

PHARMACEUTICAL SUPPLY CHAIN THEFTS REPORTING AND PREVENTION



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CA State Board of Pharmacy

Virginia Herold, Executive Officer

Judi Nurse, Pharm D, Supr. Inspector

Janice Dang, Pharm D, Supr. Inspector



CONTROLLED SUBSTANCE ABUSE

- Schedule II – V misuse/abuse second only to marijuana abuse.
- All other types of schedule I controlled substance abuse added together does not equal schedule II-V abuse
- **DARE** program decreased illegal substance use, but misconception if a drug is legal, it can't be harmful

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 / 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

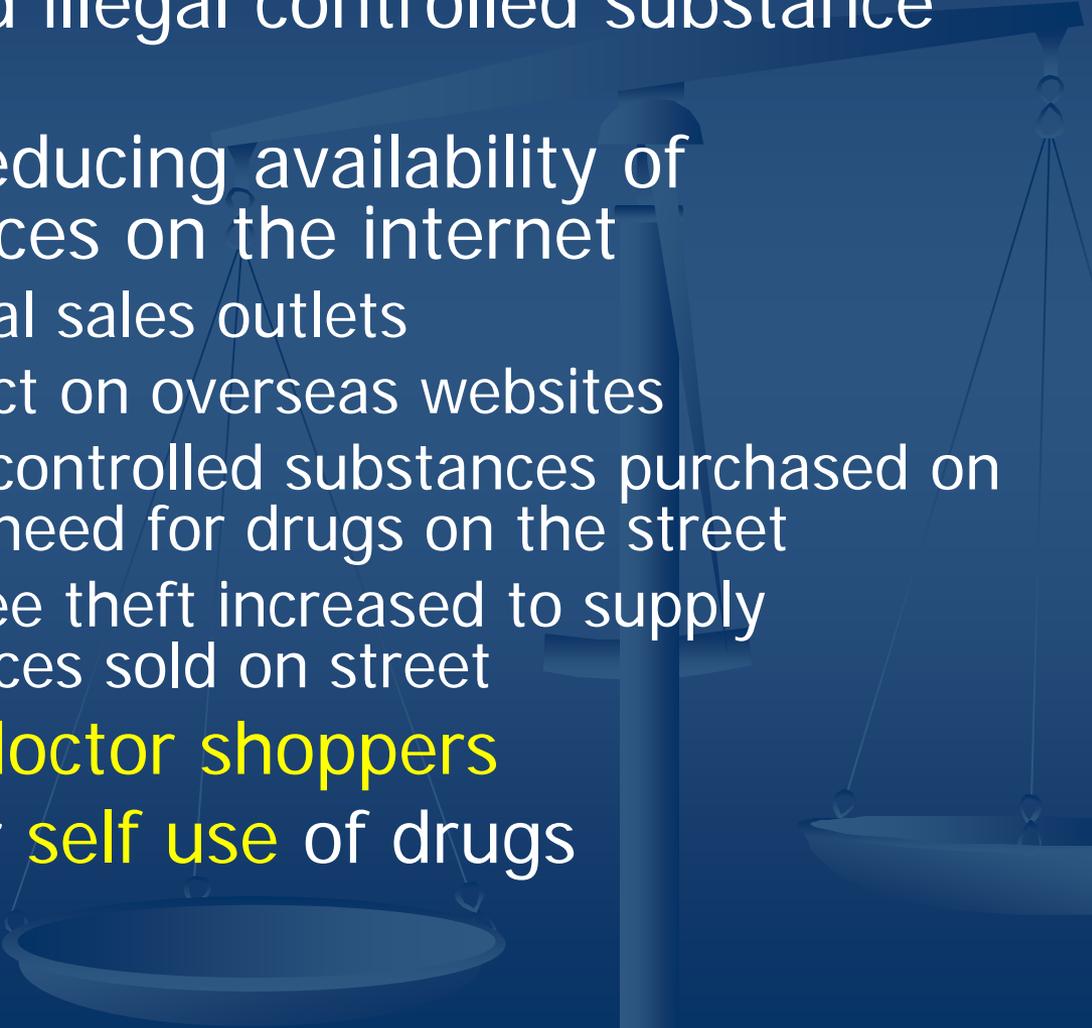
Pharmacists tend to think only of how much a drug costs or sells for, not the street value of the drug.

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

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

- Board of Pharmacy deals with the other 5%
 - Only when something wrong is it reported to us
 - We don't receive reports from the 95% of pharmacies where "things are fine "
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Why Is My Pharmacy a Target?

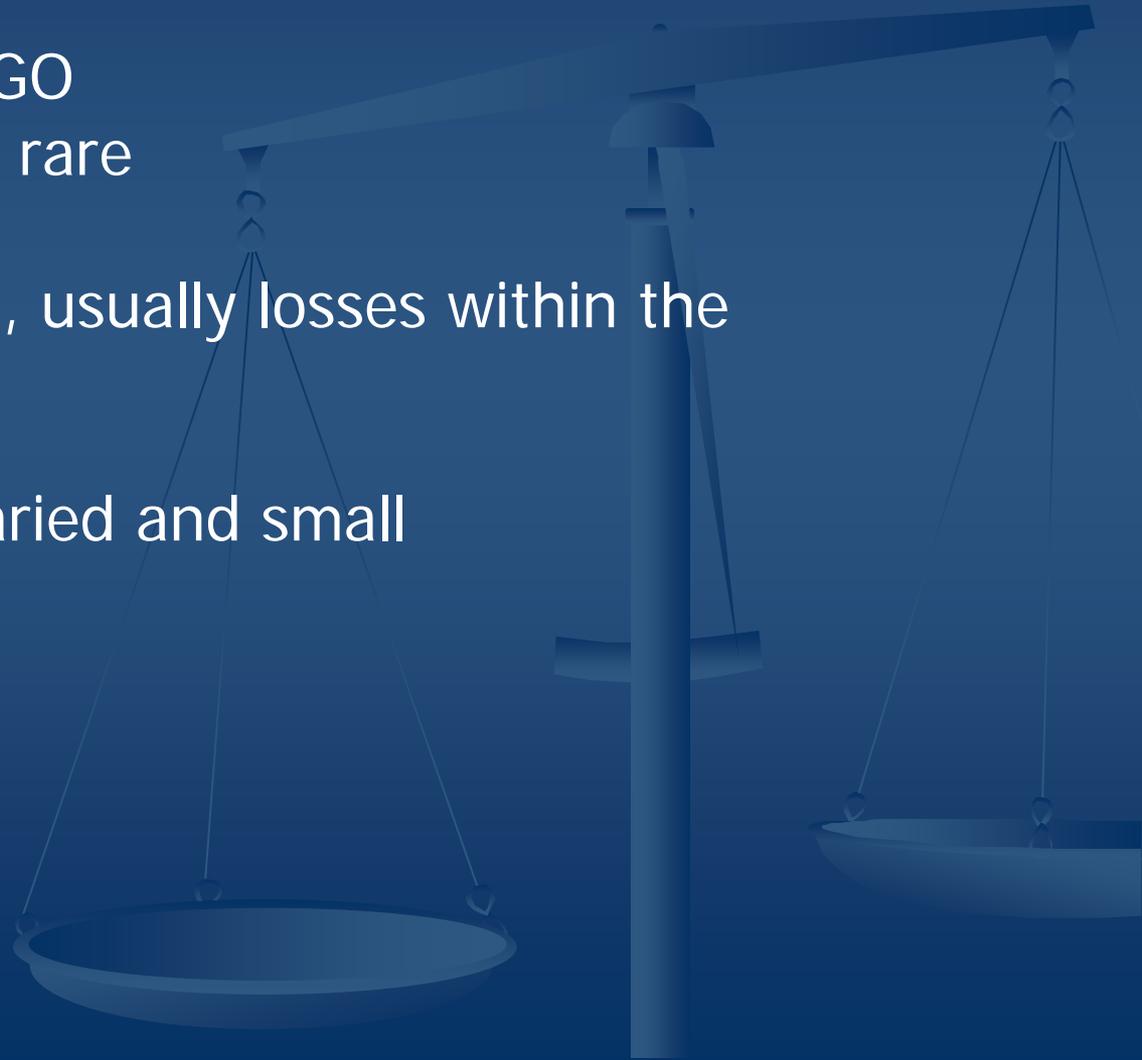
- **Internet** developed illegal controlled substance market
 - **Ryan Haight Act** reducing availability of controlled substances on the internet
 - Reduced U.S. illegal sales outlets
 - Not as much impact on overseas websites
 - More prescription controlled substances purchased on the street – more 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
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These Drugs Are Within Legitimate Supply Chain

- Only two ways those who want to illegally sell these drugs can obtain the drugs:
 - Steal drugs from a manufacturer, wholesaler, pharmacy, or patient
 - Robbery, break in, employee theft
 - Obtain a prescription and find a pharmacy to dispense that prescription
 - Sell the drugs obtained on the street illegally

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)

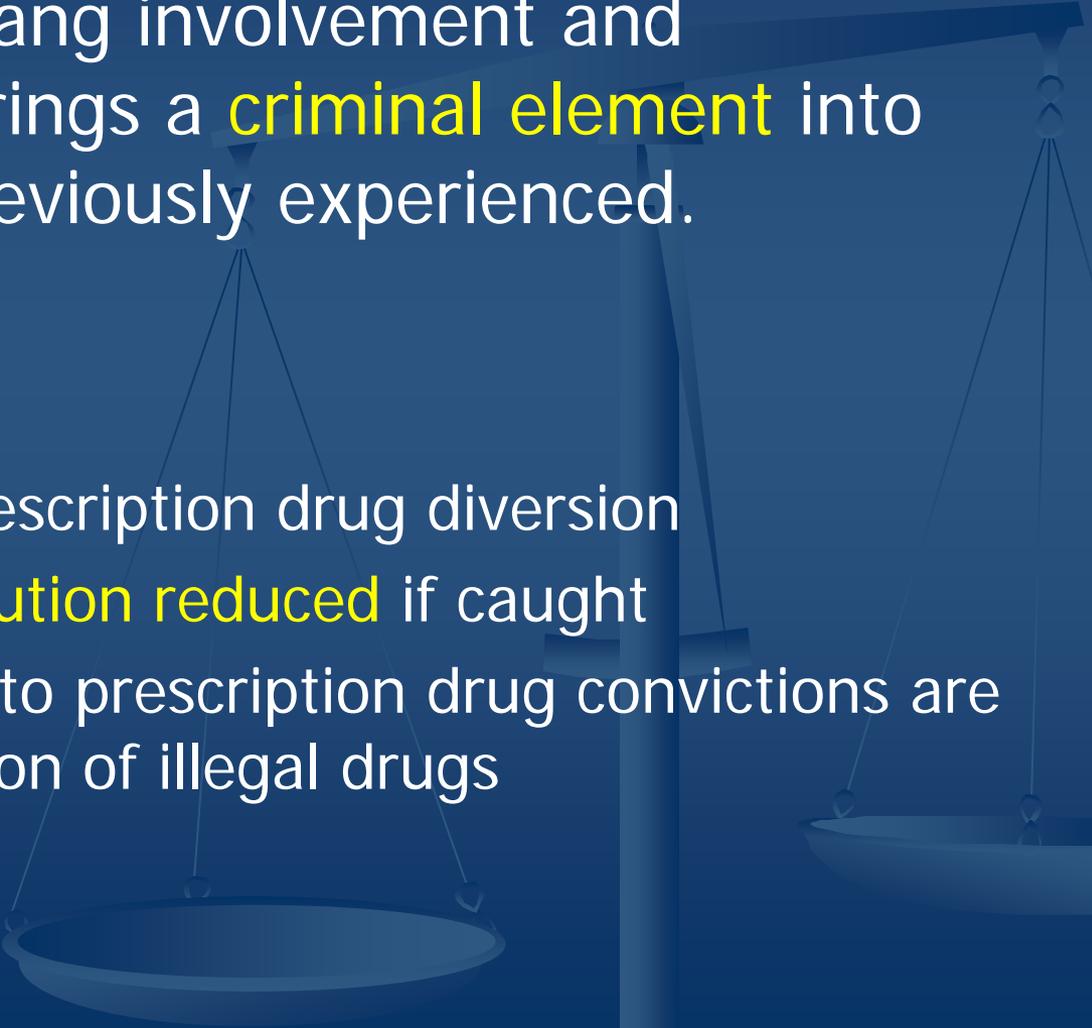
CHANGES IN CONTROLLED SUBSTANCE LOSS PROFILES (CONT)

