BY ELISABETH PENA

*The State of CME*

# AT THE END OF THE TUNNEL

Conservatism has marked the pharmaceutical industry's approach to CME following last year's release of OIG guidelines, which suggest that manufacturers should take the programs out from under marketing and sales. **THE INDUSTRY WAITS IN ANTICIPATION FOR THE FINAL APPROVAL IN SEPTEMBER** of updated standards from ACCME.

*Maria Chernock*

**THE OIG GUIDELINES AND GOVERNMENT SCRUTINY** related to Medicare and Medicaid fraud and abuse have resulted in more conservative marketing approaches by pharma. CME, with its clearly defined guidelines, provides a good opportunity for companies to share important information and scientific data in appropriate venues.

### *Marsha Meyer*

**PHARMA COMPANIES ARE TRYING TO BETTER** understand their role as providers in the education process and are navigating their way through what they perceive as a minefield.

### *William Cooney*

**THE QUESTION IS, CAN PHARMA COMPANIES FUND QUALITY CME AND, AT THE SAME TIME, BENEFIT FROM THE ACTIVITIES?** I think the answer is yes.

### *Brad Bednarz*

**THERE IS AN ABSOLUTE NEED TO GIVE CREDIBLE, BALANCED CONTINUING EDUCATION,** otherwise the activity is self defeating.

The pharmaceutical industry is slowly working its way toward standards that allow companies to fund continuing medical-education (CME) programs and still meet OIG guidelines.

On April 1, 2004, the board of directors of ACCME, by unanimous vote, adopted the updated ACCME Standards for Commercial Support of Continuing Medical Education.

The next step is to have the updated Standards for Commercial Support approved by the seven ACCME member organizations. As allowed by the ACCME's bylaws, the member organizations have 180 days to consider the document. Therefore, the member organizations have until Sept. 28, 2004, to make their decision about the updated ACCME Standards.

"Manufacturers are waiting to see if the ACCME Standards for Commercial Support due to be finalized in September will be approved by ACCME's seven parent member organizations," says Jacqueline N. Parochka, Ed.D., FACME, president of Excellence in Continuing Education Ltd. and past president, North American Association of Medical Education and Communication Companies Inc. "Once the ACCME guidelines are decided upon this fall, there is going to be a floodgate of money spent on CME. Companies are going to want to spend the dollars they allocated to CME but have not yet spent."

Last year, the Department of Health and Human Services Office of the Inspector General issued the Compliance Program Guidance for Pharmaceutical Manufacturers. The guidance suggested that manufacturers separate their grant-making functions from their sales and marketing functions to help ensure that programs are not inappropriately influenced by sales or marketing motivations and that the educational purposes of the grant are legitimate.

Objective criteria should be used for making grants that do not take into account the volume or value of purchases made by, or anticipated from, the grant recipient and that serve to ensure that the funded activities are bona fide.

Uncertainty as to how to interpret the OIG guidelines has caused a lot of manufacturers to put activities on hold until they can ensure they are compliant.

"There is a general sense of conservatism

## *Kathy Farwick*

**PHARMA COMPANIES HAVE AN ETHICAL OBLIGATION TO SUPPORT PROGRAMS THAT COMPLY WITH GUIDELINES.** CME needs to be based on good science and present a balanced view of all therapies, the benefits, as well as the risks.

within the industry; in many cases the guidelines caused paralysis," says William D. Cooney, president and CEO of MedPoint Communications Inc. "On a company-by-company basis, in the last year a lot of programs were cancelled or put on hold pending official interpretation of the guidelines."

The proposed ACCME standards call for CME providers to ensure that commercial interests do not play a role in the identification of CME needs or the selection of content or educational methods. The standards indicate there should be a determination of educational objectives, as well as a way to evaluate the activity.

While they wait for the ACCME document, companies have changed their organizational structure, corporate staffing, budget allocations, and granting practices.

## *Robert Orsetti*

**COMPANIES ARE STRUGGLING WITH WAYS AND MEANS** to operationally separate education and promotion.

"Change can be difficult, particularly within large organizations such as pharmaceutical companies," says Maria Chernock, president of ProCom International. "There are thousands of people who are involved in communications with physicians. The challenge is in communicating the new procedures and policies and then assuring that everyone adheres to them and that there is no individual interpretation of the guidelines."

