REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 1-A-10

Subject: Financial Relationships with Industry in Continuing Medical Education

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Referred to: Reference Committee on Amendments to Constitution and Bylaws (Madelyn E. Butler, MD, Chair)

The practice of medicine is inherently a moral activity, founded in a "covenant of trust" between patient and physician.[1,2,3] The respect and autonomy that medicine enjoys rest on the profession's commitment to fidelity and service in the patient-physician relationship. To sustain that commitment, medicine must ensure that physicians acquire and maintain the knowledge, skills, and values that are central to the healing profession. In return, society grants medicine considerable authority to set the ethical and professional standards of practice and the autonomy to educate practitioners.[4,5]

In recent decades, relationships between medicine and industry—by which we mean pharmaceutical, biotechnology, and medical device companies—have driven innovation in patient care, contributed to the economic well-being of the community, and provided significant resources, financial and otherwise, for professional education, to the ultimate benefit of patients and the public. In the end, however, the interests and obligations of medicine and industry diverge in important ways, rendering these relationships double edged. Where medicine's overriding responsibility is to put the needs of patients first, commercial entities must serve their shareholders and other vested stakeholders even as they engage in efforts to improve health and health care.

An increasingly urgent challenge for both medicine and industry is to devise ways to preserve strong, productive collaborations for the benefit of patients and the public at the same time they take clear, effective action to prevent relationships that damage public trust and tarnish the reputations of both parties. Medicine must address growing concern that financial ties to industry, in particular, carry ethical risks for the independence and integrity of professional education.

Medicine-industry relationships occur in research, clinical care, and beyond, not just in education, of course. The Council also recognizes that pharmaceutical, biotechnology, and medical device companies are not the only entities—commercial or otherwise—with which financial relationships can raise concerns. Yet to attempt to address the range of ethical questions that can arise across all of these different domains and among all of the different stakeholders is too ambitious a goal for a single analysis. Thus this report focuses on issues raised by financial relationships with industry for continuing medical education (CME). This allows us to explore the complex considerations at stake in a manageable context and to provide practical ethical guidance on issues that increasingly challenge medicine as a profession. It can lay the foundation for future analyses that address similar concerns as they arise in other domains and among other stakeholders.

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* Reports of the Council on Ethical and Judicial Affairs are assigned to the Reference Committee on Amendments to Constitution and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.

LIFELONG LEARNING & MEDICINE'S DUTY TO EDUCATE

> *Publicly in his oath and privately in his encounter with the patient, the physician professes two things—to be competent to help and to help with the patient's best interests in mind.*
>
> — Edmund Pellegrino

The special moral character of the interaction between patient and physician arises from the need—illness—that brings the patient into the relationship. Physicians are granted extraordinary privileges to intervene in patients' lives, to impose harm in the service of healing, to gain access to sensitive information, and to engage in intimate contact with patients that would otherwise be prohibited. Educating current and future generations of physicians to fulfill the responsibilities that flow from the patient-physician relationship is the foundation of medicine's status as a caring and competent profession. Therefore, medicine's ethical duty to educate cannot be delegated to others.

Individual physicians have an ethical obligation to dedicate themselves to "continue to study, apply, and advance scientific knowledge" and to "maintain a commitment to medical education."[6] As professionals, practicing physicians are expected to commit themselves to lifelong learning and to maintain their clinical knowledge and skills through CME and other professional development activities.[7] That commitment is reflected not only in ethical expectations and standards, but also in requirements for licensure and specialty certification, as well as hospital credentialing.

Given the wide array of diagnostic and therapeutic options available today, physicians and the patients who rely on them must be confident that treatment recommendations and clinical decisions are well informed and reflect up-to-date knowledge and practice. CME activities that are pedagogically sound, scientifically grounded, and clinically relevant are essential to ensure that physicians can provide the high quality of care their patients deserve. To achieve these goals, medicine has an ethical obligation to ensure that the profession itself sets the agenda and defines the goals of physician education; controls what subject matter is taught; determines physicians' educational needs; and takes steps to ensure the objectivity of educational content and of those who teach it.

