

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, 2021 | 1:00-5:00 p.m. ET

October 14, 2021 | 1:00-4:05 p.m. ET

Discussion Guide

Opening Remarks from FDA

FDA leadership will provide an overview of the impetus for the two-day convening, as well as the key themes they hope to cover and questions they hope to have addressed.

The Current Landscape of the Evolving Opioid and Addiction Crisis

NIDA will give a brief presentation on the current landscape of the opioid and substance use crisis and how it has changed over recent years, including the types of substances used and involved in overdoses (e.g., prescription drugs including opioid analgesics, synthetic opioids, heroin, and stimulants, and the predominance of polysubstance use), and any important shifts in demographic or geographic factors or other aspects of the crisis.

Selected FDA Actions in Response to the Opioid Crisis

This presentation will describe some of FDA's efforts to communicate and educate health professionals and patients about the risks associated with opioid analgesics, prescribing practices and other strategies to reduce these risks, and the role of opioid analgesics and other treatment approaches in the management of pain. Specifically, FDA will provide an overview of the Opioid Analgesic REMS and the evolution of this program, as well as selected changes to opioid analgesic labeling requirements.

Prescription Opioid Utilization Patterns in the U.S.

FDA will present prescription opioid utilization patterns throughout the years. The presentation will cover overall prescription volume and will also touch upon factors such as dose, co-prescribing with benzodiazepines, and prescribing in specific populations.

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

Many systems for prescriber education exist beyond the federal sphere. This session will consist of a series of remarks from representatives of federal agencies as well as state medical boards, health systems, and medical schools highlighting the differing federal, state, and graduate medical training that providers receive on safe opioid prescribing, including related topics such as pain management or recognition and treatment of opioid use disorder (OUD). Panelists will discuss where gaps or duplication may exist in prescriber training and consider these efforts in light of complementary interventions to support safe opioid prescribing, including prescribing limits and the CDC's opioid prescribing guideline.

Discussion Questions:

1. Have prescriber education efforts at the federal, state, and health system levels generally provided prescribers with the training and information needed to safely prescribe opioid analgesics? How have prescriber education efforts generally supported or aligned with other policy efforts to reduce risks related to opioid prescribing?
2. Are there overlaps or redundancies in requirements that may lead to unnecessary, burdensome, or duplicative requirements for prescribers?
3. What can we learn about implementation of prescriber education from existing educational programs at the federal, state, and health system levels in pain management, in opioid risk reduction, and in the treatment of opioid use disorder?

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

This panel discussion will explore the current and potential future role of prescriber education as trends in prescription opioid use and the broader crisis continue to evolve. Panelists will discuss key competencies that prescriber education should support and how prescriber education efforts can complement existing efforts to support improved pain management, improve provider knowledge and reduce stigma related to substance use disorders, and expand access to medications for opioid use disorder. They will also discuss gaps in current educational programs, such as those involving pain management and recognition and treatment of opioid use disorder.

Discussion Questions:

1. How can prescriber education programs be improved to support appropriate opioid prescribing, better pain management, and recognition and management of OUD?
2. What are the current knowledge gaps or important clinical challenges related to safe opioid prescribing and pain management more generally?
3. How could improved prescriber education address those challenges to achieve better outcomes for patients and make a positive impact on the opioid crisis?

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

As the nature of the opioid and substance use crisis evolves, opportunities have emerged to update, expand, and potentially streamline prescriber education requirements, including but not limited to introducing mandatory requirements under the Opioid Analgesic REMS. This panel will discuss what components of the opioid crisis could potentially be addressed through nationwide mandatory prescriber education, and what might be some specific, measurable goals for such a program. The panel will consider challenges such as alignment between federal, state, and health system requirements, as well as other complementary policies or regulations. Speakers will also explore potential unintended negative consequences including provider, patient, and health system burden, and what measures may be needed to reduce burden. The discussion will also touch on major logistical challenges that might arise from mandatory education, including the need for new or updated technologies to enable monitoring and documentation of the expanded program.

Discussion Questions:

1. How might federally mandated prescriber education via a REMS benefit patients and prescribers? Conversely, what undue burdens might it place on providers and health systems and what barriers to access might it create for patients?
2. What would appropriate program goals be for a mandatory prescriber education program through REMS? How would these goals complement the aims of other federal, state, and health system interventions?
3. What logistical challenges might arise for FDA, health systems, and providers if prescriber education were federally mandated under a REMS? How could these and other stakeholders work to mitigate those challenges?

Next Steps

In light of the previous discussions, this session will offer panelists a chance to discuss next steps and opportunities for improvement in opioid prescriber education, including what could be accomplished under a REMS or under an alternative system. Panelists will consider the current landscape, any gaps or redundancies, and the challenges of assessing the impact of education programs against the backdrop of an evolving landscape and many concurrent interventions, and discuss the implications for the future of the safe use of opioid analgesics and possibly other controlled substances.

Discussion Questions:

1. Would making prescriber education mandatory via a REMS be an effective response to the current opioid crisis? What unmet needs do you think it could address?
2. How would the effectiveness and impact of a mandatory prescriber education program be measured?
3. What lessons can we learn from the implementation of the broad range of existing prescriber education programs and requirements? How can these lessons inform decision-making regarding the future of the Opioid Analgesic REMS?
4. What would an ideal national prescriber education system look like? What practical challenges might arise in creating such a system, and how can FDA and other stakeholders mitigate those challenges?
5. What could be unintended consequences of mandatory opioid prescriber education through a REMS, and are there ways to identify and address them?