REPORT 6 OF THE COUNCIL ON MEDICAL EDUCATION (A-09)
Monitoring Trends in Financing and Availability of CME
(Informational)

EXECUTIVE SUMMARY

This report is presented at the request of the House of Delegates (HOD) in response to the Council of Medical Education's Report 5-A-07 that asks for AMA to monitor trends in financing and availability of continuing medical education (CME).

Data presented in the report will: 1) describe the demographics of the CME enterprise; 2) summarize regulatory and other activities that may impact the provision of CME; 3) explain how the AMA maintains regular communications with the spectrum of CME stakeholders; and 4) discuss the current state of commercial funding for CME and why this may be changing.

Conclusions drawn in the report are that the growth in commercial funding for CME has slowed and will likely decline in the future. In addition, there may be fewer CME providers, especially at the state level. The effects of these changes on access to CME, however, cannot be fully assessed as the full impact of what is happening in the regulatory environment and the economy has not been realized. We also do not currently know enough about the types of CME activities that physicians will prefer to use in the future.

The report recommends that the Council continue to monitor the CME environment and, when appropriate, develop a follow-up report on the state of the CME enterprise for the House of Delegates.

REPORT OF THE COUNCIL ON MEDICAL EDUCATION

CME Report 6-A-09

Subject: Monitoring Trends in Financing and Availability of CME

Presented by: Claudette E. Dalton, MD, Chair

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1 Recommendations of Council on Medical Education Report 5-A-07, "Revisiting PhRMA Code,"
2 adopted by the House of Delegates (HOD) asked:
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4 1. That our American Medical Association (AMA) continue its system for regular
5 communications with state medical society accreditors to monitor the impact of any
6 Continuing Medical Education (CME) guidelines, standards, or applicable regulations on
7 the delivery of CME at the state level; and
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9 2. That our AMA continue to monitor trends in financing and availability of CME at all levels
10 with a report back at the 2009 Annual Meeting of the House of Delegates.
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12 BACKGROUND
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14 The regulatory environment for CME is governed by multiple stakeholders with varying guidelines
15 and standards, all of which combined have an impact on the delivery of CME at both the national
16 and state levels. There are three major CME credit systems in the United States (US): The
17 American Academy of Family Physicians (AAFP) Prescribed and Elective Credit System, the
18 American Medical Association Physician Recognition Award (PRA) Credit System (*AMA PRA*
19 *Category 1* and *Category 2 Credit*™*)* and the American Osteopathic Association (AOA)
20 Categories 1-A, 1-B, 2-A and 2-B Credit System. The AMA PRA Credit System and the
21 accompanying Physician Recognition Award certificate is by far the largest of the three systems.
22 CME providers accredited through the Accreditation Council for Continuing Medical Education
23 (ACCME) or by the 46 state or territorial medical societies (SMS) recognized by the ACCME to
24 accredit intrastate CME providers are granted the privilege to certify CME activities that they
25 develop for *AMA PRA Category 1 Credit*™.
26
27 For the past decade, a major funding source for these accredited CME providers has been
28 commercial support, primarily provided by the pharmaceutical and medical device industries. In
29 recent years this funding has come under increased scrutiny by governmental agencies, the press,
30 and from within the house of medicine itself. As a result, many of the regulations affecting CME
31 have been revised or are in the process of being reevaluated, while at the same time new legislative
32 proposals have been introduced that could further affect CME. Concerns have been raised that
33 these changes could result in decreased access to CME for physicians.

DEMOGRAPHICS OF THE CME ENTERPRISE

On an annual basis, the ACCME produces a report based on self-reported data from CME providers (including those accredited directly by ACCME and those accredited by state/territorial medical societies) that describes aspects of the CME enterprise for the given year. The most recent data available from ACCME are from calendar year 2007. The following is an analysis of the 2007 ACCME annual report data compared to 2006 data and, where possible, to earlier periods of time to get a fuller picture of the changes occurring in the CME enterprise.

