Revised REPORT 17 OF THE COUNCIL ON MEDICAL EDUCATION (A-09)
Conflict of Interest and Bias in Continuing Medical Education
(Informational)

EXECUTIVE SUMMARY

This report is presented as a companion to Council on Ethical and Judicial Affairs Report 1-A-09, "Financial Relationships with Industry in Continuing Medical Education." This report traces the history and current state of commercial support for certified continuing medical education (CME) and explains the existing regulatory environment that governs the provision of CME activities so that they can be shown to be independent from commercial influence and can be certified for *AMA PRA Category 1 Credit*™, and other CME credits. Existing regulatory guidelines are sorted into the ethical framework proposed by CEJA to demonstrate how CEJA recommendations should be addressed by physicians as learners, faculty or CME providers. Strategies already in practice in the CME community for addressing the CEJA recommendations are described. The report also delineates CEJA recommendations that are aspirational in nature and for which therefore no guidance currently exists and thus will require further clarification. The report emphasizes that ultimately it is the professional responsibility of each physician, as learner, faculty or CME provider, to acquire the information necessary to judge whether a CME activity is, as CEJA proposes, ethically preferable, or ethically permissible, and then determine whether or not to participate in that activity. This report represents a compilation of existing practices in the CME community and does not introduce any new AMA policy.

REPORT OF THE COUNCIL ON MEDICAL EDUCATION

CME Report 17-A-09

Subject: Conflict of Interest and Bias in Continuing Medical Education: A Companion Report to CEJA Report 1-A-09

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INTRODUCTION

This informational report is a companion to the Council on Ethical and Judicial Affairs report "Financial Relationship with Industry in Continuing Medical Education" (Revised CEJA Report 1-A-09), and its focus is on translating the ethical framework developed by CEJA for dealing with the potential for conflict of interest (COI) and bias into workable strategies to operationalize the ethical principles outlined. The report therefore becomes a management strategy based on the premise that the pharmaceutical industry and the medical profession will continue to coexist and relate to each other, but the rules of engagement can and must evolve further.

In addition, it addresses the intersection between the CEJA report and the American Medical Association Physician's Recognition Award (AMA PRA) credit rules. The emphasis is on certified continuing medical education (CME) and its importance to concepts such as maintenance of competence, self assessment, performance in practice, and other issues. It is also about bias, in many forms, including the COI surrounding industry support of medical education, and the tools available to deal with them, such as are available in management and mitigation, as contrasted to divestment.

"Certified Continuing Medical Education" or "Certified CME" refers to educational activities developed and implemented in compliance with the certification requirements of either the AMA PRA CME Credit System or the policies of the American Academy of Family Physicians (AAFP) or the American Osteopathic Association (AOA) credit systems. Certified CME meets the requirements for Category 1 credit under AMA's PRA program by including compliance with Accreditation Council for Continuing Medical Education's (ACCME), and state and territorial medical societies' institutional accreditation standards as well as with relevant AMA ethics policy.

The relationship between physicians and the pharmaceutical industry represents one of the greatest challenges to medical professionalism. Funding of educational/promotional programs, sophisticated marketing techniques, and direct-to-consumer advertising are just a few, but important, modalities through which drug companies try to exert influence on physicians' prescribing habits.[1, 2] Understanding this relationship between the medical profession and the pharmaceutical industry, particularly as it impacts certified CME, will help physicians understand how these influences are interconnected. The resulting COI are morally important, because they address the trustworthiness which is part of the fabric of the physicians' social and professional behavior today.[1, 2]

Conflicts of interest occur when physicians have motives or are in situations that reasonable observers could conclude compromise the moral requirements of the physician's role. In terms of industry influences, financial COI occur when physicians are tempted to--or actually do--deviate

from their professional obligations for economic or other personal gain. The bias thus introduced violates both the best interests of patients and the standards of scientific integrity.[3,4]

BACKGROUND

The stage was being set for the dependence of CME on funding by the pharmaceutical and medical device industries during the 1950-1960s.[5] From about 1951 to 1961 almost 5,000 new prescription products entered the market; it was estimated that 70% of the expenditures on drugs in 1961 were for drugs not available in 1951.[6] Making all these pharmaceuticals known to the physicians of the country led to increased emphasis on branding and growth of journal and other media advertising. There also developed a flood of individual office visits by pharmaceutical representatives,[6] the "detail persons" who ultimately became very popular with physicians primarily for the drug information they brought.

A debate developed between those interested in strong ties between organized medicine and the pharmaceutical industry and those supporting the development and promotion of rational therapeutics. The public profile of the debate was raised by Senator Estes Kefauver (D-TN) Hearings of 1959-1962. The resulting Kefauver-Harris Amendments required proof of efficacy prior to drug approval as well as improving the marketing of drugs and the postgraduate pharmaceutical education of the physician work force. Emerging from the Kefauver hearings was an AMA-proposed pragmatic compromise for coexistence: carefully guarded advertising standards and improved physician education.[5]

The Kefauver hearings functioned more or less as a 'green light' to the development of educational activities over the ensuing years, and as the programs became larger and more technically sophisticated they also became more expensive. As the educational programs developed, the pharmaceutical industry developed apace as a very willing and able financial partner.

