DRUG DIVERSION: ENFORCEMENT TRENDS, INVESTIGATION, & PREVENTION

Regina F. Gurvich, MBA, CHC, CHPC

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

AGENDA

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

'National Drug Control Budget: FY 2017 Funding Highlights (Washington, DC: Executive Office of the President, Office of National Drug Control Policy), February 2017, Table 1, p.16, and Table 3, p.19.'
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


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 quantities when they are purchased or during delivery and receipt
- From automated storage and dispensing systems* (ASDU or ADU)

CAUSES AND SOURCES

- Theft of sample medications
- Re-directing expired medications for use or distribution elsewhere
- Altering or falsifying medical record documentation
- Diverting large drug quantities 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 sleepers, 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


DEA Diversion Control Website - https://www.deadiversion.usdoj.gov

REGULATORY ENFORCEMENT TRENDS

ENFORCEMENT TRENDS

- Drug diversion contributed to a 4-fold increase in substance abuse treatment admission from 1998 to 2008 for individuals ages 12 and over
- Since 2016 more people in the US have died annually from drug poisoning than from car crashes
- Healthcare providers are one of the leading sources of diverted drugs
  - Variety, types, and quantities of controlled substances purchased
  - Number of personnel involved in purchase, distribution, administration

CMS Medicare Learning Network – “Medicaid Program Integrity – What is a Prescriber’s Role in Preventing the Diversion of Prescription Drugs?”, ICN 909010 arch 2014
https://oig.hhs.gov/newsroom/spotlight/2013/diversion.asp

- Involvement of criminal networks
  - Include patient recruiters
  - Money launderers, and
  - Street dealers and gangs
- Some of these culprits have violent criminal histories, increasing the challenges and risks to law enforcement agents investigating these cases
- Top law enforcement priority
  - 9% increase in the 2016 DEA budget dedicated to diversion control
## 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**
- **Providing medically unnecessary service**
- **Billing for**
  - Services not rendered
  - Medically worthless
- **Violating statutory, regulatory or contractual provision with a nexus to payment**
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.

Human Cost

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

IS IT A BIG DEAL?

• 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
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

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'

INVESTIGATIONS

- Notifying GC if diversion is suspected (privileging investigation, as appropriate)
- Put together an investigation Work Plan / steps
- 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
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

INVESTIGATION

- 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 areas and potential for risk exposure
  - Availability of impartial and confidential in-house clinical review by ‘like’ license
- 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

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 areas and potential for risk exposure
  - Availability of impartial and confidential in-house clinical review by ‘like’ license
- 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
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

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/1Ljh4uY

ESTABLISHING RELEVANT CONTROLS

- Daily reconciliation
- Properly securing and reconciling DEA-222 forms (if applicable)
- Orders vs receipt vs stocking
- Revisiting 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
  - Storing
  - 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 to utilization of tools:
  - Screening
  - Pain scale
  - Alternative presents
- State-specific best practice guidelines

DEVELOPING ALTERNATIVE TREATMENT PROTOCOLS

- Creating and promulgating awareness of the issue
  - Mayo Clinic study indicates that up to 1 in 5 Pts with opioid Rx are at risk
- Alternative:
  - Nerve blocks
  - Periarticular injections
  - Regional 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 NPP

- 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 16, 2016, Massachusetts Executive Office of Health & Human Services, Initiative to expand on Core Competencies to Combat Opioid Epidemic

- Increase in DEA budget signals increase in enforcement
- Heightened public concerns diversion and impact on communities
- Organisational and individual liability
- Imperative of proactive rather than reactive approach to mitigation

WHY NOW?

Critical Time

FROM THE TRENCHES – CASE STUDY
THE ISSUE

- Housekeeper opens a locker in the ER staff room
- A vial with a syringe and needle stuck in the top falls on her head
- Chaos ensues…

THE PLAYERS

- Nursing (including nursing administration)
- Doctors (ER Dept Chair, Staff and PAs)
- Executive Administration
- Human Resources
- Pharmacy
- Compliance
- Security (physical, not IT)
- Consultants
- Outside Counsel
- Nurses Union

KEY STEPS

- Consultants were hired to conduct forensic interviews, review ER documentation and analyze use of the automated distribution cabinets (Omnipod) used to dispense drugs.

