducting clinically relevant and well-supported topics to be presented to a variety of providers in order to advance the entire field of medicine. The emphasis on "generally accepted" is deeply disturbing, as no advance in clinical practice ever came from only offering the status quo. No one leads from the middle.
Nonaccredited CE provider			Providers are “Accredited” and Activities are “Certified”. The intent of changing “Continuing medical education” to “accredited continuing education” may have been to be inclusive of disciplines other than physicians and to clearly distinguish "CME/CE" from non-accredited activities. Perhaps an alternative is using the terms “Certified Continuing Education” and “Non-Certified Continuing Education.”

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: Accredited CE provider, Continuing education accrediting body, and medical/healthcare association			Revise title to include: "…for the Health Professions" We are concerned that the use of the term to "non-accredited" education throughout the document sends a message that only accredited CE is of value. Independent non-accredited CE may exist without credit for a variety of reasons including lack of easy access to an accredited provider, financial cost of credit issuing, time and resources of staff to complete required processes/paperwork, none of which devalue the legitimacy of the content. While we recognize that ACCME is concerned and responsible for maintaining the integrity of accredited CE, we would urge insertion of wording in the introduction to the Standards to describe two types of education that fit into the non-accredited bucket: "independent non-accredited education and marketing/promotional presentations." We do agree that there needs to be a clear indication to the learner of which type of education is being presented and that separation of these from accredited education is prudent. We support the change from CME to CE. However, we envision that this change will cause confusion. Outside of the current independent healthcare educational environment, this change may make adherence to internal company compliance regulations problematic. For example, government and journalists will struggle with using the terms correctly and likely not make the proper distinctions necessary to accurately communicate the independence and value of "accredited CE."
Other: Answering both as accreditor and accredited provider.			The WSMA generally supports the changes except for Standard 4 and appreciates the simplifications. The narrative introduction to the Standards is excellent and provides concise context for activity Chairs who may be new to the planning process.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: Consultant			These standards don't really address the commercial bias I see every day as a medical writer who specializes in developing needs assessments for accredited CME. I'm not alone in seeing this bias, either: several other reports of bias and unethical practices were reported in a survey of writers of needs assessments in 2018. These practices included plagiarism, spinning the NA to favor the potential grantor's product, and making up faculty quotes, and making up outcomes data to please the target supporter. I also saw one instance in which the NA contained a quotation in favor of the target supporter's drug, and the speaker was an executive within the company from who support was being sought. Commercial bias in needs assessment is particularly egregious in response to RFPs issued by industry. What is being done to hold accredited providers' feet to the fire in this regard? Has anyone ever carried out a random audit of NAs written to support grant applications and specifically looked for signs of commercial bias? Something tells me it would be very easy to spot. We need to get this right because some in the medical writing field are beginning to talk about raising and training the next generation of CME writers. It's hard to explain to a student how, on the one hand, there's this great firewall protecting clinician learners from commercial bias, and then on the other hand if you want to win funding you have to spin your NA to favor the target supporter's product.
Other: Consulting company; licensed clinician			Please clarify what you mean by “accredited continuing education”. Throughout the document—even in its title—and throughout many of ACCME’s communications, you use this confusing terminology. Do you mean education developed by accredited providers? Providers are accredited to certify activities for credit; activities are certified for credit by providers accredited to do so. With a few notable exceptions, there are no accredited activities in the US. Do you mean education developed by accredited providers? Please clarify this language to ensure accuracy and alignment with standard terminology. Many providers work hard to have their staff and colleagues use correct terminology, and ACCME’s ongoing use of “accredited continuing education” is confusing and not helpful.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: I am a clinician-educator, board member of APPS, member of the Academic Consortium of Integrative Medicine and Health, and faculty provider for integrative medicine CME			As mentioned, I am supportive of raising the standards for all continuing education offerings. Since I am at Northwestern and near the ACCME, I had reached out to Dr. McMahon on behalf of the board of the American Board of Integrative Medicine- ABPS in our development of CME standards for maintenance of certification for the integrative medicine field. I was very disappointed that he declined to meet with me, as this does not indicate an effort on the part of the ACCME to work in good faith as partners in achieving the proposed standards. I would recommend having a fair and transparent process for review of ACCME review. The ACCME as the major arbiter of accredited CME should develop not only standards but actual resources and support for implementation. In addition, I would encourage the ACCME to include academic integrative medicine faculty to help develop these review processes and standards for the field. The Academic Consortium of Integrative Medicine and Health and the ABOIM are resources that should be used. Just as I, as an internist, would not feel it appropriate to judge dermatology standard of care, physicians who have completed advanced training in integrative medicine should be included to collaborate with the ACCME on developing appropriate accredited continuing education guidelines for this emerging field.
Other: I am both chair of an Accredited CE provider (WSMA CME Committee) and a member of the WSMA CME Accreditation Committee.			I assume the numbering of the standards will change when approved and somehow be incorporated into C7 potentially replacing the current numbering.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: Joint Provider			On a practical note, the term CME itself is embedded in legislation, hospital policy and reimbursement forms, etc. Have the implications of this type of language change been considered? As a member and representative of the integrative health community, we ask that a formal pathway be created, perhaps a committee that can include the voices of leaders from integrative medicine. We find that many of the new policies, as well as the recorded actions of ACCME formally and informally over the last 2 years has created an unnecessary divide. The change of the name from Continuing Medical Education to Accredited Continuing Education is highly noble to want to include all professions and elevate continuing education for all. However, it is at the same time concerning and could have unintended consequences if all stakeholders, new and old, formalized or not within the ACCME current structure, are not included. Many physicians and others have worked for decades to move forward the evidence-base of integrative health and are asking to be at the table of this conversation. Inviting that leadership in a meaningful way will only help ACCME modernize and truly be inclusive and interprofessional, address issues directly as well as build relationships instead of walls.
Other: MedChi is both an Accredited Provider and a Recognized Accreditor			The updating of the Standards is a worthy and important need to address. However, because the Standards have a deep effect on the entire accredited CME process, ACCME needs to work closer with the entire community and utilize the knowledge that each provider type, including the recognized accreditors in the state systems bring to the CME practice. Regulations cannot be developed in isolation from CME providers, specifically for the front-line CME personnel who will be charged with putting requirements into practice.
Other: physician, patient, member of certifying board, member of educational academy			truth is the principal issue. Answer, what does it take to get the patient well and keep the patient well? "Evidence-based medicine" derived from population studies does not necessarily tell me how to diagnose and treat my patient. more often than we realize, "N"=1 and an individual approach is appropriate, scientifically valid, and worthy of respect. Please do not make an absolute of the notion, "generally accepted within the profession of medicine."

