

Standard 1: Independence

[Review Standard 1 here.](#)

What new or existing challenges have you seen related to the separation of accredited CE from commercial influence that the ACCME should address? (1,500 character limit; about 250 words)

The CME Coalition supports both the spirit and wording of the current Standard 1. This Standard is the bedrock of independence.

Describe ways in which the ACCME should modernize the requirements about the independence of accredited CE from commercial influence to reflect the changing healthcare environment. (1,500 character limit; about 250 words)

The CME Coalition has no changes to suggest.

Standard 2: Resolution of Personal Conflicts of Interest

What new or existing challenges have you seen related to the identification and resolution of conflicts of interest in accredited CE that the ACCME should address? (1,500 character limit; about 250 words)

- A. In this complex era of evolution in the healthcare business sector, leaving the decision as to what to disclose up to the planner/author/faculty/reviewer may result in missed relevant financial relationships. For example, the FDA is still clarifying what smart-phone apps require FDA clearance as medical devices, and one can expect this to remain a moving target. While FDA involvement is not an ACCME criterion for deeming that something is a “healthcare product or service used on or by patients” requiring disclosure and resolution, a faculty member with a relationship with such a product/company may not perceive the app to be a healthcare product/service and not disclose the relationship. Or, the relationship may be with a food/supplement company that the discloser does not perceive to be a healthcare company, even though marketing claims refer to health and wellness benefits. These situations have the potential for relevant relationships to remain unknown to providers and learners, with no malicious intent on the part of the discloser.

- B. There is some confusion as to the role that “ownership” plays in deciding whether a conflict of interest (COI) is resolvable. While it is clear that ownership interest must be disclosed, the confusion arises from the flowchart developed in 2017 (see box B on the chart), which appears to state the ownership in any amount equates with employment by a commercial interest. Thus, one share of common stock would equal employment.

Describe ways in which the ACCME should modernize the requirements about identification and resolution of personal conflicts of interest to reflect the changing healthcare environment. (1,500 character limit; about 250 words)

- A. The CME Coalition supports a change in wording regarding disclosure of financial relationships to include ALL relationships, in any amount, within the past 12 months, with any entity that produces, markets, sells, resells, or distributes healthcare products used on or by patients, not just relevant relationships. The accredited provider would then need to determine which of those relationships are relevant to the content being controlled. Only those relationships deemed relevant to the content by the accredited provider, and thus creating a COI, would require resolution and disclosure to learners.
- B. Either delete the “ownership” mention in box B of the flowchart or establish some reasonable limits on when ownership would interfere with the ability to participate in control of content. For example, being a sole proprietor or partner in the ownership of a business would be a substantial COI that would require recusal. At what point would stock ownership be such a barrier? The Securities and Exchange Commission sets 5% ownership as the criterion for “beneficial ownership” that must be publicly reported. We agree that any amount of ownership, other than shares held in mutual funds, creates a COI that must be resolved and disclosed to learners, and the 5% level appears to be a reasonable criterion for the point at which independence may be compromised and recusal is needed. The ACCME does not currently ask for the dollar amount of any relationship, and we support continuing that, with the exception of adding a question about degree of ownership.

Standard 3: Appropriate Use of Commercial Support

[Review Standard 3 here.](#)

What new or existing challenges have you seen related to the appropriate management of commercial support of accredited CE that the ACCME should address? (1,500 character limit; about 250 words)

The CME Coalition membership is diverse, including representatives from all sides of the CE enterprise. As such, we appreciate the requirements of various stakeholders to demonstrate the impact and effectiveness of CE activities - e.g. measurement of at least competence/acquisition of skills/strategies as the ACCME/Joint Accreditation minimum vs. a commercial supporter wanting to fund only activities that have assessment of outcomes of a different minimum level, which may be set higher than change in competence. This can create differences in expectations or understanding of the

nature of independence in the area of evaluation and outcomes. Providers have the option to not seek funding from a particular grantor if the design of an activity does not allow for measurement to at least the grantor's desired level. The challenge arises when providers perceive that any limitations by the grantor oversteps the bounds of independence, while grantors do not perceive that they are prescribing methodology, but only desired level of assessment, along with expectations of as to requirements for reporting participation and satisfaction results.