Despite the clear potential for benefit from strong working relationships with industry, there is concern that medicine's reliance on industry support to CME providers, as well as individual financial ties between content developers or faculty and industry, undermines this independence and objectivity. The implications may extend well beyond continuing education—as one recent commentary noted, "[w]hat is at stake is nothing less than the privilege of autonomy in our interactions with patients, self-regulation, public esteem, and a rewarding and well-compensated career."[8]

CONTINUING MEDICAL EDUCATION

Continuing medical education today takes place in a complex, dynamic environment that hosts a mix of "promotional," "certified," and other activities. As defined by the Food and Drug Administration (FDA), promotional activities are those developed by or on behalf of a commercial entity and under the substantive influence of that entity that are designed to market health care products or services. Promotional activities, which provide information on the therapeutic use of a product or service, are governed by the labeling and advertising provisions of the Food, Drug, and Cosmetic Act.[9,10] Promotional activities may constitute protected commercial speech. These industry-developed, FDA-regulated activities lie outside the scope of the present analysis and recommendations. Our immediate concern is with certified and other (nonpromotional) educational activities.

"Certified CME" refers to educational activities developed and implemented in compliance with the certification requirements of the American Medical Association Physician Recognition Award (PRA) CME Credit System, or the accrediting policies of the American Academy of Family Physicians or American Osteopathic Association.[11] Certified CME meets the requirements for Category 1 credit under AMA's PRA program, including compliance with Accreditation Council for Continuing Medical Education (ACCME) standards and with relevant AMA ethics policy.[12]

Beyond these formal categories lie activities designed to inform and educate practicing physicians that are neither certified CME nor "industry-developed, FDA-regulated activities." These other activities may or may not be commercially supported, may or may not voluntarily adhere to AMA policy or ACCME Standards for Commercial Support[SM] despite not being formally certified or accredited, and may or may not be recognized by licensing bodies or credentialing boards as fulfilling local CME requirements.

Industry Support of CME Providers

Over the past decade, medicine has come to rely significantly on commercial funding to support professional education across the learning continuum. With respect to CME, industry support now accounts for more than half of all income to CME providers accredited by ACCME. Between 1998 and 2006, commercial support of providers accredited by ACCME increased by 300 percent to $1.2 billion.[13] There is some evidence that the rate of growth in industry support of CME may be leveling off, or even declining slightly.[14,15]

Commercial funding is not uniformly distributed across the community of diverse CME providers, which includes medical professional groups (such as state and local medical associations, as well as national specialty societies), hospitals, academic medical centers, and commercial providers (such as medical publishing/communication companies). In 2007 (the most recent year for which data are publicly available), medical schools, which accounted for 46 percent of all certified CME hours, received 20 percent of the overall total of commercial funding; publishing/education companies, which accounted for nine percent of overall certified CME hours, received 49 percent of all commercial funding.[16] Because ACCME has not yet established a uniform reporting protocol for nationally accredited providers, it is impossible to know with any real accuracy what proportion of CME providers' annual budgets derive from commercial entities.

Industry support for CME helps to meet the costs of programs and activities in the face of uncertain funding from other sources.[17] By helping to reduce costs to individual attendees industry support may make CME more accessible, especially for physicians in resource poor communities. Along with lower costs, by providing amenities that make participation attractive, industry support may encourage greater participation than would otherwise be the case, although there is no evidence either to support or to refute this hypothesis.[18] For some medical specialties that rely on high cost, sophisticated, rapidly evolving technology or devices, industry engagement in and support of CME may be essential. At the same time, however, there is growing concern within and outside medicine that industry funding can have undesired effects on CME.

At present there is no clear evidence to settle the question whether such concerns are borne out empirically. Studies suggesting a link between industry-funded educational activities and prescribing practices predate the ACCME Standards for Commercial Support[SM]. Cervero and He concluded from their review of the relevant literature that "to date there is no empirical evidence to support or refute the hypothesis that CME activities are biased."[19] They note that while there is ample evidence that CME affects physicians' prescribing practices, no studies have looked

specifically at the impact of prescribing changes on patient outcomes and thus cannot answer the important question of whether observed changes in practice were or were not in patients' interest.

However, there is evidence to suggest that industry support can influence the overall topics, speakers, and educational content of CME. Companies make educational grants consistent with their business strategies and therapeutic areas of interest,[20,21] which may tend to shift education toward benefiting funders and away from serving patient interests.[22] Industry-supported CME programs tend to address a narrower range of topics,[23] focus more on drug therapies,[24] and give more favorable treatment to company products[25] than do programs that are not funded by industry.

