



NAAMECC Comments on Certified CME

Presented to the U.S. Senate Special Committee on Aging

July 27, 2009

The North American Association of Medical Education and Communication Companies, Inc. (NAAMECC) is the trade organization representing U.S. medical education companies, as well as the clinical faculty and participants of member-developed Certified continuing medical education (CME) initiatives. We offer a special thanks to the Honorable U.S. Senator Kohl and his staff for inviting a statement regarding Certified CME and clarifying important issues in the CME enterprise in order to develop leadership positions that will guide the healthy future of independent, Certified CME.

NAAMECC's mission is to promote best practices in CME that meet the many and detailed requirements set forth for the conduct of continuing education activities for physicians, with the goal of providing education that improves patient care. NAAMECC functions as a resource for, representative of, and advocate for more than 70 medical education companies that help employ thousands of workers. NAAMECC member organizations design and develop Certified CME activities that annually reach more than 150,000 physicians and other learners in the healthcare professions.

NAAMECC supports measures promoting practices that are scientifically and ethically acceptable and preferable, including those set forth in the *International Ethical Guidelines for Biomedical Research Involving Human Subjects*. While Certified CME should not be confused with medical practices and research involving human subjects, CME stakeholders must continue to recognize and uphold their ethical responsibilities in the development of excellent continuing education.

Current Healthcare Environment and CME

In order to fully address critical issues involving Certified CME today, we begin by taking note of the current U.S. healthcare environment. In short, the U.S. healthcare system faces several complex and intersecting challenges: along with an aging population and increased needs for advanced medical treatment, we are facing significant physician shortages at both the primary care and specialty levels. In the past five years, more than 15 studies have cited the effects of

physician shortages. As noted in the 2007 report of the Association of American Medical Colleges (AAMC), *Recent Studies and Reports on Physician Shortages in the U.S.*, most of these studies show that the care of underserved and elderly populations is likely to be affected by the shortages. In addition, rising costs combined with flat reimbursement from government and private insurers place additional financial pressure on both primary care physicians and specialists. While improved methods and new pharmacologic and non-pharmacologic treatment options are detailed in more than 150,000 medical journal articles published each month, physicians request and need Certified CME to help them make sense of the evidence and share best practices.

Consider what two physicians recently wrote in evaluations of Certified CME activities they attended in Fall 2008.

“I cannot stress enough how essential my CE courses, online and live, have been to me. It helps me to stay current with the latest advancements and developments in diagnosis, treatment and management to improve patient care. I need more CME courses, live and online, in the future.”

“There is tremendous value of CME in disseminating much needed clinical updates for learners, particularly community-based, primary care practitioners, who may not be in a position to fund their CME/CE efforts on their own.”

As we debate key issues in the CME enterprise, we must remember our responsibility to consider the current healthcare environment, identify evidence-based problems, and develop solutions that increase the value and reach of CME activities that improve medical practices and patient care results.

Confusion Regarding Certified CME and Other Activities

Certified CME has often been confused with other forms of so-called “education,” as well as marketing and sales activities supported by commercial interests. Make no mistake: any type of education that does not specifically meet the ACCME guidelines for independence, management of conflicts of interest and faculty disclosure cannot be presented as Certified CME and cannot be approved for AMA physician CME credit. Accredited providers are beholden to the ACCME rules and risk losing their accredited status and the authority to certify CME activities and issue credit.

Many stakeholders within and outside the CME enterprise have confused Certified CME with promotional activities branded under the name “professional education.” In 2008, one report stated that “professional education” included:

- “CME”
- “industry marketing and promotional activities”
- “personal expenses associated with attendance at meetings”
- “educational travel grants for medical students”
- “free lunches”
- “residency positions”
- “company speakers’ bureaus”
- “free or subsidized travel”

Unfortunately, the only thing on the list above that does qualify for physician credit and meet the definition for Certified CME is “CME.” Everything else is not Certified CME. Certified CME is different. It can be funded through educational grants from pharmaceutical companies, the federal government, foundations, or registration payments from learner attendees. In those cases where a pharmaceutical manufacturer provides grant funding for a CME activity, the pharmaceutical manufacturer is not allowed to select faculty or take part in any decisions regarding the content or presentation of evidence-based material. Despite these facts, the public, news media, and some CME stakeholders still mistake Certified CME with unrelated activities.

