

Margolis-FDA Workshop: Challenges and Opportunities for REMS Integration, Innovation, and Modernization

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

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.

Patrizia Cavazzoni, 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.

FDA Speaker(s)

1:40 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.

MITRE Speaker(s)

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.

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.

3:40 p.m. Health System Perspectives

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

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.

5:10 p.m. Closing Remarks

Mark McClellan, Duke-Margolis Center for Health Policy

5:15 p.m. Adjourn

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