

Margolis-FDA Convening: Reconsidering Mandatory Opioid Prescriber Education Through a Risk Evaluation and Mitigation Strategy (REMS) in an Evolving Crisis

Virtual Public Meeting

October 13 and 14, 2021

Meeting Summary

Duke-Margolis, with support from the U.S. Food and Drug Administration (FDA), hosted a public workshop on October 13 and 14, 2021, that convened regulators, clinicians, researchers, patient advocates, and other stakeholders to discuss potential future directions for opioid prescriber education, particularly continuing education (CE) provided through FDA's Opioid Analgesic Risk Evaluation and Mitigation Strategy (OA REMS), and its role in alleviating the opioid and substance use crisis.

Drawing from a wide range of experience and perspectives — in clinical care, opioid and pain management education, patient advocacy, and public policy— participants engaged in panel discussions about the current state of prescriber education and the potential future impacts of mandatory education implemented through the OA REMS. The meeting specifically focused on considerations related to the landscape of prescriber education requirements, the potential role of prescriber education in helping to address the current opioid crisis, the future role of federally mandated prescriber education in alleviating the current opioid crisis, and future opportunities for improvement in opioid prescriber education.

Key takeaways from this meeting included:

- Panelists agreed that across-the-board, one size fits all mandatory education through a REMS is unlikely to be effective in substantially reducing risks associated with opioid analgesic prescribing. However, targeted, individualized, and customized training that is not funded by industry and instead provided through trusted sources, such as medical societies or educational institutions, could make an impact.
- Barriers to effective education include providers being overworked, with many other demands on their time and attention in addition to CE, drug utilization review by payers and the needs of providers not being met (i.e., three-hour general CE is not sufficiently engaging and does not match-up with provider-specific knowledge gaps).
- Promising opportunities for improving prescriber knowledge of critical issues such as pain management, safe prescribing, and knowledge of substance use disorders included the use of tailored educational content, making a “menu” of educational options, one-on-one conversations with practitioners to provide education specific to the clinical situations that the practitioner faces (known as academic detailing), including more opioid-related education in medical and nursing school curricula, and, ideally, pairing

educational interventions with a comprehensive interprofessional systems-based approach to addressing the crisis.

Substance Use Trends and FDA Responses to the Evolving Opioid Crisis

To set the stage for these discussions, the workshop began with a series of presentations from FDA and the National Institute on Drug Abuse (NIDA) providing historical context on how the opioid and substance use crisis has evolved in recent decades, how opioid prescribing patterns have changed during this time period, and how FDA has responded to the crisis through regulatory actions. Critical points presented included:

- The trend toward increasing illicit opioid and polysubstance use driving the increases in overdose deaths;
- Exacerbated stress, isolation, and lack of social support during the COVID-19 pandemic contributing to increased overdose deaths;
- The continued rise in opioid overdose deaths in recent years despite significant reduction in the total number, duration, and dosages of opioid prescriptions; and increases in buprenorphine dispensing for the treatment of OUD.
- An overview of FDA’s decision-making process that led to the current OA REMS and its voluntary prescriber education program; and
- Difficulties assessing the impact of the OA REMS on prescriber behavior and patient outcomes in the midst of concurrent policy interventions aimed at mitigating the opioid and substance use crisis.

Assessing the Landscape of Federal, State, and Health System Prescriber Education Requirements

The remainder of the first day of the workshop was dedicated to two panel discussions concerning the current landscape of prescriber education efforts and how prescriber education might be able to address particular aspects of the opioid crisis. The first panel overviewed the landscape of current prescriber education efforts at the federal, state, and health system levels. Panelists’ presentations described existing overlapping prescriber education requirements at the federal, state, and health system level, covering a wide variety of provider types. As the discussion began, panelists universally agreed that a mandatory, one-size-fits-all continuing education program was unlikely to be effective in eliciting positive behavior change. Panelists discussed key elements of what *does* constitute effective CE, including comprehensive needs assessments, in-depth engagement with providers, and tailored programming appropriate to the provider’s context, as well as some concerns about industry messaging in educational

content. There was also conversation around the appropriate goals of CE. Panelists discussed a potential dichotomy in regard to the function of CE: it can serve a remedial role, catching providers up on knowledge they may lack because of gaps in previous educational programming, or it can serve a more forward-looking role, keeping providers up to date with the latest developments or best practices emerging in their field. Additionally, speakers expressed support for the goals of educating providers on an ongoing basis about best practices for pain management as well as identifying and treating OUD, but they noted that mandatory CE on opioid prescribing has already been implemented at various levels of government and even within health systems.

