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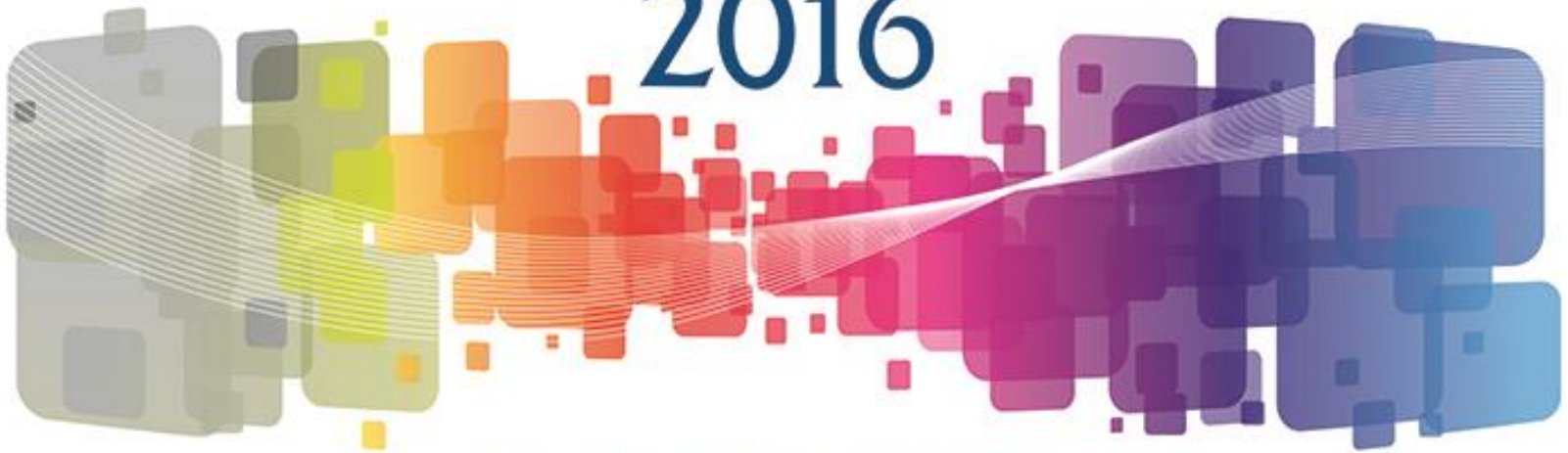

TRANSITIONS IN PHARMACY

DISNEYLAND® RESORT · OCTOBER 27th – 30th

Corresponding Responsibility: Recent developments that affect your responsibilities with Controlled Substances

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Disclosure

Financial Disclosures:

- I am a paid consultant for the Board of Pharmacy and have served as an expert witness/consultant for the Drug Enforcement Administration

Legal Disclosures:

- This program is intended for educational purposes only
- It is NOT intended to provide legal advice
- I am not your attorney
- There has been no attorney-client relationship established, and nothing said during this program is protected by that relationship
- Questions or requests for legal advice should be made where there is an attorney-client relationship

Learning Objectives

Pharmacists:

- **Define the doctrine of Corresponding Responsibility**
- **Identify "red flags" for controlled substances**
- **Define Strict Liability for PIC**
- **Explain how pharmacists might be liable for 2nd degree murder**
- **Identify pending changes for CII Inventory under California regulations**

Technicians:

- **Identify "red flags" for controlled substances**
- **Identify pending changes for CII Inventory under California regulations**

Federal Definition of Corresponding Responsibility

21 Code of Federal Regulations

§1306.04 Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective **must be issued for a legitimate medical purpose** by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but **a corresponding responsibility rests with the pharmacist who fills the prescription**. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

California Definition of Corresponding Responsibility

California Health & Safety Code

§11153. Responsibility for Legitimacy of Prescription; Corresponding Responsibility of Pharmacist;

Knowing Violation

(a) **A prescription for a controlled substance shall only be issued for a legitimate medical purpose** by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, **but a corresponding responsibility rests with the pharmacist who fills the prescription**

How is the Pharmacist's Responsibility Different than the Prescriber's

- Pharmacists must make a separate, independent determination that the prescription for a controlled substance is for a legitimate medical purpose
- It is not sufficient to merely obtain the prescriber's diagnosis or to verify with the prescriber that the prescription is legitimate
- It is very difficult to make this determination based upon a single incident, but repeated encounters and trends tend to raise **Red Flags** that the pharmacist must scrutinize

Red Flags When Filling Controlled Substance Prescriptions

https://www.youtube.com/watch?v=jdeQ0GeJjAM&sns=em

- Multiple controlled substance prescriptions
- Long distances from prescriber or patient
- Suspicious combinations of controlled substances
- Frequent/early refills of controlled substances

Red Flags When Filling Controlled Substance Prescriptions
(continued)

- Same prescriptions from the same prescriber for different patients without regard to age, weight, or other factors
- Multiple patients at the same address
- Multiple prescribers for the same controlled substance
- Cash payments

Pacifica Pharmacy
Complaint from a Concerned Citizen

BS is a concerned citizen who has no law enforcement experience. BS is a financial planner who maintains an upstairs office in the Beach Boulevard office complex where Pacifica Pharmacy is located. BS has a view of a portion of the building complex's parking lot from his office.

