Ethical and Economic Concerns Roil the CME Waters

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With critics questioning the practice of accepting industry grants to develop accredited continuing medical education programs, key stakeholders have responded by tightening their codes for ethical conduct and anticipating leaner times ahead.

The past several years have seen a "perfect storm" of ethical, economic, and political concerns sweep through the field of continuing medical education (CME). The result has been a reshaping of the CME landscape to ease concerns that drug and device makers might be unduly influencing physicians' treatment decisions.

Proposals for ways to reform the CME system range from the incremental to the swift and sudden and from voluntary guidelines to a federal law. Their collective impact will likely shrink the amount of industry money available for educational grants.

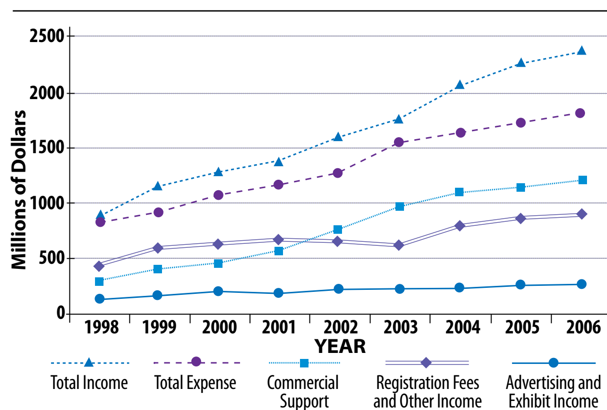

FIGURE 1 How CME is funded. (From the Macy Report, page 104)

Skepticism Reigns in All Quarters

Pressure to overhaul the system of accrediting and paying for CME and continuing physician professional development (CPPD) has been building from within and without the government. Indicators of the kinds of pressure the CME world is facing include:

- Congressional efforts to pass the Physician Payments Sunshine Act, which would require large drug companies to list virtually all payments to physicians in a federal database.[1] This would include honoraria and expenses for speaking or writing about a drug or device.
- A US Senate Finance Committee investigation that in 2007 called for better oversight of drug company payments to doctors to prevent fraud and abuse, citing in particular implicit understandings about the topics that grant-funded CME events will cover. Although company policies obey the letter of FDA regulations, wrote the investigators, they "allow this industry to walk a fine line between violating rules prohibiting off-label promotion and awarding grant money in a manner likely to increase sales of their products, including sales for off-label uses."[2]
- Fines levied against two drugmakers totaling more than $1 billion, because of educational events they sponsored in which speakers made claims that were not supported by the drugs' FDA labeling.[1]
- Convening of a blue-ribbon conference of experts who assessed the state of CME for the Josiah Macy, Jr. Foundation in November 2007. The group recommended a 5-year phased transition back to a CME system funded solely by medical schools, hospitals, and physician fees. The panel assembled data showing that makers of drugs and medical devices poured more than $1.5 billion into the development of certified CME in 2006, or 60% of the national total (Figure 1). "No amount of strengthening of the 'firewall' between commercial entities and the content and processes of CE can eliminate the potential for bias," the report said.[3]
- The recent effort within the American Medical Association to pass a resolution calling on physicians and medical institutions to refuse educational grants from commercial interests and to decline paid positions on a company's speakers bureau. The proposal was returned to the committee for further work after it was opposed by more than 40 organizations, including the Alliance for Continuing Medical Education.

CME'S CHALLENGING TIMES

- Critics question CME's independence
  - Providers depend on industry grants
  - Industry's 2006 bill: $1.5 billion
  - Congress is watching closely
- Contention at AMA over this cash
  - Ban it, ethics panel urges
  - 40 witnesses disagreed
- Key players in CME are responding
  - Accreditors: new rules
  - Industry: tighten conduct code
- PhRMA proposes:
  - Strict limits on size and type of gifts
  - No subsidized trips to resorts for CME events
  - In everything, a "modest" approach
  - Changes are voluntary
- Envisioning the future of CME
  - Less cash, more creativity
  - Learner-directed CME over the Internet
  - Performance assessment CME

Optimistic About the Future

The Alliance opposed the ban as too drastic and because it did not distinguish between independent, certified CME and company-sponsored events, which sometimes look like CME and foster confusion among physicians. There are, in fact, many times when the need for physician education on a topic intersects with industry interests. Ongoing reform efforts can adequately protect certified CME events from undue commercial influences without greatly reducing educational opportunities. It is apparent, though, that the pressure to keep industry out of the CME loop will continue, and it will be today's certified CME providers and consumers who will feel the effects of that pressure.

