# DRUG DIVERSION: ENFORCEMENT TRENDS, INVESTIGATION, & PREVENTION

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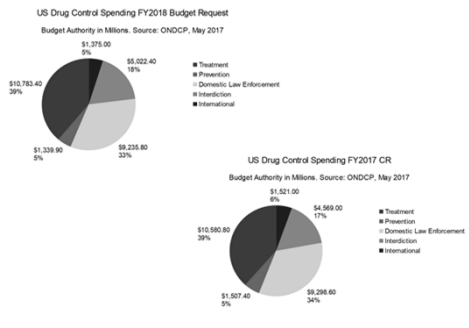
## Agenda

- Definitions, causes, and sources
- Regulations and enforcement trends
- Role of the Compliance Officer
- Investigating and preventing drug diversion
- Case study




*National Drug Control Budget: FY 2018 Funding Highlights" (Washington, DC: Executive Office of the President, Office of National Drug Control Policy), May 2017, Table 1, p. 16; Table 2, p. 18; and Table 3, p. 19.*

The estimated cost of controlled prescription drug diversion and abuse to Federal, State, and private medical insurers is approximately $72.65 billion a year.

"The President's FY 2018 Budget Request supports $27.8 billion for drug control efforts spanning prevention, treatment, interdiction, international operations, and law enforcement across 14 Executive Branch departments, the Federal Judiciary, and the District of Columbia. This represents an increase of $270.7 million (1.0 percent) over the annualized Continuing Resolution (CR) level in FY 2017 of $27.5 billion. Within this total, the Budget supports $1.3 billion in investments authorized by the Comprehensive Addiction and Recovery Act (CARA) the 21st Century Cures Act, and other opioid-specific programs to help address the opioid epidemic."

*"National Drug Control Budget: FY 2018 Funding Highlights" (Washington, DC: Executive Office of the President, Office of National Drug Control Policy), May 2017, p. 2.*

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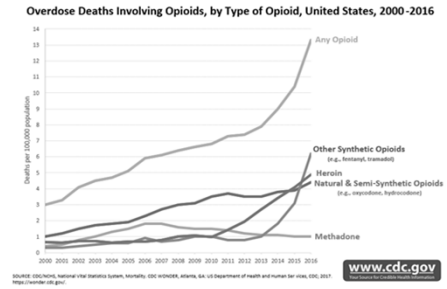



# Definition

Drug diversion is the illegal distribution or abuse of prescription drugs or their use for unintended or illicit purposes

- Often due to addiction or for financial gain
- Proliferation of pain clinics has led to an increase in the illegal distribution of expired or counterfeit medications
- High-value and Schedule II – V Controlled Substances frequently diverted:
  - Opioids
  - Performance enhancing drugs (e.g. erythropoietin, anabolic steroids)
  - Psychotropic drugs
  - Antiretroviral drugs

# The Controlled Substances Act of 1970

- **Schedule I -** drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse.
  - Example: heroin, lysergic acid diethylamide (LSD), ***marijuana (cannabis),*** 3,4-methylenedioxymethamphetamine (ecstasy), methaqualone, and peyote
- **Schedule II -** drugs, substances, or chemicals are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous.
  - Examples: Combination products with less than 15 milligrams of hydrocodone per dosage unit (Vicodin), cocaine, methamphetamine, methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone (OxyContin), fentanyl, Dexedrine, Adderall, and Ritalin
- **Schedule III -** drugs, substances, or chemicals are defined as drugs with a moderate to low potential for physical and psychological dependence. Schedule III drugs abuse potential is less than Schedule I and Schedule II drugs but more than Schedule IV.
  - Example: Products containing less than 90 milligrams of codeine per dosage unit (Tylenol with codeine), ketamine, anabolic steroids, testosterone
- **Schedule IV -** drugs, substances, or chemicals are defined as drugs with a low potential for abuse and low risk of dependence.
  - Example: Xanax, Soma, Darvon, Darvocet, Valium, Ativan, Talwin, Ambien, Tramadol
- **Schedule V -** drugs, substances, or chemicals are defined as drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics. Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes.
  - Example: cough preparations with less than 200 milligrams of codeine or per 100 milliliters (Robitussin AC), Lomotil, Motofen, Lyrica, Parepectolin

See 21 U.S.C. §802(32)(A) for the definition of a controlled substance analogue and 21 U.S.C. §813 for the schedule.

