

Building a Common Risk Evaluation and Mitigation Strategies (REMS) Platform

Hotel Monaco • Washington, DC

June 7, 2016

8:00 a.m. **Registration**

8:30 a.m. **Welcome and Introductions**
Mark McClellan, Duke-Margolis Center for Health Policy
Gregory Daniel, Duke-Margolis Center for Health Policy

8:45 a.m. **Introduction to the REMS Integration Initiative**
Presentation: **Theresa Toigo**, U.S. Food and Drug Administration

9:00 a.m. **Overview of the Common REMS Platform**
Presentation: **Adam Kroetsch**, U.S. Food and Drug Administration

9:45 a.m. **Fostering Innovation under a Common REMS Platform**
Objective: Discuss potential innovative tools and health information technology (health IT) systems that could be developed under a common REMS platform as envisioned, and identify strategies that can help to facilitate their development.

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

Panelists:

- **Shelly Spiro**, Pharmacy Health Information Technology Collaborative
- **Marie Link**, REMS Logic
- **Roger Pinsonneault**, Gemini Health
- **Paul Sheehan**, Celgene Corporation
- **Annette Stemhagen**, United BioSource Corporation
- **Katie Stabi**, University of Chicago Medicine

10:45 a.m. **Break**

11:00 a.m. **Leveraging Existing Data Standards and Partnerships to Facilitate the Development and Implementation of the Common REMS Platform**
Objective: Discuss the existing data standards that may be leveraged to develop REMS tools and relevant health IT systems, and identify any gaps or barriers that may need to be addressed to facilitate the development of common REMS data standards.

Moderator: **Gregory Daniel**, Duke-Margolis Center for Health Policy

Presentation: **Michele Davidson**, Walgreens

Panelists:

- **Gerald McEvoy**, American Society of Health-System Pharmacists

- **Scott Robertson**, Kaiser Permanente
- **Marc Overhage**, Cerner Corporation
- **Kelly Wygal**, McKesson
- **Andrew Gettinger**, U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology

12:00 p.m. **Closing Remarks**
Mark McClellan, Duke-Margolis Center for Health Policy

12:15 p.m. **Adjournment**