



February 11, 2021

The Honorable Janet Woodcock
Acting Administrator
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

RE: Evaluating the Effect of the Opioid Analgesics Risk Evaluation and Mitigation Strategy Education Program on Prescribing Behaviors and Patient Outcomes-Exploring the Path Forward for Assessment; Public Workshop; Issues Paper; Request for Comments (FDA-2020-N-1561)

Dear Acting Commissioner Woodcock,

On behalf of the Continuing Medical Education Coalition, we are writing to applaud the agency's Opioid Analgesics Risk Evaluation and Mitigation Strategy (OA REMS) program and highlight the essential role of continuing education (CE or CME) in educating prescribers and other health care providers on the treatment and monitoring of patients with pain.

The central component of the OA REMS is a voluntary CE/CME program for all health care providers who are involved in the management of patients with pain, including doctors and others who prescribe these products. Under the OA REMS, manufacturers of impacted products are meeting this requirement by providing educational grants to accredited CME providers who develop and offer the training. As a result, CME providers have demonstrated a strong track record of providing these educational activities through a variety of formats and settings — including live events, webinars, and internet-based events to facilitate didactic, case-based, interactive, multimedia, and adaptive training. During the pandemic our CME providers have accommodated live in-person courses to online courses both live and archived, to ensure that healthcare providers are up to date on the most recent blueprint.

THE VALUE OF CME

CME training is critical in supporting health care providers to generate an improved understanding of how to manage pain and the role of opioid analgesics, as well as nonpharmacologic and non-opioid analgesics, in pain management. Given the risks associated with opioid use and the potential to leverage other therapies, the information provided in these courses is essential for assisting health care providers to reduce adverse outcomes of addiction; unintentional overdose; and death that can result from inappropriate prescribing, abuse, and misuse.

With respect to the effectiveness of CME training, there have been numerous studies done to demonstrate the positive impact of participating in CME events. For example, in an analysis of 39 systematic reviews published between 1977 and 2014, researchers concluded that CME courses “can more reliably change health professionals’ knowledge and competence than their performance and patient health outcomes.”¹ More recently, data suggested that efforts to slow the opioid epidemic such as the OA REMS program may have had an impact: from 2016 to 2017, deaths attributed to prescription opioids plateaued, and, for the first time, the number of overall drug overdose deaths decreased 5.1% from 2017 to 2018. However, according to the American Medical Association, the rate has been increasing over the past year during the COVID pandemic with more than 40 states reporting increases in opioid-related deaths and growing concerns for those with substance use disorder. Clearly, the current public health emergency demands an even greater commitment to prescriber education.

CME as part of OA REMS program is inherently evidence-based, as education provided through REMS program is based on the FDA Blueprint. We appreciate that the FDA Blueprint provides effective guidelines for CME events by focusing on such topics as how to identify risk factors for abuse and addiction; the range of therapeutic options for managing pain, including nonpharmacologic approaches; how to counsel patients and caregivers about the safe use of opioid analgesics, including proper storage and disposal; and how to identify and manage patients with opioid use disorder.

Beyond the FDA’s existing requirements, we believe that CME events accredited by the Accreditation Council for Continuing Medical Education (ACCME) and other accredited organizations are especially helpful, because the scope of evaluation of effectiveness is actually *measured* in the educational activities. This helps to evaluate how well physicians understand the REMS and opioid effects on their patients.

CME PROVIDER EXPERIENCES

We are encouraged that the FDA sees CME as a valuable tool in combatting the opioids epidemic. Our members have created hundreds of hours of pain education programs and have delivered them to hundreds of thousands of physicians. Our members who participated in providing OA REMS education activities saw significant improvement in self-reported outcomes. Our members have provided education on the FDA Blueprint to hundreds of thousands of U.S. based health care providers.

A study of FDA REMS content provided by one of our members which had over 20,000 OA REMS learners analyzed the outcomes of some these programs which showed statistically significant gains in knowledge, perception, and competence in pain management including:

- Recognizing types of nociceptive pain;

¹http://www.accme.org/sites/default/files/652_20141104_Effectiveness_of_Continuing_Medical_Education_Cervero_and_Gaines.pdf

- Distinguishing treatment goals for acute vs chronic pain;
- Understanding that optimal pain management uses a multimodal care plan;
- Using an evidence-based approach to initiating opioid therapy for chronic pain; and
- Confidence in developing treatment plans for patients with acute and chronic pain.²

However, the pre-education assessment results also give an indication of the extent of existing gaps in knowledge and competence in multiple aspects of pain management. Thus, while the findings indicate that these initiatives have positively impacted provider practice, they also demonstrate that efforts to continue to improve providers' knowledge and skill in providing optimal pain management for their patients while mitigating opioid misuse are still needed.

Additionally, one of our members recently documented how they have adjusted their OA REMS programming during the pandemic. Despite the uncertainty of the past year, this national CME provider recently explained they were "enthusiastically able to meet the high need and demand of our learners by providing them with OA REMS education. Given the magnitude of the public health and safety issues posed by the COVID-19 and resulting inability to bring clinicians together in-person, we shifted to offering a series of live streamed and endured interactive online modules which provided a unique learning experience and extended the program reach to markets nationwide. Over the past several months, we have been able to exceed our learner goals for those who completed the entire Blueprint."

KEY UPDATES TO THE BLUEPRINT

Among the most important developments in the REMS program in recent years is the addition of immediate-release (IR) opioids used in the outpatient setting that are not already covered by another REMS program. In comments submitted in 2016, the CME Coalition encouraged the Extended-Release and Long-Acting (ER/LA) Opioid Analgesic REMS program, while emphasizing that IR opioids are even more likely to be abused and therefore, much more difficult to manage. We believe the updated Blueprint, which includes IR opioids, will more effectively support national efforts to address the misuse and abuse of prescription opioid analgesics.

Further, we applaud the FDA for adopting our 2016 recommendation that CME should *not* be limited to prescribers, and instead be extended to all health care providers who participate in the treatment and monitoring of pain, including pharmacists and nurses.

PROGRAM RECOMMENDATIONS

We believe the FDA should consider standardizing the REMS process, while allowing more flexibility in content. The strength of CME is that it can produce myriad educational activities that are targeted to physicians based on their professional practice gaps, individualized needs, and stages of learning

² Williamson C, et al. Pain management and opioid therapy: persistent knowledge gaps among primary care providers. *J Pain Res.* 2021; manuscript in preparation.

and change. Added flexibility will allow prescriber education to better address individual prescribers' educational and practice needs.

The effectiveness of REMS can also be measured in terms of how successfully it promotes access to education and draws the attention of the medical profession to a problem.

Through their research and experience, we believe that, rather than requiring the whole three to six hours of content outlined in the Blueprint, that counting credit hours towards a goal of three hours of REMS education should be considered. This would align OA REMS to most state requirements and allow for further customization towards specific audiences.

CONCLUSION

We appreciate FDA's commitment to ensuring health care providers are educated on the risks associated with opioid use and abuse. The OA REMS program, which leverages the expertise of the FDA and accredited CME providers, serves as a model of cooperation in helping to address public health issues. Thank you for your consideration of our recommendations and we look forward to continuing to work together to implement this vital program.

Sincerely,

A handwritten signature in cursive script that reads "Chris Lamond".

Chris Lamond
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