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Mission

The Alliance is a community of professionals dedicated to accelerating excellence in health care performance through education, advocacy, and collaboration.

June 10, 2011

THIS LETTER WAS SENT TO THE CHAIR OF EACH STATE MEDICAL SOCIETY AMA DELEGATION.

RE: CEJA Report 1-A-11: Financial Relationships with Industry in Continuing Medical Education (CME)

Reference Committee on Amendments to Constitution and Bylaws

June 19, 2011, 1:30 to 6:00 p.m.; Hyatt Regency Hotel; Chicago, IL

Dear _____:

The Alliance for Continuing Medical Education (Alliance) represents more than 2,300 professionals who strive every day to improve patient care and outcomes through the design and delivery of unbiased, evidence-based education for health care professionals. On June 19, 2011, the AMA Reference Committee on Amendments to the Constitution and Bylaws will consider CEJA Report 1-A-11 on "Financial Relationships with Industry in Continuing Medical Education". **The Alliance strongly recommends that this report be referred back to CEJA for additional consideration and modification.**

For all certified continuing medical education, Alliance members adhere to the Standards for Commercial Support promulgated by the Accreditation Council for Continuing Medical Education (ACCME), of which the AMA is a member organization. After a careful review, the Alliance has concluded that the CEJA Report 1-A-11 does not fully recognize the ACCME guidelines, is not supported by available, scholarly research and would require that providers spend time and resources developing unnecessary processes. Details regarding issues with specific recommendations in the CEJA report are included in the attached response.

Your consideration of the Alliance position would be very much appreciated.

Sincerely,

George Mejicano, MD
Alliance President

cc: Executive Director, State Medical Society

Alliance for CME Response re: CEJA Report 1-A-11

The Council on Ethical and Judicial Affairs (CEJA) of the American Medical Association (AMA) is an important entity charged with investigating “matters pertaining to the relations of physicians to one another or to the public” (CEJA bylaws 6.523). However, it has extended its jurisdiction beyond the authority granted to it by offering opinion on the much discussed and highly regulated area of relationships between certified continuing medical education (CME) and industry in Report 1-A-11. The report does not fully recognize the appropriate accreditation guidelines currently in place which govern these relationships.

The Accreditation Council for Continuing Medical Education (ACCME), a national accrediting body created, in part, by the AMA itself, issued updated Standards of Commercial Support in 2005. Most other national accrediting bodies followed, outlining acceptable guidelines for professional interactions between CME providers, CME faculty, CME participants and industry. These standards have evolved since the original release and are backed by serious consequences when violations are discovered.

In addition to accreditation standards, regulatory entities, such as the Food and Drug Administration (FDA), the Office of Inspector General (OIG), the National Institutes of Health (NIH), the United States Senate and countless regional and state agencies have investigated and issued guidance, opinion or ruling shaping these interactions.

Finally, an increasing number of organizations, professional societies, member groups, academic centers and healthcare organizations have developed and issued their own codes of ethics and standards for interactions with industry, as well as mechanisms to monitor and identify challenges to those policies.

Sets of clearly defined national standards, federal, regional and state regulation, as well as local policy and monitoring exist to manage potential influence of CME by industry. These, coupled with a troubling lack of evidence suggesting these mechanisms, as they have been in place since 2005, are ineffective, negate the need – regardless of authority – for CEJA to issue an opinion on the matter.

The Alliance offers the following comments concerning the narrative introductory points made at the beginning of the report’s recommendation section as well as on the specific recommendations themselves, as noted below:

Introductory narrative language in recommendation section (page 8, lines 37-42)

The introductory comments leading to the specific recommendations included in the report state as a premise that “available data neither support nor disprove that financial relationships influence CME.” In light of this statement, the assertion that “CME that is independent of funding or in-kind support from sources that have financial interest in physicians’ recommendations promotes confidence in the independence and integrity of professional education, as does CME in which organizers, teachers, and others involved in educating physicians do not have financial relationships with industry. . .” is not supported by available scholarly evidence. The Alliance is not aware of evidence that shows learner confidence in the

independence and integrity of CME is promoted as a consequence of no industry support or faculty relationships related to that CME. To continue by saying “When possible, CME should be provided without such support or the participation of individuals who have financial interests in the educational subject matter” is an extension of the previous assertion that is also not justified by the available evidence. The Alliance recommends that these lines be eliminated from the CEJA report.

Recommendation (b) (iii)

(b) provide the information physician learners need to make critical judgments about an educational activity, including:

(iii) what steps have been taken to mitigate the potential influence of financial relationships.

The report states that “Standards have been established to address concerns about possible influence in CME, such as the ACCME Standards for Commercial Support. . . .” The AMA (as one of the seven Member organizations of the ACCME) has a voice in establishing these standards that regulate the relationships between CME provider organizations and industry supporters. The recommendation that physicians who “organize, teach, or have other roles in CME will provide the information physician learners need to make critical judgments about an educational activity, including what steps have been taken to mitigate the potential influence of financial relationships” creates an additional standard that is not part of the current ACCME Standards for Commercial Support. While it is the case that every CME provider organization must implement a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners, there is no current requirement that this mechanism be reported to the learners. Establishing this as an expectation on the part of the learner indirectly moves the AMA into the role that has been established for the ACCME. The Alliance believes that these two lines should be eliminated from the CEJA report.

Recommendations (c) (ii) and (c) (iii):

c) protect the independence of educational activities by:

(ii) adhering to a transparent process for prospectively determining when industry support is needed;

CEJA views industry support as potentially desirable when special conditions are met (e.g. education funding sources are uncertain, access to education is limited in resource-poor or geographically remote locations, or when high cost, high quality, and technologically advanced education methods are needed).

It is unclear what group(s) would make such a determination of need for industry funding, on what criteria decisions would be made, and what system would be used to prospectively evaluate all educational activities for industry funding. The source of incremental administrative and financial resources needed to address these new requirements was not identified.

The ACCME reported that Industry support for education decreased by approximately 30%, or \$355MM between 2007 and 2009, with a corresponding decrease in the number of supported activities. Rather than seeking to limit education funding from industry resulting in a further decrease of education activities, the Alliance recommends that appropriate organizations which support the provider communities seek new sources of incremental funding for physician education.

(iii) giving preference in selecting faculty or content developers to similarly qualified experts who do not have financial interests in the educational subject matter;

Industry engages expert physicians in consulting relationships to advance the diagnosis and treatment of diseases. Prohibiting or limiting the ability of these physicians to participate in educational activities will likely reduce the quality and effectiveness of physician education. Industry also has relationships with physicians who excel in teaching other clinicians, and to eliminate or reduce the role of this group of educators could also negatively impact the quality and effectiveness of medical education. This approach conflicts with the goal of advancing patient outcomes and population health by potentially limiting access to the best available scientific information delivered by those physicians who may possess the highest level of expertise.

Under this recommendation it is possible that physicians who have spent much of their professional careers researching and understanding the diseases and infections that affect patients would not be permitted to serve as faculty or content developers. A possible result is that faculty and developers who will be utilized may not be as knowledgeable about the array of therapeutic entities, emerging therapies, barriers to care, contraindications, risk management issues, and patient adherence challenges.

As noted previously, ACCME, PhRMA, FDA, OIG, CMSS, and other groups have created and implemented methods for successfully identifying and resolving potential conflicts, while at the same time ensuring that the highest level of independent, evidence based information is made available through appropriately designed CME learning activities.

The Alliance recommends that CEJA Report 1-A-11 be referred back to CEJA for additional consideration and modification.