



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES**

DATE: November 14, 2013

LOCATION: Department of Consumer Affairs
First Floor Hearing Room
1625 North Market Blvd.
Sacramento, Ca 95834

BOARD MEMBERS

PRESENT: Stanley C. Weisser, President
Amy Gutierrez, PharmD, Vice President
Greg Lippe, Public Member, Treasurer
Victor Law, RPh
Ramón Castellblanch, PhD, Public Member
Rosalyn Hackworth, Public Member
Albert Wong, PharmD
Deborah Veale, RPh
Lavanza Butler, PharmD
Randy Kajioka, PharmD

**BOARD MEMBERS
NOT PRESENT:** Tappan Zee, Public Member
Ryan Brooks, Public Member
Shirley Wheat, Public Member

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Joshua Room, Supervising Deputy Attorney General
Michael Santiago, DCA Staff Counsel
Kristy Shellans, DCA Staff Counsel
Carolyn Klein, SSM2
Laura Hendricks, Staff Analyst

Note: A webcast of this meeting can be found at:

<http://www.youtube.com/watch?v=qYdu8wkvEgo&feature=youtu.be&noredirect=1>

CALL TO ORDER

President Weisser called the meeting to order at 10:00 a.m.

I. GENERAL ANNOUNCEMENTS

President Weisser conducted a roll call. Board members present: Randy Kajioka, Gregg Lippe, Rosalyn Hackworth, Debbie Veale, Lavanza Butler and Victor Law.

Note: Albert Wong arrived at 10:10 a.m., Amy Gutierrez arrived at 10:24 a.m. and Ramon Castellblanch arrived at 10:42 a.m.

III. DISCUSSION AND POSSIBLE ACTION TO INITIATE A RULEMAKING TO AMEND TITLE 16 CALIFORNIA CODE OF REGULATIONS SECTIONS 1715, 1735.2 AND 1784, TO UPDATE THE SELF-ASSESSMENT FORMS FOR PHARMACIES, HOSPITALS, WHOLESALERS AND COMPOUNDING PHARMACIES

Background

Pharmacy Law requires pharmacies and wholesalers to conduct self-assessments on or before July 1 of each odd-numbered year to promote compliance with various federal and state laws and regulations through self-examination and education. Self-assessment forms also serve as an easy reference guide for a Pharmacist-in-Charge (PIC) or a Designated Representative-in-Charge (DRIC). A self-assessment is required any time there is a change in the PIC or DRIC, when a new permit/license is issued; or (for a wholesaler) when there is a change of address.

Several new laws went into effect in 2013, and many of the changes to the self-assessment forms reflect these new laws:

- AB 377 – c. 687, Statutes 2012, Centralized Packaging Pharmacy
- SB 41 – c. 738, Statutes 2011, Hypodermic needles and syringes
- SB 360 – c. 418, Statutes 2011, Pharmacies: access to CURES reports
- SB 431 – c. 646, Statutes 2011, Pharmacies: regulation (mandated reporting to the board of theft, diversion or self-use of dangerous drugs by a licensee)
- SB 1301 – c. 709, statutes 2012, Prescription drugs: 90-day supply
- SB 1329 – c. 709, Statutes 2012, Prescription Drugs: collection and distribution program
- SB 1481 – c. 874, Statutes 2012, Clinical laboratories: community pharmacies

Additional changes were added where references to (existing) statutes provided clarity. For example, where the Community Pharmacy Self-Assessment addressed controlled substances

inventory (Section 19 of Form 17M-13), a new item is proposed to provide a reference to existing federal regulation that requires the inventory record indicate if the inventory was taken at the “open of business” or the “close of business.”

Title 16 CCR § 1715 incorporates two self-assessment forms:

Form 17M-13 – Community Pharmacy Self-Assessment; Hospital Outpatient Self-Assessment

Form 17M-14 – Hospital Self-Assessment

Title 16 CCR § 1735.2 incorporates one self-assessment form:

Form 17M-39 – Compounding Self-Assessment

Note: The proposed changes to Section 1735.2 and to the self-assessment do not reflect the current discussions of the Enforcement/Compounding Committee and the board related to the implementation of recently-enacted legislation (SB 294 and AB 1045) related to compounding and non-resident compounding pharmacies. The majority of the changes to Form 17M-39 reflect new items that reference requirements for a centralized hospital packaging pharmacy (as a result of AB 377, c. 687 statutes 2012).

Title 16 CCR § 1784 incorporates one self-assessment form:

17M-26 – Wholesaler Self-Assessment

The meeting materials contained the proposed regulatory text to amend Title 16 California Code of Regulations Sections 1715, 1735.2 and 1784. Also attached are proposed amendments to the four self-assessment forms, which are incorporated by reference in these sections (all with proposed revision dates of “11/13”).

Staff is not recommending that a regulation hearing be conducted on this regulatory action, unless one is requested

Discussion

Carolyn Klein provided an overview of the rulemaking and directed the board and the public to the meeting materials to view the entire rulemaking.

Ms. Klein noted that three *minor* changes had been made to the rulemaking document since the meeting materials were released. Copies of the updated language were provided to the board members and the public. Ms. Klein reported that all of the changes were about the community pharmacy self-assessment forms. Ms. Klein walked through each minor change and highlighted that none of the changes were substantive, the changes were designed to have the form better reflect the statutory language. Ms. Klein also explained that many of the changes to the forms are the result of feedback from the board inspectors on common violations they encountered.

Ms. Klein informed the board that each change was provided to legal for review to ensure the changes accurately reflect statute.

President Weisser walked the board and the public through each change on the community self-assessment form to allow for board and public comment. No comments were received from the board or from the public.

Community Pharmacy Self-Assessment

Motion: Approve the changes to the Community Pharmacy Self-Assessment Form.

M/S: Lippe/Hackworth

Support: 7 Oppose: 0 Abstain: 0

Hospital Pharmacy Self-Assessment

Motion: Approve the changes to the Hospital Pharmacy Self-Assessment Form.

M/S: Lippe/Hackworth

Support: 7 Oppose: 0 Abstain: 1

Wholesaler Self-Assessment

Motion: Approve the changes to the Wholesaler Self-Assessment Form.

M/S: Lippe/Gutierrez

Support: 9 Oppose: 0 Abstain: 0

Compounding Self-Assessment Form

Dr. Gutierrez asked if the self-assessment forms will be updated as the new compounding regulations are implemented. Ms. Herold and Mr. Room confirmed that this document will be updated as changes occur.

Motion: Approve the changes to the Compounding Self-Assessment Form

M/s: Lippe/Hackworth

Support: 9 Oppose: 0 Abstain: 0

Motion: Direct staff to initiate the formal rulemaking process to amend the text of 16 CCR Sections 1715, 1735.2 and 1784 and the Self-Assessment Forms incorporated by reference in those sections, as proposed at this meeting. Authorize the Executive Officer to make any non-substantive changes to the rulemaking package, and provide a 45-day public comment period. If no negative comments are received, direct staff to take all steps necessary to complete the rulemaking process, including the filing of the final rulemaking package with the Office of Administrative Law, delegate to the Executive Officer the authority to make any

non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt the proposed regulations at Sections 1715, 1735.2 and 1784 as described in the notice.

M/S: Lippe/Hackworth

Support: 9 Oppose: 0 Abstain: 0

IV. REGULATION REPORT

Background

Status of the Board's Proposal to Add Title 16, California Code of Regulations, Sections 1747 and 1747.1 Related to E-Pedigree – Serialized Numeric Identifiers, Specification of Pedigreed Dangerous Drugs in California by January 1, 2015 and January 2016, Identification of Non-serialized Stock Remaining After E-Pedigree Implementation (Grandfathering)

As discussed at the board meeting held October 29, 2013, the board received verbal notification on October 18, 2013, that the Office of Administrative Law (OAL) would be disapproving the board's proposed rulemaking to add Title 16, California Code of Regulations (CCR) Sections 1747 and 1747.1 related to E-Pedigree. A formal Notice of disapproval was issued thereafter on October 25, 2013.

On October 31, 2013, the board received a **Disapproval Decision** from OAL. A copy of the Disapproval Decision was provided in the meeting materials. The regulation text itself was not questioned by OAL. The basis of OAL's disapproval was discussed in length in the Disapproval Decision, and are briefly summarized below.

First, OAL determined that the "necessity standard" was not met as it relates to the requirement that certain declarations (required by 1747.1) be made under penalty of perjury. OAL stated that because the Initial Statement of Reasons did not include statement as to the specific purpose of requiring a declaration be made under penalty of perjury, nor address why this provision was necessary, the board did not meet the "necessity standard" for these declarations.

Second, OAL determined that the board's economic impact assessment did not meet the requirements of Government Code section 11346.3(b)(1) which requires an agency to assess whether and to what extent the rule would affect the following:

- The creation of or elimination of jobs within the state;
- The creation of new businesses or the elimination of existing businesses in the state;
- The expansion of businesses currently doing business within the state, and
- The benefits of the regulation to the health and welfare of California residents, worker safety and the state's environment.

Following a disapproval, the board has 120 days to correct the items identified in OAL's Disapproval Decision and resubmit the file to OAL for review. The Disapproval Decision was issued on October 31, 2013; thus, the file must be resubmitted to OAL no later than February 28, 2014.

To correct the deficiencies outlined in the Disapproval Decision, staff is preparing an *Addendum to the Initial Statement of Reasons* to address the "necessity standard" as it relates to the board's requirement that declarations be made under penalty of perjury.

Likewise, staff is preparing an *Addendum to the Economic Impact Statement* to address whether and to what extent the rule will affect the items outlined in Government Code section 11346.3(b)(1).

When finalized, staff will prepare a "Notice of Documents Added To The Rulemaking File" and issue the notice for a 15-day comment period. In accordance with the board's motion on October 29, 2013, if no negative comments are received, staff will complete the rulemaking process and resubmit the rulemaking package with OAL prior to the expiration of the 120-day period.

If comments are received related to the items outlined in the Notice, the board will need to review and accept or reject comments prior to resubmitting the file to OAL.

Discussion

Ms. Klein reported that staff is currently working on the addendum.

Ms. Shellans reported that she had provided staff with case law that illustrates why "under penalty of perjury" is important to use on forms.

V. PRESENTATION ON A PHARMACIST'S CORRESPONDING RESPONSIBILITY UNDER CALIFORNIA LAW BY BOARD STAFF

Background

In a Decision and Order initially effective June 3, 2012 (after the lapse of a 30-day stay from its initial effective date of May 4, 2012), and made a precedential decision of the Board effective August 9, 2013, the Board of Pharmacy revoked the licenses issued by the Board to Pacifica Pharmacy, PHY 46715, a pharmacy licensee, and Thang Q. Tran, RPH 41172, a pharmacist licensee, based on allegations and proof that respondents engaged in unprofessional conduct including failures to exercise the "corresponding responsibility" a pharmacy/pharmacist owes under California law to determine the legitimate medical purpose of controlled substance prescriptions before dispensing, under Health and Safety Code section 11153, subdivision (a).

The entire precedential decision, as well as a two page summary, can be found at:

<http://www.pharmacy.ca.gov/enforcement/precedential.shtml>

Discussion

President Weisser asked Mr. Room to briefly review the board's precedential decision on the Pacifica Pharmacy case.

Mr. Room commented that many pharmacists only look at each *individual* prescription and validate its legitimacy. What this decision indicates - and what the board has been trying to promote - is that a pharmacist needs to look at the patient's entire prescription profile, as well as their patient population as a whole, to identify patterns that may raise suspicion.

Mr. Room identified several "red flags" that should give a pharmacy / pharmacist the inkling of a potential problem with prescriptions and invoke in them a duty of inquiry:

- Irregularities on the face of the prescription itself
- Nervous patient demeanor
- Age or presentation of patient (e.g., youthful patients seeking chronic pain medications)
- Multiple patients at the same address(es)
- Cash payments
- Requests for early refills of prescriptions
- Prescriptions written for an unusually large quantity of drugs
- Prescriptions written for potentially duplicative drugs
- The same combinations of drugs prescribed for multiple patients
- Initial prescriptions written for stronger opiates (e.g., OxyContin 80mg)
- Long distances traveled from the patient's home to the prescriber's office or pharmacy
- Irregularities in the prescriber's qualifications in relation to the medication(s) prescribed
- Prescriptions that are written outside of the prescriber's medical specialty
- Prescriptions for medications with no logical connection to diagnosis or treatment

Mr. Room noted that pharmacists need to start thinking of themselves as potential targets for illegitimately issued prescriptions, doctor shopping, prescription fraud, drug diversion, etc.

Mr. Lippe noted that the board often sees "cocktails" of Hydrocodone, Xanax and Soma being written illegitimately for patients who had no medical need for them. Mr. Lippe asked if there is ever a legitimate purpose for these three drugs to be prescribed together for a patient. Mr. Room responded that you cannot rule out that there may be rare circumstances that would require a prescription for these drugs together. However, if a pharmacist sees multiple patients coming in with prescriptions for these drugs, especially if the prescriptions are all from the same prescriber, the pharmacist should be suspicious.

Mr. Kajioka commented that law enforcement refers to this drug combination (Hydrocodone, Xanax and Soma) as the “holy trinity.” Ms. Herold added that seeing the three of these drugs prescribed at the same time is not itself a violation, but it should raise a red flag for the pharmacist, especially if a pattern emerges.

Dr. Wong commented that prescribers need to be held responsible for overprescribing.

President Weisser commented that the board has a newly created subcommittee, chaired by Ramon Castellblanch, which deals exclusively with prescription drug abuse.

Dr. Castellblanch commented that the subcommittee is updating the website with more current information on prescription drug abuse, monitoring the implementation of the new CURES system and looking for ways to educate pharmacists on corresponding responsibility and their role in preventing prescription drug abuse.

Dr. Gutierrez asked that education for pharmacists on corresponding responsibility be agenzized for the next Prescription Drug Abuse Subcommittee meeting.

Ms. Herold provided a presentation on “Pharmaceutical Supply Chain Thefts Reporting and Prevention and Corresponding Responsibility.” The slides are included immediately following the minutes.

The board recessed to closed session at 11:29 a.m.

