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STATE AND CONSUMERS SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
ENFORCEMENT COMMITTEE
MINUTES**

DATE: September 14, 2010

LOCATION: Samuel Greenberg Board Meeting Room
Los Angeles International Airport
1 World Way
Los Angeles, CA 90045

COMMITTEE MEMBERS

PRESENT: Randy Kajioka, PharmD, Chair
Greg Lippe, Public Member
Ramón Castellblanch, Public Member
Tappan Zee, Public Member

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Tessa Fraga, Staff Analyst

Call to Order

Chair Kajioka called the meeting to order at 9:51 a.m.

1. Request from Omnicare to Modify Existing Requirements in Pharmacy Regulations:
 - 16 California Code of Regulations Section 1745 Regarding Partial Filling of Schedule II Prescriptions
 - 16 California Code of Regulations Section 1793.7 Regarding Requirements of a Pharmacy Employing Pharmacy Technicians

Chair Kajioka provided that earlier this year, the board received two requests for modifications of requirements in board regulations from Omnicare. He advised that this meeting will be the first time the board or one of its committees has the opportunity to discuss these requests.

Presentation to the Committee

Scott Huhn, PharmD, Regional Compliance Manager for Omnicare, provided a presentation to the board on each of the following requests.

1. Request to Modify 16 California Code of Regulations Section 1745 Regarding Partial Filling of Schedule II Prescriptions

Current Regulation

1745. Partial Filling of Schedule II Prescriptions.

(a) A prescription for a Schedule II controlled substance (as defined in Health and Safety Code section 11055) may be partially filled, as defined in paragraph (b), if:

- (1) The prescription is for an inpatient of a skilled nursing facility as defined in Health and Safety Code section 1250; or
- (2) The prescription is for a terminally ill patient. "Terminally ill" as used herein means a patient for whom a licensed physician and surgeon has made and documented a diagnosis of illness or disease that will result in death.

(b) A "partially filled" prescription is a prescription from which only a portion of the amount for which the prescription is written is filled at any one time; provided that regardless of how many times the prescription is partially filled, the total amount dispensed shall not exceed that written on the face of the prescription.

(c) When partially filling a prescription pursuant to subsection (a), all of the following conditions must be met:

- (1) The prescription must be tendered and at least partially filled within 60 days following the date of issue;
- (2) The pharmacist records the date and amount of each partial filling in a readily retrievable form and on the original prescription, also recording the initials of the pharmacist dispensing the prescription;**
- (3) No portion of the prescription is dispensed more than 60 days from the date of issuance of the prescription; and

(d) A pharmacist may partially fill a prescription for a controlled substance listed in Schedule II, if the pharmacist is unable to supply the full quantity ordered by the prescriber. The pharmacist shall make a notation of the quantity supplied on the face of the written prescription. The remaining portion of the prescription may be filled within 72 hours of the first partial filling. If the remaining portion is not filled within the 72-hour period, the pharmacist shall notify the prescriber. The pharmacist may not supply the drug after 72 hour period has expired without a new prescription.

Request

Modify regulation section 1745(c)(2) to allow pharmacies, when partially filling a Schedule II controlled substances prescription (C-II prescription), to modify a computer record instead of the prescription document itself. Currently, the board's requirements for partially filling a CII prescription are to annotate the prescription document itself.

This modification would require rulemaking process by the board.

Discussion

Dr. Huhn reviewed CFR section 1306.13(b) which states, "For each partial filling, the dispensing pharmacist shall record on the back of the prescription **(or on another appropriate record, uniformly maintained, and readily retrievable)** the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist."

Dr. Huhn stated that Omnicare is requesting that § 1745(c)(2) be amended to incorporate this alternative allowance from CFR § 1306.13(b). If amended, § 1745(c)(2) would read:

(2) The pharmacist records the date and amount of each partial filling in a readily retrievable form and on the original prescription (or on another appropriate record uniformly maintained and readily retrievable), also recording the initials of the pharmacist dispensing the prescription;

Dr. Huhn stated that this change would allow for the option of electronic records and would eliminate the need to retain and document a hard copy for each partial fill. He explained that it can be cumbersome to retrieve and document the hard copy for each partial fill over the course of 60 days.

Greg Lippe expressed concern that the electronic record will not be consistent with the original prescription.

Dr. Huhn provided that the original prescription would only contain the initial information and the electronic record would include all updated information.

Ramón Castellblanch requested clarification on the current standard.

Executive Officer Virginia Herold provided that the current regulation has remained unchanged since it was promulgated. She advised that at the time it was promulgated, computers were not used in pharmacies at the same level they are used today.

Supervising Inspector Robert Ratcliff added that the current regulation allows for better patient care for those people who may not live for an extended length of time. He recommended that a simple word change be made to change “and” to “or”:

(2) The pharmacist records the date and amount of each partial filling in a readily retrievable form ~~and~~ or on the original prescription, also recording the initials of the pharmacist dispensing the prescription;

Ms. Herold asked if this would create any confusion from an enforcement perspective.

Dr. Ratcliff indicated that this option would not be a problem for enforcement activities. He suggested that pharmacies develop policies and procedures to ensure that all staff pharmacists maintain records in the same manner.

Mr. Lippe expressed concern regarding this process in the event a pharmacy’s computer system crashes. He explained that if this were to happen, the information available on the hard copy would not be updated or accurate. Policies and procedures should be required to explain how records would be created and maintained.

Dr. Hunh provided that information is stored daily to either a disc or an external hard drive.

Mr. Lippe suggested that pharmacies be required to only use information on the electronic record if the original hard copy has been modified. He also suggested that pharmacies be required to only maintain electronic records if they have available technology.

Dr. Kajioke discussed that not all pharmacies have the same available technology. He cautioned the committee from being overly prescriptive in this area.

Ms. Herold suggested that the following be added to § 1745(c)(2):

A pharmacy that partially fills a prescription pursuant to this section shall do so according to policies and procedures developed by the pharmacy.

Mr. Zee expressed concern that allowing pharmacies to develop their own policies and procedures would lead to inconsistency.

Mr. Zee expressed concern that the committee is moving beyond reviewing and or modifying the section and is instead addressing the issue of how pharmacies maintain their data.

The committee further discussed the option of allowing pharmacies to maintain electronic records or document on the original prescription. This option would be consistent with existing federal regulations.

Dr. Ratcliff provided that Business and Professions Code section 4070(c) requires that changes to electronic records must be made by a pharmacist as well as all changes must be noted to indicate the type of change made. He advised that computer crashes will impact the entire pharmacy and all prescriptions to be dispensed. Mr. Ratcliff recommended that pharmacists be allowed to exercise their professional judgment in this type of situation in order to take care of the patient.

Ms. Herold asked what percentage of a prescription that is partially filled may not reach the patient in a long-term care facility.

Dr. Hunh provided that typically all of the prescription is used.

Dr. Ratcliff provided that this amendment will eliminate the need for pharmacists to refer back to the paper copy of the prescription. He stated that nothing else within the current process will change.

No public comment was provided.

MOTION: Recommend to the full board that section 1745(c)(2) be amended to read:

(2) The pharmacist records the date and amount of each partial filling in a readily retrievable form ~~and~~ or on the original prescription, also recording the initials of the pharmacist dispensing the prescription;

M/S: Zee/Lippe

Support: 4 Oppose: 0 Abstain: 0

2. Permit a waiver of 16 California Code of Regulations Section 1793.7(a) to permit a pharmacy technician to do the final check of a medication if the container is bar coded.

Current Regulation

1793.7. Requirements for Pharmacies Employing Pharmacy Technicians.

(a) Except as otherwise provided in section 1793.8, any function performed by a pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and

storage of pharmaceuticals, must be verified and documented in writing by a pharmacist. Except for the preparation of prescriptions for an inpatient of a hospital and for an inmate of a correctional facility, the pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient.

(b) Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.

(c) A pharmacy technician must wear identification clearly identifying him or her as a pharmacy technician.

(d) Any pharmacy employing or using a pharmacy technician shall develop a job description and written policies and procedures adequate to ensure compliance with the provisions of Article 11 of this Chapter, and shall maintain, for at least three years from the time of making, records adequate to establish compliance with these sections and written policies and procedures.

(e) A pharmacist shall be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients.

(f) For the preparation of a prescription for an inpatient of a licensed health facility and for a patient of a licensed home health agency, the ratio shall not be less than one pharmacist on duty for a total of two pharmacy technicians on duty. Pursuant to Business and Professions Code section 4115(g)(1), this ratio shall not apply to the preparation of a prescription for an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, or for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

There is no waiver process for such a procedure of board regulations, unless an experimental program is conducted with a school of pharmacy pursuant to 16 CCR section 1706.5. Unless this route is pursued, the board would need to consider a rulemaking process to modify section 1793.7.

1706.5 Experimental Programs In order to enable any accredited school of pharmacy recognized by the Board to experiment with new and innovative methods for drug handling, teaching, research, or to develop new and better methods or concepts involving the ethical practice of pharmacy, the Board enacts the following:

(a) The application of particular provisions of the Pharmacy Rules and Regulations contained in Title 16, California Administrative Code, Chapter 17, may be waived as to an accredited school of pharmacy recognized by the Board if the Dean of said school has filed with the Board an experimental plan or program which specifies the particular provisions to be waived, and which has been approved by the Board.

- (b) Any plan or program approved by the Board shall have: definite time limitations; progress reports which shall be filed as required by the Board.
- (c) The Board may rescind approval and terminate said plan or program at its discretion, at any time it may deem the public interest is not fully protected; nor shall any such plan or program be approved by the Board if such proposal might jeopardize public health or welfare or conflict with provisions of Chapter 9, Div. 2, Business and Professions Code.

Request

Permit a waiver of 16 California Code of Regulations Section 1793.7(a) to authorize a pharmacy technician utilizing bar-code scan under supervision of a pharmacist to perform the medication label check prior to delivery to the patient.

Discussion

Dr. Hunh stated that the goal of this request is to improve pharmaceutical care for patients, reduce medication errors, and allow pharmacists to focus on patient-centered activities such as medication therapy management.

Dr. Hunh provided that 12 states have approved this process. He stated that verification confirms that the prescription was filled according to the practitioner's order. Dr. Hunh explained that a pharmacist is actively supervising the medication verification process and is identified on the end of day reports in the operating system.

Dr. Hunh discussed the benefits of bar-code technology and added that it is recommended by the Institute for Safe Medication Practices and the National Association of Boards of Pharmacy (NABP).

Dr. Kajioka asked who would be indicated as the dispenser.

Dr. Hunh provided that both the technician and the pharmacist will be indicated as the dispenser.

Dr. Kajioka provided that the current regulation does not show that technicians have any ownership of the prescriptions that are dispensed.

Dr. Hunh sought clarification on how section 1793.8 would apply to this area.

Dr. Kajioka provided that he does not believe that the board has authority to waive a regulation unless the procedure is part of an experimental program conducted with a school of pharmacy. He requested that the board seek clarification on this issue from the board's legal counsel.

It was the consensus of the committee to seek legal clarification from board counsel and suggested that Omnicare develop an experimental program with a school of pharmacy.

Dr. Hunh asked if the board will provide any written notice to Omnicare to use to approach the schools of pharmacy.

Ms. Herold recommended that Omnicare develop a proposal to bring before the full board before approaching schools of pharmacy.

No public comment was provided.

2. Question and Answer Session on the Board's Implementation of 16 California Code of Regulations Sections 1735-1735.8, Pharmacies That Compound, and Sections 1751-1751.8, Pharmacies That Compound Sterile Injectable Medications

Chair Kajioka provided that at the last Enforcement Committee Meeting, Supervising Inspector Robert Ratcliff provided a question and answer session on the new compounding regulations that took effect in July 2010. He indicated that the answers to these and other submitted questions have been compiled into a document and will be posted on the board's Web site. Chair Kajioka stated that the board is responding to these questions to aid pharmacies in complying with the new requirements.

Chair Kajioka requested any additional questions from the public.

Public Comment

Howard Switzey, representing Kaiser Permanente, sought clarification regarding § 1735.6(a) – Compounding Facilities and Equipment with regards to the board's intent and enforcement of this requirement.

Dr. Ratcliff provided that the board will be ensuring that all equipment within the facility is calibrated and certified as required. He stated that ensuring that the facility itself meets building standards is not within the board's jurisdiction.

Dr. Ratcliff requested that all questions from the public also be submitted in writing to be added to the compounding question and answer document that will be made available on the board's Web site.

Mr. Switzey asked whether § 1735.3(b) requires that records be documented every time a product is used for compounding.

Dr. Ratcliff indicated that records for a product are to be updated with regards to use, acquisition, storage, and destruction.

Mr. Switzey provided that industry is seeking guidance regarding end product testing.

Dr. Ratcliff provided that the board expects each institution to implement process validation in this area.

Discussion continued regarding end product testing and the compounding requirements. Chair Kajioka provided that the board wants to allow flexibility in this area to allow pharmacists to exercise their professional judgment.

Chair Kajioka suggested that a small subcommittee be created to address questions regarding the compounding regulations.

There was no additional committee discussion or public comment.

3. Update on California's Drug "Take Back" Programs from Patients

Chair Kajioka provided that at the 2010 July Board Meeting, the board reviewed a proposed draft of a CalRecycle report to the Legislature on the implementation of drug take back programs from patients seeking to destroy their unwanted medications.

Chair Kajioka provided that this report to the Legislature is required by SB 966 (Simitian, Chapter 562, Statutes of 2007), and is due December 1, 2010. He stated that the legislative report must:

. . . include an evaluation of the model programs for efficacy, safety, statewide accessibility, and cost effectiveness. The report shall include the consideration of the incidence of diversion of drugs for unlawful sale and use, if any. The report also shall provide recommendations for the potential implementation of a statewide program and statutory changes.

Chair Kajioka provided that during the board meeting, staff was directed to provide comments on this draft. He indicated that these comments were submitted to CalRecycle in mid-August. Chair Kajioka added that these comments were provided in the committee's packet.

Chair Kajioka provided that on September 25, 2010, the federal Drug Enforcement Administration (DEA) will host a nationwide drug take back event so the public can dispose of its unwanted/unneeded medications.

Public Comment

Steve Gray, representing Kaiser Permanente, asked for more detail regarding the DEA event.

Ms. Herold provided that more information will be provided by a DEA representative during the next agenda item.

There was no additional committee discussion or public comment.

4. Presentation by the Michael Lewis, Diversion Program Manager, Federal Drug Enforcement Administration, Los Angeles

Chair Kajioka provided that as has been discussed at prior Enforcement Committee and Board Meetings, drug diversion issues and prescription drug abuse are serious enforcement matters for the board and other regulators.

Presentation to the Committee

Mike Lewis, Diversion Program Manager, Federal Drug Enforcement Administration, Los Angeles, provided information on DEA activities or objectives aimed at preventing drug diversion and prescription drug abuse.

Mr. Lewis provided an overview of the DEA Regulations to permit e-prescribing of controlled substances. He discussed parties involved in this process including application providers, prescribing practitioners, and pharmacies.

Mr. Lewis expressed concern that prescription drugs have impacted the attitudes of teenagers who believe that prescription drugs are “much safer” than illegal drugs. He stated that teenagers are reporting that prescription drugs are more readily available than illegal drugs and can often be found in the medicine cabinets within their homes.

Mr. Lewis discussed the increasing frequency and volume of drug diversion of controlled substances in California. He stated that diversion involves many groups including practitioners, pharmacists, employees, and patients and involves various motivations such as addiction, physical dependence, resale for money and/or illegal drugs, power, control or importance, and sex. Mr. Lewis reviewed commonly diverted drugs including oxycontin, hydrocodone, xanax (alprazolam), codeine cough syrup, amphetamines, and valium.

Mr. Lewis provided that the DEA will be hosting a National Drug Take Back Day on September 25, 2010. He explained that, together with the help of local and state law enforcement agencies, this event provides the public an opportunity to return unused controlled substances. Mr. Lewis indicated that the DEA will be providing collection boxes and will transport and incinerate the collected drugs. He advised that needles and sharps containers will not be collected.

Public Comment

Steve Gray, representing Kaiser Permanente, asked if non-controlled substances will also be collected. He asked whether posters are available to help advertise the event.

Mr. Lewis indicated that non-controlled substances will be accepted. He provided that posters are available and that the DEA has asked law enforcement and community groups to help advertise for the event.

A member of the public asked if this will be a one time event.

Mr. Lewis provided that there are plans for a second drug take back day in about 6 months.

Dr. Castellblanch asked if there will be any publicity surrounding the events planned.

Mr. Lewis provided that the DEA planned an Open House for the media and will also be planning television spots, radio and morning show announcements, and electronic banner ads. He indicated that collection site information has been posted at www.dea.gov.

Dr. Kajioka asked how other law enforcement groups can participate.

Mr. Lewis stated that the DEA has reached out to as many law enforcement agencies as possible. He indicated that some departments are unable to staff the event as it is scheduled for a Saturday and overtime is not permitted.

Ms. Herold provided that the board has already sent a subscriber alert and plans to send a second alert closer to the event.

Ms. Herold discussed the diversion cases investigated by the board. She indicated that the number of diversion cases has significantly increased over the last two years. She advised the committee that this is an important issue to be addressed by the board.

Mr. Lewis provided that the DEA would like to work closer with the board on cases and ways to prevent diversion.

Dr. Castellblanch asked if there are any available reports regarding organized crime and pharmacies.

Mr. Lewis provided that the DEA is conducting investigations regarding gangs attempting to purchase pharmacies or meet with pharmacists. He indicated that

the DEA has not produced a study or report regarding organized crime involved with pharmacies.

Orriette Quandt sought clarification on e-prescribing requirements regarding whether companies who authenticate prescriber's signatures have been identified.

Mr. Lewis provided that these companies are often working with a state regulatory board or some type of certification service. He stated that the DEA headquarters may be able to provide more information on this area.

Dr. Quandt discussed that prescribers are trying to electronically prescribe controlled substances and are being told by application providers that this practice is legal.

Mr. Lewis provided that this information should be reported to the DEA for further review.

Dr. Gray indicated that Kaiser has been notified that the Washington D.C. DEA office has a list of acceptable certifying agencies.

There was no additional committee discussion or public comment.

5. Presentation by Supervising Inspector Judi Nurse on Thefts of Drugs from Pharmacies

Presentation to the Committee

Supervising Inspector Judi Nurse provided an overview of the presentation that she and Executive Officer Virginia Herold gave in May regarding pharmacy thefts and robberies from pharmacies, and from various entities in the pharmaceutical supply chain (e.g., common carriers) to a group of San Diego pharmacists brought together by the DEA at a forum to discuss and prevent drug diversion.

Dr. Nurse discussed three main areas: (1) increased awareness among pharmacists about diversion, (2) prevention of diversion and theft from pharmacies, and (3) the importance of dispensing responsibly using corresponding responsibility. She reviewed the increase in diversion in pharmacies and indicated that the board's diversion cases have increased by 40 percent over the past few years.

Dr. Nurse explained that pharmacists are responsible for the security of the drugs and are the last line of defense against diversion of drugs to the streets, either by theft from the pharmacy or inappropriate dispensing of controlled substances.

She stated that the board's responsibility includes education and the protection of the consumer by aggressively pursuing those who do not comply.

Dr. Castellblanch asked whether oxycontin is the most commonly diverted drug.

Dr. Nurse provided that Vicodin products represent the largest volume of diverted drugs. She indicated that oxycontin and Ambien are also commonly diverted.