Number of Accredited Providers

The number of accredited CME providers remained fairly stable between 2006 and 2007, with the number of ACCME providers increasing from 729 to 736 (1%) and SMS providers decreasing from 1,684 to 1,663 (1.25%). Taken together, the total number of both national and state accredited providers decreased by 14 out of 2,413 (or less than 1%) between 2006 and 2007.

Looking back from 1998 through 2007, the number of ACCME providers increased by 104 (16%) from 632 to 736. Data for SMS providers are not directly comparable for this ten-year period, as these data were not collected for SMS providers during this time. What is known, however, is that in 2003 ACCME reported that there were 1,784 state-accredited providers; as of February 2009, there are 1,618. This signals a loss of 166 or 9.3% of SMS providers in just the last 6 years. Eighty percent (80%) of all SMS providers are community hospitals and physician clinics, 9% are state specialty societies, 3% are government agencies, 2% are foundations, 1% are consortiums, and 5% are others.

The Extent of the CME Enterprise

CME capacity at the ACCME provider level continued to grow between 2006 and 2007 at a rate beyond what would be expected with only a 1% increase in the number of providers. Table 1 shows that the number of certified CME activities produced by 736 ACCME providers increased more than 20%, the number of hours increased by over 4%, and the number of physician participants increased by 5.4%.

Table 1: ACCME Providers Capacity

	2006 ACCME	2007 ACCME	Change
Activities	93,582	113,003	20.75%
Hours	712,163	741,261	4.09%
Physician Participants	8,255,017	8,698,299	5.37%

Table 2 shows that at the SMS level, where the number of providers decreased by just over 1%, there was an 11.4% decrease in the number of certified CME activities and a 14.6 % decrease in the number of physician participants.

Table 2: SMS Providers Capacity

	2006 SMS	2007 SMS	Change
Activities	56,302	49,866	-11.43%
Hours	346,696	344,306	-0.69%
Physician Participants	3,136,610	2,679,753	-14.57%

1 *Types of Certified CME Activities Offered*
2
3 CME providers reported data on twelve different CME activity types. Tables 3 and 4 represent
4 changes from 2006 to 2007 in the types of certified CME activities developed for physicians by
5 both ACCME and SMS providers. The shift toward more performance improvement and internet-
6 based activities and away from courses and regularly scheduled series (especially for SMS
7 providers) is noteworthy.

Table 3: ACCME Provider Activities

Activity Type	**2006 ACCME**	**2007 ACCME**	**Change**
Courses (live)	41,898	40,284	-3.85%
Regularly Scheduled Series (live)	10,427	11,803	13.20%
Internet (live)	893	2,327	160.58%
Test Item Writing	35	286	717.14%
Committee Learning	129	168	30.23%
Performance Improvement	80	726	807.50%
Internet Searching & Learning	56	15,593	27,744.64%
Internet (Enduring Material)	23,939	26,763	11.80%
Other Enduring Material	6,581	6,866	4.33%
Learning from Teaching	897	1,348	50.28%
Journal CME	2,745	3,303	20.33%
Manuscript Review	5,902	4,699	-20.38%
TOTAL	93,582	113,003	20.75%

Table 4: SMS Provider Activities

Activity Type	**2006 SMS**	**2007 SMS**	**Change**
Courses (live)	34,471	32,548	-5.58%
Regularly Scheduled Series (live)	16,424	11,606	-29.34%
Internet (live)	216	300	38.89%
Test Item Writing	17	16	-6.596%
Committee Learning	813	715	-12.05%
Performance Improvement	268	522	94.78%
Internet Searching & Learning	51	376	637.25%
Internet (Enduring Material)	1,245	1,031	-17.19%
Other Enduring Material	1,630	1,276	-21.72%
Learning from Teaching	634	937	47.79%
Journal CME	514	539	4.86%
Manuscript Review	19	0	-100.00%
TOTAL	56,302	49,866	-11.43%

1 *Financial Information*
2
3 For ACCME providers, commercial support funding increased by only 1% in 2007, as compared to
4 an increase of 7.5% in 2006. ACCME providers also reported an 11.89% increase in advertising
5 and exhibit income and a 12.08% increase in other income, resulting in a 6.48% increase in total
6 income. Figure 1 demonstrates the increase in both revenues and expenses for ACCME providers
7 in the past ten years. Table 5 below reflects the actual numbers represented in Figure 1.