- 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
 - 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 –
 - Obtain large numbers of prescriptions from **unethical prescribers**
 - 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

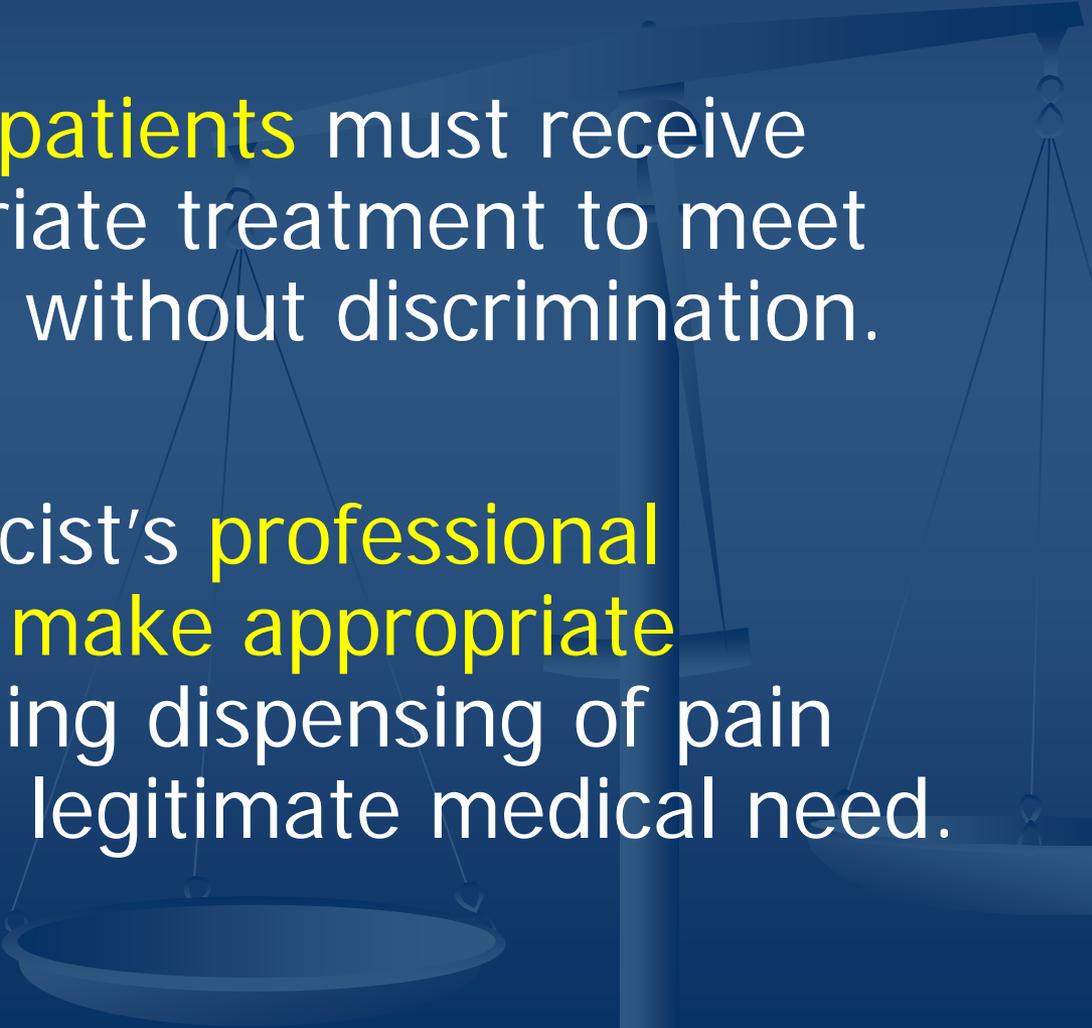
HOW OTHERS SEE PHARMACISTS

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 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

- **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.
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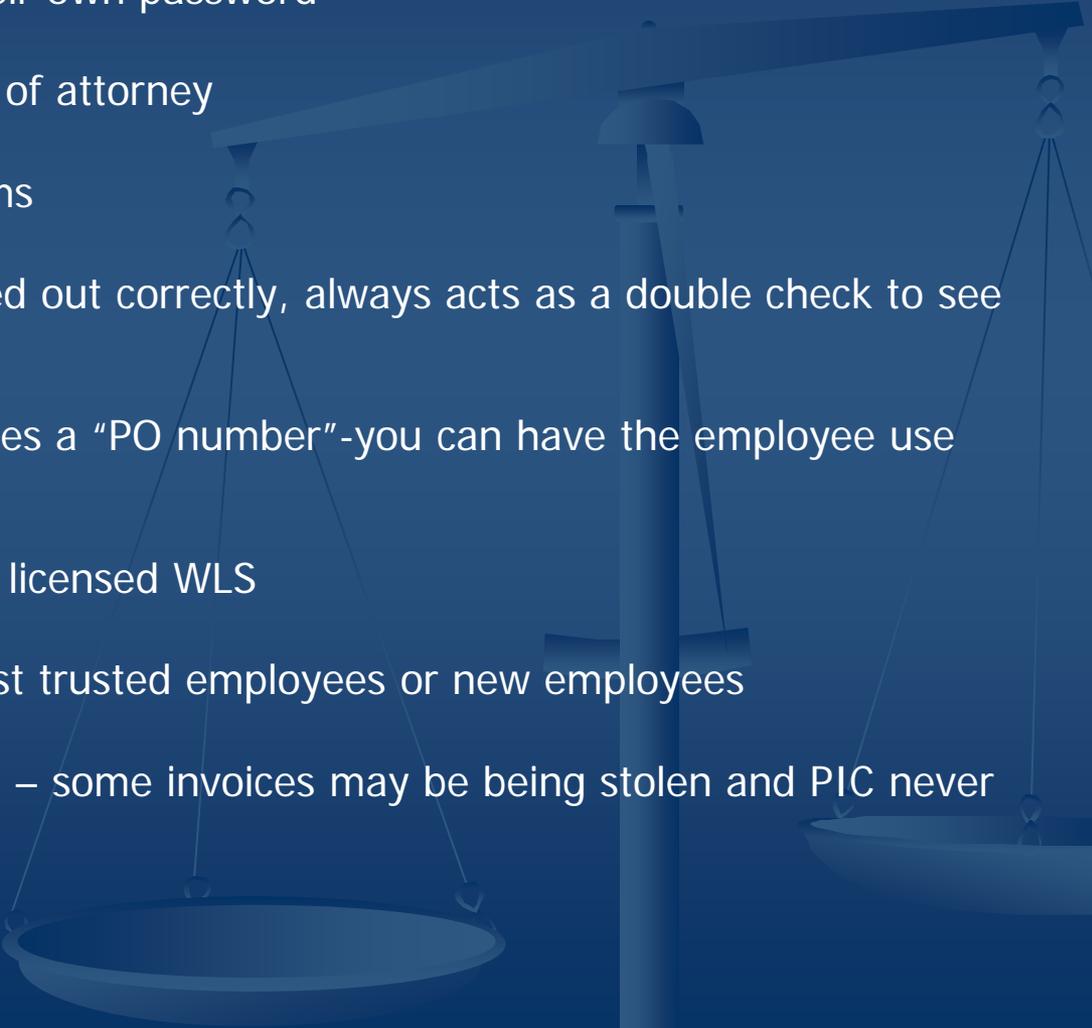
PREVENTING LOSS OF CONTROLLED SUBSTANCES FROM PHARMACY

- **Investigate employees** before hire, monitor and observe employees after hire
 - 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

