Drug Diversion: Distractions, Dilemmas, Decisions, and Duties

DEA
Pharmacy Diversion Awareness Conference
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Maryland Board of Pharmacy
Commissioner and Secretary
Objectives

To understand Maryland Board of Pharmacy Composition and Committees
To discuss compliance/disciplinary actions available to the Board.
To describe relevant cases of drug diversion that have required Board action.
To review options for avoidance/correction of drug diversion.
QUIZ: Drug Diversion Is

1. An epidemic
2. An assault on public safety
3. A war on legitimate prescription needs
4. A threat at all levels of healthcare
5. Not limited to opioids
6. All the above
Diversion:
When A Good Drug Goes Bad
Drug diversion can be defined as the diverting of legal drugs for illicit purposes. It involves the diversion of drugs from legal and medically necessary uses toward uses that are illegal and typically not medically authorized or necessary.

*Adapted from CMS statement, 2012*
Diversion

- From legitimate use to personal need
- From legitimate use to allow illegal distribution
- Robbery
- Theft
- Burglary
- Creative accountability
- “Family and Friend Discount”
Murphy’s Law
Drug Diversion Variant

- If it can happen it will;
- If it has not happened yet, it will;
- If it has not happened yet, are you sure?;
- If it cannot happen here, perhaps rethink that concept; and
- If it has happened, it may well happen again.
Maryland Board of Pharmacy

Mission Statement

“To protect Maryland consumers and to promote quality healthcare in the field of pharmacy through licensing pharmacists and registering pharmacy technicians, issuing permits to pharmacies and distributors, setting pharmacy practice standards and through developing and enforcing regulations and legislation, resolving complaints, and educating the public.”
Board of Pharmacy

Vision Statement

“Setting a standard for pharmaceutical services, which ensure safety and quality health care for the citizens of Maryland.”
Board Staff

- Executive Director
- Deputy Director(s)
- Units
  - Operations
  - Compliance
  - Regulatory/Legislative
  - Licensing
  - MIS/Data Integrity
  - Public Information
Board Commissioners

Twelve commissioners
- 10 are practicing pharmacists
- 2 are public/consumer representatives

Pharmacists
- 2 Community Practice
- 2 Chain Drug Store
- 2 Acute Care
- 2 At Large
- 1 Home Infusion
- 1 Long Term Care
Board Committees

- Disciplinary/Compliance
- Licensing
- Practice
- Public Relations
- Legislative/Regulatory
- Management Information Systems
- Others Ad Hoc
Pharmacists: 10,909
Vaccinating Pharmacists: 4,166
Pharmacy Technicians: 9,195
Pharmacy Interns: 615
Pharmacies: 2,089
Distributors: 1,066
Compliance Officer Statistics
Month of February 2016

- New Complaints: 38
- Complaints Resolved: 21
- Final disciplinary actions taken: 2
- Reversals: 0
- Summary Actions Taken: 2
Board Disciplinary Actions

- Public
- Non-Public
- Initiated by complaint or findings by Board or Drug Control inspections
- Initial Board action at Disciplinary Committee
- Case Resolution Conference may be initiated
- Full Board reviews and validates all actions
Case Resolution Conference (CRC)

- Pre-charge CRC
- Charge CRC
- CRC
  - 2 Board Commissioners
  - Board Counsel
  - Board Compliance Officer
  - Respondent
  - Defense counsel as needed

Consent Order determined

Full Board reviews all Orders
Board Disciplinary Actions
Non-Public

- Letter of Education
- Letter of Admonishment
- Relevant Continuing Education Credits may be attached
  - Separate from those required for renewal
- Disciplinary Committee
- CRC
Board Disciplinary Action Public

- Summary Suspension
- Suspension
- Revocation
- Fine
- Probation
- Show Cause Hearing
- Full Evidentiary Hearing
Examples of Disciplinary Actions

Practitioner/Licensee
Information Protected
Pharmacist - 1

- Diversion for own use
- Fraudulent prescriptions for personal needs
- Oxycodone, both sustained- and immediate-acting dosage forms
- Discovered during Division of Drug Control audit
- Terminated by employer
- Reviewed by Disciplinary Committee
- CRC requested
  - Demonstrated commitment to rehabilitation; no drug or alcohol use x 12 months
Action

- Suspension of license x 1 year
  - All but 6 months stayed
- Fine: $5,000
- Probation x 5 years
  - Cannot work alone
  - Cannot work more than 40 hours/week
  - Cannot “float”
  - Mandatory random drug screening weekly
  - Mandatory rehabilitation program
  - May appeal for modification after 2 years
Pharmacist - 2