Dr. Castellblanch sought clarification regarding diversion from manufacturers and wholesalers.

Dr. Nurse provided that the board does not regulate manufacturers.

Ms. Herold provided that wholesalers in California are taking steps to combat diversion from the drug distribution process. She provided that the board still has cases involving deliveries from a wholesaler that are not delivered directly to the pharmacist as required by law.

Dr. Nurse discussed Business and Professions Code § 4059.5 which requires that all dangerous drugs or devices be delivered to a licensed pharmacy and signed for and received by a pharmacist. She indicated that this requirement is an important security measure to ensure that pharmacists are aware of what drugs are coming in and out of the pharmacy.

Steve Gray, representing Kaiser Permanente, provided that the DEA law requires that all controlled substances are locked up in either a cage or vault within a wholesale facility. He stated that controlled substances within a hospital or pharmacy are often spread throughout inventory and are not required to be locked up. Dr. Gray provided comment on the role of common carriers with regards to the delivery of drugs. He indicated that pharmacies need help from the board, DEA, and Department of Justice to ensure that common carriers honor the law to ensure that all deliveries are delivered directly to the licensed pharmacy and are not left on a loading dock.

Dr. Castellblanch asked whether the board can enforce common carriers.

Ms. Herold provided that the board has no jurisdiction over common carriers.

Mr. Lippe asked whether it is typical to have camera surveillance over controlled substance storage areas.

Dr. Gray provided that this is not common. He indicated that Kaiser does lock up and have camera surveillance over Schedule II drugs storage areas.

There was no additional committee discussion or public comment.

The committee deferred discussion of agenda item 6 in order to discuss agenda item 7.

7. Discussion and Possible Action to Implement DCA's Recommendations of the Substance Abuse Coordination Committee, Pursuant to SB 1441, for the Pharmacists Recovery Program

Dr. Kajioka provided that SB 1441 created the Substance Abuse Coordination Committee (SACC) and required that this committee, by January 1, 2010, formulate uniform and specific standards in specified areas that each healing arts board must use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program.

Dr. Kajioka provided that to facilitate implementation of these standards, the DCA created a workgroup consisting of staff from each of the healing arts boards to draft recommended standards for the SACC consideration during public meetings.

Dr. Kajioka provided that Business and Professions Code sections 4360 thru 4373 establish the Pharmacists Recovery Program (PRP) and establish some of the functions of the program as well as program participation criteria. He stated that the board contracts with a vendor, currently Maximus, Inc. to administer the PRP. Dr. Kajioka advised that under current law, this program is only available to pharmacists and interns.

Presentation to the Committee

Assistant Executive Officer Anne Sodergren provided an overview of SB 1441 and the uniform standards regarding substance-abusing healing arts licensees.

Ms. Sodergren advised that on August 4, 2010, a subcommittee convened to further discuss uniform standard four dealing with drug testing. She indicated that the subcommittee did not complete its revision of this standard and a future meeting will be set.

Ms. Sodergren highlighted the first standard and reviewed changes needed prior to implementation.

1. **Clinical diagnostic evaluation**

- Specifies that if a licensee in a diversion program or on probation is required to undergo a clinical evaluation it shall comply with:
 - i. Qualifications for the licensed practitioner performing the evaluation
 - ii. Acceptable standards for such evaluations
 - iii. Identified elements of the report
 - iv. Timeframes to complete the process and prohibition of the evaluator having a financial relation, etc. with the licensee.
- Changes needed for implementation:

- i. Pharmacists/Interns
 - 1. Contract change for PRP participants
 - 2. Regulation change (disciplinary guidelines)
- ii. Other individuals
 - 1. Statutory change (establish program)
 - 2. Regulation change (disciplinary guidelines)

Ms. Herold asked the committee to discuss whether or not it deems this standard appropriate for all individuals. She indicated that currently, participants in the PRP undergo a clinical diagnostic evaluation; however, probationers may not.

Mr. Zee suggested that the board wait until the standards are final prior to implementation of the requirements.

Ms. Herold provided that the department has asked all healing arts boards to move forward with implementation of the standards. She indicated that the board's legal counsel has advised the board not to move too far forward until all standards are final.

Dr. Castellblanch asked whether the current evaluations act as a deterrent for current PRP participants.

Ms. Sodergren provided that the evaluations are used as a step in the rehabilitation process and not as a deterrent. She indicated that the evaluations provide baseline information regarding a participant's level of recovery, severity of substance abuse, and any underlying dual diagnosis information including mental illness.

Mr. Lippe asked whether a second evaluation is performed after a participant completes the program.

Ms. Sodergren provided that most PRP participants will be assessed regularly by a health support group facilitator (a licensed clinician). She indicated that treatment contracts also allow for annual reassessments. Ms. Sodergren stated that the board's disciplinary guidelines permit additional evaluations at the request of the board.

Dr. Castellblanch asked how the cost of the evaluation will impact pharmacy technicians.

Ms. Herold provided that the current model disciplinary guidelines do not include evaluations for technicians. She indicated that if ordered, this cost would be born by the technician. Ms. Herold suggested that the committee could recommend that evaluations be included in the model disciplinary guidelines if deemed an integral probation monitoring tool.

Mr. Lippe provided comment in support of requiring an evaluation as part of probation requirements. He stated that the evaluation would be beneficial in providing baseline information as well as identifying any risks if the individual reenters the program or has future discipline issues.

Chair Kajioka provided that an evaluation post program/probation completion would provide valuable information as to whether or not the individual is likely to relapse.

Chair Kajioka suggested that the committee revisit the standards after they have been finalized.

It was the consensus of the committee to discuss the standards at a future meeting when more information is available and the standards have been finalized. The committee requested that Ms. Herold communicate to the subcommittee the committee's interest in the standards and that it believes the clinical diagnostic evaluation is a strong and worthwhile tool.

Ms. Sodergren advised that there may be timing issues with implementing the standards as statutory changes may be needed. She indicated that regulation changes will be easier to implement.

Steve Gray, representing Kaiser Permanente, provided comment with respect to costs for pharmacy technicians. He advised that the cost of the evaluation may be covered by health insurance policies depending on what type of practitioner is required to administer the evaluation. Dr. Gray provided comment in support of the evaluations as a tool to provide baseline information when limiting a licensee's practice. He added that employers should be advised of a licensee's limited practice.

Mr. Lippe cautioned the board from focusing on the cost to a violator as a determining factor when considering whether an evaluation should be added as a requirement.

Ms. Sodergren advised that currently the board is required to post licensees' work restrictions; however, the reason for the restrictions cannot be disclosed.

Ms. Herold provided that standard discipline terms include that a licensee notifies all present and prospective employers of the terms, conditions and restrictions imposed by their decision.

Ms. Herold provided that the board may want to consider amending the disciplinary guidelines in the future to include a requirement for probationers to undergo a clinical diagnostic evaluation.

Ms. Sodergren reviewed each of the following standards and any changes needed in order to implement the requirements.

2. Temporary removal of practice for clinical evaluation

- Specifies that board will issue a cease practice order during the evaluation and review of the results by board staff.
- Specifies that the licensee will be subject to random drug testing at least two times per week.
- Sets forth the evaluation criteria that must be considered by the diversion or probation manager when determining if a licensee is safe to return to work and under what conditions.
- Changes needed for implementation:
 - Pharmacists/Interns
 - Statutory change
 - Contract change for PRP participants
 - Regulation change (disciplinary guidelines)
 - Other individuals
 - Statutory change
 - Regulation change (disciplinary guidelines)

3. Communication with a licensee's employer, if applicable

- Requires a licensee to notify the board of the names, physical addresses, mailing addresses and telephone numbers of all employers.
- Requires a licensee to give written consent authorizing the board and employers and supervisors to communicate regarding the licensee's work status, performance and monitoring.
- Changes needed for implementation:
 - Pharmacists/Interns
 - Regulation change (disciplinary guidelines)
 - Other individuals
 - Regulation change (disciplinary guidelines)

4. Drug testing

- Sets forth a minimum testing frequency of 104 random drug tests per year for the first year and a minimum of 50 random drug tests per year (from then on).
- Specifies that testing shall be observed; conducted on a random basis, as specified; and may be required on any day, including weekends or holidays.
- Requires licensees to check daily to determine if testing is required and specifies that the drug test shall be completed on the same day as notification.
- Establishes criteria for the collection sites and laboratories processing the results.
- Changes needed for implementation:
 - Pharmacists/Interns
 - Contract change for PRP participants
 - Regulation change (disciplinary guidelines)
 - Other individuals

- Statutory change (establish program)
- Regulation change (disciplinary guidelines)

Ms. Herold provided that the board currently does not test PRP participants or probationers at this high of a frequency except in extreme cases.

Ms. Sodergren provided that the subcommittee is evaluating how this standard applies to cases where a person has already progressed into recovery at the time of his or her entrance into the program and whether this high frequency is needed. She stated that there is also a concern regarding whether it is more beneficial in terms of consumer protection to test at a higher frequency to catch noncompliance or less frequently to maintain randomness.

Ms. Herold provided that drug testing can be costly and could be burdensome especially for pharmacy technicians and pharmacist interns.

Dr. Kajioka provided that he believes the frequency to be an excessive amount. He stated that he believes that removing a practitioner from work who tests positive during random testing is achieving public protection.

5. Group meeting attendance

- Sets forth the evaluation criteria that must be considered when determining the frequency of group support meetings.
- Specifies the qualifications and reporting requirements for the meeting facilitator.
- Changes needed for implementation:
 - Pharmacists/Interns
 - Contract change for PRP participants
 - Regulation change (disciplinary guidelines)
 - Other individuals
 - Statutory change (establish program)
 - Regulation change (disciplinary guidelines)

6. Type of treatment

- Sets for the evaluation criteria that must be considered when determining whether inpatient, outpatient, or other type of treatment is necessary.
- Changes needed for implementation:
 - Pharmacists/Interns
 - Contract change for PRP participants
 - Regulation change (disciplinary guidelines)
 - Other individuals
 - Statutory change (establish program)
 - Regulation change (disciplinary guidelines)

7. Worksite monitoring

- Allows for the use of worksite monitors.

- Specifies the criteria for a worksite monitor.
- Establishes the methods of monitoring that must be performed by the worksite monitor.
- Sets forth the reporting requirements by the worksite monitor; specifies that any suspected substance abuse must be verbally reported to the board and the licensee's employer within one business day; and specifies that a written report must be provided to the board within 48 hours of the occurrence.
- Requires the licensee to complete consent forms and sign an agreement with the worksite monitor and board to allow for communication.
- Changes needed for implementation:
 - Pharmacists/Interns
 - Contract change for PRP participants
 - Regulation change (disciplinary guidelines)
 - Other individuals
 - Statutory change (establish program)
 - Regulation change (disciplinary guidelines)

8. Positive drug test

- Requires the board to issue a cease practice order to a licensee's license and notify the licensee, employee and worksite monitor that the licensee may not work.
- Specifies that after notification, the board should determine if the positive drug test is evidence of prohibited use and sets forth the criteria the board must follow when making such a determination.
- Specifies that if the board determines that it was not a positive drug test, it shall immediately lift the cease practice order.
- Changes needed for implementation:
 - Pharmacists/Interns
 - Statutory change
 - Contract change for PRP participants
 - Regulation change (disciplinary guidelines)
 - Other individuals
 - Statutory change
 - Regulation change (disciplinary guidelines)

9. Ingestion of a banned substance

- Specifies that when a board confirms a positive drug test as evidence of use of a prohibited substance, the licensee has committed a major violation.
- Changes needed for implementation:
 - Pharmacists/Interns
 - Contract change for PRP participants
 - Regulation change (disciplinary guidelines)
 - Other individuals
 - Statutory change (establish program)
 - Regulation change (disciplinary guidelines)

10. Consequences for major and minor violations

- Specifies what constitutes a major violation including: failure to complete a board ordered program or undergo a clinical diagnostic evaluation; treating patients while under the influence of drugs/alcohol, and drug/alcohol related act which would constitute a violation of the state/federal laws, failure to undergo drug testing, confirmed positive drug test, knowingly defrauding or attempting to defraud a drug test.
- Specifies the consequences for a major violation including: issuing a cease practice order to the licensee; requiring a new clinical evaluation; termination of a contract/agreement; referral for disciplinary action.
- Specifies what constitutes a minor violation including: untimely receipt of required documentation; unexcused group meeting attendance; failure to contact a monitor when required; any other violations that does not present an immediate threat to the violator or the public.
- Specifies the consequences for a minor violation including: removal from practice; practice restrictions; required supervision; increased documentation; issuance of a citation and fine or working notice; re-evaluation/testing; other actions as determined by the board.
- Changes needed for implementation:
 - Pharmacists/Interns
 - Statutory change
 - Contract change for PRP participants
 - Regulation change (disciplinary guidelines)
 - Other individuals
 - Statutory change
 - Regulation change (disciplinary guidelines)

11. Return to full time practice

- Establishes the criteria to return to full time practice, including demonstrated sustained compliance, demonstrated ability to practice safely, negative drug screens for at least six months, two positive worksite monitor reports and compliance with other terms and conditions of the program.
- Changes needed for implementation:
 - Pharmacists/Interns
 - Statutory change
 - Contract change for PRP participants
 - Other individuals
 - Statutory change

12. Unrestricted practice

- Establishes the criteria for a licensee to request unrestricted practice including sustained compliance with a disciplinary order, successful completion of the recovery program, consistent and sustained participation in recovery activities, demonstrated ability to practice safely and continued sobriety of three to five years, as specified.
- Changes needed for implementation:

- Pharmacists/Interns
 - Statutory change
 - Contract change for PRP participants
- Other individuals
 - Statutory change

13. Private-sector vendor

- Specifies that the vendor must report any major violation to the board within one business and any minor violation within five business days.
- Establishes the approval process for providers or contractors that work with the vendor consistent with the uniform standards.
- Requires the vendor to discontinue the use of providers or contractors that fail to provide effective or timely services as specified.
- Changes needed for implementation:
 - Pharmacists/Interns
 - Statutory change
 - Contract change for PRP participants

14. Confidentiality

- For any participant in a diversion program whose license is on an inactive status or has practice restrictions, requires the board to disclose the licensee's name and a detailed description of any practice restrictions imposed.
- Specifies that the disclosure will not include that the restrictions are as a result of the licensee's participation in a diversion program.
- Changes needed for implementation:
 - Pharmacists/Interns
 - Statutory change
 - Contract change for PRP participants
 - Other individuals
 - Statutory change

15. Audits of private-sector vendor

- Requires an external independent audit every three years of a private-sector vendor providing monitoring services.
- Specifies that the audit must assess the vendor's performance in adhering to the uniform standards and requires the reviewer to provide a report to the board by June 30 of each three year cycle.
- Requires the board and department to respond to the findings of the audit report.
- Changes needed for implementation:
 - Pharmacists/Interns
 - Statutory change
 - Contract change for PRP participants

16. Measurable criteria for standards

- Establishes annual reporting to the department and Legislature and details the information that must be provided in the report.
- Sets forth the criteria to determine if the program protects patients from harm and is effective in assisting licensees in recovering from substance abuse in the long term.
- Changes needed for implementation:
 - Pharmacists/Interns
 - Contract change for PRP participants

Ms. Herold discussed challenges that the board may encounter when implementing the standards. She recommended that the board divide the standards into related categories for further evaluation. She discussed that once implemented, it will be more difficult to monitor probationers as their restrictions are decreased and lifted in a progressive fashion – probationary terms usually do not change during progression through probation.

Discussion continued regarding the standards. It was the consensus of the committee to wait for further clarification before making a recommendation to the board. It was requested that the standards be broken down into categories for a future discussion.

Ms. Herold discussed the department's contract and performance audit of Maximus for its diversion services. She indicated that a copy of the audit report will be posted on the board's Web site.

Mr. Lippe expressed concern regarding some of the deficiencies noted in the program regarding records and documentation.

Ms. Sodergren provided that the report focuses on the services provided by Maximus to six healing arts boards and one committee. She advised that the programs are not run the same and that the PRP reviews participants quarterly to ensure that the systematic checks are in place.

Mr. Lippe asked what follow-up will be done in response to the audit findings.

Ms. Herold provided that Maximus has had an opportunity to respond to the findings and has indicated that it will address the deficiencies.

Ms. Sodergren provided that the standards will require that the vendor be audited every three years.

Ms. Herold provided that board staff will be meeting with the department to discuss necessary follow-up action by the department.

The committee requested an update on the audit response at a future meeting.

No public comment was provided.

6. Update on the Board's Efforts to Implement Components of the Department of Consumer Affairs Consumer Protection Enforcement Initiative

Background

Beginning in July 2009, the Department of Consumer Affairs has been working with health care boards to improve capabilities to investigate and discipline errant licensees to protect the public from harm. These results yielded the Consumer Protections Enforcement Initiative (CPEI). The CPEI was comprised of a three pronged solution designed to ensure that investigation were completed and final action taken against a licensee within 12 – 18 months. The solution included legislative changes designed to remove barriers to investigations, a new computer system that would meet the boards needs to collect information and monitor performance, and additional staff resources.

Many of the legislative changes identified by the department were incorporated in SB 1111 (Negrete McLeod). Unfortunately, this bill failed passage early in the year during its first policy committee. Subsequently, the department identified provisions in the bill that could be implemented through regulation and encouraged boards to develop language and initiate the rulemaking process.

In addition to working with the department on a department-wide solution, the board also identified statutory changes that would specifically address pharmacy related issues. Language for these provisions was discussed during the January 2010 Board Meeting, and the board voted to pursue the changes. Because of the timing with the legislative cycle, these provisions were not pursued this year.

More recently, during the June 2010 Board Meeting, the board discussed proposed regulatory language developed by counsel, designed to implement the provisions requested by the department. The board expressed concern on many of the provisions and with one exception, did not take action on the items.

Ms. Herold recommended that this issue be discussed by the full board. She provided that the department is working towards standardizing performance measures to be posted on board and department Web sites.

Ms. Herold discussed several challenges impacting the board as a result of the current budget situation including a hiring freeze preventing the filling of the positions allocated by the CPEI, overtime prohibition, and furloughs. She stated that it will be a challenge for the board to meet the measuring standards and to

ensure that investigations are completed and final action is taken against a licensee within 12 – 18 months without the needed staffing.

Chair Kajioka referenced to the case timelines provided within the board packet.

Ms. Sodergren provided that the board's disciplinary guidelines have not been updated since 2008. She stated that the committee may wish to direct staff to initiate this review and bring recommendations back to the committee for evaluation.

No public comment was provided.

MOTION: Direct staff to initiate review of the disciplinary guidelines and report back recommended changes for future committee and board discussion and action.

M/S: Lippe/Kajioka

Support: 3 Oppose: 0 Abstain: 0

8. GS1 Schedules October 2010 Forum in San Francisco on Serialization and Track and Track in the Pharmaceutical Supply Chain

Background

Since 2004, California has had statutory requirements to require all drug products sold in California to be electronically tracked back to the manufacturer, tracing every change in ownership – from the manufacturer, through wholesaler(s), to the pharmacy.

This secure, chain of custody system, is intended to safeguard California's pharmaceutical supply chain to prevent drug diversion, unauthorized resales into the supply chain, and the introduction of counterfeit drugs. These requirements model those of the FDA in their 2004 counterfeit task force report.