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Other: Recognized accreditor and Accredited CE provider			Overall, there is much greater clarity with these revisions! Thank you.
Other: State Medical Society/Publisher/Accredited Provider/Recognized Accreditor			We sincerely appreciate the ACCME's commitment to update the Standards and ensure their relevance within our community. We would also like to thank the Task Force on Protecting the Integrity of Accredited Continuing Education for their work on this important project.
Patient, caregiver, member of the public			Focus on the "meat" of the standards before making unnecessary terminology changes.
Recognized Accreditor (state/territory medical society)			"Standards for Integrity and Independence in Accredited Continuing Education". The first part, Standards for Integrity and Independence, is more appropriate and communicates the intentions of the standards, however I don't agree with deleting "Medical" from the name. CME would still be appropriate even as we move toward inter-professional (medical professionals). CME has a definition. Something is lost by eliminating the word "medical".
Recognized Accreditor (state/territory medical society)			• Accredited continuing education: The term accredited continuing education replaces continuing medical education to be inclusive of all health professions. We include accredited to explicitly differentiate between accredited and nonaccredited education providers and education. "So now we can make our activities geared to nursing? LNAs? CMA? Is this leaning towards interdisciplinary continuing education? Rather than CME vs CNE? Will ACCME be changing its name then? Will we not call out activities CME activities?"
Recognized Accreditor (state/territory medical society)			As suggested by Tamar Hosansky, I will be selecting "Recognized Accreditor" in the "Demographic Information" section; however, MSSNY has a dual role in CME; we are also an ACCME-accredited provider.
Recognized Accreditor (state/territory medical society)			Consider changing “learners” to “participants” to match the term used in PARS.
Recognized Accreditor (state/territory medical society)			I am only concerned that one of my provider's accountant told them that by having to manage the commercial support as a whole (joint provider) makes them appear to IRS as with a higher income.

