NAAMECC AND SACME COLLABORATE ON JOINT SPONSOR ATTESTATION FORM

In response to the new ACCME definition of a commercial interest and the requirement for Accredited Providers to ensure that all organizations they collaborate with to jointly sponsor CME activities are not a commercial interest or owned or controlled by a commercial interest, the North American Association of Medical Education and Communication Companies (NAAMECC) and the Society for Academic Continuing Medical Education (SACME) have partnered to develop a questionnaire/attestation form. This form may be used by Accredited Providers to evaluate potential joint sponsors so that a determination can be made as to whether the non-accredited organization is eligible to serve as a joint sponsor to develop CME activities. The boards of both NAAMECC and SACME have reviewed and endorsed the form. To download the form, visit the NAAMECC website at http://www.naamecc.org/News/tabid/56/ctl/ViewItem/mid/409/ItemId/35/Default.aspx.

AMA DECIDES NOT TO SUPPORT PROPOSAL ON ELIMINATING COMMERCIAL FUNDING FOR CME

A controversial recommendation by the American Medical Association’s Council on Ethical and Judicial Affairs (CEJA) to eliminate all industry funding of continuing medical education was not approved by the AMA’s Reference Committee on Amendments to Constitution and Bylaws (RCACB). At a hearing on June 15 at the AMA’s annual House of Delegates meeting, speakers representing more than 40 organizations, including the Alliance for CME, NAAMECC, and the Council of Medical and Specialty Societies, spoke out against CEJA’s recommendation. Only a few were in support of CEJA’s proposal, which called for the elimination of industry funding from medical education, except in cases where technical training in the use of a new technique or device is required.

The report argued that industry support of professional education raises concerns that threaten the integrity of professional education and that the mechanisms in place to manage potential conflicts are not sufficient to address those concerns. The proposal was made by CEJA to end pharmaceutical company funding for residency positions and clinical fellowships; educational programs such as live or web-based CME; physician speakers’ bureaus; and travel, lodging, and amenities for CME participants. Other recommendations included a ban on industry gifts, meals and detailing at medical schools, and an unspecified effort to “secure non-commercial funding sources.” The only exception was offered for training in new diagnostic or therapeutic devices and techniques, because industry sales representatives may have to play a vital educational role as the only available teachers. However, once expertise is developed among physicians, CEJA suggested that pharmaceutical industry involvement is “no longer warranted.”

After reviewing all the testimony, RCACB decided to refer this report back to CEJA, with no action taken and/or to be taken on the report as it is presently written. According to RCACB in its decision, “Testimony emphasized that the report lacked clarity with respect to distinguishing certified continuing medical education and uncertified promotional education.” The committee cited testimony that CEJA should seek further input from all stakeholders to clarify concerns and explore options for achieving the goal of unbiased CME.

While rejected in its current form, CEJA could revise the report and resubmit it to RCACB at the next AMA annual meeting in June 2009. For more on the decision and the initial CEJA proposal, go to the AMA website and link to http://www.ama-assn.org/ama1/pub/upload/mn/20/actionsannual08.pdf.

On the subject of developing CME without industry support, Oncology Times published in its July 10 issue (volume 30, issue 13, pages 28-29) an article entitled “How They Do It: Memorial Sloan-Kettering Provides Successful CME Program with No Commercial Funding.” To read the full article, go to the following link on the OT website: http://www.oncology-times.com/pt/re/.

ACCME RESPONSE TO SENATE SPECIAL COMMITTEE

In mid-July, the Accreditation Council for CME (ACCME) responded to a letter of inquiry from the US Senate Special Committee on Aging, regarding concern the committee has about its accreditation process and mechanisms to prevent pharmaceutical industry influence. The committee, chaired by Senator Herb Kohl (D-Wisconsin), expressed concern that pharmaceutical companies use CME as a marketing tool. “Of particular concern are instances where drug companies use CME courses to encourage physicians to use their products for controversial medical practices,” writes Kohl in the letter dated June 20. The committee asked the ACCME for a description of the accreditation process and the criteria the ACCME uses to evaluate the scientific validity of course content. It also asked what mechanisms the ACCME uses to prevent industry from influencing CME courses and about further plans to develop such mechanisms. To access the full letter from Senator Kohl, please link to the following address: http://www.accme.org/dir_docs/doc_upload/4f332029-de8e-4bee-a983-0e05bfdec0d_uploaddocument.pdf.

