Strategies for Promoting the Safe Use and Appropriate Prescribing of Prescription Opioids

Meeting Objective: The objective of this public workshop is to examine strategies being utilized by policymakers, healthcare providers, health systems, payers, and pharmacy benefit managers to ensure that opioids are safely and appropriately prescribed. These approaches may include prescribing guidelines, Prescription Drug Monitoring Programs (PDMPs), provider screening and risk-assessment tools, and health system and payer strategies to manage opioid access and improve patient care.

Through this effort, and under a cooperative agreement with the FDA, the Duke-Margolis Center will:

1) Examine the landscape of health system and payer strategies to promote the safe and appropriate prescribing of opioids.
2) Discuss how health systems and payers are using data and health IT tools to support safe prescribing strategies.
3) Discuss how health system strategies were implemented, barriers to their adoption, and potential unintended consequences of adoption.
4) Discuss how to build an evidence base to support existing health system and payer interventions as well as how success may be defined and measured.

9:00 a.m. Welcome, Overview, and Meeting Objectives
Speaker: Mark McClellan, Duke-Margolis Center for Health Policy

9:15 a.m. Opening Remarks
Speaker: Scott Gottlieb, U.S. Food and Drug Administration

9:30 a.m. Targeting Key Outcomes for Measuring the Impact of Interventions
Speaker: Judy Staffa, U.S. Food and Drug Administration

9:45 a.m. Session I: Establishing Guidelines and Defining Success for Safe and Appropriate Opioid Prescribing
Moderator: Larry Greenblatt, Duke University School of Medicine

Objective: Building on the development of the CDC Guideline for Prescribing Opioids for Chronic Pain in 2016, many states, health systems, and payers have adopted prescribing limits on selection, dosage, and duration of prescription opioids, as well as other recommendations to reduce opioid medication-related risks. This session will provide an overview of the CDC guidelines, examine how these recommendations are being implemented or adapted within various systems, how prescribing guidelines are affecting prescriber behavior, and what additional data may be needed to evaluate the impact on patient outcomes.
Panel Remarks
- John Halpin, Centers for Disease Control and Prevention
- Gary Franklin, University of Washington
- Erin Krebs, University of Minnesota
- Lewis Nelson, Rutgers New Jersey Medical School
- Myra Christopher, PAINS Project

Moderated Discussion

Questions to Address:

a. How are CDC or other prescribing guidelines being implemented by policymakers, health systems, and payers?

b. How are prescribing guidelines affecting provider behavior? How is their impact on patient health and safety being measured?

c. How do we define “success” for implementing safe prescribing guidelines?

d. What are barriers or unintended consequences of adoption?

e. How can guidelines continue to be refined and improved?

11:00 a.m. Break

11:15 a.m. Session II: Improving Provider Decision-Making Tools to Support Safe and Appropriate Prescribing

Moderator: Regina LaBelle, Duke-Margolis Center for Health Policy

Objective: Health system tools incorporating PDMP data, screening and risk-assessment tools, and patient electronic health records are increasingly being used to support provider decision-making by identifying and monitoring patients who may be at risk of adverse consequences. These tools may support improved clinical care by providing real-time information to providers on concurrent prescriptions, opioid utilization, and patient risk factors. This session will examine how these tools are being used to support clinical decision-making, how they are being implemented within provider workflows, and additional data that may be needed to assess their impact on patient care.

Panel Remarks
- Kelly Clark, American Society of Addiction Medicine
- Jaya Tripathi, MITRE
- Jim Huizenga, Appriss Health
- Peter Kreiner, Brandeis University

Questions to Address:

a. What tools are currently being used to assist in clinical decision-making? Have these tools been validated? What are their strengths and weaknesses?

b. How can these tools be better leveraged or integrated to improve clinical care and reduce risks related to aberrant drug behavior, opioid use disorders, and accidental overdose?
c. What are barriers to further adoption or integration?
d. What additional data may be needed to assess the efficacy or impact on patient outcomes?

Moderated Discussion

12:30 p.m. Lunch

1:30 p.m. Session III: Provider and Health System Approaches to Manage Opioid Access and Improve Patient Safety
Moderator: Mark McClellan, Duke-Margolis Center for Health Policy

Objective: Building on the tools and interventions discussed in the first two sessions, this session will examine innovative healthcare delivery system approaches to manage opioid access and improve patient safety. Strategies utilized by health systems as part of a multifaceted approach may include provider education, prescribing and dispensing limits, monitoring processes, risk-assessment tools, and interventions to change provider or patient behavior. Participants will examine strategies and tools being utilized by commercial and public systems, how these efforts are part of a comprehensive approach to the opioid epidemic, and future data needs to assess the impact of these initiatives on patient outcomes.

Panel Remarks
- Thomas Emmendorfer, U.S. Department of Veterans Affairs
- Michael Kanter, Southern California Permanente Medical Group
- Jessica Kattan, New York City Department of Health and Mental Hygiene
- M. Kit Delgado, University of Pennsylvania

Moderated Discussion

Questions to Address:
a. What strategies or tools are being used by health systems to manage opioid access, improve patient safety?
b. How are health systems identifying risky prescribing or patients at-risk of adverse events? Have these strategies been validated?
c. What intervention strategies are being used to reduce these risks and improve patient care?
d. What are emerging best practices or lessons learned from these experiences?

2:45 p.m. Break

3:00 p.m. Session IV: Payer and PBM Approaches to Manage Opioid Access and Improve Patient Safety
Moderator: Gregory Daniel, Duke-Margolis Center for Health Policy
Objective: This session will examine innovative payer and PBM approaches that combine multiple strategies to help manage opioid access and improve patient safety. Strategies utilized by payers as part of a comprehensive approach may include may include drug utilization reviews, formulary controls, patient or provider outreach efforts, and patient review and restriction programs. Participants will examine strategies and tools being utilized by commercial and public systems, how these efforts are part of a comprehensive approach to the opioid epidemic, and future data needs to assess the impact of these initiatives on patient outcomes.

Panel Remarks
- Dick Creager, CVS Health
- Ellie Garrett, Minnesota Department of Human Services
- Anuradha Rao-Patel, BlueCross BlueShield North Carolina
- Kate Berry, America’s Health Insurance Plans

Moderated Discussion

Questions to Address:

a. What strategies or tools are being used by payers and PBMs to manage opioid access and improve patient safety?

b. How are payers and PBMs identifying risky prescribing or patients at-risk of adverse events? Have these strategies been validated?

c. What intervention strategies are being used to reduce these risks and improve patient care?

d. What are emerging best practices or lessons learned from these experiences?

e. What additional data may be needed to assess the efficacy or impact on patient outcomes?

4:15 p.m. Closing Remarks
Mark McClellan, Duke-Margolis Center for Health Policy

4:30 p.m. Adjournment

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