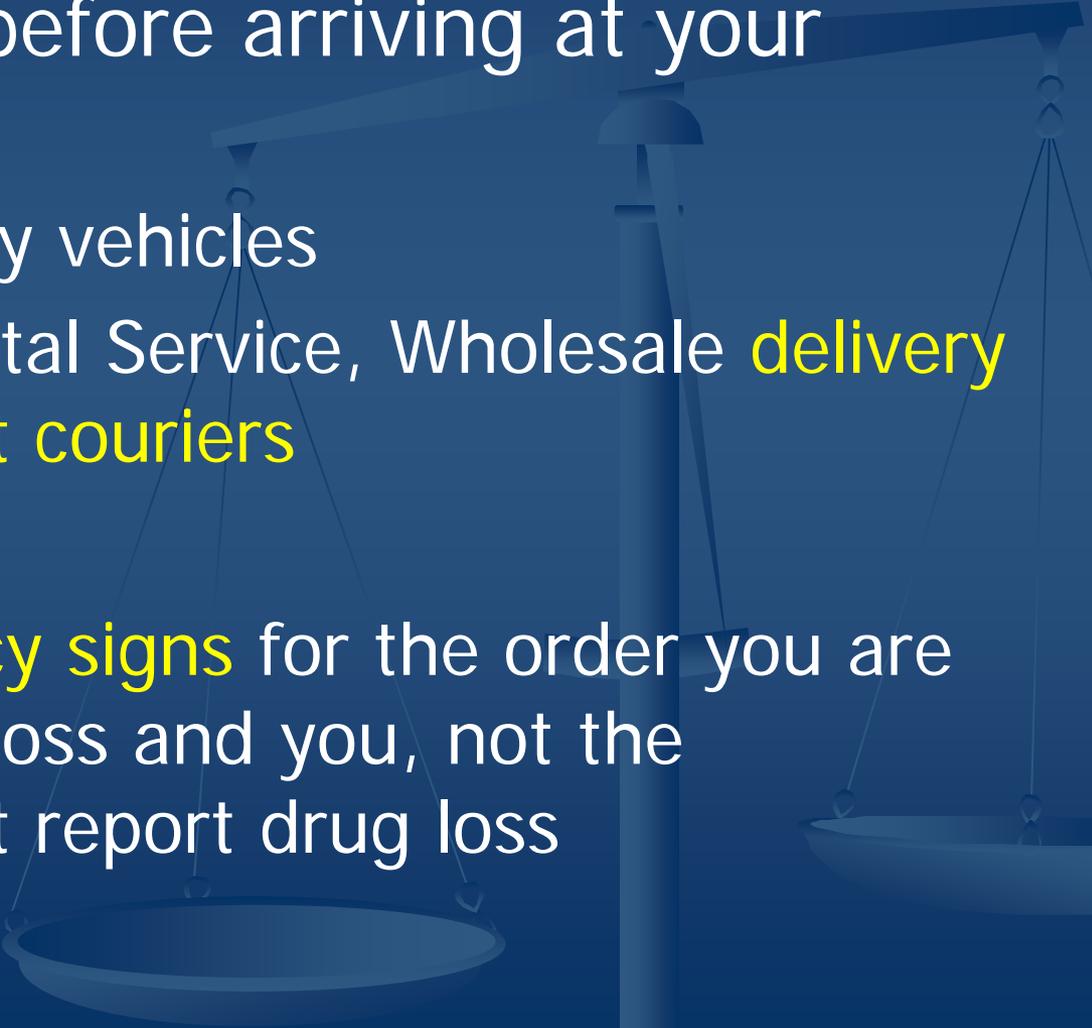
Pharmacy Prescription Drug Ordering

- 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
- -if more than one employee is allowed to order, do not use the same password
- -limit the amount of "super users"
- -try to minimize the number of orders placed per day, so that "extra" orders stick out.
- -try to minimize the amount 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
 - -do NOT 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.
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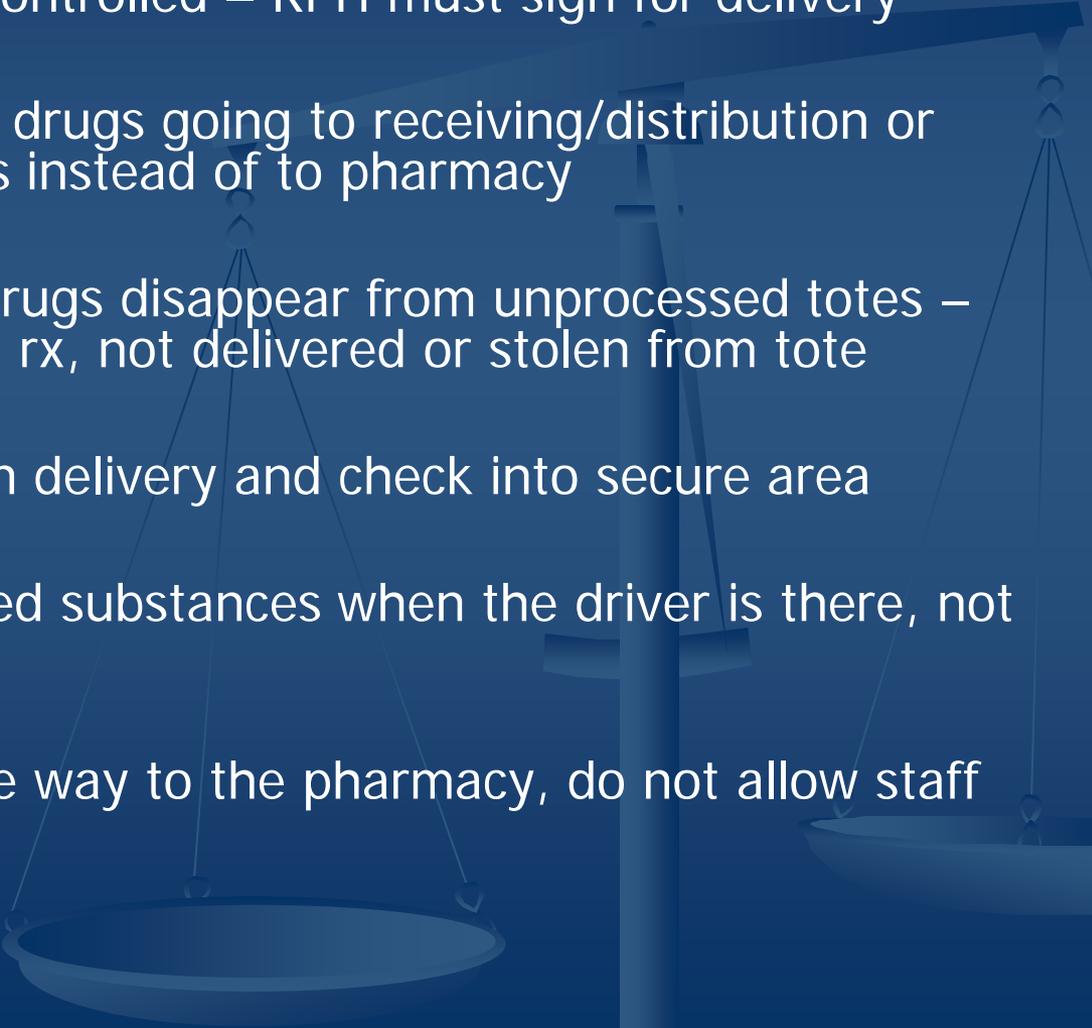
PHARMACY IN-TRANSIT LOSSES

- 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
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PHARMACY -RECEIPT OF DRUGS

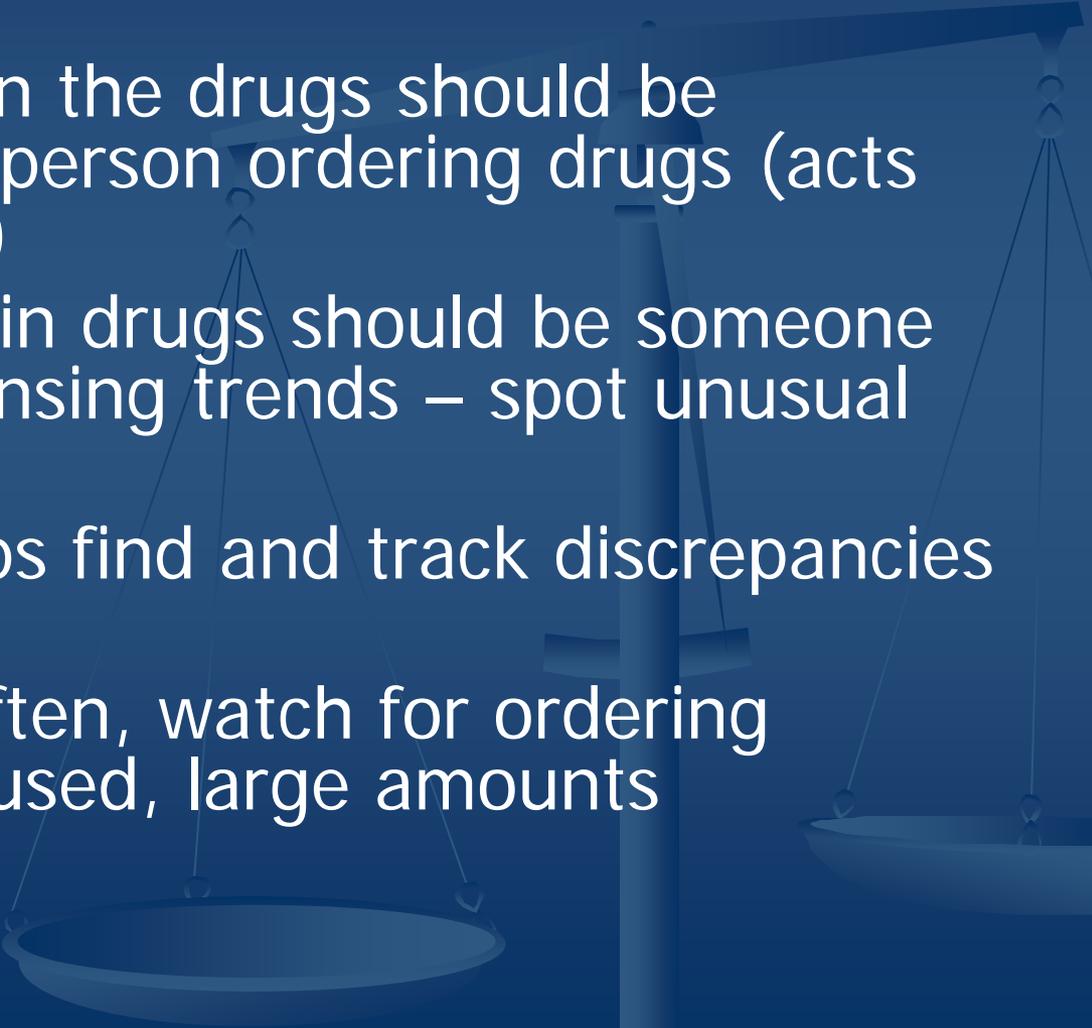
- CA Pharmacy Law requires **Pharmacist sign for all dangerous drug deliveries**
 - Code section written to protect Pharmacists
 - Drug could not be ordered and delivered to pharmacy and then diverted without a pharmacist knowing.

Prescription Drug Delivery to Pharmacy

- -non-controlled same as controlled – RPH must sign for delivery
 - 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 – 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
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Pharmacy

Order Check In – Controlled Substances

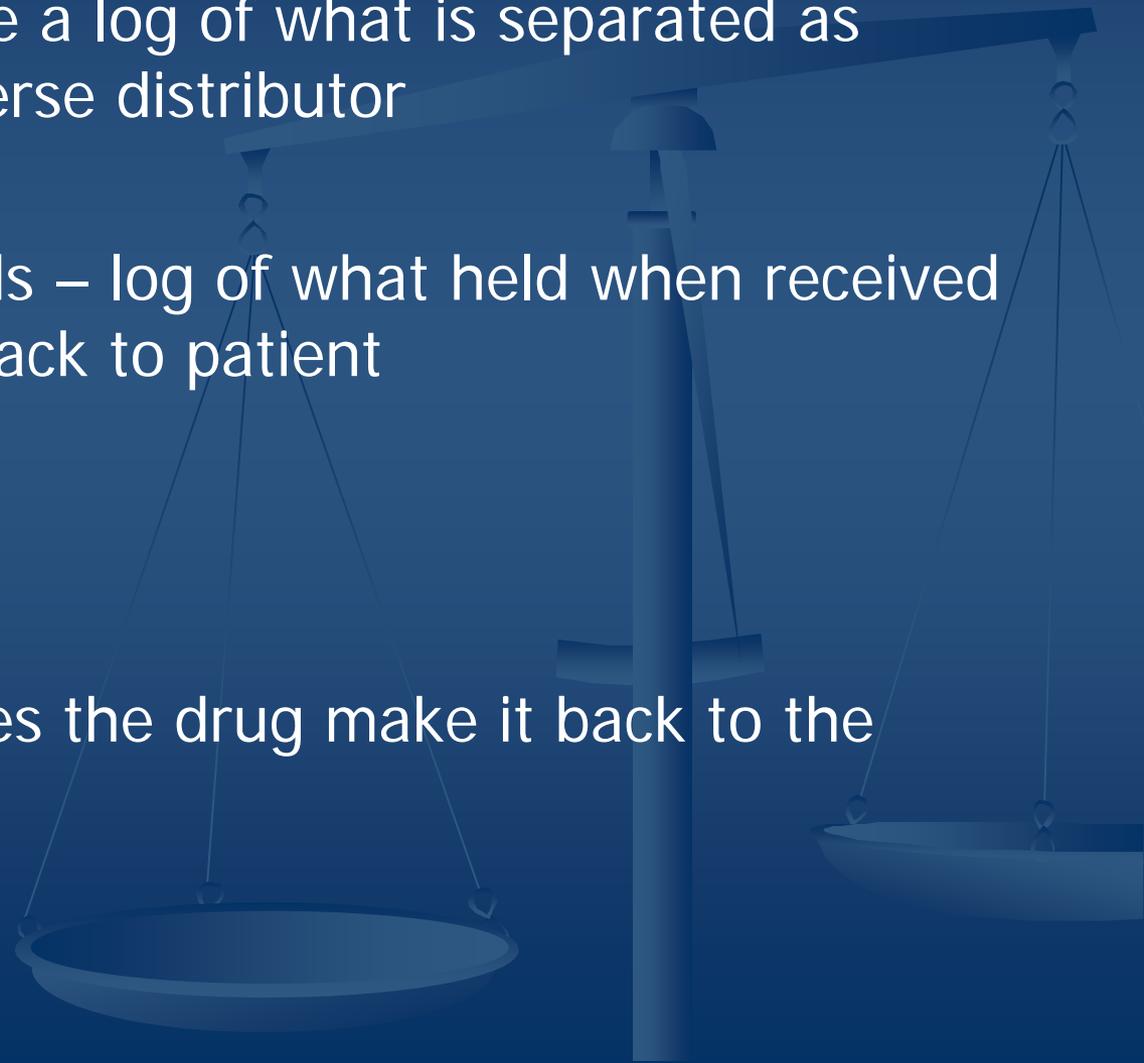
- -person checking in the drugs should be different from the person ordering drugs (acts as a double check)
 - - person checking in drugs should be someone familiar with dispensing trends – spot unusual orders
 - -perpetual log helps find and track discrepancies sooner
 - -review invoices often, watch 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
 - Store drugs, likely to be stolen, preferably 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
 - Store where staff can easily see who frequents the storage area.
 - Not in back of storage bays that cannot be easily viewed
 - Not near the restroom
 - Not near a rear exit
 - Not near storage area for employee personal items
 - Watch that fast movers are not stored too near any public access
 - Watch trash

Prescription Drug Storage (cont)

