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Draft NAAMECC Comments to the AMA

Council on Ethical and Judicial Affairs and Council on Medical Education

CME Stakeholders Meeting – February 25, 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 two AMA Council Chairs, Regina M. Benjamin, MD, MBA, and Claudette C. Dalton, MD, for bringing together stakeholders in order to address the key questions posed in this meeting and 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 100 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.

Like CEJA and the Council on Medical Education, 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 the three specific questions identified by AMA for today's meeting, 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 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.

CEJA Opinions and Guidance for the CME Enterprise

Several AMA CEJA opinions are relevant to today's 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 CEJA 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." Ethical 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 CEJA opinion on CME also addresses appropriate practices for physicians serving as speakers, moderators, or other faculty at a Certified CME activity.

The CEJA opinions regarding CME and Gifts to Physicians from Industry contributed to physician awareness and a movement of increased ethical sensitivity, scrutiny, and rulemaking. Acting counter to the CEJA opinion on CME, a minority of bad actors broke existing rules and guidelines. 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, audits, 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)
- Enforcement action by the Office of Inspector General of the Department of Health and Human Services, which, according to the guidance, "has put teeth

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

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 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

In addition to the statement above, NAAMECC offers the following brief comments to specifically address the questions posited by the AMA for this stakeholders meeting.

Response to AMA Questions

When is conflicted expertise essential in CME? How can we tell when it is no longer needed?

Conflicted expertise is often essential for the development of excellent CME. In most professional fields, a correlational relationship exists between expertise and conflicts. One cannot develop expertise in a vacuum. Expertise is earned through years of study, practice, partnership and interaction with key stakeholders. All of these factors result in some form of conflict.

Take the simple example of an automobile mechanic. A mechanic develops expertise through years of practice, apprenticeships, partnerships, continuing education, and interaction with auto manufacturers, dealers, parts, tool and diagnostic companies. These relationships and other conflicts don't hinder the expert mechanic's ability to effectively and efficiently fix a car. Just the opposite; the relationships and related conflicts often are the raw materials required to forge the expertise. In short, an expert without conflict may well be an expert with no "expertise."

Because expertise is commonly an unavoidable necessity for evidence-based CME, conflicts must be managed by answering two questions:

1. Are all relevant conflicts identified and communicated to the learners? and
2. Was the content of the education biased because of the conflicts or any other factors (e.g., incomplete data, unscientific personal experience)?

It should be noted that bias may or may not stem from conflicts. As Jerome Groopman, MD, noted in his best-selling non-fiction book, *How Doctors Think*, bias can develop from well-intentioned, but unscientific or inaccurate personal observations. The CME enterprise, fortunately, has three possible remedies for bias. Initially, the accredited provider must conduct a clinical review of the content to ensure that it meets the definition of CME and ACCME content validation value statements. Second, the attendees evaluate activities for bias and can report issues to both the accredited provider and the ACCME. Because attendees receive no compensation for participating in a CME activity, they have no incentive to favorably evaluate it. Last, the ACCME is now auditing CME activities to identify and address possible issues of bias.

The updated ACCME criteria, combined with new policies and compliance measures, address issues of conflicts and bias in CME. All stakeholders should monitor the effectiveness of these quality improvement steps prior to developing or implementing additional changes.

Another means of detecting bias is feedback from peers working together on an educational initiative as well as the learner recipient of the education. Detractors of the current system for evaluating and monitoring CME minimize the ability of physicians, acknowledged as highly educated and highly sophisticated individuals, to detect bias in CME. There are no data to support this concern. And every accredited provider can provide CEJA and others with data that demonstrates how they detect and act upon bias reports or concerns.

What unique challenges do you as a stakeholder face regarding CME?

NAAMECC member organizations face three significant challenges regarding CME today, as follows.

1. **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, Congress, and some CME stakeholders still mistake Certified CME for unrelated activities.

2. Lack of widespread faculty education regarding their roles in CME.

Multiple CME faculty training initiatives have been undertaken. The AMA CEJA opinion on CME identifies appropriate roles and considerations for CME faculty members and moderators. NAAMECC members have initiated individual faculty training programs and attestation forms to promote the development of evidence-based presentations. In 2008, the Alliance for CME and Society for Academic CME collaboratively developed the National Faculty Education Initiative and verification database to improve faculty knowledge regarding CME and compliance with accreditation policies and other guidelines.

While each of these initiatives has enhanced physician CME faculty knowledge, widespread education should be developed and encouraged by physician member organizations and other stakeholders. Most of the negative news stories regarding CME over the past year have focused on faculty practices. Additional education for CME faculty members will result in continuous improvements to CME quality and credibility.

3. **Increased staffing needs and training to comply with multiple and sometimes conflicting compliance measures**

   All quality-minded CME stakeholders have implemented changes over the past four years to improve compliance. Funders have implemented unique grant management systems, provider evaluation tools, and CME policies. Education providers have changed structures, added compliance staff, and implemented policies covering conflict of interest identification and resolution, honoraria, faculty management, and educational partner management. The ACCME has implemented new criteria, policies, definitions, rapid response measures for non-compliance, monitoring, and an increased fee structure for accredited providers. As a result of all these changes, NAAMECC member organizations have faced increased costs in both human resources, staff training and technology systems to meet the new standards and requirements during a time of decreased education funding. In order to measure the true impact of recent changes, the CME enterprise would benefit from fewer new proposals and more analysis of the compliance measures already in effect.

