



Ms. Geraldine Betts, Program Administrator
Department of Professional and Financial Regulation
Office of Professional and Occupational Regulation
Maine Board of Pharmacy
35 State House Station
Augusta, ME 04333

May 14, 2019

RE: Notice of Agency Rulemaking to Implement 2017 Public Law, Chapter 267, 32 M.R.S. § 13759, “An Act to Prohibit Certain Gifts to Health Care Practitioners”

Dear Ms. Betts,

The Continuing Medical Education (“CME”) Coalition (www.cmecoalition.org) appreciates this opportunity to comment on the Maine Board of Pharmacy’s proposal to implement the 2017 Public Law entitled “An Act to Prohibit Certain Gifts to Health Care Practitioners.”¹ The CME Coalition is an advocacy organization composed of, and representing, continuing medical education providers, supporters, and beneficiaries. Our member organizations manage and support development of healthcare continuing education programs that impact more than 500,000 physicians, nurse and pharmacists annually, many of whom are in Maine. Our experiences working daily with CME providers have put us in a unique position to understand the impacts of this proposal, which we contend will have an unintended, detrimental effect on the continuing education of medical professionals that ultimately will impact patient outcomes.

While we fully support the purpose of the Act curtailing “gifts” to an individual “who is licensed, registered, or otherwise authorized to prescribe and administer drugs in the course of that individual’s professional practice” directly by manufacturers and wholesalers, we do not believe that the Act’s purpose is served by limiting honoraria provided to speakers engaged by our member organizations to “an annual limit of \$250 in retail value.” We believe that such a limitation applied to the activities of our member organizations will have a chilling effect on the provision of professional training to Maine medical professionals by other Maine medical professionals. Therefore, we request that this proposal be amended to exempt any continuing medical education program provided by an accredited provider from the \$250 annual limit.

About the CME Coalition

The CME Coalition represents a collection of continuing medical education provider companies throughout the United States, in addition to other supporters of CME and the vital role it plays in our healthcare system. Our member organizations manage and support development of healthcare continuing education programs that impact more than 500,000 physicians, nurses and pharmacists annually, some of whom reside and practice in Maine.

¹ Chapter 267, 32 M.R.S. § 13759 (hereafter the “Act”).

Graduation from medical school and completion of residency training are the first steps in a career-long educational process for physicians. To take advantage of the growing array of diagnostic and treatment options, physicians must continually update their technical knowledge and practice skills. CME is a mainstay for such learning. Most State licensing authorities require physicians to complete a certain number of hours of accredited CME within prescribed timeframes to maintain their medical licenses. Hospitals and other institutions may impose additional CME requirements upon physicians who practice at their facilities.

More than 400,000 medical journal articles are published each year, making the practice of medicine very dynamic. The sheer volume of new scientific data and changes in medicine requires as many appropriate avenues for funding certified CME as possible. In addition, the changes to practice in medicine occur rapidly. The nature of medicine involves constant advancement, testing, and application. Medicine features landmark breakthroughs, such as the discovery and testing of a new therapeutic agent.

Although it represents a shrinking percentage of the nation's annual spend on CME, commercial support still accounts for nearly a fifth of all accredited CME provided to doctors. Shielded from influence by strict conflict of interest rules under the accreditation code of the Accreditation Council for Continuing Medical Education, pharmaceutical and medical device makers underwrite an important portion of medical educational programming through their support of independent grants.

Changes in medicine often are revolutionary. Patients and society demand that our physicians receive information instantaneously, and that updates in treatment, diagnosis, and prevention are disseminated to physicians as soon as practically possible. Without CME, health care practitioners cannot get the most recent and up-to-date advances.

How CME Improves Patient Outcomes

In order to appreciate the rationale for supporting physician participation in continuing education, it is necessary to have an appreciation for the intrinsic value of CME and the role it plays in our healthcare system. Several studies in the past few years have analyzed the impact of continuing medical education on improving patient care. These studies have repeatedly shown that physicians who are educated about the latest advances in evidence-based practice will make more informed treatment decisions, resulting in improved patient outcomes.