We welcome any additional feedback you may have about the proposed Standards for Integrity and Independence of Accredited Continuing Education.			
Organization Type	**Accreditor**	**Provider Type**	**Comments**
Recognized Accreditor (state/territory medical society)			I think the proposed standards as written is a job well done and quite thoughtful. The definition of new terms like eligible and ineligible entities and accredited continuing education are all good. I still think that mitigate is a compromising term to use instead of resolve as it is. Are we beholden to just one word? See comments about Standard 3.
Recognized Accreditor (state/territory medical society)			It would be helpful to have a “Definitions” list to go out with the new Standards, that providers and SMS can refer to clarify confusion and ensure equivalency with interpretation and education, as well as supplemental information/guidance and resources. Additionally, it would be helpful to create/update flowcharts. On behalf of CMA, overall much clearer and concise - thank you!
Recognized Accreditor (state/territory medical society)			Our team highly commends you on the way the standards have been reorganized, beginning with those applicable to all "ACE", followed by those that are generally supported. Provides GREAT clarification! Will ACCME be providing a list of new acronyms? (ex: CME vs. ACE)
Recognized Accreditor (state/territory medical society)			Redefining commercial interests as an ineligible entity is overkill. We are used to the term commercial interest. You can say a commercial interest is an ineligible entity, but changes in definitions can be problematic. The same goes for the word Mitigate. Unnecessary and confusing.
Recognized Accreditor (state/territory medical society)			The one area that still needs some work with sharpening the expectation involving the inventors that form start-ups that are really only pre-viable pseudo-companies. Many of these inventions never make it to market, and yet these inventors are considered 'employees' even when they don't receive salary.
Recognized Accreditor (state/territory medical society)			Working with commercial interests will be important. They do provide financial support for many activities and I think it is important to not treat them as "the big bad wolf." Having clear guidelines will be of utmost importance and recognizing time restrictions for some providers in terms of their ability to be compliant is also a consideration. I appreciate the simplification of the standards and I hope we can achieve greater clarity in a few areas moving forward.

AMERICAN ACADEMY OF FAMILY PHYSICIANS

February 18, 2020

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Re: ACCME Call for Comment: Standards for Integrity and Independence in Accredited Continuing Education

Dear Drs. Zanolli and McMahon:

On behalf of the American Academy of Family Physicians (AAFP), I am outlining the recommended revisions to the draft standards proposed in the ACCME Call for Comment: Standards for Integrity and Independence in Accredited Continuing Education.

The American Academy of Family Physicians is the national medical association representing 134,600 family physician and medical student members in 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and Guam, as well as internationally. It is the only medical society devoted solely to primary care. Family physicians conduct approximately one in five office visits – that is 193 million visits annually – 67 million more than the next largest medical specialty.

The AAFP exists to support family physicians so they can spend more time providing quality, cost-effective patient care. In 1947, the AAFP created the nation's first continuing medical education (CME) credit/accreditation system to emphasize the importance of physicians engaging in lifelong learning and CME. The AAFP continues to accredit over 19,000 educational sessions each year produced by more than 1,250 CME provider organizations nationwide. AAFP members alone report more than seven million AAFP credits each year.

The AAFP was an integral member of the original task force charged with establishing the ACCME Standards for Commercial Support (the Standards) in 1992 and was a member of the 2004 task force established to consider revisions to the Standards. Since its inception, the AAFP has adopted the Standards as its own, which is reflected in the AAFP Credit System Eligibility Requirements.

