

# PHARMACEUTICAL SUPPLY CHAIN THEFTS REPORTING AND PREVENTION

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[www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)

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# Statutory Mandate

Protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

# Pharmacies - On the Front Lines of “War on Prescription Drug Abuse”

## Street value of common controlled substances

- Dilaudid 4mg \$15.00-\$20.00 per tablet
- Fentanyl - \$10.00 per patch
- **Hydrocodone** - \$1.00 - \$5.00 per tablet
- methadone - \$10.00 per tablet
- methylphenidate - \$5.00 per tablet
- morphine - \$30.00 per/10 tablets
- MS Contin 60mg - \$20.00 per dose
- Oxycodone 80mg - \$12.00 - \$40.00 per tablet
- Oxycontin 80mg - \$35.00 - \$50.00 per tablet
- **promethazine & Codeine** - LA - \$200 - \$300 (sometimes \$600) / pint
- Tussionex - \$30 - \$40 per pint
- diazepam 5mg - \$1.00 - \$2.00 per tablet
- Vicodin ES - \$5.00 per tablet
- **Xanax 2mg** - \$3.00 - \$5.00 per tablet

\*National Prescription Drug Threat Assessment 2009- California

Pharmacists tend to think only of how much a drug costs or sells for, not the street value of the drug.

**Oxycontin 30mg IR** - \$1.00/mg **Opana** - \$35.00 - \$50.00/tab

# Ninety Five Percent of Pharmacies Are Very Efficient, Honest, Extremely Professional

- ▣ Board deals with the other 5%
- ▣ Only when something is wrong does it get reported to us
- ▣ We don't receive reports from the 95% of pharmacies where "things are fine"

# These Drugs Are Within Legitimate Supply Chain

- ▣ 2 ways to obtain the prescription drugs:
  1. Steal from a manufacturer, wholesaler, pharmacy, or patient
    - Robbery, break in, employee theft sell the drugs
  2. Obtain a prescription and find a pharmacy to dispense
    - sell the drugs on the street illegally

# Why Is My Pharmacy a Target?

- ▣ **Internet** developed illegal controlled substance market
- ▣ **Ryan Haight Act** reducing availability of controlled substances on the internet
  - Reduced U.S. illegal sales outlets
  - Not as much impact on overseas websites
- THUS:
  - More prescription controlled substances purchased on the street – more need for drugs on the street
  - Pharmacy employee theft increased to supply controlled substances sold on street
- ▣ Patients who are **doctor shoppers**
- ▣ **Employee** theft for **self use** of drugs

# Coming in the Near Future

- ▣ Recent efforts by the DEA to stem the seemingly unrestricted flow of controlled substances into the supply chain
  - impact on wholesalers
  - impact on pharmacies
- ▣ Impact on supply?

- ▣ Basic law of economics: supply & demand
- ▣ What will happen if the flow of controlled substances drops?
- ▣ What will happen to patients in need?

# CHANGES IN CONTROLLED SUBSTANCE LOSS PROFILE

- ▣ 2000 - TEN YEARS AGO  
**manufacturing** losses rare
- ▣ wholesale losses rare, usually losses within the  
**wholesale** premises
- ▣ **pharmacy** losses – varied and small  
some self use

# CHANGES IN CONTROLLED SUBSTANCE LOSS PROFILE (CONT)

## ▣ 2010 – TODAY

### ■ Manufacturing

- ▣ Eli Lilly Warehouse - \$75 million
  - ▣ Eli Lilly truck \$37 million
  - ▣ Teva truck - \$11.8 million
  - ▣ Novo Nordisk truck - \$11 million
  - ▣ Astellas truck - \$10 million
  - ▣ Unknown company - \$8 million
  - ▣ GSK Warehouse - \$5 million
  - ▣ Exel Distribution Center - \$3 million
  - ▣ Dey Pharmaceuticals 2 trucks - \$2 million each
- \*CBI Bio/Pharmaceutical Summit on Finished Product Supply Chain

# CHANGES IN CONTROLLED SUBSTANCE LOSS PROFILES (CONT)

- ▣ 2013
  - Wholesaling
    - ▣ **Internal** losses
    - ▣ **In-Transit** losses
      - Manufacturer to wholesaler – **concealed** losses in large shipment
      - Wholesaler to **pharmacy**
    - ▣ **Theft from**
      - wholesaler's **delivery vehicle** and drug contents
      - **contract delivery** drivers
      - **contract mail** delivery services (UPS, Fed Ex)