Complicated boundary relationships, always present to some extent, ultimately led to more Congressional hearings in 1976 by Sen. Gaylord Nelson (D-WI), with little effect. In the early 1990s, extravagant marketing practices by the pharmaceutical industry led to additional hearings held by Sen. Edward Kennedy (D-MA).[5] Threat of government regulation during this period led to the development of self-regulatory plans by both the pharmaceutical industry and the medical profession.

Beginning in 2005, the US Senate Finance Committee initiated an investigation into the high cost of pharmaceuticals, with a focus on how pharmaceutical companies used educational grants to build market share for newer, more lucrative products. The resulting report published April 6, 2007 concluded that, while there appeared to be "promising trends in pharmaceutical manufacturers' use of educational grants," concerns remained regarding issues such as veiled advertising, kickbacks, bias in clinical protocols, and off-label promotion. In addition, the Senate Special Committee on Aging has been exploring issues that concern elderly Americans, many of whom are reported to be struggling to meet rising health care and prescription drug costs. In June 2007, this Special Committee hosted a series of hearings under the title, "Paid to Prescribe?: Exploring the Relationships Between Doctors and the Drug Industry." Legislation has been proposed in the form of the Physician Payment Sunshine Act (5.301), introduced in January 2009, which would require manufacturers and group purchasing organizations to report on a wide range of payments to physicians and physician-owned entities.

THE DUTY TO EDUCATE

The AMA has long recognized the important role of education in the physician's professional development. The importance of that role emanates from the AMA's Principles of Medical Ethics, which describes physicians' ethical and professional obligation to continue their education throughout their professional life:

V. A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated. (AMA Code of Medical Ethics, Adopted by the AMA's House of Delegates June 17, 2001)[7]

This statement clearly declares that education for the medical profession is an imperative to maintain competence and, as such, is also a necessary component of professionalism and one of the standards of conduct that define the ethical behavior of physicians. This understanding is further articulated in the definition of CME that has been approved by the AMA House of Delegates:

CME consists of educational activities which serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, the public or the profession. The content of CME is the body of knowledge and skills generally recognized and accepted by the profession as within the basic medical sciences, the discipline of clinical medicine, and the provision of health care to the public. (AMA Policy H-300.988, AMA Policy Database) [8]

At its first meeting in 1847, the AMA heard reports from two committees: the Committee on Ethics and the Committee on Education. Thus, since its founding, the education of physicians has been a part of the AMA's responsibility both to the profession and the public. The Committee on Education eventually evolved, in 1904, into the AMA's Council on Medical Education, which has historically been involved in all aspects of the continuum of medical education. In 1968, after several studies on the subject of postgraduate medical education, the Council on Medical Education developed the PRA specifically to recognize the important role CME plays in the professional life of physicians and the patients they serve by providing "recognition for the many thousands of physicians who regularly participate in CME" and encouraging "all physicians to keep up-to-date and to improve their knowledge and judgment" through their involvement in CME. The House of Delegates' approval of the PRA signaled the beginning of the AMA PRA CME credit system.

Currently there are three major CME credit systems in the United States: The AAFP Prescribed and Elective Credit System, the AMA PRA Credit System (*AMA PRA Category 1 Credit*™ and *AMA PRA Category 2 Credit*™) and the AOA Categories 1-A, 1-B, 2-A and 2-B Credit System. CME providers that wish to certify activities for AOA or AAFP credits apply directly to these organizations for approval to award these credits. The AMA PRA Credit System is currently the largest of the three CME credit systems. AMA PRA credit is recognized by hospital credentialing bodies, the majority of state medical licensure boards and medical specialty certifying boards, as well as other organizations that require evidence of participation in CME.

Starting in the early 1960s, the AMA began to evaluate organizations interested in providing CME and to recognize those that met a series of AMA requirements. The mechanism to achieve this type of recognition has changed over the years and, since 1981, institutional accreditation by the ACCME has been used by the AMA to recognize institutions in the US that are worthy of the privilege to designate continuing medical education activities for AMA credit, while preserving the right to withdraw that privilege if an institution violates the AMA PRA credit rules. In order for an institution in the US to designate and award *AMA PRA Category 1 Credit*™, the CME provider

must thus be directly accredited by the ACCME or one of 47 territorial or state medical societies (SMS) recognized by ACCME to accredit intrastate CME providers. In the latest data reported by ACCME, as of March 2009, there were 735 ACCME-accredited providers and 1,592 SMS-accredited providers. Among the organizations accredited directly by the ACCME, there are 270 non-profit physician membership organizations such as national specialty societies, 150 publishing/education companies, 123 medical schools, and 93 hospital/healthcare delivery systems. Among the organizations accredited by the SMS, eighty percent are hospitals or physician clinics and nine percent are state specialty societies. The accredited providers are responsible to the ACCME or SMS for their compliance with the accreditation criteria, including the Standards for Commercial Support, and to the AMA for their compliance with the AMA PRA credit rules or certification standards as promulgated by the AMA Council on Medical Education. This report therefore addresses the intersection of the CEJA report with AMA PRA credit rules.

