



December 03, 2021

Division of Dockets Management
U.S. Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. FDA-2021-N-0951

To Whom It May Concern:

On behalf of the [Continuing Medical Education \(CME\) Coalition](#), I am writing to urge the Food and Drug Administration (FDA) and the Duke-Margolis Center for Health Policy to consider the full scope and ramifications of implementing mandatory opioid prescriber education through a risk evaluation and mitigation strategy (REMS).

Founded in 2011, the CME Coalition represents a collection of CME stakeholders throughout the United States in addition to other supporters of CME. Our member organizations manage and support the development of healthcare continuing education programs that impact more than 500 thousand physicians, nurses, and pharmacists annually.

Graduation from medical school and completion of residency training are the first steps in a careerlong 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 thousand 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, and it also features landmark breakthroughs, such as the discovery and testing of novel therapeutic agents.

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.

Many public and private entities utilize CME programs to encourage safe and effective prescribing practices for opioids, and our Coalition members have developed and presented multiple continuing education programs for health care practitioners based on the blueprints provided by the FDA with support from the REMS program companies.

In assessing the outcomes of these continuing education programs, our members have found consistent and statistically significant improvements in knowledge gaps surrounding opioid education, and improvements — such as proper extended-release opioid conversion — were noted within 90-day follow-up data, suggesting incorporation of the learning into daily practice. These data demonstrate the ability of CME to address knowledge gaps and improve practices among providers in the evidence-based use of opioids to treat patients.¹ This paper — in addition to other outcomes and needs assessments — depict the need for increasing the size and scope of the Opioid REMS program. Indeed, we urge you to seek additional resources for the program to ensure that more clinicians benefit from the education being offered.

The CME Coalition appreciates the FDA's and Duke-Margolis Center for Health Policy's efforts to address the opioid crisis, and we are encouraged that the FDA sees CME as a valuable tool in combatting the opioid epidemic. In fact, 39 states² already require CME on the use of opioids and controlled substances. While the CME Coalition respects required education, we agree with the vast majority of the presenters at your meeting that required Opioid REMS is not a workable solution to the crisis.

Specifically, we are concerned that a mandatory opioid REMS program could create a tremendous bottleneck at pharmacy counters across the country. Requiring pharmacy

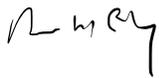
¹ Williamson C, Martin BJ, Argoff C, Gharibo C, McCarberg B, Atkinson T, Berger L, Sullivan T. Pain Management and Opioid Therapy: Persistent Knowledge Gaps Among Primary Care Providers. *J Pain Res*, available at <https://doi.org/10.2147/JPR.S316637>.

² AL, AK, AZ, CA, CO, CT, DE, FL, GA, IL, IN, IA, KY, ME, MA, MI, MS, NE, NV, NH, NJ, NM, NY, NC, OH, OK, OR, PA, RI, SC, TN, TX, UT, VA, WA, WV, and WI. Federation of State Medical Boards, Continuing Medical Education: Board-by-Board Overview, available at <https://www.fsmb.org/siteassets/advocacy/key-issues/continuing-medical-education-by-state.pdf>.

personnel to confirm that the prescribing clinician has met the mandatory opioid REMS education requirements could create massive delays in receiving necessary medications as pharmacists would now be tasked with carrying out a burdensome verification process. This could exhaust time and resources that could be otherwise used to deliver critical patient care services.

Again, we strongly recommend that FDA consider the ramifications of implementing mandatory opioid prescriber education through REMS and explore other avenues by which the opioid crisis may be remedied — including strengthening company support for the program. As the opioid epidemic continues to worsen in the United States, it is imperative that opioid education programs be adequately resourced. We thank you for your consideration of our comments on this important issue and look forward to the opportunity to serve as a subject matter resource as you explore the topic of prescriber education for opioids whilst ensuring that health care providers are not overly burdened as a result.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew Rosenberg". The signature is fluid and cursive, with the first name "Andrew" and last name "Rosenberg" clearly distinguishable.

Andrew Rosenberg, J.D.

Senior Advisor

CME Coalition

Washington, DC