# Welcome to the Wild West

- ▣ 2013 Pharmacy
  - Total number of pharmacies reporting losses has increased
  - Total amount of controlled substances lost, increased
  - Individuals stealing from pharmacy
    - Pharmacy technicians, clerks, delivery drivers steal to sell and or self use
    - Pharmacists usually steal to self use
    - More frequent theft by females than anticipated
    - Employees knowing someone or affiliated themselves with gangs
    - Avoid stealing becoming a supplement to regular income
  - Specific drugs lost more frequently
    - Vicodin products
    - Oxycontin
    - Alprazolam
    - Promethazine & Codeine

# WHY IS MY PHARMACY A TARGET? WHO IS DOING THIS?

- Diverter groups –
  - Find **unethical prescribers** to write Rx
  - Prescriptions dispensed by **unethical pharmacies**
  - Dispensed prescriptions sold or **turned over to drug dealers**
  - **Drugs sold on the street** by drug dealers
  
- Gang involvement
  - Encourage **pharmacy staff to steal** from pharmacy stock
    - Your staff are **targets**
    - Demographics of a thief changing
  - Responsible for **armed robberies**
  - Responsible for **night break ins**
  
- **Organized Crime** Involvement- theft at all levels of distribution

# Pharmacy Related Criminal Activity

- ▣ Diverter groups, gang involvement and organized crime brings a **criminal element** into pharmacies not previously experienced.
- ▣ Criminals know:
  - **Profit high** with prescription drug diversion
  - Chances of **prosecution reduced** if caught
  - **Sentences** related to prescription drug convictions are less than distribution of illegal drugs

# WHAT IS EVERY PHARMACIST'S PROFESSIONAL RESPONSIBILITY ?

A. **Prevent loss** of controlled substances from your pharmacy

6700 pharmacies in CA. If each pharmacy loses 1000 Vicodin per year, that is 6.7 million Vicodin on the street illegally

B. **Appropriately dispense** controlled substance prescriptions only for a legitimate medical need

# HOW OTHERS SEE PHARMACISTS

THE PHARMACIST IS THE FINAL CHECK OF THE  
LEGITIMACY OF A PRESCRIPTION

Your decision determines if the drug is dispensed to a patient for appropriate medical treatment or if the drug goes to the street to be consumed by someone not authorized to receive the drug.

If the patient is an addict and/or physician a criminal, the pharmacist's decision is the last and final check to protect the health and safety of the patient and the public

# APPROPRIATE CARE OF LEGITIMATE PAIN PATIENTS

BUT:

- ▣ **Legitimate pain patients** must receive prompt, appropriate treatment to meet their pain needs without discrimination.
- ▣ It is the pharmacist's **professional responsibility to make appropriate decisions** regarding dispensing of pain medication for a legitimate medical need.

# Today, and under development

- ▣ The California Board of Pharmacy is working with the Medical Board on issues of mutual concern involving the prescribing and dispensing of controlled substances
- ▣ Task Force formed – 1st meeting in September
- ▣ Other prescribers being invited to join
- ▣ Use of CURES

# PREVENTING LOSS OF CONTROLLED SUBSTANCES FROM PHARMACY

1. **Investigate employees** before hire, monitor and observe employees after hire
2. Losses occur at any step in process of drug movement into and through a pharmacy.
  - **Ordering** prescription drugs
  - Prescription drugs **in transit**
  - **Receipt** of prescription drugs by pharmacy
  - **Pharmacy check in** of prescription drug delivery
  - Review of purchase invoices **by Pharmacist In Charge**
  - Appropriate **storage** of prescription drugs in pharmacy
  - Prescription Drugs **stolen while stored** in pharmacy
  - Night break in, robberies – RPH prepare **psychologically** for robbery

\*Best practice to develop parameters and monitor each step to prevent or detect drug losses from pharmacy

# Pharmacy Prescription Drug Ordering

- Best case scenario: one person orders, one password. Do not share wholesaler passwords
- Second person check in orders so ordering and check in person know what the other is doing and there are double checks in the system. One RPH as a part of the system and procedure  
Also:
  - -if more than one employee is allowed to order, do not use the same password
  - -limit the amount of “super users”
  - -minimize the number of orders placed per day, so that “extra” orders stick out.
  - -minimize the number of locations/terminals which can be used for ordering
  - -if you have on-line ordering, watch orders placed from an off site location (home, etc).