Since the AMA recognizes an ethical responsibility to "continue to study" and "maintain a commitment to medical education," it is critical that accredited CME providers and physicians alike understand and comply with the "AMA Council on Ethical and Judicial Affairs opinions that address the ethical obligations that underpin physician participation in CME" (AMA PRA Book, 2006 Revision). Thus, the Council on Medical Education has explicitly linked the AMA PRA CME Credit system with the CEJA opinions by requiring that activities that are certified for *AMA PRA Category 1 Credit*™ by accredited CME providers comply not only with the AMA PRA credit standards developed by the Council on Medical Education but also with the pertinent CEJA opinions. Consequently, what distinguishes activities certified by accredited CME providers for AMA PRA credit from other non-certified education or promotional activities is the rigorous process that is applied to assure that accreditation, certification, and CEJA standards are upheld in the development of educational activities that provide valid and independent evidence for clinical decisions.

The AMA maintains a strong ongoing commitment to continuous physician professional development. The AMA PRA credit system continues to evolve in response to the changing needs of physicians seeking high quality certified CME. Advances in technology resulted in AMA recognition and approval of Internet Point of Care as a certified CME format in 2005. Similarly, in 2004, an understanding of innovative and expanded educational concepts resulted in the AMA's approval of Performance Improvement CME.

THE CURRENT STATE OF COMMERCIAL SUPPORT

For the past decade or more, a major funding source for accredited CME providers has been commercial support, primarily provided by the pharmaceutical, biomedical and medical device industries. In recent years this funding has come under increased scrutiny by governmental agencies, the media, and from within the house of medicine itself. As a result, many of the regulations affecting CME have been revised or are in the process of being reevaluated, while at the same time new legislative proposals have been introduced that could further affect funding of CME.

On an annual basis, the ACCME produces a report based on self-reported data from CME providers (including those accredited directly by ACCME and those accredited by state/territorial medical societies) that describes aspects of the CME enterprise for the given year. The most recent data available from ACCME are from calendar year 2007.[9] Significant findings from these data are that the number of ACCME directly accredited CME providers and the number of activities they produced continued to grow in 2007. At the same time the number of SMS accredited CME providers, the vast majority of which, as already stated, are community hospitals and physician clinics, and the number of activities they produced declined. Similarly, commercial support

increased slightly for ACCME CME providers (though at a slower rate of growth than in the past), while for local CME providers commercial support declined.

While the level of commercial support received varies significantly, both in actual dollars and as a percentage of total income, among the different types of providers as defined by the ACCME, as well as among providers within the same grouping, the aggregate amounts received by CME providers authorized to award *AMA PRA Category 1 Credit*™ in the US are as follows: In 2007 ACCME directly accredited providers reported a total income of $2.5 billion of which $1.2 billion (or 47%) was received through commercial support from industry for CME activities. SMS accredited providers reported a total income of $145.9 million, of which $37.5 million, (or 26%) was received through commercial support from industry. In the same timeframe, ACCME directly accredited providers reported expenses totaling $1.9 billion while SMS accredited providers reported expenses totaling $145.6 million. It is unclear if these financial data represent CME providers' total operating costs incurred during this reporting period. "Overhead" costs such as office space, staff salaries/benefits, and in-kind volunteer work may not have been reported consistently by all provider types. It is therefore possible, indeed likely, that commercial support funds a far smaller portion of the CME enterprise than these data initially suggest. That said, concerns have been raised that a decrease in commercial support, obtained through educational grants, could result in decreased access to CME for physicians especially at the local level.

REGULATIONS, REPORTS AND GUIDELINES THAT AFFECT CERTIFIED CME

CME providers and physicians that participate as content developers, faculty or learners in certified CME activities are impacted by a number of regulations, reports, and guidelines that affect the manner in which certified CME activities are developed. The main policies or guidance that CME providers and individuals have been required or advised to follow in order to manage and control commercial influence in certified CME activities are described below.

CEJA Ethical Opinions 8.061 and 9.011

Two current CEJA opinions relate directly to commercial influence of physicians and commercial influence in CME activities. Opinion 8.061, "Gifts to Physicians from Industry" (Adopted December 1990; updated June 1996 and June 1998)[10] reflects concerns about certain gifts from industry to physicians that may not be consistent with, the Principles of Medical Ethics and sets forth specific guidelines to avoid the acceptance of inappropriate gifts. Opinion 9.011, "Continuing Medical Education" (Issued December 1993; updated June 1996),[11] provides guidelines for physicians as learners, faculty and CME providers related to a physician's ethical obligation to maintain his or her medical expertise through CME and also to make sure that the content of the CME activity is appropriate.

