



The State of New Jersey



Office of the Attorney General



NEW JERSEY DIVISION OF
CONSUMER AFFAIRS



NABP

NATIONAL ASSOCIATION OF
BOARDS OF PHARMACY

New Jersey Board of Pharmacy Drug Diversion Prevention & Reporting

Presented by

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Disclosure Declaration

- I do not have (nor does any immediate family member have) a vested interest in or affiliation with any cooperate organization offering financial support or grant monies for this continuing education activity, or any affiliation with an organization whose philosophy could potentially bias my presentation.
- This presentation is solely for informational purposes and does not represent the views, statements, or opinions of the New Jersey Board of Pharmacy, New Jersey Division of Consumer Affairs and /or the New Jersey Office of the Attorney General.

Objectives

- Describe how to recognize the signs of an impaired co-worker
- Discuss different methods of drug diversion and strategies to prevent controlled substances loss and theft
- Describe laws and regulations regarding the handling and security of controlled dangerous substances
- Describe the elements and requirements of a Drug Enforcement Agency Audit

New Jersey Board of Pharmacy

- Oldest professional licensing board in New Jersey
- Established in 1877 to protect the public by regulating the dispensing of prescription medications
- Purpose
 - Protect the health, safety and welfare of the people of New Jersey
 - Regulate the practice of pharmacies, pharmacists, pharmacy externs and interns, and pharmacy technicians

New Jersey Board of Pharmacy

- The Board protects the public:
 - Insures pharmacists and pharmacy technicians meet all of the necessary requirements for licensure;
 - Investigates and disciplines any pharmacist and pharmacy technician in violation of NJ Board of Pharmacy's laws;
 - Enforces education and training requirements;
 - Requires all pharmacies be registered by the State and renew their permits annually;
 - Ensures patients receive the prescribed medication
 - Routinely inspects pharmacies for regulatory compliance

Controlled Dangerous Substances (CDS) Abuse

- Americans abuse prescription drugs more than cocaine, heroin, and hallucinogens combined
- One in four teenagers have misused prescription drugs, 33% increase in past 5 years
- Source: Parents and Grandparents
- 70% of Americans take 1 prescription drug and 50% take 2 prescription drugs

Pharmacist CDS Abuse

- An estimated 18% to 21% of pharmacists have misused prescription drugs.
- In most of those cases, addiction developed after taking medications that had been prescribed for physical ailments, notably pain
- Post-surgery and/or post injury

Nurse CDS Abuse

- An estimated 10% of nurses are dependent on some type of drug.
- The American Nurses Association analogy: One of 10 nurses is probably struggling with some type of addiction.
- 3 million nurses in USA
~300,000 may be substance abusers
- Post surgery and/or post injury

Physician CDS Abuse

- Approximately 10% to 12% of physicians will develop a substance use disorder during their careers
- Abuse rate similar to or exceeding that of the general population
- High risk areas:
 - Anesthesia
 - Hospice
 - Pain Management

Sound Advice



**KEEP
CALM
AND
DON'T FREAK
OUT**

Methods of CDS diversion

- Narcotic pull for excessive amounts of patients
- Pull larger dose than patient receives
- Pattern of broken vials and ampoules. Excessive “accidents”. Check rubber stoppers for punctures
- Vial breakage is clean. Vials are sheared without fragments
- Intact narcotics thrown in general trash
- Pulverized or broken tablets. Pieces of tablet or powder of capsule missing
- Injectable vial caps are jammed back on to conceal punctured rubber stoppers

Methods of CDS diversion

- Substituting diluent for active injectable narcotic in IV bags
- Remove drug from IV drips
- Substituting look alike legend drug tablets for active narcotic tablets
- Curved needle used to go between metal lid and caps on vials
- Users are created and deleted in a short period of time. Upon review, users are fictitious
- Employees work and make transactions during off-shifts or unscheduled times

Recognizing impaired co-worker

- Work performance
 - Absenteeism
 - Low productivity, poor performance, unreliability
 - Excessive time spent with CDS inventory
 - Staff or co-worker complaints
- Behavior
 - Declining interpersonal relations, personality change
 - Deterioration of personal hygiene and appearance
 - Confusion, memory loss, declining attention to detail

Enabling the impaired worker

- Making excuse for poor performance
- Not witnessing waste or transactions
- Not co-signing transactions
- Ignoring signs and symptoms
- Accepting unusual situations
- Not reporting to supervisor or management

CDS Diversion Prevention

- Perpetual Inventory
- Random audit for top 5 in 10% diversion risk
- Inventory all CDS (CI to CV) annually at the same day and month as Biennial Inventory
- Different pharmacist orders, receives, and distributes CDS. All transactions with a co-signature
- Prescription appropriateness analysis
 - Patient type and behavior
 - Diagnosis
 - Quantity
 - Prescriber and practice type