## Causes and sources

- Theft of sample medications
- Substituting or changing medications provided to patients
- Re-directing expired medications for use or distribution elsewhere
- Altering or falsifying medical record documentation
- 'Wasting' of medications
- Forged or counterfeit prescriptions
- Diverting large drug quantitates when they are purchased or during delivery and receipt
- From automated storage and dispensing systems* (ASDU or ADU)

## Drug diversion @ HealthCare facilities

- New and complex drug diversion schemes are fueling this epidemic of prescription drug abuse
- Until recently, it was believed that most diverted controlled substances came from doctor shoppers, prescription forgery rings, pharmacy thefts, pill mills, and rogue Internet pharmacies
- Drug diversion has been associated with virtually every category of healthcare worker – from professional clinical staff to EMTs, nurses, to facility staff
  - Theft of drugs by employees with access to bulk pharmacy supplies or computerized medication delivery cabinets
  - Addicted employees stealing controlled substances intended for patients for personal use by substituting non-controlled substances for the ordered medication
- Even if the quantity of drugs that are diverted is relatively small, the hospital's liability is significant

OIG Spotlight on Drug Diversion – https://oig.hhs.gov/newsroom/spotlight/2013/diversion.asp; DEA Diversion Control Website - https://www.deadiversion.usdoj.gov 8

## Impact on Patient Care

- Denying patients appropriate pain relief
- Exposure to blood borne pathogens
- Falsification of records (fraud)
- Theft
- Recognition of patient harm stemming from:
  - Diversion of scheduled (non prn) doses
  - Exauduration of pain scale at the time medication is diverted
  - Substitution and tampering
  - Transmission of infection
  - Impairment resulting in patient harm or reckless endangerment

# Impact on Institution

- Regulatory and civil liability
- Negative publicity
- Licensure and certification
- Participation in Federally sponsored programs (Medicare/Medicaid)
- Jeopardizing facilities' compliance with Medicare Conditions of Participation (CoP)
- Costs of remediation

# Human Costs

About 100 people die from drug overdoses daily, with opioids accounting for 75%

- Reliable statistics on the prevalence of drug diversion by nurses are not available
- By its nature, diversion is a clandestine activity, and methods in place in many institutions leave cases undiscovered or unreported
- Drug diversion by healthcare providers is universal among institutions in the US

If your institution is not finding and reporting drug diversion, review your program with the goal of identifying its weak points

# Regulations & Impact

Legal Framework

- **Controlled Substances Act**

*This law regulates the manufacture and distribution of many drugs, including controlled substances*

- ***Conditions of Participation***

To qualify for Medicare certification and reimbursement, providers, and suppliers of health services must comply with minimum health and safety standards called "Conditions of Participation" ("CoPs"), including proper securing and distribution of drugs.

- **JCAHO Requirements (or those related to Certifications of ACS, procedural suits, etc.)**

*JCAHO standards are the basis of an objective evaluation process that can help health care organizations measure, assess, and improve performance.*

- **Pharmacist licensure requirements**

*Each state board of pharmacy has a set of requirements that a pharmacist must meet.*

Impact

- Civil, criminal, and regulatory liability (FCA, certification status, CoPs)
- Impact on corporate liability rating and insurability (MedMal, D&O, etc.)
- Reputational harm (PR & Media attention)
- Impact on non-for-profit/ charitable status

# ANTICIPATION, DETERRENCE, AVOIDANCE

A few thoughts

## Why don't we hear about it more?

- Under-reporting
  - to appropriate oversight agencies
  - To licensing authorities
- Fear of negative publicity
- Concern of State and Federal agency involvement
- Uncertainty about reporting requirements
- Justification that terminating the offender is enough

## Profiling The Diverter

- Can be exemplary employees
- Someone you least expect
- Often first to volunteer to pick up extra shifts

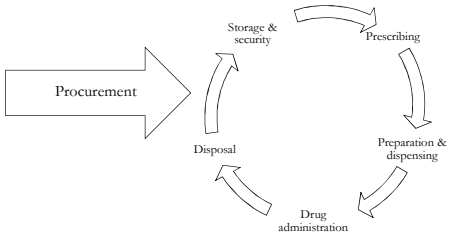
*Things to watch for:*

- Increasing absenteeism
- Frequent/prolonged disappearances from work area/site (bathroom breaks, etc…)
- Personality changes
- Progressive deterioration in personal appearance/hygiene
- Increasing absenteeism
- Frequent/prolonged disappearances from work area/site (bathroom breaks, etc…)