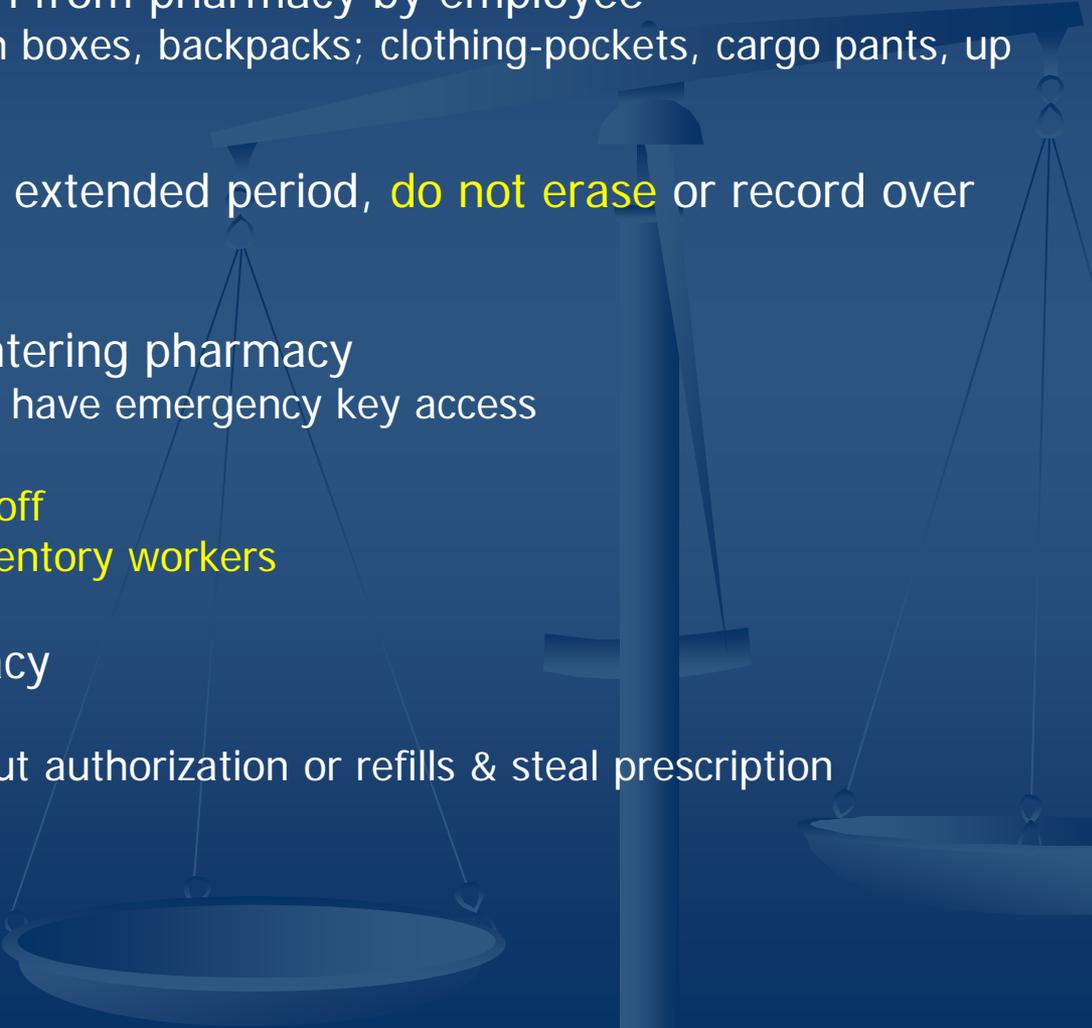
- Expired drugs – make a log of what is separated as expired awaiting reverse distributor
- Hospital – home meds – log of what held when received and when released back to patient
- Will call
- Return to stock – does the drug make it back to the stock shelves



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 very 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
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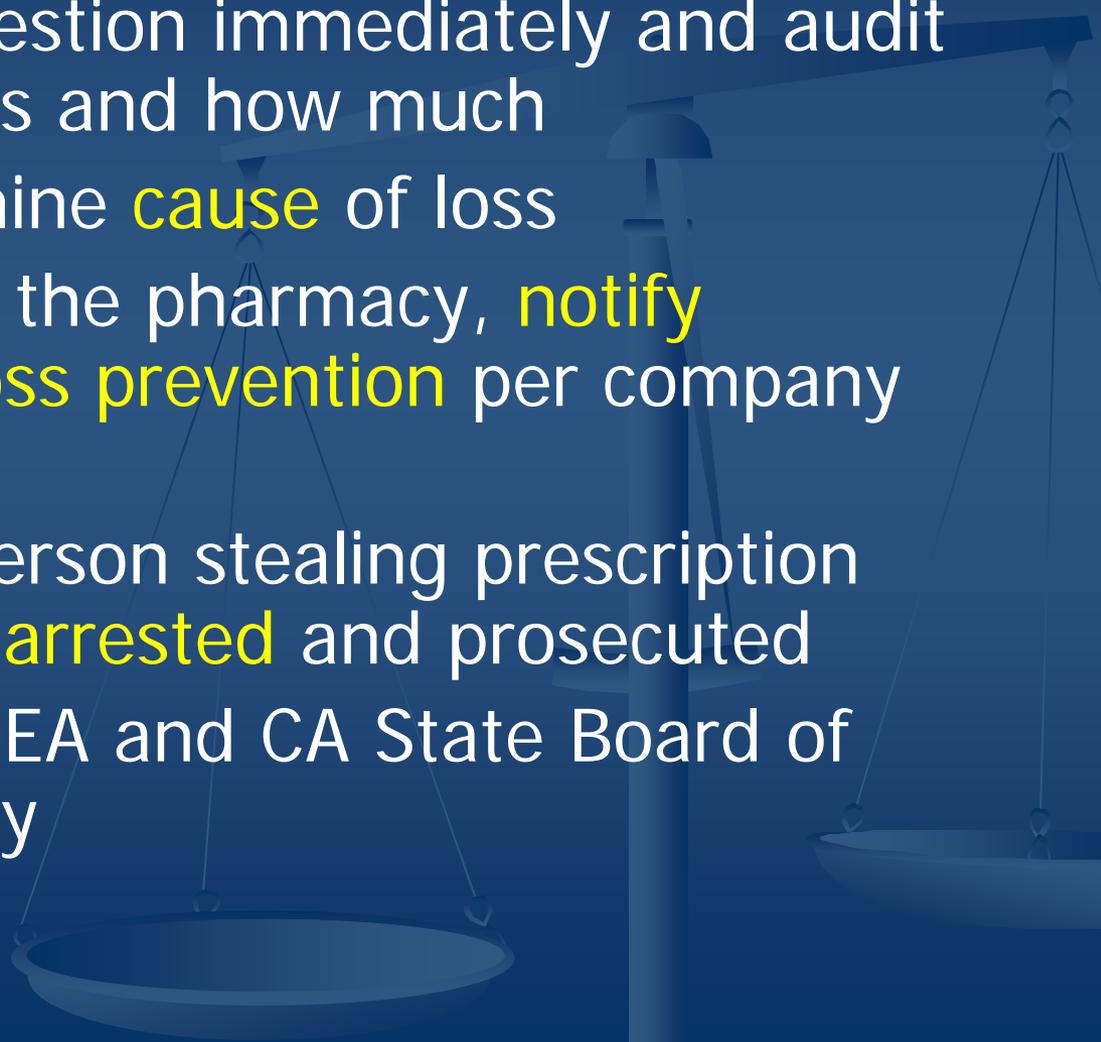
Dispensing Process Controlled Substances

- -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 in question immediately and audit to determine if loss and how much
 - Attempt to determine **cause** of loss
 - If you do not own the pharmacy, **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 supply frequently

suspected loss – count weekly and then increasingly more often until you identify when and how much is being lost.

identified loss – count as frequently as needed to determine what occurring

ie. 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 by determining 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

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

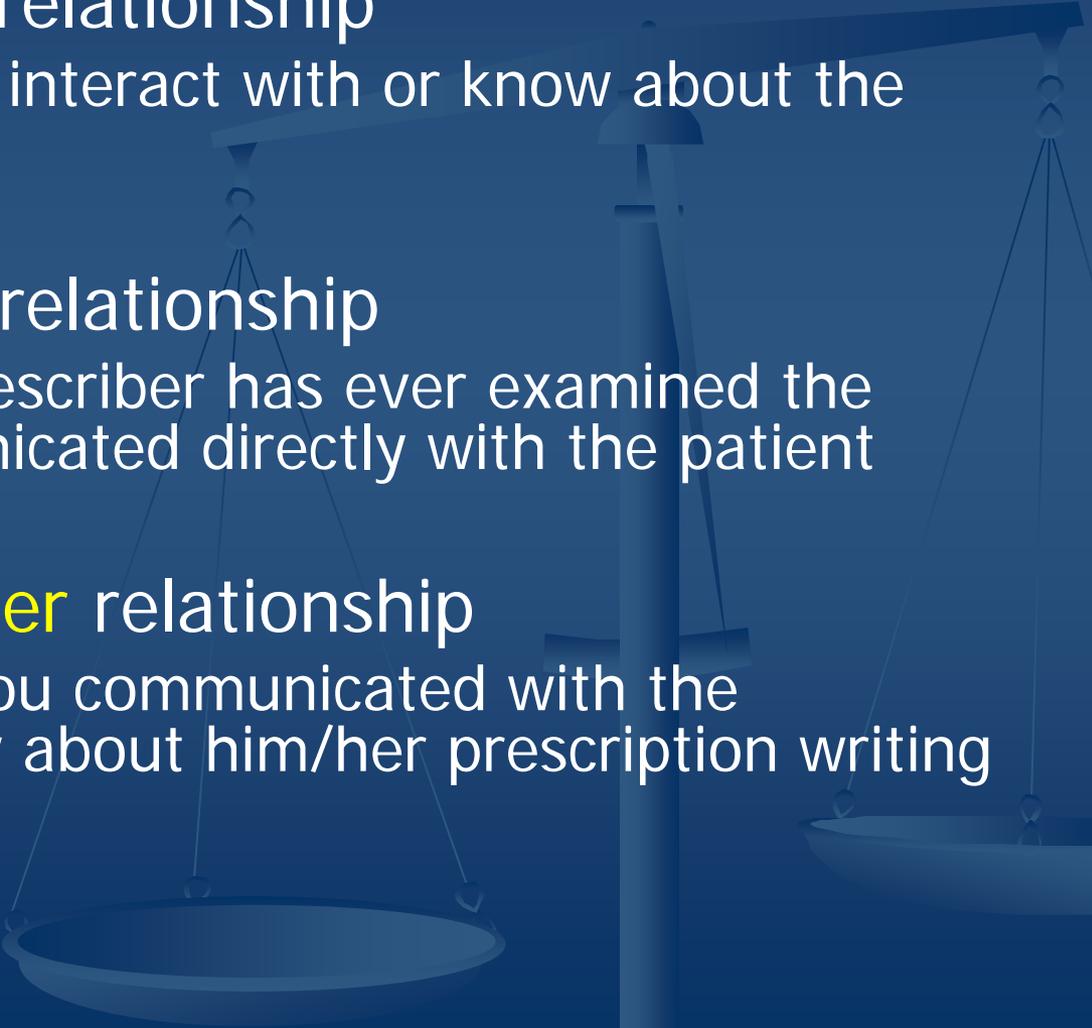
Reporting Impaired Licensees Mentally, Chemically, Physically

- 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

Appropriately Dispensing Controlled Substances – Corresponding Responsibility

- CA Health & Safety Code Section 11153
 - Prescriber must write a prescription for a **legitimate medical purpose** during his/her usual course of practice
 - Pharmacist has a **corresponding responsibility** to determine that prescription is for a legitimate medical need.
- CA Code of Regulations 1761(b)
 - even after **speaking with prescriber** – may refuse to fill rx

Corresponding Responsibility (cont)