Figure 1: ACCME Provider Revenues and Expenses 1998-2007

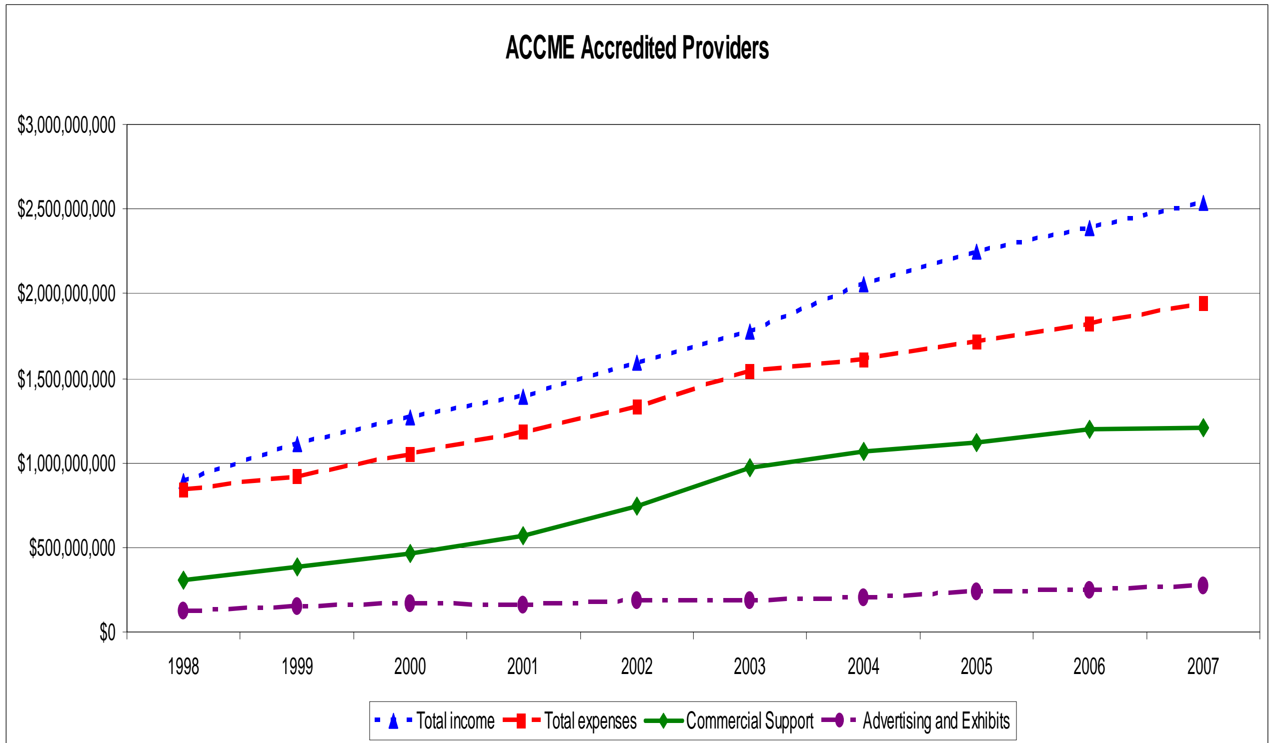

Table 5: ACCME Provider Revenues and Expenses 1998-2007

ACCME Providers	1998	2006	2007	Change between 2006 and 2007	Change since 1998
Total income	$888,544,752	$2,384,581,430	$2,539,198,654	6.48%	185.77%
Commercial Support	$301,949,112	$1,199,405,519	$1,211,345,204	1.00%	301.18%
Advertising and Exhibits	$125,901,112	$244,913,684	$274,033,556	11.89%	117.66%
Other Income	$460,694,528	$940,262,227	$1,053,819,894	12.08%	128.75%
Total expenses	$842,061,037	$1,820,708,534	$1,943,285,741	6.73%	130.78%

