BY TAREN GROM

CME CONTENT, DELIVERY, AND ACCREDITATION

Without Commercial Interest

Ostermueller . From the pharmaceutical companies' standpoint, they will require their CME providers or partners to meet these new standards. The implication from the provider side is to meet and adhere to those standards in a fashion that is fully consistent with client expectations. And those client expectations are increasing.

The American Medical Association defines continuing medical education (CME) as educational activities that serve to maintain,develop, or increase the knowledge, skills, professional performance, and relationships that a physician uses to provide services for patients, the public, or the profession. The content of CME is that 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 healthcare to the public. What is not recognized by the AMA, the Pharmaceutical Research and Manufacturers of America (PhRMA), the Office of the Inspector General (OIG), or the Accreditation Council for Continuing Medical Education (ACCME) is a promotional connection by a commercial sponsor to the CME activity.

YET, CME PROGRAMS ARE THE NO. 2 PLACE PHARMACEUTICAL COMPANIES SPEND THEIR MARKETING DOLLARS (after samples). Last year, drug companies spent about $12.5 billion promoting their products, including $2.1 billion on meetings and $7.2 billion for salesforces according to some industry statistics. In the past, CME events were used by pharmaceutical companies to promote their products to doctors, but were not supposed to be blatant promotional conferences. Tougher guidelines from PhRMA and a draft guidance under review by the ACCME (to review the draft guidance visit accme.org) now prohibit any commercial attachment to a CME program by the company supporting the program through an unrestricted educational grant. To keep the program independent of commercial interests, the content and delivery need to be controlled by a CME-accredited provider that does not have a commercial interest relevant to the content of the CME being planned or presented.

Operating Standards

LESCOSKY. In an industry dedicated to bettering the public health, it's in our best interest to voluntarily police ourselves. PhRMA and ACCME guidelines are designed to serve this purpose. By using a voluntary mechanism, industries such as ours hope to continually improve our own enforcement mechanisms without the need for additional government intervention. Over the past few years, scientific information exchange has increased significantly because of the numerous communication methods now available, the Internet and DVDs, for example. When these new communication methods become available, sometimes there is a gap in understanding how to apply previous guidelines to these new media. This is particularly the case when there is a public health need for this information. The ACCME guideline draft is based on the previous guidelines and is very similar to what is in effect now; but the draft goes to the next step to provide more details and specific examples of how to interpret the principles. The interpretation process is important if an industry is policing itself. This is a continual evaluation of what has worked and what hasn't, and it allows the industry and physicians and the scientific community in general to move forward in a constructive manner.

ROSENBERG. The PhRMA code is a baseline for where companies should be. The ACCME guidelines are a draft, and the feeling is that these aren't going to stick as they are written now. With that in mind, we don't have to make many revisions. Some people are saying the proposed guidelines are not what will be adopted. Nevertheless, the guidelines won't have us do anything differently, because we've always taken this charge very seriously. Commercial supporters are taking the PhRMA code very seriously, which makes the job from the CME provider point of view easier because they are following the guidelines for commercial support anyway. In the spirit of excellent CME, it's always about excellent content and excellent faculty — that will not change no matter how the guidelines shake out.

OSTERMUELLER. The release of the PhRMA code last July was a paradigm shift; it was a very clear changing point with respect to the practices that industry will have to adhere to in the future and the impact it will have on tradi-

THE PRINCIPALS ...

TIGHE BLAZIER. Senior VP, sales and marketing, *MD net guide*, Plainsboro, N.J.; *MD net guide* integrates both electronic and print media to provide physicians with user-friendly access to online medical content. For more information, visit mdnetguide.com.

SIMONE KARP, R.PH. Co-founder and executive VP of business development, CECity.com, Pittsburgh; CECity.com is a provider of online healthcare education platforms and professional community relationship-management solutions. For more information, visit cecity.com.

LEONARD LESCOSKY. Director, regulatory affairs, Solvay Pharmaceuticals Inc. Marietta, Ga.; Solvay Pharmaceuticals is a research-based pharmaceutical company, and is a member of Solvay SA. For more information, visit solvaypharmaceuticals-us.com.

TOM OSTERMUELLER. President and CEO, Pharmedica Holdings LLC, Killingworth, Conn.; Pharmedica provides strategic medical education and communication initiatives; high-tech solutions to communication challenges; audio, video, and multimedia programs; and a full line of editorial services. For more information, visit pharmedica.com.

J. BRIAN O'TOOLE, PH.D. VP, director of continuing professional education, Medical Education Group LLC, Euro RSCG, Trevose, Pa.; MEG produces CME programs that are scientifically accurate and clinically relevant to improve patient care. For more information, visit megcme.com.

KAREN M. OVERSTREET, ED.D., R.PH., FACME. Executive VP, operations, Nexus Communications Inc., North Wales, Pa.; Nexus offers creative solutions to product life-cycle management challenges, including thought-leader development, publication planning, and medical education. For more information, e-mail Dr. Overstreet at karen.overstreet@nexuscominc.com.

ERIC D. PETERSON. VP, professional and patient programs and executive director, Institute for Continuing Healthcare Education, CoMed Communications Inc., Philadelphia; the ICHE is an accredited provider of continuing educational activities for physicians, pharmacists, nurses, clinical laboratory personnel. CoMed is an operating unit of Vox Medica. For information, visit voxmedica.com.

MARK RICKARDS. Chief operating officer, S.G. Madison, Irving, Texas; S.G. Madison, a medical education and communication firm, is an inChord Communications Inc. company. For more information, visit sgmadison.com.

THOMAS A. ROGERS. VP and general manager, MINDSPAN, Mahwah, N.J.; MINDSPAN is an e-business company that leverages competencies in technology and content development to support, expand, and enhance communication between pharmaceutical marketers and their customers. For more information, visit mindspanonline.com.