The AAFP takes this call for comment on the proposed revisions to the Standards seriously and appreciates the ACCME continuously engaging the AAFP for feedback throughout this process. Overall the Standards are achieving what they were created to accomplish. Our recommendations are based upon our robust experience reviewing and auditing thousands of AAFP accredited educational sessions against the Standards and feedback elicited from members and CME provider organizations that apply for AAFP credit.

New Name

The AAFP appreciates the change to the name of the Standards and believes it will positively shift away from the perception that the Standards are only for commercially supported activities.

Eligibility

The AAFP appreciates the ACCME efforts to address accredited provider eligibility given the extent to which the external environment has changed since the definition of a commercial interest was last reviewed. The AAFP agrees that determining accredited provider eligibility lies with the Accreditor. The AAFP also believes that the definitions of eligible and ineligible entities have a broader impact than defining which organizations are eligible for accreditation. They are the underpinning of the standards, and providers utilize them on a daily basis in the planning and implementation of their accredited education. While the definitions may be sufficient for the ACCME to determine the eligibility of an organization, they do not empower accredited providers to make the decisions necessary to develop independent accredited education. Given the changing landscape, the AAFP acknowledges there will always be some organizations for which it will be more difficult to determine eligibility and, thus, require significant review and evaluation; however, those types of organizations should be in the minority. In order to provide clarity, the AAFP strongly recommends that the ACCME create additional implementation tools and guidance on these definitions and examples**. Specifically, the ACCME should more clearly define *primary business* and how the definition is to be used.** As an example, would an organization be ineligible if it does not meet the definition of an ineligible entity because its primary purpose is not producing marketing, selling, reselling or distributing healthcare products used by or on patients, but does meet one of the examples of ineligible entities? Examples of this would be a provider of clinical services directly to patients that also sells dietary supplements in their office, or a technology company whose primary business is not healthcare but does make a health-related wearable device.

Standard 1: Ensure Content is Valid

In general, the AAFP supports the changes made to Standard 1, specifically Standard 1.4 and applauds the ACCME efforts by which these changes bring ACCME and AAFP standards into further alignment on content eligibility.

Standard 1.2

It is important to recognize that accredited CME includes clinical and nonclinical topics. While the AAFP supports the ACCME guidance on clinical content, the AAFP

recommends the ACCME also require that nonclinical content be held to similar expectations. Additionally, the AAFP noted that the ACCME definition of CME is inclusive of nonclinical topics and was not mentioned in the ACCME requirements. As such, the AAFP recommends revising proposed Standard 1.2 as follows:

(Language that is deleted is indicated by ~~strikeout~~. New language is indicated by bold, double underscore.)

*Accredited education must ~~give a~~ **be** fair and balanced **and comply with the ACCME definition of CME** ~~view of all diagnostic and therapeutic options~~.*

Standard 1.5

The AAFP supports Standard 1.5 and recommends it be moved to the Eligibility section.

Standard 2: Prevent Marketing or Sales in Accredited Continuing Education

The AAFP recommends revisions to the title of Standard 2 to appropriately reflect that the intent is broader than just the prevention of marketing or sales in accredited education. Accredited education should also be independent from the influence of an ineligible entity. The AAFP recommends the title of Standard 2 be modified as follows:

***Protect the Independence and** Prevent Marketing or Sales in Accredited Continuing Education*

Standard 2.1

The AAFP believes it is the intent of the ACCME to prohibit ineligible entities from recommending or selecting faculty in accredited education. The changes made to standard 2.1 no longer explicitly state this and the AAFP believes this expectation is no longer clear. The AAFP recommends the following revisions to Standard 2.1:

*The accredited provider must ensure that all decisions related to the planning, **faculty selection**, delivery, and evaluation of accredited education are made without any influence or involvement from the owners or employees of an ineligible entity.*

Standard 2.2

The AAFP appreciates the ACCME changes to Standard 2.2 to address all promotion in CME. The AAFP believes that accredited CME should be a safe space for learners that is free from promotion, not just promotion from Commercial Interests or Ineligible Entities.

