



October 30, 2017

Comments on “Limitations on and Obligations Associated with Acceptance of Compensation from Pharmaceutical Manufacturers by Prescribers”

Introduction

The CME Coalition appreciates this opportunity to comment on the New Jersey Division of Consumer Affairs’ proposed new rules, N.J.A.C. 13:45A, entitled “Limitations on and Obligations Associated with Acceptance of Compensation from Pharmaceutical Manufacturers by Prescribers.” As outlined in the proposal, the state is hoping to “strengthen enforcement efforts to address prescriber acceptance of items of value from drug manufacturers” beyond the current standards set by the state’s Board of Medical Examiners.

We believe that this proposed rule rightly incorporates strong protections to exempt accredited continuing medical education from the prohibition against industry support. Despite this goal, however, the rule proposes taking some steps that may adversely, albeit unintentionally, impact the availability of continuing medical education (CME) activities in the state, and we seek to ensure that those effects will not hinder physicians’ access to the critical lessons that CME offers.

To the degree it aims to limit inappropriate industry payments to physicians, the rule’s provisions are workable for the CME community. However, as detailed below, the rule’s limitations on the value of meals that may be provided physicians severely limits the venues available for multi-hour CME programs and could pose a significant hurdle for health professionals seeking to access such CME activities. While we do not expect this was the intention of the rule, the enforcement of a “modest meals” provision will unnecessarily complicate event planning for those hoping to help New Jersey physicians and could place an unreasonable burden on health professionals hoping to benefit from CME.

About the CME Coalition

The CME Coalition represents a collection of New Jersey and non-New Jersey based continuing medical education provider companies, 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, a large number of which take place in New Jersey.

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 dwindling 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, pharmaceutical and medical device makers underwrite an important portion of medical educational programming through their support of independent grants. Unless replaced somehow by government dollars, this support is vital to the continued education of our healthcare providers.

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. Such advances are pivotal in allowing physicians to begin implementing

How CME Improves Patient Outcomes

In order to appreciate the rationale for supporting, rather than discouraging, 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."¹ Another study found that physicians who attended an industry-supported educational activity for chronic obstructive pulmonary disease were 50 percent more

¹ *Multiple Sclerosis CME/CE Live Intervention Demonstrates Improved Clinician Knowledge*, published by Med-IQ October 2, 2012

likely to provide evidence-based care than nonparticipants were.² In 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.³ 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.⁴ 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 medicines will produce enduring social gains only 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.

The Proposed Rule Should be Adjusted in Two Ways

In tackling what it views as a glut of inappropriate payments to physicians, the New Jersey Division of Consumer Affairs has proposed a rule that would effectively prevent physicians participating in multi-hour, accredited CME activities from receiving any food or drink. While the wide-ranging rule starts with a worthy goal of ensuring that providers are not unduly influenced by industry, some of the proposed language leads to practices that violate common sense.

² *Improving COPD Patient Outcomes: Breaking Down the Barriers to Optimal Care*. American College of Chest Physicians annual meeting Chest 2010 in Vancouver, British Columbia.

³ Drexel, C. et al. *J Clin Hypertens* (Greenwich). 2011 Feb;13(2):97-105

⁴ 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.

Meals

In no place is this more clear than the rule's approach to meals that may be provided at CME events. Per the rule, "modest meals" provided cannot exceed \$15.00 per prescriber at a presentation or educational event, with no explicit exceptions. Of course, health professionals don't make the catering decisions for the events that they choose to attend, and the practical effect of this rule would be to create an unworkable scenario for New Jersey health professionals seeking multi-hour CME programs.

Indeed, based on the typical venues used for CME seminars, the \$15 threshold would present a significant challenge for event organizers and health professionals trying to adhere to the law, rather than merely ensuring that the provided meals are modest. For example, the events menu for the [Newark Airport Marriott Hotel](#) shows that the cheapest *breakfast* option is available for \$25.00 per person, with lunch starting at \$35.00. In the New York suburbs, the [Wilshire Grand Hotel](#) in West Orange offers catered breakfast starting at \$16.95 – before service charges and taxes. And even further south, the Holiday Inn in East Windsor — the site for New Jersey's 2017 CME Provider Conference — offers its most basic breakfast package for \$18.95 per individual. Lunch or Dinner prices are considerably higher.

The continental breakfasts offered by each of the aforementioned hotels would clearly be described as "modest" under any reasonable standard, yet not one would meet the rule's rigid standard. Should the rule be finalized as written, there is a significant chance that physicians will need to provide their own sustenance for a day of training, which is neither rational nor reasonable. That end result — discouraging physicians from taking advantage of vital educational resources due to the inadequate refreshment provided at those events — is an unacceptable consequence for a rule that aims to benefit patients and ensure that physicians maintain their professional obligations.

We encourage you to eliminate the \$15 threshold from the proposed rule.

Fellowship Support

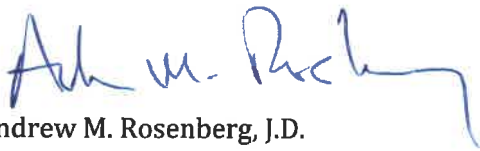
Many of our members hold intensive training sessions for fellows and residents in training. These are typically one to two day events held in conjunction with major medical meetings such as ASCO or ACC. The events feature skills training, and lecturers that they would not be able to receive in their home institutions.

While these events support the travel and lodging of medical trainees, under the rule as written it is unclear if companies will be able to support these activities. We encourage you to include fellowship support for medical trainees in your final rule.

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 provision of refreshments from accredited CME activities will have an unmistakable and deleterious impact on physician participation in CME, and this serves no good end. Any miniscule benefit that might be gained from eliminating the provision of reasonable meals and sustenance is simply not matched by the predictable, negative impact on facilitating and encouraging physician participation in continued learning. We also encourage you to rewrite the rule so as to support fellowships for medical trainees in the state.

Sincerely,

A handwritten signature in blue ink, appearing to read "Andrew M. Rosenberg". The signature is fluid and cursive, with a long horizontal stroke at the end.

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