

Call for Comments:

The ACCME Will Ensure Current Processes of Attaining Commercial Support Will Not Undermine the Independence of Continuing Medical Education

The ACCME Standards for Commercial Support, when adhered to by accredited providers of CME, are an effective means to mitigate the potential for bias in the content of independent medical education activities. The Potomac Center for Medical Education believes in and supports the ACCME Standards for Commercial Support.

Since the inception of the SCS in 2004 the ACCME has made significant progress at clarifying definitions and specifying expectations regarding provider compliance and practices. The result has been strict limitations on supporter/provider communications, clarification of provider responsibilities for content development and faculty relationships, clarity of policies and practices, and documentation requirements. Current practices for disclosure of potential conflicts of interest ultimately ensure transparency by informing learners appropriately at the beginning of each activity.

In order to ensure the independence of accredited education the provider must be in control of all elements of planning and implementing activities including assessing learner needs; defining learning objectives and content; selection of all faculty, planners and authors; determination of educational methods and materials; evaluation and outcomes assessment.

We support the ACCME Board of Directors statement that, “CME providers can receive commercial support from industry. CME providers cannot receive guidance, either nuanced or direct, on the content of the activity or on who should deliver that content.”

Specifically, we believe it is not appropriate for accredited providers to have communication with commercial supporters about topics, content, faculty or planners for a CME activity. Any such involvement would be reasonably construed as directing or influencing the content of an activity and therefore would be in non-compliance with the Standards for Commercial Support.

However, we believe it is reasonable and important for accredited providers to receive from commercial supporter’s general *information about their interest in offering funding* for independent medical education in therapeutic areas of interest to the commercial supporter. Further, as a practical matter, we believe it is appropriate for commercial

supporters to identify the level or amount of funds available. In current practice this information is offered by some companies without any communication, direct or nuanced, about the content or faculty of an activity. Such information is appropriately communicated by a Request for Proposal or a web site. It may be accessible to a subset or the universe of accredited providers.

Among the consequences of limiting communication between providers and commercial supporters about the availability of funding as suggested are:

- Discourages commercial supporters from providing funding for CME activities
- Wastes providers time and resources guessing at supporters' interests and funding levels
- Discourages innovation and creativity in CME by eliminating the ability of providers to develop novel instructional design and delivery approaches.

In order to ensure the transparency of their review processes, and the inability to influence content and faculty selection, it is necessary for commercial supporters to define the criteria by which grant requests are evaluated so long as the criteria relate to the quality of the application and not the content or speakers. This practice is standard operating procedure for government contracts which publish the evaluation criteria in the RFP. The lack of published criteria, and obligation to provide feedback, exposes the system to greater suspicion and concern that grant requests were selected based on prior relationships or sidebar conversations about content of faculty.

Call for Comments:

The ACCME Believes that Due Consideration be Given to the Elimination of Commercial Support of Continuing Medical Education Activities

The Potomac Center for Medical Education supports the ACCME Standard for Commercial Support as the effective and appropriate mechanism to manage the potential for bias in industry supported CME and to ensure the independence of CME from industry influence. The conditions governing the receipt of industry support for CME and restrictions on communication or interaction about the content or selection of faculty are clear and effective.

There is no evidence or even well supported inference that commercial support of CME leads to education that is biased or potentially deleterious to patient care. There is no reason to consider the elimination of commercial support for accredited CME. In fact, the only existing evidence suggests that bias in commercially supported CME does not exist and the impact on supporting changes in clinical practice and patient care are positive.

Continued commercial support of CME is desirable and necessary. It represents a large percent of overall CME funding. There are no sources of money available to fill the gap should commercial support be reduced or eliminated. Commercially supported CME is valued by physicians as a source of new and relevant information about advances in medical science and clinical practice.

Industry support for physician education is currently promotional education and independent accredited education. Should the requirements for commercial support of CME become overly restrictive, resources will shift to promotion, thus compromising the quality and objectivity of information provided to physicians.

The ACCME proposed four conditions to determine the appropriateness of commercial support are overreaching, impractical, arbitrary and too restrictive.