Under scrutiny by many is the grant-review process.

"The grant-review process now is longer, more complicated, and much more involved with the legal departments than before," says

## *Dr. George Mammen*

**THERE HAS BEEN A LOT OF SCRUTINY SURROUNDING PROMOTIONAL ACTIVITIES** and many companies view CME as being safer in terms of managing risk.

## *Jacqueline Parochka*

**IF COMPANIES FOLLOW THE REGULATIONS, DELIVER FAIR, BALANCED, AND SCIENTIFICALLY RIGOROUS INFORMATION, AND AVOID KICKBACKS TO PHYSICIANS AND OTHER HEALTHCARE PROVIDERS,** then they should be able to stay out of trouble.

George Mammen, Ph.D., MBA, senior VP, general manager, of DiMedix LLC. "This is a new process. In many cases, companies often don't have enough resources in terms of legal support and legal personnel to review projects and grants."

Companies are approving grants just a

month or two before the actual program, which experts say makes putting together CME programs very challenging.

"Pharmaceutical manufacturers are being very careful, scrutinizing every process, and putting into place all the right steps to ensure compliance with the OIG guidelines," says Marsha J. Meyer, R.Ph., senior VP of clinical information at Continuing Medical Education Inc. "This has added multiple layers to the approval processes and reviews for grants. It is taking more time to get a grant approved than it has in the past and that ultimately impacts the timeline associated with the delivery of the educational activities."

Additionally, the proposed ACCME draft standards call for CME providers to ensure that commercial interest does not play a role in the identification of CME needs; determination of educational objectives; selection and presentation of content; selection of all persons and organizations that will be in a position to control the content of the CME; selection of educational methods; and evaluation of the activity. The cautious and differing approaches being taken by pharmaceutical firms have added to the slowdown.

"There is no standardized process from company to company on how they approve grants," Ms. Meyer says. "Pharma is taking time to figure out all the processes that need to be put into place, and the processes vary company to company. For CME providers, this has significantly lengthened the grant-request process."

From a provider perspective, the most challenging aspect of the new guidelines is determining the interpretations, policies, and expectations of individual companies as applied to the guidelines, says Robert F. Orsetti, assistant VP, continuing education, University of Medicine & Dentistry of New Jersey.

"While there is general agreement with respect to the need to comply, what is permitted and disallowed among companies can vary widely," he says. "Providers have an obligation to enforce their guideline policies and practices, while counseling companies in matters that go beyond that which is permissible. Should agreement not be reached, providers should avoid project involvement."

Another area that is problematic, in the short term, is the issue of conflict of interest.

"The ACCME draft standards require further interpretation in two key areas, conflict of interest and failure to disclose," Mr. Orsetti says. "The draft standards require providers to develop policies for resolution of conflicts of interest. The industry is uncertain as to exactly how the yet-to-be-defined policies will be applied and to what degree they will affect content and faculty. There is also potential for such policies to vary widely. Disqualification of invited speakers who fail to disclose commercial affiliations is potentially problematic. For example, an otherwise qualified speaker with solid credentials may refuse to disclose simply on the basis of privacy or because of free-speech beliefs. This may be a special problem for non-U.S. speakers. In any case, the learning experience may be diminished."

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

"People may be excluded as planning members, as teachers, as faculty members, and as authors if their disclosure reveals that they have a conflict of interest," says Kathy Farwick, BSN,

## Drawing the Line

**The North American Association of Medical Education and Communication Companies Inc. recently surveyed its members to determine what changes were being made internally in response to the OIG guidelines.* The association polled members as to whether medical-education communications companies provide CME only; promotion only; or a combination of both?**

Continue both CME-certified and promotional activities
**26%**

Create separate company for CME
**23%**

Choose between promotional or CME work on a case-by-case basis
**14%**

Separate CME and promotion account teams
**9%**

Provide promotional activities only
**5%**

Other decision
**2%**

* The survey response rate was 48.7%, representing input from 19 member companies.