CLAUDIA ROSENBERG, PH.D. President, Curatio CME Institute, Yardley, Pa.; Curatio provides CME-accredited programs for physicians and certified continuing education for healthcare professionals, including pharmacists and nurses. For more information, e-mail Dr. Rosenberg at claudia.rosenberg@curatiocme.com.

BRIAN P. RUSSELL. President, CoMed Communications Inc., and principal, Vox Medica Inc., Philadelphia; CoMed, an operating unit of Vox Medica, provides strategic educational and informational communications services. For information, visit voxmedica.com.

LAURA SHEPHERD. Managing director, Fusion Medical Education LLC, Yardley, Pa.; Fusion, a division of Axis Healthcare Communications LLC, partners with leading medical experts, universities, and medical specialty groups to develop CME meetings, training, preceptor programs, Websites, books, videos, and other relevant media. For more information, e-mail Laura Shepherd at laura.shepherd@fusion-meded.com.

MIKE SQUIRES. VP, medical education, MDchoice Medical Education Online, Somerville, N.J.; MDchoice, a division of ChoiceMedia, is dedicated to effectively growing physician access to relevant online education and developing better ways for pharmaceutical companies to support the potential of online CME. For more information, visit mdchoice.com.

MAUREEN STELLWAG. Director, educational and marketing development, Newton Gravity Shift, Pennington, N.J.; Newton Gravity Shift is a provider of e-business applications and technology that enhance communication and streamline business processes. For more information, visit newtongravityshift.com.

DIANNE THARP, R.PH. CE director, Alert Marketing, Sunnyvale, Calif.; Alert Marketing, a division of Jobson LLC, provides media for the delivery of healthcare information and education to professionals and consumers. For more information, visit alertmarketing.com.

Rogers. The essence of CME always has been to provide evidence-based clinical information that drives disease state awareness, treatment options, and ultimately provides better patient care.

tional marketing activities. As such, clients are turning to a real educational thrust and CME as an activity, as opposed to promotional spending. Clients need to get real data and real information and ultimately real education out to their customers. They need to build their franchises to compete effectively based upon the best data and education that they can provide to physicians.

KARP. As a result of the PhRMA code, we are seeing a shift in roles and responsibilities. Commercial supporters need qualified organizations that can provide the infrastructure and the resources necessary to execute without their input. The independence and control of the CME activity is being more clearly defined. The commercial supporter of a CME activity is recognized as having provided an educational grant for support of the program.

RICKARDS. Although it's too early to know exactly how the guidelines will impact the industry, or even if they will be adopted, we can be certain that CME will continue to be an essential component of medical communication programs. Physicians and other healthcare providers see CME as an important resource for accessing the latest information on new methods of diagnosis and treatment. We don't anticipate that will change.

Stellwag. The combination of the PhRMA code, the OIG compliance guidance, and the new draft from the ACCME are challenging pharma companies to rethink how they do business, how they are promoting their products, and how they are communicating with their prescribers.

KARP. As a result of the PhRMA code, we are seeing a move away from traditional promotional activities and a shift in resource allocation to more CME activities. We are also seeing growth in the eCME space. The growth of eCME is being driven by the needs of the healthcare professional, as well as the relatively low cost of distribution to leverage and extend CME to eCME.

ROGERS. The guidelines will strengthen the importance of providing evidence-based information that is free of commercial bias. I don't think the ACCME-proposed revisions will negatively impact industry-supported CME, but they will require people to be more cognizant of the commercial bias issue. The essence of CME always has been to provide evidence-based clinical information that drives disease state awareness, treatment options, and ultimately provides better patient care.

O'TOOLE. It is generally agreed that the PhRMA code would shift more funding from promotional to CME, and, while it is not explicit, it is presumed to be "certified" educational activities. The OIG draft will tend to do the same because of the requirements of certified CME, i.e., independence from the commercial supporter, but I don't think the other shoe has dropped on the OIG draft. Now we have the ACCME proposed draft, which suggests that if an accredited provider receives a contribution from a commercial interest that, by way of a number of subjective criteria, there may be a conflict of interest that would preclude involvement. The various codes and guidelines engender some contradiction.

SHEPHERD. Because the dissemination of information via CME programs is still considered one of the more credible sources of medical information for healthcare professionals, CME programs will continue to be one of the most desirable and effective avenues for industry to disseminate information. I do believe that the proposed guidelines are helping to make the industry more cognizant of its role in these programs and this isn't a bad thing. If there have been abuses in the system, I think that the responsibility has to be shared. To a large extent, as a program sponsor, it is part of the accredited provider's responsibility to educate industry as to what it can and can't do. CME providers that sponsor and accredit programs are accountable to the standards set by the ACCME. These standards require that the sponsors maintain ownership and control of these programs, which should include providing direction and oversight to the program's supporter about its appropriate role in the process. Education and knowledge about the process, and its enforcement, is a trickle-down effect.I have heard concerns from various groups that these new codes, standards, and guidelines will result in industry pulling away from CME. However, I believe it is just the opposite. I think we will see more industry dollars that were previously spent on promotional activities now allocated to CME activities.

OSTERMUELLER. There is increased sensitivity to the guidelines that are in effect. Our clients are taking these guidelines very seriously. From the pharmaceutical companies' standpoint, they will require their CME providers or partners to meet these new standards. The implication from the provider side is to meet and adhere to those standards in a fashion that is fully consistent with client expectations. And those client expectations are increasing. Having increasingly rigorous standards, whether they be PhRMA guidelines or the current or new draft ACCME guidelines, is part of the continuum to ensure that the industry as a whole is adhering to standards that everybody is expected to live up to.