- **Patient/pharmacy** relationship
 - How much do you interact with or know about the patient
 - **Patient/prescriber** relationship
 - Are you certain prescriber has ever examined the patient or communicated directly with the patient
 - **Pharmacy/prescriber** relationship
 - How much have you communicated with the prescriber or know about him/her prescription writing practices
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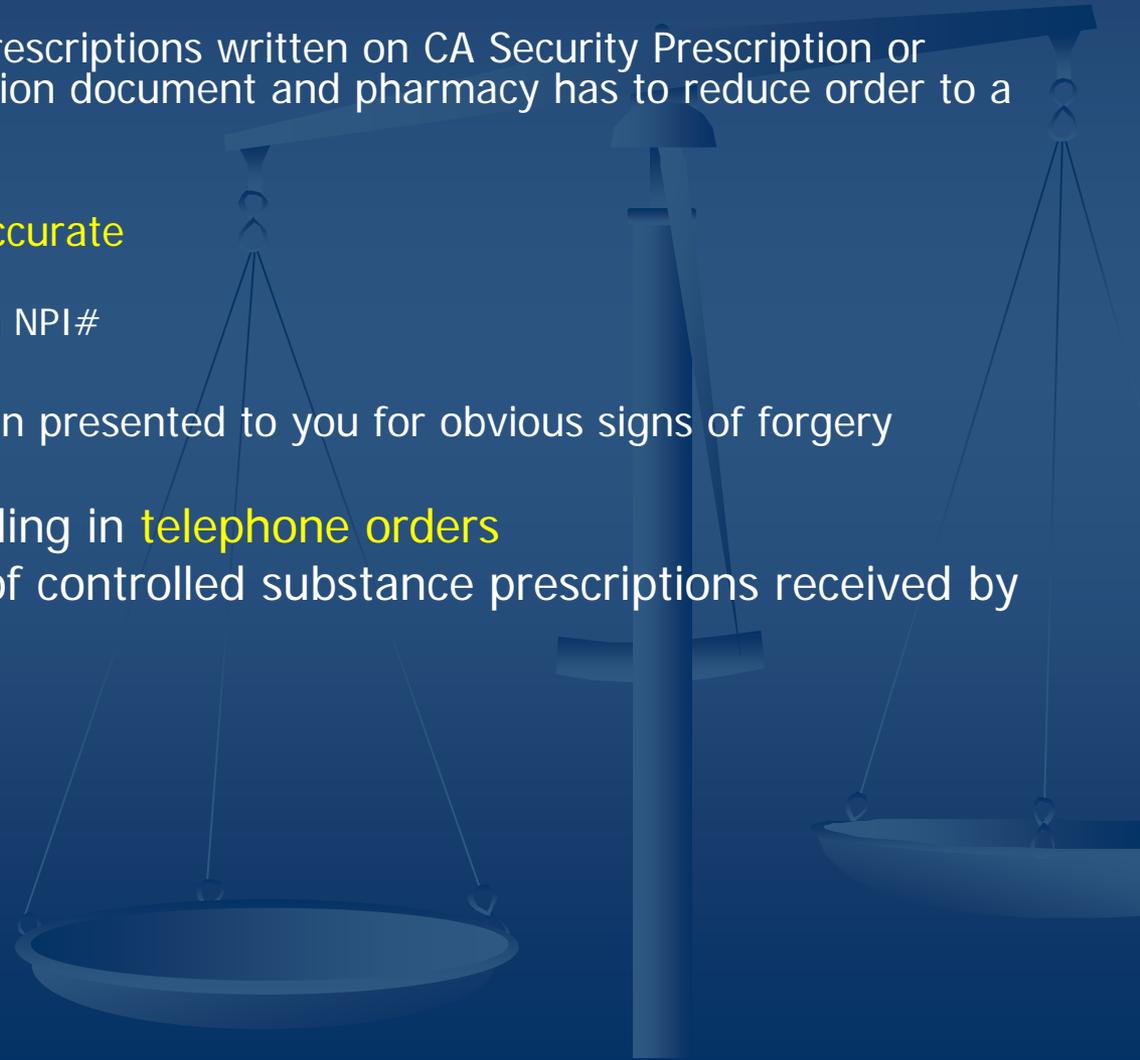
Should I Dispense This Prescription?

- Considerations
 - The prescription document
 - The prescriber
 - The patient
 - Appropriate drug therapy



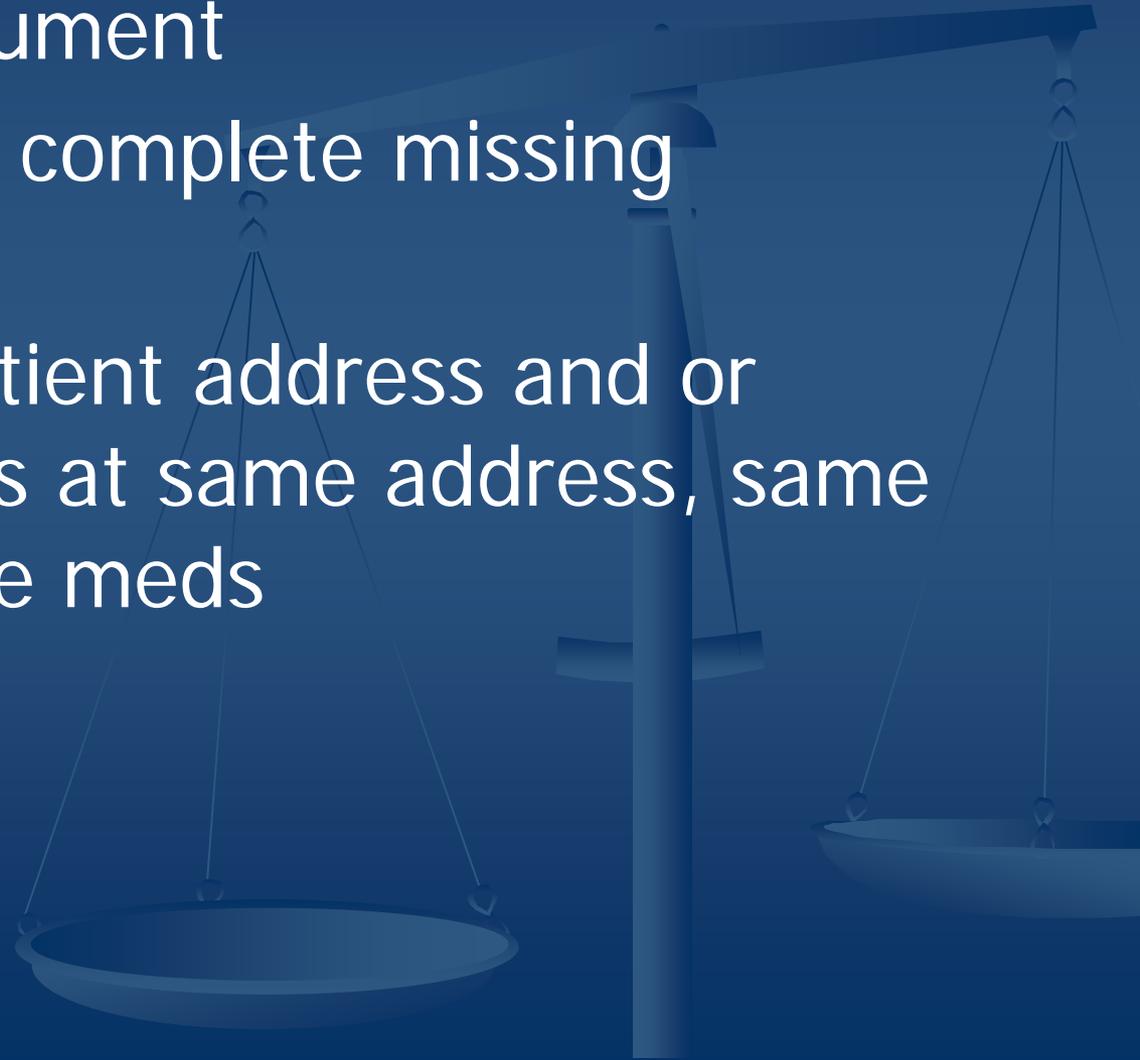
Evaluation of the Prescription

- CA Security Prescription
 - Are controlled substance prescriptions written on CA Security Prescription or written on normal prescription document and pharmacy has to reduce order to a telephonic order
 - Is prescriber information accurate
 - DEA number
 - Telephone number – from NPI#
 - Evaluate written prescription presented to you for obvious signs of forgery
- Do you know the person calling in telephone orders
- Are you sure of the source of controlled substance prescriptions received by fax.



OBVIOUS PROBLEMS WITH PRESCRIPTION DOCUMENT

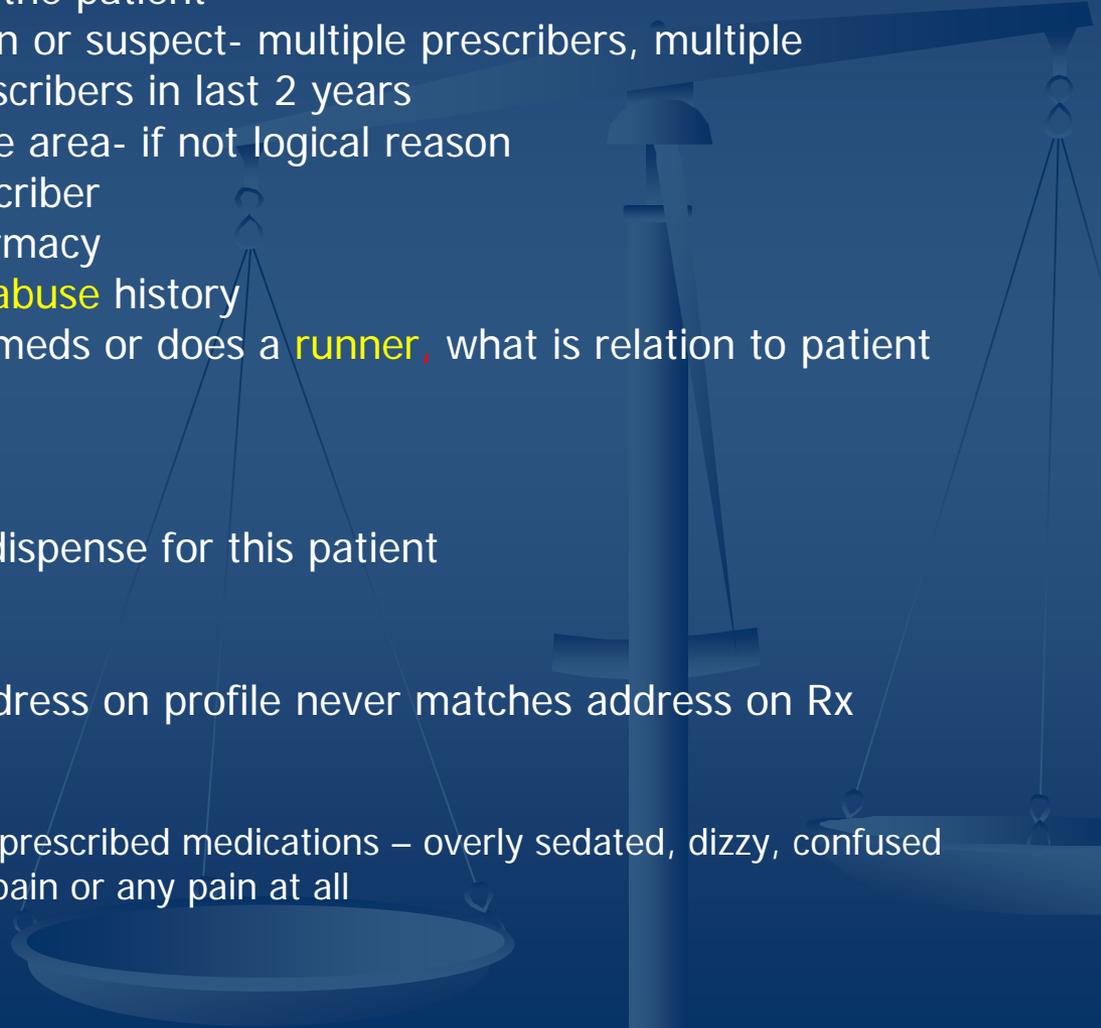
- CA security document
- Prescription not complete missing information
- Non existent patient address and or multiple patients at same address, same doctor and same meds