All educational activities certified for *AMA PRA Category 1 Credit*™ must conform to these opinions; thus, accredited CME providers must conform to these opinions in developing certified activities. As already stated, if an accredited CME provider refuses or fails to comply with AMA PRA requirements for designating *AMA PRA Category 1 Credit*™, including compliance with these CEJA opinions, the AMA may withdraw that provider's privilege to designate and award credits for CME activities.[12]

ACCME Standards for Commercial Support (SCS) – Standards to Ensure the Independence of CME Activities

In 1987, the ACCME first adopted its "Guidelines for Commercial Support," which were updated and expanded into the 1992 "Standards for Commercial Support (SCS)." In 2004, the ACCME adopted the most recent update of the standards. This update describes practices that the ACCME considers appropriate for accredited providers to ensure that their CME activities are independent, free of commercial bias and beyond the control of persons or organizations with an economic interest in influencing the content of CME. The updated 2004 SCS describe six Standards: (1) independence (from commercial influence), (2) resolution of personal conflicts of interest, (3) appropriate use of commercial support, (4) appropriate management of associated commercial promotion, (5) content and format without commercial bias, and (6) disclosures relevant to potential commercial bias[13] (see Appendix).

CME providers must comply with these standards in order to be accredited by the ACCME or by a territorial or SMS that is recognized by ACCME to accredit intrastate CME providers. Although ACCME accreditation is a voluntary process, the AMA has determined that US CME providers that want to designate and award *AMA PRA Category 1 Credits*™ must be accredited through the ACCME/SMS system. Thus, the loss of ACCME/SMS accreditation means that a CME provider may not provide *AMA PRA Category 1 Credit*™ to its physician learners.

The ACCME Standards for Commercial Support have come to be widely recognized as credible principles to support the independence of CME. The SCS have been adopted by other organizations that certify activities including: The AAFP, the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC). As a result, compliance with the ACCME Standards for Commercial Support is an expectation of major organizations that certify activities for continuing education credit.

PhRMA Code

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents research-based pharmaceutical and biotechnology companies that develop and market new medicines for patients. In July 2008, PhRMA adopted an updated voluntary *Code on Interactions with Healthcare Professionals*[14] that became effective in January 2009. This Code is intended to ensure that pharmaceutical and biotechnology companies' interactions with healthcare professionals are professional exchanges designed to benefit patients and enhance the practice of medicine. The Code is based on the principle that a healthcare professional's care of patients should be centered solely on patients' medical needs and the healthcare professional's medical knowledge and experience. This Code builds upon the standards set forth in its predecessor, the *PhRMA Code on Interactions with Healthcare Professionals* that took effect on July 1, 2002. Like the 2002 version, the new Code addresses interactions between physicians and industry representatives with respect to marketed products and related pre-launch activities. Companies that publicly announce their commitment to abide by the Code and who complete an annual certification that they have policies and procedures in place to foster compliance with the Code will be identified by PhRMA on a public web site. In addition, companies are encouraged to seek external verification at least once every three years to demonstrate that the company has implemented policies and procedures to foster compliance with the Code.

While the PhRMA code is directed to pharmaceutical and biotechnology companies, its principles mirror those that direct both CME providers and faculty that interact with the companies that provide commercial support for certified CME activities.

Report of an Association of American Medical Colleges' Task Force on Industry Funding of Medical Education

In 2006, AAMC charged a special Task Force on Industry Funding of Medical Education with forming consensus principles to guide the AAMC, medical schools, and teaching hospitals in developing policies and procedures to manage industry gifting practices and financial support of medical education for students, trainees, faculty, and community physicians. The resultant report, published in June 2008, sets forth the directive for medical schools and teaching hospitals to manage all COI through effective self-regulation. The report acknowledges the implementation of new policies and procedures in several medical schools and teaching hospitals to address industry support of medical education, and it advises all academic medical centers to accelerate their adoption of policies that better manage, and when necessary prohibit, academic-industry interactions that can create COI and undermine professionalism. In addition, the report states that "industry should voluntarily discontinue those practices that compromise professionalism as well as public trust."[15]

Its member organizations look to the AAMC for guidance on issues related to medical education and the certification of CME activities, and the recommendations in this report are, in fact, already being adopted by some medical schools and teaching hospitals.

ETHICAL FRAMEWORK PROPOSED BY CEJA

Revised CEJA Report 1-A-09 recommends that the following ethical framework be adopted:

Medicine's autonomy and authority to self-regulate depend on its ability to ensure that physicians acquire, maintain, and apply the values, knowledge, skills, and judgment essential for quality patient care. To fulfill that obligation, the profession must safeguard the independence and integrity of continuing medical education.

Relationships with industry—i.e., pharmaceutical, biotechnology, and medical device companies—can offer enormous benefit to the profession and the patients it serves. However, commercial funding for professional education can pose significant ethical challenges to medicine's ability to focus primarily on the needs of patients and ensure quality education for physicians.

The considerations below define an ethical framework to guide professional practice with respect to financial relationships in the context of continuing medical education. Physicians should seek out CME activities based on the following guidelines:

It is ethically preferable that:

1. CME providers accept funding only from sources that have no direct financial interest in a physician's clinical recommendations; and that

2. Individuals who program, develop content for, or teach in CME activities:

a. have no current, recent (within the preceding 12 months), or potential direct financial interest (e.g., royalties or ownership interest) in the educational subject matter; and

b. are not currently and have not recently been (within the preceding 12 months) involved in a compensated relationship (e.g., direct employment, service on a speakers bureau, service as a consultant or expert witness) with a commercial entity that has a financial interest in the educational subject matter.