Source: The North American Association of Medical Education and Communication Companies Inc., Gurnee, Ill. For more information, visit naamecc.org.

## Physicians' Media Preferences

**Which of the following professional education resources do you find reliable?**

Peer-reviewed journals
**85.4%**

CME programs offered by a third party
**56.7%**

Journal supplements/reprints
**53.7%**

CME programs sponsored by pharmaceutical companies
**45.2%**

Sponsored dinner meetings
**45.2%**

Symposium highlights/newsletters
**41.8%**

Slide kits/CD-ROM
**20.2%**

Sponsored teleconferences
**19.8%**

Third-party audio/video
**14.4%**

Manufacturers' product brochures
**12.1%**

Third-party Websites
**9.7%**

Manufacturers' Websites
**4.6%**

Source: Matalia Group, Kulpsville, Pa.; the survey was funded by Aventis' U.S. Scientific Publications. For more information, visit mataliagroup.com or aventis.com.

director of scientific events, education and publications, at Kendle International Inc. "The problem is that many of the most knowledgeable experts in a therapeutic area may have a conflict of interest because they work with pharmaceutical companies as clinical investigators, they author manuscripts, and they act as consultants and advisors. The ACCME guidelines are not very specific about what constitutes conflict of interest. This is a gray area that has pharma companies taking a wait-and-see attitude."

Mr. Orsetti believes, however, as companies gain familiarity with the standards in the long term, this will not be a detrimental issue.

## Evaluating a Return

All of these issues have created confusion about ROI as well. Although the value of CME activities is well established, experts question whether pharmaceutical companies should continue to measure ROI. The OIG guidelines state that when evaluating educational or research grants provided by manufacturers to physicians, manufacturers should determine if the funding is based, in any way expressly or implicitly, on the physician's referral of the manufacturer's product. If so, the funding implicates the antikickback statute.

"Because of the OIG guidelines, many state attorneys general have said if pharma companies fund CME activities with the intent to have a marketing impact this could be an OIG actionable issue," Mr. Cooney says. "If companies measure the ROI of their CME activities, that suggests intent to achieve marketing results."

Because regulatory bodies specifically prohibit the commingling of marketing/sales with education, measuring ROI of CME is prohibited and always construed as a sales metric, Ms. Meyer says.

"Good CME providers should measure the educational impact of their CME programs on clinician learners and then share those data with the pharmaceutical company in a way that doesn't violate the guidelines," she says. "Through surveys and evaluations, providers can gather data on how educational information enhanced or augmented attendees' points of view on treating a particular disease state and then assess whether learning took place. Some of these data can be shared with supporters in an aggregate form. Also, as long as promotional materials are not distributed and no promotional activity occurs relative to the educational program, commercial supporters can attend CME events, but only as observers."

Experts suggest that instead of ROI, companies should look to evaluate return on education, or ROE, which can be measured from a different perspective.

> ***Uncertainty as to how to interpret the OIG guidelines and the anticipation of the ACCME guidelines*** has caused many manufacturers to put activities on hold until they can ensure that they are compliant.

"Return on education can be assessed by determining whether the knowledge that physicians gained transfers to clinical practice," Ms. Chernock says. "We should be evaluating whether this knowledge has resulted in more positive patient outcomes. If CME accomplishes this goal, then ROI takes on a broader meaning. When education from CME programs results in changes in treatment practice and more positive patient outcomes, the ultimate result would be improved public health and the potential for the reduction of overall healthcare costs related to pharmacological intervention. This takes time to achieve, but this is a way CME measurements should be driven."

One of the ways to determine if new knowledge from CME has been transferred to clinical practice is to conduct pre- and post-test evaluations to identify adoption levels of new information. This can be done through surveys or focus groups. In addition, Ms. Chernock says some healthcare systems use electronic medical records to collect patient data.

"There is the potential for healthcare systems to audit patient records to determine if physicians who have attended various CME programs in diabetes or dyslipidemia, for example, have changed patient-treatment strategies, which ultimately impact patient outcomes," she says. "To measure public health, local and national epidemiologic data are indicators as are government surveys conducted by the Health and Human Services Department that track public health trends by disease category."