VI. CLOSED SESSION

Pursuant to Government Code Section 11126(c)(3), the Board Will Convene in Closed Session to Deliberate on Disciplinary Matters

ADJOURNMENT

PHARMACEUTICAL SUPPLY CHAIN THEFTS REPORTING AND PREVENTION



11/14/2013

CA State Board of Pharmacy
Virginia Herold, Executive Officer

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

Street value of common controlled substances

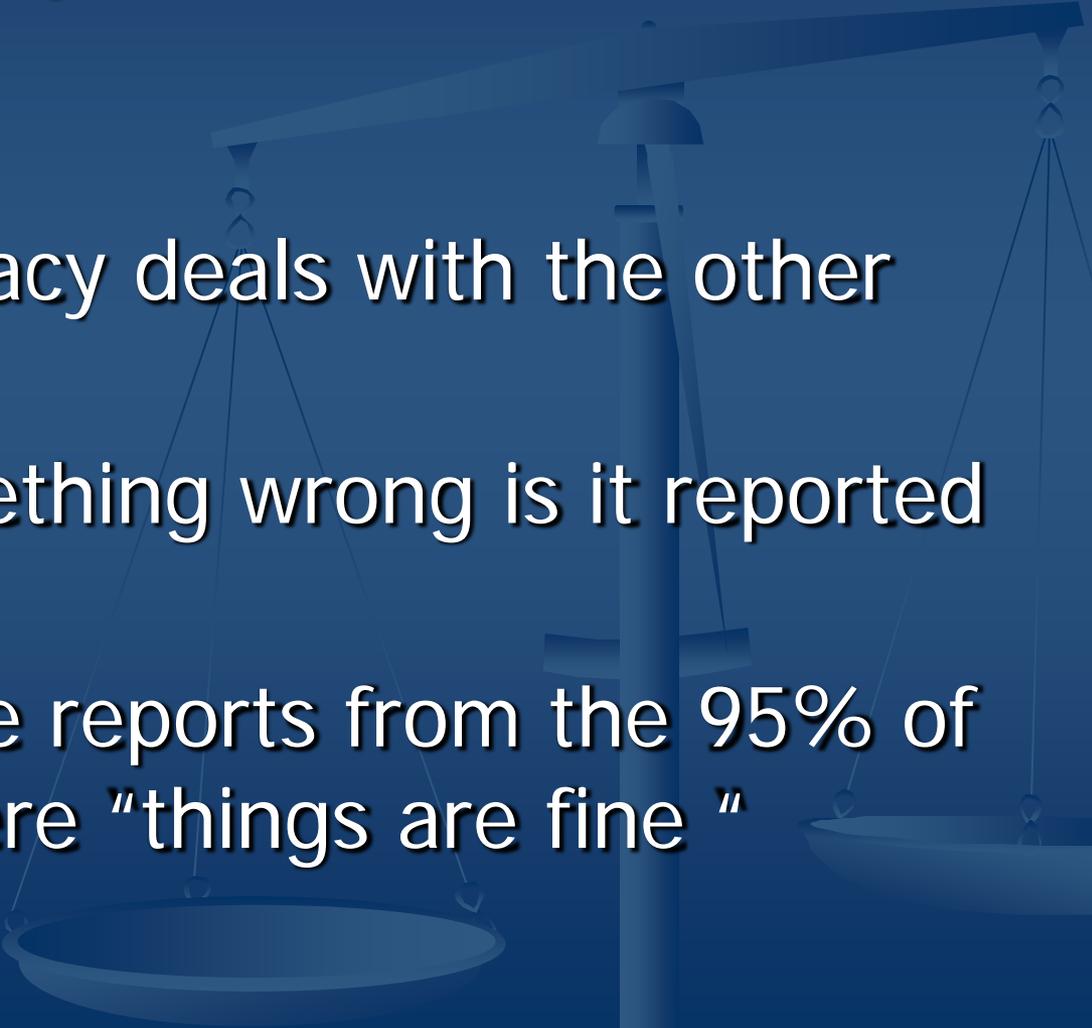
- Dilaudid 4mg \$15.00-\$20.00 per tablet
- Fentanyl - \$10.00 per patch
- **Hydrocodone** - \$1.00 - \$5.00 per tablet
- methadone - \$10.00 per tablet
- methylphenidate - \$5.00 per tablet
- morphine - \$30.00 per/10 tablets
- MS Contin 60mg - \$20.00 per dose
- Oxycodone 80mg - \$12.00 - \$40.00 per 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

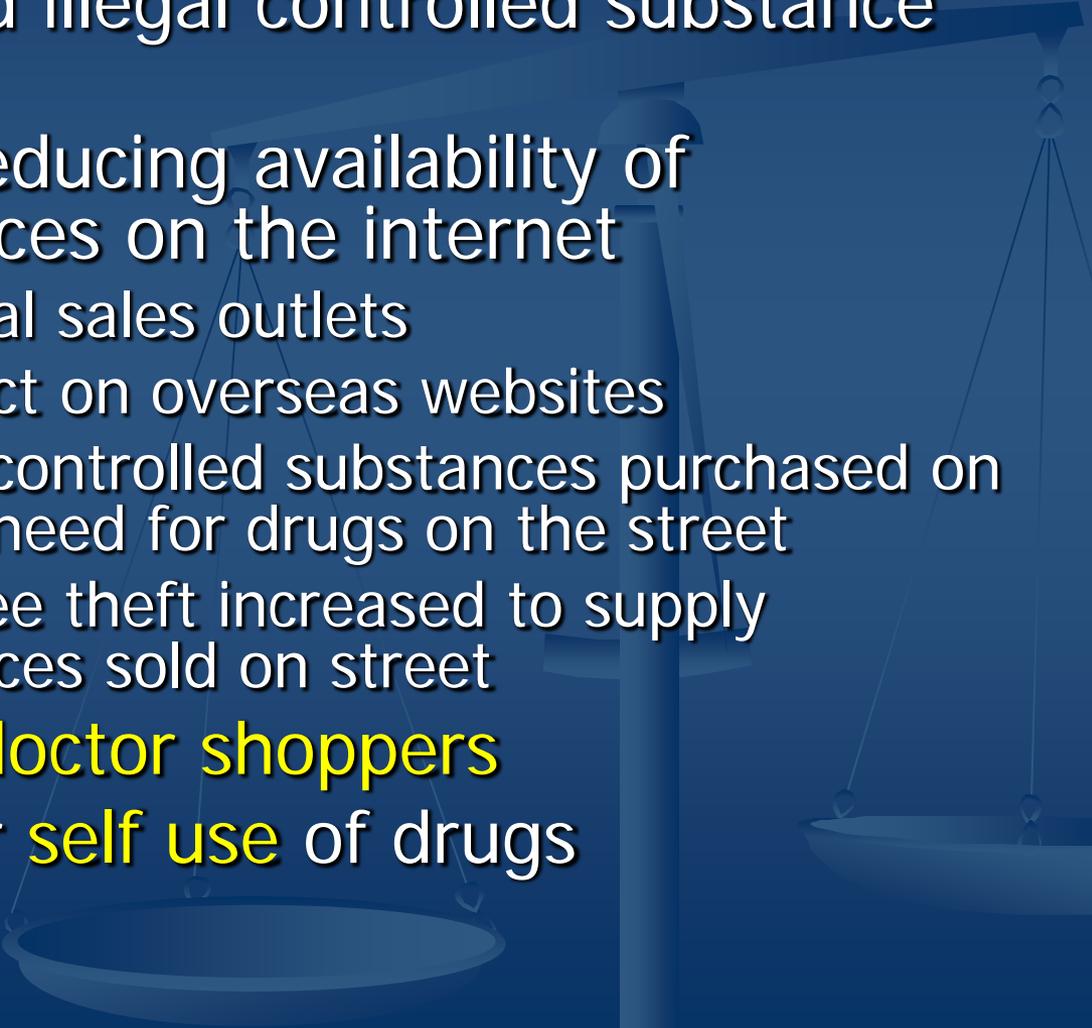
Pharmacists tend to think only of how much a drug costs or sells for, not the street value of the drug.

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
- 

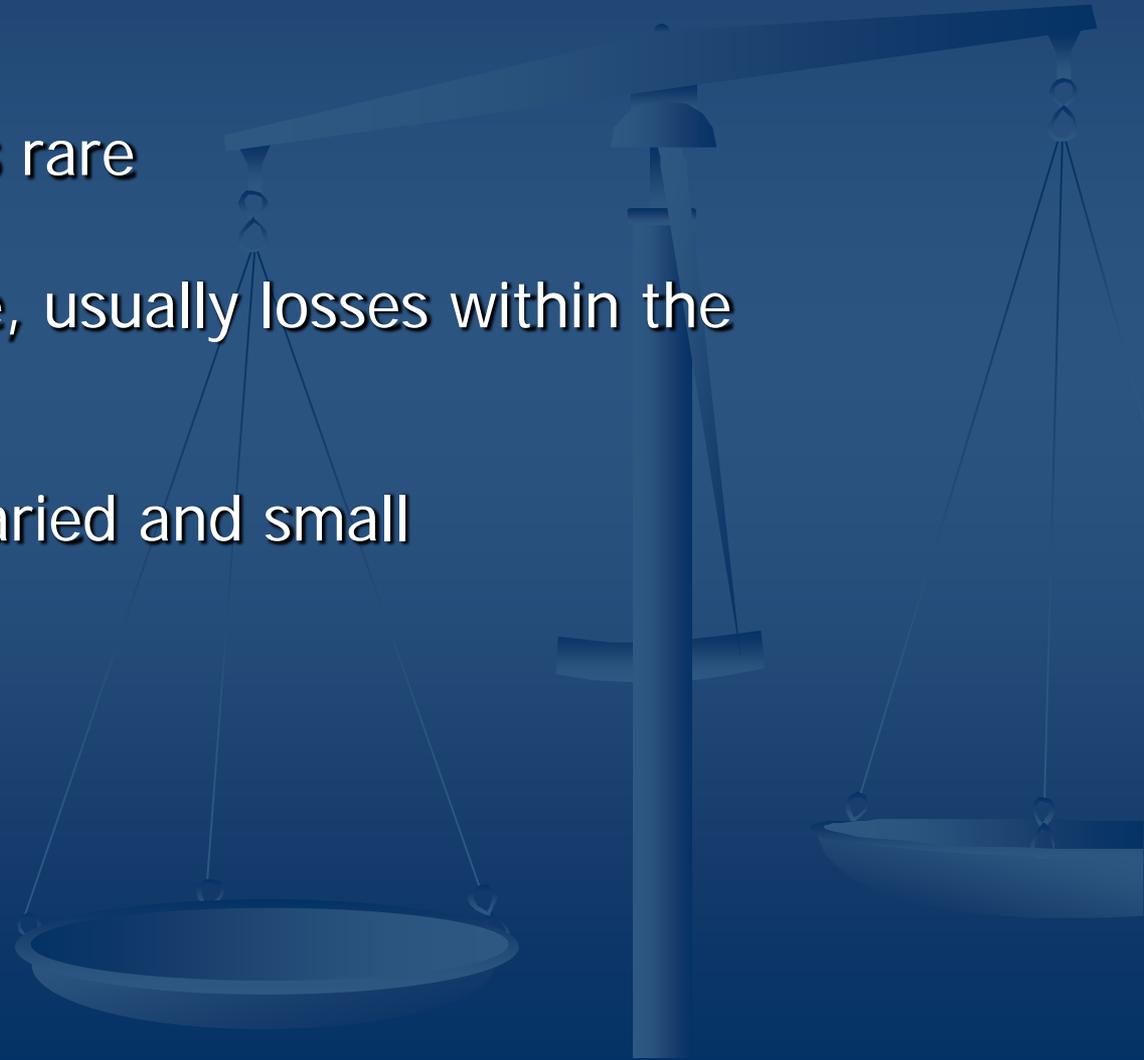
These Drugs Are Within Legitimate Supply Chain

- Few ways exist for those who want to illegally sell these drugs to obtain them:
 - Steal 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, or via Craigs list or ebay

CHANGES IN CONTROLLED SUBSTANCE LOSS PROFILE

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)

■ TODAY

■ Manufacturing Thefts

- Eli Lilly Warehouse - **\$75 million**
 - Eli Lilly truck **\$37 million**
 - Teva truck - \$11.8 million
 - Novo Novodisk 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

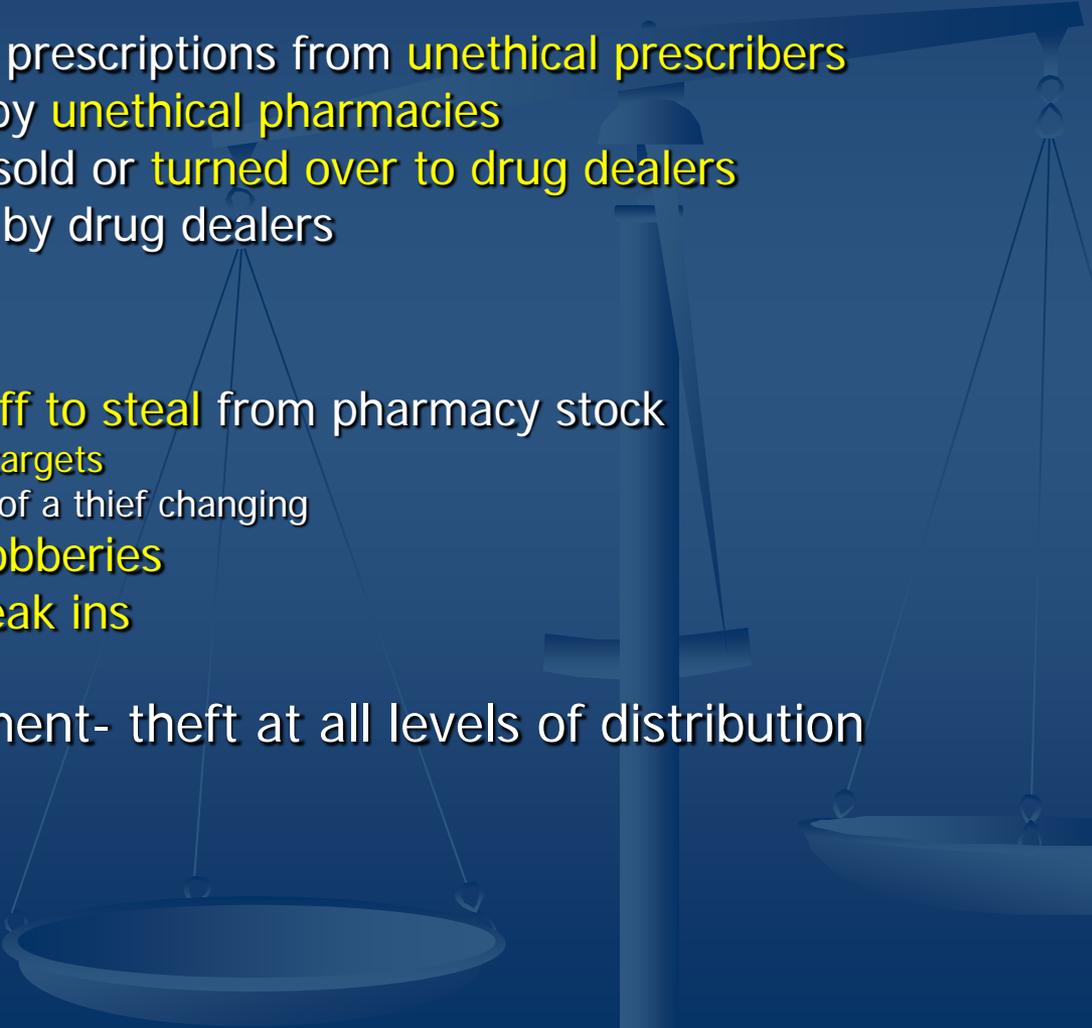
CHANGES IN CONTROLLED SUBSTANCE LOSS PROFILES (CONT)

- 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)
 - Increasing quantities sales to pharmacies/pain cln