Standard 2.3

The AAFP agrees that accredited providers should not share learner data without their consent. Further, the AAFP believes understanding and complying with the details of applicable data sharing law/regulations is a standard business practice and expectation of a CME provider organization that does not need oversight or regulation by accreditors. As written, the AAFP believes Standard 2.3 puts undue burden on the

accreditor determining compliance and on the provider to comply with an additional standard that may not align with other requirements to which they must comply. When a learner grants permission for their data to be shared, the onus should be on them to understand what will be shared, with whom it will be shared, and how it will be used. As such, the AAFP strongly recommends the following revision to Standard 2.3:

> *The accredited provider must not share the names and contact information of learners with any ineligible entities or their agents without the explicit consent of the individual learners ~~each time the data is to be shared. This consent must include the name of the ineligible entity receiving the learner information and describe how the entity intends to use the information.~~*

Standard 3: Identify, Mitigate, and Disclose Relevant Financial Relationships with Ineligible Entities

The AAFP appreciates the manner in which the ACCME has broken down the steps to Standard 3 and for integrating current requirements and FAQs into one location.

It is the AAFP's interpretation that the term *conflict of interest* would no longer exist and would now be referred to as a *relevant financial relationship*.

Standard 3.1

The AAFP supports the change to Standard 3.1 in requiring providers to collect from their content controllers *all* financial relationships with ineligible entities. Additionally, the AAFP recommends the following addition to the disclosure information collected in order to assist providers in identifying relevant financial relationships:

a. *The name of the ineligible entity with which the person has a financial relationship*
b. *The nature of the financial relationship.*
c. ***The topic area of the financial relationship.***

Standard 3.3

Additionally, the AAFP recommends the following revision to Standard 3.3 to provide additional clarity about current expectations:

> *Identify relevant financial relationships: Review the information about financial relationships to determine which relationships are relevant. Financial relationships are relevant if the educational content **an individual can control** is related to the business lines or products of the ineligible entity.*

Standard 4: Manage Commercial Support Appropriately

Standard 4.1

The AAFP interprets Standard 4.1 as follows: The AAFP considers the accredited provider to be the CME provider organization applying for AAFP credit. In the scenario

where the provider is only seeking AAFP credit, the organization that applied for credit would be the *accredited provider* and thereby would be responsible for all decision making and disbursement regarding commercial support as described in Standard 4. Likewise, if for an accredited CME activity there are two accredited providers collaborating and one provider serves as the ACCME accredited provider of record and the other serves as the AAFP accredited provider of record, it is the AAFP's interpretation that either the AAFP or the ACCME accredited provider could serve in this capacity and be compliant with Standard 4.

Standard 5: Manage Ancillary Marketing Around Accredited Continuing Education

Standard 5.2

It is the AAFP's understanding that the ACCME intends to define nonaccredited education as all education that is not accredited. This could include marketing, sales, or other promotional activities developed by or with influence from ineligible entities as well as nonaccredited educational information and resources developed independently by an accredited provider or eligible entity. The AAFP agrees learners should be able to easily distinguish between accredited education and all other activities, both educational and promotional. The AAFP also agrees that marketing, sales, or other promotion should not occur in the physical space immediately before or after accredited education in order to further emphasize this distinction. **The AAFP does not agree that independent, non-promotional, yet non-accredited education must be separate from accredited education.** Education that is not accredited cannot be assumed to be inherently bad, it simply means it was not explicitly designed to meet the accreditor's requirements.

An example of this would be a legislative update, membership update, or wellbeing exercise presented in between accredited presentations. This type of important non-accredited education should not have to be artificially segregated from accredited CME. Learners benefit from all types of accredited and non-accredited activities at live events and as long as the learner can clearly distinguish between these types of activities, it should be left to the learner to make these informed decisions. As a physician, the proposed language would negate education that I attend and find valuable at accredited educational conferences.