Condition Number 1:

A comprehensive needs assessment provides insights to the specific educational needs of a target audience and should consider several and varied sources of information

including government reports and data when available. However, such information does not usually provide the depth and insights necessary to identify the nuanced points.

Many organizations receiving commercial support provide valuable sources of information which are needs assessment essentials. These include academic medical centers and professional associations which publish practice guidelines, research, professional journals, surveys and other data sources offering useful insights to gaps in knowledge and educational needs. Patient registries, a valued source of practice information for needs assessments, are often supported by industry. Surveys and focus groups conducted by AMCs, associations and MECCS are important sources of information to set priorities for education. All accredited CME providers regularly conduct evaluations of their activities and outcomes assessments to define practice changes. Feedback from learners provides guidance on additional educational gaps and needs which help to translate knowledge into clinical practice changes.

Therefore, it would be a setback for the practice of CME and the ability to finely pinpoint the educational needs of physician learners to handicap providers by limiting the sources of needs assessment data to organizations not receiving commercial support. Again, the source of funding an organization receives does not in itself create a bias.

Condition Number 2:

The availability of 'bona fide performance measurements' is spotty and limited to select therapeutic areas with large patient populations. These data and reports are valuable as general sources of needs assessment data but without complimentary or alternative sources of data they lack the depth necessary to focus the level and scope of the learning objectives. Also, such performance measures are a retrospective view of practice patterns and are not useful for CME which is designed to impart information on new developments and therapeutic options.

Condition Number 3:

When the ACCME Standards for Commercial Support are followed the content of a CME program is not influenced by the supporter and thus, is unrelated to the funding. The content of a CME activity, be it a curriculum, research from recent studies, opinions of thought leaders, peer to peer case presentations, etc. is determined by the planners and faculty based upon the learning objectives. A well constructed CME program should draw upon multiple sources of information from which content is derived. Limiting content to existing continuing education curricula is too restrictive. Curricula are not available for all specialties, sub specialties and disease states. Curricula may not reflect the most current information as they are only updated periodically. Reliance upon

curricula would slow communication of new information and the uptake of new practices. Curricula follow actual clinical practice; they do not drive innovations in practice.

Condition Number 4:

The requirement to warrant CME content as free of commercial bias prior to receiving funding is impractical as well as undesirable. In the lifecycle of a CME activity the source of funding (tuition, grant from industry, institutional operating budget, association dues) is defined in the early stages of planning after the needs assessment and learning objectives have been defined. The review of content for a live meeting, internet program or publication as a precondition for commercial support might encourage the company (supporter) to make funding decisions based upon the content, rather than the need for education.

ACCME Proposes Additional Features of Independence in Accredited Continuing Medical Education

The ACCME Standards for Commercial Support, when adhered to by accredited providers of CME, are an effective means to mitigate the potential for bias in the content of independent medical education activities supported by commercial interests. The Potomac Center for Medical Education believes in and supports the ACCME Standards for Commercial Support.

Regarding the questions posed by the ACCME, we believe the imposition of the exclusion of medical writers and faculty who participate in promotional activities from CME is overreaching, impractical, unenforceable, and damaging to the CME enterprise.

The rationale for the suggested change is without basis in fact or evidence. It is not clear what ‘problem’ ACCME is looking to solve. The cited ‘recent significant external actions’ are taken out of context. The May 2008 Attorneys General settlement with a commercial supporter does not stipulate that a promotional speaker cannot also be a CME speaker. Rather it states that the supporter (in this case Merck) cannot know who the speakers will be in advance of funding the activity. The July 2008 Taskforce on Industry Funding of Medical Education states that “academic medical centers should make clear that participation by their faculty in industry-sponsored speakers’ bureaus should be strongly discouraged,” but does not disqualify speakers based on their participation in speaker’s bureaus.

Therefore, PCME strongly supports the following policy:

Faculty, consultants, writers, and others in a position to influence the content of a CME activity who participate in the creation or presentation of promotional programs on behalf of a commercial interest may participate in accredited CME activities if their conflicts of interest are appropriately disclosed, vetted, and resolved.