The available data by no means demonstrate conclusively that commercial funding unduly biases continuing professional education. They do suggest, however, that in addition to its primary *ethical* commitments, medicine has reason to be concerned about possible unintended and undesirable effects of industry support and should take steps to address the potential for industry funding to undermine—or be perceived to undermine—the quality and credibility of CME.

Individual Relationships with Industry

In addition to concerns about the effects of industry funding for CME providers, there are concerns about how financial ties with industry may affect the objectivity of individual physicians and others who develop content for or teach in CME activities. We must be clear: Our concern is not with egregious lapses of judgment or with corruption, but with the subtle bias that financial ties create. Research indicates that relationships in which benefits—financial compensation, gifts, favors, or other perceived benevolent gestures—are bestowed on one party by another introduce unconscious bias favoring the giver. This occurs independent of the magnitude of the perceived benefit and even when individuals are alert to the possibility of bias and strive to be objective.[26,27,28] Emerging neurobiological data confirm that such influence operates below the level of conscious awareness.[29] As Cervero and He note, the majority of physicians "may not be aware of how industry support of a CME activity may influence their clinical decisions."[30]

What has not been as clearly demonstrated is to what extent the amount of a financial interest may influence perception and judgment. Although clear evidence is lacking, most policies on conflict of interest at least tacitly assume that the greater the financial interest, the more problematic that interest is. Yet different institutions set the threshold of concern at significantly different amounts. For example, the University of Massachusetts–Worcester requires faculty members involved in nonclinical research to disclose financial interests in commercial entity of more than 5 percent equity or $100,000, while faculty involved in clinical research must disclose all equity interests and nonequity interests over $1,000.[31] Northwestern University, meanwhile, requires reporting of external income above $10,000 a year.[32] Trying to define any specific threshold is essentially an arbitrary exercise.

New Trends in Institutional Policy

As relationships between medicine and industry have come under greater public scrutiny in recent years, many academic medical centers, state and medical specialty societies, and health care organizations have moved toward policies that more vigorously address the potential for conflict of interest and bias with respect to physicians' interactions with industry. While many of these policies focus particularly on gifts, consulting arrangements, and other specific physician-industry relationships, several also address CME. For example, since September 2008 Stanford School of Medicine has prohibited direct commercial support for individual CME activities, requiring that (unrestricted) support from commercial funders be made to its Center for CME for broadly defined

areas of interest.[33] The University of Pittsburgh similarly requires that industry support of CME be negotiated through the university's Center for Continuing Education in the Health Sciences.[34]

State medical societies have begun adopting similar policies with respect to industry support for their CME activities. The nonprofit Physicians' Institute for Excellence in Medicine, affiliated with the Medical Association of Georgia (MAG) serves as an intermediary between state CME providers and industry funders not only for the MAG, but for 11 other state medical societies as well.[35] The Wisconsin Medical Society's newly updated policy on conflict of interest maintains that a CME provider should not accept industry support directly, but should create a fund to which commercial supporters may make unrestricted donations, with funding subsequently dispersed to CME programs according to publicly disclosed policies adopted by the fund.[36]

Medical specialty societies at the local and national level are also taking a new stance toward commercial supporters of their educational programming. Under policy adopted in 2006, the North American Spine Society (NASS) requires disclosure not only by speakers, faculty, and moderators in NASS educational activities, but also by audience members who offer comments or questions. NASS members are expected to encourage disclosure when they believe there has been a lapse and report ongoing failure to disclose. Members who fail to disclose their financial interests are subject to discipline through the organization's Professional Conduct and Ethics Committee.[37] In November 2007, the Oregon Academy of Family Physicians (OAFP) discontinued accepting industry support for OAFP-sponsored CME activities.[38] The Academy also seeks to evaluate industry's role in developing third-party programs it considers offering to its membership.

ENSURING THE INDEPENDENCE, OBJECTIVITY & INTEGRITY OF CME

Financial relationships inevitably create conditions that can give rise to conflict of interests. When they do arise, not all conflicts are equally problematic ethically; but even minor conflicts of interest can undermine confidence in the independence and objectivity of the individuals, organizations, or activities involved. In some cases, the *appearance* of conflict of interest can be as damaging as the existence of an actual conflict. There are three options to address such undesired consequences: avoid the possibility altogether by not permitting conditions that give rise to potential bias or influence; implement strategies to mitigate actual or perceived bias or influence; or both. Each option has ethical and practical advantages and disadvantages.