In a letter of response, dated July 11, Murray Kopelow, MD, chief executive, ACCME, responded to the four questions in a 26-page letter to Senator Kohl. In his letter, Dr. Kopelow wrote, “Providers are not eligible for accreditation if they present activities that promote
treatments that are known to have risks or dangers that outweigh the benefits or are known to be ineffective in the treatment of patients. An organization whose program of CME is devoted to advocacy of unscientific modalities of diagnosis or therapy is not eligible to apply for ACCME accreditation. Accredited providers are responsible for validating the clinical content of CME activities that they provide.”

To read the full response, please link to the following address: http://www.accme.org/dir_docs/doc_upload/6d4d0864-2f45-4185-975c-cd8954feb966_uploaddocument.pdf.

**Pfizer Ends Funding for Medical Education Companies, Changes Grant Policies Effective Immediately**

On July 2, pharmaceutical giant Pfizer, Inc., announced that it will no longer award grants to medical education companies, causing a tidal wave of concern and commentary within the CME community. According to the letter Pfizer will continue to support CME programs at many of the world’s leading academic medical centers and teaching hospitals, as well as programs sponsored by associations, medical societies, and community hospitals, in keeping with the shared goal of improving public health. Effective immediately Pfizer is eliminating all direct funding for physician continuing medical education (CME) programs provided by medical education and communication companies (MECCs). The company will honor existing commitments.

In recently published interviews with trade publications Medical Meetings and Medical Marketing and Media (MMM), Mike Saxton, MEd, Senior Director, Team Leader, Medical Education Group, Pfizer, said, “We are eliminating support for commercial CME providers, whether they are for profit or nonprofit, and regardless of whether they have firewalls. Our intention is to send a signal that funds must be used exclusively for independent education. We think this is the responsible decision at this point in time in order to help demonstrate and even preserve the opportunity for industry to support quality education.”

The major policy shift appears to be in response to ongoing concerns that pharmaceutical industry support biases CME content. “We understand that even the appearance of conflicts in CME is damaging and we are determined to take actions that are in the best interests of patients and physicians,” said Pfizer Chief Medical Officer Dr. Joseph Feczko in a recent statement.

However, according to Mr. Saxton, the change in funding is not a drastic financial shift in grant allocation. He stated that Pfizer had awarded approximately 17 percent of its CME funding to medical education and communication companies in 2008. “That figure will now drop to zero,” he said. According to their own data, Pfizer spent around $6 million on CME grants in the first quarter of 2008, with $3.4 million going to a nine-organization consortium developing education on smoking cessation. At this rate, funding would total about $24 million in CME spending for the year, which is significantly less than provided by in previous years. It has been reported in Medical Meetings that in 2005, Pfizer spent $314 million on all forms of CME, including accredited and non-accredited programs, according to Verispan figures. In 2006, CME support dropped to $285 million, again according to Verispan. Last year, the manufacturer reported spending around $80 million on CME.

(Note: In May 2007, Pfizer began posting its grants to medical, scientific, and patient organizations, as well as its charitable contributions, online.)

While supported by a number of professional societies and medical institutions that would remain on the receiving end of grants under the new policy, to the surprise of very few, the Pfizer announcement was not met with open arms within the CME world. In an open letter dated July 8, the North American Association of Medical Education and Communication Companies (NAAMECC) responded to the Pfizer announcement:

“Everyone, including Pfizer, agrees that CME is an essential element of continuous physician learning and improvement and contributes significantly to patient care and well-being. The Association and its members understand and accept our responsibility to plan and deliver CME subject to the highest ethical and operational guidelines designed to ensure and protect its independence, accuracy, integrity, and validity. We believe Pfizer’s actions, although well intentioned, are misguided and not based on empirical evidence. Rather than engaging in an unproductive debate about who should be entitled to receive funding from commercial interests to support the continuing professional development of physicians, it is in everyone’s best interest to join together to develop management tools to ensure the public that CME activities are independent, valid, and responsive to the educational needs of physicians.

