Promising Legal Responses to the Epidemic of Prescription Drug Overdoses in the United States

December 2-3, 2008
Goals and Objectives

Create a list of promising legal measures to prevent prescription drug overdoses that can be shared with a broader audience after the conference.

Discuss the strengths and weaknesses of each of the promising practices identified.

Identify opportunities for collaboration between public health, drug control authorities, and other partners with an interest in prescription drug overdose prevention.
Participants

- Local, state, and federal representatives
- Public Health
- Prescription Drug Monitoring Programs and Other Regulators
- Law Enforcement
- Judiciary
The “Promising Strategies”

- Prescription Drug Monitoring Programs [PMPs]
  - Overview
  - Interstate Data Sharing [Operational and Legal Issues]
  - “Doctor Shopping” Statutes
Non-PMP Strategies

- State-Issued Prescription Forms
- Maine Unused Drug Disposal Project
- Louisiana Pain Management Clinic Legislation
- Drug Courts
- Washington Prescribing Guidelines and Subsequent Litigation
PMP Overview

• Controlled Substance Schedules
  • Schedule I substances have no recognized use in medical treatment
  • Schedules II-V have legitimate medical uses. Schedule II substances have the highest potential for abuse and Schedule V substances have the lowest potential.
California PMP Implemented in 1940

- Triplicate prescription program: The state issued blanks to practitioners to write prescriptions for what are now schedule II drugs.

- Law enforcement used the data to target patients, prescribers, or pharmacies that obtained, prescribed, or dispensed drugs substances in unusual quantities or unusual frequencies.
1943 - 1988

Several states implemented PMPs
Electronic Transmission of Data

- Billing data routinely moved via computer from pharmacies to insurance companies by the early 90s
- Oklahoma developed and implemented the first electronic PMP
- Cost effectiveness provided incentive for PMPs to convert and to expand the controlled substances that they tracked.
38 States Now Have PMPs

Harold Rogers grants have provided an incentive
All collect prescription data electronically and most require submission of schedules II-IV data
Funding/staffing level and stage of operational development vary widely
Substantial Uniformity in Terms of Data Collected

Operational PMPs all collect the basic elements of a prescription:

- prescription number
- patient identity
- date dispensed
- drug and quantity dispensed
- prescriber and dispenser identity.
Interstate PMP Data Sharing

The Problem

There is nothing to prevent a patient from filling a prescription in another state, and it may be easily accomplished in a city or state just across the border.
Potential Solution

Pharmacists “sign up” with other PMPs, but that is inefficient

Better approach: development of a “hub and spoke” system

- Could facilitate efficient transmission of PMP data among all states
- Obviates need for 49 separate exchange agreements [Note: CA/NV agreement]
- ...but only Kentucky and Ohio have committed resources
Legal Issues

Federal and state confidentiality and privacy laws and regulations must be assessed.
HIPAA Privacy Rule

- Shields “protected health information” held by “covered entities” such as physicians and pharmacists
- Potentially relevant exceptions/exemptions
  - fraud and abuse prevention
  - controlled substance regulation
  - public health activities
  - law enforcement
  - treatment purposes
  - disclosures required by law (e.g. child abuse)
State Privacy/Confidentiality Laws

- PMPs typically are required to:
  - Designate data as confidential and exempt the data from public records or open records laws.
  - Delineate persons allowed access, under what circumstances, and lawful purposes for which accessed data may be used.
  - Comply with all relevant state and federal privacy and confidentiality laws

**“Hub” system involves additional complexities**
Interstate Data Sharing Laws

Some states have express authority

Kentucky: PMP may provide data to a “certified or full-time peace officer of another state”

Legal counsel should be consulted regarding authority to share date with other states
“Doctor Shopping”

Obtaining, or attempting to obtain (and failing to disclose), the same or similar prescriptions from multiple prescribers within an inappropriate time frame
“Doctor Shopping” Statutes

- Controlled substances acts generally make it unlawful to obtain, or attempt to obtain, a controlled substance by deceit or fraud.
- Laws in 13 states have been amended to more particularly describe and prohibit doctor shopping.
- Regardless of the historical motivation for passage of these laws, consideration should be given to using them to identify persons in need of assessment and referral for treatment.
Florida Law

No person may “withhold from a practitioner from whom the person seeks to obtain a controlled substance or a prescription for a controlled substance that the person making the request has received a controlled substance or a prescription for a controlled substance of like therapeutic use from another practitioner within the previous 30 days....”
Non-PMP Strategies

State-Issued Prescription Forms

- “Traditional” multiple copy programs no longer exist

- New York, California, and Texas supplement electronic transmission with paper, serialized prescription forms
California

- Triplicate prescriptions form 1940-1988
- Electronic transmission of Schedule II data in 1988
- Transitioned in 2004 from triplicate to tamper-resistant forms from state-approved security printers
Texas

Schedule II triplicate form from 1982-1999
Electronic transmission added in 1999
Expanded to Schedules III and IV in 2008
Triplicate or secure single-serialized form (authorized in 2002) must still be used for Schedule II
New York

- Historical use of triplicate form
- Expanded through 70s and 80s to cover lower scheduled drugs
- Electronic transmission implemented in 2006, accompanied by use of a secure single-serialized form
Advocates of paper-based systems maintain that paper trails have a significant influence in reducing the availability of prescription drugs subject to abuse.