- Definition of the “relevant period” for the investigation was agreed upon by all players.

- The entire process from the ordering of drugs, to posting of orders in the electronic health record, to reserving drugs from Omnipro, to administering the medication, documenting the administration and procedures for waste of excess narcotics were discussed with each interviewee to determine consistency and understanding of hospital policy and best practice.
CHAO ENSUES

- Everyone is on the defensive as facts are gathered.

What do we know?

- Verbal orders are issued, not followed up by written orders, against hospital policy.
- Nurses are not obtaining medications correctly from the Omnipro cabinets. Wrong patients are getting charged.
- Nurses are not consistently documenting the administration of medication.
- The ER Chair wants to blame Nursing.
- Nursing wants to blame the ER docs and Pas.
- Standard change of shift processes regarding counting of narcotics are not being followed.
- Pharmacy does not appropriately reconcile narcotics that are dispensed through the Omnipro cabinets.
- Nursing administration is conducting interviews in a biased manner, shutting out the consultants.
  - For instance, the Director of Nursing hugs(!) an interviewee who is a prime suspect for drug diversion after her interview is over.

WHAT ELSE DO WE KNOW?

- The Union took the position that nurses were being singled out as being at fault for the alleged diversion.
- Union representative mandated their presence at all member’s interviews.
- The ER nursing staff threatened a walkout and/or work slowdown as well as notified Administration that they were going to leaflet on the perimeter of the hospital.
- In a show of solidarity, all of the ER day staff marched into Administration to protest the investigations.
- Administration, understandably, wanted quick resolution and end to the disruption.
THE FEDS AND THE STATE

- DEA notification is required for all material theft of narcotics in the hospital setting. The reports are made by the head of Pharmacy.
- As well, in New York City, the Bureau of Narcotics Enforcement is also notified and can re-interview people at will.
- It was decided in this case to make the report to the DEA under privilege and guidance by outside legal counsel.

RESOLUTION

- About nine months later -
  - One nurse terminated.
  - Final written warnings issued to other nurses and PAs.
  - One nurse put on probation and reassigned to a floor.
  - She wound up failing probation and being terminated from employment.
  - Overhaul of processes in the ER and Pharmacy.

AND THEY ALL LIVED HAPPILY EVER AFTER

The End

(of that story)
INVESTIGATION OF SUSPICIONS

- Diversion team put on alert
- Verification of data and analysis of situation
  - Nurse(s) immediately removed from patient contact or intercepted; drug cabinets access discontinued
  - Urine drug screen (12 panel)
  - Suspension pending conclusion of investigation
- Initial interview of nurse 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?"
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

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 / OIG (suspecting cases)
- Law Enforcement (crimes, issues of abuse/ neglect/ recklessness endangerment, fraud
- OIG
- Accreditation agencies (Joint Commission, AAAASF, etc.) (www.jointcommission.org)
- Professional Liability Carrier(s)
GOING FORWARD

A few thoughts

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 Drs, 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
<table>
<thead>
<tr>
<th>No.</th>
<th>Best Practice Element</th>
<th>INTEGRITY %</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**ORIGINAL PREFERENCES**

- St. Mary's is committed to providing patients with exceptional care.
- The hospital has a policy for managing medication in a safe and productive manner.
- The hospital will be evaluated by the administration on an ongoing basis.
- Change when the balance of the system changes.

**PREFERENCEs & DEFINITIONS**

- No change in dosage or concentration.
- No change in dosage or concentration.
- No change in dosage or concentration.
- No change in dosage or concentration.

**ADDITIONAL INFORMATION**

- No change in dosage or concentration.
- No change in dosage or concentration.
- No change in dosage or concentration.
- No change in dosage or concentration.

**ADDITIONAL COMMENT**

- No change in dosage or concentration.
- No change in dosage or concentration.
- No change in dosage or concentration.
- No change in dosage or concentration.