Guidance for the CME Enterprise

Several opinions developed by the American Medical Association (AMA), as well as requirements for providers of Certified CME set forth by the Accreditation Council for CME (ACCME), are relevant to discussion of CME conflicts, challenges, and commercial funding. As noted in AMA Ethical Opinion 9.011 regarding Continuing Medical Education, “only by participating in continuing medical education (CME) can they (physicians) continue to serve patients to the best of their abilities and live up to professional standards of excellence.” Further, this AMA opinion guides physicians to analyze CME options and choose “only those activities which are of high quality and appropriate for the physician’s educational needs.” AMA Opinion 9.011 also counsels physicians to participate only in CME activities that “are responsibly conducted by qualified faculty” and “conform to Opinion 8.061, ‘Gifts to Physicians from

Industry.” The AMA opinion on CME also addresses appropriate practices for physicians serving as speakers, moderators, or other faculty at a Certified CME activity.

Responses to Past Mistakes in CME

Acting counter to the AMA opinions on CME, as well as ACCME standards and policies, a minority of bad actors broke existing rules and guidelines in the past. In response, the CME enterprise made significant improvements to its rules and structure between 2004 and 2008. The framework of Certified CME is now guided by more stringent standards, monitoring, and guidelines, including:

- Multiple requirements set forth by the board that accredits providers of CME, the Accreditation Council for Continuing Medical Education (ACCME), including:
 - ACCME Accreditation Criteria 1 through 15 (setting forth the minimum requirements to ensure educational rigor and independence)
 - ACCME Elements addressing appropriate educational Purpose/Mission, Planning, and Evaluation/Improvement
 - ACCME Standards for Commercial Support^[1] requiring 1) Independence, 2) Resolution of Conflicts of Interest, 3) Appropriate Use of Commercial Support Grant Funding, 4) Appropriate Management, 5) Development of Content and Format without Commercial Bias, and 6) Disclosures to ensure transparency
 - ACCME Content Validation Value Statements requiring CME content to 1) include evidence-based clinical recommendations, 2) rely on research that conforms to generally accepted standards of experimental design, data collection and analysis, and 3) meet the definition of CME and not provide patient care recommendations in which risks outweigh the benefits
 - ACCME Audits of accredited education providers to ensure they fully comply with all criteria and policies
 - ACCME rapid response measures (announced in 2008) to identify compliance infractions, place accredited providers on probation, and work with these organizations to bring them back into compliance
 - ACCME on-site audits of educational activities (beginning in 2009)

^[1] Available at http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf (“Standards for Commercial Support”).

- Enforcement action by the Office of Inspector General of the Department of Health and Human Services, which, according to the guidance, "has put teeth into compliance by industry, as the penalties for non-compliance include very large fines and potential incarceration."
- The U.S. Food and Drug Administration's (FDA's) standards for ensuring the independence of CME, which, while adopted by the agency primarily to address the use of CME as a subterfuge for "off-label" promotion, nevertheless establishes standards for ensuring the independence of CME from commercial influence.
- Several codes related to conduct and/or ethical interaction have recently been developed, including updates to the Pharmaceutical Research and Manufacturers of America (PhRMA) *Code on Interactions with Healthcare Professionals*, the Advanced Medical Technology Association (AdvaMed) *Code of Ethics on Interactions with Health Care Professionals*, and a newly developed *Code of Conduct for Commercially Supported CME*, which is a collaborative initiative involving NAAMECC and other leading CME organizations.

Accredited education providers, non-accredited education partners, and grant funders of Certified CME all must abide by updated rules that ensure the following:

- Grant funders, including pharmaceutical and medical device manufacturers, are not allowed any control over the specific content, speakers, or management of CME
- All education is independently reviewed and edited to address any possible bias
- Presentations must be evidence-based and meet updated criteria and guidelines set forth by the ACCME
- Compliance with ACCME Standards for Commercial Support
- Rapid response to any non-compliance findings of ACCME on-site audits of CME activities

Of great significance is the fact that no physician can be compensated simply to attend Certified CME activities. Learners at these activities have no incentive to participate or favorably evaluate presentations that do not comply with ACCME, FDA, and HHS OIG requirements for Certified CME. Perhaps this is why the 2008 Manhattan Research survey of 902 physicians showed that 92 percent of physicians who participated in CME believed it was not biased and a similar

percentage (91 percent) either supported or did not oppose commercial support of CME. This evidence, combined with the conclusion of the 2008 ACCME literature review that “there is no evidence to support or refute” speculation that commercial support produces bias in CME activities, forces stakeholders to consider the following:

1. Widespread education about ethical roles of physicians as CME participants and faculty,
2. Rigorous enforcement of updated CME compliance policies and measures, and
3. Cautious consideration of actions that limit freedoms of physician choice or harm development of quality education, especially in the absence of evidence to support additional changes

Response to 2009 Institute of Medicine Report on Conflicts

Despite all the best intentions, the federal Institute of Medicine is making proposals for CME’s future based on facts from the distant past. In its 2009 report on *Conflict of Interest in Medical Research, Education, and Practice*, the IOM released a report (underwritten by the Josiah Macy, Jr. Foundation) calling for an end to educational grants from pharmaceutical and medical device manufacturers.