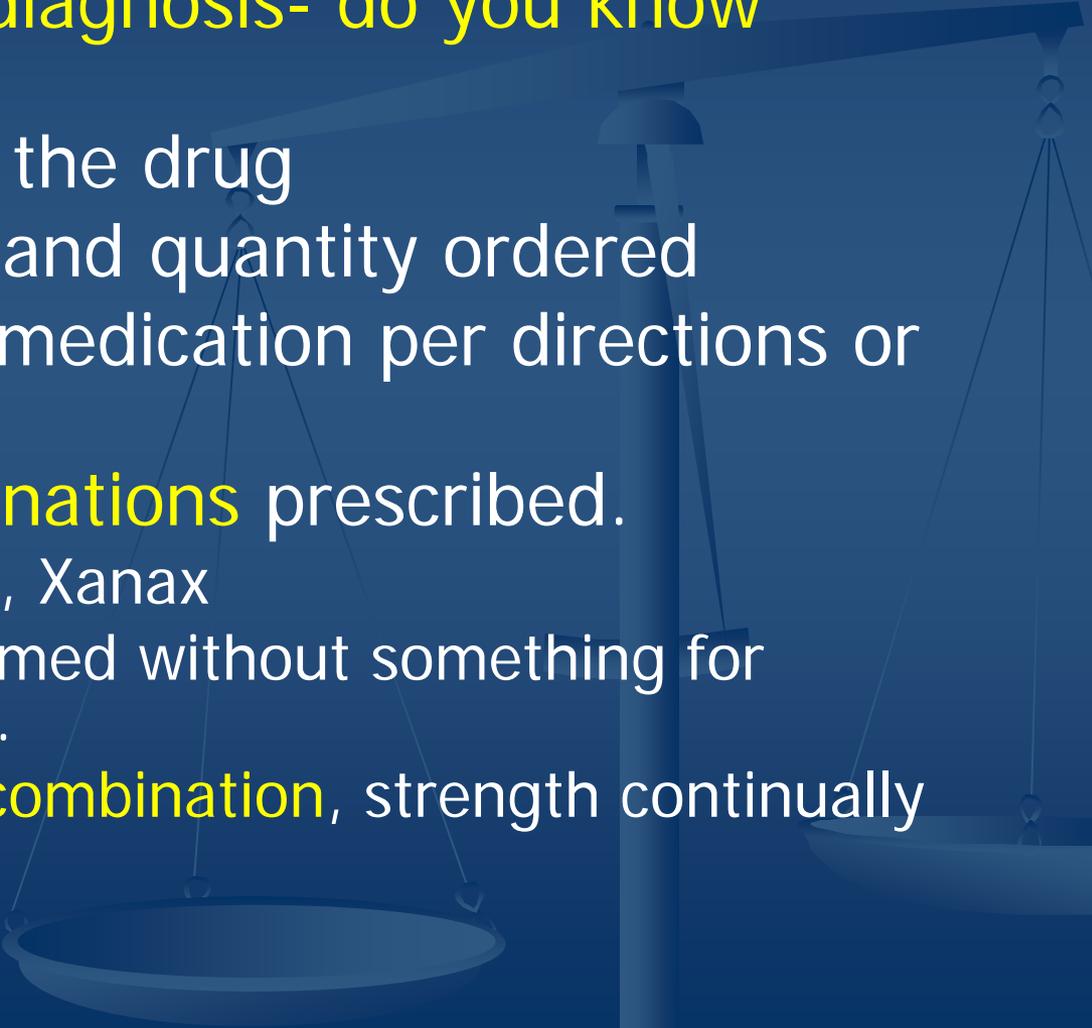
Evaluation of the Prescriber

- Status of **CA license** to practice medicine
 - Status of **DEA registration**
 - Status of **Medi-Cal provider** number
 - What is prescriber **specialty**- MBC data self reported
 - Any prior **discipline** of any type, **civil action, arrests. Google prescriber**
 - **Reputation or prescriber**
 - Prescribing practices
 - **Do you fill a mix of** dangerous drug and controlled substance prescriptions from this prescriber or only controlled substances – excessive percentage of controlled substances – usual **10-20%**
 - Does prescriber write for the **same combination of drugs**, same quantity and same directions for all or most patients
 - Do **one or 2 prescribers** represent a very high percentage of your controlled substance dispensing
 - How many rx's per day are filled for one prescriber.
- Is pharmacist ignoring warning signs and continuing to fill controlled substances for a particular prescriber

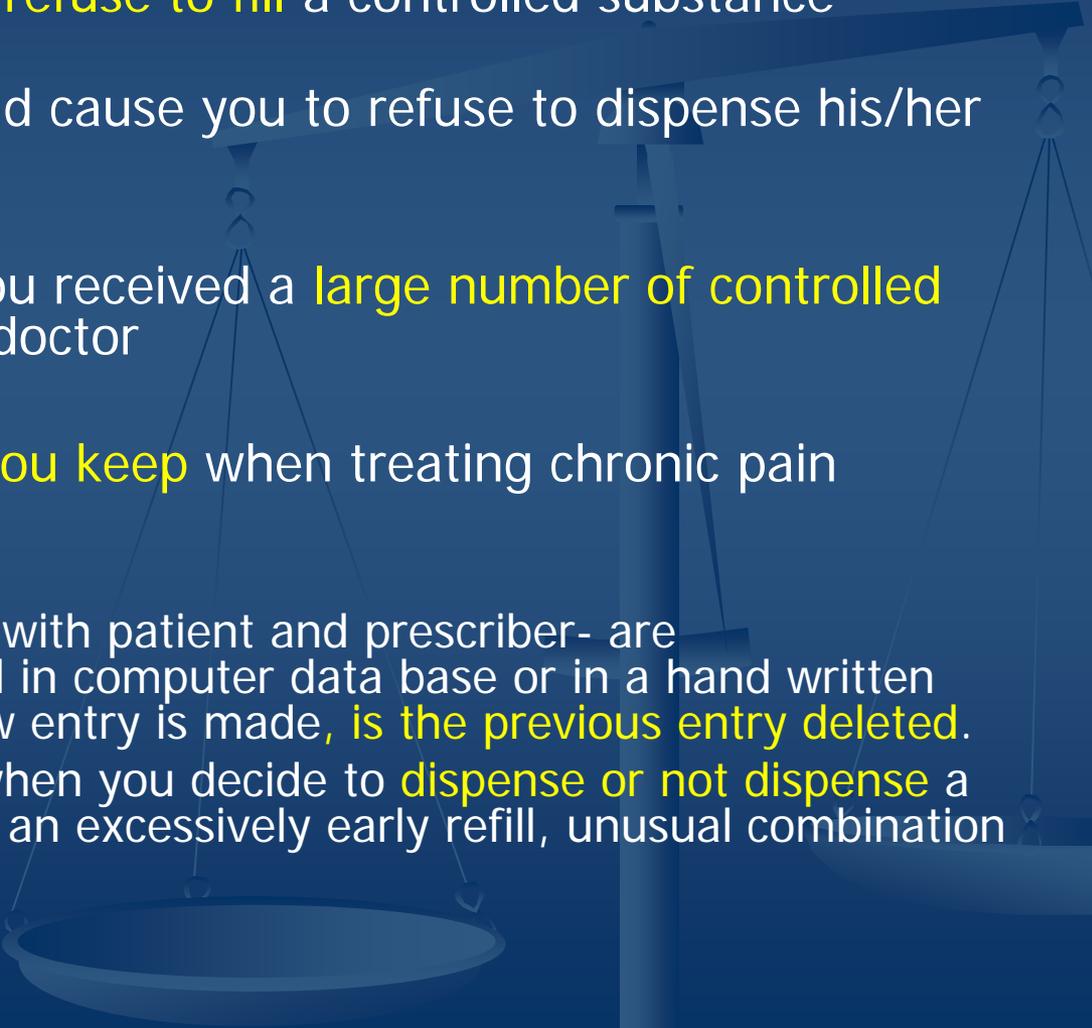
Evaluation of Information Available about the Patient

- Does the pharmacy know or **ID** the patient
 - **CURES report** if patient unknown or suspect- multiple prescribers, multiple pharmacies. How many prescribers in last 2 years
 - Does **patient live** in normal trade area- if not logical reason
 - Distance patient lives from prescriber
 - Distance prescriber is from pharmacy
 - Does patient have **addiction or abuse** history
 - Does patient pick up their own meds or does a **runner**, what is relation to patient
 - Patient **age**
 - **Diagnosis**
 - **Signed pain contract**
 - What **other medication** do you dispense for this patient
 - Method of payment – **cash**
 - Frequent **early refill** attempts
 - Frequent **address changes** – address on profile never matches address on Rx
 - Patient **appearance**
 - Does patient fit the diagnosis
 - Evaluate for adverse effects of prescribed medications – overly sedated, dizzy, confused
 - Does patient appear in severe pain or any pain at all
- 

Evaluation of Drug Therapy

- Does drug match diagnosis- do you know diagnosis
 - Abuse potential of the drug
 - Length of therapy and quantity ordered
 - Does patient take medication per directions or early refills
 - Are unusual combinations prescribed.
 - Oxycontin, Vicodin, Xanax
 - Time release pain med without something for breakthrough pain.
 - Same medication combination, strength continually
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Pharmacist - Evaluate Your Own Practice

- What would cause you to **refuse to fill** a controlled substance prescription
 - What about a **doctor** would cause you to refuse to dispense his/her prescriptions
 - How would you react if you received a **large number of controlled substances** from a single doctor
 - What **documentation** do **you keep** when treating chronic pain patients
 - **CURES** data
 - **Notes of communication** with patient and prescriber- are communications retained in computer data base or in a hand written document or when a new entry is made, **is the previous entry deleted.**
 - **How do you document** when you decide to **dispense or not dispense** a prescription that may be an excessively early refill, unusual combination of therapy etc.
- 

Pharmacist Real-Time Access to CURES Data

- ABSOLUTELY THE MOST IMPORTANT TOOL YOU HAVE TO ASSIST YOU WITH DECISION MAKING – IT'S FREE!
 - Pharmacist must be affiliated with a pharmacy
 - Pharmacist can only access CURES data to evaluate prescription history of a patient being treated by the affiliated pharmacy
 - Pharmacist must apply to Bureau of Narcotic Enforcement to receive real time access to CURES data
 - That application will be investigated to determine
 - if pharmacy is in good standing with board of pharmacy and DEA
 - If pharmacist is in good standing with board of pharmacy
- *Real time access important for staff working pm's, nights and week ends when prescriber not available.

REMEMBER

- YOU ARE THE PERSON WITH RESPONSIBILITY FOR THE SECURITY OF THE DRUGS. YOU ARE THE LAST LINE OF DEFENSE AGAINST DIVERSION OF THOSE DRUGS TO THE STREET, EITHER BY THEFT FROM YOUR PHARMACY OR INAPPROPRIATE DISPENSING OF CONTROLLED SUBSTANCES

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■ QUESTIONS?