CDS Diversion Prevention continued

- Use the Prescription Monitoring Program (PMP)
 - Pharmacies and Pharmacists must register
 - Daily submission of CDS data from pharmacies
 - Prescribers – optional registration/use
- Utilize Video Surveillance Technology
- Automated dispensing technology; Monitor transaction:
 - Accuracy
 - Quantity
 - Type
 - Resolution reasons

Security Requirements

13:45H-2.2 PHYSICAL SECURITY CONTROLS FOR NONPRACTITIONERS: STORAGE AREAS

- “Substantially constructed cabinet”
- Large quantities
 - A vault constructed before 9/1/1971
 - Substantial construction with a steel door, combination or key lock, and an alarm system
 - A vault constructed after 9/1/1971
 - The walls, floors and ceilings - eight inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with 1/2 inch steel rods tied six inches on center
 - 30 man-minutes against surreptitious entry, ten man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;
 - self-closing and self-locking “day gate” for use during the hours of operation in which the vault door is open;
 - Vault is equipped with an alarm, central station protection 24hrs

Handling and Documentation of Expired and Wasted Narcotics

- Locked drop box - Secure expired/wasted narcotics in the pharmacy.
- Documentation and co-signature required with narcotic waste.
- Medication Pending Destruction Report.
- Use at least two or more pharmacists to verify, document (DEA 41), and destroy narcotics.



CDS Diversion, Theft, or Loss



CDS Diversion, Theft, or Loss

- “Significant” event
 - Quantity of CDS lost in relation to the type of business
 - Type of CDS; Likely candidate for diversion/theft
 - Attributed to a unique activity
 - Pattern of loss
 - Local trends or indicators of potential diversion

Quiz Time

- Which is a regulatory reportable “significant” theft, loss, or diversion event:
 1. One (1) oxycodone tablet is missing. The pharmacy orders 1,200 tablets per month
 2. A bottle of acetaminophen with codeine is found intact and sealed on the floor outside of the employee bathroom
 3. 10 vials of fentanyl 250mcg/5mL is missing. The pharmacy orders 5,000 vials per month
 4. Two oxycodone/acetaminophen 5mg/325mg tablets are found crushed in the bottom of the manufacturer’s bottle on the fourth Friday of every month. The pharmacy orders 15,000 oxycodone/acetaminophen 5mg/325mg tablets each month
 5. You witness a pharmacist filling a legitimate prescription for guaifenesin with codeine. The pharmacist is pouring guaifenesin with codeine liquid into a prescription bottle and he sneezes and spills two ounces of the liquid all over the counter.
 6. 3 and 4
 7. All of the Above
 8. None of the Above

Quiz Time

- Which is a regulatory reportable “significant” theft, loss, or diversion event:
 1. One (1) oxycodone tablet is missing. The pharmacy orders 1,200 tablets per month
 2. A bottle of acetaminophen with codeine is found intact and sealed on the floor outside of the employee bathroom
 3. 10 vials of fentanyl 250mcg/5mL is missing. The pharmacy orders 5,000 vials per month
 4. Two oxycodone/acetaminophen 5mg/325mg tablets are found crushed in the bottom of the manufacturer’s bottle on the fourth Friday of every month. The pharmacy orders 15,000 oxycodone/acetaminophen 5mg/325mg tablets each month
 5. You witness a pharmacist filling a legitimate prescription for guaifenesin with codeine. The pharmacist is pouring guaifenesin with codeine liquid into a prescription bottle and he sneezes and spills two ounces of the liquid all over the counter.
 6. **3 and 4**
 7. All of the Above
 8. None of the Above

Quiz Time

- Which is a regulatory reportable “significant” theft, loss, or diversion event:
 1. One (1) oxycodone tablet is missing. The pharmacy orders 1,200 tablets per month
 2. A bottle of acetaminophen with codeine is found intact and sealed on the floor outside of the employee bathroom
 3. 10 vials of fentanyl 250mcg/5mL is missing. The pharmacy orders 5,000 vials per month
 - **Significant because fentanyl is a top drug sought for diversion and quantity of loss**
 4. Two oxycodone/acetaminophen 5mg/325mg tablets are found crushed in the bottom of the manufacturer’s bottle on the fourth Friday of every month. The pharmacy orders 15,000 oxycodone/acetaminophen 5mg/325mg tablets each month
 - **Significant pattern of loss**
 5. You witness a pharmacist filling a legitimate prescription for guaifenesin with codeine. The pharmacist is pouring guaifenesin with codeine liquid into a prescription bottle and he sneezes and spills two ounces of the liquid all over the counter.
- 6. **3 and 4**

Reporting Diversion, Loss, & Theft

- Drug Enforcement Agency (DEA) within 24 hrs of discovery NOT after investigation
 - Call Newark Field Division Office (973) 776-1100
 - Fax (973) 776-1166
 - Online DEA 106 Form

<https://www.deadiversion.usdoj.gov/webforms/dtlLogin.jsp>.