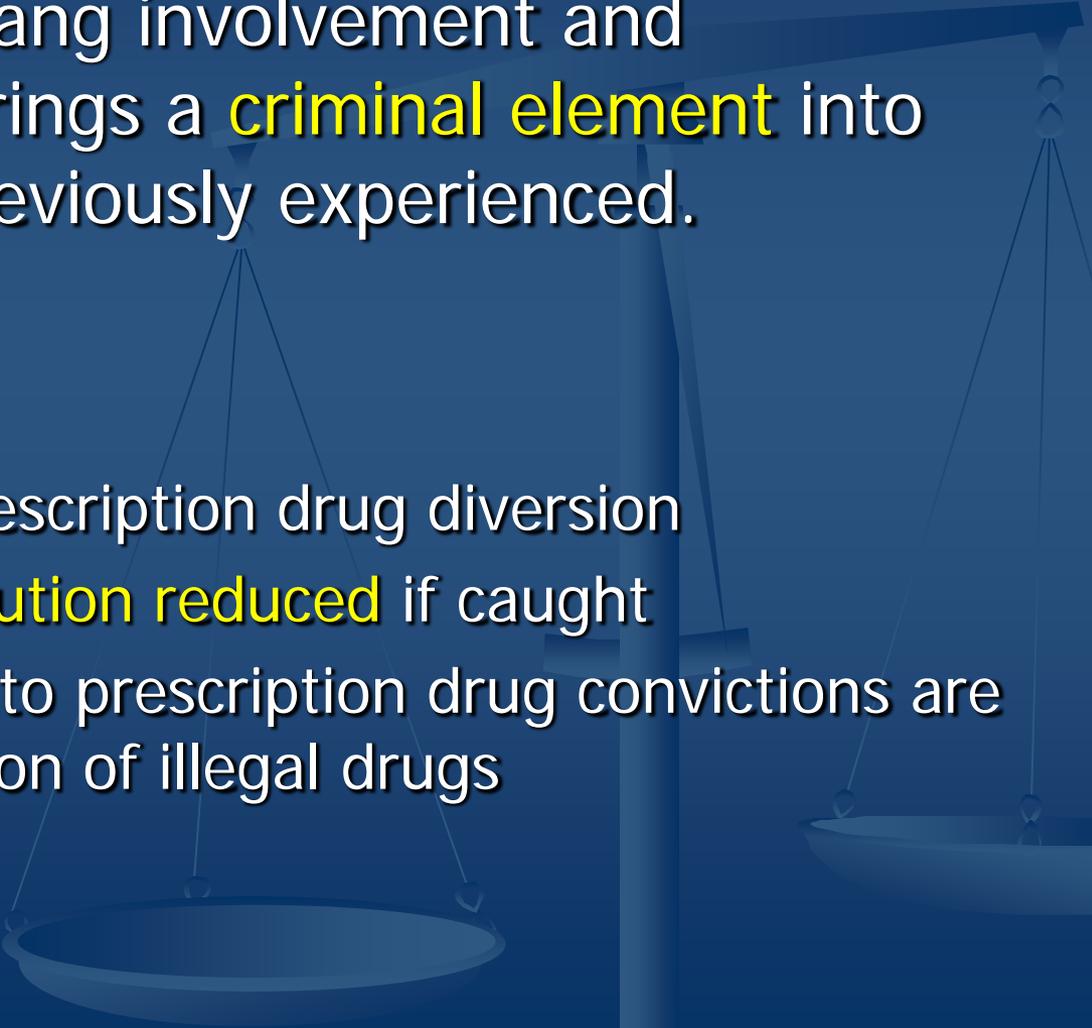
CHANGES IN CONTROLLED SUBSTANCE LOSS PROFILES (CONT)

- 2013 Pharmacy
 - Total number of pharmacies reporting losses has increased
 - Total amount of controlled substances lost reported at one time has 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
 - Hydrocodone 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
- 

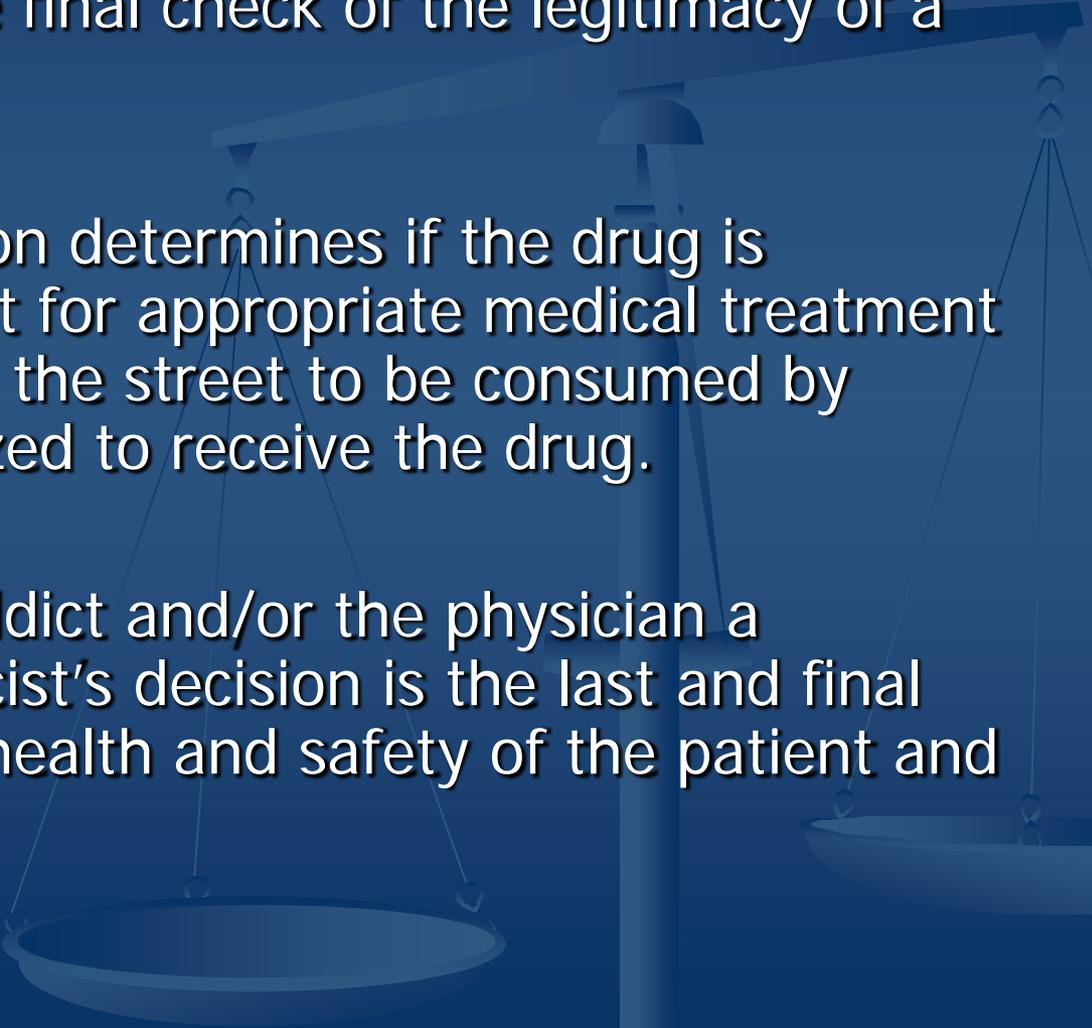
WHAT IS EVERY PHARMACIST'S PROFESSIONAL RESPONSIBILITY ?

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

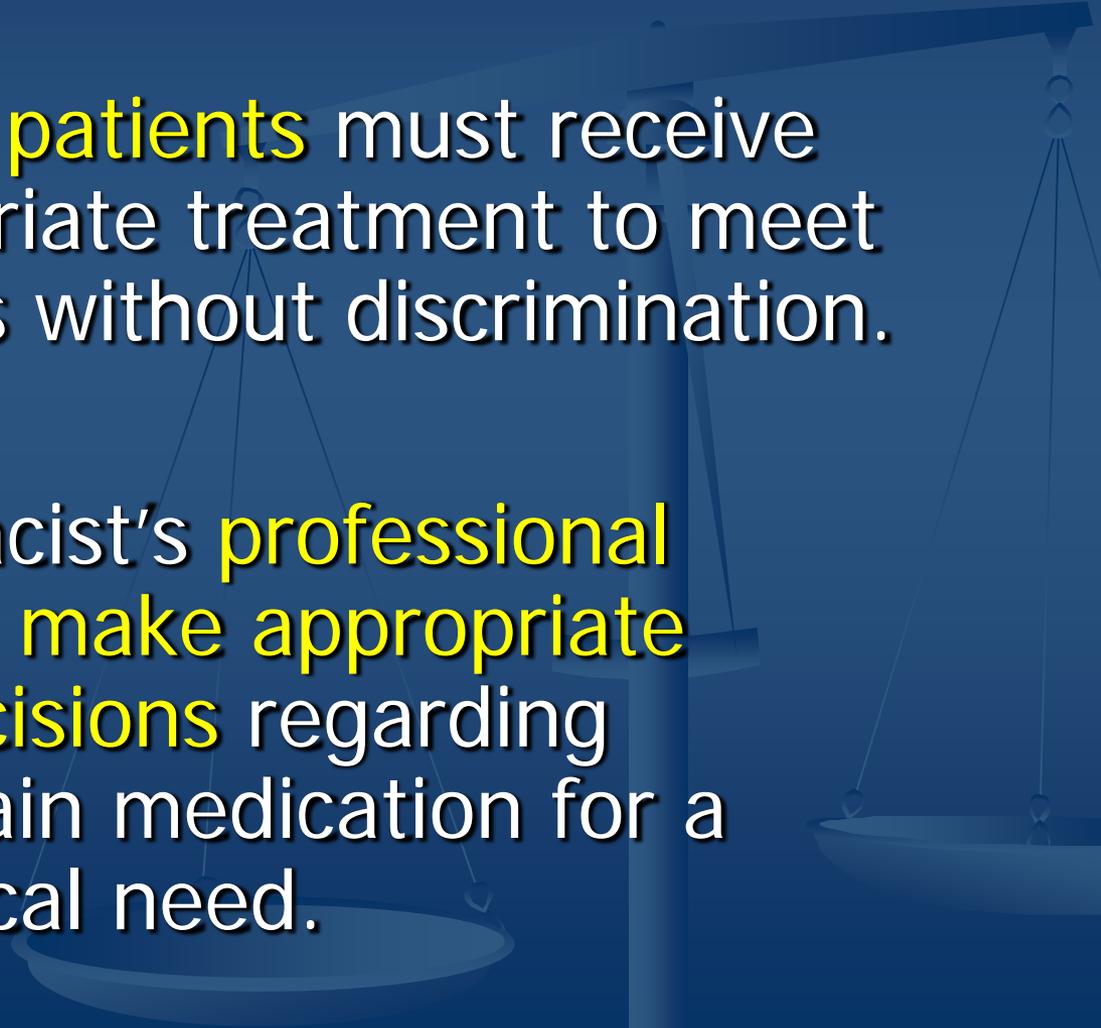
6700 pharmacies in CA. If each pharmacy loses 1000 hydrocodone per year, that is 6.7 million hydrocodone on the street illegally

- 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
 - A pharmacist's 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 the 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

- **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 professional decisions** regarding dispensing of pain medication for a legitimate medical need.
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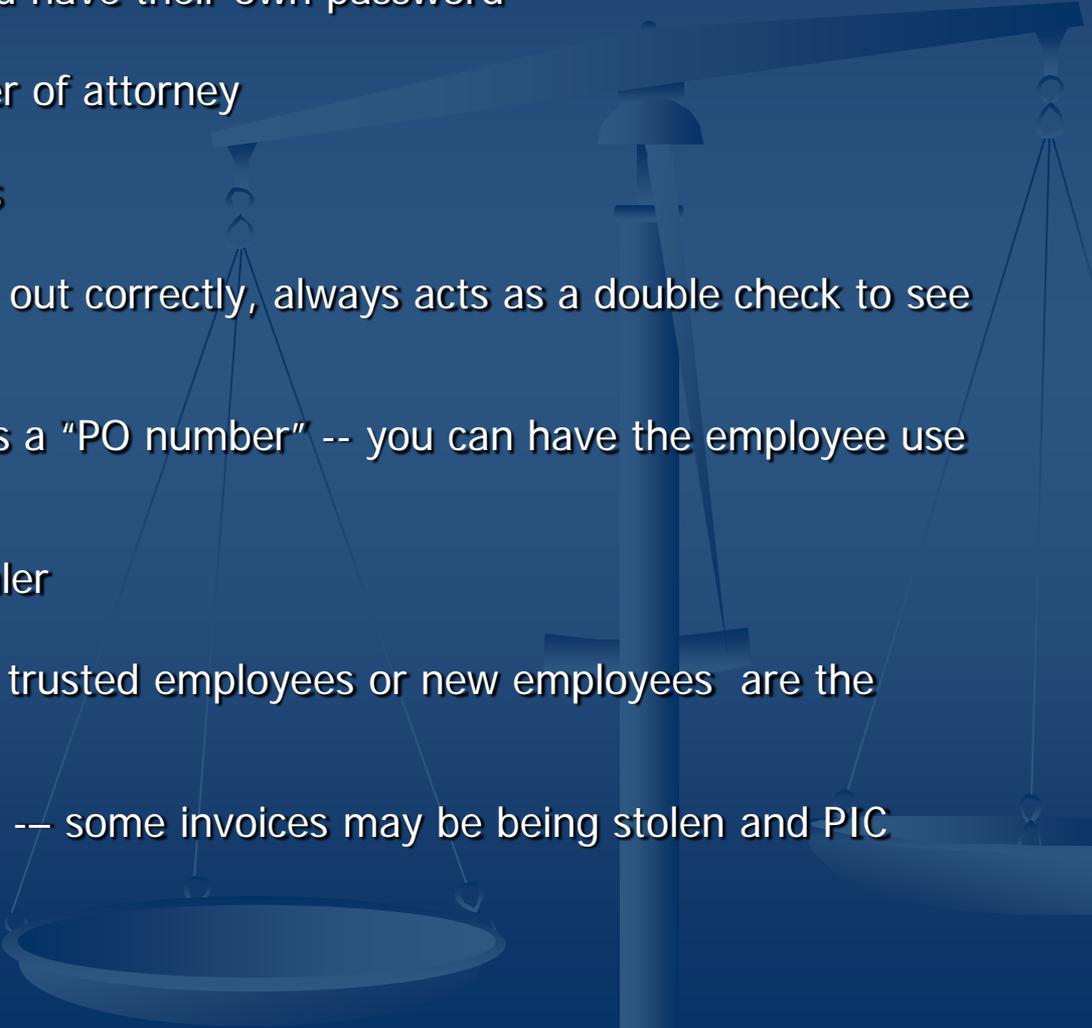
PREVENTING LOSS OF CONTROLLED SUBSTANCES FROM PHARMACY

- **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"
 - minimize the number of orders placed per day, so that "extra" orders stick out
 - minimize the amount of locations/terminals which can be used for ordering
 - if ordering online, watch orders placed from an off site location (home, etc).