Post-CME activity surveys are another way to measure return on education.

"Every CME program should have an evaluation tool that appraises the speaker, the content, how useful the content will be to the physician's practice, and the event's effectiveness at delivering key scientific messages," Ms. Farwick says.

Another issue stemming from the new guidelines is whether the industry is prepared to fund outcome measurements. Mr. Orsetti says sophisticated ROI measurements and analyses, as well as less sophisticated methods, such as use of audience response systems, are costly.

"Return on investment, or return on education, as some prefer, has been measured traditionally by assessing a participant's satisfaction with content delivered, faculty presentation capabilities, and meeting-room amenities and comfort; this is a rather superficial approach," he says. "At the upper end of return on education measurement techniques are computer-generated programs that analyze specific program components against practice guidelines, evidence-based medicine recommendations, national and local practice trends, colleague performance, chart review, and other parameters to assess whether learning has occurred and changed behavior."

More recently, Mr. Orsetti says, participants have been asked to commit to specific behavior changes in their practices or in patient management and to permit follow-up to determine whether the desired change has occurred.

CME activity and how it has impacted physician behavior and patient outcomes is something that now should be assessed through the provider, not directly by the pharmaceutical company, according to the proposed ACCME standards.

"A series of evaluations are needed after the event to measure how effective the program is," Dr. Mammen says. "Ideally, providers should do evaluations three, six, and 12 months after a CME activity to measure how the program affected a physician's prescribing and patient care and look at whether those changes in behavior impacted patient outcomes. Unless we do these types of evaluations, we cannot know how effective programs really are."

While return has become more difficult to determine under the new guidelines, experts say this is not a reason to drop CME programs.

"The fundamental process by which doctors decide to adopt new therapies and practices is based on the medical-education process much more than promotional content," Mr. Cooney says. "When it becomes harder for companies to measure ROI it is more difficult to defend the spend on a project-by-project

basis, but the fundamental need to fund education in different therapeutic areas is too great for the industry to back away from."

## Taking CME Out of Marketing

To meet the guidelines of detangling marketing and promotional departments from scientific and educational staff, pharmaceutical companies are separating their staff internally. CME providers are doing the same and, in some cases, creating separate companies or divisions to house CME activities (for more information, see box page 26). Providers who continue to offer both promotional and CME services may face having to choose which service to provide to their pharmaceutical clients.

"We have been informed by some clients that we can be their CME vendor or their promotional education vendor, but not both," says Brad Bednarz, president of Icon Custom Communications. "In some cases this separation limits our ability to offer products and services throughout an organization. This is a big issue since it could lead to clients being cut off from new and innovative ideas."

As pharmaceutical companies establish firewalls separating CME from marketing, another impact is that marketing may not know about CME activities or spending.

"The most challenging aspect of the guidelines is the reorganization within the pharmaceutical companies that is totally separating the CME component from promotional education," Mr. Bednarz says. "This separation has marketing questioning the dollars being spent for CME programs, which could lead to a decline in spending and become an issue for providers."

"With CME, manufacturers have to assume a hands-off approach, which might make them nervous, particularly if they are unfamiliar with the accredited provider or don't have a long-standing relationship with that provider," Dr. Parochka says. "Many medical-education and communication companies have indicated CME is temporarily 'on-hold.' When the dust settles and everyone becomes comfortable with the guidelines and his or her new roles and responsibilities, then manufacturers will begin spending more on CME. I suspect CME spending will increase after September 2004."

Mr. Orsetti says separate budgets for marketing and CME will be a positive move for CME.

"A few leading companies have acknowledged the importance of CME to physician learning and improved patient care and the overall value to their organizations and are placing CME budgets under the direct control of their medical departments," he says. "Thus, medical professionals and the educators they manage will evaluate and fund proposed programs that meet guideline requirements and fulfill clearly defined and assessed medical needs. This new model should improve the quality and appropriateness of CME programming substantially and raise CME to a higher plane within the industry, while achieving greater attention and respect among healthcare practitioners."

> ***Experts suggest that instead of ROI, companies should look to evaluate return on education, or ROE,*** which can be measured from a different perspective.