Examining the Potential Role of Prescriber Education in Helping to Address the Current Opioid Crisis

The second panel echoed many similar points about engaging providers through effective educational approaches based on principles of adult learning – as opposed to what some felt can become burdensome and ineffective programming if not executed correctly. Speakers recommended that the goals of opioid prescriber education should align with providers’ needs and knowledge gaps and be relevant to their clinical settings — tailored to real-world situations and challenges faced by the prescriber. This necessitates a holistic view of both the provider and the patient, which panelists contrasted with undue focus on monitoring and limiting opioid prescriptions. If the ultimate goal of education is to change prescriber behavior, that may be best accomplished via a one-on-one engagement like academic detailing, which allows for far more customization and in-depth interaction with a provider. Scaling up programs like academic detailing to effect widespread behavior change remains challenging, however, since these methods are time- and resource-intensive. Panelists generally agreed that these types of custom approaches would be challenging to implement via a REMS.

Throughout the discussion, speakers noted the difficulty in measuring and understanding the effectiveness of educational interventions with respect to impact on patient outcomes. Though opioid prescriptions have declined, it is difficult to attribute prescribing trends to educational interventions, since so many other policy interventions were implemented during the same time period in which CE requirements were expanded. Furthermore, even if educational interventions have contributed to decreasing prescribing rates, it is unknown the extent to which prescriber education efforts have affected or will affect public health outcomes, given the fact that opioid overdose deaths have continued to rise even as prescriptions have declined. Prescriber education is only one tool to improving patient outcomes. Other approaches can include reimbursement and care delivery systems that incentivize high quality treatment, and several panelists suggested that the impact of prescriber education will be limited without accompanying interventions to address these other factors. Identifying meaningful outcome metrics and conducting analyses that can tease out the impact of CE is another ongoing challenge.

Considerations for the Future Role of Federally Mandated Prescriber Education in Alleviating the Current Opioid Crisis

The second day of the workshop convened two more expert panels to discuss how the OA REMS can continue to evolve to help mitigate the current opioid crisis. In the first session of the day, panelists considered the future role of federally mandated prescriber education, including challenges and benefits that could be associated with OA REMS CE if it were made mandatory. The panelists agreed, echoing comments from the first day's discussions, that education is most impactful when it is appropriately tailored and targeted to providers. Appropriately tailored education would require identification of gaps and educational needs unique to providers' daily practice, setting, and patient populations. There were concerns, however, that educational requirements can limit access to opioids for patients who need them, and that a federal mandate could add a further barrier to access by discouraging providers from prescribing opioid analgesics. Panelists also addressed equity considerations associated with barriers to access, most notably the fact that patients of color and lower-income patients can already face more difficulty accessing opioid analgesics and could be disproportionately affected by these changes. There was also discussion of some successes stemming from state-level interventions, and panelists suggested policy changes at the state and health system levels could be better suited to the issue than the REMS program.

Future Opportunities for Improvements in Opioid Prescriber Education

In the final session of the workshop, panelists explored potential next steps for the OA REMS Program. Panelists brought together lessons learned throughout the two-day workshop with their own perspectives for an ideal educational program under the OA REMS. They reiterated the idea that mandatory education through the OA REMS could have significant unintended consequences, including discouraging providers from treating chronic pain patients and limiting appropriate patient access to opioid analgesics, and questioned how well-suited a REMS program focused on prescription opioids would be to the current substance crisis driven by illicit substances. Additionally, panelists questioned the value added by such a program, given the plethora of already available education, and stressed that mandatory education through the REMS is not a solution that fits the problem. Lastly, the panel reflected on the need for complementing safe prescribing efforts with holistic, whole-person approaches to patient care that can improve patient outcomes with respect to pain management and addiction. A number of panelists expressed skepticism as to whether mandatory education provided through a REMS could effectively incorporate these topics and reiterated the importance of reducing payment barriers to alternative pain management approaches and medications for opioid use disorder (MOUD), as well as sustained support from policymakers and health systems in implementing models that can support high-quality care.

Key Themes and Next Steps

Throughout the workshop, speakers recommended tailored and targeted prescriber education as well as implementing a whole-person approach to patient care. Panelists reiterated that before designing tailored opioid prescriber education, it's important for CE providers conduct comprehensive needs assessments to identify and address gaps and educational needs that support continuous improvement unique to prescriber setting, practice, and patient population. Speakers also largely agreed that REMS, as a federal-level intervention, would be an ineffective policy instrument for such carefully targeted approaches. Nonetheless, speakers did note that the scope and logistics of any mandatory prescriber education will depend on the size of the prescriber audience seeking to be reached. There remains the possibility of connecting prescriber education requirements to existing tools such as state PDMPs and medical and other professional board oversight. Additionally, applying a whole-person approach to opioid prescriber education can help address the social, emotional, and psychological factors that affect patients living with pain or OUD. Focusing less on prescription thresholds and more on understanding the patient could make prescriber education more effective and more meaningful for providers. Ultimately, education can be an appropriate lever for modifying prescriber behavior, but improperly targeted or redundant educational interventions can have significant and negative unintended consequences.

FDA appreciates the feedback it received from the experts and stakeholders who participated in the workshop, those who attended and contributed via comments and Q&A, and public comments submitted in response to the [Federal Register Notice](#) for the meeting. All of these sources of feedback will inform FDA's ongoing work on addressing the opioid crisis.