STELLWAG. The combination of the PhRMA code, the OIG compliance guidance, and the new draft from the ACCME is challenging pharma companies to rethink how they do business, how they are promoting their products, and how they are communicating with their

AMA Study: Physicians' Use of Internet Rising

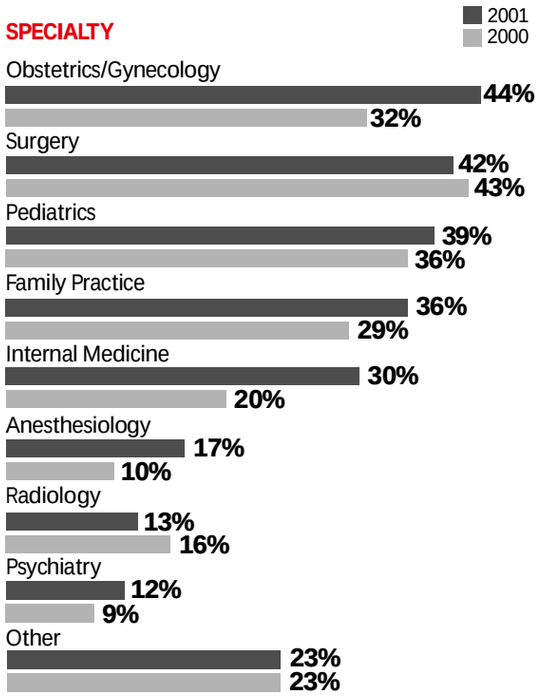
ALMOST HALF OF PHYSICIANS REPORT THAT THE WORLD WIDE WEB HAS HAD A MAJOR IMPACT ON THE WAY THEY PRACTICE MEDICINE, according to a July 2002 survey by the American Medical Association (AMA). The rising influence of the Internet on clinical medicine has propelled an increase in the frequency and duration of Web use among the 78% of physicians who now make use of cyberspace.

These new findings come from the 2002 AMA Study on Physicians' Use of the World Wide Web, which interviewed a total of 977 physicians in the United States from August to December 2001. The survey is the fourth analysis of nationwide patterns of online physicians conducted by the AMA. The top-line findings of the new survey reveal the following trends in physician Web use:

- Physician use of the Web is becoming more frequent. Two-thirds of online physicians access the Web daily, an increase of 24% since 1997.
- Physicians who use the Web have extended the hours they spend online. The average number of hours a physician uses the Web per week jumped from 4.3 in 1997 to 7.1 in 2001.
- Additional growth can be expected in the number of hours spent on the Web, with physicians indicating they expect to use the Internet an average of 9.6 hours per week during the next 6 months.
- Although there is still a trend for younger physicians to use the Web more than older physicians, the percentage of older physicians using the Web increased rapidly from the previous year. In 2001, 65% of physicians 60 years of age or older used the Web, compared with 43% in 2000.
- About 3 of 10 physicians using the Internet currently have a Website, a proportion that has remained constant since 1999.
- The primary reasons physicians have a site on the Web is to promote and advertise their practice or provide patient education and information. In 2001, the percentage of physicians using the Web to advertise and promote their practice grew by 11% from the previous year.

MORE DOCTORS ARE GOING ONLINE

An examination of medical specialists who use the Web reveals that Website development has been most prevalent among physicians in obstetrics/gynecology and internal medicine.



The sample of physicians interviewed for the 2002 AMA Study on Physicians' Use of the World Wide Web was selected randomly from the AMA's Physician Masterfile, a comprehensive database of information on all physicians in the United States, including members and nonmembers of the AMA. Physicians who were employed by the federal government, 70 years of age or older, or in residency training were excluded from participating in the AMA survey.

Source: American Medical Association, Chicago. For more information, visit ama-assn.org.

prescribers. The PhRMA guidelines limit marketing activities and what sometimes is viewed as abuse of industry-supported CME. This has had a positive effect by refocusing efforts and the dollars that are being spent on education for physicians, bringing a new level of respect and credibility to the industry.

O'TOOLE. I definitely believe that we need new guidelines, but I also believe that we need an enforcement system. I would conjecture that 90% to 95% of the accredited providers comply to the letter of the law but the remaining 5% to 10% have motivated the direction and intensity of the draft document.

BLAZIER. The impact was apparent almost immediately after the PhRMA guidelines were released. Pharmaceutical companies are proceeding much more cautiously in the area of CME.

PETERSON. The PhRMA code mostly does not address CME, and those portions that do only reconfirm the requirements of the ACCME Standards for Commercial support. The effects of the OIG draft compliance document on CME are more indirect. OIG proposed that the PhRMA code serve as a minimum standard of compliance. The OIG has enforcement authority that goes far beyond that of the FDA, and the organization tends to get industry's attention. The "one-two" punch of the PhRMA guidelines and the OIG effectively making them mandatory has caused many companies to overhaul a whole range of their activities, including how they fund CME and how they conduct their relationships with CME providers. Working with industry supporters is a little chaotic at the moment because policies seem to change daily. It should settle down in time and this certainly isn't the first pendulum swing we have seen.

RUSSELL. One specific issue that is raised by the OIG document relates to fair market value and may be applied to honoraria. How do you determine what the fair market value is of a community oncologist's time? How does this compare with the fair market value of a world famous research cardiologist? I am not sure how one answers these questions, but we are going to have to come up with some sort of reasonable approach.

PETERSON. The PhRMA code closed a huge loophole in the tendency to use consultant and advisory meetings as dissemination techniques. The company can't talk off label in a normal interaction with a physician. But, if that physician is a consultant, the company can talk off label, ask their opinions — it's a quid pro quo relationship, which was the reason for that safe harbor. What happened was that companies were using that relationship to push certain data to certain physicians, without doing anything with the information they received back from those physicians. And that was abusive, and it's over.

THARP. New guidelines are needed to demonstrate that the industry is capable of self-regulation to maintain separation of education from promotion per FDA guidelines. However, they should not have the effect of reducing the array of CE providers available to only hospitals and academic institutions.

ROGERS. I believe the ACCME wants to be proactive as opposed to being dictated to by the DDMAC, the FDA, and the OIG. This way the industry has control of the guidelines as opposed to having requirements forced upon it that might be more restrictive.

