Welcome and Introduction

Mark McClellan, Duke-Margolis Center for Health Policy

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

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

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

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

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-Sturrup, 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 into 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