



Tufts Health Care Institute Program on Opioid Risk Management
*Risk Evaluation and Mitigation Strategy for Prescription Opioids:
An In-Depth Review of Fundamental Issues*

The Colonnade Hotel * 120 Huntington Avenue * Boston, Mass.

Objectives:

- Understand the potential value and limitations of REMS in addressing prescription opioid abuse, misuse and diversion.
- Review and critique of current REMS programs.
- Establish principles for effective training of prescribers and pharmacists in the REMS context.
- Establish best practices in training patients on using prescription opioids safely in REMS context.
- Understand the technical considerations of potential REMS systems for opioid distribution.
- Understand how to evaluate programs to determine if they are effective and if they have unintended consequences.

Agenda:

Time	DAY 1: Thursday, July 23, 2009 Boston Ballroom- 2 nd Floor	Speaker
8:00 a.m.	Introduction	Nathaniel Katz, MD, MS Program Director
8:15 a.m.	Opening Remarks	Michael Klein, PhD Director, Controlled Substance Staff Food and Drug Administration
9:00 a.m.	How Industry Uses Root Causes Analysis to Manage Risk and Linkage to REMS Intervention	John Carroll, PhD Professor of Behavior & Policy Studies MIT Sloan School of Management
9:45 a.m.	What is the Public Health Rationale for Prescription Opioid REMS to Addressing Public Health Concerns	John Brownstein, PhD Assistant Professor Children's Hospital, Boston Harvard Medical School Harvard-MIT Division of Health Sciences and Technology

10:30 a.m.	Break	
10:45 a.m.	The REMS Experience: Update and Review	Edgar Adams, ScD Executive Director, Epidemiology Covance
11:15 a.m.	Practitioner Education: What are the Core Elements of Safe Opioid Prescribing?	Lynn Webster, MD Medical Director Lifetree Clinical Research and Pain Clinic
12 noon	Lunch Braemore/Kenmore Room (Lobby)	
1:00 p.m.	Practitioner Education: What Forms of Training and Feedback will Change Practitioner Behavior? Boston Ballroom	Thomas Kosten, MD JH Waggoner Chair and Professor of Psychiatry and Neuroscience Baylor College of Medicine
1:45 p.m.	Patient Education: What Do We Want Patients Do with their Opioids?	Seddon Savage, MS, MD Director, Dartmouth Center on Addiction, Recovery and Education Pain Consultation, Manchester VA Medical Center
2:15 p.m.	Patient Education: What Methods do Practitioners Use to Train Patients to Respect Opioids?	Will Rowe Chief Executive Officer American Pain Foundation
3:00 p.m.	Break	
3:30 p.m.	Unintended Consequences: Potential Patient Barriers to Accessing Prescription Opioids Because of REMS	Richard Payne, MD, PhD Professor of Medicine and Divinity Duke Institute on Care at the End of Life
4:15 p.m.	Discussion	
4:45 p.m.	Wrap up of Day 1	Nathaniel Katz, MD, MS
5:00 p.m.	Briefing Session for Day 2 Breakout Leaders Board Room—5th floor	Nathaniel Katz, MD, MS George Kenna, PhD, RPh
6 – 8 p.m.	Wine and cheese reception Huntington Three— Lobby	

Time	DAY 2: Friday, July 24, 2009 Boston Ballroom-2 nd Floor	Speaker
8:00 a.m.	Introduction to Day 2	Nathaniel Katz, MD, MS
8:15 a.m.	Retail Pharmacy REMS for Opioids; Challenges and Solutions	Roger Pinsonneault, RPh Senior Director, Product Management RelayHealth
8:45 a.m.	Distribution of Controlled Substances in the US: A Primer	Anita Ducca, MS Healthcare Distribution Management Association Senior, Director, Regulatory Affairs and Healthcare Policy
9:15 a.m.	How Do We Evaluate the Effectiveness of REMS: Core Requirements	Nabarun Dasgupta, MPH Department of Epidemiology School of Public Health University of North Carolina
9:45 a.m.	Break	
10:15 a.m.	Breakout Groups on the responsibilities, objectives and basic principles of implementing a REMS program:	
Group 1	Colonnade East-5th floor Practitioners <ul style="list-style-type: none"> • What desired practitioner behaviors do we want? • What is safe-opioid prescribing behavior? • What are the key elements of safe practice? • Develop a checklist that physicians can use on a systematic basis with patients. 	Lynn Webster and Nathaniel Katz
Group 2	Colonnade East-5th floor Patients: <ul style="list-style-type: none"> • What are the patient behaviors that we want to decrease abuse? • What do we want patients to do? • How do we know if they are following suggestions? • Develop a checklist that patients can receive and implement to reduce abuse, accidental ingestion, or access. 	Seddon Savage and Will Rowe

12:30 p.m.	Lunch Boston Ballroom-2 nd Floor	
1:30 p.m.	Reports from the Breakout Groups	
2:30 p.m.	Wrap-up and Adjourn	Nathaniel Katz, MD, MS
2:45 p.m.	Authors' Meeting	Huntington 3