RUSSELL. There are ways within the current regulatory framework as to how CME is accredited and ways to address a lack of fair balance.

PETERSON. There may be an increase in CME funding because reps can no longer take their physicians to play golf, to the theater, or to a ball game. Companies have to find ways to get to physicians, and what they are going to turn to is legitimate CME.

SHEPHERD. If the ACCME guidelines are to be understood and adhered to, they need to be clear and thorough. Presently, they are open to wide interpretation or do not cover every scenario. If we were to give the guidelines to 10 different people, there could be at least five different interpretations. I think that what is and isn't allowed oftentimes is dependent on the provider, and this inconsistency can be confusing. It also promotes the practice of shopping around for a provider who may be more lenient.

BLAZIER. I think the PhRMA code was necessary to address the pressures placed on the pharmaceutical industry by the media, government, MCOs, and some physicians. The PhRMA code is a proactive, voluntary step taken by the industry to ensure that promotional and educational activities are in the best interest of the patient and carried out professionally. Because this code has buy-in at the CEO level, I am confident that it will achieve the desired goal.

RUSSELL. The PhRMA code was probably necessary. The pharmaceutical salesforce has doubled during the past five years and as a result it has become harder and harder for reps to see physicians. The so-called "dine-and-dash" and similar programs were all clever schemes invented by representatives to get at least five minutes with a physician. I don't think anyone was proud of them but unless everyone stopped, no one would stop and the stories in the press were getting pretty ugly. The OIG addresses issues of fraud and abuse and in particular "inducement to refer" patients for treatments that are reimbursed through government health programs. While this has always been an issue in some way or another, CME has never been more than a peripheral issue. As for the ACCME draft standards, it is far less clear that they are necessary. Data released by the ACCME from accreditation surveys show that significant numbers of providers have trouble complying with the current fairly straightforward standards. One wonders why they didn't decide to step up enforcement of their current standards rather than introduce a rather esoteric document. While we know that many providers have had difficulty complying with the current standards, what we don't know is if there are data to show that they were not serving their purpose — separating commercial interests from CME. We would like to see that.

Avoiding Conflicts

SQUIRES. The PhRMA code has been very positive for the growth of CME programs, because we are seeing more funds being shifted to education. The ACCME guidelines are a recalibration of the basic guidelines, which have been in place for a number of years to deal with conflict of interest. However, things have changed in the past decade, and it's time to reassess the situation. My concern is that the draft guidelines may go too far in the other direction and that people with expertise in an area may be excluded because they may have had relationships or support from pharmaceutical companies. If we were to exclude all the people who have these ties, who are we left with? Information from

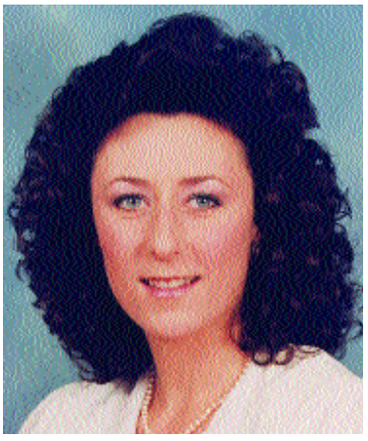
Peterson. The "one-two" punch of the PhRMA guidelines and the OIG effectively making them mandatory has caused many companies to overhaul a whole range of their activities including how they fund CME and how they conduct their relationships with CME providers.

Russell. Conflict of interest depends on the context. Perhaps a better question would be: Is it possible for industry to collaborate with providers in a way that produces high-quality CME that serves the needs of physicians and the patients under their care without being unduly influenced by commercial influence? The answer to that question is an emphatic "yes."

the ACCME indicates that half of the funding for CME programs comes from the pharmaceutical industry. There also is considerable funding for clinical research from the pharmaceutical industry. It doesn't seem to be a practical solution to exclude people who have these relationships or who receive funding from the pharmaceutical companies from speaking or from taking on other roles; many of these people are the same people who are the most knowledgeable. The question still is how to proceed to make the substance of CME programs appropriate, while eliminating real conflict and the appearance of conflict?

Effective Medical Education: Shifting the Paradigm to Influence Behavior Change

MOST PEOPLE INVOLVED IN HEALTHCARE RECOGNIZE THE IMPORTANCE OF MEDICAL EDUCATION — both certified continuing education (CE) activities and other educational endeavors, such as reading journals and attending grand rounds. Not only is medical education a professional responsibility, it is required in many states for relicensure and in many institutions for admitting privileges and credentialing for numerous procedures. However, according to Karen Overstreet, Ed.D., R.Ph., FACME, executive VP of operations at Nexus Communications, medical education recently has received a lot of criticism.



Overstreet. Not only is medical education a professional responsibility, it is required in many states for relicensure and in many institutions for admitting privileges and credentialing for numerous procedures.

EDUCATION NEEDS TO CHANGE

Several studies have reported that individual educational activities are not very effective in changing physician behavior or producing desired patient-care outcomes. One of the reasons often cited for poor educational outcomes is the lack of good design in many CE activities.

In addition, healthcare is evolving rapidly. Patients don't want to have to worry about how their personal physician finds time to keep up with the medical literature or how many medical errors occur in the hospital where a family member recently had surgery. The healthcare and medical-education community needs to address these critically important areas, but traditional educational strategies have not been particularly effective. Contemporary healthcare necessitates finding new ways for physicians to learn and new methods for educators to use to facilitate learning opportunities for clinicians.

NEW PARADIGM

Amidst the growing confusion about, and intense scrutiny of, commercial support and medical education, characteristics of good education have been identified. The challenge is now for the stakeholders of medical education, including both the providers and the supporters, to collaborate to build a new system that will be responsive to the changing healthcare environment.