---

**BEST PRACTICE**

- St. Mary's is committed to providing patients with exceptional care.
- The hospital has a policy for managing medication in a safe and productive manner.
- The hospital will be evaluated by the administration on an ongoing basis.
- Change when the balance of the system changes.

**PREFERENCEs & DEFINITIONS**

- No change in dosage or concentration.
- No change in dosage or concentration.
- No change in dosage or concentration.
- No change in dosage or concentration.

**ADDITIONAL INFORMATION**

- No change in dosage or concentration.
- No change in dosage or concentration.
- No change in dosage or concentration.
- No change in dosage or concentration.

**ADDITIONAL COMMENT**

- No change in dosage or concentration.
- No change in dosage or concentration.
- No change in dosage or concentration.
- No change in dosage or concentration.
Norman Werther, MD, of Willow Grove, PA, was found guilty in U.S. District Court, Eastern District of Pennsylvania, of one count of Distribution of a Controlled Substance Resulting in Death, five counts of Conspiracy to Distribute a Controlled Substance; one count of Maintaining a Drug-Involved Premises; 117 counts of Money Laundering, and over 180 counts of Distribution of a Controlled Substance. According to court documents, from on or about February 2009, to on or about August 2011, Werther, while running a family practice/physical therapy and rehabilitation practice, conspired to distribute Oxycodone, a Schedule II Controlled Substance, to pseudo (fake) patients recruited by one of the at least six different drug trafficking organizations (DTO). Werther was part of a multi-million dollar drug conspiracy involving thousands of illegal prescriptions, phony patients, and multiple DTOs. Werther was paid for each prescription he wrote to these pseudo patients, who in turn, provided the pills to the heads of each DTO to be resold in bulk to street level drug traffickers for a profit. During the course of the conspiracy, Werther was responsible for the illegal distribution of over 1,000,000 Oxycodone pills.

Werther was also convicted of causing the death of a patient not related to any of the six DTOs by illegally prescribing this patient, an admitted recovering drug addict who Werther had been treating with Suboxone, large amounts of Oxycodone pills; this patient died within 24 hours of ingesting the Oxycodone pills he obtained via a prescription from Werther.

Werther was sentenced to 25 years incarceration, followed by three years supervised release. Werther was also ordered to pay a $25,000 fine; a $30,900 special assessment fee; and forfeit $10,000,000.00. Werther has appealed his conviction.

REFERENCES


WERther, Norman, MD
Willow Grove, PA

- Date of Arrest: 8/10/2011  
- Date of Conviction: 9/24/2013  
- Judicial Status: Jury Conviction  
- DEA Registration: Surrendered 8/22/2011  
- In Brief: Norman Werther, MD, of Willow Grove, PA, was found guilty in U.S. District Court, Eastern District of Pennsylvania, of one count of Distribution of a Controlled Substance Resulting in Death, five counts of Conspiracy to Distribute a Controlled Substance; one count of Maintaining a Drug-Involved Premises; 117 counts of Money Laundering, and over 180 counts of Distribution of a Controlled Substance. According to court documents, from on or about February 2009, to on or about August 2011, Werther, while running a family practice/physical therapy and rehabilitation practice, conspired to distribute Oxycodone, a Schedule II Controlled Substance, to pseudo (fake) patients recruited by one of the at least six different drug trafficking organizations (DTO). Werther was part of a multi-million dollar drug conspiracy involving thousands of illegal prescriptions, phony patients, and multiple DTOs. Werther was paid for each prescription he wrote to these pseudo patients, who in turn, provided the pills to the heads of each DTO to be resold in bulk to street level drug traffickers for a profit. During the course of the conspiracy, Werther was responsible for the illegal distribution of over 1,000,000 Oxycodone pills.

 Werther was also convicted of causing the death of a patient not related to any of the six DTOs by illegally prescribing this patient, an admitted recovering drug addict who Werther had been treating with Suboxone, large amounts of Oxycodone pills; this patient died within 24 hours of ingesting the Oxycodone pills he obtained via a prescription from Werther.

Werther was sentenced to 25 years incarceration, followed by three years supervised release. Werther was also ordered to pay a $25,000 fine; a $30,900 special assessment fee; and forfeit $10,000,000.00. Werther has appealed his conviction.