

REPORT OF THE COUNCIL ON MEDICAL EDUCATION

CME Report 5-A-07

Subject: Revisiting PhRMA Code

Presented by: Melissa K. Thomas, MD, PhD, Chair

Referred to: Reference Committee C
(Edward C. Tanner, MD, Chair)

1 The following recommendation from CME Report 6-A-06 was adopted in lieu of Resolution 302
2 (A-05) which had been referred to the Board of Trustees.

3
4 That our American Medical Association study the impact of any industry, accreditation or
5 governmental CME guidelines on accredited CME providers and report back at the 2007
6 Annual Meeting of the House of Delegates.

7 8 BACKGROUND

9
10 The PhRMA Code on Interactions with Healthcare Professionals was adopted on July 1, 2002. This
11 voluntary code addresses the interactions between pharmaceutical companies and health care
12 professionals that relate to the marketing of pharmaceutical products. A portion of the code also
13 provides guidance on the appropriate role of the pharmaceutical company in the support of bona
14 fide CME. Concerns have been raised that implementation of this code might have a negative
15 impact on commercial funding for CME.

16
17 By design, the PhRMA code directly parallels the principles outlined in AMA's CEJA opinions
18 8.061 "Gifts to physicians from industry," and 9.011 "Ethical issues in CME," adoption of which
19 predated the code. In fact, implementation of the PhRMA code signaled an important milestone in
20 the CME industry by demonstrating that the medical profession and the pharmaceutical industry
21 were consistent in their views of how commercially supported CME should be conducted and how
22 the pharmaceutical industry should interact with physicians.

23
24 Since the PhRMA Code's implementation, other regulatory bodies have approved standards and
25 issued guidelines that have had an even greater impact on CME in terms of additional
26 administrative requirements and potential legal risks. In September 2004, the Accreditation Council
27 for Continuing Medical Education (ACCME) adopted the Updated Standards for Commercial
28 Support that directly apply to the 1,704 state, and 747 nationally accredited CME providers. In
29 addition, in April 2003, the Office of Inspector General (OIG) issued its "Compliance Program
30 Guidance for Pharmaceutical Manufacturers." Unlike the voluntary nature of the PhRMA code,
31 non-compliance with the federal laws and regulations on which the compliance guidance is based
32 can result in severe penalties, fines, and imprisonment; failure to meet the ACCME standards can
33 result in loss of accreditation.

1 DISCUSSION

2
3 Data gathered from the ACCME, state medical societies, and participants at the 2006 Annual
4 Conference of National Task Force on Industry/Provider Collaboration (hosted by the AMA)
5 indicates that while there may be a confluence of standards, guidelines, and regulations impacting
6 how CME is delivered, there is no evidence that physicians are experiencing difficulty with the
7 overall availability of CME. The most recent data available from the ACCME 2005 Annual Report
8 indicates an increase in the number of CME activities (19.5%), physician participation (26.7%),
9 and commercial support for CME (14.9%) between 2003 and 2005 for nationally accredited CME
10 providers. The national data also indicate that while the largest number of CME activities in which
11 physicians participate continue to be live activities, there has been an increasing percentage of
12 activities being presented through enduring materials, journal CME, and other formats. The
13 availability of CME for physicians is reported to have increased rather than decreased.

14
15 Data from state-accredited CME providers (whose programs serve approximately 30% of physician
16 participants) do indicate that while the overall numbers of CME providers and the availability of
17 commercial support for state accredited CME providers have decreased by 3% and 27%
18 respectively, the number of physician participants has actually grown by 5.8%. State medical
19 societies that accredit these CME providers have reported that the greatest challenges for these
20 state-accredited CME providers come from the administrative burden of accreditation requirements
21 and the new, more complex, systems that have been implemented for seeking grants from
22 commercial interests. The latter is consistent with the data that suggest that commercial support
23 may be harder to obtain for small state-accredited CME providers.

24
25 The state medical societies that accredit intrastate CME providers were surveyed in December
26 2006 regarding the impact on the independence and availability of CME of the new standards,
27 guidelines, and regulations with 77% responding. The vast majority of state medical societies feel
28 that these standards, guidelines, and regulations have had either a positive impact or no impact on
29 the CME activities being offered by intrastate CME providers. A small minority reported a
30 negative impact on the independence of CME for their physicians due to the new federal
31 regulations (8%), the PhRMA Code (8%), and the ACCME Updated Standards for Commercial
32 Support (5.7%). A larger minority reported a negative impact on the availability of CME for their
33 physicians due to the new federal regulations (8%), the PhRMA code (22.9%), and the ACCME
34 Updated Standards for Commercial Support (28.6%). The negative impact was generally attributed
35 to the state-accredited CME providers having difficulty in obtaining grants to assist in financing
36 CME activities. However 97% of state medical societies responding reported that their perception
37 is that physicians are able to obtain the CME that they need.

38
39 When queried, participants at the National Task Force on CME Provider/Industry Collaboration
40 Conference in October 2006, representing both accredited CME providers and commercial
41 interests, responded that the new federal regulations (50%), the PhRMA code (58%) and the
42 ACCME Standards for Commercial Support (70%) have had either a positive or no impact on the
43 relationship between industry and CME providers.

44
45 In summary, the delivery of CME has been impacted by both voluntary and mandatory regulatory
46 standards and guidelines at the state and national levels. However, there does not appear to be
47 current evidence to support the position that these standards, regulations, or guidelines have
48 resulted in a decrease in the availability of CME to serve the physician community at the national

1 level, but there is evidence that there is less commercial support at the state level which has the
2 potential to impact the availability of CME over time.

3
4 RECOMMENDATIONS
5

6 The Council on Medical Education recommends that the following be adopted and that the
7 remainder of the report be filed.

8

9 1. That our American Medical Association continue its system for regular communications
10 with state medical society accreditors to monitor the impact of any CME guidelines,
11 standards, or applicable regulations on the delivery of CME at the state level. (Directive to
12 Take Action)

13

14 2. That our AMA continue to monitor trends in financing and availability of CME at all levels
15 with a report back at the 2009 Annual Meeting of the House of Delegates (Directive to
16 Take Action)

Fiscal Note: Less than \$500.