California's law has been amended twice since 2004 – in 2006 and 2008. The implementation of e-pedigree requirements in California is now on a phased-in schedule between 2015 and July 2017. Before these dates arrive, it was hoped that a federal law would be enacted to establish national standards for strengthening the supply chain.

Nevertheless, since the 2008 legislation, various companies in the supply chain have been working on the serialization piece to comply with California's requirements.

Chair Kajioka provided that in October 2010, GS1, which is a worldwide standards-setting organization, will hold a forum on serialization and track and trace in California.

No public comment was provided.

9. Public Comment for Items Not on the Agenda

No public comment was provided.

The meeting was adjourned at 1:34 p.m.

DRUG ENFORCEMENT ADMINISTRATION



Office of Diversion Control

DRUG ENFORCEMENT ADMINISTRATION

Comprehensive Drug Abuse Prevention and Control Act of 1970



The Controlled Substance Act (CSA)



Electronic Prescriptions for Controlled Substances

Federal Register Publication

- Interim Final Rule with Request for Comment
- Effective June 1, 2010
- Comment period ended June 1, 2010
- More than 90 comments received

Overview

- Practitioners have the option of signing and transmitting prescriptions for controlled substances electronically
- Permits pharmacies to receive, dispense, and archive electronic prescriptions
- CII-V prescriptions permissible

Overview

- Electronic prescriptions for controlled substances are voluntary from DEA's perspective
- Written, manually signed, and oral prescriptions for controlled substances, where applicable, still permitted

Who is Affected

- **Application providers** that develop, sell, and host electronic prescription applications and pharmacy applications
- **DEA-registered practitioners** who want to sign and transmit controlled substances prescriptions electronically
- **DEA-registered pharmacies** that want to process electronic prescriptions for controlled substances

How are they Affected

- **Application providers:** undergo third-party audit or certification to determine whether application meets requirements
- **Prescribing practitioners:** select application, identity proofing, set access controls, sign prescriptions
- **Pharmacies:** select application, set access controls, process prescriptions, archive prescriptions

Application Providers

- Prior to use for controlled substances prescriptions must undergo independent audit or certification
 - WebTrust, SysTrust, SAS 70
 - Certified Information System Auditor
 - Independent certification organization approved by DEA
- Audit/certification must be conducted:
 - Before used to create, sign, transmit or process prescriptions
 - Whenever functionality related to controlled substance prescription requirements is altered or every two years, whichever comes first
- Audit/certification must determine whether application meets DEA's requirements
- Auditor issues report to application provider

Identity Proofing

- The process by which a credential service provider or certification authority validates sufficient information to uniquely identify a person
- Necessary to verify that a person is who he claims to be

How it Works

- Identity proofing conducted by credential service providers or certification authorities
- Prescribing practitioners must undergo identity proofing
- Remote identity proofing permissible
- Institutional practitioners may use different method specific to their needs

Two-Factor Authentication

- After identity verified, practitioner will be issued two-factor authentication credential
- Protects practitioner from misuse of credential and from external threats
- Two-factors – two of the following:
 - Something you know – password, PIN
 - Something you have – separate hard token
 - Something you are – a biometric

Two-Factor Authentication

- Persons prescribing controlled substances have two factors
- Hard token could be a USB device, a smart card, PDA, cell phone, one-time password device
- Any biometric that meets DEA's requirements is acceptable

Transmission

- Prescription must be transmitted as soon as possible after signature
- Prescription must remain electronic; conversion to fax NOT permitted
- Prescription may be printed after signature so long as labeled “Copy only - not valid for Dispensing”

Pharmacy Overview

- Application provider makes audit or certification report available to pharmacy
- Pharmacies may only process electronic prescriptions using applications determined to meet DEA's requirements
- Pharmacy receives prescription, archives all records for two years

Pharmacy Access Controls

- Ensure that only individuals authorized to enter information regarding dispensing and annotate or alter (where permissible) prescription information are allowed to do so
- Pharmacy sets access controls to ensure only authorized persons can annotate, alter (where permissible), delete prescriptions

Receipt of Prescriptions

- Pharmacy receives prescription which has been digitally signed by last intermediary OR
- Pharmacy receives prescriptions and digitally signs upon receipt
- Pharmacy receives prescription signed with practitioner's digital certificate

Pharmacy Annotations, Records

- All annotations must be electronic
- Prescriptions can be retrieved by practitioner name, patient name, drug name, date dispensed; sortable
- Pharmacy records must be backed up daily
- All records must be retained electronically

Teen Attitudes

1 in 5 of teens report abusing Rx medications at least once in their life

41% believe that Rx meds are “much safer” than illegal drugs

1 in 10 reports having abused a prescription pain reliever in last year

61% report Rx pain relievers are easier to get than illegal drugs

SOURCE: 2008 Partnership Attitude and Tracking Study (PATS)
Released February 2009 by The Partnership for a Drug-Free America

Why Pharmaceutical Drugs?

Oxycontin and Methadone = Heroin

Methamphetamine = amphetamines

Hydrocodone = Morphine

Xanax used to buffer illicit drug effects

Synergistic effects sought Marijuana + Codeine

Diversion from the “Closed System”

Practitioners

- illegal distribution
- self abuse

Pharmacists

- illegal distribution
- self abuse

Employee pilferage

- hospitals
 - practitioners' offices
 - nursing homes
 - retail pharmacies
- manufacturing/distribution facilities

“Patients”

- individual
- organized drug ring

Pharming - teenagers using a combination of drugs and alcohol



Motivation for Diversion

Addiction

Physical Dependence

Resale for \$\$\$\$\$\$\$\$

Resale for illegal drugs

Power, Control or Importance, Sex

Safe product to take due to manufacturing standards

Diverted Pharmaceuticals

Oxycontin 80 mg

Street Price \$20-\$25 per tablet

Hydrocodone

Street Price \$5 per tablet

Vicodin, Lorcet, Lortab, Norco

Xanax (Alprazolam)

Street Price \$3-5 per tablet

Amphetamines
and Valium

Street Price \$2 per tablet

Codeine Cough Syrup

Street Price \$200-\$300 per pint and
\$1,000 to \$1900 per gallon

National Takeback Initiative

Designed to work with local state and local law enforcement

Scheduled for September 25, 2010 from 10:00 a.m. to 2:00 p.m.

DEA is providing boxes and will transport and incinerate the collected controlled substances

Got Drugs?

Turn in your unused or expired medication for safe disposal
Saturday, Sept. 25th

Visit www.dea.gov
for a collection
site near you.



For more
information,
please visit
www.dea.gov



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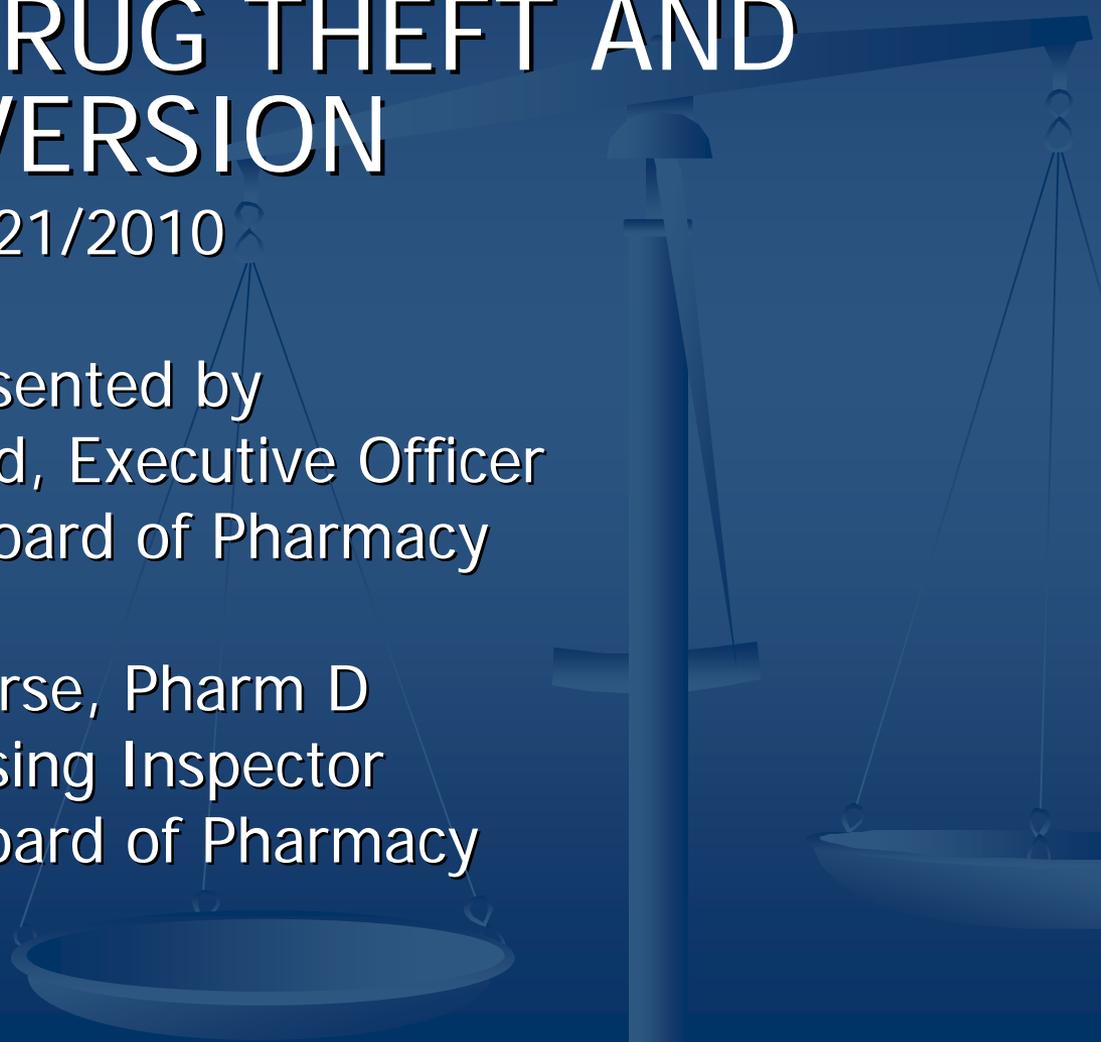
Diversion Program Manager Michael Lewis
Los Angeles Field Division
1-213-621-6711

Michael.J.Lewis@USDOJ.GOV



Office of Diversion Control

PHARMACY DRUG THEFT AND DIVERSION

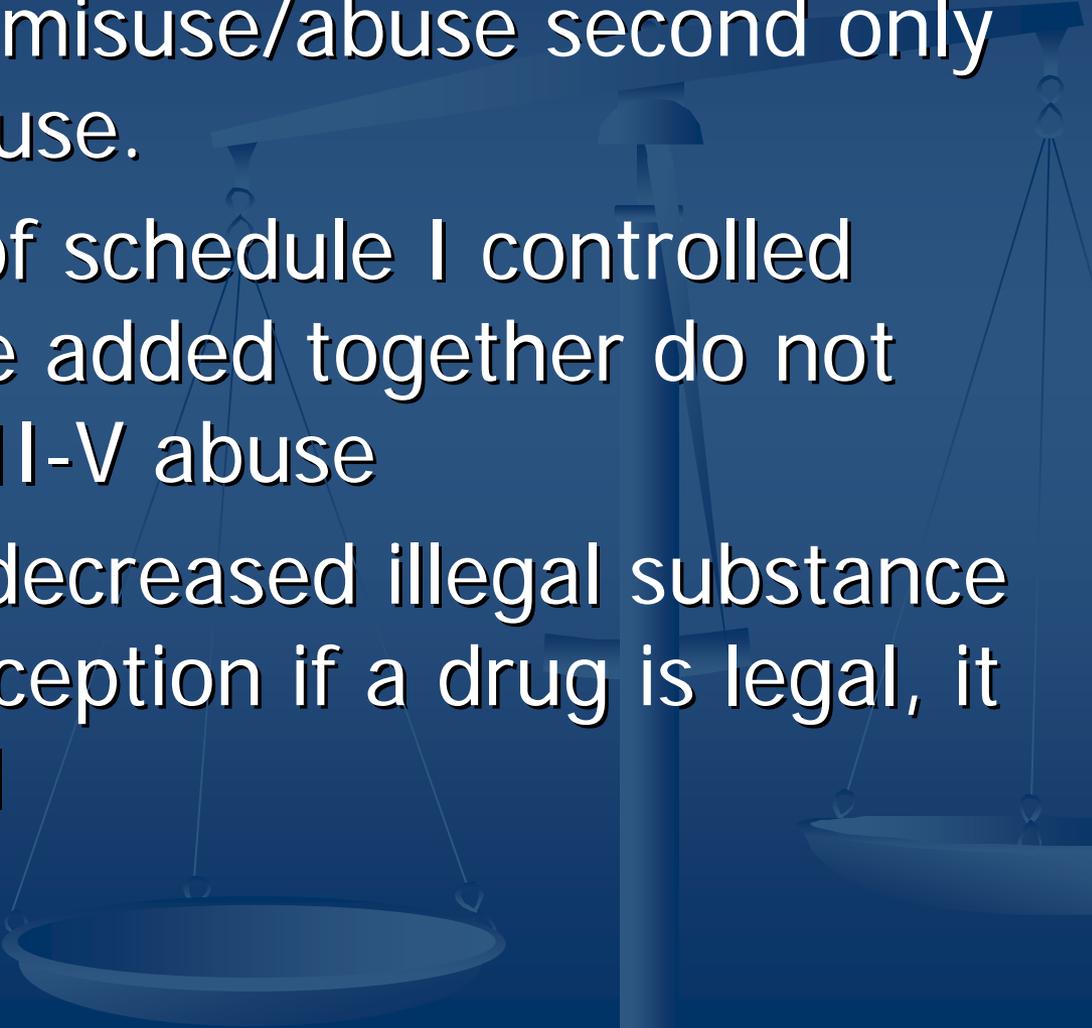
A faint, stylized graphic of a balance scale is visible in the background on the right side of the slide. The scale is tilted, with the right pan being lower than the left pan. The entire slide has a dark blue background.

5/21/2010

Presented by
Virginia Herold, Executive Officer
CA State Board of Pharmacy

Judi Nurse, Pharm D
Supervising Inspector
CA State Board of Pharmacy

CONTROLLED SUBSTANCE ABUSE

- Schedule II – V misuse/abuse second only to marijuana abuse.
 - All other types of schedule I controlled substance abuse added together do 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 Line of “War on Prescription Drug Abuse”

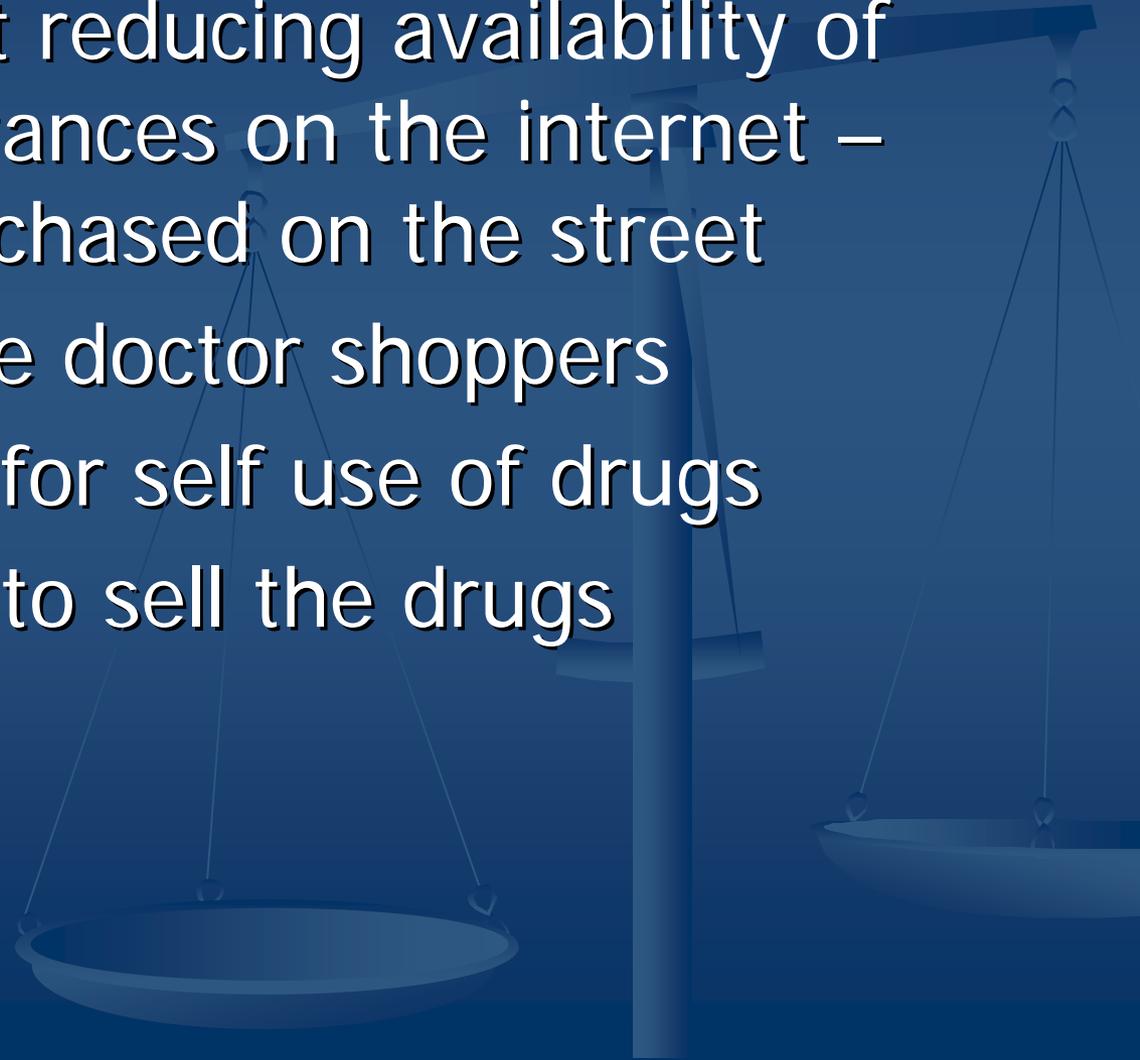
Street value of common controlled substances

- 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 4mg - \$3.00 -\$5.00 per tablet

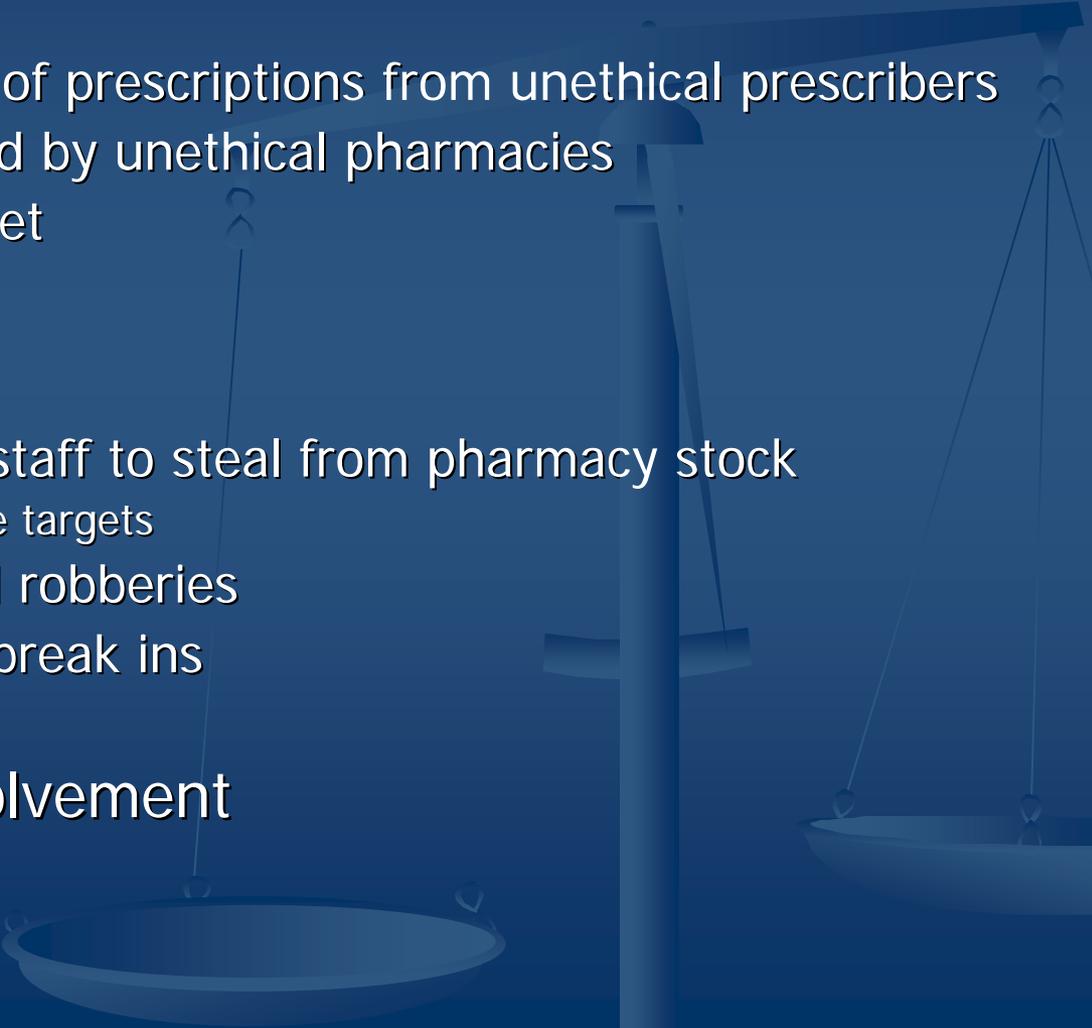
*National Prescription Drug Threat Assessment 2009- California

Why Is My Pharmacy A Target?