- Can amend submission within 30 days
 - Save amendment key number
- Save final form for two years
- Need NDC number of CDS
- Liquids and injectables are reported in total milliliters (mLs)

Reporting Diversion, Loss, & Theft

- The New Jersey Board of Pharmacy immediately following notification of the DEA
 - Submit notification to the Executive Director of the NJ Board of Pharmacy
 - Submit a copy of the completed DEA 106 Form
 - Forward any Amendments to the DEA 106 Form

Reporting Diversion, Loss, & Theft

- The New Jersey Drug Control Unit (DCU) within 24 hrs of discovery
 - Call (973) 504-6351
 - Complete and fax form DDC-52 to (973) 504-6326
download from
[www.njpublicsafety.com/ca/drug/CDSLloss .pdf](http://www.njpublicsafety.com/ca/drug/CDSLloss.pdf) to
Attention: Drug Control Unit

Reporting Diversion, Loss, & Theft

- Contact local Police Department if CDS loss attributable to a crime
- If local Police contacted, the New Jersey Department of Health (DOH) must be immediately contacted
 - via the web-based Hippocrates program, found at <https://hippocrates.nj.gov/common/processLoginAuthentication.action>.
 - If the Hippocrates report cannot be submitted electronically, call (800) 792-9770.

Reporting Diversion, Loss, & Theft

- If the CDS diversion, theft, or loss involves a health care practitioner
 - The practitioner's governing Board must be contacted
 - Health Care Professional Responsibility and Reporting Enhancement Act Reporting Form must be filled out download from www.njconsumeraffairs.gov/Pages/hcreporting.aspx
 - Within seven days of the event
 - Send to: Francine Widrich New Jersey Division of Consumer Affairs PO Box 46024 Newark, NJ 07102
 - You may also call (973) 504-6310 to request a fax number and fax the report.

Quiz Time

- You must report a discovered CDS diversion, loss, or theft to the DEA within 24 hours regardless if the investigation is incomplete or all of the facts have not been confirmed
- True or False

Quiz Time

- You must report a discovered CDS diversion, loss, or theft to the DEA within 24 hours regardless if the investigation is incomplete or all of the facts have not been confirmed
- **True**

DEA Audit

- A copy of the previous or specified biennial CDS inventory.
 - The biennial CDS inventory must contain:
 - Separate reports of Schedule II CDS and Schedule III-V CDS
 - All CDS in active, secured inventory
 - All CDS (expired, damaged, unusable) pending for destruction and/or in “return bins” for internal removal/wasting or for acquisition and removal by a reverse distributor
 - All CDS secured in remote automated dispensing machines (eg, hospitals, long-term acute care)
- Copies of purchases of selected CDS within a specified time period
- Copies of selected CDS destroyed/wasted within a specified time period
- Copies of documentation of selected CDS dispensed within a specified time period
- Documentation of estimated or calculated CDS lost to diversion, theft, or loss

DEA Audit

- Documentation of all suspected diverter's or diverters' transactions and activities with selected CDS
- A physical inventory of selected CDS in active inventory, pending for destruction, and CDS inventory in remote automated dispensing machines, if applicable (physical inventory will be performed on site and with DEA agents present)
- Documentation of all professional staff and/or corporate owners/management affiliated with business, to include but not limited to job position, contact information, professional license numbers, and driver's license numbers
- A summary of the origin and nature of the business, institution, and/or organization
- A copy of all CDS policies and procedures

DEA Audit

- DEA investigators will utilize a computation sheet that matches all CDS received/purchased with CDS dispensed/wasted and look for an accounting balance of zero
- Received + Purchased CDS inventory =
Dispensed + Wasted CDS inventory

DEA Audit Accounting ≠ 0



DEA Audit Accounting ≠ 0

- Corrective action plan
- Recommendations for improvement
- Citations
- Fines

Other Regulatory Agencies



**FREAK
OUT
AND
THROW
STUFF**

Other Regulatory Agencies

- Other regulatory agencies or entities may cite or fine for regulatory non-compliance or violations
- NJDOH
- NJBOP
- NJDCU
- NJ Attorney General's Office

Summary

- Policy and Procedures
 - Retrievable and relevant
 - Revise and review annually
 - Develop processes that lead to quick discovery
- Vigilance
- Accountability of staff
- Routine audits, quality checks, and safety measures
- Mitigate risks
 - Failure Mode Effect Analysis (FMEA)
 - Root Cause Analysis (RCA)

Questions?