CHARACTERISTICS OF EFFECTIVE MEDICAL EDUCATION

- Uses effective educational design and adult education principles
- Identifies gaps in clinical practice
- Facilitates clinicians' critical reflection on practice
- Incorporates interactivity
- Involves multiple interventions
- Encourages ongoing evaluation and application
- Recognizes and reinforces good practice
- Is supported by sound science and content validation
- Identifies barriers to change
- Includes other stakeholders in the healthcare system

CHARACTERISTICS OF TRADITIONAL MEDICAL EDUCATION

- Didactic, passive format
- Minimal collaboration between planners and participants
- Lack of timely response
- Focus on course production rather than content
- Emphasis on credit
- Little evidence of impact (rarely influences behavior)

THARP. If the ACCME draft standards are adopted in whole, the only providers of CME considered to have noncommercial interests will be "hospitals, medical schools, and academic medical centers." Every other medical education company will not be able to plan, develop, manage, present, or evaluate CME by virtue of a commercial interest. Further, the availability of subject-matter experts to author or present on topics will be curtailed based on any history of commercial support. This would be a serious disservice to healthcare professionals who could learn from such experts in a educational forum.

PETERSON. If adopted as they are drafted, the new ACCME standards will have a profound effect on CME — perhaps much of this unintentional. The draft contains a great deal of imprecise language that hopefully will be worked out before final standards are adopted. What concerns us most is the possibility that the most qualified indi-

Why Medical Education Needs to Change

Changes in medical-care delivery, bioinformatics, and the public at large necessitate that healthcare professionals need a new kind of medical education.

INFORMATION EXPLOSION

- Results of 10,000 randomized clinical trials are published every year in more than 20,000 medical journals
- Physicians have only about one hour per week to read medical journals
- The half-life of treatment guidelines is about two years; the half-life of medical information is decreasing over time
- Only 12% to 28% of family practitioners report being able to understand published clinical data enough to explain it to others

PROLIFERATION OF PRODUCTS AND INCREASE IN DISEASE PREVALENCE

- In 1998 alone we gained:
  - 90 prescription drugs
  - 30 new chemical entities
  - 124 new indications for existing products
  - 344 generic products
  - 7 over-the-counter products
- 100 million Americans have at least one chronic disease; the number will grow to 134 million by 2020; this accounts for 70% of Americans' personal expenditures for healthcare

HEALTHCARE AND PUBLIC FORCES PUSHING FOR CHANGE AND ACCOUNTABILITY

- Evidence-based medicine and content validation initiatives by the ACCME and AAFP
- Maintenance of competencies by specialty societies
- Intolerance of variation by insurers, hospital administrators, and the public
- Demanding, more informed patients
- Growth of informatics
- Systems and team issues
- Reports from the Institute of Medicine — medical errors and quality chasm

Sources: H. Fineberg, Reform of the continuum of health professions education, 13th Annual Conference of the National Task Force on Provider/Industry Collaboration, Baltimore, September 2002; J. Ward, The stakeholders and their stakes, Changing Physicians' Behavior (conference), Madison, Wisc., October 2002; J. Grimshaw, What works, and thoughts on getting more things to work, Changing Physicians' Behavior (conference), Madison, Wisc., October 2002; J. Parboosingh, Implications from "communities of practice' for changing clinicians' behaviors, Changing Physicians' Behavior (conference), Madison, Wisc., October 2002.

Karp. As a result of the PhRMA code, we are seeing a shift in roles and responsibilities. Commercial supporters need qualified organizations that can provide the infrastructure and the resources necessary to execute without their input. The independence and control of the CME activity is being more clearly defined.

viduals may be excluded from serving as faculty for CME activities.

THARP. According to the ACCME draft, provider/pharmaceutical partnerships aren't possible without a conflict of interest. But I believe that they are. The CME provider has an underlying interest in adhering to standards for quality programming from both an ethical and economic perspective. Commercial programming posing as education will not fool healthcare professionals, will not ensure that the provider maintains accreditation status, and will not lead to future business. Pharmaceutical companies want, sometimes need, and always appreciate good direction on keeping educational programs clean.

ROGERS. I was a pharmaceutical marketer, and CME was always part of the marketing mix. And since it was part of the marketing mix, the ultimate goal was to try to increase education but at the same time move business. Because of media scrutiny, one needs to take a step back and ensure that the ACCME standards and the PhRMA code are being adhered to and that the basis for every CME program is educational and nonpromotional. The two should be separated similar to the separation of church and state.

Squires. My concern is that the draft guidelines may go too far in the other direction and that people with expertise in an area may be excluded because they may have had relationships or support from pharmaceutical companies. If we were to exclude all the people who have these ties, who are we left with?

SHEPHERD. No one stands to win if a conflict of interest is uncovered. Industry is certainly aware at this point that it must be mindful of how it is are perceived. In the long run, it does not benefit companies to participate in a situation that could in any way be perceived as a conflict of interest. Most well-informed pharmaceutical companies are seeking avenues in which they will not be at risk for this negative perception. Most are taking these initiatives very seriously. Many are even going so far as to establish internal departments whose focus is to set new business standards and their own compliance guidelines.

O'TOOLE. Companies have created policies and procedures that make it feasible to partner with a provider without a conflict of interest. There also is the notion of integrity and honesty that guide many of us in our work. The secret is making sure that the rules are clearly written, are applicable to every environment, are known and understood by all, and are enforceable.

RUSSELL. Conflict of interest depends on the context. Perhaps a better question would be the following: Is it possible for industry to collaborate with providers in a way that produces high-quality CME that serves the needs of physicians and the patients under their care without being unduly influenced by commercial influence? The answer to that question is an emphatic "yes." Many of us are doing it every day.

RICKARDS. Not only are provider/pharmaceutical partnerships possible without a conflict of interest, the guidelines currently in place have allowed these relationships to exist for sometime without a conflict of interest. It's a flawed premise to assume that there's currently a large-scale problem with commercial sponsorship and conflict of interest in terms of CME content development. The existing guidelines very clearly prohibit product promotion as part of CME, and while working within those guidelines, CME providers have provided thousands of valuable, conflict-free CME programs that have helped physicians to expand their ability to provide quality healthcare to patients.