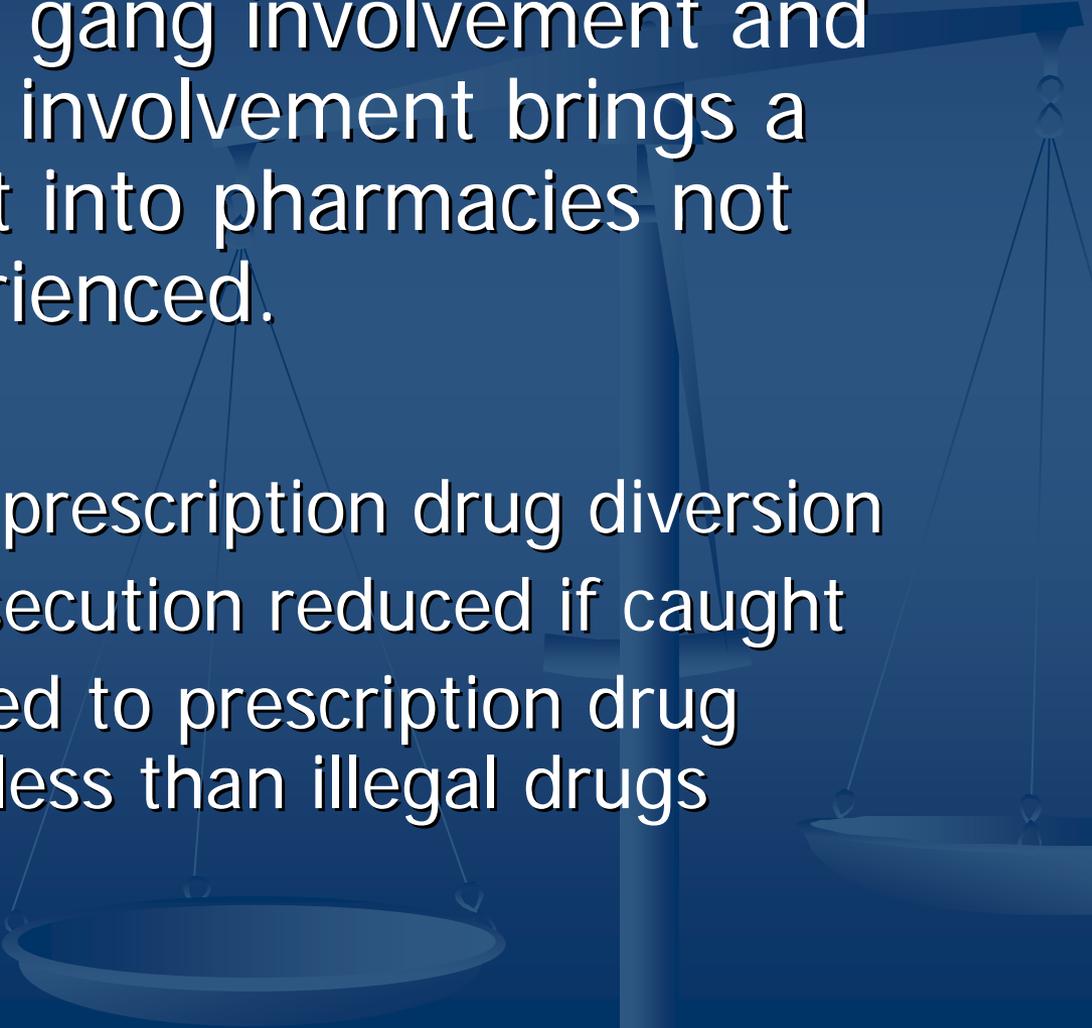
- Ryan Haight Act reducing availability of controlled substances on the internet – more drugs purchased on the street
- Patients who are doctor shoppers
- Employee theft for self use of drugs
- Employee theft to sell the drugs



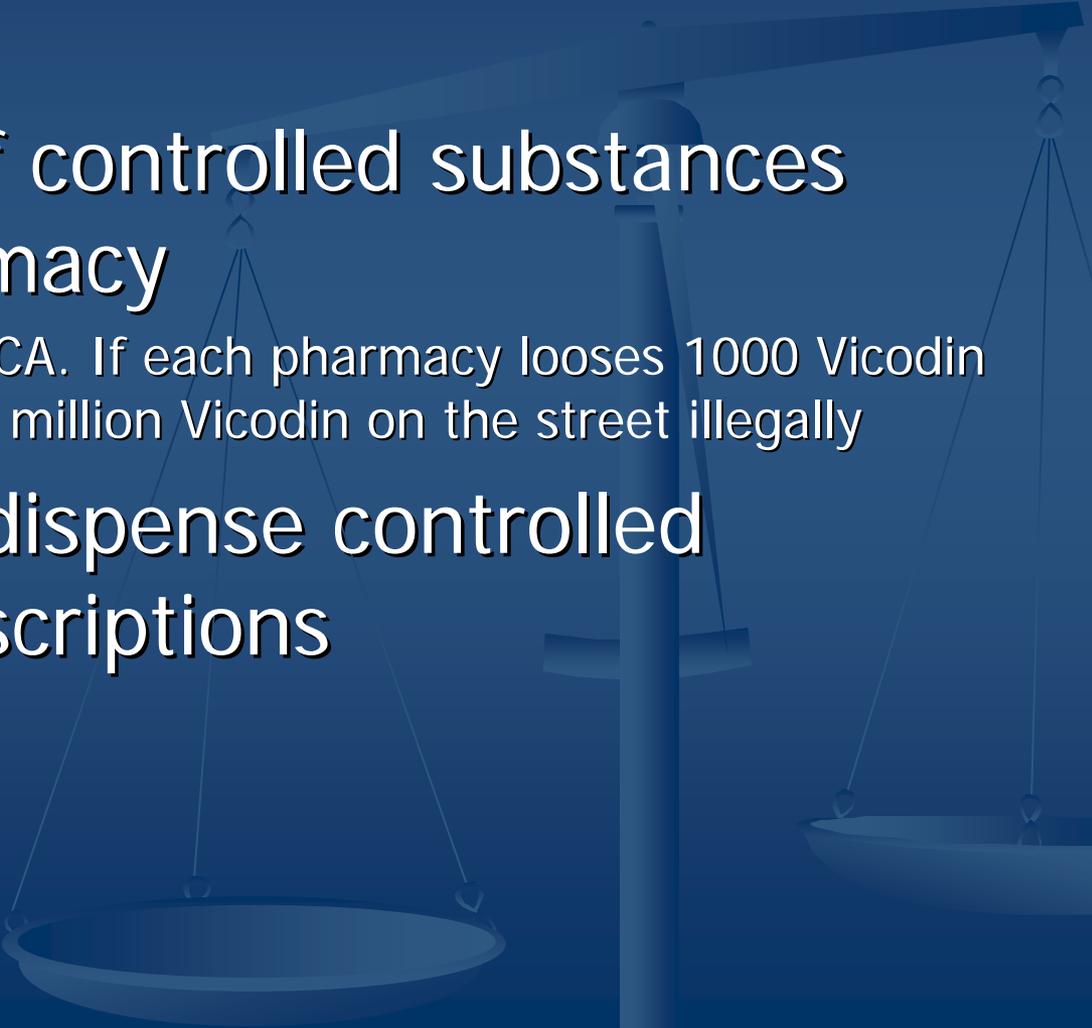
WHY IS MY PHARMACY A TARGET? (cont)

- Diverter groups –
 - Obtain large numbers of prescriptions from unethical prescribers
 - Prescriptions dispensed by unethical pharmacies
 - Drugs sold on the street
 - Gang involvement
 - Encourage pharmacy staff to steal from pharmacy stock
 - Your staff are targets
 - Responsible for armed robberies
 - Responsible for night break ins
 - Organized Crime Involvement
- 

Pharmacy Related Criminal Activity

- Diverter groups, gang involvement and organized crime involvement 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 illegal drugs
- 

PHARMACIST PROFESSIONAL RESPONSIBILITY



A. Prevent loss of controlled substances from the pharmacy

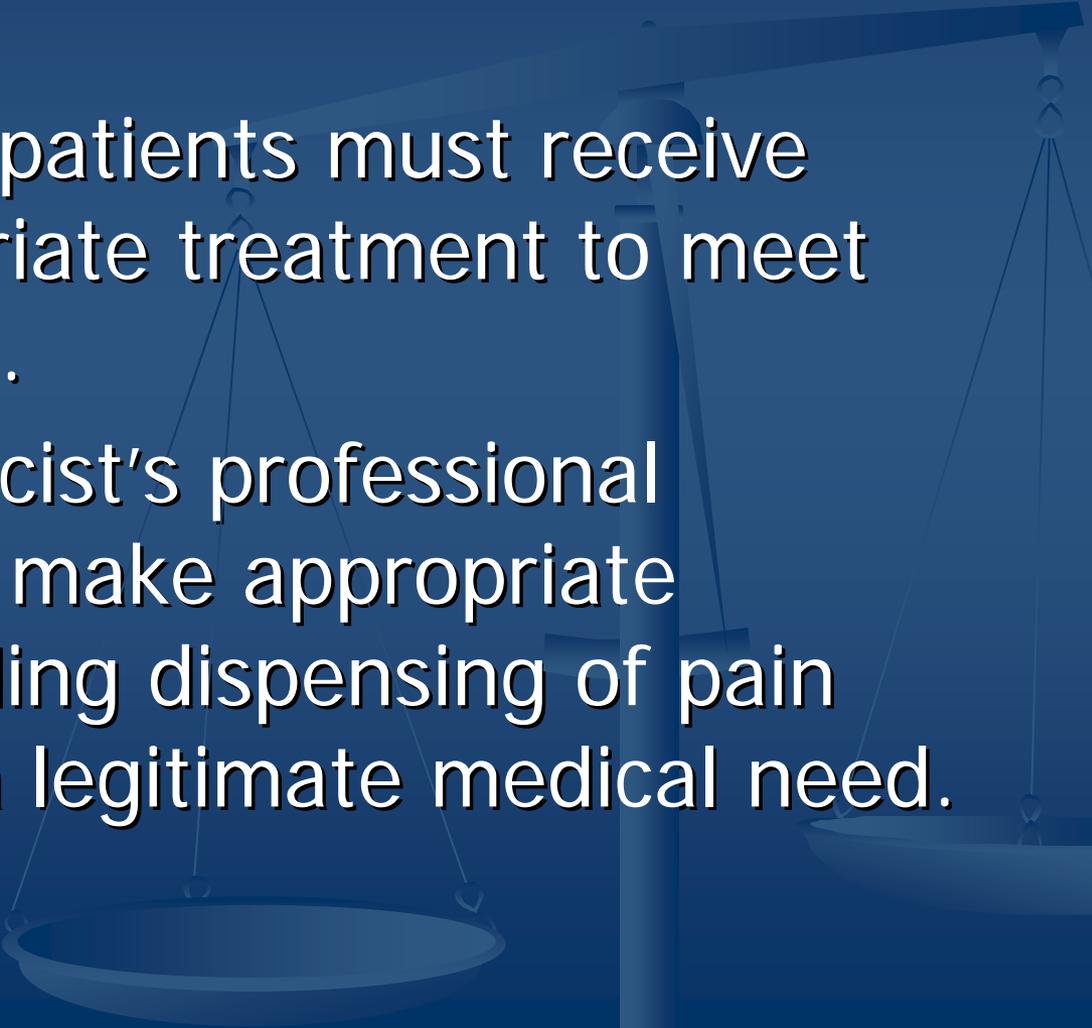
6700 pharmacies in CA. If each pharmacy loses 1000 Vicodin per year, that is 6.7 million Vicodin on the street illegally

B. Appropriately dispense controlled substance prescriptions

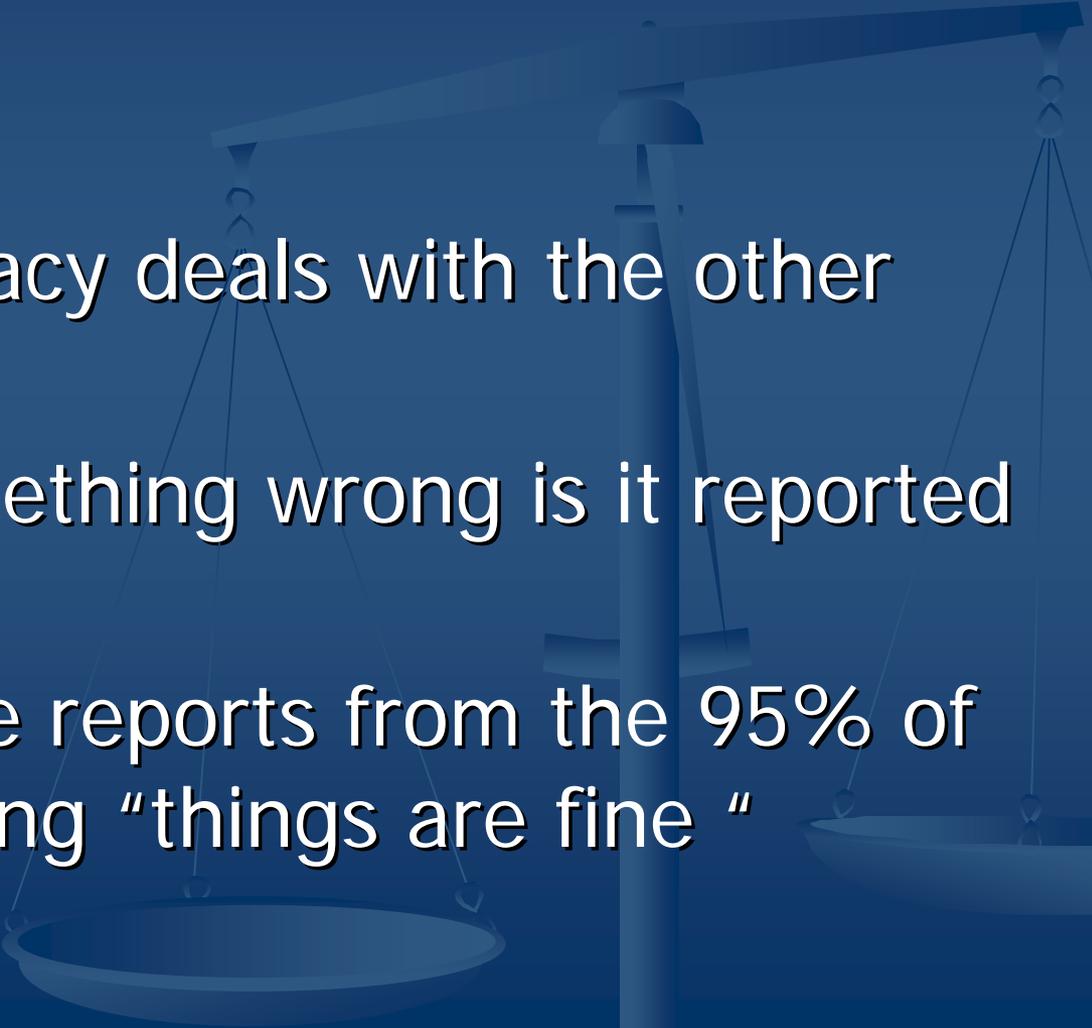
THE PHARMACIST IS THE FINAL CHECK OF
THE LEGITIMACY OF A PRESCRIPTION.

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.