Avoiding Conditions that Can Compromise the Integrity of CME

The ethical aspiration should be to avoid the potential for bias or the chance that confidence in the integrity and independence of professional education could be diminished. In the context of CME, this would mean declining to accept or seek support for professional education activities from commercial funders who have significant financial interests in physicians' clinical decisions.

Avoiding the potential for influence entirely has the virtue of ethical clarity and practical simplicity. Doing so would strongly underscore medicine's defining professional commitment to independence, objectivity, and fidelity to patients. Eliminating industry funding would have the further practical advantage of eliminating the administrative and resource costs that must otherwise be devoted to mitigating influence.[39] These costs may be particularly challenging for smaller CME providers, notably at the state and local level.[40]

In their roles as CME providers, content developers, and faculty, physicians should strive to avoid financial relationships with industry. In testimony to the U.S. Senate Special Committee on Aging, ACCME indicated that as of July 2009 some 20 percent of nationally accredited CME providers no longer accept commercial support.[41] The Institute of Medicine has called for development of a new

system of funding CME that is free of industry influence.[42] Medicine should cultivate alternative sources of support, should design and conduct educational activities so as to reduce costs, and should identify content developers and faculty members who do not have problematic ties with industry, to ensure independent, unbiased, high quality educational programming that best meets physicians' needs and is accessible and affordable for all practitioners.

Yet it is not always feasible, or necessarily desirable, for professional education to disengage from industry completely. Thus we must also define conditions under which maintaining financial relationships with industry can be ethically justifiable. Such conditions involve implementing strategies to mitigate the potential for bias or influence when not accepting support from a commercial source would significantly undermine medicine's capacity to ensure that physicians have access to appropriate, high quality CME.

Mitigating Potential Influence That Cannot Be Avoided

While there should be a strong presumption that as CME providers, content developers, and faculty members physicians should not have concurrent financial ties to industry, it is important to recognize that not all relationships with industry are equally problematic. A relationship that is only indirectly related to an educational activity, modest in scope, or distant in time is not likely to adversely affect—or be perceived to affect—the activity in question. For example, having once conducted sponsored research or accepted a modest honorarium for speaking on behalf of a company would not necessarily create such clear potential for bias as to preclude an individual with the appropriate expertise developing content or serving as a faculty member for a given CME activity.[43]

Financial relationships that are direct or substantial, however, have significant potential to undermine confidence in, if not the actual independence and objectivity of educational activities. Examples of direct and/or substantial financial interests include ownership or equity interest in the industry funder, royalties, ongoing compensated relationships (e.g., consulting arrangements or service on scientific advisory bodies or speakers bureaus),[44] or relationships that involve fiduciary responsibilities on behalf of the funder (such as service on a corporate board of directors) or decision-making authority in financial matters.[45] When participation in CME by individuals or organizations that have direct, substantial financial ties with an industry funder cannot reasonably be avoided, ethically strong practice requires that strategies be implemented to mitigate the possible influence of such ties on educational activities.

Transparency is essential in mitigating the potential of financial relationships to create bias (or the appearance of bias). As the ACCME Standards for Commercial Support[SM] recognize, disclosing the existence of a financial relationship is a necessary first step,[46] but it is not sufficient and may even have perverse effects. Disclosure places the burden on those to whom it is made—in our context, it requires learners themselves to determine how skeptical they should be about the objectivity of an educational activity.[47] To the extent that disclosure fosters the impression that the presenter is particularly honest and trustworthy, it can encourage false confidence in the objectivity of the activity.[48] To the extent that the presenter believes disclosing a financial relationship is adequate to mitigate its potential influence, the individual may not strive as hard to ensure objectivity.[49] Disclosure plays an important role in mitigating the potential influence of financial relationships, one whose value may be enhanced when both the existence and the magnitude of a financial relationship is disclosed,[50] but it cannot be the only strategy relied on.

Creating a "firewall" between industry funders and decisions about educational goals, content, faculty, pedagogical methods and materials, and other substantive dimensions of CME activities is

also an important strategy for mitigating the influence of financial relationships. Both ACCME and the Inspector General of the Department of Health and Human Services have recommended clearly separating decisions about funding from substantive decisions about CME activities. ACCME standards require that a CME provider ensure the independence of key decisions, although the standards do not provide specific guidance about how to do so.[51] (HHS guidance for industry requires that manufacturers clearly separate their sales and marketing functions from their grant-making functions.[52]) Emerging strategies to create strong firewalls include pooling monies from multiple commercial sources and disbursing support to individual activities through a "blind trust" model. In such models, funders have no knowledge of which programs their grants or gifts supported,[53] nor are CME providers, content developers, or faculty aware of which funder supported their activities. Where it is not feasible to create a blind trust to manage industry support, one strategy to help protect the independence and integrity of CME would be to have activities routinely supported by multiple, competing funders.