- Fraudulent prescriptions filled for CDS
  - Oxycodone SR and IR
  - Hydrocodone with acetaminophen
- Apparent diversion for street re-sale by patients
- Initially presented by representative of pain management office in next-door practice, including affected patients
Pharmacist - 2

- Requests for prescriptions ongoing over 11 months
- Facility person presented new prescriptions and drivers’ licenses
- Pharmacist “validated” prescriptions with physician’s office
- Discovered during BOP and DDC inspections
Action

- Initial Summary Suspension implemented

- CRC Requested

Resolution

- Suspension maintained for 6 months, then stayed
- Probation x 3 years
- CE to identify fraudulent Rx
- Take and pass MPJE
- Fine: $5,000
Pharmacy Technician

Technician modified electronic “pill count” for hydrocodone 10mg/ APAP 650 mg & hydrocodone 5 mg/ 325 mg

1074 “lost” doses

Diverted the “deleted” count to friends who resold on the street

Received cash payment for diverted drugs

Terminated and legal action initiated
Action

Circuit Court
- Nolle prosed for 3 counts
- Technician pled guilty on 4th count

Board Action
- Revocation
- No appeal
Pharmacy

Fraudulent Prescriptions over 18 months
C-II through C-IV
– 30,000 units of oxycodone in various doses and dosage forms
– 24,000 dose of methadone
– 20,000 doses of alprazolam

Summary Suspension

Appealed to CRC
Action

- Suspension for 1 year
- $10,000 fine
- Probation after suspension for 3 years
  - Assure all pharmacists are fully compliant with CDS prescribing and dispensing
  - Discontinue association with Methadone Clinic
  - Provide a Board Newsletter article about CDS risk awareness and avoidance.
Where Can We Go?
What to Do?

- Awareness of risk is an excellent defense against occurrence or recurrence.
  - Individual practitioner
  - System-related
  - Surprise!

- The best defense is an aggressive offense
  - Act before you have to react
  - If it happened before, it can happen again

- QA/QI Plan must address
It Is A Delicate Balance

Benefits:

– Meeting legitimate, defined patient needs such as chronic or acute pain control
– Provide needed access to medications

Risks:

– Diversion, addiction, overdose
– Legal and licensure action
What About Red Flags?

A Pharmacy Inspector Makes a Suggestion
Red Flag Warnings

- Cash Payments
  - No Insurance
  - Out of Network
- Pattern prescribing
  - Too many prescriptions for the same drugs, same quantities, from the same prescriber or practice;
- Prescribing combinations of frequently abused controlled substances
  - Pre-printed prescription;
- Scattered geography of patients;
- Shared addresses of patients on the same day;
Red Flags II

- Overall volume of CDS Rx
  - Pattern out of the ordinary;
- Quantity and strength of drugs prescribed;
  - High dose; large quantity
- Patients with the same diagnosis code from the same prescriber or practice;
- Prescriptions written by prescribers not consistent with area of specialty
  - Dermatologist as Director of Pain Management
  - Improper Methadone Clinic
Red Flags - III

Patient insisting on one specific brand; e.g., OxyContin®

- The generic just does not work;
- I really need the OA not the OP version;
- The only one that works is what I used to get; and
- I’d rather pay cash because insurance will not cover.

- Red Flag Information Based on DEA Final Orders, 2013
Always

- Know the patient or family member
- Contact the prescriber directly
- Obtain history and validating diagnosis
- Document all contacts
- Follow up fully on any incomplete information or calls
- Report, report!
- If in doubt, do not dispense
PDMP

Please Don’t Mess Up My Prescription?

Prescription Drug Monitoring Program!

- Provide real-time electronic access to patients’ CDS Rx history;
- Identify aberrant drug using behavior;
- Improve ability to identify possible substance use risk;
- Improve ability to safely and effectively manage patients’ clinical need for CDS; and
- Increase confidence in all levels of prescribing and dispensing decisions.

Based in part on Maryland Legislative Coalition statement 2015
Goals of PDMP

- Assist prescribing and dispensing professionals in identification and prevention of prescription drug abuse;
- Assist law enforcement and regulatory agencies in the identification and investigation of potential prescription drug diversion; and
- Promote a balanced use of prescription data that preserves the professional practice of healthcare providers and legitimate patient access to optimal pharmaceutical care.
CRISP

The Chesapeake Regional Information System for our Patients (CRISP) makes CDS prescription data collected by the PDMP available to healthcare providers.

The CRISP health information exchange (HIE) query portal is the authorized source for provider access to PDMP data.

CRISP provides user registration and technical support services for providers accessing medication history and other clinical information available using HIE.

Mandatory vs. Voluntary?
Thank you!

"Idiopathic from the Latin meaning we are idiots because he can’t figure out the cause."

Gregory House; House, MD

Are there any questions?