The AAFP accredits individual CME activities including evaluating each individual session/topic covered within an accredited activity. There are times when the AAFP may deny some sessions while approving others within an accredited activity. Some of the sessions denied may be developed independently and free from influence from an ineligible entity but are denied because they do not meet AAFP's eligibility requirements for accredited CME. **The AAFP believes that if quality, independent non-accredited education is clearly identified as non-accredited CME to learners, it should not have to be separated.** If this standard is implemented as currently written, the AAFP may no longer adopt the Standards as our own and instead establish our own standards on independence. This regression in harmonization would be at the detriment of the CME community. **As such, the AAFP views this as a very critical issue and strongly recommends modifying Standard 5.2.a as follows:**

The accredited provider must ensure that learners can easily distinguish between accredited education and other activities, such as nonaccredited education and marketing.

a. Live continuing education activities: Marketing, exhibits, and nonaccredited education ***developed by or with influence from an ineligible entity*** *must not occur in the physical space immediately before or after an accredited education activity, and must not be interleafed within the accredited education. Learners must not be presented with product promotion or product-specific advertisement while engaged in accredited education and must not be required to interact with representatives of ineligible entities.*

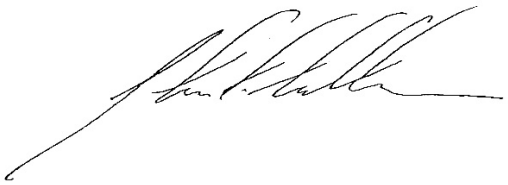
Standard 5.3

It is the AAFP's expectation and interpretation that there are no changes to the requirements for journal advertisements.

We look forward to continuing to discuss this important issue with the ACCME. It is the AAFP's fervent hope that the AAFP and ACCME will be able to work together on mutually agreeable revisions to the Standards so the AAFP can continue to adopt the Standards as its own. Please contact Amy Smith, Director of Continuing Professional Development Accreditation at 913-906-6057 or amys@aafp.org with questions or concerns.

Thank you for your consideration.

Sincerely,



John S. Cullen, MD, FAAFP
Board Chair
American Academy of Family Physicians

CK/AS/cmc

cc: Amy Smith, MBA, AAFP Director of CPD Accreditation
Norman Kahn, MD, Co-Chair, Task Force on Protecting the Integrity of Accredited CE
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February 20, 2020

Graham McMahon, MD
President and Chief Executive Officer
Accreditation Council for Continuing Medical Education
401 N. Michigan Ave., Suite 1850
Chicago, IL 60611

Dear Dr. McMahon:

Thank you for the opportunity to submit comments on the proposed Standards for Integrity and Independence in Accredited Continuing Education on behalf of the Council of Medical Specialty Societies. While we expect that many of our 46-member societies will submit individual letters to ACCME, we wanted to highlight the major themes that have emerged from our Continuing Professional Development (CPD) constituency's discussions. Additionally, we wanted to address overarching harmonization issues of importance to CMSS and its member organizations.

Major themes for CMSS response to ACCME's Call for Comment on proposed Standards

Eligibility
CMSS suggests aligning the definition of an "ineligible entity" with the CMSS Code for Interaction with Companies definition of "company." ACCME should also more clearly define "primary business" and how the definition is to be used. See alignment section below for further details. To ensure transparency throughout the processes of implementation and reaccreditation, actionable specificity is needed in the standards, including for terms such as "owner," "employee," and "executive role."

Standard 1.4
Accredited providers (eligible entities) can effectively teach about how to consider use of emerging approaches to diagnosis and/or treatment modalities that are controversial or not generally accepted. Our accredited providers have the ability to present and discuss these innovative practices and cutting-edge advances without advocating for their use. Learners benefit from accessing this information in a non-biased manner through accredited continuing education (CE), following ACCME and other requirements for balance and scientific evidence. Recognizing the rapid pace of change, it is critical that specialty societies provide an alternative to learning about new technologies and treatments solely from the companies that develop them.