Best Practices

LESCOSKY. It is important to be sure that the provider and the sponsor are clear as to their respective roles and responsibilities. This is often accomplished through contract provisions, which indicate that both parties agree to the same operating principles, such as those found in the ISSEA, ACCME, and PhRMA codes.

ROSENBERG. CME always goes back to quality. Once we identify where the gaps are, we can provide high-quality content and high-quality faculty to meet this need. We've had great success in looking at a disease state as a whole. By doing a needs assessment and pulling together key opinion leaders and also community physicians, the panel can provide their input as to where they see gaps in a category, identify up-and-coming research developments, and what they see as being practical for CME at the community level. And the commercial supporter is providing the grant for this overall effort. These are great experiences, because these are very physician-driven events. We can get to the important issues across the therapeutic area. Key thought leaders bring their experience, their issues, and their insights to improve patient care. From that, we can determine the best ways to reach the physician learners in terms of creating the activities. It's a much bigger picture in terms of driving CME as opposed to specific tactics or specific activities. By having community physicians collaborate with key opinion leaders, we not only address the gap between the key opinion leaders and the community doctor in terms of practice,

but we can identify and create effective methods for reaching the community physician.

ROGERS. We are seeing more CME devoted to broad types of categories, such as cardiovascular disease as opposed to just hypertension. When CME becomes broader, the sponsoring body is less scrutinized if it happens to have a product that treats hypertension, for instance. There is less skepticism if the focus of the CME event is on the overall cardiovascular disease epidemic as opposed to specifically the treatment of hypertension. The sponsor is viewed as being more objective especially if it has a product on the market that treats a specific disease.

SHEPHERD. Expectations will have to change on every level. Instead of each group trying to determine what it can get from the other, or what it can get away with, the focus will have to be in terms of what can be accomplished together. I have noticed that there is a lot of focus on the industry's role and practices in CME. But I think it is important to recognize that there are other parties in the mix that also will need to change their practices, and do things differently if everyone is to be on equal ground to work together. For example, while it is natural to perceive academic and medical institution providers as solely concerned with academic pursuits, when it comes to their role in providing CME for industry-supported programs, many are highly motivated by financial gains. These organizations realize they can benefit greatly if they sponsor an industry-supported program, and some are charging astronomical amounts of money to accredit a program when they know it is industry supported. We continually look for an accredited university or medical school provider that is motivated by the desire to put good education out there, rather than one that is concentrating its efforts on our financial relationship. It has become increasingly difficult to find. I am hoping that one of the outcomes of these new standards and guidelines is that it will provide a balanced focus on the role of all parties involved. This will help to promote true collaboration.

SQUIRES. The single best practice is to clearly define the general objectives of the medical-education program up front. The objectives and program also must be clearly supported by science. And, these scientific objectives must be clearly communicated throughout the process to help physicians learn something new.

STELLWAG. From the CME provider standpoint and the med-ed company, both need to understand all of the guidelines and make sure their interpretation of those guidelines are in agreement. From my experience, a lot of the marketing teams and the medical-education teams within pharma are two separate entities. Because there now are so many guidelines, people

Top 10 Meeting Trends for 2003

10 9 8 7 6 5 4 3 2 1

TECHNOLOGY RULES: Demand for T1 lines, wireless Internet, and high-speed Internet access in guestrooms is becoming the norm for meeting planners today. LCD and data projectors are rapidly becoming the new "standard" for meetings.

MEETINGS ARE STRATEGIC AND HIGHER LEVEL: Today's meetings are strategic, participants are at higher levels within their organizations than previously, and the content across industries is focused on top-line revenue growth, new business planning, and strategic marketing.

SHRINKING MEETING BUDGETS: Companies have trimmed meeting budgets significantly, and in some cases have cut them drastically. Additionally, meeting planners are apprehensive to commit to conference space early.

INTENSE PRICING PRESSURE: This originates from customers as well as from more traditional hotels and resorts competing for conference business, especially during valley periods. This is generating creative responses — packages completely customized for the client.

SHORTER AND MORE COST-EFFICIENT MEETINGS: Meetings booked for 2003 are occurring on a less frequent basis than previously, and in many cases are slightly shorter in length. Conferences tend to be more regional in nature to enable automobile transportation, generating air travel cost savings.

WEBSITES EXCEL IN DEVELOPING NEW BUSINESS: Property Websites are important marketing tools today, especially for developing new business relationships and generating requests for proposals.

BOOKING PACE SHOWS IMPROVEMENT: New meeting booking activity for the first quarter of 2003 is stronger than the same period in 2002. Booking lead-time, however, remains very short term, as companies delay commitments to maximize price advantages.

PRIVATE FUNCTIONS CONTINUE, BUT ARE SCALED BACK: Private food and beverage functions continue to be requested as part of a meeting. These functions, however, are much more conservative in nature and are purchased at a lower price point.

DEMAND FOR VIDEOCONFERENCING NEARLY NONEXISTENT: Following the events of Sept. 11, 2001, videoconferencing seemed to offer tremendous opportunity for corporate meetings. Demand tapered off and today is nearly non-existent, however there is demand for videoconferencing and Web-casting.

EVEN FEWER PROFESSIONAL MEETING PLANNERS: As companies continue to trim personnel budgets, decisions related to site selection and meeting expenditures are being assumed more and more by senior-level management staff. These professionals often delegate coordination of the details to their administrative assistants. A growing number of companies are electing to outsource all of their meeting and event business to third-party planners.

Note: These trends are across all industries.
Source: Burt Cabañas, Chairman and CEO of Benchmark Hospitality, an international hospitality management company based in The Woodlands, Texas. For more information, visit benchmarkhospitality.com.

Rosenberg. In the spirit of excellent CME, it's always about excellent content and excellent faculty — that will not change no matter how the guidelines shake out.

are starting to reach out through medical education to get the word out about products and they are becoming a lot savvier.