APPROPRIATE CARE OF LEGITIMATE PAIN PATIENTS

- Legitimate pain patients must receive prompt, appropriate treatment to meet their pain needs.
 - It is the pharmacist's professional responsibility to make appropriate decisions regarding dispensing of pain medication for a legitimate medical need.
- 

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

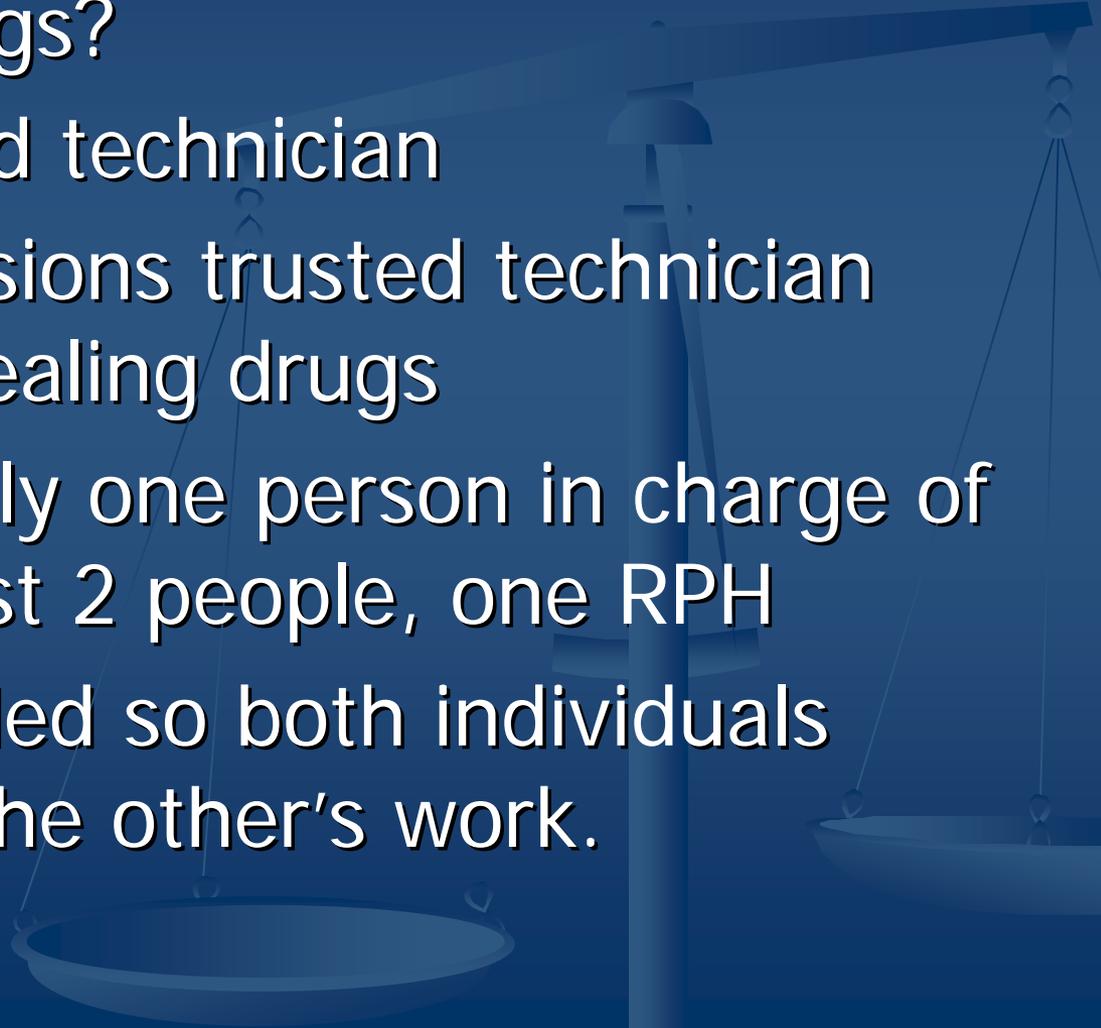
- Board of Pharmacy deals with the other 5%
 - Only when something wrong is it reported to us
 - We don't receive reports from the 95% of pharmacies saying "things are fine "
- 

PREVENTING LOSS OF CONTROLLED SUBSTANCES FROM PHARMACY

- 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
 - Appropriate storage of prescription drugs in pharmacy
 - Review of purchase invoices by Pharmacist In Charge
 - Prescription Drugs stolen while stored in pharmacy
 - Night break in, robberies

*Best practice to develop parameters and monitor each step to prevent or detect drug losses from pharmacy
- Investigate employees before hire, monitor and observe employees after hire

PHARMACY – ORDERING DRUGS

- Who orders drugs?
 - Usually a trusted technician
 - Numerous occasions trusted technician ordering and stealing drugs
 - Do not place only one person in charge of ordering, at least 2 people, one RPH
 - Have work divided so both individuals check and see the other's work.
- 

PHARMACY IN-TRANSIT LOSSES

- Drugs diverted before arriving at your pharmacy
 - 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
- Hijacking delivery vehicles

PHARMACY -RECEIPT OF DRUGS

- Who signs for the drug delivery at pharmacy?
- CA Pharmacy Law requires Pharmacist-In-Charge preferably or a pharmacist 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.

PHARMACY DRUG ORDER CHECK –IN & PROPER STORAGE

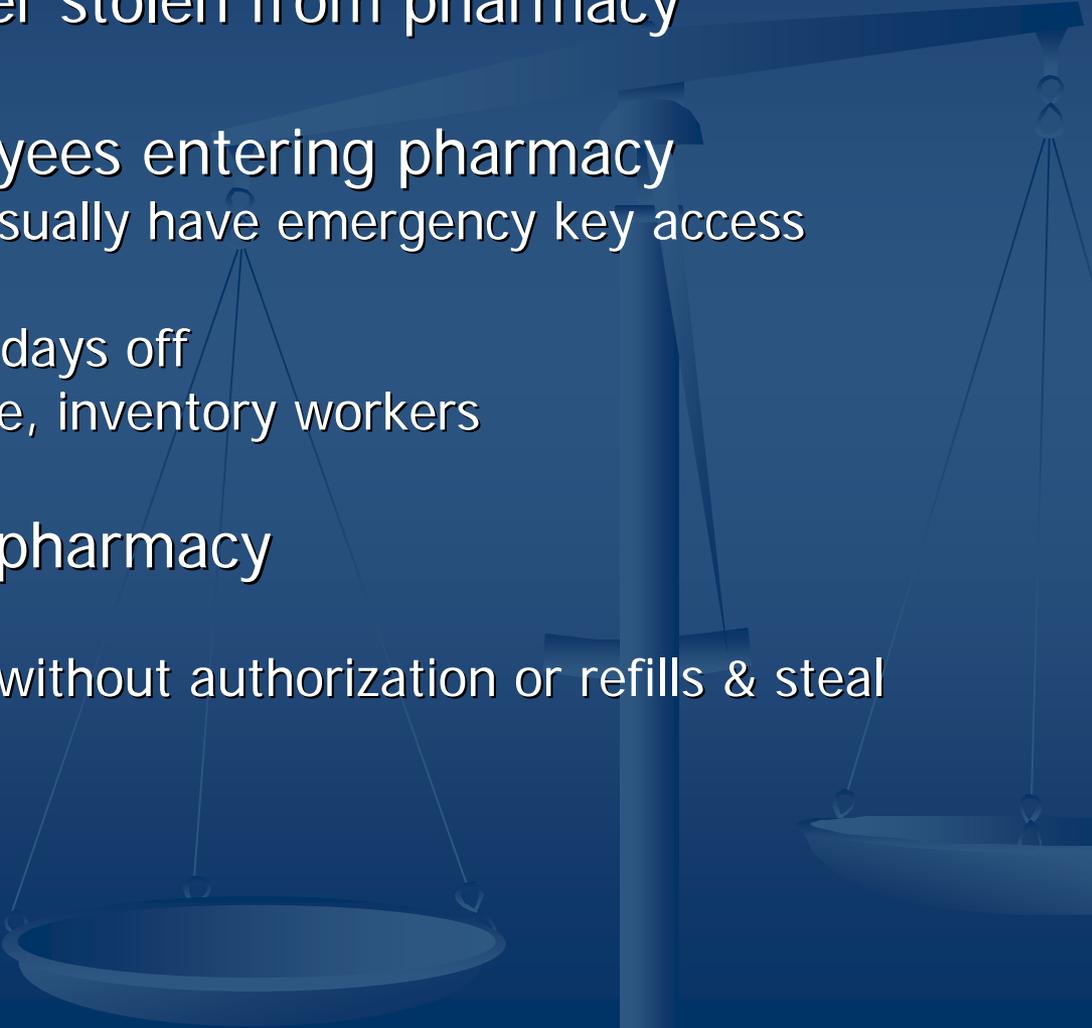
- Complete check in of drug orders and put drug containers away on shelves
 - Drugs disappear from unattended totes and unknown if used for a waiting order or disappeared
 - Invoicing can be stolen along with the drug to prevent loss from being discovered
- The safest place for drugs is stored in their proper place on the shelves
 - Store drugs likely to be stolen either in a locked area with only RPH access or ...
 - 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
 - Document items stored in the “expired” or “returns” area of pharmacy
 - Process RTS promptly and get back on the shelf- caution if one person

volunteer s for that task

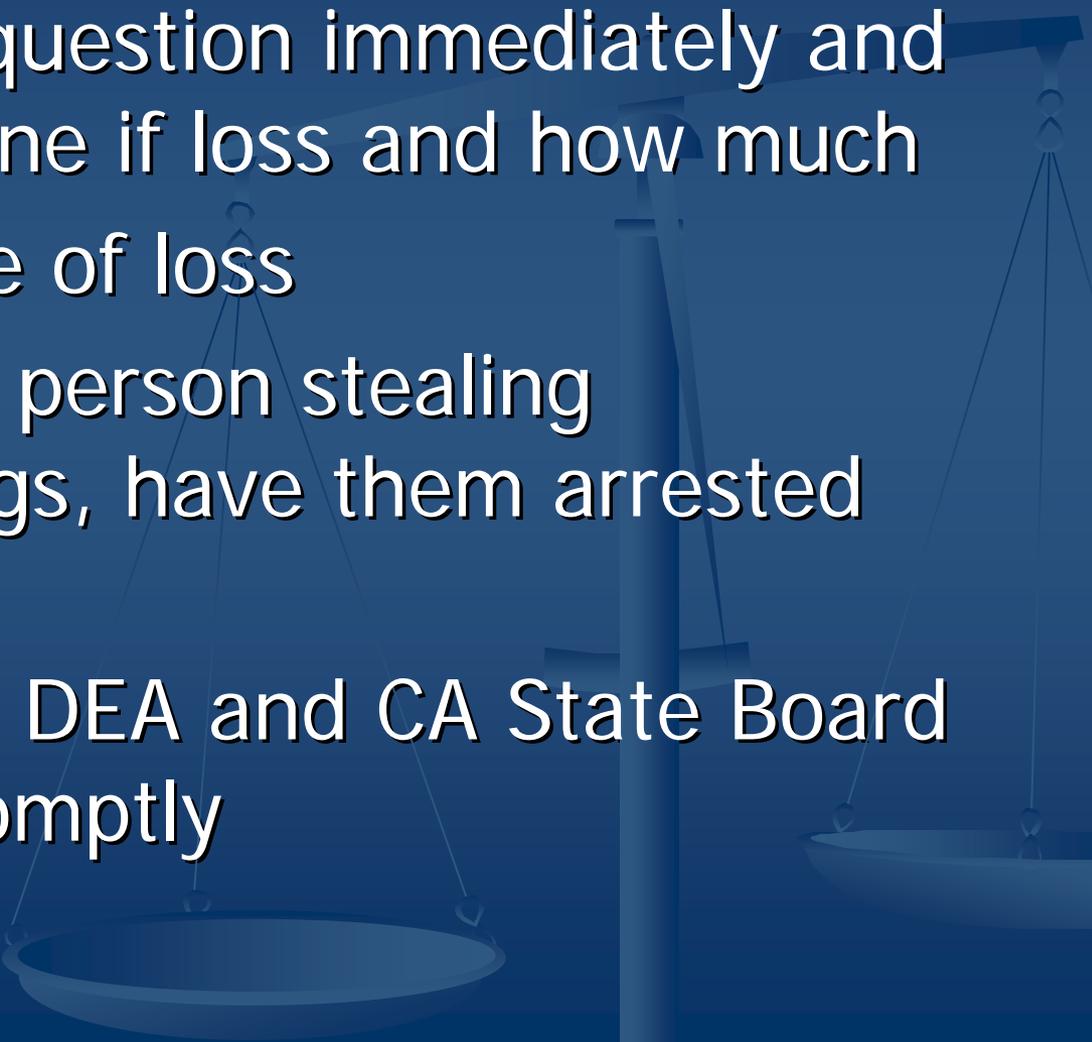
PIC REVIEW OF PURCHASE INVOICES

- Pharmacist-In-Charge must review invoices for dangerous drugs received by pharmacy
 - 100,000 tablets of Vicodin stolen by ordering technician from a San Diego hospital and no one at hospital knew until police arrested technician
 - 450,000 tablets of generic Vicodin stolen from a retail pharmacy by trusted technician. Pharmacy had no idea drugs were missing
 - Review invoices very carefully for days Pharmacist in Charge does not work

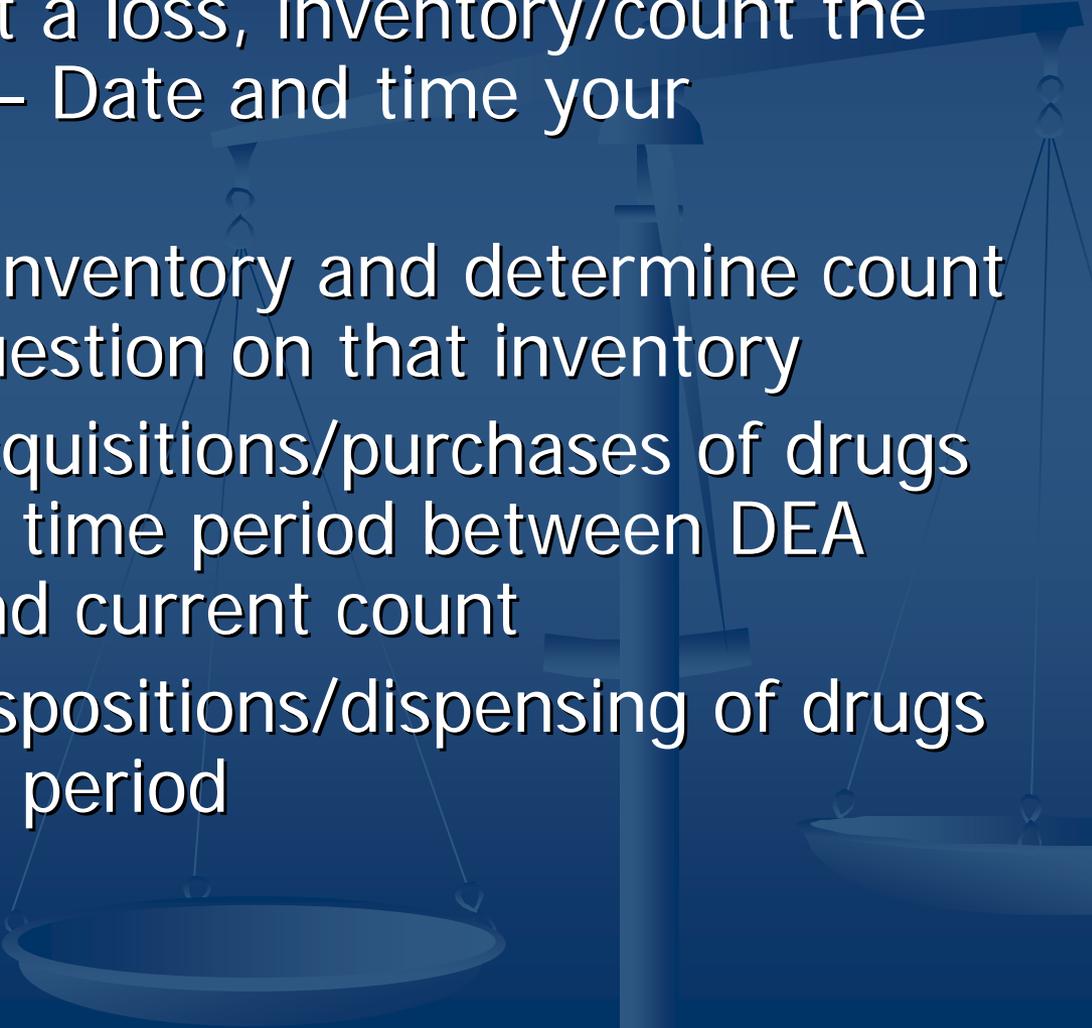
DRUGS STOLEN FROM STOCK

- Drugs hidden and later stolen from pharmacy
 - 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
- 

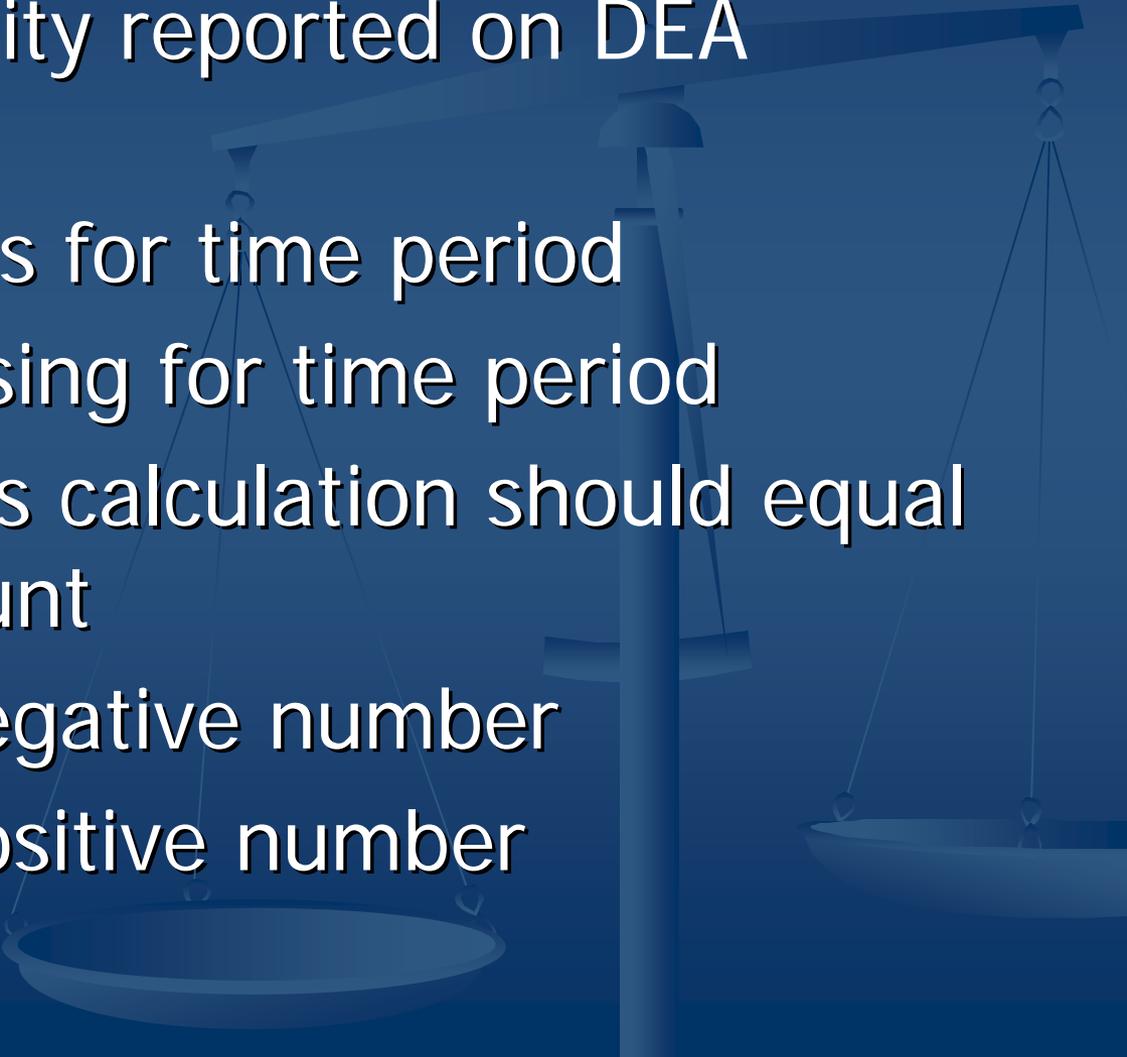
What Do I Do When I Think A Drug Is Missing?