# Pharmacy Prescription Drug Ordering (cont)

- ▣ CSOS -- everyone should have their own password
- ▣ 222 forms -- limit who has power of attorney
- ▣ Never pre-sign 222 order forms
- ▣ “Want list” works because if filled out correctly, always acts as a double check to see who ordered and what ordered
- ▣ Standardize how your facility uses a “PO number”-- you can have the employee use their initials
- ▣ Make sure you buy from a BOP licensed WLS
- ▣ Be observant – many times most trusted employees or new employees
- ▣ Reconcile statements to invoices – some invoices may be being stolen and PIC never sees them.

# PHARMACY IN-TRANSIT LOSSES

- ▣ Drugs diverted before arriving at your pharmacy
  - Hijacked delivery vehicles
  - UPS, Fed X, Postal Service, Wholesale delivery drivers, contract couriers
  - Cross docking

If your pharmacy signs for the order you are responsible for loss and you, not the wholesaler must report drug loss

# PHARMACY -RECEIPT OF DRUGS

- ▣ CA Pharmacy Law requires **Pharmacist-In-Charge sign for all dangerous drug deliveries**

- Code section written to protect Pharmacist -In-Charge

Ensuring that drugs cannot be ordered and delivered to pharmacy -- and then diverted -- without a pharmacist knowing.

# Prescription Drug Delivery to Pharmacy

- ▣ RPH must sign for delivery -- non-controlled & controlled
- ▣ Hospital only-deliveries of drugs going to receiving/distribution or other delivery warehouses instead of to pharmacy
- ▣ Rapidly check-in orders -- drugs disappear from unprocessed totes – e.g., unknown if used for filling rx, not delivered, or stolen from tote
- ▣ Shorten the time between delivery and check into secure area
- ▣ Count and check controlled substances when the driver is there, not after the fact
- ▣ Let the driver come all the way to the pharmacy, do not allow staff to meet halfway

# Pharmacy Order Check In – Controlled Substances

- ▣ Person checking in the drugs should be different from the person ordering drugs (acts as a double check)
- ▣ Person checking in drugs should be someone familiar with dispensing trends – spot unusual orders
- ▣ Perpetual log helps find and track discrepancies sooner
- ▣ Review invoices often, watch for ordering trends, drugs not used, large amounts

# PRESCRIPTION DRUG STORAGE

- ▣ The safest place for drugs is stored in their proper place on the shelves
  1. Store drugs likely to be stolen in a locked area with only RPH access
    - ▣ Key in possession or RPH only.
    - ▣ Do not leave key in lock or hung on a hook for easy access by non RPH
  2. Store where staff can easily see who frequents the storage area.  
NOT:
    - in back of storage bays that cannot be easily viewed
    - near the restroom
    - near a rear exit
    - near storage area for employee personal items
  3. Watch that fast movers are not stored too near any public access
  4. Watch trash

# Prescription Drug Storage (cont)

5. Expired drugs – make a log of what is separated as expired awaiting reverse distributor
6. Hospital – home meds – log of what held when received and when released back to patient
7. Will call
8. Return to stock – does the drug make it back to the stock shelves

# PIC REVIEW OF PURCHASE INVOICES

- ▣ Pharmacist-In-Charge must review invoices for dangerous drugs received by pharmacy
  - 100,000 tablets of Vicodin stolen by ordering technician from a childrens hospital and no one at hospital knew until police arrested trusted employee. Did not normally stock Vicodin tabs
  - 450,000 tablets of generic Vicodin stolen from a retail pharmacy by trusted employee. Pharmacy had no idea drugs were missing
  - 55,000 HPAP products stolen in 14 days from hospital pharmacy

Review invoices FREQUENTLY & carefully especially for days pharmacist-in-charge does not work

-- review for trends, drugs not used, large amounts ordered

# DRUGS STOLEN FROM STOCK

- ▣ Drugs **hidden and later** stolen from pharmacy by employee
  - **Trash; in belongings** – lunch boxes, backpacks; clothing-pockets, cargo pants, up sleeves,
- ▣ **Security Cameras**- record for extended period, **do not erase** or record over previous data
- ▣ Non pharmacy employees entering pharmacy
  - **Front end managers** usually have emergency key access
  - **Family** members
  - Employees **visiting on days off**
  - **Custodial, maintenance, inventory workers**
- ▣ How drugs leave the pharmacy
  - Hidden
  - Dispense prescription without authorization or refills & steal prescription
  - Night break ins
  - Robberies