PETERSON. Here are a few pearls: If the CME provider knows that a fair-balanced discussion of a given therapeutic area is not going to make a commercial supporter happy, he or she can save themselves, and the supporter, a lot grief by not pursuing the funding. Have a very frank conversation at the outset about what the commercial supporter hopes to gain by supporting CME. If the supporter has expectations that go beyond what ethical, compliant CME can do, the CME provider can walk away without hard feelings.

eCME Adoption

SQUIRES. eCME is still sitting in too many silos; there are more than 230 Websites that offer CME. One of the things that CME online has done is provide the opportunity for primary-care physicians, as well as specialists, to access information in specialty areas that aren't necessarily their own. In the past, the only print journals that physicians had access to, besides general journals such as *JAMA* and *The New England Journal of Medicine*, were their specialty journals. This precluded physicians from seeing the latest information in related specialties or unrelated specialties that might impact their own silo. The Web has opened doors to enable physicians to move outside of their own silo. Physicians can access information across the board, but the problem remains that physicians don't necessarily know where the latest information is located.

Rickards. It's a flawed premise to assume that there's currently a large-scale problem with commercial sponsorship and conflict of interest in terms of CME content development. The existing guidelines very clearly prohibit product promotion as part of CME.

RICKARDS. Even before the new PhRMA code was introduced, there was an increased interest in finding new and innovative means for disseminating the latest medical information, both within the CME environment and outside of it. Using Web-based technology is just one of the new ways of doing this. We've found that Web-based education is appealing to many physicians because it is easily accessible, it requires less time than other CME programs, and they can go through the information at their own pace.

ROSENBERG. Commercial supporters that I've talked to anticipate that there will be more eCME. The platform for eCME has increased and as physicians become more comfortable seeking out CME online that will increase growth in this area as well.

KARP. We work with CME providers to deliver their programs via multiple electronic venues, thereby leveraging the valuable content and extending the reach to many healthcare providers. We are seeing a substantial increase in interest from end users desiring eCME. The growth rate of eCME has been tremendous during the past five years.

ROSENBERG. eCME allows providers the opportunity to do new and different things online — simulations, videos, and interactive activities. My feeling is that the more interactive an activity is, the better people will learn. The downside is that we are always guessing who has what type of hardware. Therefore the activity has to be created to accommodate the person who has a high-speed connection and the person who has a dial-in modem. The other downside of eCME is that not everyone wants to be tied to the computer. When we talk about enduring materials, some people like to listen to a CD in their car, and no matter how far we get electronically, people will always want to hold something in their hands. But, eCME is an area in which we can do things that aren't possible with other media, such as simulations.

OSTERMUELLER. We believe there will be growth in eCME delivered through electronic sources, whether it be over the Internet or CD-ROMs, where the physician can participate in an event from his or her home or office and still receive the CME benefit.

ROGERS. I certainly think that eCME will increase, not necessarily because of the new PhRMA code, but as much as a preference-driven requirement. Physicians want other accessibility options to secure educational types of opportunities. Greater access and convenience to viewers will offer an increase in eCME opportunities. All of those things are good — access and preference are the things that healthcare providers are asking for. eCME is an extension of the tried-and-true CME offerings. I've never thought that eCME should be a replacement for conventional programs, rather as an integrated approach that can offer increased synergy. The advantages of eCME, which encompasses Internet, e-mail, CD-ROMs, are access, convenience, and preference. We have the technology at our doorstep. Physicians have Palm Pilots, Internet access, and they've integrated technology into their practices because their patient base has. And because of their busy schedules physicians have to be able to secure educational opportunities through a number of different vehicles within the "e" realm, whether they are CD-ROMs, DVDs, the Web, or e-mail, as well as traditional events. The disadvantage from an e-standpoint is that while e-programs have been accepted by physicians, that acceptance is still not near where it ultimately needs

Blazier. I have seen a positive trend in the area of eCME. The PhRMA code is one reason; another is that the Internet is proving to be an effective way to reach most physicians and the only way to reach some physicians.

to be, where "e" can be totally integrated into their learning efforts.

ROGERS. The advantage of a traditional setup is that it's tried and true. Physicians have experience with these events, so we don't have to convince them to secure an educational experience through some new way of doing things. The disadvantage is that traditional programs don't offer all of the preference opportunities that e-programs may. For example, with a live event, a provider is limited by the number of people who make themselves available, no matter how many places across the country the event is being held.

SQUIRES. There is a lot of opportunity, from both the physician side and the pharmaceutical funding side, to increase the amount of online CME. Pharmaceutical companies and others have underestimated the impact that eCME has had and will continue to have. At this point, half of all physicians, according to the latest AMA survey, use CME online. CME online is different than a live event. Participants at live events are automatically credited. Online, physicians are looking for information that can be digested, and sometimes that means reading the whole article online or participating in the entire event, and then taking the post-test activity to receive their credit. While only 5% to 10% of the physicians who look at CME information online request credit for that program, that's not a negative; that's a plus. Physicians don't need to fill out the credit form to get the critical information that they need.

Lescosky. In an industry dedicated to bettering public health, it's in our best interest to voluntarily police ourselves. By using a voluntary mechanism, industries, such as ours, hope to continually improve our own enforcement mechanisms without the need for additional government intervention.

PETERSON. I don't think that eCME has found its place yet. I don't think CME has adapted itself well to the medium. People have done all sorts of different things to try to make use of it. But there are some problems. Our credit economy — seat hours — doesn't translate well with people's habits online. There has been a recent subtle change in direction by the AMA. In the AMA's most recent PRA handbook, the designation statement does not include the word "hours." And that is a move away from the concept that one hour in the lecture hall equals one credit. This doesn't answer the question for eCME, because who is going to spend an hour online? Spending even 15 minutes online is an extraordinarily long time.