CA State Board of Pharmacy

916-574-7900

www.Pharmacy.ca.gov

Virginia.Herold@dca.ca.gov

Judi.Nurse@dca.ca.gov

Janice.Dang@dca.ca.gov

QUESTIONS



Contact Us

www.pharmacy.ca.gov

916-574-7900

Internet Prescriptions/ Internet Pharmacy

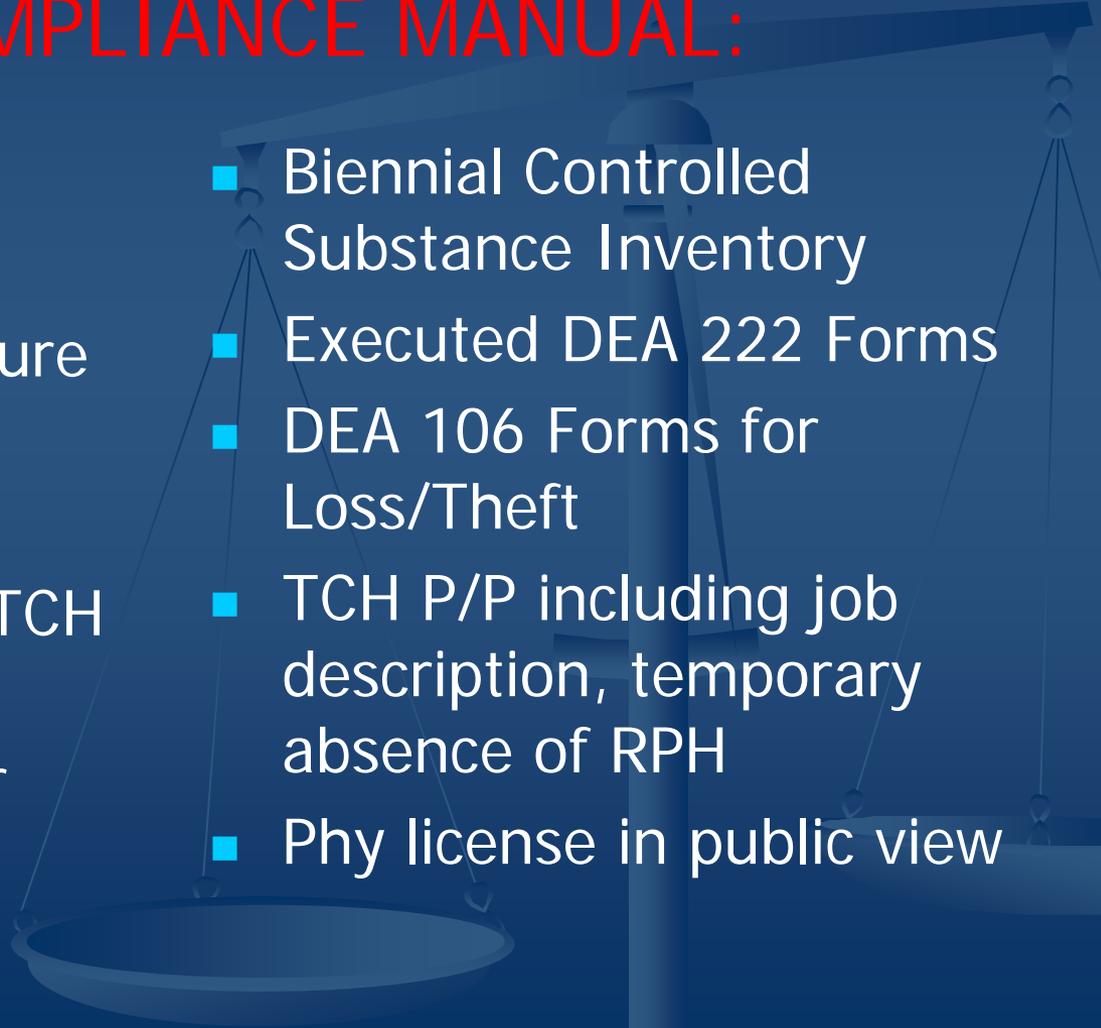
- Business & Professions Code section 4067
 - Dispensing internet prescription for a CA patient without a good faith medical exam can result in a fine of \$25,000 per prescription.
 - This code section written to stop this profit based dispensing of drugs to CA patients. You dispense those prescriptions you will be fined \$25,000 per prescription
 - Good faith medical exam is usually defined as one actual examination by the prescriber
 - Good faith medical exam is not –
 - Dispensing based only on a questionnaire completed by the patient on the internet
 - Dispensing utilizing medical records provided by patient documenting previous medical treatment

Don't Let Your Pharmacy be a Victim of Internet Dispensing Scam

- Internet marketer **cold calls** pharmacy
- Offers you as many **prescriptions per day** as you want to dispense
- You **access website** and request number of prescriptions you want to dispense.
- Prescription labels, ancillary patient information and shipping **label print out** at your pharmacy
- **Prescription documents held by website**, not your pharmacy. If inspected not able to access documents
- You dispense rx, and mail to patient
- You are **paid by the internet marketer** not the patient
- Usually \$5.00 to \$10.00 plus cost of drug. The internet marketer charges the patient as much as \$200 for the prescription
- **Cheaper for patient to pay for prescriber office visit and pay pharmacy cost of drug**
- You have no patient/pharmacy relationship. You have no physician/pharmacy relationship. You don't know if there is a prescriber/patient relationship. You have only a **pharmacy/internet marketer relationship**

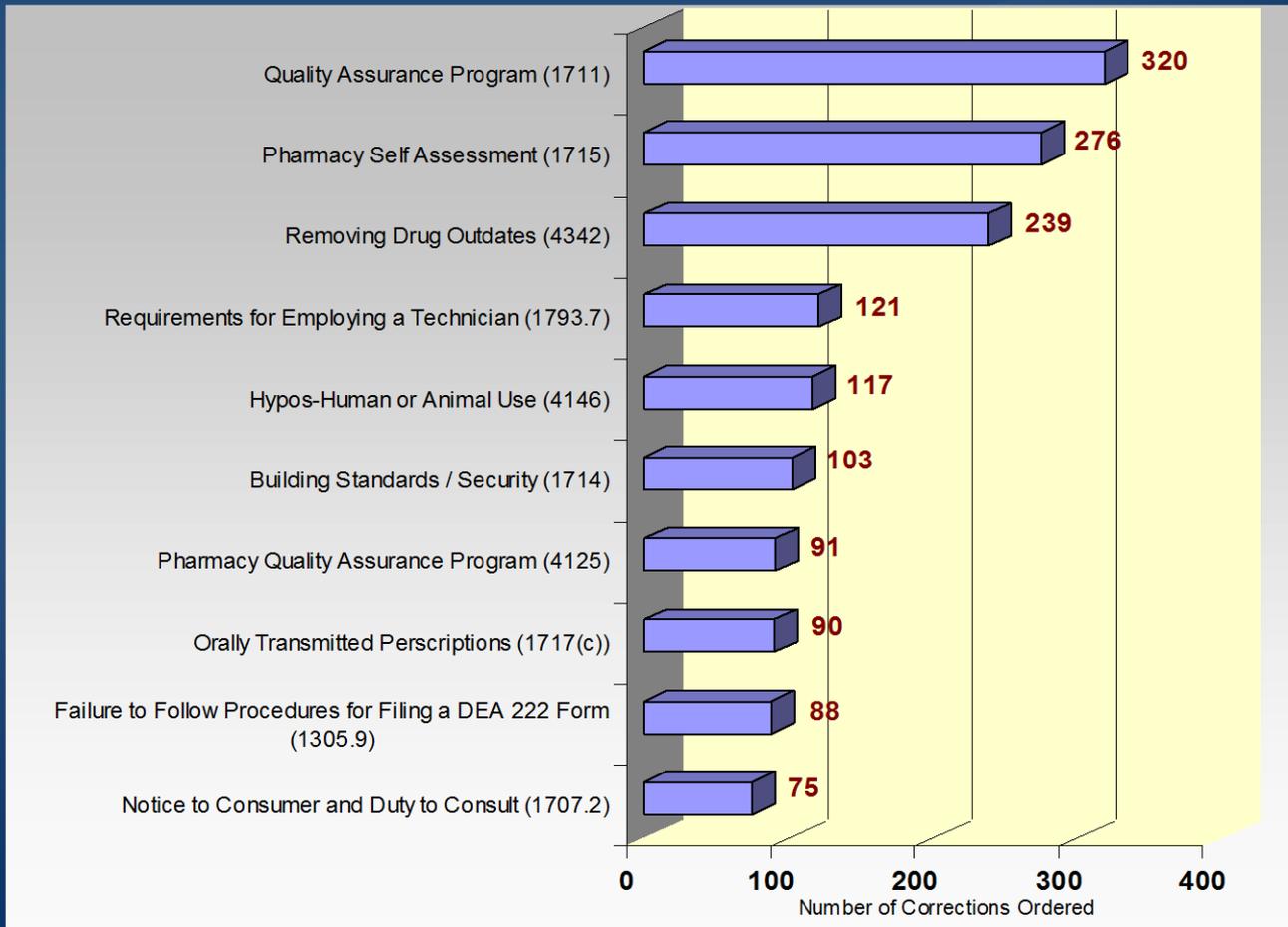
HOW TO PREPARE FOR A PHARMACY INSPECTION

PHARMACY COMPLIANCE MANUAL:

- 
- Self Assessment
 - Quality Assurance
 - 4104 Policy & Procedure
 - Copies of RPH & TCH licenses
 - Master list of RPH & TCH initials/signature
 - Power of Attorney for DEA 222 Forms
 - Biennial Controlled Substance Inventory
 - Executed DEA 222 Forms
 - DEA 106 Forms for Loss/Theft
 - TCH P/P including job description, temporary absence of RPH
 - Phy license in public view