1 There are little historical financial data for SMS providers because they did not submit complete
2 financial information to the ACCME until 2006. Between 2006 and 2007, commercial support for
3 SMS providers decreased by 4.66%. Advertising and exhibit income stayed about the same and
4 other income (such as registration fees, internal allocations, government and foundation grants)
5 increased by 15.63%, resulting in a total reported income increase of 8.49%. At the same time,
6 SMS providers reported a 6.71% increase in expenses.

Table 6: SMS Provider Revenues and Expenses 2006-2007

SMS Providers	2006	2007	Change
Total income	$134,499,284	$145,923,641	8.49%
Commercial Support	$39,415,446	$37,579,668	-4.66%
Advertising and Exhibits	$10,200,468	$10,197,519	-0.03%
Other Income	$84, 883,370	$98,146,454	15.6%
Total expenses	$136,454,743	$145,604,957	6.71%

7 In 2007, commercial support represented 47% of the total income for ACCME providers but only
8 about 26% of the total income for SMS providers.
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10 *Distribution of Commercial Support Among Providers*
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12 When the 2007 data are further analyzed by type of ACCME provider, they reveal that some
13 provider types receive different proportions of the total pool of commercial support than would be
14 expected based on their numbers or the size of their CME programs. For example, Publishing and
15 Medical Education Communication Companies received virtually half of all the commercial
16 support given for CME in 2007 but produced less than 10% of all the CME hours/credits.
17 Likewise, medical schools received one-fifth of all the commercial support in 2007 and produced
18 over 44% of all the hours/credits. The following table compares provider types in relation to the
19 percents of the total commercial support received, total activities produced, total CME hours, and
20 physician participants.

Table 7: Comparison of ACCME Provider Types and Total Commercial Support

Provider Type	% Provider Type	% of Total Commercial Support	% Activities Produced	% CME Hours	% Physician Participants
Non-Profit Physician Membership Organization	36.68%	17.78%	20.44%	23.31%	26.15%
Publishing/ Medical Education Communication Company	20.38%	49.07%	30.52%	9.12%	29.77%

Provider Type	% Provider Type	% of Total Commercial Support	% Activities Produced	% CME Hours	% Physician Participants
School of Medicine	16.71%	20.29%	30.13%	44.59%	31.04%
Hospital/Health Care Delivery System	12.64%	3.92%	7.09%	11.58%	9.21%
Non-Profit (Other)	5.16%	6.47%	2.57%	3.73%	1.28%
Not Classified	4.48%	2.42%	5.18%	2.83%	1.10%
Insurance Company / Managed Care Company	1.90%	0.03%	2.00%	0.42%	0.56%

2007 ACCME Annual Report Summary

Significant findings from these data are that the number of ACCME providers and the number of activities they produced continued to grow in 2007, while the number of SMS providers and the number of activities they produced declined. Similarly, commercial support increased slightly for ACCME providers (though at a slower rate of growth than in the past), while for SMS providers commercial support declined. In addition, the distribution of total commercial support is disproportionate in terms of ACCME provider types and size of these programs. Finally, there appears to be a shift away from live activities to more internet-based CME.

THE REGULATORY ENVIRONMENT

The future of both the CME enterprise and how CME is funded will undoubtedly be shaped by the outcome of myriad activities occurring in the regulatory environment.