It is ethically permissible that:

3. CME providers accept funding from industry sources if the following conditions are met:

a. the educational activity is planned by the provider based on needs identified independent of and prior to solicitation or acceptance of the funding; and
b. the provider is not required to accept advice or services concerning educational content, faculty or content developers, or other educational matters as a condition of funding; and
c. the source of the funding is clearly disclosed; and
d. the CME provider is not overly reliant on funding from industry sources.

4. CME providers permit individuals who have modest financial interests in the educational subject matter to program, develop content for, or teach in CME activities if the following conditions are met:

a. the existence and magnitude of any financial interests are clearly disclosed; and
b. steps are taken to eliminate or mitigate the potential influence of those interests.

5. CME providers permit an individual who currently has a direct, substantial, and unavoidable financial interest in the educational subject matter (e.g., as the inventor of a new device) to program, develop content for, or teach in a CME activity only if the following conditions are met:

a. the individual is demonstrably uniquely qualified as an expert in the relevant body of knowledge or skills; and
b. participants are clearly informed about the nature and magnitude of the individual's specific financial interest in the subject matter; and
c. there is a demonstrated, compelling need for the specific CME activity in the professional community that cannot otherwise be met; and
d. steps are taken to mitigate the potential influence of the unavoidable financial interest to the greatest extent possible; and
e. every effort is made to develop a pool of qualified, independent experts as quickly as possible.

CME PRACTICES THAT ADDRESS THE PROPOSED ETHICAL FRAMEWORK

The reports, guidelines, and standards described earlier in this report provide guidance to physicians in their roles as learners, CME providers (e.g., members of CME committees responsible for reviewing, modifying and approving activities for *AMA PRA Category 1 Credit™*, members of activity planning committees, and/or as activity directors) and faculty/authors for implementing or participating in certified CME activities. Because physicians may serve in more than one capacity, it is important that they understand their duties in each of these three roles.

Many of these guidelines, as well as the body and recommendations of the CEJA report, address components of the CEJA recommendations such as disclosure of conflicts of interest and mitigating the potential influence of commercial interests.

Ethically preferable CME:

Duties of CME providers in *ethically preferable* certified CME derived from existing guidelines

CME providers should ensure that the certified CME activities are balanced, with faculty members presenting a broad range of scientifically supportable viewpoints related to the topic at hand.[11] Educational materials that are part of a CME activity, such as slides, abstracts, or handouts cannot contain any advertising, trade name, or a product-group message.[13] The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.[13] Presentations about pharmaceutical choices must give a balanced view of available therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, where available, trade names from several companies should be used, and not trade names from just a single company.[13] Academic medical centers should prohibit physicians, trainees, and students in their role as faculty from allowing their professional presentations of any kind, oral or written, to be ghostwritten by any party, industry, or otherwise.[15]

CME providers also must be able to show, in keeping with the tenets CEJA proposes for what is *ethically preferable*, (i.e., no commercial support and no individual financial relationships with industry) that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation, or evaluation of the CME activity. For an individual with no relevant financial relationship(s), the learners must be informed that no relevant financial relationship(s) exist.[13] Providers must ensure that this information is disclosed to learners prior to the beginning of the educational activity.[13]

Duties of CME faculty in *ethically preferable* certified CME derived from existing guidelines

Physicians serving as presenters, moderators, or other faculty at a CME conference should ensure that a) research findings and therapeutic recommendations are based on scientifically accurate, up-to-date information and are presented in a balanced, objective manner; and b) the content of their presentation is not modified or influenced by representatives of industry or other financial contributors, and they do not employ materials whose content is shaped by industry.[11] Educational materials that are part of a CME activity, such as slides, abstracts, and handouts, cannot contain any advertising, trade name, or a product-group message.[13] In addition, professional presentations of any kind, oral or written, should not be ghostwritten by any party, industry, or otherwise.[15]

Ethically permissible CME:

Duties of CME providers in *ethically permissible* certified CME derived from existing guidelines

In addition to the duties of CME providers described under the *ethically preferable* framework, the further obligations of the CME providers under the *ethically permissible* framework, where there may be commercial funding and individuals may have financial interests, are as follows*:*

Funding from industry or others may be accepted in accordance with Opinion 8.061, "Gifts to Physicians from Industry".[11] Such financial support for CME is intended to support education on a full range of treatment options and not to promote a particular medicine.[14]

The CME providers must make all decisions regarding the disposition and disbursement of commercial support.[13] Providers cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other educational matters, including content from a commercial interest, as conditions of contributing funds or services.[13] All commercial support associated with a CME activity must be given with the full knowledge and approval of the CME providers.[13] The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the providers and their educational partner(s).[13.] No payments from commercial funders shall be given directly to the director of the activity, planning committee members, teachers or authors, joint sponsor, or any others involved with the supported activity.[13] When companies help fund medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers (CME providers) of the conferences or lectures.[10,13,14] CME providers should ensure that representatives of industry or other financial contributors do not exert control over the choice of moderators, presenters, or other faculty, or modify the content of faculty presentations.[11] The company should not provide any advice or guidance to the CME providers, even if asked by the providers, regarding the content or faculty for a particular CME program funded by a grant from the company.[14]

