



## Call for Comment - Complaints Process: Providers' Responsibility to Learners

Transcript of Audio FAQ  
August 12, 2010

<http://education.accme.org/audio/accme-commentary/call-comment-complaints-process-providers-responsibility>

***Description: Complaints Process: Providers' Responsibilities to Learners***  
***ACCME Chief Executive, Murray Kopelow, MD, explains a new Call for Comment on a proposal regarding providers' responsibilities to learners when an activity is found in Noncompliance through the complaints process***

The ACCME is seeking comment from the public and the CME enterprise. For further information and/or to respond to this Complaints Process Call for Comment, please [click here](#). **The deadline for submitting comments is September 27, 2010.**

The ACCME has had a rule making policy since 2008. In this policy we call for comment when we adopt a new change in policy or practice that will change how the providers conduct their business of continuing medical education. If you remember we asked for comment three times in 2009. One of these comments was on the Complaints and Inquiries Process. And now we are proposing another modification or addition to the Complaints and Inquiries Process and we are seeking your comments. We're proposing a policy on a provider's responsibility to learners. The policy reads:

"When the ACCME Complaints Process determines that an activity is found to be in Noncompliance with the ACCME Standard for Commercial Support 1, Standard for Commercial Support 5, or the Content Value Statements, the accredited provider is required to provide corrective information to the learners, faculty and planners. The provider will submit to the ACCME a report describing the action that was taken and the information that was transmitted. Providers will determine how to communicate the corrective information and are under no obligation to communicate that the activity was found not in compliance with ACCME requirements."

Standard 1 of the Standards for Commercial Support reads:

"The CME provider must ensure that the following decisions were made free of the control of a commercial interest: identification of CME needs; determination of educational objectives; selection and presentation of content; selection of all persons and organizations that will be in a position to control the content of the CME; selection of educational methods; and evaluation of the activity."



Standard 1.2 of the Standards reads: "A commercial interest cannot take the role of a non-accredited partner in a joint sponsorship relationship."

Standard 5 of the Standards for Commercial Support refers to content and format without commercial bias and it has two parts, 5.1 and 5.2.

5.1 reads: "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 of a commercial interest."

5.2 reads: "Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company."

There are three Content Validation Statements that this policy refers to. The first is: "All the recommendations involving clinical medicine in a CME activity must be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients."

The second statement reads: "All scientific research referred to, reported or used in CME in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection and analysis."

The third statement has three parts: "Providers are not eligible for ACCME accreditation or reaccreditation if they present activities that promote, 1. Recommendations, treatment or manners of practicing medicine that are not within the definition of CME, or 2. known to have risks or dangers that outweigh the benefits, or 3. known to be ineffective in the treatment of patients."

So, we propose a special policy that requires special action on the part of accredited providers, who in the Complaints and Inquiries Process are found out of compliance with Standard 1, Standard 5, or the Content Validation Statements.

How it would work is that when a provider is found out of compliance, they'd be asked to change their practice. They'd be asked to explain to the ACCME how they would change their practice, or how they did change their practice. Included in this changes — to share with the learner some corrective information. For example, valid information replacing the old; balanced information replacing the old; or unbiased information. The provider would need to report back to the ACCME on the corrective action taken and on what information was shared with the learners. This is the extent of the corrective action the ACCME would require.



In summary, providers found not in compliance during the Complaints and Inquiries Process with Standard 1, 5, or the Content Validation Statements, corrective action must follow. One of the corrective actions is that the provider distributes information to the learners about what was wrong with the activity. The issues are brought to closure when the provider informs the ACCME of the information that was transmitted.

We look forward to receiving your comments on this new policy. Thank you.

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