Senate Finance Committee and Senate Special Committee on Aging

Beginning in 2005, the US Senate Finance Committee initiated an investigation into the high cost of pharmaceuticals, with a focus on how pharmaceutical companies used educational grants to build market share for newer, more lucrative products. This investigation included not only requests for information from 23 of the largest pharmaceutical companies, but also a request of ACCME to provide information on the accreditation system's oversight of commercial support of CME, the management of commercial support by accredited providers, and the requirements of the ACCME's Standards for Commercial Support. The resulting report published in April 2007 concluded that while there appeared to be "promising trends in pharmaceutical manufacturers' use of educational grants," concerns remained regarding issues such as veiled advertising, kickbacks, bias in clinical protocols, and off-label promotion. Further, the report indicated that the ACCME accreditation process may not be sufficiently rigorous to alleviate these concerns. The ACCME immediately responded with changes in its system in an attempt to address the Senate Finance Committee's concerns.

The work of the Senate Finance Committee continues with ongoing investigations of industry as well as investigations of prominent medical specialty societies and health care organizations, all of

which have been enjoined to defend their practices and document that there was no industry influence in the development of their educational activities or in clinical positions or reports issued by these organizations. This level of governmental scrutiny is unfamiliar to CME providers and has caused escalating concerns about the risks and benefits of accepting commercial support for CME activities.

In addition, the Senate Special Committee on Aging is exploring issues that concern elderly Americans, many of whom are reported to be struggling to meet rising health care and prescription drug costs. In June 2007, this Special Committee hosted a series of hearings under the title, "Paid to Prescribe?: Exploring the Relationships Between Doctors and the Drug Industry." The AMA was among the major organizations that presented testimony to the Special Committee regarding the ethics that govern the interactions between physicians and the pharmaceutical industry.

Proposed Legislation

The Physician Payment Sunshine Act, introduced by Senators Charles Grassley and Herb Kohl on January 22, 2009, would require manufacturers and group purchasing organizations to report on a wide range of payments to physicians and physician-owned entities. This legislation has the potential to negatively impact the CME enterprise if provisions such as reporting the value of CME as a payment to physician learners and/or reporting faculty honoraria in certified CME activities are not excluded. The additional burden on CME providers and commercial interests would be significant if the bill were to pass in its current form. Such reporting might also be viewed as a deterrent to faculty and physician learners from participating in bona fide CME activities if these are supported by industry.

Accreditation Council for Continuing Medical Education

In 2006, the ACCME set forth new criteria for accreditation that require CME providers to document how educational activities are designed to change competence, performance or patient outcomes. In this new system it is no longer sufficient merely to demonstrate a change in knowledge; providers must now document that they analyze changes in learners' competence, performance or patient outcomes. The first ACCME cohort of CME providers reviewed under these new criteria were evaluated in November 2008. Only one provider among a total of 83 achieved accreditation with commendation. This is a significant variation from the past five years, which saw an average of 9.8% of providers receiving accreditation with commendation. Results from subsequent cohorts will be analyzed to determine whether this was just a one-time occurrence as opposed to the emergence of a new trend.

State medical societies that are recognized by ACCME will be required to implement equivalent systems for the accreditation of intrastate CME providers by 2010. At present, there is little information about how these new criteria are being evaluated, nor are there many examples of compliance for CME providers to model. Compounding this, the ACCME has significantly increased fees for CME providers at both the national and state levels. Small CME providers, such as community hospitals that operate with part-time staff and minimal resources, may begin to question whether the added investment needed to maintain an accredited CME program in this system is worth the costs.

In addition, in June and August 2008, the ACCME issued calls for comments related to several questions, including:

1) Should those who write promotional materials be excluded from having any role in writing CME content?
2) Should those who teach in promotional activities be excluded from teaching in independent CME activities?
3) Should commercial support of continuing medical education end, or should a new paradigm for commercial support be implemented?
4) How should appropriate interactions between accredited providers and commercial supporters be defined? Dozens of stakeholders, including the AMA, responded to these calls for comments. The ACCME has indicated that it will analyze the findings and will announce its decisions in late 2009.

