

## Challenges and Opportunities for REMS Integration, Innovation, and Modernization

Tuesday, October 11, 2022 | 1:00 p.m. – 5:15 p.m.

### Agenda

**1:00 p.m. Welcome and Introduction**

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

**1:10 p.m. Opening Remarks from FDA**

FDA leadership will provide a high-level overview of REMS integration into healthcare workflows via digital tools and data infrastructure, as well as the meeting objectives.

*Marta Sokolowska, U.S. Food and Drug Administration*

**1:20 p.m. REMS Integration Project Overview**

FDA will review the timeline of work and progress to date on REMS integration.

*Edward Millikan, U.S. Food and Drug Administration*

*George Neyarapally, U.S. Food and Drug Administration*

**1:30 p.m. REMS Integration Prototype Demonstration**

In a recorded demonstration, the MITRE team will introduce the functionality of the REMS integration prototype, explaining how and when the prototype would be used by providers, pharmacists, patients, and other stakeholders.

*Lauren DiCristofaro, MITRE*

*Sahil Malhotra, MITRE*

*Nicole Ng, MITRE*

**2:00 p.m. Prescriber Perspectives**

Providers who regularly prescribe drugs with associated REMS requirements will discuss challenges and opportunities related to potential implementation of the REMS integration prototype for use during routine medical care.

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

*Lane Abernathy, Patient Advocate*

*Robert Cotes, American Psychiatric Association*

*Ilona Frieden, American Academy of Dermatology*

**2:45 p.m. BREAK**

**2:55 p.m. Pharmacy Perspectives**

Representatives from major pharmacies and pharmacy associations will discuss challenges and opportunities related to potential implementation of the REMS integration prototype in pharmacy settings.

*Moderator: Dure Kim, Duke-Margolis Center for Health Policy*

*Michelle Kershaw, CVS Pharmacy*

*Michele Kidd, Accredo Health Group*

*Jennifer Martin, U.S. Department of Veterans Affairs*

*John Simon, Patient Advocate*

**3:40 p.m. Health System Perspectives**

Representatives from major health systems will discuss considerations for potential implementation of the REMS integration prototype and potential impacts for their health system operations.

*Moderator: Rachele Hendricks-Sturup, Duke-Margolis Center for Health Policy*

*Laurie Adami, Patient Advocate*

*A.J. Burnett, Intermountain Health*

*Ann McGee, Duke University Hospital Center for Medication Policy*

*Diana Schreier, Mayo Clinic Department of Pharmacy*

**4:25 p.m. Implementation Considerations & Next Steps**

Building on feedback from the previous sessions, panelists will discuss features and functionalities that should be built in to the REMS integration prototype to ensure it is effective and easy to use for all stakeholders involved. Panelists will also consider broader implications the prototype might have for REMS, such as how centralized data collection as a result of integration could be used to move toward a “learning REMS” system with the ability to adapt to provider and patient needs.

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

*Danielle Boyce, Patient Advocate*

*Cathy Graeff, National Association of Chain Drug Stores*

*Jason Leedy, Examoto*

*Sean Mackey, Stanford Health Care*

**5:10 p.m. Closing Remarks**

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

**5:15 p.m. Adjourn**