Some examples of recent studies include an industry-supported CME program for multiple sclerosis, which demonstrated “statistically significant changes in participant knowledge and competence across a broad range of patient-care topics.”² Another study found that physicians who attended an industry-supported educational activity for chronic obstructive pulmonary disease were 50 percent more likely to provide evidence-based care than nonparticipants were.³ In

² *Multiple Sclerosis CME/CE Live Intervention Demonstrates Improved Clinician Knowledge*, published by Med-IQ October 2, 2012

³ *Improving COPD Patient Outcomes: Breaking Down the Barriers to Optimal Care*. American College of Chest Physicians annual meeting Chest 2010 in Vancouver, British Columbia.

addition, patients suffering from hypertension were 52 percent more likely to receive evidence-based hypertension care when they were seen by physicians who attended an industry-supported educational activity than those seen by nonparticipants.⁴ Yet another study showed that “heart disease patients whose general practitioners participated in an interactive, case-based CME program had a significantly reduced risk of death over 10 years compared with those whose doctors didn't receive the education.”

The Journal of Cancer Education published a study in April 2014 that surveyed close to 300 oncologists about the role of industry-supported CME in their professional development and patient care.⁵ The study found that 90 percent of oncologists “agree” or “strongly agree” that commercial support may be more necessary for oncology than for other specialties due to the rate at which cancer therapies are introduced. Respondents indicated that commercial support plays an important role in providing this cutting-edge information. Three-quarters of the oncologists indicated that commercial support is a significant reason high-quality oncology CME is available. Furthermore, approximately 88 percent said it is “somewhat” to “very likely” that implementation of new or emerging therapies would be slower if commercial support is reduced, and 89 percent said implementation of evidence-based medicine would be slower. When asked about their concerns with removing commercial support, oncologists responded that the lack of commercial support for CME would negatively impact the cost of CME, the availability of professional development opportunities, and access to CME.

In summary, the creation of new therapies will only produce enduring social gains if physicians are properly trained and educated about these advances. Pharmaceutical and medical device companies invest billions of dollars in creating new treatments for patients every year. Patients count on doctors to be up-to-date with these latest medical breakthroughs, and CME provides doctors with that knowledge.

Why We Support an Exemption to the Proposed Rule for Accredited Providers

Providers accredited by the Accreditation Council for Continuing Medical Education (“ACCME”) and other national accreditors must abide by a strict set of standards designed to ensure that accredited programs are free from undue influence by pharmaceutical manufacturers. These include limitations surrounding the selection and use of facility, choice of venues, and the content design of the actual program. Also, accredited providers are subject to routine oversight and audits designed to ensure compliance with their accreditors’ standards, with any failures resulting in sanctions on the offending provider up to and including loss of accreditation. We believe the current accrediting system more than satisfactorily addresses any concerns that the Maine Legislature and the Board of Pharmacy may have about such programs.

The \$250 annual limit will limit our members’ ability to recruit accomplished Maine medical professionals to share their knowledge with other medical professionals and improve the practice of medicine throughout Maine. Physicians take time away from their individual practices to

⁴ Drexel, C. et al. J Clin Hypertens (Greenwich). 2011 Feb;13(2):97-105

⁵ Robinson, C et al. *The Consequences of Diminishing Industry Support on the Independent Education Landscape: An Evidence-Based Analysis of the Perceived and Realistic Impact on Professional Development and Patient Care Among Oncologists*, J Cancer Educ. 2014

discuss and educate other Maine medical professionals on current scientific developments of importance to the Maine medical community and the patients it serves. Many of Maine physicians' speaking opportunities are in less-populated regions that require considerable travel time and time away from work. It is typical for physicians to miss a full day or more of work to give an educational talk to a rural community hospital in Maine (or other rural states). Those hospitals, and other sites of CME, may be a considerable drive away from the closest regional airports, imposing additional time and financial costs.

We believe that Maine's citizens deserve to be treated by medical professionals who are fully conversant with the available treatment options available so that they can choose the best options available for their patients. Therefore, we believe it is in Maine's best interests to not stifle but to support accredited CME programs by allowing them to utilize respected faculty. However, as currently drafted, we believe this proposed rule does not meet that need by failing to allow for CME providers to reasonably compensate Maine faculty for work involved in delivering accredited educational programs. In short, the proposed rule disincentivizes Maine faculty members from participating in CME activities.

Conclusion

We are passionate about continuing medical education because we see the direct beneficial impact it has on physician excellence and patient outcomes. Eliminating the proposed rule's strict limitation on the provision of honoraria to faculty members participating in *accredited* CME activities will allow physicians to continue to participate in CME without the risk of conflict-of-interest Maine rightly seeks to curtail.

Sincerely,

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