How can we ensure that medicine sets the agenda for CME overall so that it meets the needs of patients and physicians rather than the interests of commercial supporters?

Certified CME that meets the definition of CME and complies with ACCME criteria, policies, content validation value statements, and the Standards for Commercial Support is, in fact, meeting the needs of patients and physicians. While commercial supporters may choose to fund education in specific disease or therapeutic areas, they do so because they are conducting research and development of drugs, biologics, and devices in these areas for the benefit of patients. It is appropriate that they support providers who commit to education that is focused on ensuring that evidence-based data are the foundation for any drug or therapeutic decisions by clinicians. It is unethical for any physician to present commercially

biased or promotional information in a Certified CME activity. In addition, because physician CME attendees have no incentive to participate in education that places the interests of commercial supporters above those of patients and physicians, medicine will continue to set the agenda for CME.

Development of excellent Certified CME is a collaboration of accredited providers, physician faculty, and other educational partners. As part of their missions, many accredited providers make a commitment to develop education that benefits their physician membership, patients, and other constituents. By developing education consistent with their missions, regardless of funding sources, accredited providers and their partners will ensure that CME meets the needs of patients and physicians.

Funding for continuing medical education has changed dramatically over the past five years. Prior to 2003, most funding came solely from education grants awarded by pharmaceutical and medical device marketing departments. Given the changes in regulatory and accreditation board requirements previously mentioned, most bio-pharmaceutical companies fully separated their marketing and sales efforts from funding of CME-certified activities. In addition, industry also made multi-million-dollar investments in the development of independent medical education departments and online grant management systems to ensure independence from potential bias and elimination of possible favoritism and other negative consequences. Last, the ACCME and other accreditation boards implemented updated accreditation criteria, standards, and policies to prevent undue influence from industry on the content of CME activities. We note additional factors affecting the current state of funding from commercial interests:

- Competitive environment for grant support fosters creativity and improves the quality of educational design and outcomes.
- Improvement in the funding process is evident; grant support decision makers are mostly experienced educators that define success as demonstrating a positive impact on the learner that has resulted in the development of more sophisticated grant submissions that include in-depth gap analysis, behavioral based learning objectives, and clear methods for assessing educational effectiveness.
- We are unaware of any empirical evidence regarding flaws in the current funding system.

- We appreciate and support many of the accreditation and regulatory changes that have been made and believe the current system improvements require appropriate time to take effect in order to make an objective assessment of their ability to continue to improve CME and CE.
- Within the emerging funding environment, we have seen the advent of new collaborative relationships among stakeholders (medical education companies, academic medical centers, hospitals, societies, etc.) and believe this will further improve CE and CME quality.
- We strongly encourage and support funding from new, additional and multiple sources. In fact, many NAAMECC members have pioneered grant funding initiatives with non-commercial sources, including the federal government, U.S. Centers for Disease Control and Prevention, retail and manufacturing companies (e.g., McDonalds Corp.) that develop non-pharmaceutical goods and services.

There are two critical questions that must be answered in any discussion regarding the CME agenda and improvement today:

1. **Is the current system for CME advancing and improving patient care and physician education or failing?** If the former, our debate should focus on adjustments that can continue the progress and improvement. We are confident that the continuing healthcare education being developed today is more effective and of higher caliber than CME developed just a few years ago. This is partly due to demands by physicians and other participants and partly due to an increased focus on quality and compliance by media, government and accreditation boards that accredit education providers.

2. The second question required in this discussion is **"What are the intended and possibly unintended consequences of any significant recommended changes or proposals?"** We are witnessing perception and financial challenges in CME. Legislative and regulatory bodies are considering significant changes to the U.S. healthcare framework. Practicing physicians are economically squeezed and strapped for time to educate themselves and pursue lifelong learning. Consumers are benefitting from life-improving and life-extending healthcare at the same time they are being inundated and confused by an explosion of advertising and web-based information. The evidence supporting any policy changes for CME must be

fully analyzed and openly discussed to determine potential consequences prior to the release of reports or proposals. The last thing the field of continuing healthcare education needs at this juncture is to cripple the progress we have made and harm healthcare practitioners and patients alike.

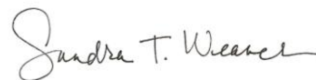
Conclusion

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 the AMA CEJA and Council on Medical Education to foster this discussion and encourage you to consider the recommendations above, as well as the following:

- firmly restate CEJA's principles, including those addressing ethical behavior of CME attendees and faculty
- help physicians in training and practice fully understand all the current criteria, policies, and need for ethical behavior, and
- monitor the current progress being made to ensure that rules are enforced and new avenues for support of excellent 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 support a healthy future for Certified CME activities while helping improve evidence-based education and related patient care.

Best Regards,



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