Pharmacy Prescription Drug Ordering (cont)

- CSOS orders -- 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 his or her initials
 - buy from a BOP licensed wholesaler
 - be observant – many times most trusted employees or new employees are the thieves
 - 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

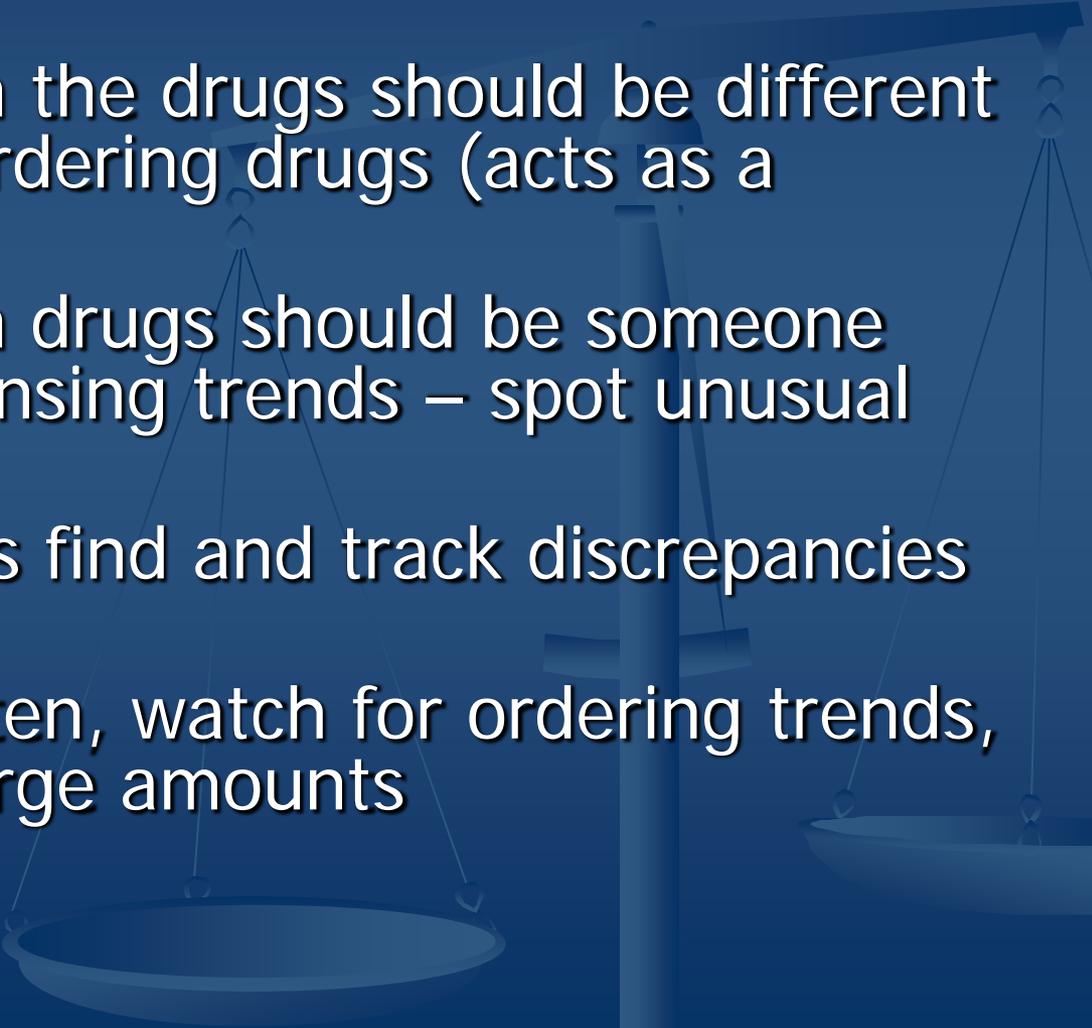
- CA Pharmacy Law requires **Pharmacist-In-Charge sign for all dangerous drug deliveries**
 - Code section written to protect Pharmacist – In-Charge
 - Drug could not be ordered and delivered to pharmacy and then diverted without a pharmacist knowing.

Prescription Drug Delivery to Pharmacy

- Deliveries of 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

Pharmacy

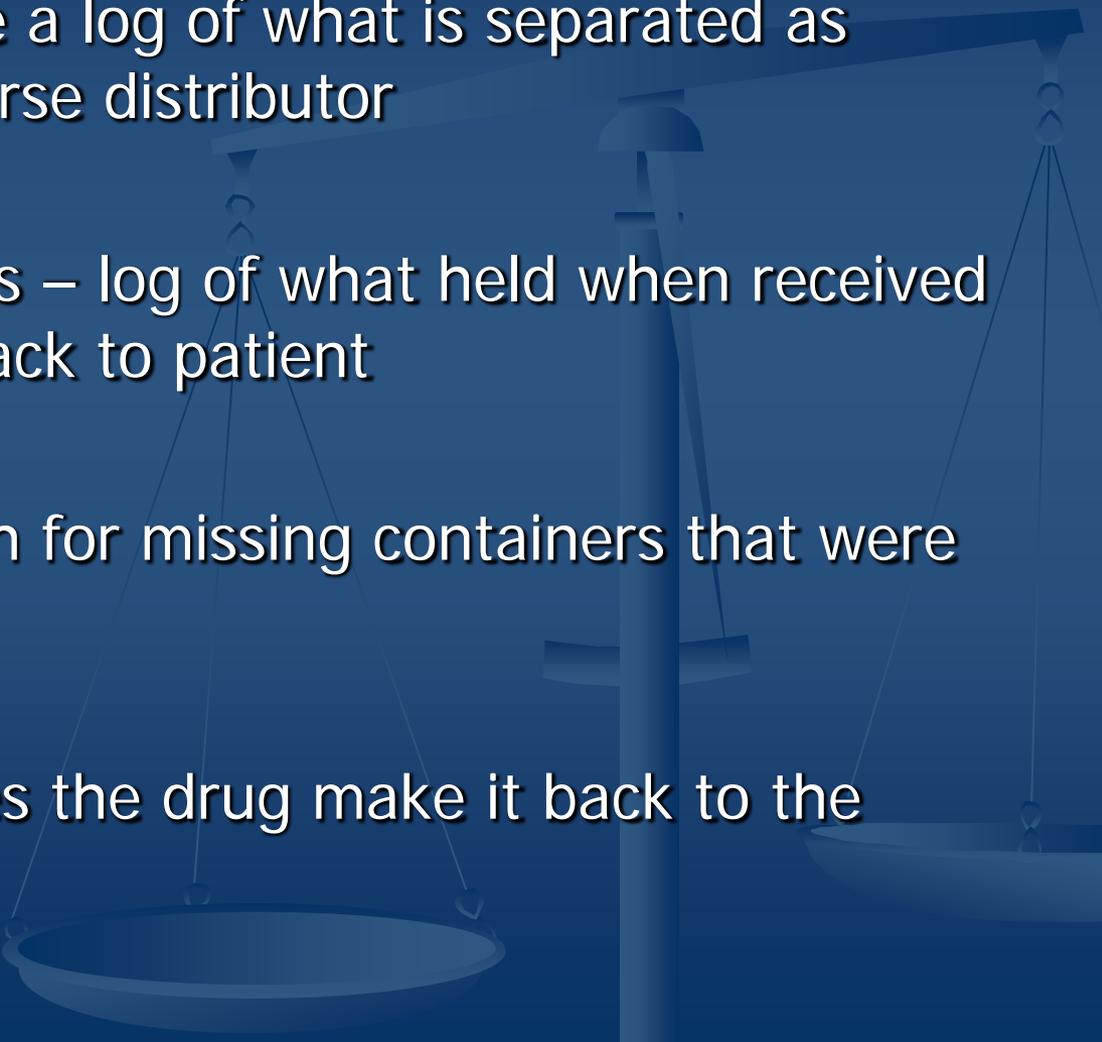
Order Check In – Controlled Substances

- 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

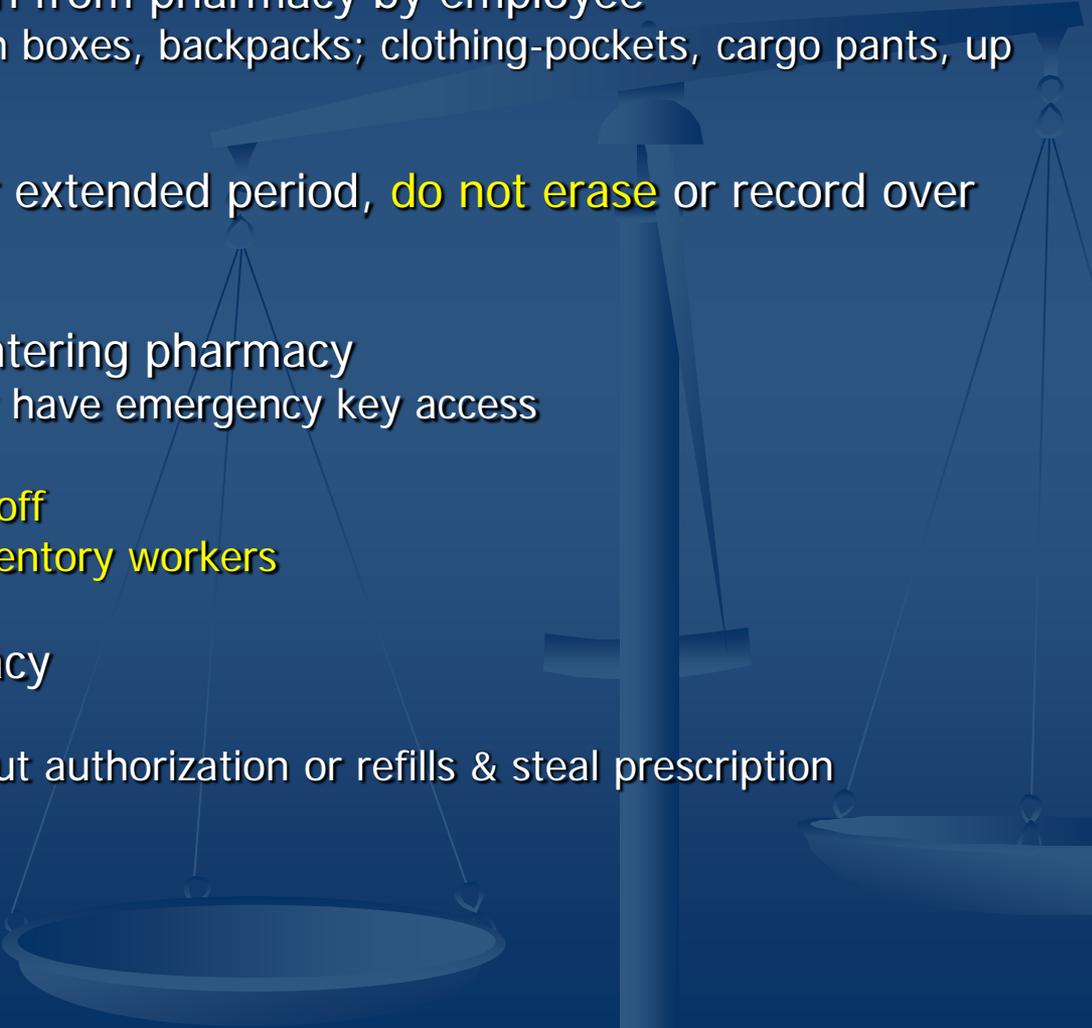
Prescription Drug Storage (cont)

- 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 areas – watch for missing containers that were filled
 - Return to stock – does the drug make it back to the stock shelves?
- 