## Monitoring: Usual Suspects

- Correlation of Dx, Rx, and documentation
- Appropriateness of wasting – consistency of utilization vs. waste; timeliness
- Utilization of all Rx prescribed to Pt
- Documenting pain scores inconsistent with colleagues
- Giving implausible excuses for not administering narcotics ("may be discharged today")
- Documenting administration of narcotics at the time of and after the discharge
- Administering narcotics to patients for whom it is not appropriate

## Prevention along the chain




## Integrating prevention practices

- Establishing oversight authority with clear reporting lines and ongoing monitoring activities
- Immediate communication of 'red flags' through the proper chain of command
  - Individual MD request for controlled substance (or family members)
- Implementation of e-prescribing (i-Stop in New York)
- Review of personnel involved in procurement, job rotations, and mandatory vacations for purchasing staff & management
- Segregation of duties
- Monitoring for COI / potential collusion

Centers for Medicare & Medicaid Services: "Partners in Integrity: What is the Prescriber's Role in Preventing the Diversion of Prescription Drugs?" January 2014. Available at http://go.cms.gov/1Ljb8eY

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## Establishing relevant controls

- Daily reconciliation
- Properly securing and reconciling DEA-222 forms (if applicable)
- Orders vs receipts vs stocking
- Reviewing and securing delivery process
  - PharmD sign-off of receipt
  - Controlled and secure delivery to floors (if applicable)
- Access to pharmacy vault
  - Limited (periodic review of access)
  - Secure
  - Monitored
- Ad hoc inventory review

## System controls

- Access controls to ASDU
  - Limiting number of staff with access
  - Limiting number of "Super Users"/"Administrators"
- Ongoing review of ASDU reports
  - By frequency of discrepancies (individual & area)
  - Higher wasting
  - Higher utilization

## Policies and procedures

- Risk assessment and process revisions documented through policies and procedures for
  - Ordering
  - Receiving
  - Stocking
  - Wasting
  - Destruction
  - Reporting
- Staff education
  - On processes
  - Reporting obligations and timelines
  - Proper use of ASDU system
    - Physical access
    - Software

# Engaging clinicians

- In March of 2016 the Centers for Disease Control and Prevention (CDC), developed the first-ever guidelines for dispensing addictive painkillers
  - The guidelines urge doctors to avoid prescribing opioids for patients with chronic pain, noting that the risks of such drugs outweigh the benefits for some people.
- In light of the new guidelines, some physicians are now
  - Requiring patients to sign "pain management contracts"
  - Agreement to random drug tests before receiving an opioid prescription
  - Some are implementing opioid prescribing guidelines.
- Access to tools ≠ utilization of tools:
  - Screening
  - Pain scale
  - Alternative protocols
- State-specific best practice guidelines

Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain--United States, 2016. JAMA. 2016;315(15):1624-1645.

# Developing alternative treatment protocols

- Creating and promulgating awareness of the issue
  - Mayo Clinic study indicates that up to 1 in 5 Pt with opioid Rx are at risk
- Alternative:
  - Nerve blocks,
  - Periarticular injections
  - Neuraxial anesthesia
  - Anti-inflammatory drugs
  - Multi-modal therapies with post-op pain pumps
- Avoiding Rx for minor ailments (toothache, sprained ankle, etc.)
- Ongoing education
  - Clinicians
  - Patients

# Integrating prevention protocols into practice & ENGAGING Non-Physician Providers

- **Preventing Prescription Drug Misuse:** *Screening, Evaluation, and Prevention*
- **Treating Patients At-Risk for Substance Use Disorders:** *Engage Patients in Safe, Informed, and Patient-Centered Treatment Planning*
- **Managing Substance Use Disorders as a Chronic Disease:** *Eliminate Stigma and Build Awareness of Social Determinants*

August 22, 2016, Massachusetts Executive Office of Health & Human Services, Initiative to expand on Core Competencies to Combat Opioid Epidemic (http://www.mass.gov/eohhs/gov/newsroom/press-releases/eohhs/core-competencies-to-combat-opioid-epidemic-expanded-.html)

## What is the CCO's role?

- Drug diversion prevention, training, and controls must be incorporated in the elements of Compliance Program
- Efforts expanded, findings, and reports should be incorporated into overall Compliance Program dashboards
  - Management level compliance committee
  - Board level compliance committee
- Licensed professionals (PharmD, MD, DO, et al) expected to take an active part in prevention and reporting of diversions, and 'red flags'