- Count drugs in question immediately and audit to determine if loss and how much
 - Determine cause of loss
 - If you identify a person stealing prescription drugs, have them arrested and prosecuted
 - Report losses to DEA and CA State Board of Pharmacy promptly
- 

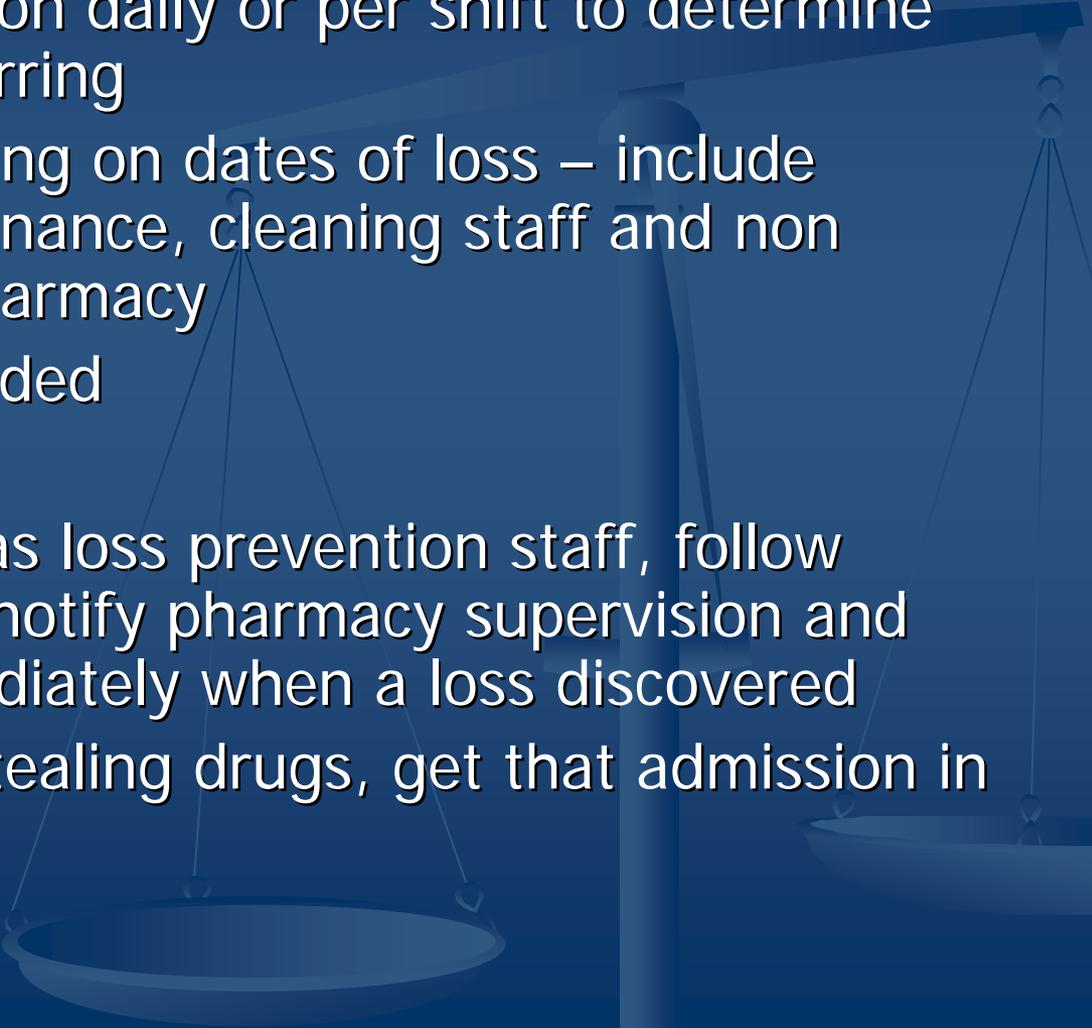
Determine Amount of Loss

- As soon as suspect a loss, inventory/count the drugs in question – Date and time your inventory
 - Retrieve last DEA 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 DEA inventory
 - Add in purchases for time period
 - Subtract dispensing for time period
 - The result of this calculation should equal your current count
 - If you have a negative number
 - If you have a positive number
- 

Determine Cause of Loss

- Count drugs in question daily or per shift to determine when losses are occurring
 - Determine staff working on dates of loss – include ancillary staff, maintenance, cleaning staff and non employees visiting pharmacy
 - Install cameras if needed
 - Interview staff
 - If your corporation has loss prevention staff, follow corporate policy and notify pharmacy supervision and loss prevention immediately when a loss discovered
 - If employee admits stealing drugs, get that admission in writing
- 

WHAT DO I DO IF I IDENTIFY PERSON STEALING

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

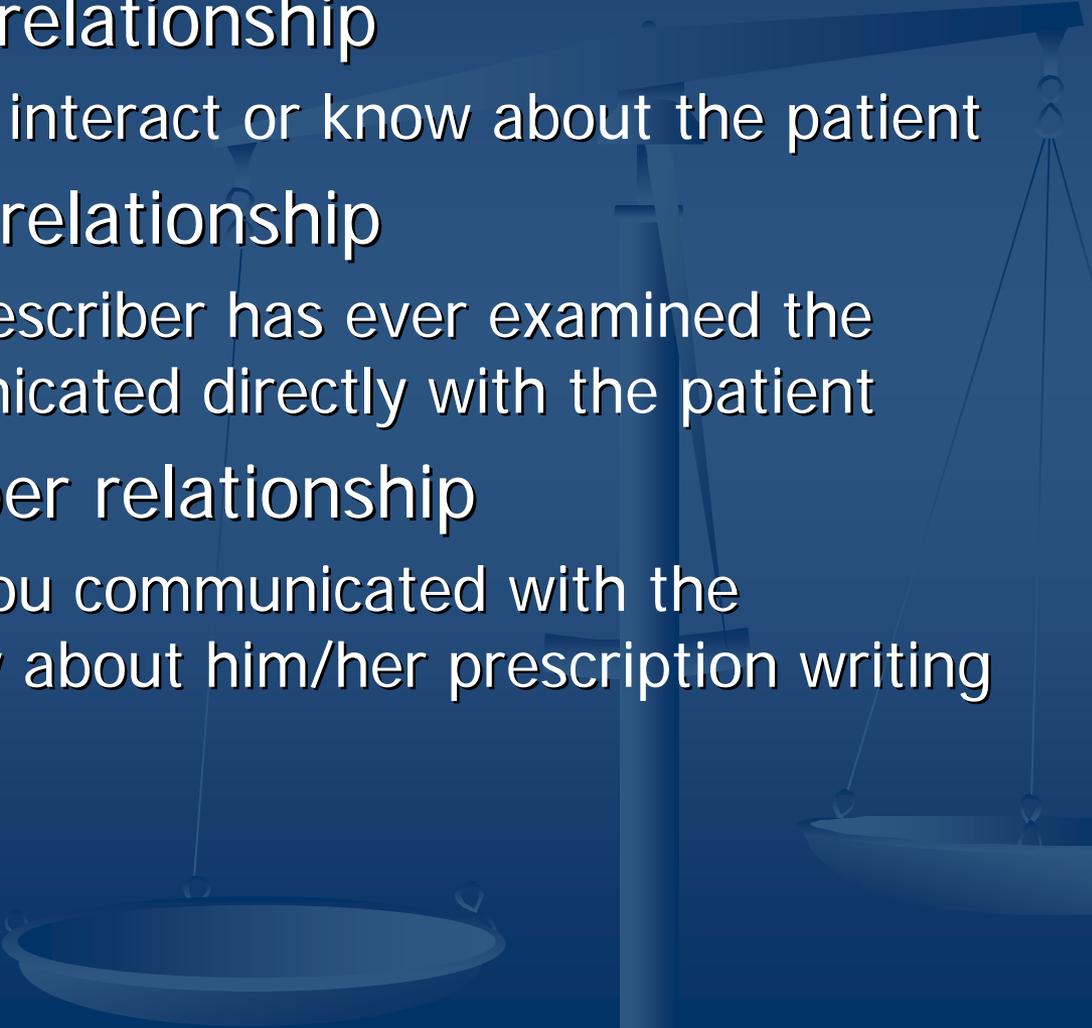
Reporting Impaired Licensees Mentally, Chemically, Physically

- 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. (PRH, Technician, Intern Pharmacist)
 - Pharmacy must report to board within 30 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.

Corresponding Responsibility (cont)

- Patient/pharmacy relationship
 - How much do you interact 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

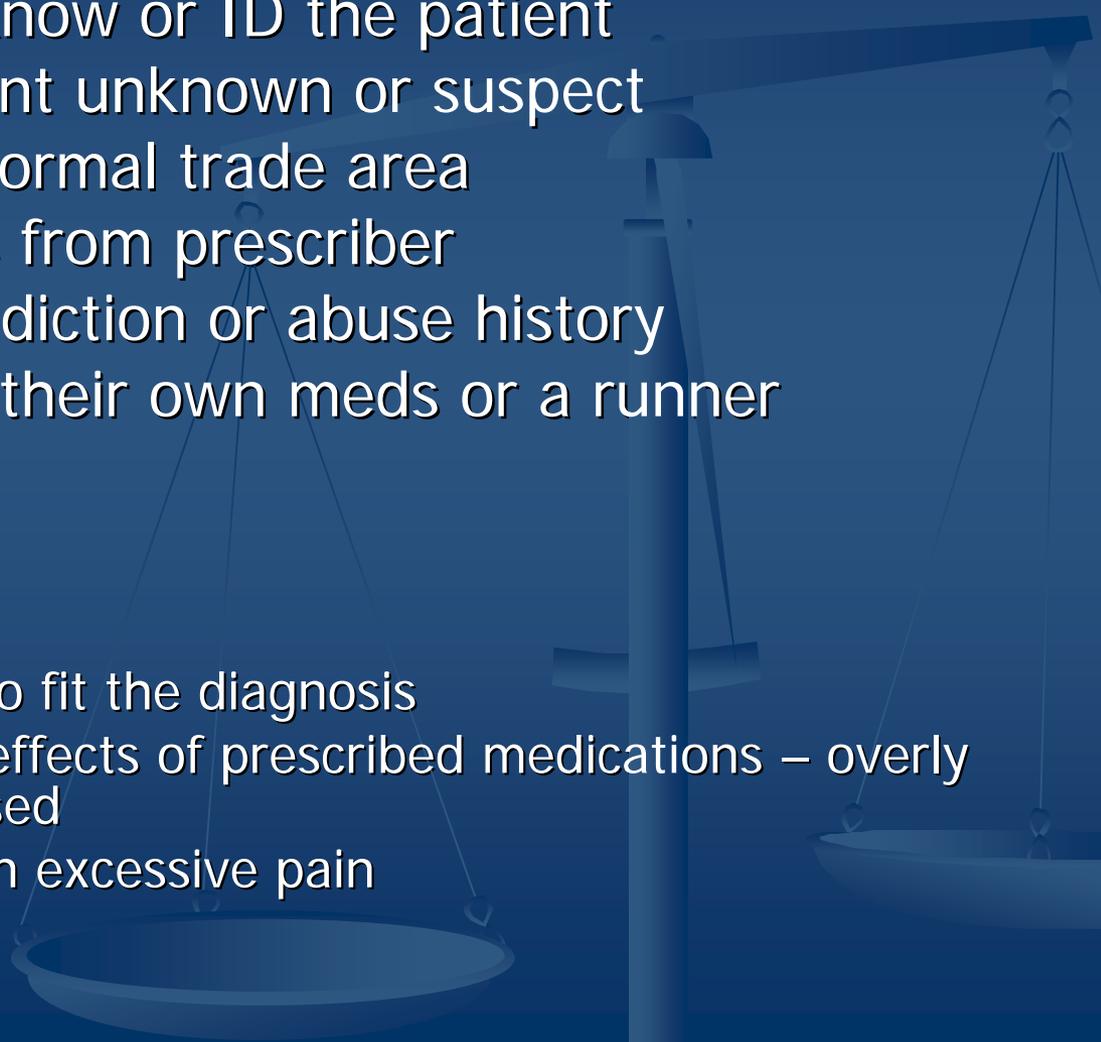
- CA Security Prescription
 - Are controlled substance prescriptions written on CA Security Prescription or written on normal prescription document and pharmacy has to reduce order to a telephonic order
 - Is prescriber information accurate
 - DEA number
 - Telephone number
 - Be cautious of strange prescriptions with last name of doctor beginning with the letter "A"
 - Is the document legitimate
 - 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.

Evaluation of the Prescriber

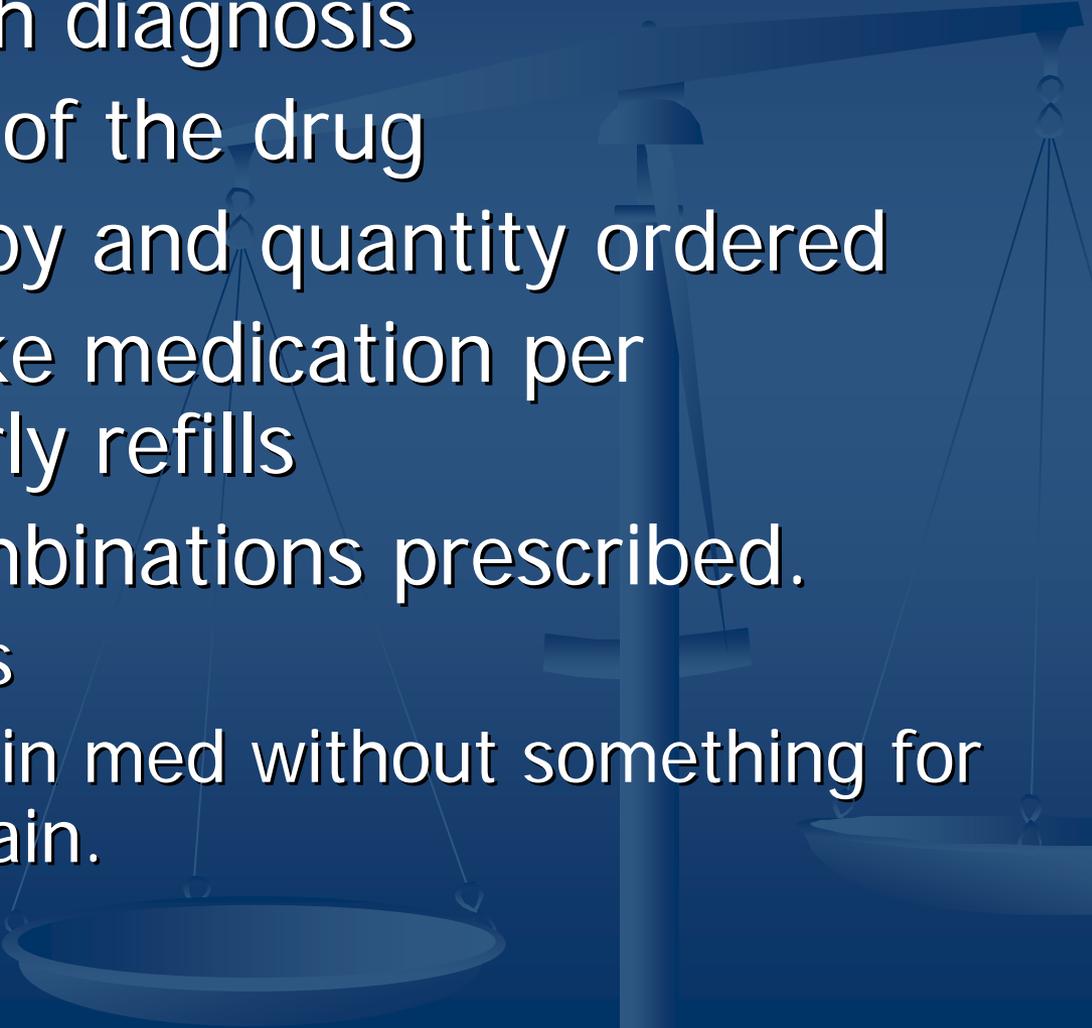
- Status of CA license to practice medicine
- Status of DEA registration
- Status of Medi-Cal provider number
- What is prescriber specialty
- Prescribing practices
 - Do you fill a mix of dangerous drug and controlled substance prescriptions from this prescriber or only controlled substances – excessive 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
- Any prior discipline of any type
- Is pharmacist ignoring warning signs and continuing to fill controlled substances for a particular prescriber

*

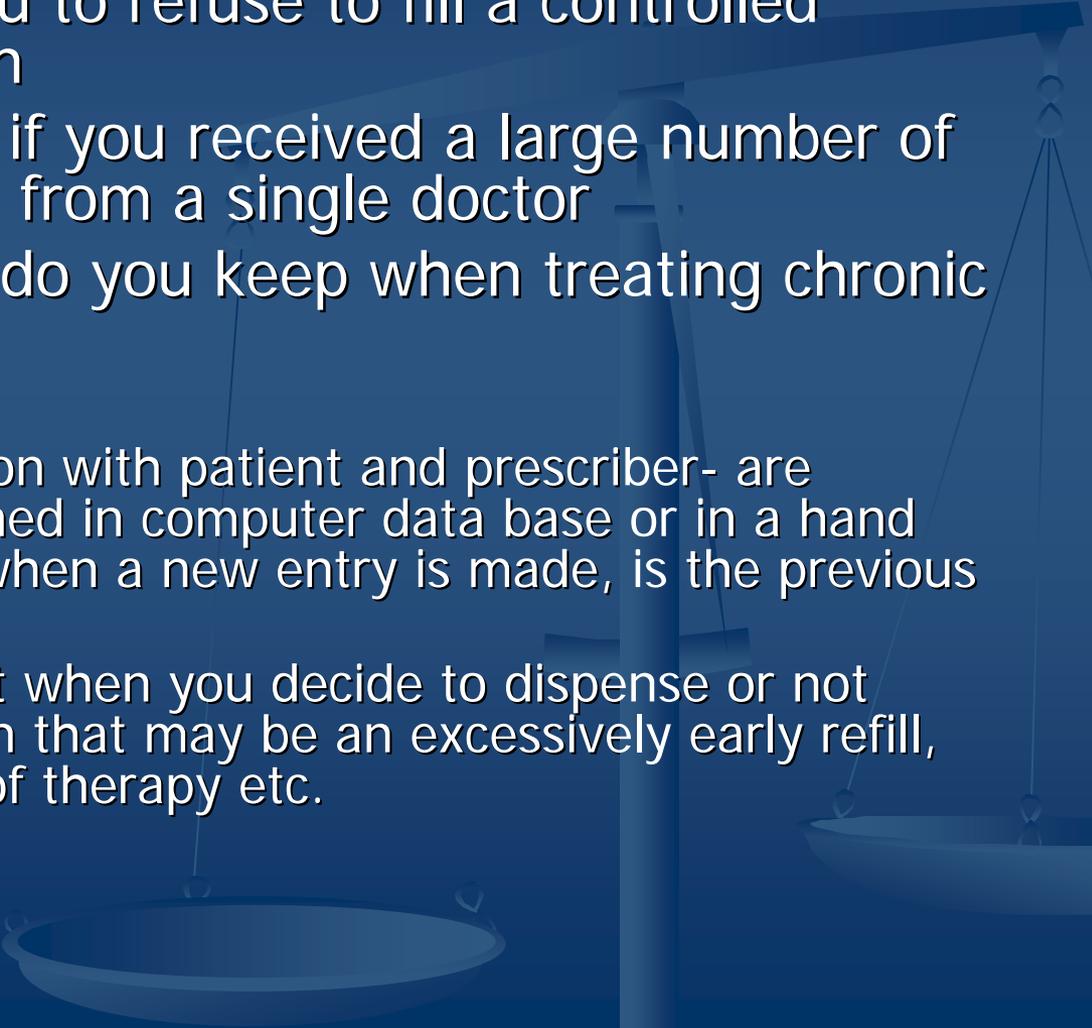
Evaluation of Information Available about the Patient

- Does the pharmacy know or ID the patient
 - CURES report if patient unknown or suspect
 - Does patient live in normal trade area
 - Distance patient lives from prescriber
 - Does patient have addiction or abuse history
 - Does patient pick up their own meds or a runner
 - Patient age
 - Diagnosis
 - Patient appearance
 - Does patient appear to fit the diagnosis
 - Evaluate for adverse effects of prescribed medications – overly sedated, dizzy, confused
 - Does patient appear in excessive pain
- 

Evaluation of Drug Therapy

- Does drug match 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.
 - Uppers/downers
 - Time release pain med without something for breakthrough pain.
- 

Pharmacist - Evaluate Your Own Practice

- What would cause you to refuse to fill a controlled substance prescription
 - 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

- 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.