Another way to mitigate the influence of financial relationships when they cannot be eliminated is to change the terms of those relationships. A CME provider, for example, could set an upper limit on how great a proportion of its income derives from industry support to avoid becoming overly reliant on commercial funding. Among individuals who develop content for or teach in CME activities, strategies must be tailored to the nature and magnitude of their varying individual relationships. For example, physicians participating as content developers or faculty in a CME activity could be required to desist from speaking on behalf of the activity's industry supporter for a defined period before and after the activity. Similarly, an individual could forgo royalties or other compensation from the company for a defined interval following his or her participation (whether as content developer or faculty) in an industry-funded CME activity. It will be important, of course, that in seeking to change the terms of problematic relationships decisions be made fairly and consistently across individual cases.

Exceptional Cases

Sometimes a financial interest cannot be avoided and is extraordinarily difficult or even impossible to mitigate. In most cases, participation in CME by providers, content developers, or faculty members who have direct, and unavoidable financial interests would not be ethically acceptable. However, in certain compelling circumstances, it may be justifiable to allow such participation—for example, when an individual who has a significant financial interest to participate in a CME activity has unique expertise. In the earliest stage of adoption of a new medical device, technique, or technology, the only individuals truly qualified to train physicians in its use are often those who developed the innovation. Yet these are the very individuals who often have the most substantial and direct interests at stake, whether through employment, ongoing relationships with manufacturers, or other direct financial interests in the adoption and dissemination of the new device, technique, or technology.

Similarly, some essential educational activities may not be feasible without financial or in-kind support from industry—for example, the provision of cadavers or high-cost, sophisticated equipment to train physicians in new surgical procedures or the use of new technologies. Such support may be vital to the professional community, but, like individual financial ties, also creates potential for bias.

Criteria for determining when it is ethically justifiable to permit participation by someone who has a direct, substantial, unavoidable, and irreducible financial interest in a CME activity might include a variety of considerations. For example, that the dissemination of the device, technique or technology will be of significant benefit to patients and to the public and the professional

community; that the individual is uniquely qualified as an expert in the relevant body of knowledge or skills; that disclosure includes the nature and magnitude of the specific financial interest at stake; that there is demonstrated, compelling need for the specific CME activity; and that all feasible steps are taken to mitigate influence.[54] Comparable criteria might apply when an educational activity cannot reasonably be carried out without financial or in-kind support from sources that have a direct financial interest in physicians' clinical recommendations.

Understanding Key Ethical Criteria

Current guidelines for CME do not distinguish among financial relationships based on their different potential to undermine the independence and objectivity of educational activities. Nor do they provide specific guidance for how to manage potential conflicts of interest when such conflicts are disclosed. At present there are no specific, publicly agreed on understandings of key criteria proposed above: "substantial interest," "significant benefit," "uniquely qualified," or "compelling need." Attempting to provide specific, concrete delineations of these criteria would be an essentially arbitrary exercise—what is a "substantial" interest for one practitioner may not be for another. Inevitably, these criteria must be interpreted case by case, based on knowledge of the particular circumstances and on the exercise of judgment. In other contexts, physicians routinely make similar judgments under conditions of uncertainty.

Judgments about some criteria, such as "significant benefit," will be reasonably familiar; others are more challenging. While we cannot offer precise definitions, it is possible to suggest considerations that might come into play. For example, current standards require CME providers to design activities to address demonstrated educational needs;[55,56] a "compelling need" for a particular educational activity may be present when a new therapy becomes available to treat a disease that is prevalent in the local community for which there is otherwise no satisfactory treatment.

Similarly, an individual might be considered "uniquely qualified" when he or she is the only expert (or one of only a very few) who has significant knowledge about or experience in treating a rare disease or who was involved in the early development or testing of a new treatment, device, or technology. To some extent, the need to rely on conflicted expertise may be dictated by local conditions—CME providers in small or rural communities, for example, may not always be able to obtain the services of experts who do not have problematic ties to industry. In any event, it will no longer be appropriate to speak of an expert being "uniquely qualified" when a substantial body of peer-reviewed evidence has evolved in a given subject area, or when a cohort of individuals who do not have direct, substantial, unavoidable, and irreducible financial interests have become experienced in using a new medication, device, or technology and are available to teach others.