"The industry is in a transitional phase," Dr. Mammen says. "By 2005 medical-education departments and their budgets will sit firmly within medical affairs."

## Physician Expectations

CME is one of the most important sources of information for physicians and providers, ranked second only to peer-reviewed publications in importance. Two major factors physicians consider when deciding on a CME activity is topic of interest and the quality of the presenter. These basic criteria have not changed, but experts say physicians now are taking disclosure information into consideration.

"Physicians attending CME events are now looking at thought-leader disclosure information," Mr. Bednarz says. "If the information presented was credible, this was not a criteria that they had previously used to determine whether to attend a meeting. These are very intelligent, well-trained, and educated individuals who quickly see through any type of educational initiative that is not balanced and objective."

Because physicians have less time to spend with patients and longer office hours, they are often not able to attend national and regional meetings. Dr. Parochka says CME providers are being forced to think of ways to bring the CME activities to the physician's home or office.

"Many providers have begun producing enduring materials, such as home-study courses, and are offering Internet-based case-learning activities and mediated conferences, such as teleconferences and Web casts," she says. "Some of these methods have been more successful than others. The total impact of enduring materials remains an unknown. Although many self-directed learning packages are distributed, few physicians apply for credit as a result of participation."

In addition to changing physician expectations, the guidelines have created challenges in attracting physicians to CME activities. Previously, many companies' sales reps were involved in recruiting physicians and healthcare professionals to attend CME meetings.

Dr. Parochka points out that a lack of a consistent definition is creating confusion in this area. Section 4.5 of the ACCME's proposed guidelines indicates that the provider cannot use sales representatives to distribute enduring materials or arrange for electronic activities.

"What is unclear is whether sales representatives will be able to distribute 'save-the-date' cards and brochure announcements," she says. "In the past, audience recruitment has been a shared responsibility."

With sales reps' involvement in recruitment for CME no longer being clear, companies are having to find new ways to fill these events.

"Defining the appropriate role of reps in the field has been a difficult area for companies," Mr. Cooney says. "Most companies have simply pulled back, becoming very conservative in what they allow field representatives to do with regard to CME activities."

"Audience generation is the most challenging aspect right now," Dr. Mammen says. "Sales reps at some companies are not involved with recruitment for CME programs anymore. Throughout industry there are a lot of great events being organized and held but many of them are poorly attended."

In addition to contending with guidelines, the pharmaceutical industry faces public scrutiny, especially in relation to promotional activities and payments to doctors.

"CME, when done properly, is perceived to be a positive," Dr. Mammen says. "It is educational, it is hands off, and companies that do CME well will be perceived positively by the public."

As the shift toward nonpartisan CME activities continues, academic institutions increas-

## Sound Bites from the Field

## The CME Perspective

**PHARMAVOICE ASKED CONTINUING MEDICAL EDUCATION PROVIDERS, AS WELL AS THOSE INVOLVED IN CME, TO COMMENT ON THE TRENDS AND CHALLENGES IN THIS EVOLVING ARENA.**

Barbara Blasso is President of CMEScholar, a division of International Meetings & Science, Stamford, Conn., a full-service medical-education and communications company and a division of Grey Healthcare Group. For more information, visit aboutimsci.com.

"Because of the need to separate promotional and CME services for their clients, agencies are setting up separate divisions to handle CME exclusively, often with firewalls (different locations), separate financial identities (separate tax numbers), and different staffs. Increasingly, medical-communication firms have expanded the role of the CME director to include a more comprehensive compliance review for program activity to include examining the evidence supporting the needs assessment and learning objectives. Similarly, some CME programs are now delineating the levels of evidence supporting critical areas of content."

Donna M. Fucello is Executive Director of INNOVIA Education Institute LLC, Columbia, Md., a wholly owned ACCME-accredited subsidiary of Columbia MedCom Group. For more information, visit innoviaeducation.com.