The CME providers must have implemented a mechanism to identify and resolve all COI prior to the education activity being delivered to learners.[13] Strategies that CME Providers may use to resolve COI or mitigate the potential influence of the financial interests may include, but are not limited to:

1) having content reviewed and revised as necessary by experts that do not have relationships with the commercial entity;
2) limiting the presentation to pathophysiology and mechanisms of disease rather than therapeutic recommendations;
3) selecting another speaker to present clinical implications after the primary speaker that has a COI has reported a scientific discovery;
4) changing the focus of the presentation so that the content is not about products or services of the COI;
5) limiting the presentation to research results and assigning another speaker with no COI to address the broader implications of clinical care when an individual with a COI is a principal investigator on a project funded by industry; or
6) limiting the sources for recommendations that the speaker with a COI may use such as the AAFP Evidenced-Based CME Requirements.[16]

In addition to these strategies to resolve COI in advance, CME providers may also assign clinical practitioners to monitor educational activities so that they may be able to address any perceived commercial bias during a live presentation immediately if it occurs.

CME providers must also assure that arrangements for commercial exhibits or advertisements do not influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.[13] Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from certified CME.[13]

CME providers must further ensure the disclosure to learners of any individuals' relevant financial relationship(s), including the following information: (a) the name of the individual; (b) the name of the commercial interest(s); (c) the nature of the relationship the person has with each commercial interest.[13] In addition, the CME providers must also disclose to learners the source of all support from commercial interests. Further, when commercial support is "in-kind," the nature of the support must be disclosed to learners.[13] Disclosure must never include the use of a trade name or a product-group message.[13]

Duties of CME faculty in *ethically permissible* certified CME derived from existing guidelines

In addition to the duties of faculty described under the *ethically preferable* framework, the further obligations of the faculty under the *ethically permissible* framework are as follows*:*

Faculty must be aware of and abide by the providers' written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers, and authors.[13] Faculty should only accept honoraria or reimbursement of out-of–pocket expenses in compliance with the providers' written policies and procedures and directly from the providers, joint sponsor or designated educational partner. At no time should the faculty accept direct payment from the commercial funder.[13]

Ethical Issues for physician learners in all CEJA categories

For physician learners, the same issues arise whether the activity falls into either the *ethically preferable* or *ethically permissible* frameworks. Physician-learners should seek out CME activities that are based on the CEJA ethical framework.

The physician choosing among CME activities should assess the activities' educational value and select only those activities which are of high quality and appropriate for the physician's educational needs. When selecting formal CME activities, the physician should, at a minimum, choose only those activities that:

(a) are offered by sponsors accredited by the Accreditation Council for Continuing Medical Education (ACCME), the American Academy of Family Physicians (AAFP), a state (or territorial) medical society (or the American Osteopathic Association as referenced in the body of the CEJA report);
(b) contain information on subjects relevant to the physician's needs;
(c) are responsibly conducted by qualified faculty; and
(d) conform to Opinion 8.061, "Gifts to Physicians from Industry."[11]

The educational value of the CME conference or activity must be the primary consideration in the physician's decision to attend or participate. Though amenities unrelated to the educational purpose of the activity may play a role in the physician's decision to participate, this role should be secondary to the educational content of the conference.[11]

Subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging, registration fees, or other personal expenses of physician learners attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians' time.[10,13,14,15]

From the Council on Medical Education's perspective, the learner has an ongoing obligation to understand the sources of funding and the methods by which the CME activity was developed. Physician learners should critically review the scientific information that is presented to determine whether any bias can be detected. The funding information should be transparent to the learner but

if it is not, the learner should seek it. These guidelines apply to the learner in all of the categories proposed by CEJA. Learners, as part of the evaluation process of the CME activity, are usually asked to assess the presence or absence of bias, and they should be prepared to make this judgment routinely. At all times, the learner must be ready to understand and judge the extent of the separation of content and funding and assess the value of the content accordingly.

The Council on Medical Education acknowledges that some of the CEJA recommendations are aspirational and there may not be existing guidelines or regulations to guide physicians and the CME community on how to demonstrate compliance. Additional interpretations, time, and experience will be needed before clarity in application and eventual compliance with these recommendations can be demonstrated. Specifically, the CEJA recommendations and terms requiring clarification are as underlined below:

3d. the CME provider is not overly reliant on funding from industry sources.

5a. the individual is demonstrably uniquely qualified as an expert in the relevant body of knowledge or skills.
5c. there is a demonstrated, compelling need for the specific CME activity in the professional community that cannot otherwise be met.

5e. every effort is made to develop a pool of qualified, independent experts as quickly as possible.