Less money for educational grants will mean reductions in the overall number of certified CME offerings, and physicians may have fewer opportunities to earn certified CME at no cost. In some cases, the most obvious change will be in the way that commercially sponsored marketing events look because of the new no-gifts policy. After January 1, 2009, the drug companies' trade group, the Pharmaceutical Research and Manufacturers of America (PhRMA), will have a stricter code of conduct in effect that will prohibit sweetening medical education events with lavish meals, resort locales, entertainment, or "goody bags."

ROUTES TO *AMA PRA CATEGORY 1 CREDIT*™

- ☑ CME event by accredited provider (credit varies)
- ☑ Article publication (10 credits)
  - — Credits to first author
  - — Journal must be listed in MEDLINE
- ☑ Poster presentation (5 credits)
  - — At accredited meetings only
  - — Printed abstract required
- ☑ Medically related advanced degrees (25 credits)
- ☑ Board certification and maintenance (25 credits)
- ☑ 1 year accredited residency or fellowship (20 credits)
- ☑ Independent learning (credit varies)
  - — AMA's advance OK needed
  - — Final report required
- ☑ International Conference Recognition program (credit varies)

Source: American Medical Association

A Loophole No More

The Accreditation Council for Continuing Medical Education (ACCME) has strengthened its efforts at keeping commercial money from influencing the content of certified CME by implementing a revised definition of "commercial interest" that closes a loophole that might have allowed companies to jointly sponsor certified CME. ACCME has also adopted Conflict of Interest Principles that are quite specific.

The principal aim of the ACCME Standards of Commercial Support is to ensure that attendees at a CME event are made aware, before an activity begins, of all the speakers' financial conflicts of interest during the previous 12 months.

It is not enough to declare the conflicts, though; the provider must explain what was done while planning the CME program to resolve these conflicts so that they do not unduly influence the presentation. One might, for example, resolve conflicts by limiting a speaker's duties to an unrelated part of the event or having a peer reviewer assess the speaker's presentation for bias.

The reforms that may have the greatest impact on the availability of CME are those in the new PhRMA Code on Interactions with Healthcare Professionals. Although participation is voluntary, the PhRMA Code asks firms that adopt it to reaffirm this annually and to report on how they handled any infractions.

ARE THE CREDITS REAL?

ACCME-accredited CME providers in the United States are required to include two statements on their promotional materials. One must identify the source of their accreditation (typically ACCME or an ACCME-recognized state medical society), and the other lists the maximum number of credits a physician can earn for the activity.

Under the AMA's system, CME providers must print the full trademark phrase "*AMA PRA Category 1 Credit*™" on their materials. If credit is not indicated in this manner, physicians should question whether the activity is in fact eligible for *AMA PRA Category 1 Credit*™.

Detailed Rules for Industry

The PhRMA Code addresses a wide variety of industry/physician interactions at company-directed educational events in which there is potential for financial conflicts of interest:

- At the lowest level, a no-gifts policy will end the small, industry-financed perks that have proliferated in doctors' offices over the years, such as free pens, coffee mugs, and self-stick notes.
- In the middle ground, the Code deals with issues such as whether a drug company representative can bring in food for a lunchtime presentation at a medical office (yes), or whether the rep can take the doctor out for a presentation over lunch at a restaurant (no).
- At the top level, it eliminates the perceived extravagances that have drawn the most criticism. For instance, it requires speaker training meetings to be held in "modest" locations (never a resort); demands that speakers and consultants be paid at fair market value for services actually rendered; requires that honoraria be "modest"; prohibits in-kind gifts like tickets to sporting events; prohibits paying attendees to attend informational events; and warns against packing speakers bureau lists with the names of "token consultants" in order to be able to pay their expenses.

With respect to certified CME, the Code cautions firms that giving grants to underwrite independent CME does not entitle them to any say in planning or implementation. The Code requires companies to estab-

lish clear criteria for awarding these grants and to move responsibility for choosing recipients out of the marketing department and into a fully independent unit of the company.

Speakers' Honoraria

At CME events, honoraria and expense reimbursements must be reasonable, and their cost must come from the original grant—the sponsoring company may not pay doctors directly. In addition, the donor company may not provide a separate lunch, and (under ACCME accreditation standards) it cannot have any product displays or handouts in the area where the event occurs.

A recent addition to the PhRMA code is its requirement that, at *company-directed* educational events, the sponsoring company and the speakers must clearly communicate to attendees that they are attending a marketing event, not an independent, certified CME program.

Despite the likelihood that more rigid controls will diminish company sponsorships, many are optimistic about the future of certified CME. Lean times will force the marketplace to look at new models of CME/CPPD and new ways of demonstrating the value of certified CME.