INSPECTION PROCESS

Top 10 Corrections



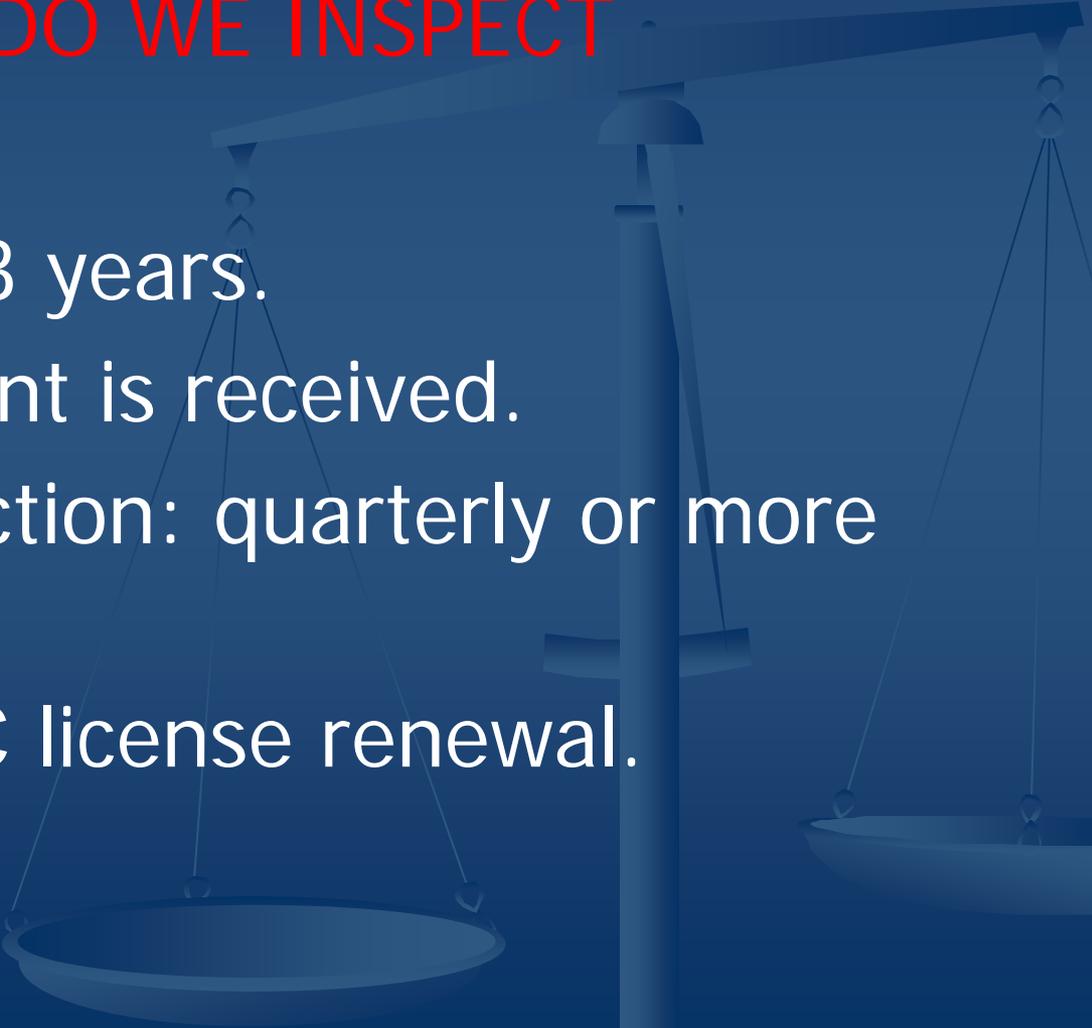
INSPECTION PROCESS

WHAT DO WE INSPECT

- Pharmacies (5993)
 - Hospital Pharmacies (491)
 - Drug rooms (44)
 - Licensed Sterile Compounders (221)
 - Clinics (1084)
 - Licensed Correctional Facilities (45)
 - Wholesalers (455)
 - Veterinary Food Animal Retailers (23)
 - Probationers (100)
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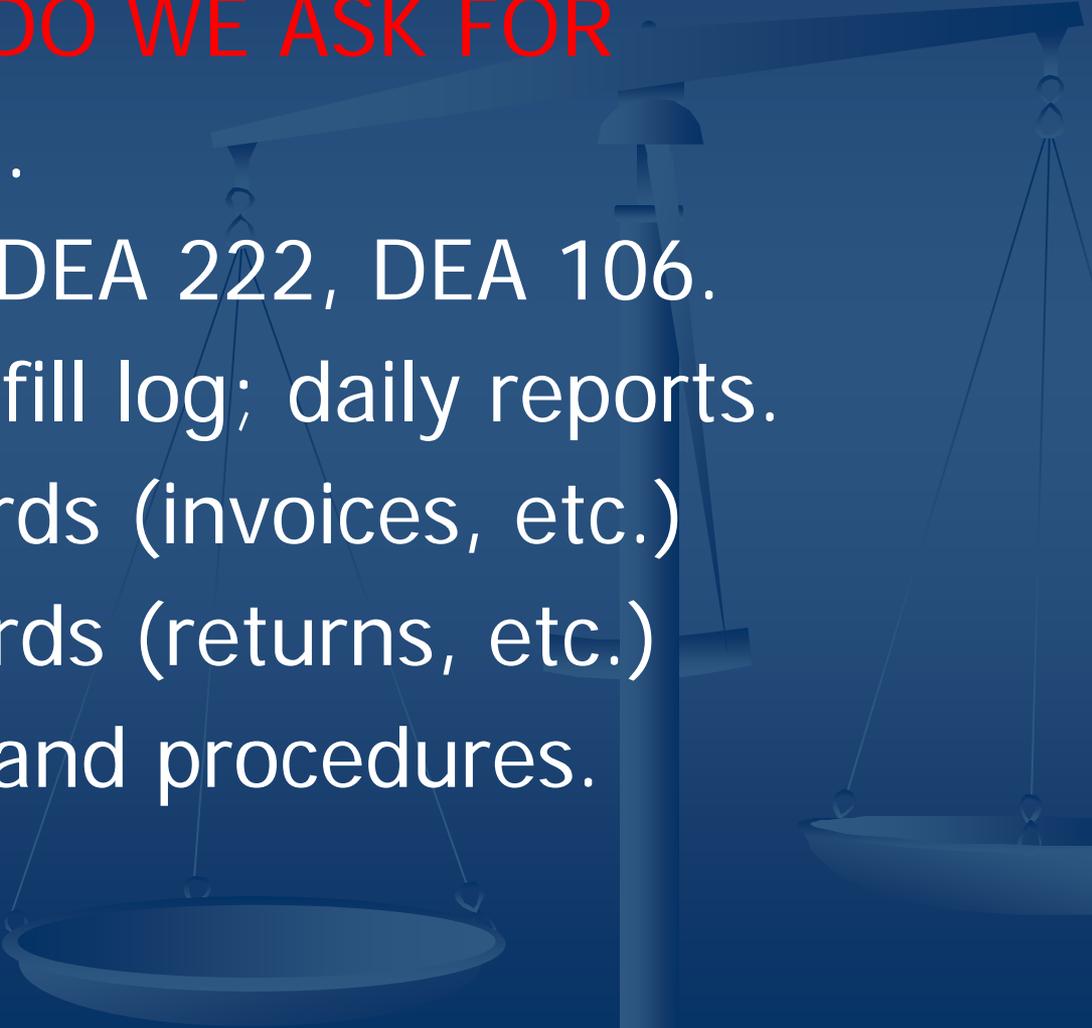
INSPECTION PROCESS

WHEN DO WE INSPECT

- Routine: Every 3 years.
 - When a complaint is received.
 - Probation inspection: quarterly or more frequent.
 - Annually for LSC license renewal.
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INSPECTION PROCESS

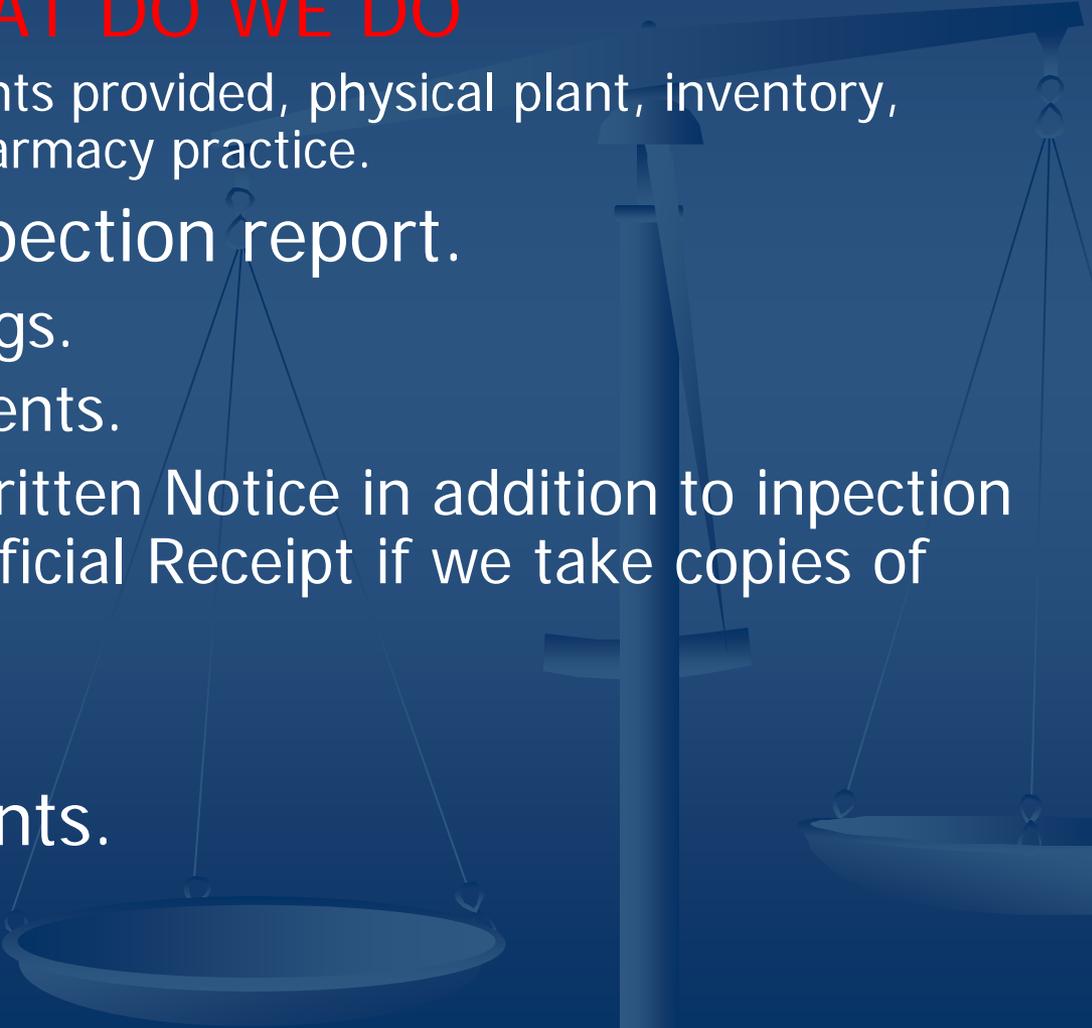
WHAT DO WE ASK FOR

- Self-Assessment.
 - DEA Inventory, DEA 222, DEA 106.
 - Prescriptions; refill log; daily reports.
 - Acquisition records (invoices, etc.)
 - Disposition records (returns, etc.)
 - Review policies and procedures.
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INSPECTION PROCESS

WHAT DO WE DO

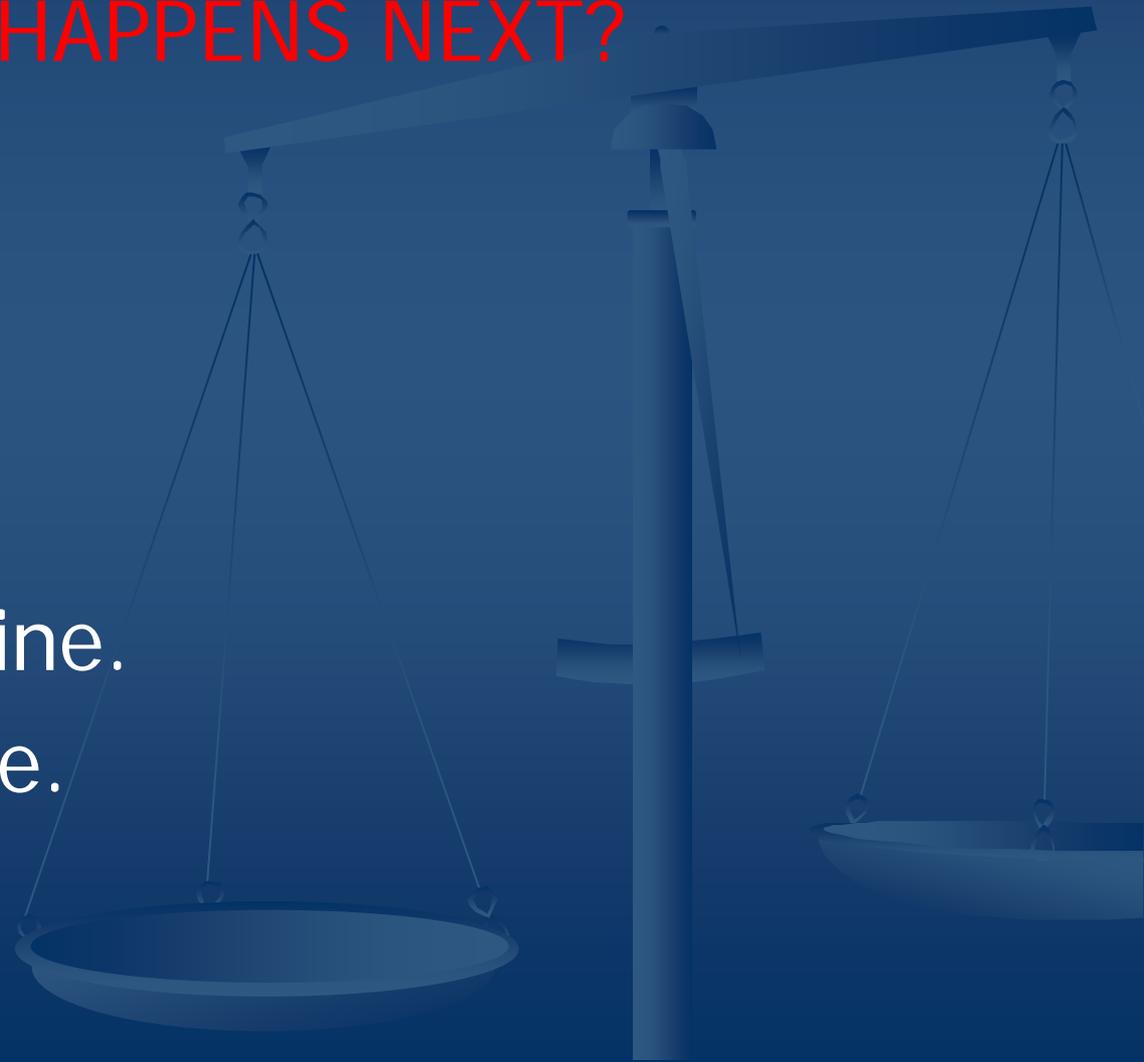
Review records and documents provided, physical plant, inventory, security, sanitation, pharmacy practice.

1. Complete an inspection report.
 - Document findings.
 - Inspector comments.
 - May include a Written Notice in addition to inspection report and an Official Receipt if we take copies of any documents.
 2. Exit interview.
 3. Licensee comments.
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INSPECTION PROCESS

WHAT HAPPENS NEXT?

- Discussion.
- Correction.
- Written notice.
- Informal Discipline.
- Formal Discipline.



DISCIPLINARY PROCESS



- Informal Discipline
 - Letter of Admonishment
 - Citation without Fine
 - Citation with Fine

BPC 4315 – LOA; BPC 4314 – C&F

Appeal process – Office Conference, Administrative Hearing

- Formal Discipline- Administrative action taken against either pharmacy license or pharmacist license.
 - Probation
 - Suspension
 - Revocation
 - Require participation in Pharmacist Recovery Program

Accusation filed by CA State Attorney General, Administrative Hearing or Stipulated Agreement. Appeal process to Superior Court

Thank You