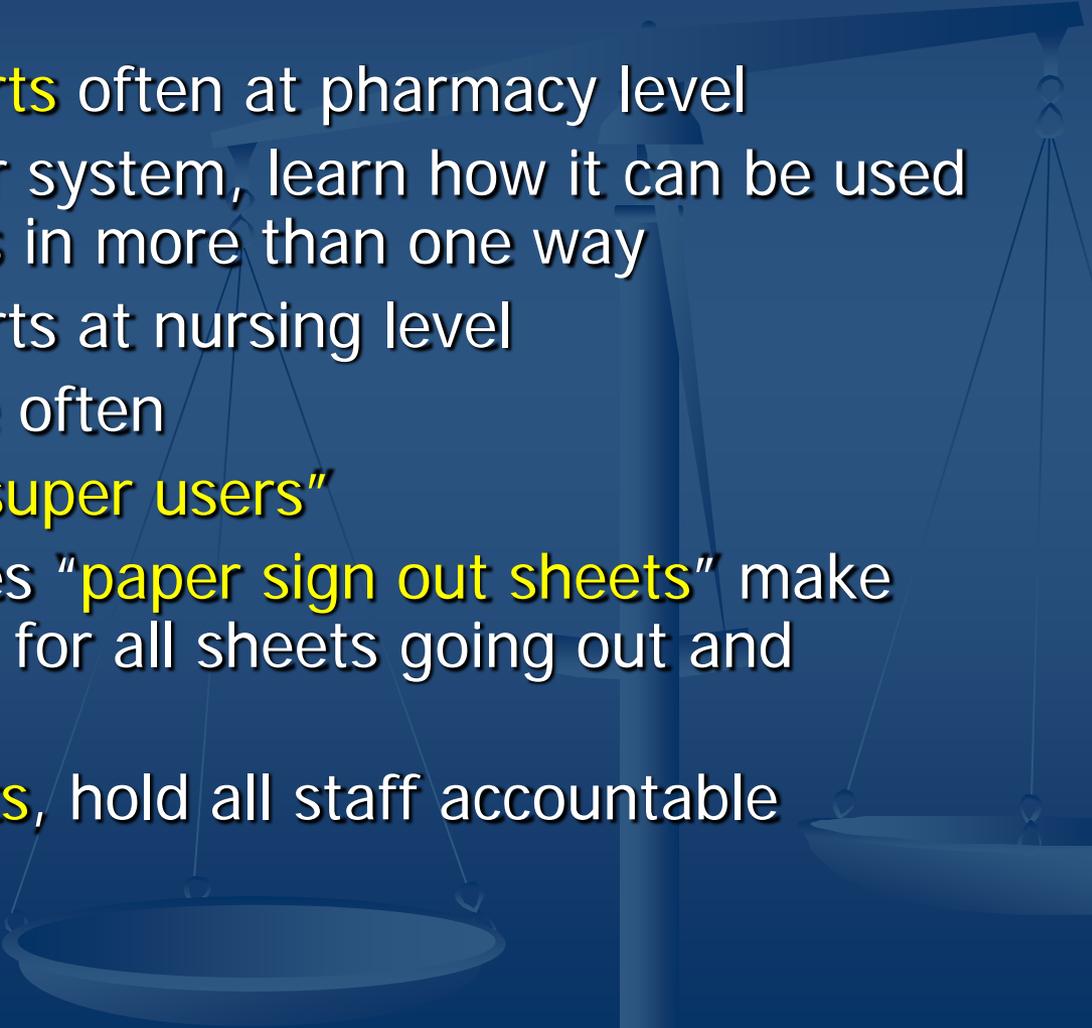
PIC REVIEW OF PURCHASE INVOICES

- 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
- 

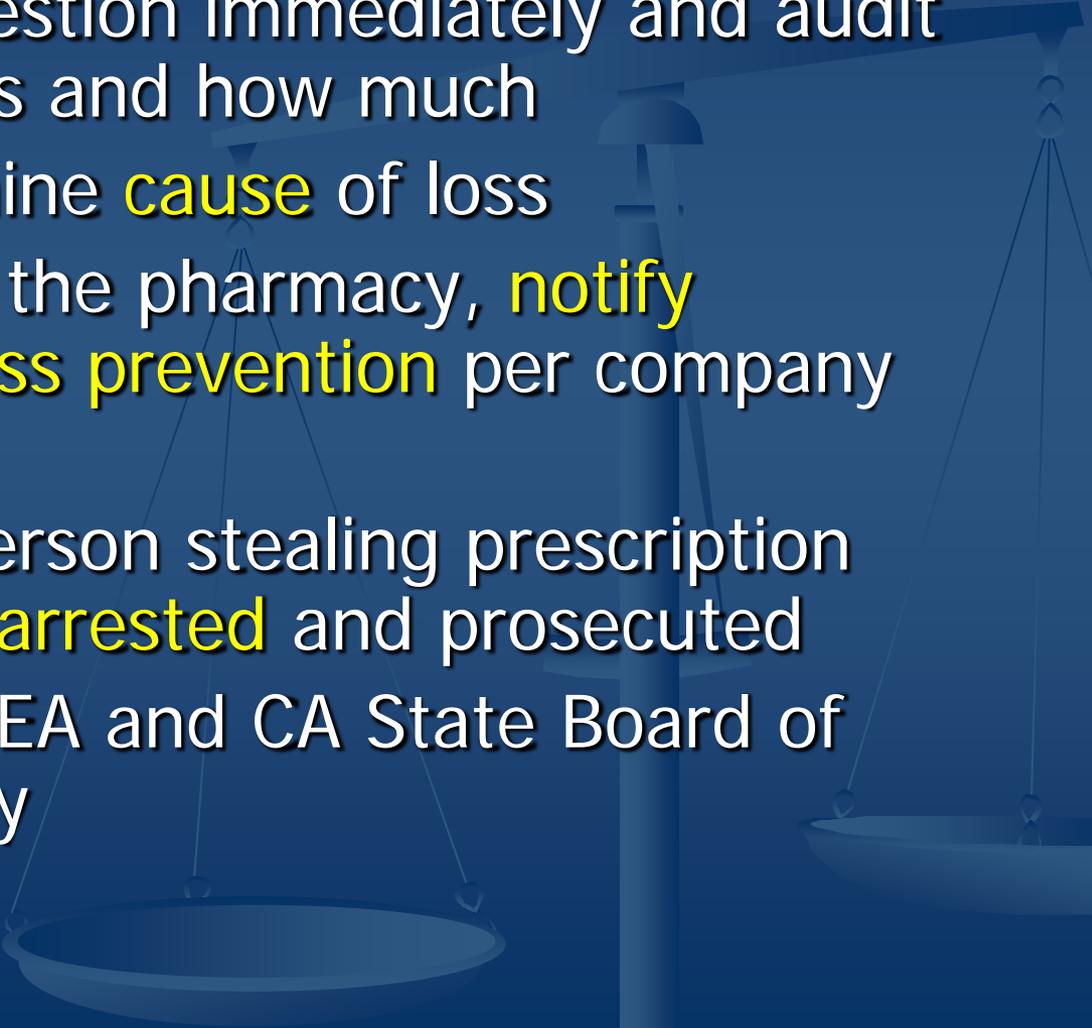
Dispensing Process Controlled Substances

- **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

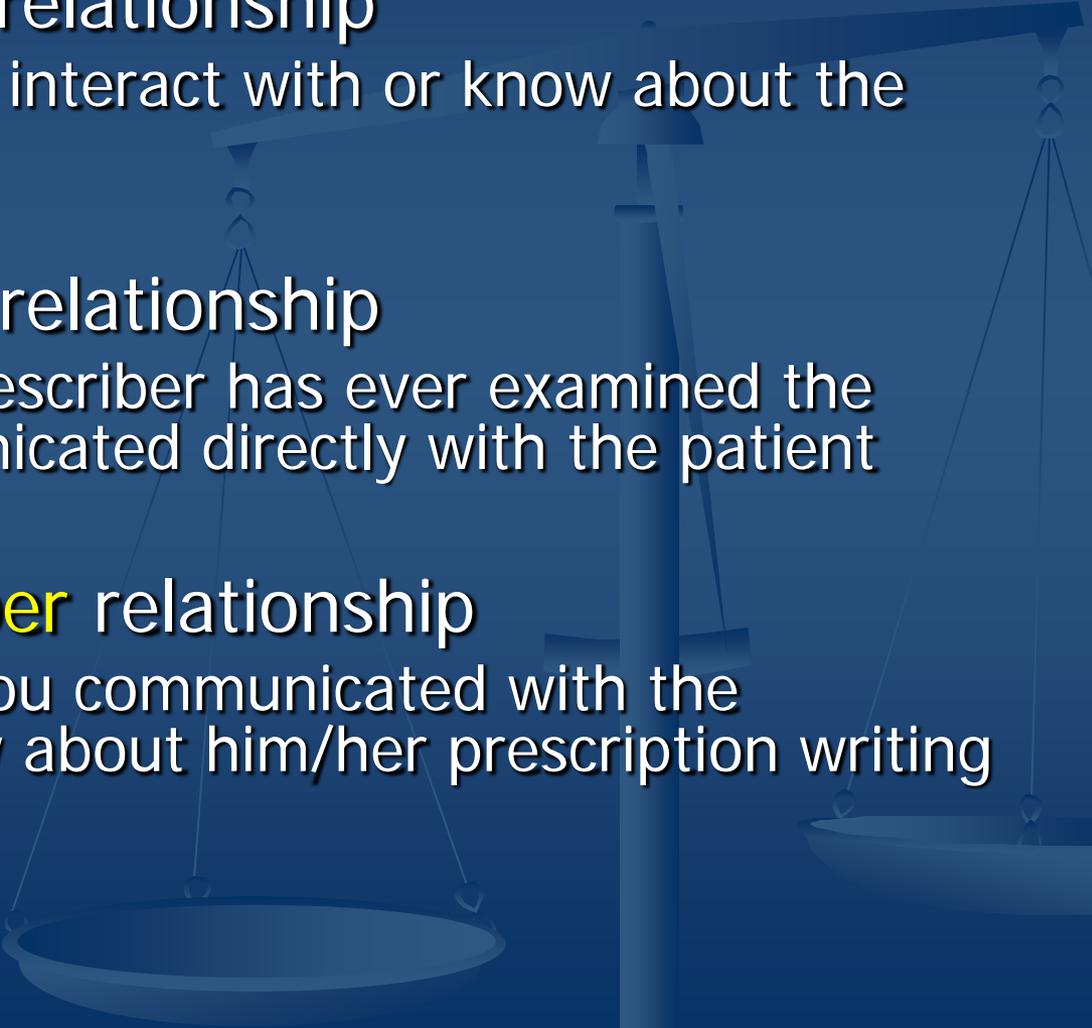
Reporting Impaired Licensees Mentally, Chemically, Physically

- 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

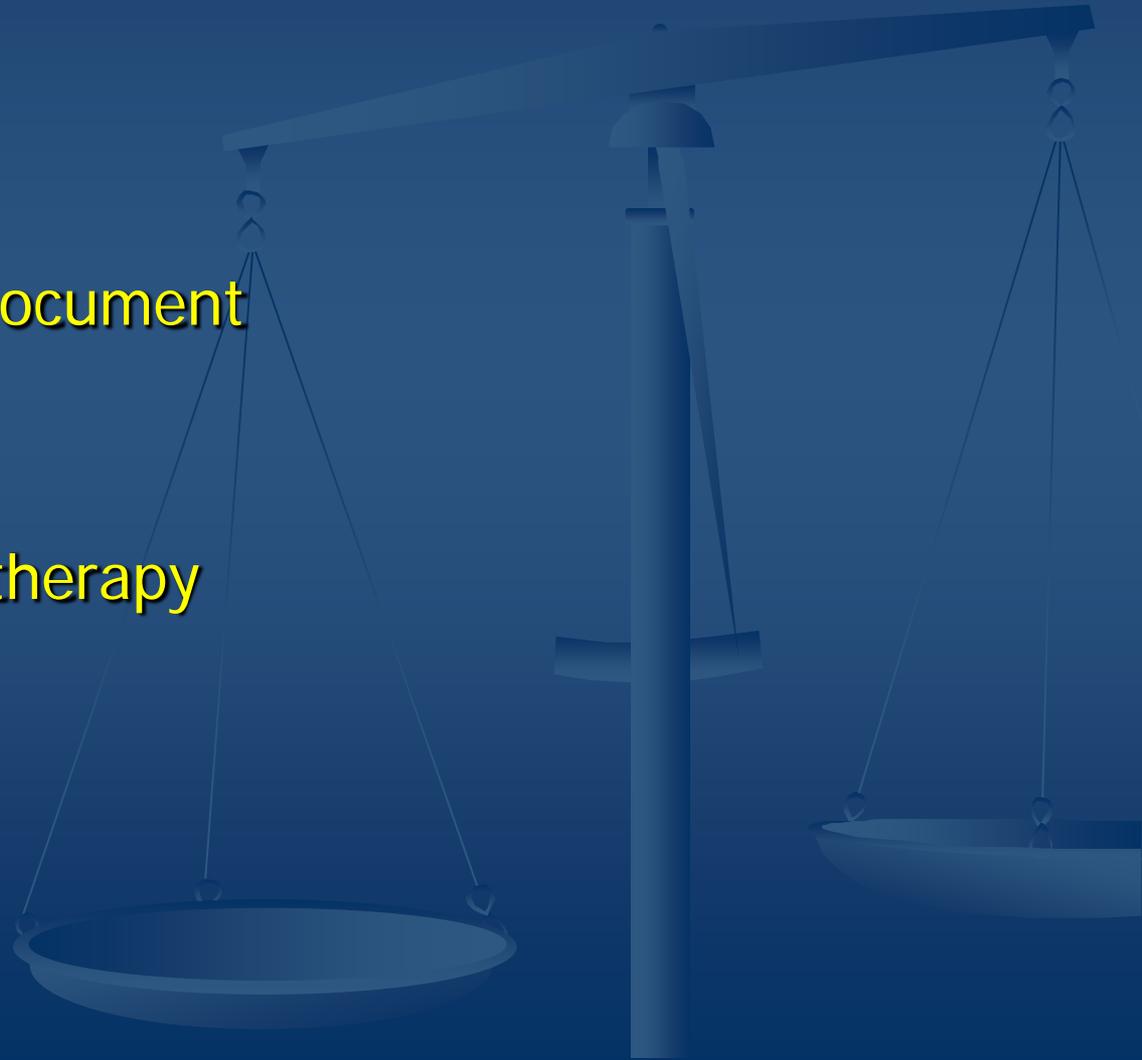
- CA Health & Safety Code Section 11153
 - Prescriber must write a prescription for a **legitimate medical purpose** during his/her usual course of practice
 - Pharmacist has a **corresponding responsibility** to determine that prescription is for a legitimate medical need.
- CA Code of Regulations 1761(b)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

Corresponding Responsibility (cont)

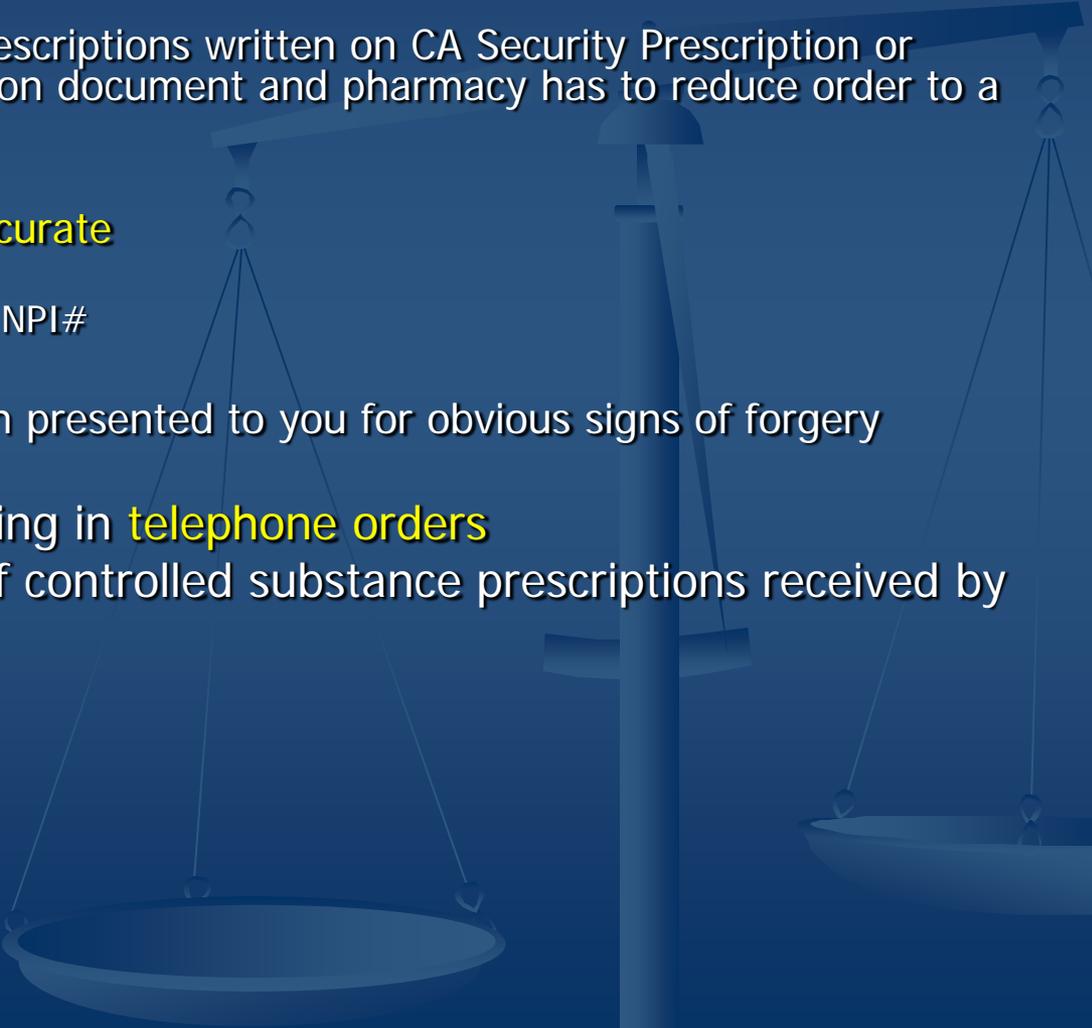
- **Patient/pharmacy** relationship
 - How much do you interact with or know about the patient
 - **Patient/prescriber** relationship
 - Are you certain prescriber has ever examined the patient or communicated directly with the patient
 - **Pharmacy/prescriber** relationship
 - How much have you communicated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

Should I Dispense This Prescription?