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

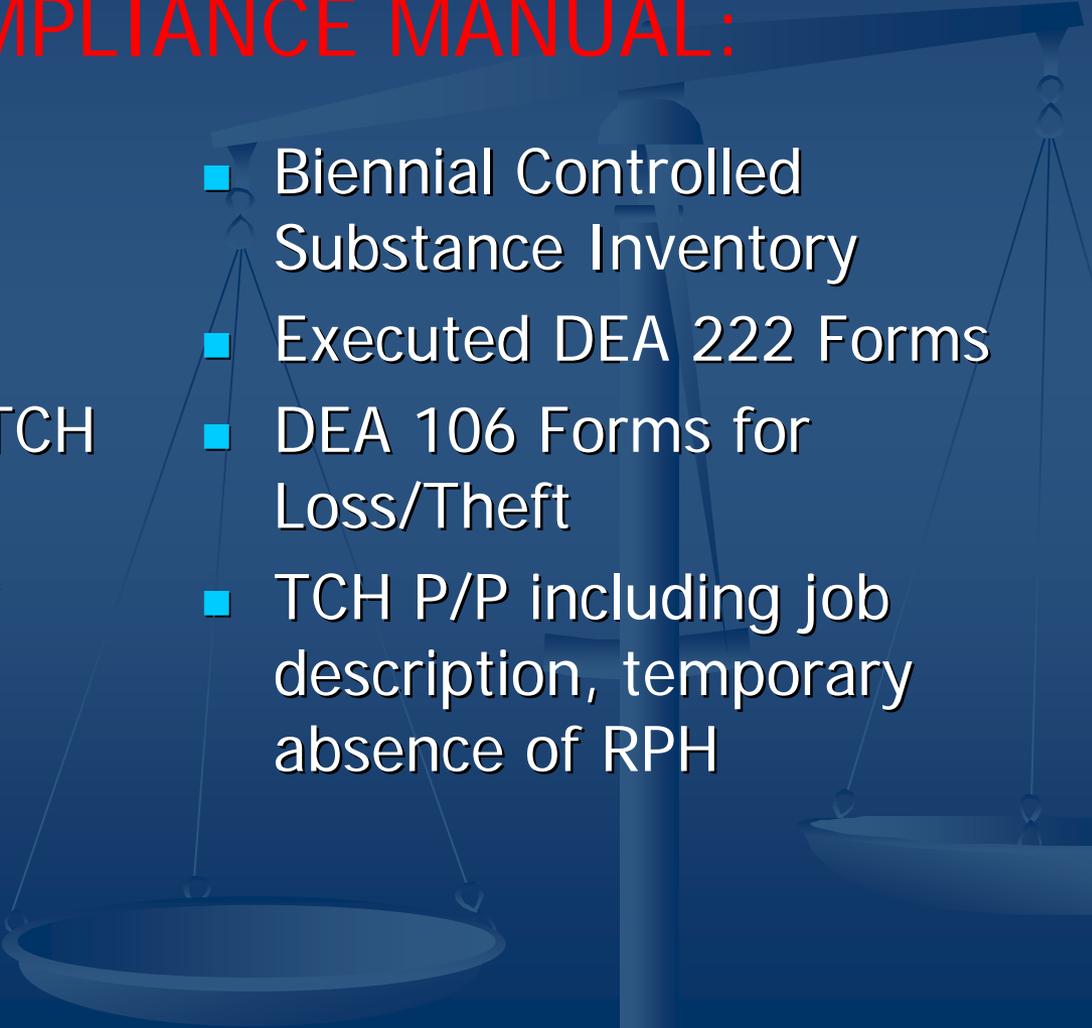
- Internet marketer cold calls pharmacy
- Offers you as many prescriptions per day as you want to dispense
- You access website and request number of prescriptions you want to dispense.
- Prescription labels, ancillary patient information and shipping label print out at your pharmacy
- Prescription documents 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

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

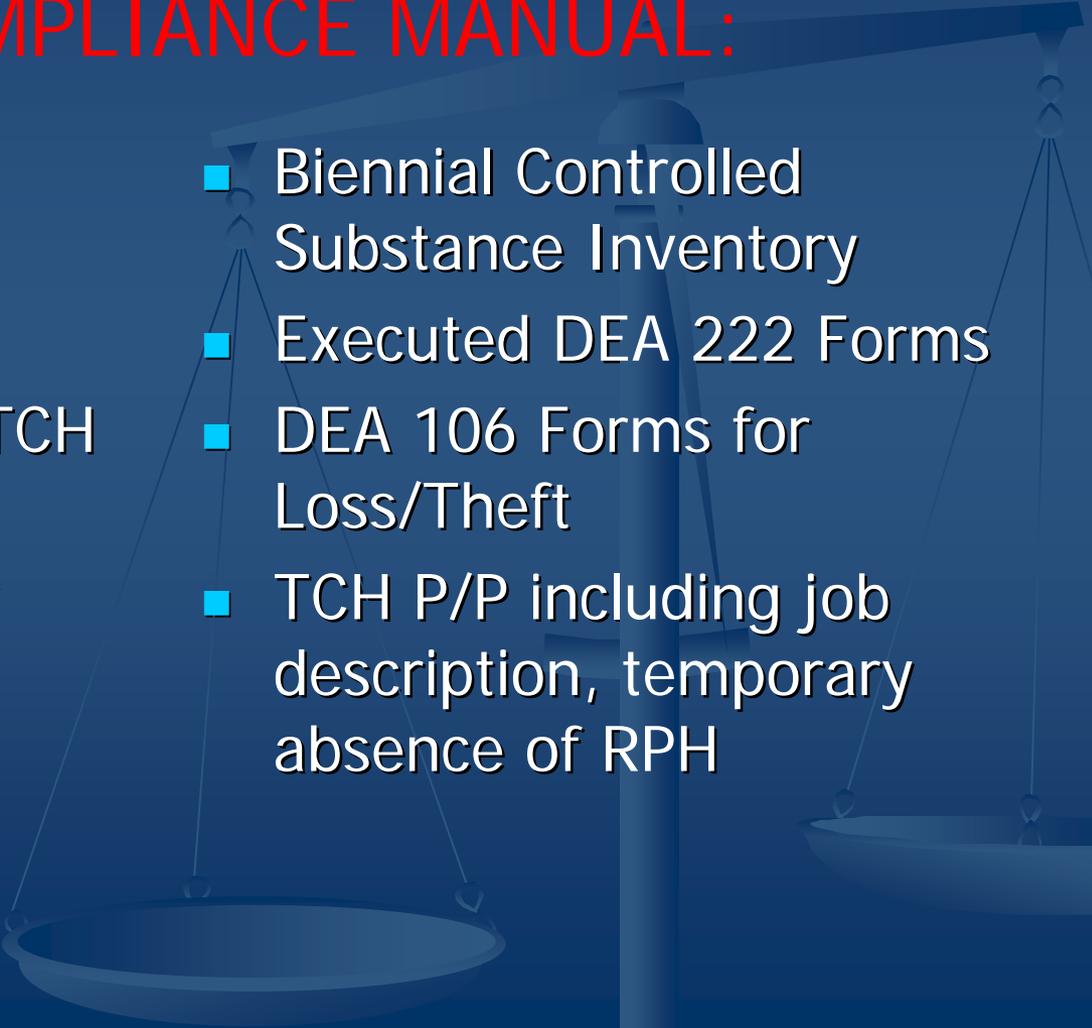
HOW TO PREPARE FOR A PHARMACY INSPECTION

PHARMACY COMPLIANCE MANUAL:

- Self Assessment
 - 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
- 

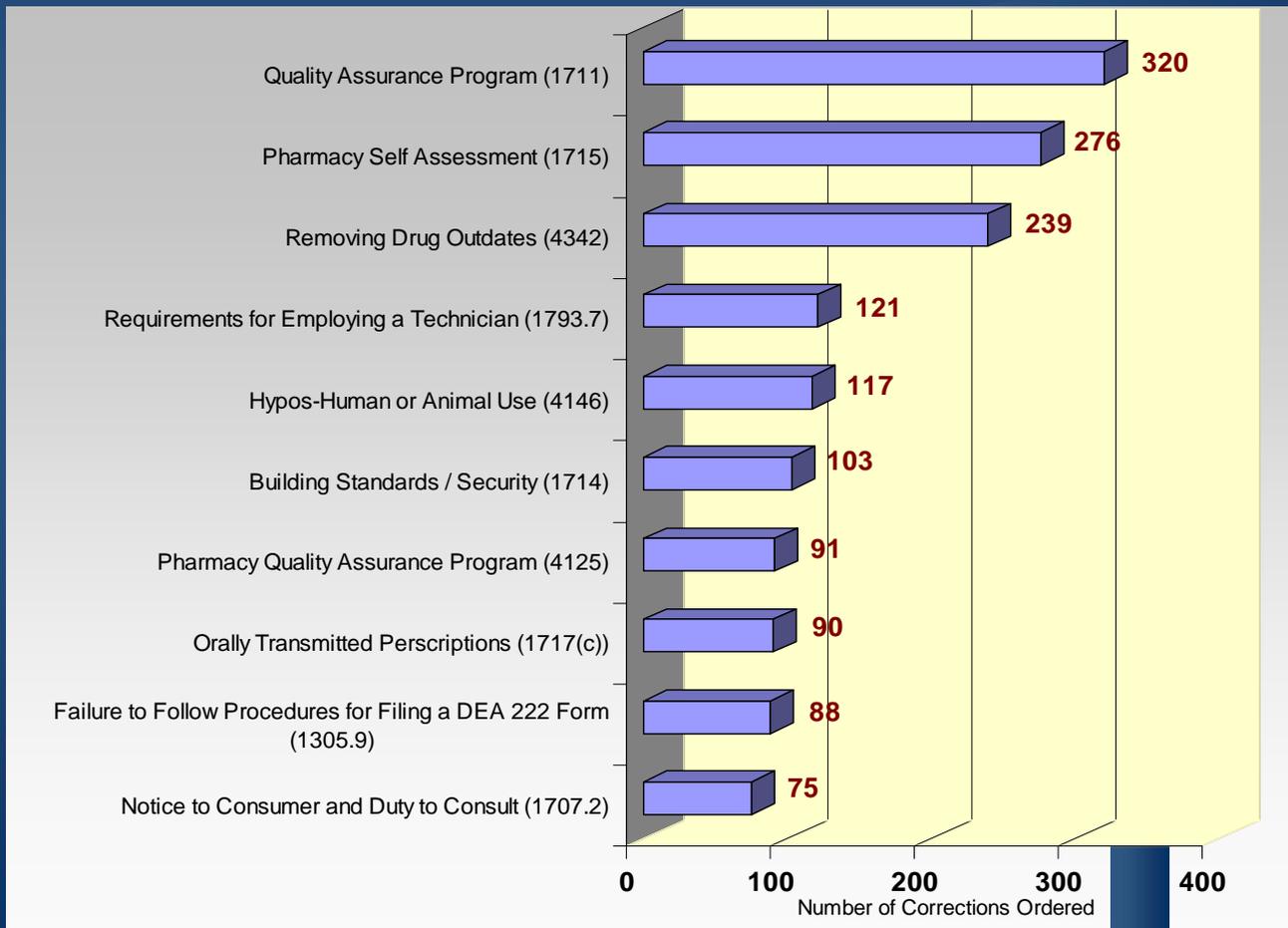
RECOMMENDATION

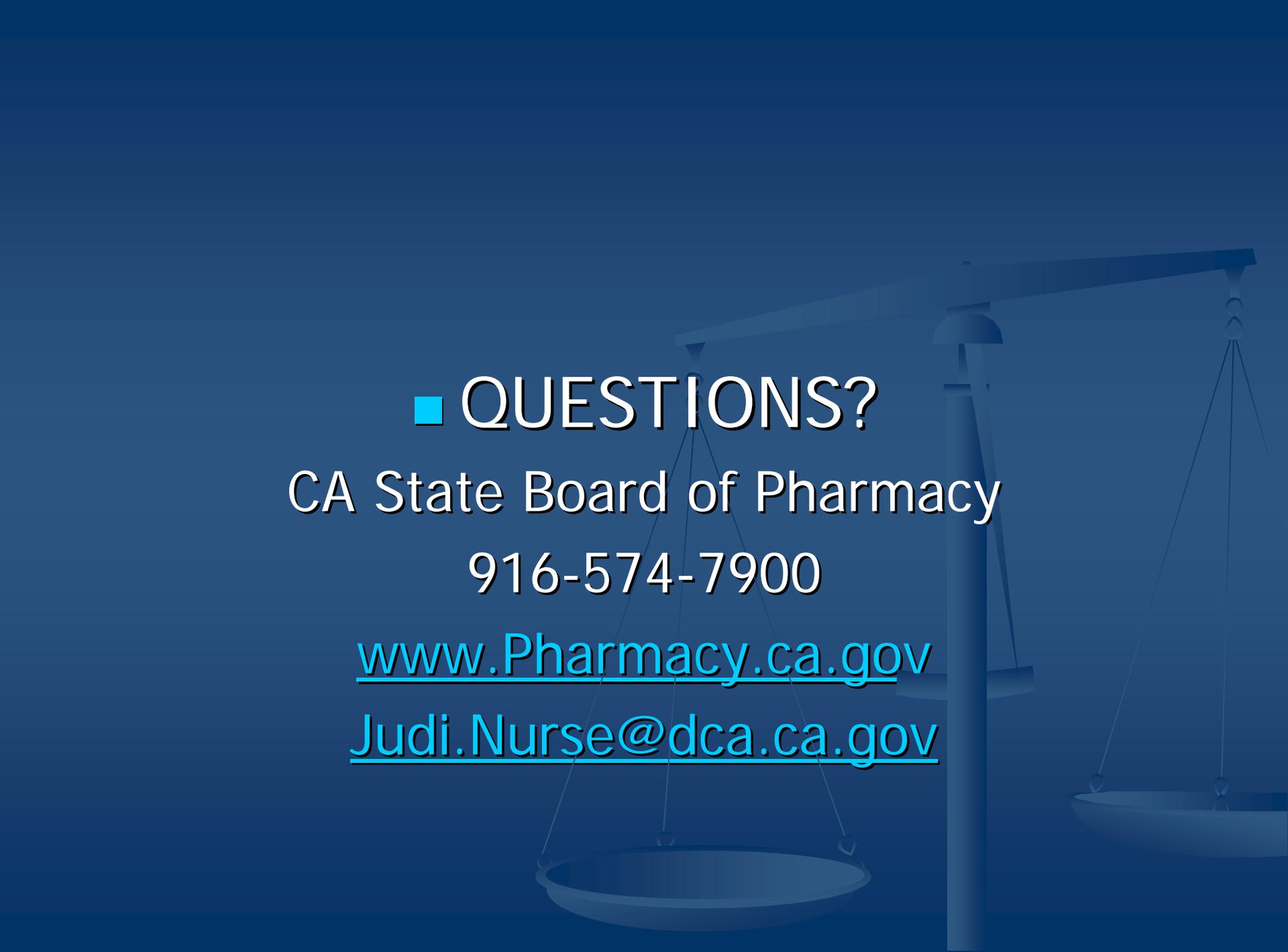
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- 

INSPECTION PROCESS

Top 10 Corrections





- QUESTIONS?