Describe ways in which the ACCME should modernize the requirements about appropriate management of commercial support of accredited CE to reflect the changing healthcare environment. (1,500 character limit; about 250 words)

It would be helpful if ACCME would clarify what is meant by the provider controlling the evaluation of the activity (as stated in Standard 1). Can commercial supporters require, as a condition of funding, that grant requests for activities must include a commitment to assess participant outcomes to a minimum level, without specifying the methodology of how competence, performance, patient outcomes, or public health is to be measured, as a condition of funding? The ACCME should issue a "clear" FAQ or guiding principle that if/when a supporter says – as a matter of their policy – they only support activities with certain outcomes, that does NOT constitute control/influence. It is in the interest of all parties to develop educational activities that have the desired impact on learning and change. The CME Coalition supports efforts to allow competitive and comparative analysis of the effectiveness of education by grantors, providers and accreditors.

Standard 4: Appropriate Management of Associated Commercial Promotion

[Review Standard 4 here.](#)

What new or existing challenges have you seen related to the appropriate management of associated commercial promotion that the ACCME should address? (1,500 character limit; about 250 words)

Recent refinements of the ACCME position on separation of commercial promotion from independent continuing education **at live activities** has led to some challenges for providers. The CME Coalition supports upholding not only the letter of the requirements but also the spirit of separation. That said, some clarification appears needed.

Specifically:

- There is a perception that nothing that is not certified for credit can occur on the same space

as the certified live activity. 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.

- We agree that content that does not meet the content validity requirements of CME/CE cannot be intermingled on an agenda and should not be presented at any time in conjunction with certified CE content.
- Definitively, what can be in the “conference bag” handed out in the registration area of an activity or conference? Can promotional material with logos and product images be included in the “stuffing” of the bag as long as it is not included in documents transferring educational content to the learner- or on the exterior of the bag?

Describe ways in which the ACCME should modernize the requirements about appropriate management of associated commercial promotion to reflect the changing healthcare environment. (1,500 character limit; about 250 words)

We understand that ACCME does not wish to establish a minimum time separation in the same space, when such it necessary based on facility arrangements. However, we suggest that the following constructs be adopted in a policy statement:

- No intermingling of promotional and certified content on an agenda in the same educational space, without adequate separation in **time**
- Enough time between the end of one type of content to allow participants to gather material and leave if they choose to do so. This will be determined by the size of the audience and the nature of the activity. It should be generously estimated, rather than assuming participants will immediately end any discussion with peers and proceed to exit. Providers should document in the activity file their rationale for selecting the duration of the break for that specific circumstance.
- Clear notice to learners, through signage, audio-visual means and from the podium, at the start of and end of any promotional or certified session when there is a transition of content type (promotional to certified or *vice versa*)
- **Promotional educational activities may occur simultaneously with certified content, as long as they are in separate spaces and are not competing for the same audience (e.g. there are separate tracks in a conference with differing time slots so that one audience has free time, while another has a CE session)**
- Written clarification in policy as to what is allowed to be included (or what must be excluded) in conference bags/lanyards/badges.

Standard 5: Content and Format without Commercial Bias

[Review Standard 5 here.](#)

What new or existing challenges have you seen related to accredited CE content and format without commercial bias that the ACCME should address? (1,500 character limit; about 250 words)

When developing an activity related to medical devices, it is difficult to report on evidence without reference to the actual device by brand name in order to distinguish it from other similar devices (e.g. total hip replacement systems, pacemakers and cardiac leads). And, for some audiences, a link to the brand name once in the content of a pharmaceutical agent may be needed to help the learner understand the content. This is particularly more likely to happen in team-based education, where not all team members are familiar with generic names. Currently, Standard 4 prohibits use of trade names in educational content, whereas Standard 5 indicates that trade names should not be used, indicating to the savvy reader that this is not an absolute prohibition (which would have used the term “must”), and instructions are provided should trade names be needed. Providers are confused by these two opposing views.

Describe ways in which the ACCME should modernize the requirements about accredited CE content and format without commercial bias to reflect the changing healthcare environment. (1,500 character limit; about 250 words)

The CME Coalition requests that the ACCME consider editing the language of Standard 4.3 to exclude “trade names” or otherwise revise to remove conflicting statements of expectations.

We also suggest the development of an FAQ that provides clear examples of reasonable use of trade names. Trade names inclusion must also be at the discretion and approval of the accredited provider.

Standard 6: Disclosures Relevant to Potential Commercial Bias

[Review Standard 6 here.](#)

What new or existing challenges have you seen related to disclosures relevant to potential commercial bias in accredited CE that the ACCME should address? (1,500 character limit; about 250 words)

The CME Coalition has not identified any challenges with regard to implementing Standard 6.

Describe ways in which the ACCME should modernize the requirements about disclosures relevant to

potential commercial bias in accredited CE to reflect the changing healthcare environment. (1,500 character limit; about 250 words)

The CME Coalition supports the current wording.

