Center for Health Policy at BROOKINGS

Incorporating Continuing Education into Single-Drug REMS: Exploring the Challenges and Opportunities

The Brookings Institution • Washington, DC
May 18, 2015

8:30 a.m. **Registration**

9:00 a.m. **Welcome, Overview, and Meeting Objectives**
Mark McClellan, Senior Fellow and Director, Health Care Innovation and Value Initiative, The Brookings Institution

9:10 a.m. **Incorporating Continuing Education into REMS**
Claudia Manzo, Director, Office of Medication Error Prevention and Risk Management, U.S. Food and Drug Administration

9:25 a.m. **Lessons from the ER/LA Opioid REMS Development Process**

- Terry Toigo, Associate Director of Drug Safety Operations, Office of the Center Director, U.S. Food and Drug Administration
- Linda Kitlinski, REMS Education Consultant, Retired Co-Chair of RPC CE Sub-team
- Kate Regnier, Executive Vice President, Accreditation Council for Continuing Medical Education

10:00 a.m. **Session I: Defining the Critical Elements that are Essential for CE as part of a REMS**
Mark McClellan, *Moderator*

Panelists:

- Rachel Sobel, Senior Director, Epidemiology, Pfizer
- Kathy Chappell, Vice President, Accreditation Program and Institute for Credentialing Research, American Nurses Credentialing Center
- Maureen Cahill, Associate, Nursing Regulation, National Council of State Boards of Nursing
- Anne Grupe, Director, Continuing Medical Education, American Society of Clinical Oncology
- Julie Webb, Vice President, Office of Professional Development, American Society of Health-System Pharmacists

11:00 a.m. **Break**

11:15 a.m. **Session II: CE Programs for Single Drug REMS: Developing Valid and High-Impact Content**
Mark McClellan, *Moderator*

Panelists:

- Gary Appio, Head, US Risk Safety Management, Novartis Pharmaceutical Corp.
- Kishore Gopu, Director, REMS Operations, Teva

- Julie White, Director, The Barry M. Manuel Office of Continuing Medical Education, Boston University School of Medicine
- Eric Peterson, Senior Director, Performance Improvement CME, American Academy of Physician Assistants
- Peter Vlasses, Executive Director, Accreditation Council for Pharmacy Education

12:30 p.m. **Lunch**

1:30 p.m. **Session III: CE Programs for Single Drug REMS: Best-Practices for Implementation and Uptake**
Mark McClellan, *Moderator*

Panelists:
- Paul Coplan, Executive Director, Risk Management and Epidemiology, Purdue Pharmaceuticals
- Eric Davis, Director of Medical Services, Mylan
- Ann Karty, Medical Director, Continuing Education, American Academy of Family Physicians
- Cyndi Grimes, Director, Continuing Medical Education, Medscape
- Simone Karp, Chief Business Officer, CECity

2:45 p.m. **Break**

3:00 p.m. **Session IV: Identifying Other Key Facilitators and Barriers to REMS CE Development and Uptake**
Mark McClellan, *Moderator*

3:30 p.m. **Session V: Major Takeaways and Next Steps**

4:00 p.m. **Closing Remarks**
Mark McClellan

4:15 p.m. **Adjournment**

Convened by the Center for Health Policy at Brookings and supported by a cooperative agreement with the U.S. Food and Drug Administration.