AMA Council on Ethical and Judicial Affairs (CEJA)

In June 2008, CEJA submitted a report to the AMA HOD regarding industry support for CME. This report was referred back to CEJA. Working collaboratively with the Council on Medical Education, CEJA has been gathering input from multiple stakeholders on this issue, with the goal of submitting a new report to the HOD. The CME enterprise is monitoring this activity closely, since AMA policy regarding the ethical use of commercial support will most certainly have an impact on certified CME.

Association of American Medical Colleges (AAMC)

In June, 2008, the Association of American Medical Colleges issued a report on "Industry Funding of Medical Education," which called for strict limits on industry support of medical education. AAMC's leadership has urged medical schools and teaching hospitals to implement policies and procedures consistent with the report's guidelines. Specific guidelines that may have a demonstrable impact on CME include: 1) establishing a central CME office to distribute industry support for CME; 2) discouraging participation by faculty in industry-sponsored speaker's bureaus; and 3) prohibiting presentations to be ghostwritten. Many medical schools currently do not have policies governing interactions with the drug and device industries like those advocated by the AAMC and are now evaluating their practices as a result of this report. Given that many of the medical school faculty who present in independent certified CME activities are the same key opinion leaders who also speak for industry, compliance with the AAMC guidelines could critically affect the pool of qualified speakers in either or both venues.

Pharmaceutical Research and Manufacturers of America (PhRMA) Code

In July 2008, PhRMA adopted a new "Code on Interactions with Healthcare Professionals" in an effort to ensure that pharmaceutical marketing practices comply with the highest ethical standards. This voluntary code, which took effect in January 2009, includes more explicit standards regarding the independence of continuing medical education in that the code calls for companies to separate CME grant making functions from sales and marketing departments and makes clear that the commercial supporter should not provide any advice or guidance to the independent CME provider regarding the content or faculty for a certified CME activity that it funds. The new code is consistent with the spirit of the existing CEJA guidelines and the ACCME Standards for Commercial Support; practices for compliance with these already have been implemented throughout the CME enterprise. Therefore, because the new PhRMA code largely reinforces

existing practices related to CME, it is not expected that there would be any significant negative impact on funding for CME as a result of its adoption.

OTHER FACTORS AFFECTING THE CME ENVIRONMENT

In addition to the regulatory bodies that have an interest in the CME enterprise, there are other prominent organizations which have also been studying and opining on CME practices and commercial support. Notable among these are: 1) the Macy Foundation, which rendered a report in 2007 calling for an end to commercial support of CME and an overhaul of the accreditation system; 2) a joint effort by the Mayo Clinic, the Society for Academic Continuing Medical Education (SACME), and the ACCME to develop consensus on an agenda for the evolution of research and strategic management of CME that will positively impact on the integrity and effectiveness of the whole CME enterprise, still in progress; and 3) an Institute of Medicine (IOM) Consensus Report, due sometime in 2009, that will examine and describe conflicts of interest involving health care professionals and industry in different contexts and propose principles to inform the design of policies, guidelines, and other tools to identify and manage conflicts of interest in these contexts without damaging constructive collaboration with industry. All of these efforts have the potential to cause additional transformations for CME and will need to be evaluated closely.

Another factor impacting the CME environment is the media. While often not well informed about the difference between certified CME and promotional activities, the media has nevertheless reported on situations that would suggest that CME providers, faculty and learners all have been improperly influenced by interactions with commercial interests as related to CME. These stories provoke a defensive reaction from CME providers who are ill-prepared to deliver a comprehensive response and look to national organizations, like the AMA, to bring factual information to the public.

COMMUNICATIONS WITH STATE MEDICAL SOCIETY ACCREDITORS AND OTHER CME STAKEHOLDERS

The AMA is in regular communication with state/territorial medical society accreditors through the Division of Continuing Physician Professional Development. In 2008, these communication efforts were enhanced with the addition of an invitational meeting at AMA headquarters which provided an open forum for those state medical societies recognized as intrastate accreditors to discuss issues related to the current CME environment and the CME providers they accredit. The majority of these SMS providers, community hospitals, have limited resources to demonstrate compliance with the new accreditation standards and these programs have been among the first to feel the effects of declining industry support. If the implementation of new ACCME criteria is perceived to be too onerous and alternative funding sources are not identified, it is likely that the number of SMS providers will continue to decline.

