

## **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

### **Agenda: Day One**

**1:00 pm Welcome and Overview**

**Mark McClellan**, Duke-Margolis Center for Health Policy

**1:10 pm 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.

**Speaker:**

- **Patrizia Cavazzoni**, U.S. Food and Drug Administration

**1:20 pm 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.

**Speaker:**

- **Wilson Compton**, National Institute on Drug Abuse

**1:50 pm 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.

**Speaker:**

- **Doris Auth**, U.S. Food and Drug Administration

**2:15 pm 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.

**Speaker:**

- **Corinne Woods**, U.S. Food and Drug Administration

**2:35 pm 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, and whether they include broader topics such as pain management or recognition and treatment of opioid use disorder. 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.

Moderator: **Marianne Hamilton Lopez**, Duke-Margolis Center for Health Policy

**Speakers:**

- **Kathy Chappell**, American Nurses Credentialing Center
- **Blake Fagan**, Mountain Area Health Education Center
- **Adriane Fugh-Berman**, Georgetown University Medical Center
- **Graham McMahon**, Accreditation Council for Continuing Medical Education
- **Lisa Robin**, Federation of State Medical Boards
- **Kristine Schmit**, Centers for Disease Control and Prevention

**3:40 pm Break**

**3:55 pm      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.

Moderator: **Mark McClellan**, Duke-Margolis Center for Health Policy

**Speakers:**

- **Theresa Campo**, American Association of Nurse Practitioners
- **Penney Cowan**, World Patients Alliance
- **David Fiellin**, Yale School of Medicine
- **Erin Krebs**, Minneapolis Veterans Affairs Health Care System
- **Mary Lynn McPherson**, University of Maryland Center to Advance Chronic Pain Research

**4:55 pm      Closing Remarks**  
**Mark McClellan**, Duke-Margolis Center for Health Policy

**5:00 pm      Adjourn Day One**

## Agenda: Day Two

**1:00 pm**      **Welcome and Day 2 Overview**

**Mark McClellan**, Duke-Margolis Center for Health Policy

**1:10 pm**      **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.

Moderator: **Marianne Hamilton Lopez**, Duke-Margolis Center for Health Policy

**Speakers:**

- **Bobby Mukkamala**, American Medical Association
- **Elyse Powell**, North Carolina Department of Health and Human Services
- **Anuradha Rao-Patel**, North Carolina State Medical Board
- **Steve Singer**, Accreditation Council for Continuing Medical Education

**2:30 pm**      **Break**

**2:45 pm**      **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.

Moderator: **Mark McClellan**, Duke-Margolis Center for Health Policy

**Speakers:**

- **Stefan Kertesz**, University of Alabama Birmingham
- **Kate Nicholson**, National Pain Advocacy Center
- **Daniel Pace**, American Academy of PAs
- **Friedhelm Sandbrink**, Veterans Health Administration
- **David Tauben**, University of Washington (Professor Emeritus)

**4:00 pm**

**Closing Remarks**

**Mark McClellan**, Duke-Margolis Center for Health Policy

**4:05 pm**

**Adjourn**