ROUTES TO *AMA PRA CATEGORY 2 CREDIT*™

- ☑ Covers diverse learning experiences, eg:
  - — Unstructured online searching
  - — Consultation with experts
  - — Self-assessment activities
- ☑ Value is self-determined
- ☑ Must meet AMA rules on CME
- ☑ 1 credit per 60 minutes

Source: American Medical Association

Learner-directed CME at Home

For instance, it might be time to de-emphasize the lecture/seminar model that predominates in certified CME and embrace an Internet-based model. Busy physicians would appreciate being able to earn CME credits without having to take time away from their practices, and after the initial production costs had been covered, the incremental cost for each additional physician to attend an Internet event is minimal. This learner-directed model could also give physicians access to many more options in certified CME.

Once a CME provider starts thinking outside the box, it quickly becomes obvious that there are many ways that physicians learn, and only a small fraction of this learning takes place inside big lecture halls. In fact, the AMA, which sets the standards for what may be designated for AMA PRA credits, recognizes many learning models beyond lectures and seminars for which CME providers may award credit. In addition, physicians may receive additional credits by applying directly to the AMA for such activities as teaching classes in category 1 activities, submitting posters for professional meetings, or reviewing manuscripts. Recognition of this type of self-directed CME will continue to grow in the future.

More than 60 medical licensing and certification boards require evidence of certified CME for physicians to meet licensure and certification requirements. In the future, these boards may tie maintenance of licensure and certification to "performance improvement CME" (PI CME), in which the physician—using a PI CME learning model—would do a self-assessment based on established performance measures, implement clinical changes that

A CME Lexicon

Continuing Medical Education (CME): CME consists of educational activities that 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.

Activity: An educational event/intervention for physicians that is based upon identified needs, has a purpose or objectives, and is evaluated to assure the needs are met.

Accredited CME: The ACCME uses the term "accredited CME" to encompass the educational programs and educational activities of providers accredited within its system.

Certified CME: The term used to describe CME activities that have been determined to meet the requirements for credit as established by the AMA, AOA, AAFP, and other organizations with recognized CME credit systems.

Commercial Interest: A commercial interest is any entity producing, marketing, reselling, or distributing health care goods or services consumed by, or used on, patients. The ACCME does not consider providers of clinical service directly to patients to be commercial interests. A commercial interest is not eligible for ACCME accreditation.

Commercial Support: Financial, or in-kind, contributions given by a commercial interest, that are used to pay all or part of the costs of a CME activity.

Conflict of Interest: When an individual's interests are aligned with those of a commercial interest, the interests of the individual are in "conflict" with the interests of the public. The ACCME considers financial relationships to create actual conflicts of interest in CME when individuals have both a financial relationship with a commercial interest and the opportunity to affect the content of CME about the products or services of that commercial interest.

are known to be effective, and then do a reassessment after a period of time. Although separate now, licensing and certification could become more closely linked through this process.

Individualized CME Ahead?

The Internet has made so much more data available from government, hospitals, and quality improvement departments that it does not seem far-fetched to look forward to a day when we could combine these data sets to create clinical norms. That would allow us to use the data to see how an individual physician's performance compares to clinical guidelines and design the exact tool for performance improvement CME that the doctor needs.

For those involved in certifying, producing, and attending certified CME programs, it would be shortsighted and naive to believe that the funding model that exists today will make it through the next several years without changes. The reality of the current system depends heavily on commercial support. Certainly the nature of the support from, and possibly the quantity of dollars spent by, commercial interests will change.

In the short term, it would be difficult to provide the breadth and quality of CME available today without commercial support. But, given the perfect storm raging now, this is the appropriate time to look toward the funding and learning models that will be needed after the storm has passed.

THE BOTTOM LINE

Heeding the increasingly loud calls for reform in the American system of CME/CPPD, key players in the system have adopted tighter codes of conduct for physicians, providers of CME, and the industry representatives whose firms for a decade have underwritten most of the courses offered to doctors. The controversy already is affecting the amount of funding available for CME, however, and now is the time to consider the funding and learning models that could replace those currently in use.

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References

1. Physician Payments Sunshine Act of 2007, S 2029, 110th Cong, 1st Sess (2007).
2. Committee Staff Report to the Chairman and Ranking Member. Use of Educational Grants by Pharmaceutical Manufacturers. Washington, DC: United State Senate Committee on Finance, April 2007.
3. Hager M, Russell S, Fletcher SW. Continuing Education in the Health Professions: Improving Healthcare Through Lifelong Learning (A Conference Sponsored by the Josiah Macy, Jr. Foundation). Bermuda, November 2007.