RUSSELL. People are doing case learning online. That makes good use of the medium. Another approach to eCME is to extend the live courses. There is a lot of streaming video with synchronization to slides. Those are just spin-offs and not the most imaginative use of the medium, but if one is going to invest in a live program why not send it out another way. I can't cite a lot of statistics, but I'm not hearing anybody talk about participation rates in eCME being very high. That doesn't mean physicians aren't accessing these programs and finding the material they like, but it will still take some time for this medium to mature.

PETERSON. eCME may become more popular if the proposed ban — in the ACCME draft standards — on allowing representatives to distribute enduring materials is adopted. It is not clear that this will happen and even if it does, it will take some time to see a shift.

RUSSELL. What might drive eCME is if the ACCME goes through with the proposal that reps can't touch enduring materials. Then there will be a strategic change to make more use of eCME, but it won't be because of physician preference. The accredited provider has to request and authorize distribution of enduring materials by the company. The proposed regulation would prohibit reps from handing out monographs and other types of enduring materials. There are a lot of monographs that include off-label information. From the company's point of view the worry is that the rep will detail from the monograph and that would be illegal. Some companies will allow this if the rep is not able to interact with the material, which means it comes sealed in an envelope or shrink-wrapped. If this proposed regulation goes through, it means that rather than shipping monographs, sealed or otherwise, in gross to a company to be distributed by reps during the physician visits, we'll have to buy mailing lists, etc., which adds to the cost. It also disincentivizes the industry from supporting enduring materials. Let's be honest, one of the reasons companies support these activities is that these are another resource for the rep to help build relationships with physicians.

BLAZIER. I have seen a positive trend in the area of eCME. The PhRMA code is one reason. Another is that the Internet is proving to be an effective way to reach most physicians and the only way to reach some physicians. The Internet has great appeal to the busy physician. According to the Boston Consulting Group, the physicians spending the most time in patient care are the physicians who are most likely to use the Internet to seek medical information. All of the research that I have examined shows that an increasing number of physicians are turning to the Internet for CME credit. In addition to offering the marketer potential access to a no-see, high-prescribing physician, the Internet offers the physician 24/7 convenience, zero travel expense, the ability to proceed at their own speed, interactivity to enhance the learning experience, and an abundance of programs in most therapeutic areas. The cost for the technology

behind the online CME has decreased considerably, so when done right eCME can be very efficient. The challenge that the Internet presents is that it is a vast and growing medium. There are more than 19,000 hours of eCME available. Driving the right physicians to an eCME program is a challenge that must be addressed, preferably before the final budget is set for the program. A strategy to raise awareness and drive traffic should be a part of any eCME program.

OSTERMUELLER. There are different features and benefits associated with delivering CME in person or having physicians access CME electronically. The key question is not whether physicians prefer CME or eCME — it's that some physicians will prefer one or the other at different times and for different reasons. The bottom line is that both will have a role in the future of continuing medical education.

Return on Education

PETERSON. CME is nonpromotional by definition. If there is a need to remove its "promotional aspect" it wasn't really CME in the first place. ROI is an economic concept that seeks to measure returns in terms of sales as a result of dollars invested in promotion. Perhaps a more appropriate concept is "return on education." Here we would measure the educational impact — such as improvement in patient care — of the activities as compared with the dollars invested in that education.

KARP. In the past few years, we have seen a shift in perspective away from ROI toward return on education or ROE and a high interest in learning how CME programs benefit providers, their practice, and their patients. As we move toward the realization of ROE, we see the need for increased access and distribution of CME to the healthcare professional and a need for educational platforms that can deliver eCME, as well as provide metrics to quantify and qualify the impact of eCME on physician practice.

OSTERMUELLER. One of the challenges of measuring the ROI of any program is isolating a single variable and measuring that variable. The ultimate goal is having prescriptions written and patients using a particular drug, but there are many things in the marketplace at any point in time that affect this. Through online initiatives, we can identify who accessed a particular program. It might be possible to monitor the practices of a group of physicians who participated in an online event against a group of physicians who didn't partake in a similar program and measure any differences in the practices of one versus the other. When we talk about measuring the impact of individual elements of a marketing plan, this is the Holy Grail of sales and marketing. There are aspects of the electronic media that afford better opportunities to do this as opposed to nonelectronic media.

ROGERS. It's difficult for marketers to tell their superiors that they are going to invest money in something and not have a ROI. There has to be some sort of ROI. With an educational program, the return might be increased share of voice, increased awareness of a disease state, which in the long term could lead to increased business. With every dollar invested, there is an opportunity to get a return, be it educational or promotional. The essence of CME is about information and education. We should measure access, participation, and better patient care. I don't have all the answers as to how that can be done, but those are the key factors to measure. If we focus too much on ROI for an educational event, I think we get lost as to what the ultimate goal is — and that is medical education.

KARP. It's important to use interactivity, solid adult learning design, and to make the program look attractive, but not to the point that users lose focus on the education. Our most popular programs are re-creations of live symposia that combine speakers' slides, audio, and transcribed audio in a self-controlled format, allowing for a true self-paced learning experience.

Shepherd. Because the dissemination of information via CME programs is still considered one of the more credible sources of medical information for healthcare professionals, CME programs will continue to be one of the most desirable and effective avenues for the industry to disseminate information.

SQUIRES. Companies put a budget against a particular therapeutic area or drug with the goal to maximize the use of the drug in appropriate ways to produce better healthcare. So however the budget is divided into marketing or education, as long as objectives and processes are clearly established in an ethical manner based on science, companies will reach their goals of improving healthcare and meeting financial targets. If the education uses science, based on the latest information, to allow physicians to follow the best practices, then we've done our job.

ROGERS. Participation is one area of ROI that can be improved by eCME. If we can turn a traditional CME event that touches 1,000 physicians across the country into an event that touches 5,000, because the event is not only live but has an added e-component, with the same investment, then automatically the ROI can be increased through participation. This can then lead to improved disease awareness and better patient care. ✦

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