

ALERT! ACCME's Call for Comment: Standards for Integrity and Independence in Accredited Continuing Education An Opinion Piece by a Chief Accreditation Officer

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©CloudCME, February 14, 2020

On January 7, 2020, ACCME notified accredited providers of its call for comment regarding the proposed revisions of its former *Standards for Commercial Support: Standards to Ensure Independence in CME Activities* (revised in 2004) provided in the information packet titled, *Standards for Integrity and Independence in Accredited Continuing Education*SM.

The ACCME Board of Directors will finalize the proposed *Standards for Integrity and Independence in Accredited Continuing Education*SM at its March 2020 meeting and will communicate a transition plan for implementation and compliance. These Standards will not only impact direct ACCME accredited providers but Joint Accreditation for Interprofessional Continuing Education™ accredited providers as well. Participation in this call for comment is important so your feedback is taken into consideration! **ACCME is accepting comments from stakeholders through February 21, 2020, at 5 PM, CST.**

Summary of the Significant Proposed Changes

This review provides insight to the significant proposed changes and does not include all proposed changes.

Because the Standards were last revised 15 years ago, the first change of note is the document title itself. The previous title, *Standards for Commercial Support: Standards to Ensure Independence in CME Activities*, changed to, *Standards for Integrity and Independence in Accredited Continuing Education*SM, reflects the ever-changing healthcare landscape. With the creation of Joint Accreditation™, the new title reflects a shift in focus strictly on continuing medical education to accredited continuing education that is inclusive across the healthcare professions.

Eligibility

(Formerly the Definition of a Commercial Interest)

This section will replace the current section titled, *Definition of a Commercial Interest*, and is comprised of two sections that define and provide examples of Eligible and Ineligible organizations that can or cannot be accredited by ACCME. In the expanded definitions and examples provided, less emphasis is placed on the terms non-profit and for-profit but in the organization's mission statement, function and organizational structure that determines eligibility as an accredited provider. The increased clarity provided is sure to reduce confusion that has been long-standing.

Standard 1: Ensure Content is Valid

(Formerly "Clinical Content Validation Policy")

The *Clinical Content Validation* policy has been renamed to *Ensure Content is Valid* and is no longer a stand-alone policy. While the three existing validity statements have wording modifications, it is significant that two additional statements have been added:

"Accredited education must give a fair and balanced view of diagnostic and therapeutic options.

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."

The first statement is clear – an accredited continuing education activity cannot merely include one diagnostic or therapeutic option but must address several scientifically accepted options. As no two patients are alike, one diagnostic or therapeutic option would not work for **all** patients.

The latter statement is significant in now allowing "diagnosis and treatment that are controversial or not generally accepted" to be included within accredited activity content but it cannot instruct healthcare professionals "how or when to use them." One has to ask, if the inclusion of controversial or not generally accepted diagnosis or treatment in accredited activities would be **perceived by** learners as advocacy to some degree? If we cannot teach learners how or when to use them, then what is the benefit in including this information in accredited activity content? Perhaps the feeling is that learners can further explore these options through self-learning for patient care decision-making.

Standard 2: Prevent Marketing or Sales in Accredited Continuing Education

(Formerly Standard 1 “Independence” and Standard 5 “Content and Format without Commercial Bias”)

There are three policy statements that make up Standard 2. The three policy statements include:

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 or involvement from the owners and employees of an ineligible entity.”

While the expectation has always been that decisions were made free of the control of commercial interests (i.e. ineligible entities) and that accredited providers own this responsibility, it is important to note that this policy specifically states “without any influence or involvement from the **owners** and employees of an ineligible entity.” While it has always been understood that employees of an ineligible entity could not influence accredited activities, now we see the need to specify owners as well.

2.2: “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.”

This policy statement recognizes the potential conflicts of interest when faculty include promotion of their own products or services in accredited education and prohibits this. Up to this point in time, *The ACCME Standards for Commercial Support* recognized and focused on conflicts of interest in relation to faculty that had financial relationships with commercial interests. With this addition, ACCME is recognizing that faculty who have the potential to increase their financial gain in using accredited education to promote their own products and services is equally concerning and may be perceived as commercial bias by learners.

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.”

For the first time, ACCME is acknowledging that learners’ names and contact information can be shared with ineligible entities **IF** learners give consent each time their data is going to be shared. Learners must be informed of who will be receiving their data and for what purpose each time their consent is requested. Let’s first discuss that “explicit consent of the individual learners each time the data is to be shared” implies that learners must “opt in.” Given that commercial support, monetary and in-kind, is widely received to support accredited continuing education, I think it is reasonable to believe that in most cases the ineligible entities would

really like to have learners' names and contact information! A few concerns come to mind. Will accredited providers be responsible for ensuring that learners' information is not used by the ineligible entity for another non-stated purpose? If so, how will accredited providers monitor this? If learners have to provide consent each time their information will be shared with an ineligible entity, will they start to experience "consent fatigue." Physicians have long complained about evaluation fatigue, post-test fatigue, now we are going to add "consent fatigue" – why not a global opt in? If there is an entire section titled, "Prevent Marketing or Sales in Accredited Continuing Education" with multiple prevention policies, for what other purpose would an ineligible entity want learners' names and contact information if not for sales or marketing purposes? Of all the policies in the new *Standards for Integrity and Independence in Accredited Continuing Education*SM, this is the most thought provoking.