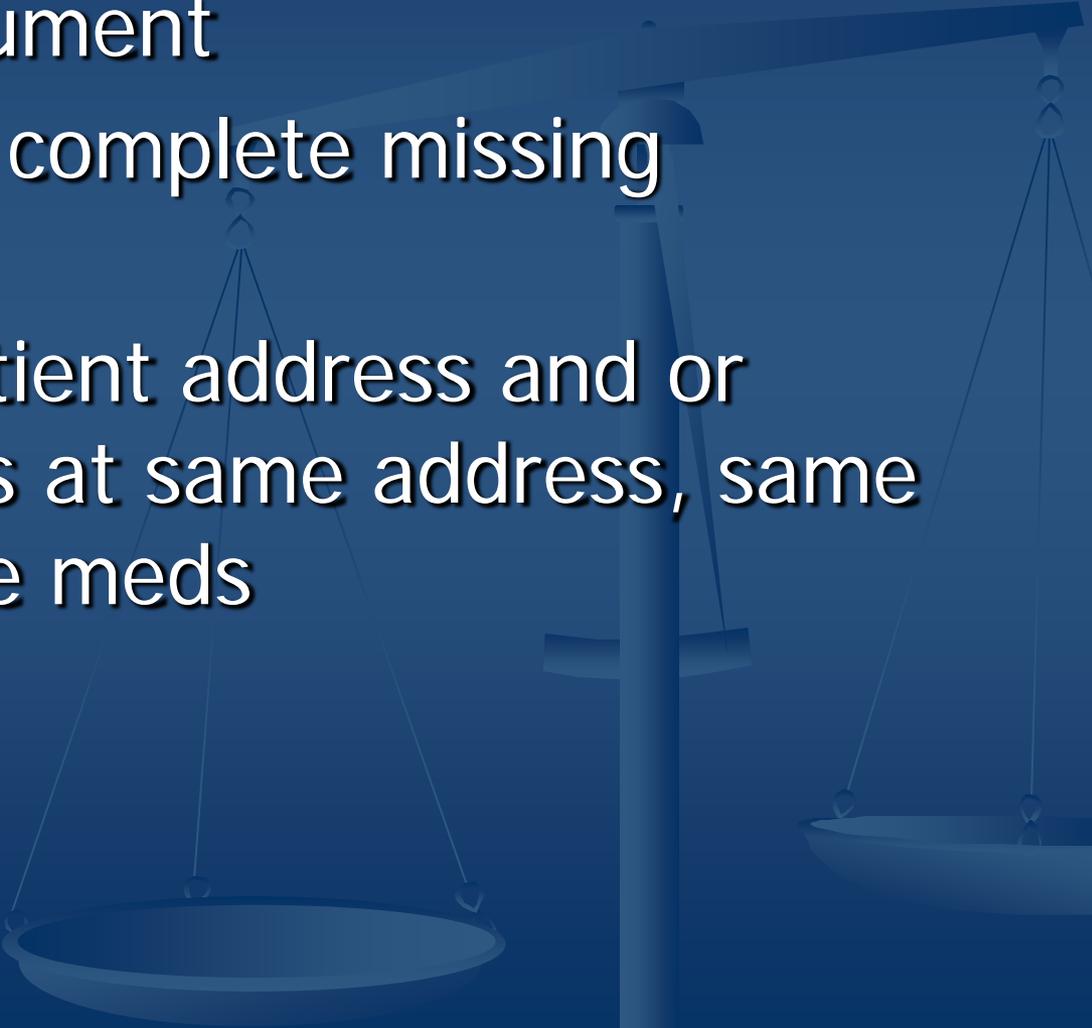
- Considerations
 - The **prescription document**
 - The **prescriber**
 - The **patient**
 - Appropriate **drug therapy**



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.
- 

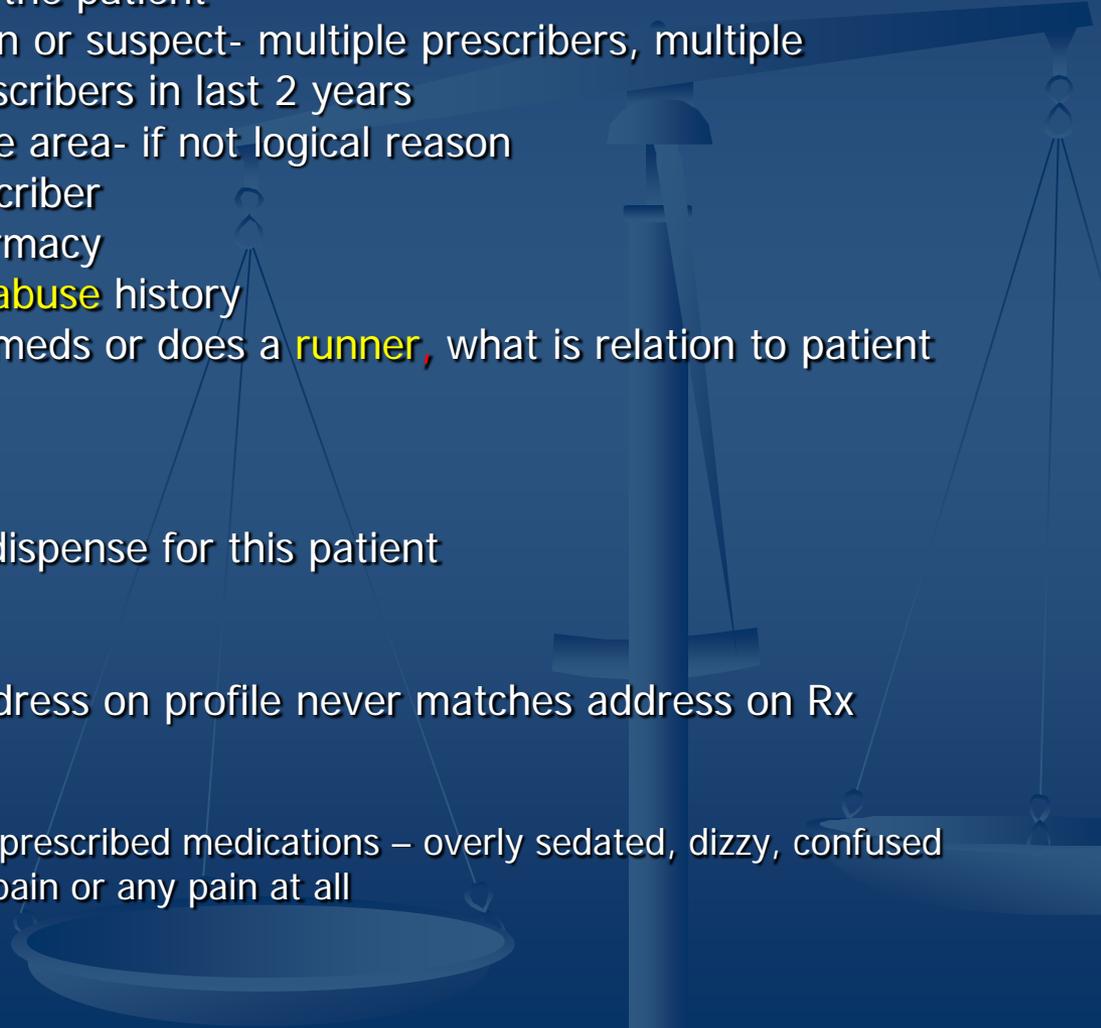
OBVIOUS PROBLEMS WITH PRESCRIPTION DOCUMENT

- 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

Pharmacist - Evaluate Your Own Practice

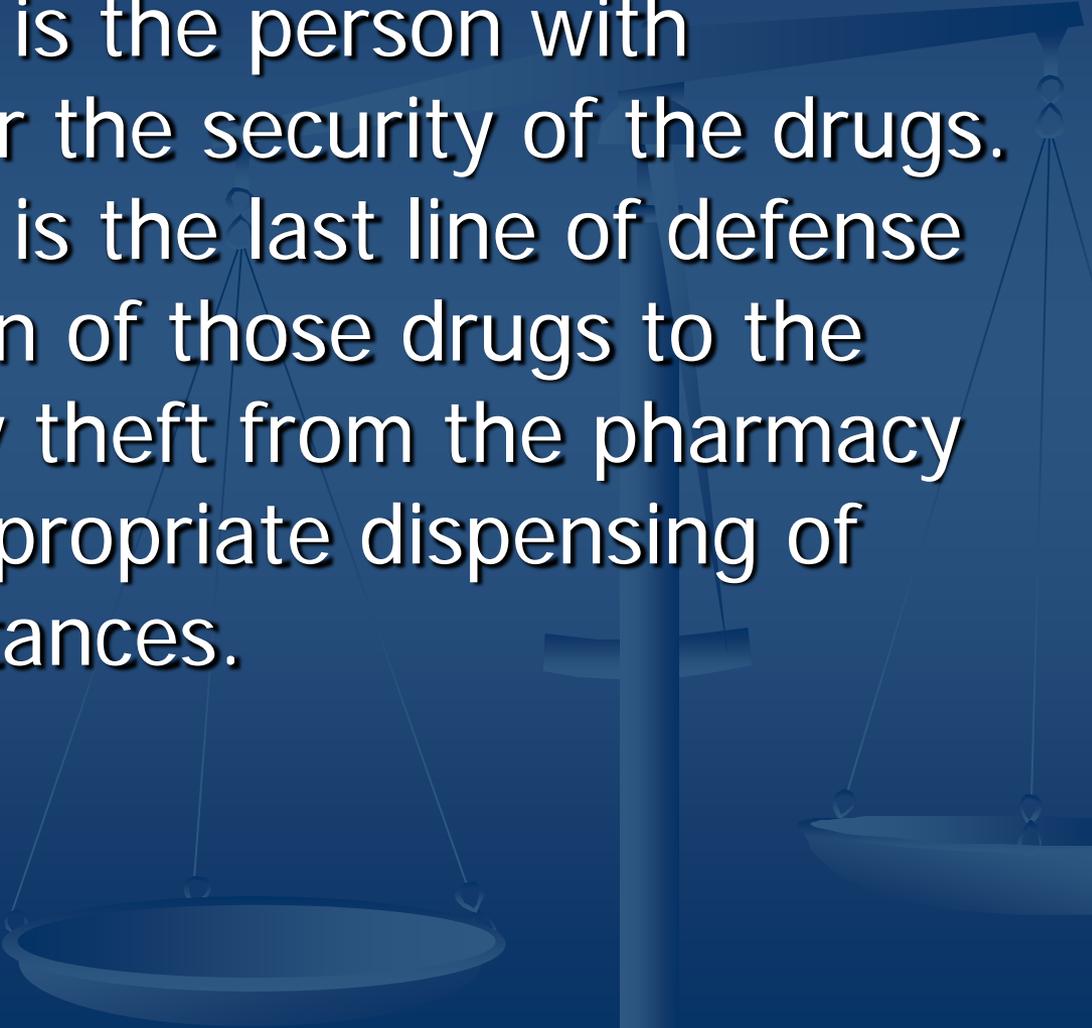
- What would cause you to **refuse to fill** a controlled substance prescription
- What about a **doctor** would cause you to refuse to dispense his/her prescriptions
- How would you react if you received a **large number of controlled substances** from a single doctor
- What **documentation** do **you 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

The pharmacist is the person with responsibility for the security of the drugs. The pharmacist is the last line of defense against diversion of those drugs to the street, either by theft from the pharmacy or through inappropriate dispensing of controlled substances.

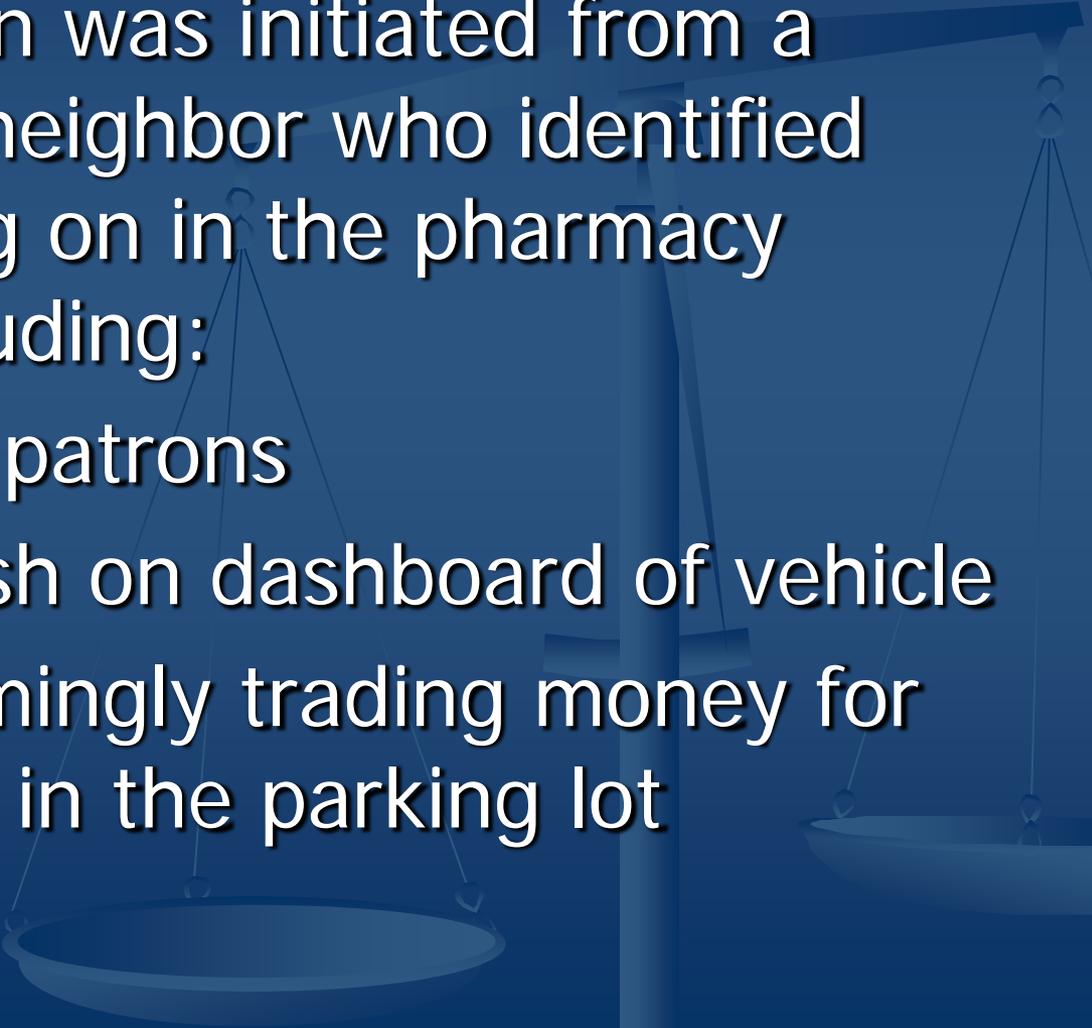


Corresponding Responsibility

- Precedential Decision -- designated by board effective August 2013
- Following a hearing, an administrative law judge revoked the pharmacy and pharmacist licenses involved in excessive furnishing of controlled substances and failure to exercise corresponding responsibility, plus costs of \$40,000; a decision adopted by the board