"One of the latest trends in CME is the focus on return on education (ROE). ROE strategies help to evaluate or measure specific outcomes of educational activities among target audiences. These strategies can be implemented through the use of a variety and combination of tools. At INNOVIA we employ the use of pre- and post-tests, real-time evaluations, and follow-up evaluation instruments that assess how knowledge, abilities, skills, or behaviors have changed based on the content presented. In most cases, the main goal of an activity is to enhance the ways in which a healthcare provider diagnoses and treats a patient. Strong evaluation methods help to determine if the education had an impact on the providers' ability to do so. Additionally, it provides supporters with relevant information to determine if the education they support is in line with their overall educational strategies and objectives."

Terry Nugent is Director of Marketing of Medical Marketing Service Inc., Wood Dale, Ill., a leading supplier of lists and direct-marketing services to the CME community. For more information, visit mmslists.com.

"There is pressure from clients to separate CME sources from promotional sources, an about face from previous calls to integrate services for one-stop shopping. CME continues to be the only way to disseminate information on off-label uses. Such use is of paramount importance for the benefit of all parties concerned in fast-paced fields such as oncology, where a substantial portion of drug therapy is off label and imminent mortality creates desperate times that demand desperate measures."

Mark Rickards is President of Cadent Medical Communications, Irving, Texas, a medical-education division of inChord Communications Inc. For more information, visit cadentmed.com.

"There are a number of trends evolving in the world of CME right now. One is the sheer growth in the number of educational opportunities available for medical professionals to attend. As a result, those who are producing educational programs are increasingly challenged to develop programs that distinguish themselves based on the quality of educational information provided and are easy for participants to attend. We've found success in creating CME opportunities that allow participants to learn from their home, office, or even hotel room using the telephone, Internet, or a combination of the two. We've also seen an increasing level of interest in programs that are shorter in time but more focused or potent in terms of content, such as those using case-study formats. Probably the biggest trend driving the CME environment is the continuing growth of new healthcare technologies and solutions for patients. After all, it's the new technology, medicines, and treatment paradigms that create the need for education in the first place."

Laura Shepherd is Managing Director of Fusion Medical Education LLC, Yardley, Pa., a division of Axis Healthcare Communications LLC, which develops meetings and materials that are in compliance with the PhRMA code, the standards set forth by ACCME, and the recommendation and opinions of the FDA and the AMA. For more information, visit fusion-meded.com.

"The latest trend is a move toward a more vigorous evaluation of whether a program for which CME accreditation is being sought truly fits into the category of a justifiable CME offering. More emphasis will be placed on needs assessment results and documentation and whether the learning objectives address a truly otherwise unmet educational need. Equally important is a trend toward evaluation of the program on the backend."

Harry Sweeney is Chairman and CEO of Dorland Global Health Communications, Philadelphia, a full-service health communications agency that offers marketing communications, advertising, public relations, and medical-education programs. For more information, visit dorland.com.

"The latest trend in the private sector CME community is worry and concern. The piling on of guidelines (PhRMA Code, AMA Gifts to Physicians Policy, ACCME Standards of Commercial Support, FDA pronouncements), the chilling effect of the OIG guidance, and recent initiatives to criminalize off-label speech, as well as attempts on the part of academic centers and professional associations to monopolize the production of CME activities, is creating significant stress and turmoil among publishers, independent CME providers, and others engaged in this important endeavor."

ingly are being brought in to participate.

"Several academic providers have been requested to partner with pharma companies and medical-education companies for the provision of CME credit," Mr. Orsetti says. "This trend would seem to be a direct outgrowth of the OIG guidance, but collectively reflects the interpretations of the other guidances, which require developmental objectivity and independence. Since education is the mission of academic institutions and because they do not have commercial product interests, the industry seems to believe that there is less risk for noncompliance or negative public perception when academic providers review and approve programs for credit."✦

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PharmaVoice welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

## Experts on this topic

**BRAD BEDNARZ.** President, Icon Custom Communications, Teterboro, N.J.; Icon Custom Communications, a MediMedia company, specializes in taking complex medical information, identifying the core messages, and creating compelling visual programs that educate target audiences while fulfilling clients' goals. For more information, visit medimedia.com.

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**WILLIAM D. COONEY.** President and CEO, MedPoint Communications Inc., Evanston, Ill.; MedPoint Communications is a provider of medical-education and communications services to the healthcare industry. For more information, visit medpt.com.

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