The Division of Continuing Physician Professional Development also maintains regular communications with other stakeholders throughout the CME enterprise, including the Alliance for Continuing Medical Education, Council of Medical Specialty Societies, Conjoint Committee for Continuing Medical Education, American Academy of Family Physicians, American Osteopathic Association, AAMC, American Association of Medical Society Executives, SACME, the Joint Commission, Federation of State Medical Boards, American Hospital Association, and Association for Hospital Medical Education, to name a few. Issues related to the future of CME are focal in the discussions with these organizations. In addition, the AMA staffs the National Task Force on CME Provider/Industry Collaboration that regularly meets to discuss the ongoing prospects for commercial funding of CME. Information on these discussions is routinely reported to the Council on Medical Education. A common theme rising from these deliberations is that the CME enterprise is in a period of change that will be impacted by many variables. One area of consensus about the future of CME appears to be that performance improvement continuing medical education (PI CME), the model promulgated through the AMA Physician's Recognition Award credit system and also adopted by the AAFP, will be a critical component, but how this new learning model will be funded is still a question.

INDUSTRY SUPPORT FOR CONTINUING MEDICAL EDUCATION

CME providers and industry are experimenting with new models for commercial funding. One such effort has been lead by the Physicians' Institute for Excellence in Medicine, a non-profit subsidiary of the Medical Association of Georgia. In this initiative, pooled funds from industry are distributed through several states medical societies for certified CME activities to be developed by SMS providers. This pooling in effect removes the direct contact between the commercial supporter and the CME provider. The Division of Continuing Physician Professional Development is monitoring this activity which, if successful and adopted, may reduce concerns about the influence of industry on patient care recommendations in CME activities.

Industry is also reexamining its practices with regard to awarding grants for CME. Almost all companies now have centralized CME funding operations and have implemented online grant application processes that are more exacting than past processes. Many of these companies employ individuals with extensive educational backgrounds to review and approve these grant requests. This has put many community hospital CME providers at a disadvantage as the part-time staffs that generally administer these programs have little or no experience in grant writing. In addition, at least one pharmaceutical company has taken the position that it will no longer provide direct funding to medical education communication companies.

Nevertheless, industry professionals at the National Task Force and other meetings have reported that while new regulations and increased scrutiny by the press and governmental agencies will have some impact on CME funding, the most significant issue that will affect commercial funding in the future is the current economy. In fact, these representatives point out that with fewer new drugs in the pipeline for Food and Drug Administration (FDA) approval, with patents expiring for major revenue producing drugs, and with continued consolidation of major pharmaceutical firms, it is expected that not only will support for CME decrease, but commercial funding for exhibits and advertising will also significantly decline. Unless the economy rebounds and the regulatory barriers are mitigated, it is unlikely that the CME enterprise will continue to receive commercial support at the same level as in the past decade.

SUMMARY

While the 2007 ACCME data indicate that the CME enterprise as a whole has not experienced a decrease in the number of activities, the growth in commercial funding for CME has slowed. There is mounting evidence that such funding is likely to decline in the future due to the economy and changes within the pharmaceutical industry. The impact of evolving regulatory standards and guidelines on CME providers is difficult to predict, but early indicators suggest that there may be fewer CME providers, especially at the state level. The effect of the migration from live to internet-based activities also has not been fully assimilated. In addition, physicians' ability to bear a greater portion of the cost for CME in this economy is not known. Therefore, the impact on access to affordable CME for physicians in the future cannot be accurately assessed at this time.

The Council on Medical Education will continue to monitor the continuing medical education environment and, when appropriate, develop a follow-up report on the state of the CME enterprise to the House of Delegates.