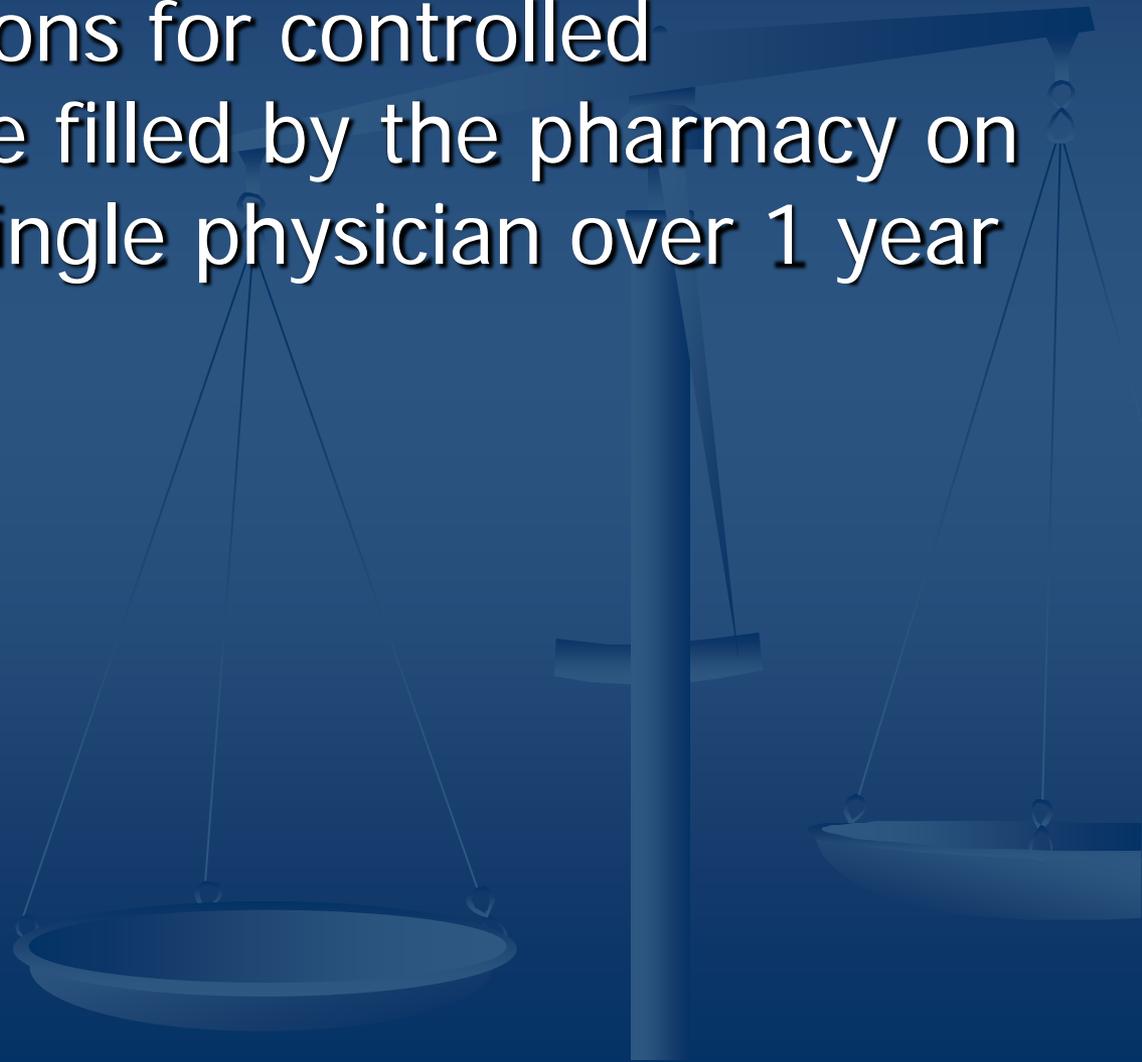
See the Decision

- Available from www.pharmacy.ca.gov
 - > Enforcement
 - > Precedential decision
- The principal portion of the decision notes a number of red flags the pharmacy and the pharmacist failed to heed and their failure to exercise corresponding responsibility in filling controlled substances written by one physician.

- 
- The investigation was initiated from a complaint by a neighbor who identified drug deals going on in the pharmacy parking lot, including:
 - many young patrons
 - spread of cash on dashboard of vehicle
 - persons seemingly trading money for prescriptions in the parking lot

According to CURES

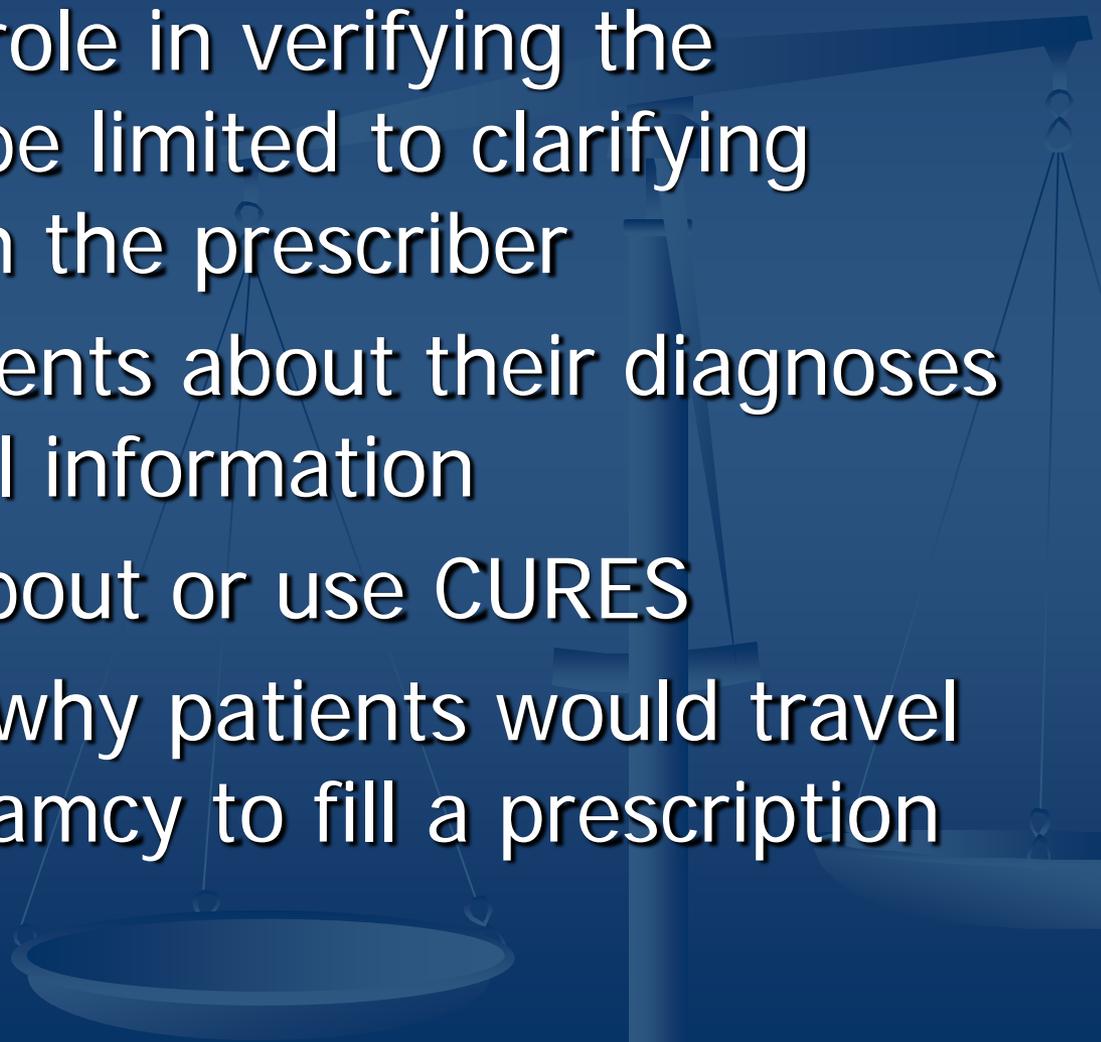
- 1,844 prescriptions for controlled substances were filled by the pharmacy on the order of a single physician over 1 year



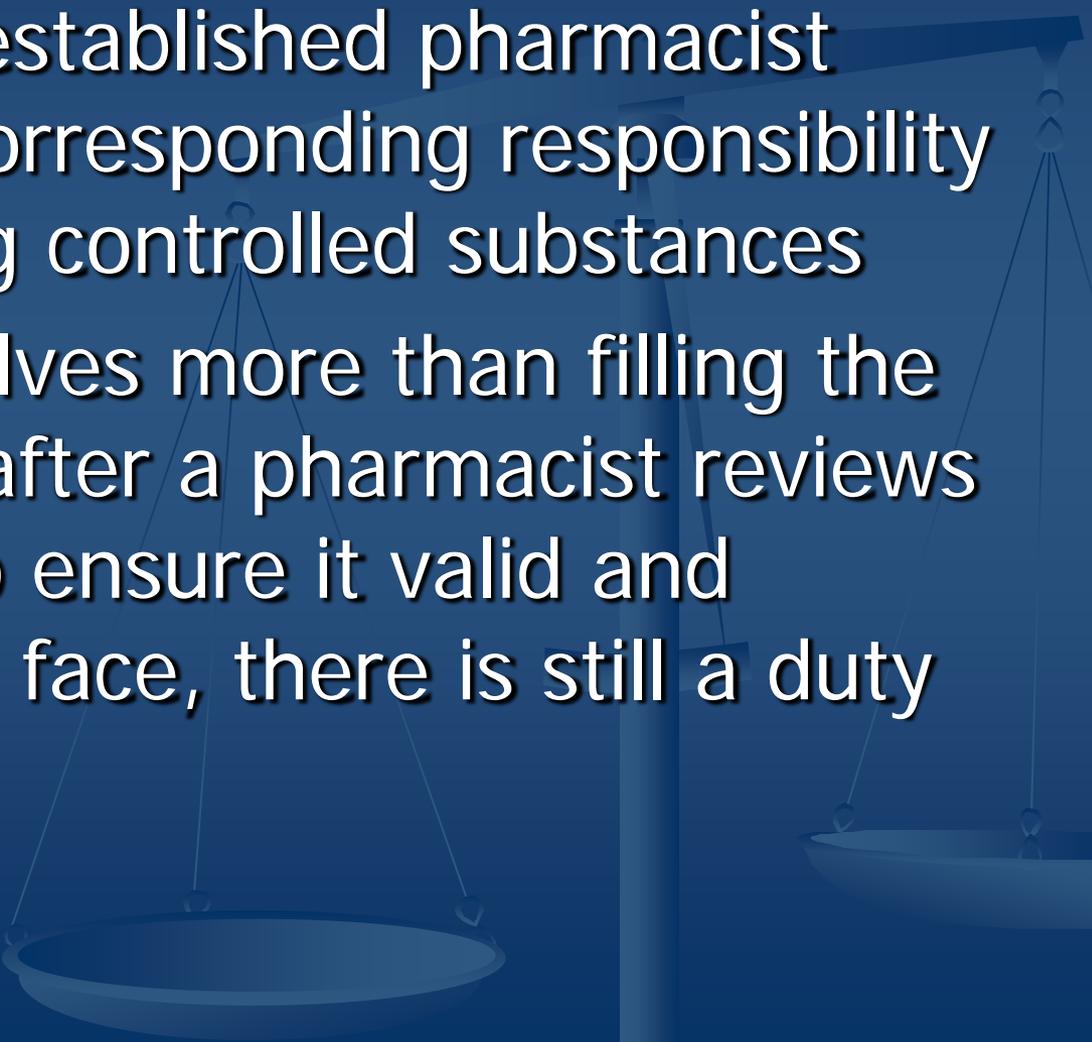
Actions by Pharmacist

- Pharmacist did not:
 - contact the prescriber of the 1844 CS prescriptions filled by pharmacy
 - routinely verify prescriptions with prescribers
 - ask about their prescribing practices

Actions by Pharmacist

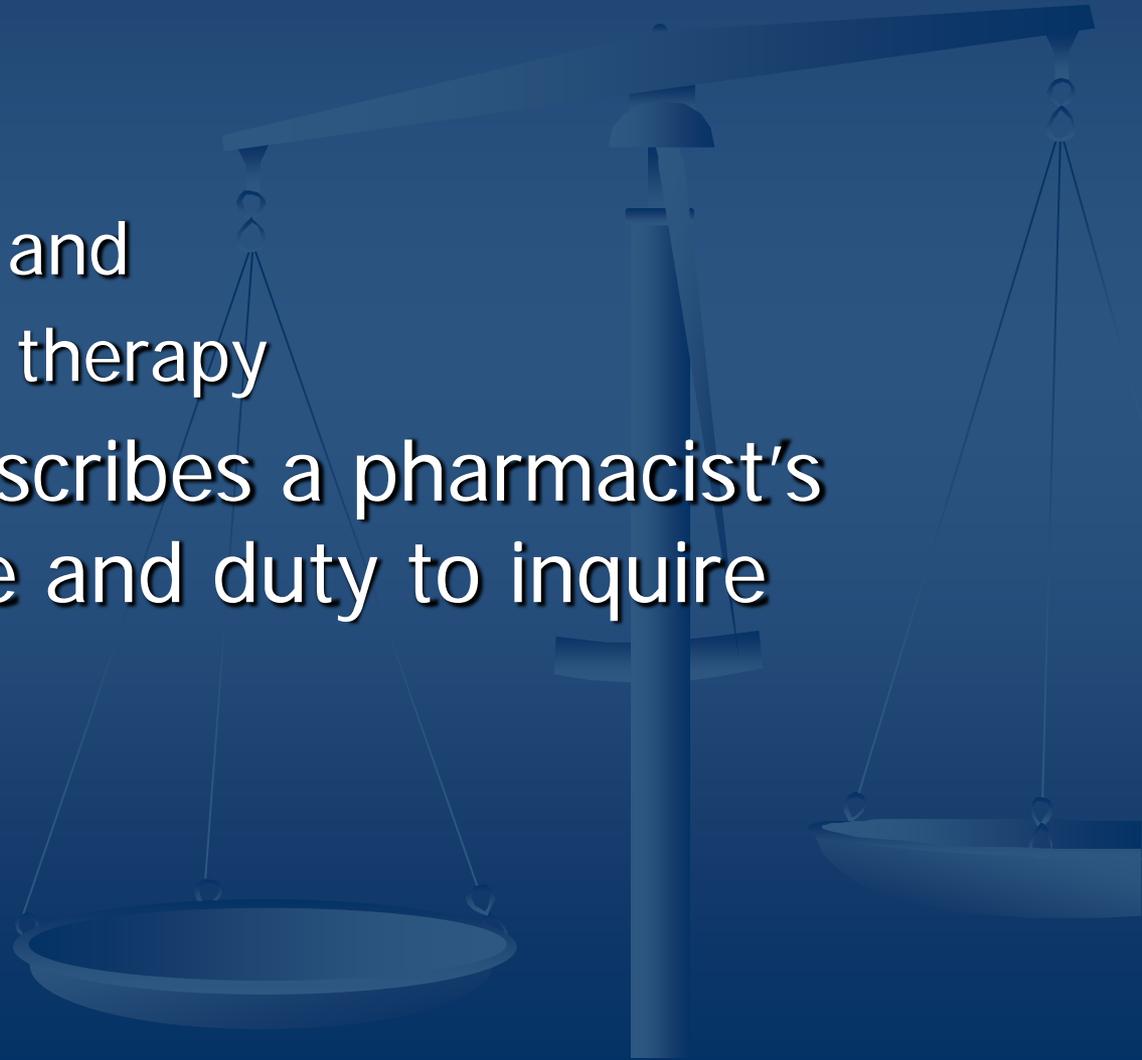
- Considered his role in verifying the prescription to be limited to clarifying information with the prescriber
 - Did not ask patients about their diagnoses or other medical information
 - Did not know about or use CURES
 - Did not inquire why patients would travel so far to a pharmacy to fill a prescription
- 

During the Trial

- Expert witness established pharmacist must exercise corresponding responsibility when dispensing controlled substances
 - A duty that involves more than filling the prescription -- after a pharmacist reviews a prescription to ensure it valid and legitimate on its face, there is still a duty to
- 

A pharmacist's duty to:

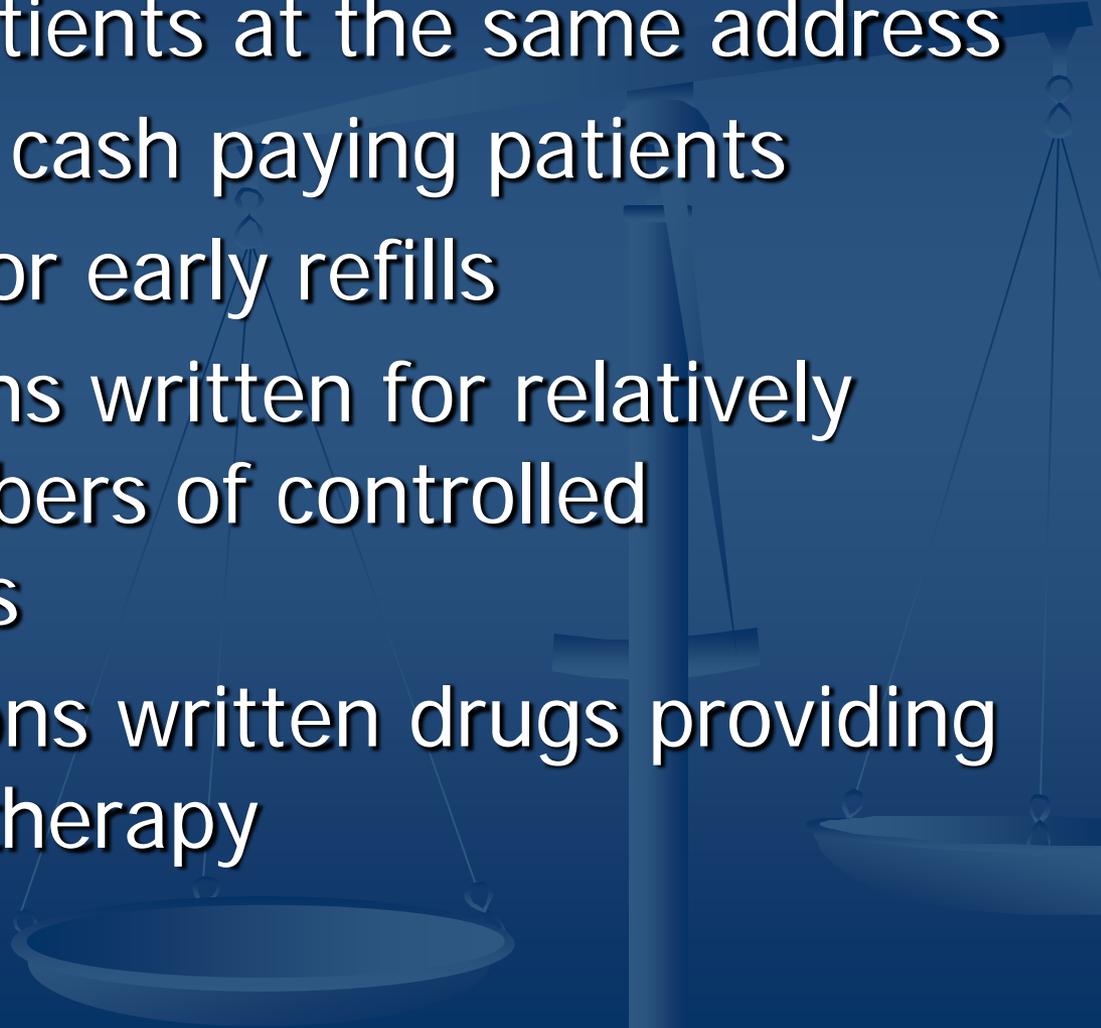
- Evaluate:
 - The patient,
 - The prescriber, and
 - The medication therapy
- The decision describes a pharmacist's standard of care and duty to inquire



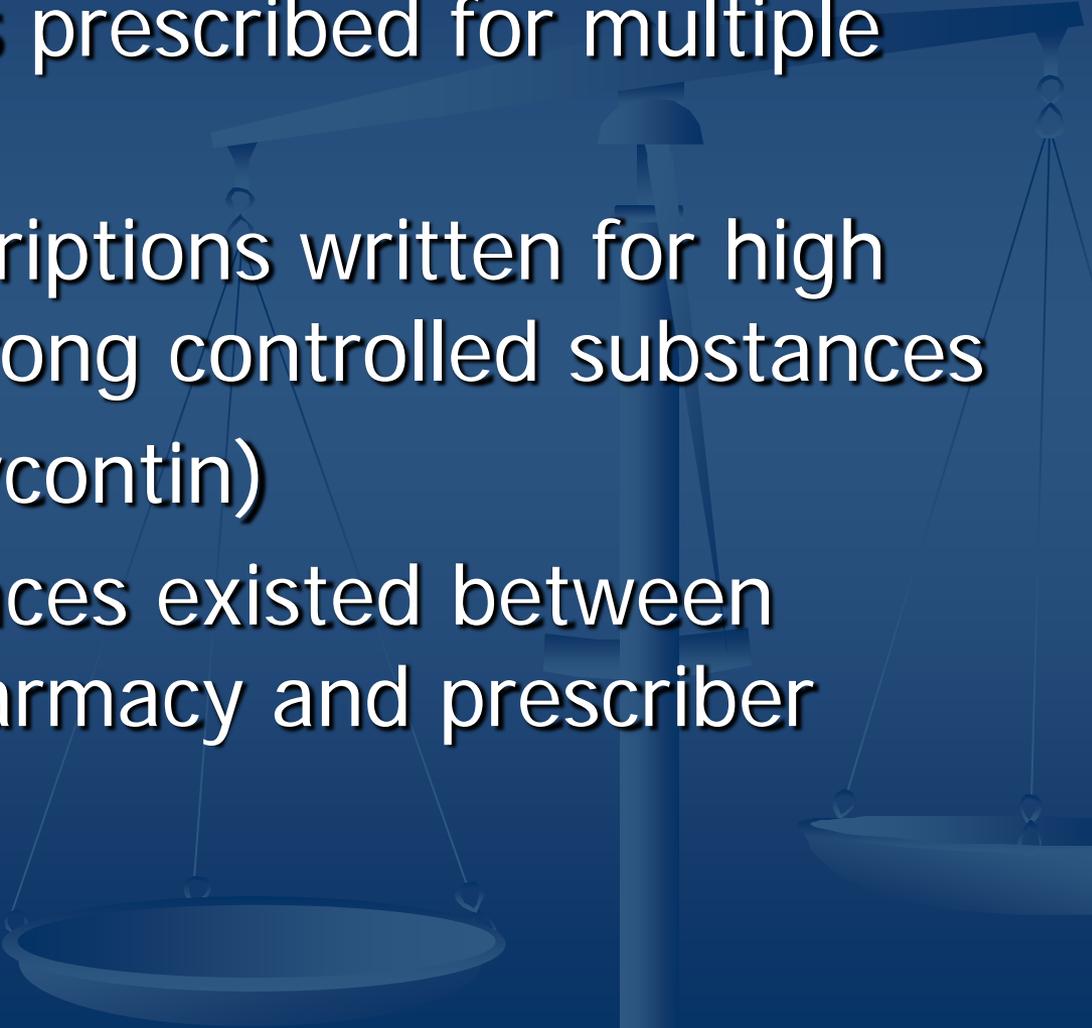
Red Flags Identified

- Irregularities that a pharmacy and pharmacist should investigate before filling:
 - Problems on the written prescription document
 - Nervous patient demeanor
 - Age of patient (young patients receiving chronic pain meds)

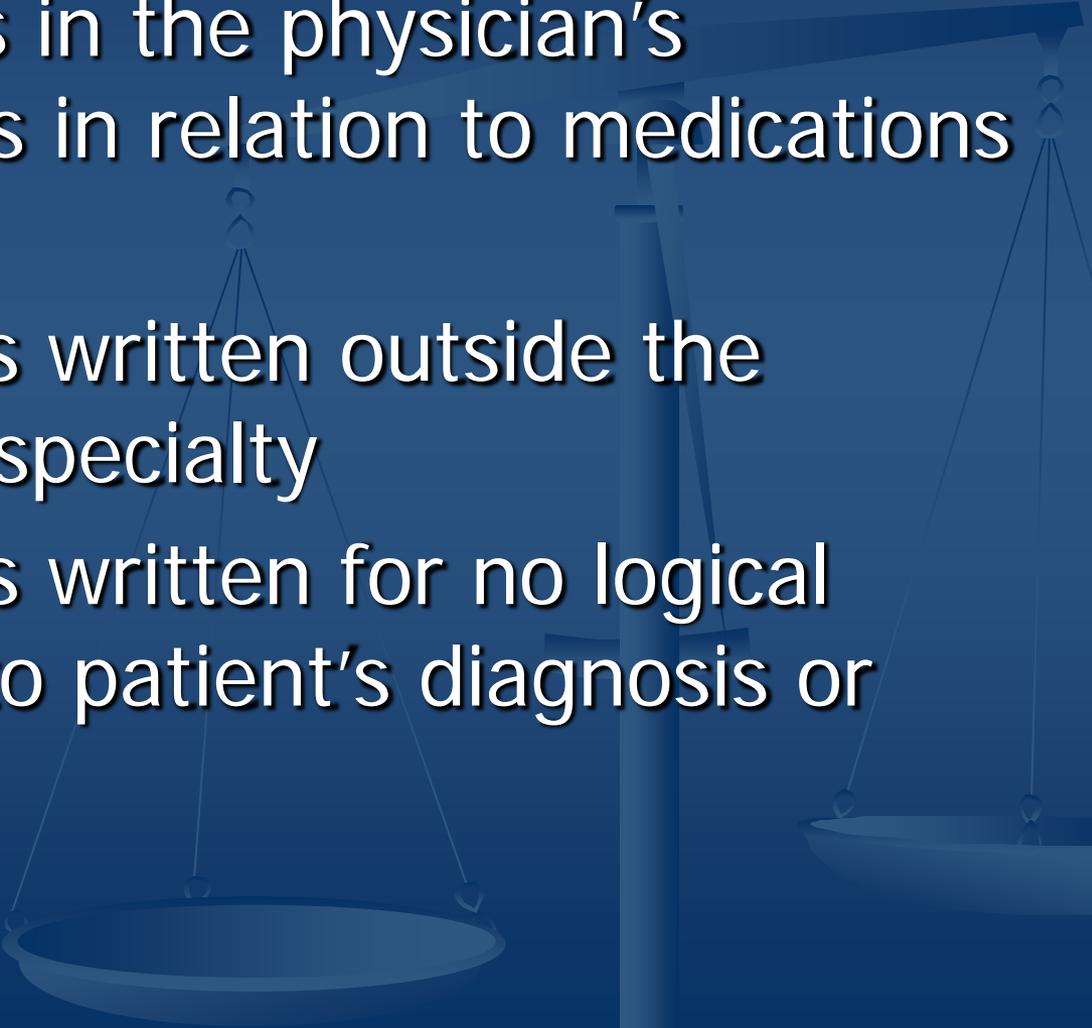
More Red Flags

- Multiple patients at the same address
 - Number of cash paying patients
 - Requests for early refills
 - Prescriptions written for relatively large numbers of controlled substances
 - Prescriptions written drugs providing duplicate therapy
- 

More Red Flags

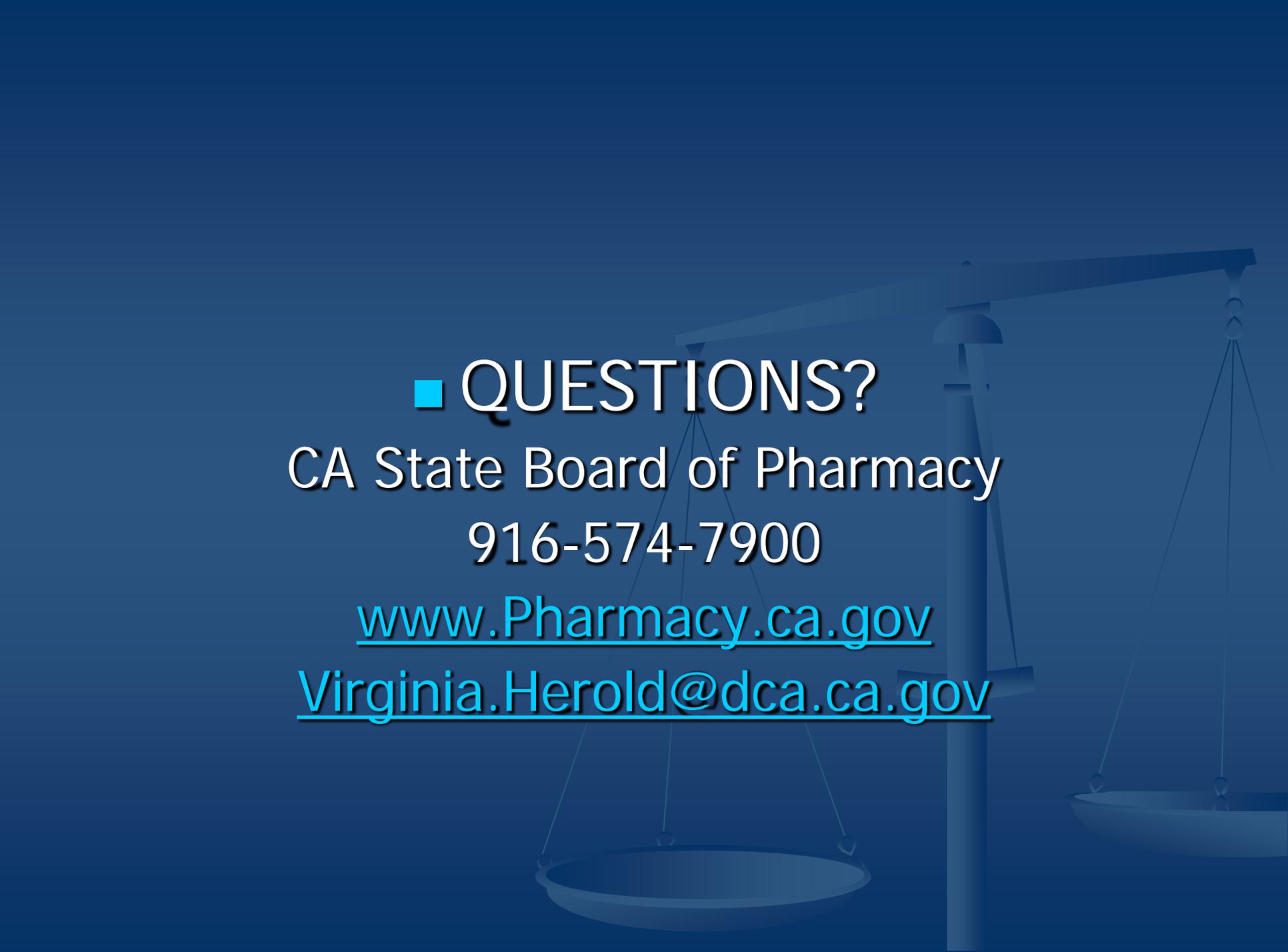
- same drugs prescribed for multiple patients
 - initial prescriptions written for high doses of strong controlled substances (80 mg Oxycontin)
 - large distances existed between patient, pharmacy and prescriber
- 

More Red Flags

- irregularities in the physician's qualifications in relation to medications prescribed
 - prescriptions written outside the prescriber's specialty
 - prescriptions written for no logical connection to patient's diagnosis or treatment
- 

Corresponding Responsibility:

- Decision states whenever a pharmacist believes that a prescription may not have been written for a legitimate medical purpose, the pharmacist must inquire. If the results of the inquiry do not overcome the pharmacist's concern about a prescription being written for a legitimate medical purpose, the pharmacist must not fill the prescription.



- QUESTIONS?

CA State Board of Pharmacy

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