At the end of the day, we believe such a collaborative approach will provide the greatest benefit to the public health, and the Association and its member companies will continue to work toward that end, and we are heartened by the support for our position by many stakeholders in the CME enterprise.”

In a similar response, also dated July 8, the Coalition for Healthcare Communication (CHC) issued this response:

“While a strong supporter of self-regulation in the CME enterprise, the Coalition for Healthcare Communication believes that Pfizer’s recent decision to eliminate direct funding of CME through “independent commercial providers” is an honest but misguided attempt to blunt public criticism of commercial support. Unfortunately, this decision supports much of the misinformed criticism of the industry, flies in the face of objective evidence, and does not address the true challenges facing health care providers and patients today.

In the midst of recent public criticism of industry supported CME, accredited medical education companies have an unequaled record of compliance with conflict of interest rules and provide much of the best CME available today to the nation’s physicians and other healthcare providers. Indeed, the Coalition believes accredited medical education companies should continue to receive strong support from the industry and the public given their leadership in improving patient care with CME through innovation, excellence, and entrepreneurship.”
News from Around the CME Industry

To read the full text, go to the CHC web site at:
http://www.cohealthcom.org/content/library/Coalition_Statement_Pfizer_July08.pdf.

Additional responses have come directly from education providers as well. Pri-Med, a global provider of innovative, cutting-edge clinical education that is designed to meet the individual learning needs of specialists and primary care practitioners (PCPs), in their letter dated July 16 issued the following statement:

“Today, the debate surrounding the relationship between physicians and pharmaceutical/biotech/medical device companies, and thus the organizations that operate in these areas, has cast a cloud of confusion and uncertainty on the continuing medical education enterprise. The public reporting on this issue has been prolific but limited in breadth to organizations, the government, and the media, without fully engaging the practicing clinicians in the dialogue. At Pri-Med, we aspire to give the practicing clinicians a voice in the discussion.

We know that you share our belief that CME is essential to better patient care and that we should be focused on how to deliver more of the education that physicians need instead of looking for ways to restrict access. And that is why we are writing to you.”

To read the full text of the Pri-Med letter, go online to

ACCME BOARD OF DIRECTORS MEET

On July 20, the Board of Directors of the Accreditation Council for Continuing Medical Education (ACCME) met and issued a number of decisions. Below is a look at some of the executive summary.

ACCREDITATION, RECOGNITION, AND SUBSTANTIAL EQUIVALENCE DECISION MAKING

The ACCME ratified Accreditation, Reaccreditation, and Progress Report decisions for 124 providers. This included six providers that received Accreditation with Commendation, which is associated with a six-year term of accreditation, as well as six initial applicants receiving Provisional Accreditation. Five providers received Non-Accreditation from Initial Accreditation, and two providers received Non-Accreditation from Probation due to failure to demonstrate compliance with ACCME’s requirements through Progress Reports. The ACCME ratified Recognition decisions for six state medical society accreditors. There are now 738 ACCME accredited providers and 1639 state or territorial medical society accredited providers. In addition, two providers received Non-Accreditation due to failure to submit their annual reports.

In addition, the Board of Directors recognized the Substantial Equivalency of the continuing medical education accreditation system of the Royal College of Physicians and Surgeons of Canada with the continuing medical education accreditation system of the ACCME. The process of “Recognizing Substantial Equivalency” is a voluntary peer review process for determining if national CME accreditation programs meet international standards. This formal self-assessment and external review process conducted between the ACCME and the Royal College of Physicians and Surgeons of Canada is the first time these international standards have been applied.

ACCME REVENUE ENHANCEMENTS

The ACCME will be increasing its revenues by a) charging a one-time assessment to ACCME-accredited providers, payable in 2009, and b) raising its annual fees payable in 2011. Details of the assessment and annual fee increase will soon be communicated directly to providers and accreditors.