Standard 2.2
Our societies request that ACCME specify its intent with this standard. In this rapidly changing health care environment, ACCME should clarify whether this proposed standard relates solely to products/services that are used by or on patients (which aligns with the definition of "ineligible entity"), or whether faculty should also refrain from marketing of books, consulting services, or other non-medical products and services. It would be helpful for ACCME to provide examples related to this Standard.

Standard 2.3
Our member societies agree that accredited providers should not share learner data without their consent. Accredited providers must obey all applicable laws governing privacy and sharing of personal information. As written, Standard 2.3 puts undue burden on the accreditor to determine compliance. The issue should be managed/developed by the eligible entities within already existing legal parameters.

Standard 3
CMSS member societies expressed concern with the documentation that would be required to demonstrate how accredited providers determined relevance from all disclosed financial relationships with ineligible entities and how they subsequently mitigated those relevant financial relationships. Some of our member societies have already moved toward universal disclosures across all society-related activities. In addition, some member societies expressed concern regarding the lack of a reasonable threshold for financial disclosures.

Standard 4.1
Members raised concerns with how accredited providers would need to disburse all commercial support and pay/reimburse expenses of planners, faculty, and others in control of content in jointly provided activities. This standard could unnecessarily interfere with accounting and logistics of accredited programs. To maintain compliance with ACCME standards for commercial support at jointly provided activities, the Standard could be revised to permit an accounting or oversight of the commercial support by the accredited provider.

Standard 5.2.a
Further clarification is needed with some terms used in this Standard related to live CE activities:

- Physical space: would this encompass a specific meeting room, a hall, and/or convention center?
- Immediately: how much time would need to elapse between sessions?
- Interleafed: This term is more synonymous with journals; a preferred term for live activities would be sequential or concurrent.

As referenced in Standard 5, "nonaccredited education" does not necessarily mean that the content is promotional or that it is being delivered by an ineligible entity. Rather, there are times when accredited providers choose to develop and deliver clearly identified high-quality, independent nonaccredited education, such as posters or town halls, in conjunction with accredited content. These nonaccredited activities should not have to be separated. If ACCME's intent is to better distinguish accredited education from promotional content developed and delivered by ineligible entities, that should be clearly specified.

Opportunities for Alignment and Harmonization

CMSS strongly encourages the ACCME to take this opportunity to align these Standards with the CMSS Code for Interaction with Companies and the proposals from the Working Group on Uniform Disclosure, led by the Association of American Medical Colleges (AAMC) in cooperation with American Society of Clinical Oncology (ASCO), Journal of the American Medical Association (JAMA), and CMSS. There would be significant benefit to individual researchers and authors who submit to journals and serve as CME planners, faculty and abstract authors to have a consistent standard across required disclosures. Learners would also benefit from consistent disclosure standards.

ACCME definition of "ineligible entity" and CMSS definition of "company"
For reference, the definition of "company" from the CMSS Code for Interaction with Companies is:

"For-profit entities that develop, produce, market or distribute drugs, devices, services or therapies used to diagnose, treat, monitor, manage, and alleviate health conditions." The following changes would bring the ACCME definition of ineligible entity into closer alignment:

- Consider that the word "company" may be clearer to both providers and patients than "ineligible entity
- Include the verb "develops" in ACCME's definition, which would more closely tie with the listing of bio-medical startups in ACCME's list of ineligible entities.
- Noting "for-profit" in the definition would be a clear descriptor to help providers and others distinguish companies from eligible entities, since the ACCME notes specifically that nonprofit organizations are considered eligible.
- Expand "healthcare products used by or on patients" with "drugs, devices, services or therapies used to diagnose, treat, monitor, manage, and alleviate health conditions." Again, this definition would more closely align with the listing of marketing/communication firms whose business centers on services rather than products.

ACCME alignment of disclosure look-back period

Standard 3.1 notes that information should be collected about all relationships with ineligible entities from the past 12 months. The latest draft from the AAMC Working Group on Uniform Disclosure for submission to medical journals proposes a 24-month look-back period for collecting information on relationships with companies. Although the focus of the AAMC Working Group has been on author disclosures in submissions to medical journals, extending uniform disclosure criteria to CME planners and faculty would be of great benefit to the research and education communities.