Policies Supplementing the Standards for Commercial Support: Standards to Ensure Independence in CME ActivitiesSM

ACCME Policy: Definition of a Commercial Interest

Current definition: A *commercial interest* is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The ACCME does not consider providers of clinical service directly to patients to be commercial interests - unless the provider of clinical service is owned, or controlled by, an ACCME-defined commercial interest.

[Review the complete policy here.](#)

What new or existing challenges have you seen related to the ACCME definition of a commercial interest that the ACCME should address? (1,500 character limit; about 250 words)

ACCME and ANCC currently consider retail pharmacies to be commercial interests and, therefore, pharmacists who work for these pharmacies are employees of a commercial interest, with all of the limitations on planning, teaching, and other involvement in CME. ACPE does not have this restriction. Several factors lead the CME Coalition to identify this as a challenge:

- The evolving role of the retail pharmacist in providing direct care to patients under collaborative agreements with physicians. This includes but is not limited to recommending and implementing immunizations for teens and adults in most states; routine monitoring and titration of medication response for chronic diseases such as type 2 diabetes; and counseling patients on management of minor side effects of agents. In other words, they are providing more direct care than specialty pharmacies, who are exempt unless they are owned/controlled by a commercial interest.
- The everchanging business scene, with CVS buying Aetna- making that insurance carrier no longer exempt, in all probability; Amazon buying PillPack.
- The growth of team-based education- with the community pharmacist being a key link in public health initiatives such as influenza and pneumococcal immunization campaigns. Excluding the retail pharmacist from participation as planner/faculty disrupts peer to peer learning and may leave key effective strategies to overcoming barriers to immunization unexplored
- Confusion for Jointly Accredited providers as to who can and who cannot be planner/faculty when ACPE credit is offered, since there is supposed to be only one set of criteria for all JA accreditors

Should the ACCME definition of a commercial interest be:

Expanded

Narrowed

Unchanged **Yes**

Please explain. (1,500 character limit; about 250 words)

The definition is sufficient as written. It needs to be sufficiently generic and applicable, given the ever-changing nature of products and services.

Should the list of organizations that are not defined as commercial interests and therefore are

eligible for accreditation be modified?

Yes

No

Please explain. (1,500 character limit; about 250 words)

The CME Coalition requests that retail pharmacies be included in the list of exempt organizations to reflect the evolving role of the retail pharmacy and pharmacist. See comments above.

ACCME Policy: Financial Relationships and Conflicts of Interest

[Review the policy here.](#)

What new or existing challenges have you seen related to the ACCME policy on financial relationships and conflicts of interest that an evolved policy should address? (1,500 character limit; about 250 words)

Should the ACCME definition of financial relationships and conflicts of interest be:

Expanded **Yes**

Narrowed

Unchanged

Please explain. (1,500 character limit; about 250 words)

The CME Coalition suggests that ACCME expand the Policy to incorporate the discussion of ownership as a COI as noted above in our comments on Standard 2.

Additional Feedback

Are there additional standards or policies that would help to ensure that accredited CE remains independent of commercial influence and free of promotion and marketing activities? (1,500 character limit; about 250 words)

The CME Coalition suggests the need for a policy statement, FAQ or new section of the SCS that addresses the separation of promotion from education on platforms such as apps, digital devices, or EHRs, as these delivery formats are rapidly developing and do not appear to fit into Internet-based or other current formats.

Also, for computer based activities (may need to change that term to be more inclusive of current technology), there appears to be a need to further clarify 2 points:

- Does Standard 4.2 also allow for links in the opposite direction, from commercial supporter site to educational site, as long as link is to a landing page other than the actual activity and the learner is provided clear notice to the learner of the change in websites?
- Can certified content and non-certified, but not promotional, content (such as news, opinion, or other editorial content developed independent of any CI) be hosted on the same web domain, as long as that site is not owned or controlled by a CI and the learner has clear notice of what is and what is not certified? The current technology allows for separation of content on distinct web pages within the same web domain, including controlling who has access to the various web pages, without requiring registration and branding of a separate domain just for certified content. Is this acceptable?

Are there modifications to the construct and organization of the Standards that would be helpful in ensuring independence? (1,500 character limit; about 250 words)

The CME Coalition supports the current construct and organization of the Standards.

Do you have recommendations for literature or research that we should review when considering changes to the Standards? (1,500 character limit; about 250 words)

Here is a link to the Securities and Exchange Commission website referencing the requirement to report beneficial ownership of outstanding equity of an entity (5% rule):

<https://www.sec.gov/smallbusiness/goingpublic/officersanddirectors>