



Coalition for Healthcare Communication

Response to Proposed Changes in ACCME Standards for Commercial Support

March 23, 2007

I. Background

The Coalition for Healthcare Communication is pleased to comment on the proposals announced by the Accreditation Council for Continuing Medical Education (ACCME) on February 26, 2007.* The views presented here reflect the informed opinions of a committee of experienced CME professionals who have been active in the Coalition.

The Coalition strongly supports the objectives of ACCME to ensure CME activities of excellence and independence. These objectives are shared and recognized by industry groups and regulatory agencies throughout the country. In addition, the Coalition recognizes the ACCME as the leader in CME accreditation around the world, with standards for commercial support that far exceed those established in any other nation. The Coalition believes in continuous improvement of the CME enterprise and as such we look to support all actions that help preserve the integrity and value of CME.

The Coalition further believes in the need to continue to evolve the elements, policies and standards of the ACCME to further the cause of effective and independent CME. In doing so, the Coalition urges the ACCME to respect a principle of equity that treats all accredited providers equally, whether not-for-profit or for-profit. No organization should be exempt from meeting the standards of commercial support. In fact, we believe the ACCME Board members should be particularly sensitive the possibility of a perceived conflict of interest based on the fact that the current exemptions to the standards include institutions represented by the ACCME board members.

* The Coalition for Healthcare Communication is a group of trade associations and companies in the fields of medical marketing, publishing, continuing medical education and related areas. Its members include the American Association of Advertising Agencies, the Association of Medical Publications, the American Business Media, the Healthcare and Communications Council, The Medical Marketing Association and the Healthcare Businesswomen's Association.

II. General Comments

The Coalition respectfully suggests ACCME provide background information to the CME community on the genesis and the intended goals of the two current proposals. After doing so, we recommend ACCME permit additional comments before taking final action. With common background and understanding of the intent of these proposals, all contributing parties will be better able to provide meaningful input and offer additional ideas and solutions to ACCME.

Additionally, the CME community at large will be in a better position to assess the short and long range impact of the proposals, as well as avoid unintended consequences that might interfere with the provision of robust and important CME programs.

III. Written Agreements

This proposed change appears intended to support the independent decision-making role of all accredited providers. Unfortunately, the Coalition fears the proposal may blur SCS 1.1 rather than sharpening it. At this point, we know of no failure of the existing standard that requires this change. If there has been a breach of this standard, the Coalition recommends that ACCME fully investigate it and sanction providers if needed.

At the same time, we fear that the proposed change will be misinterpreted and serve to curtail meaningful dialog and collaboration on the architecture of educational programming. For example, a grantor may have had successful experiences with particular resources regarding venue selection, logistics or outcomes measurement. While it may be inappropriate to mandate such suppliers, clearly grantors should be able to respond to provider requests for suggestions. We fear that this proposed change would be interpreted to prohibit such dialogue. Inhibiting this sort of communication and collaboration could well impair efforts to improved educational design, cost effective programming, physician performance and improved patient care.

IV. Expanded Definition of Commercial Interest

The proposed change appears intended to support traditional ACCME standards to assure independent and non-biased educational programs regardless of the source of funding. This is a laudable and fundamental goal. Unfortunately, as with the first proposal, the industry is unclear about the precise problem ACCME is hoping to solve or safeguard against.

We understand that the proposed change in the definition of commercial support may be an attempt by ACCME to formalize what medical education and

communications companies (MECCs) and grantors have already spent considerable time, energy, and money to implement, i.e., effective “firewalls” to ensure independence from conflicts of interest. Assuming this is the intent of ACCME, the challenge for all parties is to identify appropriate ways to conduct business that makes is abundantly clear to ACCME, the government, and the public that unbiased educational programming is being developed by each provider type.

Meanwhile, the Coalition is concerned about the apparent inequity in the expanded definition of a “commercial interest,” which appears to assume that MECCs are less independent (or more subject to bias) than other provider types. No provider should be exempt from the standards defining “commercial interest.” This is particularly applicable when some organizations listed as exempt are parents of the ACCME. Such a situation would open the ACCME itself to scrutiny by the press and public policy makers.

It will be particularly important that any expanded definition, if adopted, be evenly applied. Indeed, the Coalition recommends that ACCME consider adopting the term “financial interest” rather than “commercial interest” to more adequately label the object of the ACCME’s legitimate concern. There are potential conflicts of interest among all provider types, including those in the currently exempt groups. For example, the proposal states that the ACCME does not consider providers of clinical service directly to patients to be commercial interests. Yet there are many examples of these organizations introducing potential bias in their education programs, including profiting from the administration and use of facilities, procedures, drugs and other medical services.

Meanwhile, we note that MECCs have been very aggressive in developing “fire walls” over the past several years, including separating people, management, locations, servers, policies, and processes, in order to insure separation and integrity of the CME effort, and to satisfy HHS-IG guidance and grantor concerns.

In addition, the Coalition fears that the proposal may potentially have a detrimental effect on all provider types through an interpretation that joint sponsorship will not be allowed. Many universities, hospitals and not-for-profits use logistic and implementation joint sponsors to keep costs down and insure trained professionals handle those aspects of the endeavor. This change could have a chilling effect in the short term as many organizations are not structured to reflect this change.

Because the proposed wording has a high probability for multiple interpretations, we strongly recommend that ACCME provide more direction to the CME community on its intent before proceeding. We recommend that ACCME

propose specific examples and scenarios that would be acceptable and unacceptable to ACCME, and that the community be allowed to comment on them before ACCME makes a final decision.

V. Summary and Conclusion

The Coalition for Healthcare Communications suggests ACCME publish the specific reasons for the proposed changes, as well as evidence that the changes are needed. We strongly recommend that the CME community then be allowed to comment again before the ACCME makes a final decision. In so doing, standards based on the principals of unbiased, high quality education should be developed that apply equally to all provider types. If the ACCME intends to develop a new “fire wall” policy, it would be very useful to have an open dialogue on the best options, and in final guidance to identify very specific examples of structure, policy and process that will and will not be acceptable for compliance.

If the ACCME proceeds as suggested, the entire CME community will be in a better position to identify the principals and details of any new standards. Thank you for considering our comments. We look forward to participating in further stages of this proceeding.

Sincerely,

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