# Dispensing Process Controlled Substances

- ▣ -perpetual log useful
- ▣ -run discrepancy reports often at pharmacy level
- ▣ -if you use a computer system, learn how it can be used to track discrepancies in more than one way
- ▣ -run discrepancy reports at nursing level
- ▣ -do an inventory more often
- ▣ -limit the amount of “super users”
- ▣ -if your facility still uses “paper sign out sheets” make sure you can account for all sheets going out and returning
- ▣ -watch override reports, hold all staff accountable

# Drugs Quarantined for Return or Destruction

- ▣ -secure drugs to be returned, they are still part of your inventory
- ▣ Make a **written inventory of all prescription drugs leaving your pharmacy**, either for destruction or credit to a reverse distributor. You are responsible for the disposition record.
- ▣ -make sure your **reverse distributor is licensed with the CA Board of Pharmacy**
- ▣ -retain your disposition record (inventory) and reverse distributor paperwork for **3 years**

# What Do I Do When I Think A Drug Is Missing?

- ▣ **Count** drugs immediately --audit to determine if loss and how much
- ▣ Determine **cause** of loss
- ▣ If you are not the pharmacy owner, **notify management or loss prevention** per company procedure
- ▣ If you identify a person stealing prescription drugs, have them **arrested** and prosecuted
- ▣ **Report losses** to DEA and CA State Board of Pharmacy promptly

# HOW TO DETERMINE CAUSE OF LOSS

- ▣ Determine WHEN loss is occurring by counting stock frequently  
– count weekly and then increasingly more often until you identify when and how much is being lost.  
Count as frequently as needed to determine what occurring before pharmacy opens, when you go to lunch, when staff go to lunch, when each staff member leaves for day and other staff remain, when each staff person arrives, at end of day
- ▣ Determine WHO is responsible for loss --who is working when losses occur? check schedule, monitor staff, may interview staff at some point, if know loss is ancillary staff may have another RPH assist in monitoring and counting if RPH suspected or unknown who suspect is, quiet investigation may be more productive

Each situation unique and requires RPH judgment

Install cameras or use other technology as needed

If someone admits stealing, get the admission in writing, then arrest

**YOU MUST STOP THE LOSSES - DON'T LET LOSSES CONTINUE WHILE YOU CONDUCT EXTENSIVE INVESTIGATION**

# How Do You Determine If You Have a Loss

- ▣ **Perpetual inventory**- count and check inventory
- ▣ If no perpetual ---as soon as suspect a loss, **inventory/count the drugs** in question - **Date and time your inventory**
- ▣ Retrieve **last DEA biennial** inventory and determine count for the drugs in question on that inventory
- ▣ Determine **total acquisitions/purchases** of drugs in question for the time period between DEA inventory count and current count
- ▣ Determine **total dispositions/dispensing** of drugs in question for the period

# Calculating Potential Controlled Substance Losses

- ▣ Start with quantity reported on last biennial DEA inventory
  - ▣ Add in purchases for time period
  - ▣ Subtract dispensing for time period, return credits, destruction, previous reported DEA 106 losses (any drug leaving the pharmacy)
  - ▣ The result of this calculation should equal your current count
  - ▣ If you have a **negative number (LOSS)**
  - ▣ If you have a **positive number (OVER)**
- \*\*\***both** loss and overage is a **violation**  
inventory must be accurate at all times

# WHAT DO I DO IF I IDENTIFY PERSON STEALING

- ▣ Contact DEA, Diversion Office if you need assistance reporting theft to local law enforcement or...
- ▣ call local law enforcement and have the person arrested

## Required reporting:

- ▣ Report suspicion of loss to DEA immediately and report significant loss to DEA on electronic DEA 106 form found on DEA website
- ▣ Report in writing all controlled substance losses to CA State Board of Pharmacy within 30 days of discovery of the loss.
  - May use DEA 106 form or...
  - May use a form of your own design

# Reporting Impaired Licensees Mentally, Chemically, Physically

- ▣ Business & Professions Code Section 4104
  - Policy and procedure to take action to protect public when a licensed person employed by your pharmacy is known to be mentally, chemically or physically impaired to the extent it affects their ability to practice their profession or occupation. (RPH, Technician, Intern Pharmacist)
  - Pharmacy must report to board within 14 days discovery of above impairment
  - Code section has a list of documents pharmacy required to provide to board
  - Anyone reporting is immune from civil or criminal liability for reporting