Harmonization of disclosure categories

Standard 3.1b provides examples of disclosure categories but does not provide a strict categorization to follow. Society volunteers have provided consistent anecdotal feedback that it is a significant burden to ensure complete and accurate disclosures when categories vary across organizations. Similar to the benefits of harmonizing the look-back period, it would be a marked improvement if physicians and others participating in CE, journal publications and other activities that require disclosure could have a consistent approach to documenting relationships with companies.

The AAMC Working Group have proposed a harmonized disclosure form and have also been in discussions with the ICMJE as they are considering an update to their disclosure form as well. The CMSS Task Force on Disclosure Harmonization will work toward uniform disclosure across all society activities. An ACCME endorsement of a harmonized disclosure form would greatly increase the likelihood of its wide adoption, to the ultimate benefit of learners and audiences.

Again, thank you for the opportunity to submit comments on the proposed Standards for Integrity and Independence in Accredited Continuing Education on behalf of CMSS. CMSS, its 46 members, and the 800,000 US physicians they represent look forward to working closely with ACCME to ensure high-quality continuing education. To discuss this letter, CMSS's comments, or CMSS, please contact me.

Sincerely,

Helen Burstin, MD, MPH, MACP
Executive Vice President and CEO
Council of Medical Specialty Societies

February 21, 2020

Tamar Hosansky
Vice President of Communications
Accreditation Council for Continuing Medical Education
thosansky@accme.org

Re: SACME Response to Proposed Standards for Integrity and Independence in Accredited Continuing Education

Dear Tamar,

You and the Council invited stakeholders to participate in commenting about the proposed revisions to the rules that protect the independence and integrity of accredited continuing education for healthcare professionals. First adopted in 1992, the Standards were last updated in 2004.

As a spokesperson for the Society for Academic Continuing Medical Education (SACME), I had the Board of Directors review all of the proposed revisions. Much of these revisions related to clarifications, simplifications, and new terms or structure. The proposed standards nicely summarized these changes in each of the five standards.

Overall, the SACME Board found the revisions by the Task Force on Protecting the Integrity for Accredited Continuing Education to be very appropriate. We had no difficulty with the wording and intended meaning. For each of the 5 standards, we found no need for modifications and did not foresee any additional challenges or unintended consequences in implementing each revised standard.

The next page mentions some specific comments for your awareness. Let me know if you wish for me to pursue any additional perspective from the Society about this revised document which has become a model, adopted by accreditors across the health professions.

Best wishes,

Bill

William Rayburn, MD, MBA
President
Society for Academic Continuing Medical Education

Noteworthy Positives

- Agree with the new name, new overview, and brief introductions
- Agree with four new terms
- Standard 1: point 4 (approaches to diagnosis or treatment that are controversial or not generally accepted…)
- Standard 2: point 3 (not share names and contact information of learners with any ineligible entities…)
- Standard 3: point 1b (individual stocks and stock options should be disclosed; diversified mutual funds do not…)
- Standard 3: points 2 a, b, c (three exceptions to this exclusion- employees of ineligible entities can participate as planners or faculty…)
- Standard 4: point 1a (ineligible entities must not pay directly for any of the expenses related to the education or the learners)
- Standard 5: point 4 (disclose to the learners the name of ineligible entities…about the nature of the support if it was in-kind…)

Areas for Further Discussion

- Eligibility: organizations that may be accredited: pharmacies; organizations that cannot be accredited: compounding pharmacies
- Eligibility: organizations that may be accredited: technology or data management companies…non-health related (explain, examples)
- Standard 4: Accredited providers must pay or reimburse expenses to individual such as faculty, joint providers cannot make these payments (may be an issue)
- Standard 5: points 1 a, b, c (be prepared to clarify)
- Industry and medical schools often work together in research. It is unfortunate for certain industry-sponsored research-related education to not be given credit