RECOGNITION REQUIREMENTS

The ACCME adopted new Recognition Requirements as the basis for ACCME Recognition decisions of state accreditors in 2010 and beyond. The ACCME will provide a “comment period” for the Recognized Accreditors before making these Markers of Equivalency final.

ACCREDITATION WITH NURSING AND PHARMACY

The ACCME is proceeding with implementing a system for offering a joint accreditation process for select providers who are implementing truly “interprofessional” continuing education programs. At the July meeting, ACCME adopted a proposal for a system entitled, “Joint Accreditation for the Provider of Continuing Education for the Healthcare Team Accreditation of Continuing Education Planned by the Team for the Team” as the basis for this combined accreditation process.

RAPID RESPONSE

The ACCME modified its definition of “adverse action” as it applies to ACCME’s Procedure on Reconsideration/Appeal to limit adverse actions to Non-Accreditation. Providers receiving a decision of PROBATION will no longer have access to the Reconsideration or Appeal process but rather will be required to rapidly demonstrate full compliance with ACCME’s requirements.

ELECTIONS

To terms beginning in December 2008, the ACCME elected Edward Susank as an ACCME Director representing the public and elected to the Accreditation Review Committee (ARC) Suzanne Ziemnik, MEd Senior Vice President of Education and Assessment for the American Society of Clinical Pathology.
MORE DISCUSSION . . .

The Board also discussed issues and proposed policies related to further separation of promotion and education. Some of these proposed policies would be issued as “calls-for-comment” to the CME community before final policy is adopted.

For the full executive summary, go to the ACCME web site and link to http://www.accme.org/dir_docs/whats_new/5477d479-97e5-4753-80d6-b25ff8e2e24ce_uploadfile.pdf.

PhRMA Revised Marketing Code Press Released

Reflecting the continuing pressure on pharmaceutical, research, and biotechnology companies to pursue policies and practices that best serve the needs of patients and the healthcare community, on July 10, the Pharmaceutical Research and Manufacturers of America (PhRMA) Board of Directors announced it has “adopted measures to enhance the PhRMA Code on Interactions with Healthcare Professionals.”

The newly revised PhRMA Code, which updates changes made in the previous 2002 version, is part of an ongoing effort to ensure that pharmaceutical marketing practices comply with the highest ethical standards.

The voluntary PhRMA Code on Interactions with Healthcare Professionals, which will take effect in January 2009, reaffirms that interactions between company representatives and healthcare professionals “should be focused on informing the healthcare professionals about products, providing scientific and educational information, and supporting medical research and education.”

According to the PhRMA, “several of the changes to the Code, like PhRMA’s recent acceptance of the revised Physician Payments Sunshine Act in the Senate, reflect PhRMA’s position that appropriate transparency in relationships with healthcare professionals can help build and maintain patient trust in the healthcare system.”

Among its changes, the revised Code:

- Prohibits distribution of non-educational items (such as pens, mugs, and other “reminder” objects typically adorned with a company or product logo) to healthcare providers and their staff.
- Prohibits company sales representatives from providing restaurant meals to healthcare professionals, but allows them to provide occasional meals in healthcare professionals’ offices in conjunction with informational presentations.
- Includes new provisions that require companies to ensure that their representatives are sufficiently trained about applicable laws, regulations, and industry codes of practice—including this Code—that govern interactions with healthcare professionals.
- Provides that each company will state its intentions to abide by the Code and that company CEOs and Compliance Officers will certify each year that they have processes in place to comply, a process patterned after the concept of Sarbanes-Oxley compliance mechanisms.
- Other additions to the Code include “more detailed standards regarding the independence of continuing medical education (CME); principles on the responsible use of non-patient identified prescriber data; and additional guidance for speaking and consulting arrangements with healthcare professionals, including disclosure requirements for healthcare providers who are members of committees that set formularies or develop clinical practice guidelines and who also serve as speakers or consultants for a pharmaceutical company.”

As of publication of this issue of CE Measure, research finds that 32 major pharmaceutical companies have signed off on the revised code. For the full text of the Code, go to the PhRMA web site at http://www.phrma.org/news_room/press_releases/phrma_code_reinforces_commitment_to_responsible_interactions_with_healthcare_professionals/.