Some of the report’s conclusions (Eliminate non-educational interventions from university campuses) make sense. But when you dig into the report’s findings on CME, you find mostly outdated data and arguments that do not take into account the dramatic regulatory and accreditation board rules now required to ensure that CME excludes industry influence and addresses all conflicts of interest.

Most important, the report generally confuses Certified CME with other forms of so-called “education” and relationships that have nothing to do with CME. Again, Certified CME activities only are those developed by accredited providers of CME in compliance with all ACCME standards and guidelines, as well as FDA and Health and Human Services Office of Inspector General Compliance Guidance requirements that ensure CME is “independent from promotional influence.”

But by trying to address conflicts in research, education, and practice, the IOM mistakenly blends Certified CME with non-CME interactions. The result? Confusion and outdated data regarding CME, not clarity.

A few examples:

- In the report's table 5-1, the IOM mentions that drug companies provide lunches, pens, snacks, and dinners for medical students in the third year of schooling. The report complains of "non-educational" interventions in the learning environment. Worthy complaint, but the comments deal with grad school and do not apply in the least to Certified CME activities that occur after physicians are practicing.
- The IOM report cites studies about "influence" by manufacturers that date back to 1986. Oddly enough, the report does not mention at all the academic literature survey on bias produced by the ACCME in 2008 concluding that "no empirical evidence" exists to support a connection between industry grant funding for Certified CME and bias.
- In a flagrant violation of the principle of "evidence-based" reporting, the IOM report includes a "personal account" in which an unknown person states that CME speakers were hired on the basis of their support for a "sponsor's message." If this were the case, it would be a clear violation of ACCME standards and would cause the accredited provider to either be placed on probation or lose its accreditation. The report fails to mention that accredited providers must collect audience evaluations regarding any possible bias and have policies to address any such issues. In addition, the ACCME has a process for handling complaints and has implemented a monitoring system to detect and address any bias. Last, the report fails to mention that physicians are not compelled to attend any CME activity (they can get a year's worth of required credits over a few days at a single society annual meeting). Physicians attend CME because it's useful and needed, given the current explosion of healthcare information. Physician CME attendees also are required to evaluate activities for bias, and this information is easily obtained.
- The IOM report claims that bad CME activities were developed related to the federal Neurontin and Vioxx cases. The problem? The violations cited by the IOM report are specifically addressed and prohibited by current regulations (the CME enterprise has addressed past problems).
- The IOM report admonishes the ACCME by citing 2001 and 2003 articles stating that the ACCME Standards for Commercial Support of CME activities do not deter industry influence. Two problems: 1) the original articles did not include evidence to support the claim, and 2) the ACCME updated the Standards in 2004, as well as several new policies approved in subsequent years, to ensure that Certified CME is independent from promotional influence.

The CME enterprise has undergone many positive changes during the past five years. The media, public, and other stakeholders should acknowledge these improvements and support the development of independent, Certified CME.

Conclusion

In conclusion, NAAMECC would like to offer its thanks for your continued consideration and open dialogue regarding evidence and proposals that could improve patient care and public trust. We strongly support the efforts of U.S. Sen. Kohl and the Special Committee on Aging to foster this discussion and encourage you to consider the recommendations above, as well as the following:

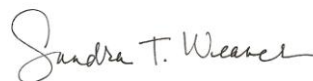
- support legislation and association efforts to educate physicians regarding all the current Certified CME criteria, policies, and need for ethical behavior, and
- monitor the current progress being made to ensure that regulations and standards are enforced and new avenues for support of Certified CME are opened.

Fruitful debate regarding ethical physician behavior can only be ensured when evidence-based ideas from all relevant stakeholders and education providers – academic institutions, medical education companies, professional societies, hospitals, and others – are included. By considering the suggested changes above, you will contribute to supporting a healthy future for Certified CME activities while helping improve evidence-based education and related patient care.

Best Regards,



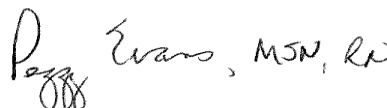
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