In addition, recommendation 4 allows CME providers to permit individuals who have "modest" financial interests in the educational subject matter to program, develop content for, or teach in CME activities if certain conditions are met, but the term "modest" is not defined and therefore subject to interpretation.

This report has described the inextricable link between the CEJA ethical opinions and the AMA PRA credit system; therefore, activities that do not conform to the CEJA ethical framework or other pertinent CEJA opinions by using the mechanisms outlined above and/or other mechanisms to reach the stated CEJA objectives, may not be certified for *AMA PRA Category 1 Credit*™.

It should be noted that neither the CEJA report nor this report addresses promotional or industry designed, Food and Drug Administration-regulated events. Promotional events, as already stated in previous CEJA opinions, should be clearly indicated as such. There cannot be *AMA PRA Category 1 Credit*™ given for those activities. All physicians should be aware of the difference between purely promotional and certified CME activities.

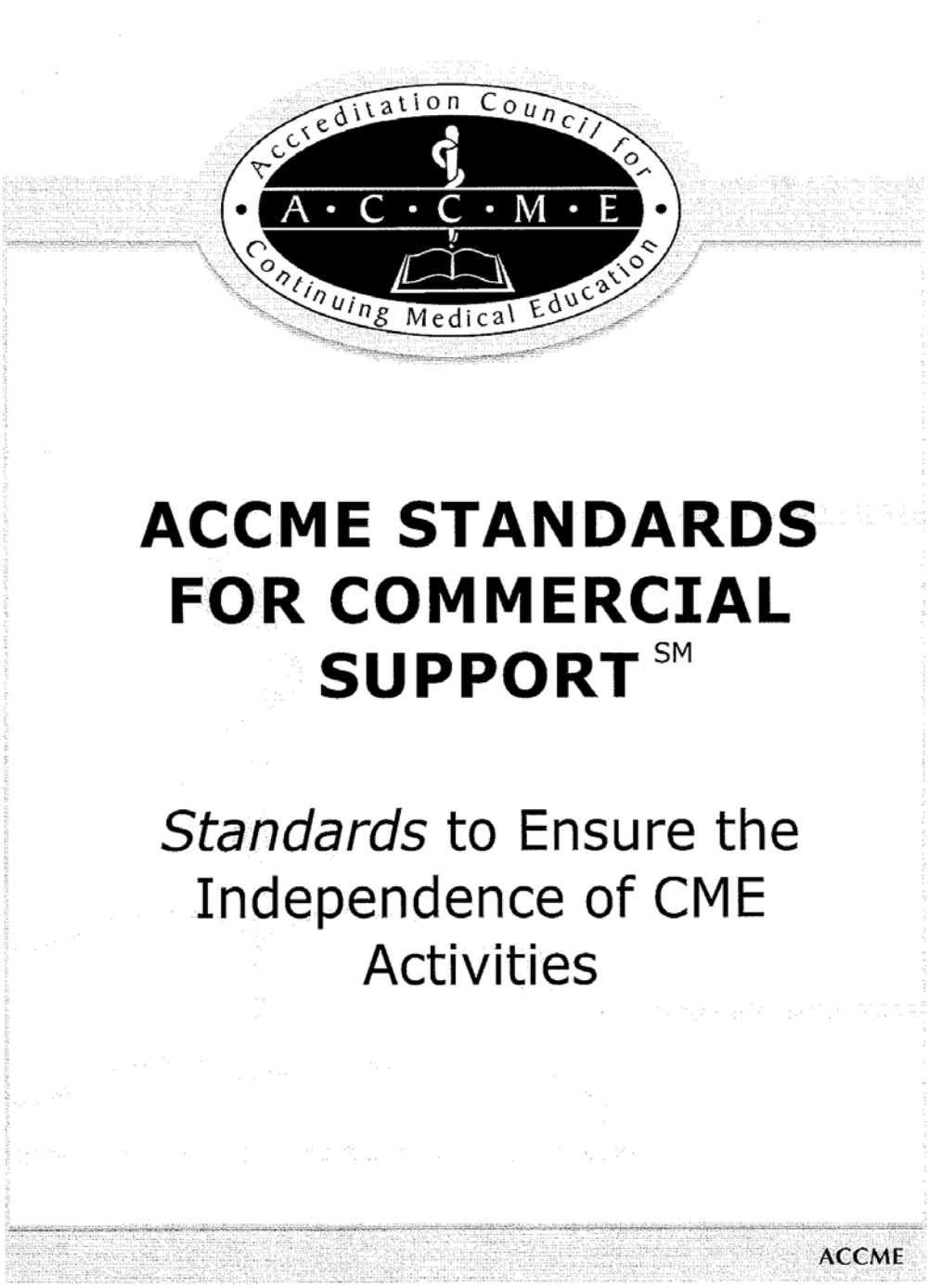
SUMMARY

This report represents a compilation of existing practices in the CME community and does not introduce any new AMA policy. The report traces the history of commercial support for CME and explains the existing regulatory environment in which certain activities that demonstrate independence from commercial influence may be certified for AMA PRA and other CME credits. Some of the current guidelines are sorted into the ethical framework proposed by CEJA to demonstrate where CEJA recommendations are already being addressed in the development of certified activities. The AMA has explicitly stated that compliance with CEJA opinions is a requirement for designating a CME activity for *AMA PRA Category 1 Credit*™. Accordingly, all activities planned in the future will need to comply with the new CEJA recommendations if the new ethical framework is adopted by the House of Delegates. In addition, these activities must

also comply with the requirements of the AMA PRA credit system and the accreditation criteria and standards of the ACCME and recognized state and territorial medical societies.