CA State Board of Pharmacy

916-574-7900

www.Pharmacy.ca.gov

Judi.Nurse@dca.ca.gov

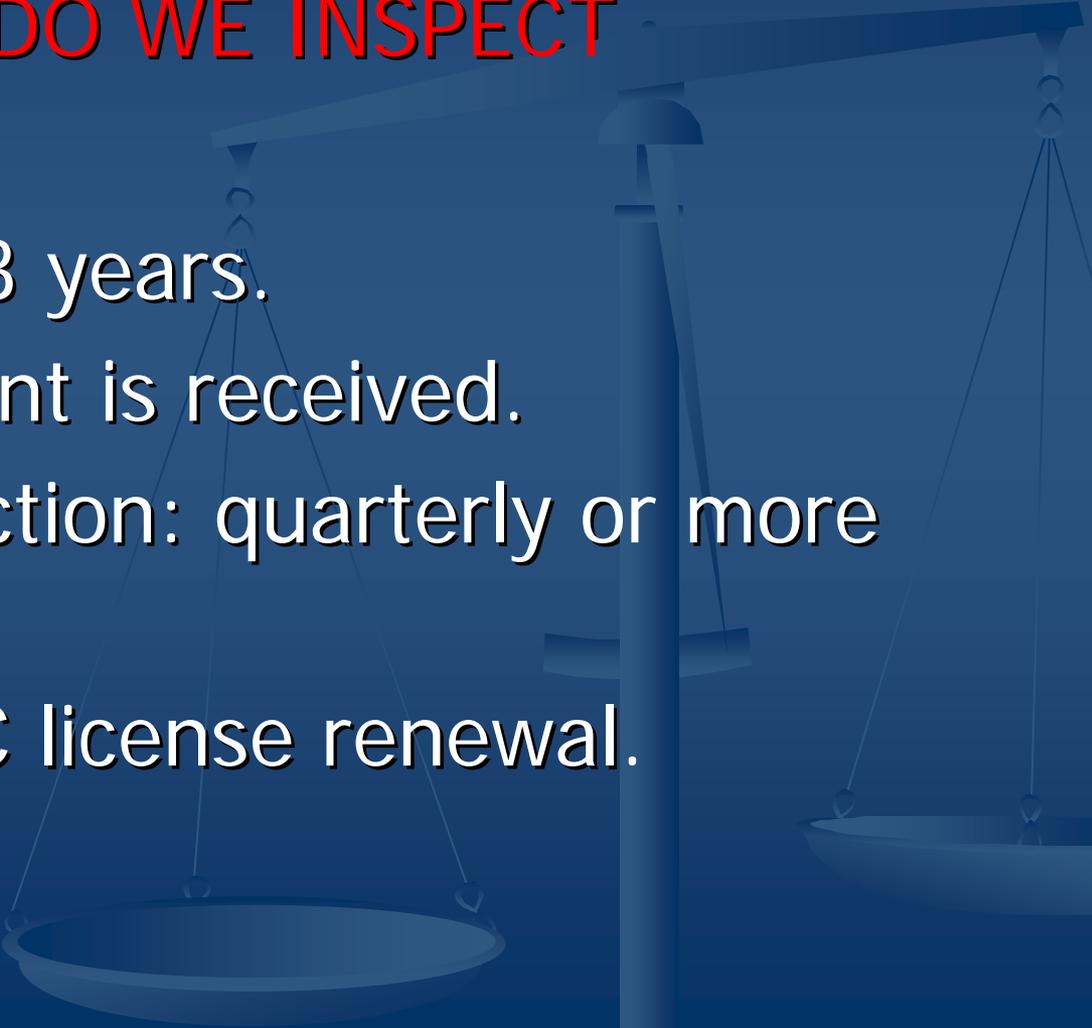
INSPECTION PROCESS

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)
- 

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.
- 

INSPECTION PROCESS

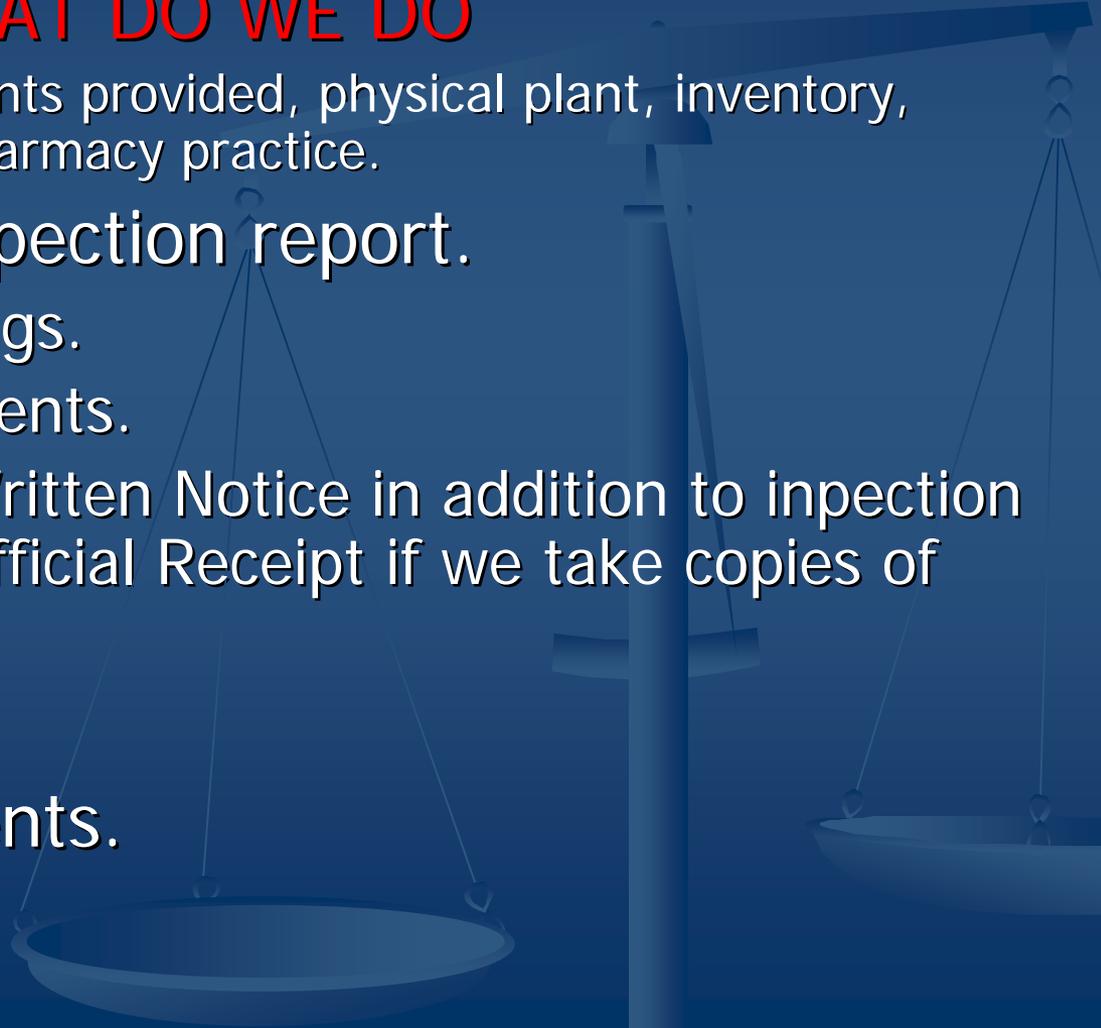
WHAT DO WE ASK FOR

- 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.

INSPECTION PROCESS

WHAT DO WE DO

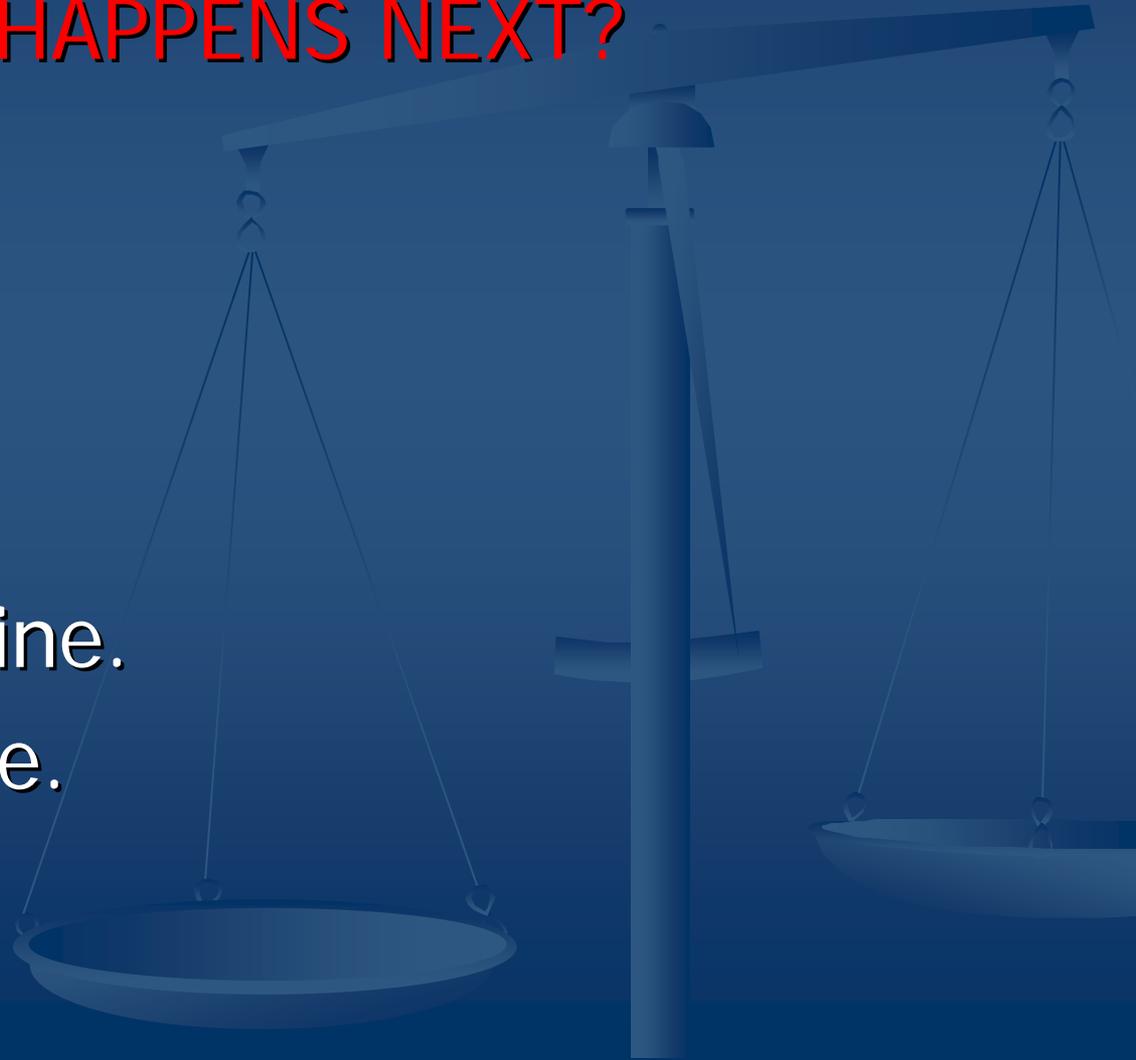
Review records and documents provided, physical plant, inventory, security, sanitation, pharmacy practice.

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.
- 

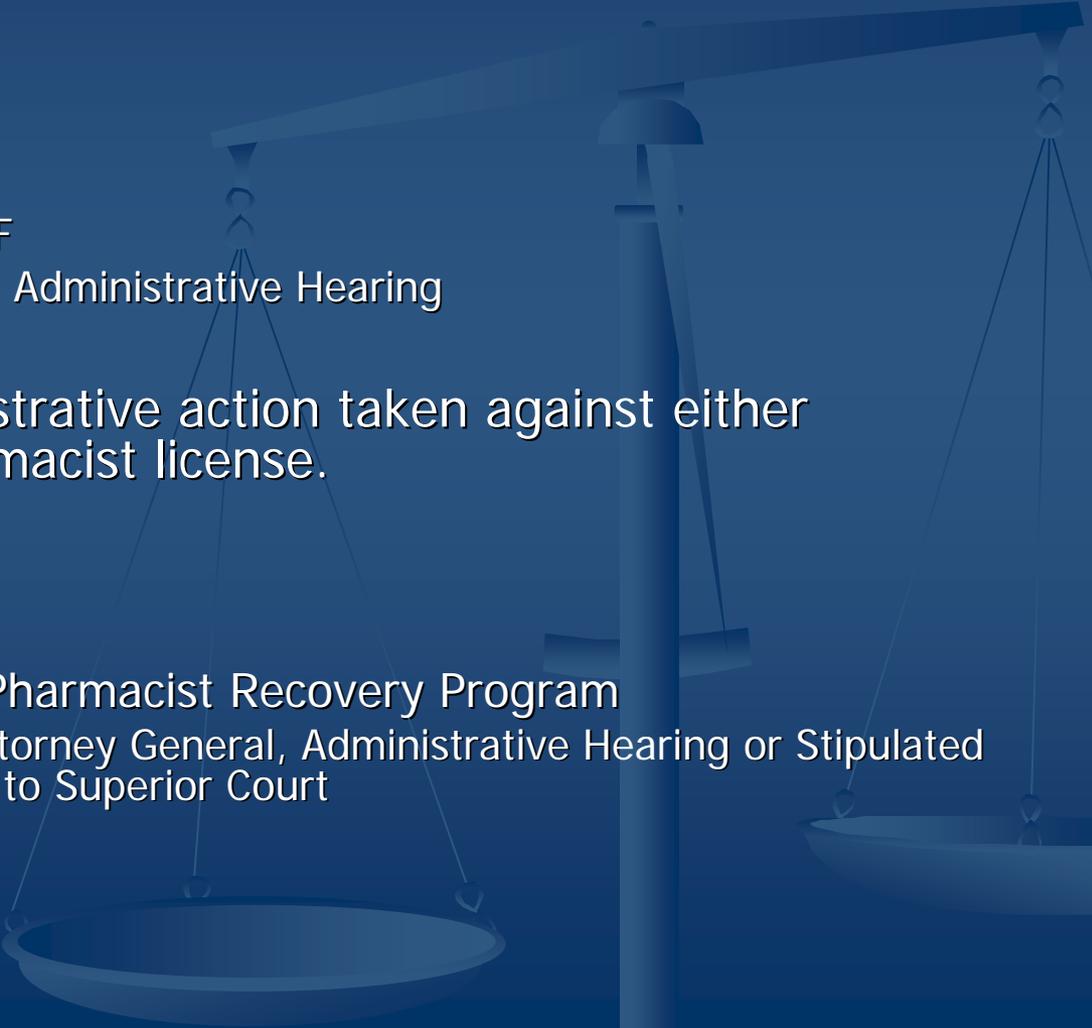
INSPECTION PROCESS

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

QUESTIONS



Contact Us

www.pharmacy.ca.gov

916-574-7900



SB 1441

Uniform Standards
Regarding Substance-Abusing
Healing Arts Licensees



Diagnostic Evaluation

- Board may require a licensee in a diversion program or on probation.
- Qualifications for the licensed practitioner.
- Required elements of the evaluation.
- Provides for timeframes.



Diagnostic Evaluation

- Pharmacists/Interns
 - Contract change for PRP participants
 - Regulation change (disciplinary guidelines)
- Other individuals
 - Statutory change (establish program)
 - Regulation change (disciplinary guidelines)



Temporary removal of practice for clinical evaluation

- Cease practice during the evaluation.
- Random drug testing at least two times per week.
- Evaluation criteria for return to work conditions.
 - 30 days of negative urine screens

Temporary removal of practice for clinical evaluation

- Pharmacists/Interns
 - Statutory change
 - Contract change for PRP participants
 - Regulation change (disciplinary guidelines)
- Other individuals
 - Statutory change
 - Regulation change (disciplinary guidelines)



Communication with Licensee's Employer

- Notification of the names, addresses and telephone numbers of all employers.
- Requires written consent for the board and employers to communicate.



Communication with Licensee's Employer

- Pharmacists/Interns
 - Regulation change (disciplinary guidelines)
- Other individuals
 - Regulation change (disciplinary guidelines)



Drug testing – Currently under revision

- Requires 104 random drug tests per year for the first year
- Requires a minimum of 50 random drug tests from then on
- Observed testing
- Daily check-in and same day testing
- Criteria for collection sites and labs processing the results



Drug testing – Currently under revision

- Pharmacists/Interns

- Contract change for PRP participants
- Regulation change (disciplinary guidelines)

- Other individuals

- Statutory change (establish program)
- Regulation change (disciplinary guidelines)



Group Meeting Attendance

- Evaluation criteria used to determine meeting frequency
- Qualifications and reporting requirements for facilitator



Group Meeting Attendance

- Pharmacists/Interns
 - Contract change for PRP participants
 - Regulation change (disciplinary guidelines)
- Other individuals
 - Statutory change (establish program)
 - Regulation change (disciplinary guidelines)



Type of treatment

- Criteria that must be considered when determining whether inpatient, outpatient, or other type of treatment is necessary.

Type of treatment

- Pharmacists/Interns
 - Contract change for PRP participants
 - Regulation change (disciplinary guidelines)
- Other individuals
 - Statutory change (establish program)
 - Regulation change (disciplinary guidelines)

Worksite monitoring

- Criteria for a worksite monitor
- Methods of monitoring used by monitor
- Reporting requirements by the worksite monitor
 1. Specifies that any suspected substance abuse must be verbally reported to the board and the licensee's employer within one business day
 2. Specifies that a written report must be provided to the board within 48 hours of the occurrence
- Completion of consent forms to allow for communication.



Worksite monitoring

- Pharmacists/Interns
 - Contract change for PRP participants
 - Regulation change (disciplinary guidelines)
- Other individuals
 - Statutory change (establish program)
 - Regulation change (disciplinary guidelines)



Positive drug test

- Temporary cease practice
- Determine if the positive drug test is evidence of prohibited use
- Criteria used to make the determination



Positive drug test

- Pharmacists/Interns
 - Statutory change
 - Contract change for PRP participants
 - Regulation change (disciplinary guidelines)
- Other individuals
 - Statutory change
 - Regulation change (disciplinary guidelines)



Ingestion of a banned substance

- A confirmed positive drug test is evidence of use of a prohibited substance
- Constitutes a major violation (refers to standard 10)



Ingestion of a banned substance

- Pharmacists/Interns
 - Contract change for PRP participants
 - Regulation change (disciplinary guidelines)
- Other individuals
 - Statutory change (establish program)
 - Regulation change (disciplinary guidelines)

Consequences for major and minor violations

- Major Violation Defined
 1. Failure to complete a board ordered program or undergo a clinical diagnostic evaluation
 2. Treating patients while under the influence of drugs/alcohol
 3. Any drug/alcohol related act which would constitute a violation of the state/federal laws,
 4. Failure to undergo drug testing, confirmed positive drug test, knowingly defrauding or attempting to defraud a drug test.
- Consequences for a major violation
 1. Cease practice order
 - Require new clinical evaluation
 - Negative drug screens for 30 days
 2. Termination of a contract/agreement
 3. Referral for disciplinary action

Consequences for major and minor violations

- Pharmacists/Interns
 - Statutory change
 - Contract change for PRP participants
 - Regulation change (disciplinary guidelines)
- Other individuals
 - Statutory change
 - Regulation change (disciplinary guidelines)

Consequences for major and minor violations

- Minor violation includes
 1. Untimely receipt of required documentation
 2. Unexcused group meeting attendance
 3. Failure to contact a monitor when required
 4. Any other violations that does not present an immediate threat to the violator or the public.
- Consequences for a minor violation
 1. Removal from practice
 2. Practice restrictions
 3. Required supervision
 4. Increased documentation
 5. Issuance of a citation and fine or working notice
 6. Re-evaluation/testing
 7. Other actions as determined by the board.

Consequences for major and minor violations

- Pharmacists/Interns
 - Statutory change
 - Contract change for PRP participants
 - Regulation change (disciplinary guidelines)
- Other individuals
 - Statutory change
 - Regulation change (disciplinary guidelines)



Return to full time practice

- Criteria to return to full time practice
 1. Demonstrated sustained compliance
 2. Demonstrated ability to practice safely
 3. Negative drug screens for at least six months
 4. Two positive worksite monitor reports
 5. Compliance with other terms and conditions of the program.



Return to full time practice

- Pharmacists/Interns
 - Statutory Change
 - Contract change for PRP participants
- Other individuals
 - Statutory change



Unrestricted practice

- Criteria for a licensee to request unrestricted practice
 1. Sustained compliance with a disciplinary order
 2. Successful completion of the recovery program
 3. Consistent and sustained participation in recovery activities
 4. Demonstrated ability to practice safely
 5. Continued sobriety of three to five years, as specified.



Unrestricted practice

- Pharmacists/Interns
 - Statutory Change
 - Contract change for PRP participants
- Other individuals
 - Statutory change



Private-sector vendor

- Reporting any major violation to the board within one business and any minor violation within five business days
- Approval process for providers or contractors that work with the vendor
- Discontinue the use of providers or contractors that fail to provide effective or timely services as specified.



Private-sector vendor

- Pharmacists/Interns
 - Statutory Change
 - Contract change for PRP participants



Confidentiality

- Requires the board to disclose the licensee's name and a detailed description of any practice restrictions imposed for participants in a diversion program whose been issued a cease practice order or has practice restrictions
- Disclosure will not include that the restrictions are as a result of the participation in a diversion program



Confidentiality

- Pharmacists/Interns
 - Statutory Change
 - Contract change for PRP participants
- Other individuals
 - Statutory change



Audits of private-sector vendor

- Requires an external independent audit every three years
- Audit must assess the vendor's performance in adhering to the uniform standards
- Requires the reviewer to provide a report to the board by June 30 of each three year cycle
- Requires the board and department to respond to the findings of the audit report



Audits of private-sector vendor

- Pharmacists/Interns
 - Statutory Change
 - Contract change for PRP participants



Measurable criteria for standards

- Establish annual reporting to the department and Legislature
- Details the information that must be provided in the report
- Establish criteria to determine if:
 1. The program protects patients from harm
 2. Is effective in assisting licensees in recovering from substance abuse in the long term.



Measurable criteria for standards

- Pharmacists/Interns
 - Contract change for PRP participants