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

(Formerly Standard 6 "Disclosure Relevant to Potential Commercial Bias," Standard 2 "Resolution of Personal Conflicts of Interest" and Financial Relationships and Conflict of Interest Policy)

Definition of Relevant Financial Relationships: "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."

The proposed Standard 3 marks several significant changes for accredited providers when managing disclosure of financial relationships by those in a position to control accredited activity content. The first change is a change in term from "resolve" to "mitigate." If a person in control of content declares a financial relationship in their disclosure form and it presents a conflict of interest, accredited providers were required to "resolve" the conflict of interest. The term resolve indicates a firm finality of the conflict of interest that was not always achievable. Changing the term and expectation to mitigate, is to lessen the effect of these relationships on accredited continuing education – a more realistic and achievable expectation. Mitigation must be completed prior to the individual starting their activity role. It is important to note that financial relationships are not defined by a dollar amount.

The next change in expectations is that accredited providers must obtain, from **all** those who control content and their spouse or partner, **all of their financial relationships** with ineligible entities within the previous 12 months. It is the responsibility of the accredited provider to determine which of the financial relationships are relevant and to ensure that commercial bias is not introduced into accredited activity content.

The next change is related to the disclosure information that must be presented to learners prior to their engagement in the accredited continuing education activity. This information must now include a statement that all relevant financial relationships have

been mitigated when financial relationships have been disclosed. Note that if those who are in control of content do not have relevant financial relationships with ineligible entities, this must be disclosed to learners as well.

Lastly, there is an exception for self-directed continuing education:

“Exception for self-directed continuing education: In self-directed accredited continuing education, where the learner is in control of content and there are no planners or faculty (such as a bedside, case conversation among peers), there is less opportunity for commercial bias. In these cases, accredited providers do not need to identify, mitigate, or disclose relevant financial relationships. However, when accredited providers serve as a source of information for the self-directed learner, they should direct learners only to resources and methods for learning that are not controlled by ineligible entities.”

Standard 4: Manage Commercial Support Appropriately

(Formerly Standard 3 “Appropriate Use of Commercial Support”)

The proposed Standard 4 is a simplified version of Standard 3 in the existing *Standards for Commercial Support*. Because Standard 4 is simplified, there appears to be less restrictions placed in managing commercial support. There is one addition that is noteworthy. Accredited providers must pay/reimburse expenses to individuals and joint providers are no longer permitted to. As a former executive director of an accredited education department, our policy was that joint providers would not reimburse expenses related to the activity. Our ability to continue to engage and utilize faculty, contractors, writers, SME’s, long-term was, in part, dependent on timely and accurate payment. It was to our advantage to ensure timely payment and other factors were carried out to the satisfaction of these collaborators to which we had years of training invested and built a good working rapport.

Standard 5: Manage Ancillary Marketing around Accredited Education

(Formerly Standard 4 “Appropriate Management of Associated Commercial Promotion”)

The proposed Standard 5 is a simplified version of Standard 4 in the *Standards for Commercial Support: Standards to Ensure Independence in CME Activities*. Of note, is that it must be clear to learners which activities are accredited education from those that are marketing or non-accredited continuing education. For accredited providers that utilize learning management systems, does this mean that non-accredited activities cannot display in a list intermingled with accredited activities? Or would non-accredited activities have to be displayed and accessed from a separate listing clearly labeled non-accredited activities or something to that effect?

Standard 6: Formerly “Disclosures Relevant to Potential Commercial Bias”

There is no longer a Standard 6 in the new *Standards for Integrity and Independence in Accredited Continuing Education*SM. Disclosures are now addressed in Standard 3.

One can appreciate ACCME’s approach to bring clarity and to simplify the Standards. Accredited providers typically support any efforts towards this end; however, the *Standards for Integrity and Independence in Accredited Continuing Education*SM seem more ambiguous than the existing Standards for Commercial Support. If the proposed Standards are approved by ACCME’s Board of Directors, I for one will miss the existing Standards and the clear statements of each sub-standard.

In my past experience, working for for-profit organizations that received numerous educational grants from commercial interests (ineligible entities), I relied heavily on the Standards that were written in black and white to uphold the spirit of ACCME’s Criteria and Standards for Commercial Support. A former manager of mine once said - everyday Jennifer comes into work, puts on her suit of armor and battles to uphold ACCME’s standards – this is, in part, Jennifer’s daily job responsibilities. The real question is will these simplified *Standards for Integrity and Independence in Accredited Continuing Education*SM liberate accredited providers and contribute to an easier accredited activity development process without compromising the separation of sales, marketing, bias, etc. in the process or are we taking a slight step backwards?

Regardless of what the final version of the *Standards for Integrity and Independence in Accredited Continuing Education*SM may be, CloudCME® will implement solutions to facilitate compliance.

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