CME providers should be transparent about what considerations led them to decide to permit an individual with a problematic financial interest to participate as a content developer or faculty member in a particular CME program or activity. The goal is to ensure that decisions are made objectively and are justifiable based on considerations the CME provider believes will be persuasive to the professional community at large. As the community gains experience in working with these criteria it is to be expected that consensus will coalesce around core interpretations. As Harvard Medical School notes in its conflict of interest policy:

> These classifications are not intended to serve as a rigid or comprehensive code of conduct or to define "black letter" rules with respect to conflict of interest. It is expected that the guidelines will be applied in accordance with the spirit of the mission of Harvard Medical School in education, research and patient care. By this process, it is expected that a common institutional experience in the application of these guidelines will gradually evolve.[57]

RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder of this report be filed:

The respect and autonomy that medicine enjoys rest on the profession's commitment to fidelity and service in the patient-physician relationship. To sustain that commitment, medicine must ensure that physicians acquire and maintain the knowledge, skills, and values central to the healing profession. This includes an obligation to ensure that the profession itself defines the goals of physician education, determines physicians' educational needs, and thus sets the agenda for continuing medical education (CME).

Financial and/or in-kind support of CME from sources that have a direct financial interest in physicians' recommendations puts the profession's ethical obligations at risk. It creates conditions in which financial interests could influence the availability and/or content of education. Similarly, current, recent (within the preceding 12 months), or anticipated (e.g., royalties or ownership interest) financial relationships between such firms and individuals who develop content for or teach in CME create conditions in which CME content may be influenced inappropriately.

When possible, CME should be provided without funding or in-kind support from sources that have a direct financial interest in physicians' clinical recommendations, and individuals who develop content for or teach in CME should have no current, recent, or anticipated direct financial interest in the educational subject matter, since avoiding such arrangements strengthens the confidence that physicians acquire and maintain knowledge, skills, and values that are independently judged important by the profession.

In some circumstances, however, access to appropriate, high quality, independent CME may be seriously impaired if support from industry is refused. For example, when expensive equipment is needed, accepting funds or in-kind support from multiple, competing firms might result in more independence than refusing such support. When such support is needed, physicians who organize CME, teach in CME, or have other roles in continuing physician education should adhere to the guidelines below to protect the interests of patients and promote the integrity and independence of education. Physicians attending CME should expect compliance with these guidelines:

1. When funding or in-kind support is provided by sources with a direct financial interest in physicians' recommendations:

    a. the educational activity has been planned by the provider based on needs identified independent of and prior to solicitation or acceptance of the support; and

    b. the CME provider can articulate a compelling reason(s) to accept such support for the educational activity or activities; and

    c. the CME provider declines any support that is conditioned on the provider's acceptance of advice or services concerning educational content, faculty, content developers, or other educational matters; and

    d. the source and magnitude of the funding or in-kind support are clearly disclosed; and

e. the CME provider mitigates the potential for influence, for example, through the use of firewalls, blind trusts, having multiple rather than single sources of support, or other mechanisms; and

f. the CME provider routinely audits the level of industry support it receives to ensure that it maintains the independence and integrity of its educational mission and programs.

2. When participation as a content developer or faculty member by an individual who has a *modest* financial relationship with the commercial supporter is necessary to ensure that physicians have access to appropriate, high quality professional education:

   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.

3. When participation as a content developer or faculty member by an individual who has a *direct, substantial, and unavoidable* financial interest in the educational subject matter (e.g., as the inventor of a new device) is required because the individual is a uniquely qualified expert:

   a. there is a demonstrated, compelling need for the specific CME activity in the professional community that cannot otherwise be met; and

   b. the CME provider is able to justify its determination that the individual is uniquely qualified; and

   c. steps are taken to mitigate the potential influence of the unavoidable financial interest (e.g., using independent review of content); and

   d. the nature and magnitude of the individual's specific financial interest in the subject matter are clearly disclosed; and

   e. the activity contributes overall to the timely development of a pool of qualified, independent experts in the relevant field.

4. Continuing medical education that is offered for credit has adhered to all applicable professional standards for accreditation.

(New HOD/CEJA Policy)

Fiscal Note: Staff cost estimated at less than $500 to implement.

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