Opponents counter that they have a deleterious effect on patient access to needed medications.
Evaluation

- A few limited studies suggesting reduction in use
- No published peer-reviewed papers evaluating the process measures of paper prescription monitoring programs
Conclusion

Future research to evaluate the impact on medical use and access, abuse and diversion, and clinical and economic outcomes is imperative.

Outcome measures are needed to fully evaluate the impact on patients along with drug abuse and diversion.
Maine Unused Drug Disposal Project

- Unused medications are a source of diversion to drug abusers
- Conservative estimate: 4.3 million pounds of annual “wastage” (obviously an environmental issue as well)
- DEA regulations prohibit non-registrant transfers
- Pharmacy-based systems not feasible
Getting It Implemented

A committed Senate sponsor and buy-in by a variety of interested groups were essential to passage of the legislation authorizing the “Maine Mailback Program”

Eventually funded with EPA grant and state dollars
Operational Elements

- Prepaid mailers available at pharmacies
- Unused drugs mailed directly to Maine DEA
- Postal service granted a waiver after lengthy negotiations
- Movement of mailers is coded for tracking from pharmacy to user to MDEA
- Meds destroyed by MDEA
4-County/11-Site Pilot

- Uncertainty as to adequacy of data
- No comparable data from other states for verification of findings
“Findings”

- Envelope contained more than $7,000 worth of oxycodone
- Average participant age is 70
- 15% didn’t know drug type
- Environmental motivation: 83%
- Safety motivation: 8%
“More Needs to be Done”

- Recommend state offices for adherence and compliance
- NASMHPD has not initiated any action
- NIH is edging around to funding academically-based units
- EPA has funded some additional research
Louisiana Pain Management Clinic Legislation

- Calcasieu Parish DWI citations increased 58% from 2004-2006
- Impaired driving increasingly cause by abuse of prescription drugs
- More impairment now from prescription drugs than alcohol
- 50-100 deaths/year in 2006-07 (25-50/100,000 persons)
Pain Management Clinic Licensure Act (eff. 7/1/05)

- Regulates facilities primarily engaged in treating pain with prescription drugs
- Physician must own and operate the clinic
- Suggestions for improvement
  - Tighten exceptions for “urgent care facilities” and “other treatment modalities”
  - Authorize agencies to inspect and investigate
Pain Management Clinic Drug Abuse and Overdose Prevention Act (eff. 8/15/07)

Unlawful for any physician or other licensed health care practitioner to assist anyone in obtaining controlled substances through misrepresentation, fraud, etc.

Violation of the statute carries a penalty of up to five years imprisonment and a fine of not more than $50,000
Good News

Coroner estimates that the parish could experience a 50% reduction in 2008 deaths from the prior years’ figures.
Across the Border

- Pain management clinic activity along the I-10 corridor in southeastern Texas
- Prescription drug overdose deaths increased in Jefferson County from 5 in 2005 to 55 in 2006
- Pain management clinic legislation is contemplated as a result of cross-border task force work
Drug Courts

Judicially-supervised dockets that strike a balance between the:

- Need to protect community safety and the need to improve public health
- Need for treatment and the need to hold people accountable for their action

An alternative to the “traditional” correctional system’s “revolving door”
Background

- Miami created the first drug court in 1989
- 2200 courts operate today in all states and territories, serving 120,000 adults and juveniles annually
- Still, only the “tip of the iceberg”
Targeting Non-Violent Offenders

Some alternative approaches

- Diversion (charges are held until program completion, and upon successful completion, they are dismissed)
- Probation (participant pleads guilty and is placed on probation with the successful completion of Drug Court as a special condition of probation)
- Probation revocation (participant on probation and in violation for reasons caused by drug addiction continues on probation and is placed in Drug Court)
“Drug Courts Work”

Crime reduction: 2005 GAO report and subsequent studies

Cost savings:
- Cost-benefit studies: $10K vs. $36K
- Urban Institute estimate: $3.36/$1 cost-benefit ratio

Eastern Kentucky Drug Court Judge reports positive prescription drug abuser results
Washington Prescribing Guidelines

State agency medical directors developed interagency opioid dosing guidelines for chronic non-cancer pain [published in March 2007]

Recommendations in two parts
Recommendations – Part 1

Recommendations regarding 3 aspects of clinical practice

- Initiating/transitioning from acute to chronic pain care
- Assessing/monitoring ongoing opioid treatment
- Weaning from opioid if trial fails to improve function/reduce pain
Recommendations – Part 2

Referral to a pain management specialist for evaluation should occur when primary care provider is treating a patient whose morphine equivalent dose (MED) exceeds 120mg/day.
Legal Challenge

- Class action lawsuit file in federal court
- Early procedural stage
- Numerous counts alleged
“Hindsight” Suggestions

- Evaluate legal authority
- Develop interagency plan
- Consult with external stakeholders
Washington’s Next Steps?

Department of Health recently created the Prescription Opiate Morbidity and Mortality Prevention Workgroup