# INVESTIGATION

## Investigation of Suspicions

- Diversion team put on alert
- Verification of data and analysis of situation
- If Clinician - immediately removed from patient contact or intercepted; drug cabinet access discontinued
- Urine drug screen (12 panel)
- Suspension pending conclusion of investigation
- Initial interview of alleged offender including review of underlying medical record and drug cabinet records (if available/ identified)
- If interviews involve multiple staff:
  - Consistency of interview questions (standard for union staff)
  - Documentation consistency retention
- Periodic communications with diversion/ investigative team

**"To privilege or not to privilege?"**

## Investigations

- Notifying GC if diversion is suspected (privileging investigation, as appropriate)
- Put together an investigation Work Plan
- Conducting staff interviews
- Review of medical records
- Reconciling discrepancies
- Identifying and quantifying the issue (scope)
- Analyzing potential repayment and self-disclosure (FCA) obligations
- Reviewing DEA reporting requirements
- ***Developing and retaining documentation trail***

## Decision points

- Who leads investigation –
  - Generally – CCO, with support of GC, HR, Clinical leads
- In-house or outsource; fully or partially
  - Organizational sensitivities
  - Scope of the discovered issue and potential for risk exposure
  - Availability of impartial and confidential in-house clinical review by 'like' licensure
- Expert witness use
  - Retained through attorney-client privilege
  - Available to testify, if needed
  - Have experience testifying as an expert
  - Carefully selected in same specialty, same experience
  - Facilitating expert witness review, and report

## If Diversion is Confirmed

- Determine employment disposition(s) and implications
  - Part time, Locum
  - Union implications
- Review clinical documentation
  - Consider billing implications and rebill if necessary (self-disclosure potential)
  - Coordinate medical record amendment, if necessary, with HIM
- Was patient safety affected
  - Notify patients if applicable

## Resolving the issues

- If repayment obligation is identified
  - Define scope
  - Self-disclosure requirement
- Re-billing for patients with missing medication/ services
- Address patient safety/ care issues

## Corrective actions

- Implementing written policies, procedures, and standards
- Reviewing communication flow to ensure transparency
- Initiating internal monitoring and auditing
- Training and education
  - Re-train staff in affected areas

For significant findings:

  - Develop and implement organizational communication plan
  - Report the event through appropriate Board level committee
- Consider HR policy on mandatory drug testing

## Monitoring - Reconciliation

- What should be reconciled:
  - Drug inventory at the start of the day/ shift
  - Drug disbursements
  - Supply on hand at the end of the day/ shift
- Proper and ongoing monitoring detect issues in real time
- Publicizing the processes deters potential offenders

## Ad hoc and periodic auditing

- Identify vulnerabilities/ prescription spikes/ by provider
- Review sample of medical records/ administration records/ orders
- Review ASDU activity logs
- Reconcile variances
- Discuss findings with appropriate clinical/ administrative staff

## Reporting

- Drug Enforcement Agency
  - Prompt reporting is expected (Form 106) (www.deadiversion.usdoj.gov)
- Pharmacy Board/ American Society of Health-System Pharmacists (www.ashp.org)
- State Licensure Board(s)
- Department of Health (patient harm issues)
- DEA position that obtaining certain information
- FDA/ OCI (tampering cases)
- Law Enforcement (crimes, issues of abuse/ neglect/ reckless endangerment, fraud
- OIG
- Accreditation agencies (Joint Commission, AAAASF, etc.) (www.jointcommission.org)
- Professional Liability Carrier(s)
- **Reporting timeline**

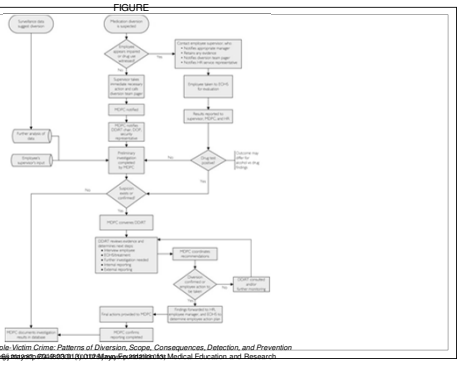
## Communicating Closure

"*Never waste the opportunity offered by a good crisis.*"

*Machiavelli, Churchill, Thatcher, Rahm Emanuel…*

- Taking a lead in 'telling the story'
- Contextualizing the incident
- Communication plan
  - Leadership & Board
  - Line staff
  - "Teachable moments"

FIGURE



*Diversion of Drugs Within Health Care Facilities, a Multiple-Victim Crime: Patterns of Diversion, Scope, Consequences, Detection, and Prevention*
*Mayo Clinic Proceedings*2012 87, 674-682DOI: (10.1016/j.mayocp.2012.05.011)Mayo Foundation for Medical Education and Research