The mechanisms, tactics, and strategies described in this report relate to some--though not all--of the CEJA recommendations and are meant to be illustrative and not exhaustive of the work already in place in the CME community to address commercial influence in certified CME activities. Such practices would satisfy the Council on Medical Education that CME providers and individuals responsible for developing CME activities certified for *AMA PRA Category 1 Credit*™ are adhering to the ethical framework described by CEJA and upholding the AMA principles that guide the development of certified CME. Ultimately it is the responsibility of each physician, as learner, faculty, or CME provider, to acquire the information necessary to judge whether or not to participate in a CME activity, and when attending an activity to be a critical evaluator of scientific information presented as well as obtaining information on the level of the evidence associated with the content of the activity.

APPENDIX


Accreditation Council for
A • C • C • M • E
Continuing Medical Education
ACCME STANDARDS FOR COMMERCIAL SUPPORT SM
Standards to Ensure the Independence of CME Activities
ACCME

The ACCME Standards for Commercial Support℠

Standards to Ensure Independence in CME Activities

STANDARD 1: Independence

1.1 A CME provider must ensure that the following decisions were made free of the control of a commercial interest. (See www.accme.org for a definition of a 'commercial interest' and some exemptions.)

(a) Identification of CME needs;
(b) Determination of educational objectives;
(c) Selection and presentation of content;
(d) Selection of all persons and organizations that will be in a position to control the content of the CME;
(e) Selection of educational methods;
(f) Evaluation of the activity.

1.2 A commercial interest cannot take the role of non-accredited partner in a joint sponsorship relationship.⌘

STANDARD 2: Resolution of Personal Conflicts of Interest

2.1 The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. The ACCME defines "'relevant' financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

2.2 An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

2.3 The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.⌘

STANDARD 3: Appropriate Use of Commercial Support

3.1 The provider must make all decisions regarding the disposition and disbursement of commercial support.

3.2 A provider cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as conditions of contributing funds or services.

3.3 All commercial support associated with a CME activity must be given with the full knowledge and approval of the provider.

Written agreement documenting terms of support

3.4 The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the provider and its educational partner(s). The agreement must include the provider, even if the support is given directly to the provider's educational partner or a joint sponsor.

3.5 The written agreement must specify the commercial interest that is the source of commercial support.

3.6 Both the commercial supporter and the provider must sign the written agreement between the commercial supporter and the provider.

Expenditures for an individual providing CME

3.7 The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.

3.8 The provider, the joint sponsor, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of-pocket expenses in compliance with the provider's written policies and procedures.

3.9 No other payment shall be given to the director of the activity, planning committee members, teachers or authors, joint sponsor, or any others involved with the supported activity.

3.10 If teachers or authors are listed on the agenda as facilitating or conducting a presentation or session, but participate in the remainder of an educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their teacher or author role only.

Expenditures for learners

3.11 Social events or meals at CME activities cannot compete with or take precedence over the educational events.

ACCME®

3.12 The provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity. The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, joint sponsor or educational partner.

Accountability

3.13 The provider must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support. ⌘

STANDARD 4. Appropriate Management of Associated Commercial Promotion

4.1 Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.

4.2 Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME.

- For *print*, advertisements and promotional materials will not be interleafed within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as these materials are not related to the CME content they face **and** are not paid for by the commercial supporters of the CME activity.
- For *computer based*, advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleafed between computer 'windows' or screens of the CME content
- For *audio and video recording*, advertisements and promotional materials will not be included within the CME. There will be no 'commercial breaks.'
- For *live, face-to-face CME*, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Providers cannot allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CME activity.

4.3 Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or a product-group message.

4.4 Print or electronic information distributed about the non-CME elements of a CME activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions, may include product-promotion material or product-specific advertisement.

4.5 A provider cannot use a commercial interest as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities. ⌘

STANDARD 5. Content and Format without Commercial Bias

5.1 The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.

5.2 Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company.⌘

STANDARD 6.Disclosures Relevant to Potential Commercial Bias

Relevant financial relationships of those with control over CME content

6.1 An individual must disclose to learners any relevant financial relationship(s), to include the following information:

- The name of the individual;
- The name of the commercial interest(s);
- The nature of the relationship the person has with each commercial interest.

6.2 For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

Commercial support for the CME activity.

6.3 The source of all support from commercial interests must be disclosed to learners. When commercial support is 'in-kind' the nature of the support must be disclosed to learners.

6.4 'Disclosure' must never include the use of a trade name or a product-group message.

Timing of disclosure

6.5 A provider must disclose the above information to learners prior to the beginning of the educational activity. ⌘

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