While the ACCME has expressed concern that safeguards to assure CME is free of commercial bias have not been successful, there are no studies or evidence that directly address the question of whether commercial support produces bias in accredited CME activities.

There exists widespread concern about the impact of commercial support on research and education. Whether this support produces inherent bias in accredited CME activities is important but is not known.

Prior to making potentially damaging changes to the CME enterprise, research is necessary to address questions about the relationship between commercial support and bias in CME. These questions include:

- Does commercial support produce bias in CME activities?
- What are the mechanisms by which bias is produced?
- Are accreditation guidelines or other strategies effective in preventing bias?
- How does commercial support of CME contribute to physicians' behavior change relative to other influences?
- Does commercially supported CME lead to changes in the quality or cost of patient care?

In its commentary, the ACCME outlines that "Physicians paid by a commercial interest to do promotional presentations on a product could not teach in accredited continuing medical education on the same product." The implications of this would be to limit faculty from speaking in a therapeutic area. CME content does not address a 'product,' but rather a therapeutic area with various treatment options without regard for the source of commercial support.

Question 1: *Should those who write promotional materials be excluded from having any role in writing CME content?*

PCME believes that all medical writers should disclose conflicts of interest which should be vetted and resolved, when necessary, in order to participate in CME activities. Writers should not be excluded from having a role in writing CME content in a therapeutic area because they have worked on promotional materials for a product in that therapeutic area.

The exclusion of medical writers who participate in promotional activities from CME activities would be difficult to enforce and detrimental to the CME enterprise in the following ways:

- A) The exclusion of writers from CME would be difficult to enforce as many writers are freelance consultants. A restriction of this type is punitive and discourages disclosure of conflicts of interest and would be difficult to verify. Therefore, conflicts of interest would become more challenging to manage.

- B) The exclusion of writers from CME demonstrates a lack of understanding about promotional education, which is regulated by the FDA, vetted by the medical/legal process of the commercial interests, and limited to “on label” content. The content in promotional programs is more controlled and restricted than in accredited CME
- C) The exclusion of writers from CME will significantly impact the quality and value of CME activities. CME providers utilize staff and freelance writers to collaborate with researchers and faculty who may not possess the communication skills nor instructional design expertise to make their presentations relevant and compelling to the target audience.
- D) The exclusion of writers from CME will undermine the premise and credibility of the SCS by discounting the ability of compliance to resolve conflicts of interest through the defined process of CME providers.

Question 2: *Should those who teach in promotional activities be excluded from teaching in independent CME activities:*

PCME believes that medical professionals who teach should disclose conflicts of interest which should be vetted and resolved, when necessary, in order to participate in CME activities. Faculty should not be excluded from having a role in presenting CME content in a therapeutic area because they have worked on promotional materials for a product in that therapeutic area.

The exclusion of faculty who participate in promotional activities from CME activities would be detrimental to the CME enterprise in the following ways:

- A) Professional associations will be forced to exclude a majority of the presenters at their national and local meetings.
- B) Teaching institutions and community hospitals will face greater challenges finding faculty to participate in CME activities. Academic institutions may encounter difficulties recruiting faculty due to limited income potential from outside sources.
- C) The overall quality of CME will be compromised because talented teachers will be forced to choose between CME and promotional programs, which have higher compensation
- D) Investigators are often obligated to speak on behalf of the companies supporting their research in a promotional setting to ensure the dissemination of their data, thus eliminating them from CME activities.

- E) The credibility of the ACCME and the Standards for Commercial Support will be severely compromised by a tacit acknowledgement of the ACCME's inability to manage conflicts of interest through its processes.
- F) Much of the CME and research currently presented in the United States will be driven to other countries by forcing presenters who have participated in promotional programs to seek alternative venues.

We strongly support strict adherence to the ACCME Standards for Commercial Support as the best and most appropriate means to manage conflicts of interest in CME through disclosure processes and vetting of apparent conflicts, including disclosure to learners.