

# **Responding to Signals of Prescription Opioid Abuse and Diversion**

## **Stakeholder Perspectives on Information Sharing**

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**Grant M. Carrow, Ph.D.**

**Massachusetts Department of Public Health  
Center for Quality Assurance and Control**

# Department of Public Health

## Mission Statement

- We believe in the power of prevention.
- We work to help all people reach their full potential for health.
- We ensure that the people of the Commonwealth receive quality health care and live in a safe and healthy environment.
- We build partnerships to maximize access to affordable, high quality health care.
- We are especially dedicated to the health concerns of those most in need.
- We empower our communities to help themselves.
- We protect, preserve, and improve the health of all the Commonwealth's residents.

# Drug Control Program Mission

- Ensure pharmaceuticals available for medical use

- Prevent drug diversion, prescription fraud, illicit use and abuse



# FDA Guidance on Stakeholder Input

- When planning risk assessment and risk minimization activities, sponsors should consider input from healthcare participants likely to be affected by these activities (e.g., from consumers, pharmacists and pharmacies, physicians, nurses, and third-party payers).

# FDA Guidance on RiskMAP Tools

- 1. Targeted education and outreach**
  - communicate risks and appropriate safety behaviors to healthcare practitioners or patients
- 2. Reminder systems**
  - foster reduced-risk prescribing, dispensing and use
- 3. Performance linked access systems**
  - guide prescribing, dispensing, and use of the product to target the population and conditions of use most likely to confer benefits and to minimize particular risks

# FDA Guidance on RiskMAP Tool Development

- Identify the key stakeholders who have the capacity to minimize the product's risks (such as physicians, pharmacists, pharmacies, nurses, patients, and third-party payers) and define the anticipated role of each group.
- Consider, and seek to avoid, unintended consequences of tool implementation that obstruct risk minimization and product benefit, such as obstructing patient access or driving patients to seek alternative product sources (e.g., Internet sales, counterfeit products) or less appropriate products.

Source: FDA Guidance for Industry: Development and Use of Risk Minimization Action Plans, 2005.

# FDA Guidance on RiskMAP Tool Development

- Since tool performance will often depend upon the understanding, cooperation, efforts, and resources of healthcare providers, pharmacists, and patients, evaluation of acceptability and unintended consequences for individual tools may help to improve the use of tools and thus their performance.

# Information Sharing Work Group

- Identify underlying issues that should guide policy on exchange of information between pharmaceutical companies and law enforcement, professional boards of registration and public health.



# Information Sharing Work Group

- Who? Information sources and targets
- What? Signal types
- When? Signal prioritization and triage
- How? Modes of information sharing

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