In November and December 2009, BS heard vehicles entering and leaving the parking lot and loud voices. On more than one occasion, BS looked out his window and observed cars parked randomly about the parking lot.

He saw individuals going from the parking lot into and out of the area where Pacifica Pharmacy was located. The persons moving about the parking lot were relatively young - in their 20s and 30s - and they walked between the cars that were parked there.

Pacifica Pharmacy
Complaint from a Concerned Citizen
(continued)

On one occasion, he observed cash spread across the dashboard of a vehicle below his office; a man sitting inside that vehicle interacted with others who approached the vehicle from other areas oft he parking lot.

The abnormal activity in the parking lot continued for weeks. On at least one occasion, BS saw money and prescriptions changing hands in the parking lot.

After filing complaints with both the building manager and the Huntington Beach Police Department did not resolve the problem, BS contacted the Board of Pharmacy

Red Flags Identified in the Pacifica Pharmacy Case

Irregularities on the face of the prescription itself;

Nervous patient demeanor;

Age or presentation of patient (e.g., youthful patients seeking chronic pain medications);

Multiple patients at the same address(es);

Cash payments;

Red Flags Identified in the Pacifica Pharmacy Case (continued)

Requests for early refills of prescriptions;

Prescriptions written for an unusually large quantity of drugs;

Prescriptions written for potentially duplicative drugs;

The same combinations of drugs prescribed for multiple patients;

Initial prescriptions written for stronger opiates (e.g., OxyContin 80mg);

Red Flags Identified in the Pacifica Pharmacy Case (continued)

Long distances traveled from the patient's home to the prescriber's office or pharmacy;

Irregularities in the prescriber's qualifications in relation to the medication(s) prescribed;

Prescriptions that are written outside of the prescriber's medical specialty; and

Prescriptions for medications with no logical connection to diagnosis or treatment;

In the Matter of the Accusation Against Pacifica Pharmacy; Thang Tran

DISCIPLINARY ORDER: On the basis of the factual findings and legal conclusions made in the 40-page Proposed Decision made the Decision and Order of the Board, the decision ordered:

- that Original Permit No. PHY 46715 issued to Pacifica Pharmacy Corp. is revoked;
- that Original Pharmacist License No. RPH 4117 issued to Thang Q. Tran is revoked; and
- that Pacifica Pharmacy Corp. and Thang Q. Tran shall pay to the Board of Pharmacy costs of investigation and enforcement in the total amount of $39,666.00.

Strict Liability for the Pharmacist-In-Charge

The Board of Pharmacy holds the Pharmacist-In-Charge strictly liable for all activities occurring within the pharmacy.

In the case of Sternberg v California State Board of Pharmacy, this position was affirmed by the Court of Appeals in California

Appellant Sternberg was PIC at a Big Box store in Los Angeles County.

Strict Liability for the Pharmacist-In-Charge (continued)

The Board revoked his license, stayed the revocation, and placed his license on probation for three years with specific conditions

Between 9/1/06 and 8/31/08, one of his technicians stole 216,630 tablets of Norco® with a street value of $1,083,150

Sternberg claimed no knowledge of the thefts while they were occurring, and that the state proved no evidence of complicity with the technician involved with the theft.

Details of the Sternberg Case

- The pharmacy technician accomplished this theft as follows: She would place orders for up to 3,000 Norco® tablets (six bottles with 500 tablets per bottle) to be delivered to the pharmacy on a day she was scheduled to work.

- She did this approximately 85 times, as often as three times a week. When orders arrived, she would take the delivery to a work station farthest away from the pharmacist's station.

Details of the Sternberg Case
(continued)

- She would then remove the six bottles, hide them in the store room, and destroy the packing invoice.
- When the pharmacist on duty took a lunch break, she would go to the store room, put three bottles in her purse, and take them out to her car.
- Later in the day, when the pharmacist was on a break, she would take the other three bottles to her car in the same manner.

Details of the Sternberg Case
(continued)

- Her theft was discovered when Sternberg found a bottle of Norco® in the store room.
- The pharmacy did not normally stock Norco®.
- The store initiated a loss prevention investigation, and the technician was caught on surveillance and arrested with 3,000 Norco® tablets.

The Charges

(1) a violation of Business and Professions Code sections 4301, subdivisions (j) and (o), 4005, 4081, and 4105, and California Code of Regulations, title 16, section 1718, for failure to maintain a complete and accurate record for all controlled substances/dangerous drugs received, sold, or otherwise disposed of;

(2) a violation of sections 4301, subdivisions (j) and (o), 4081, subdivision (a), and 4105 for failing to maintain records of acquisition and disposition for three years;

(3) a violation of sections 4301, subdivision (o) and 4059.5 for allowing the technician, a nonpharmacist, to order and sign for three deliveries of the Norco;

The Charges
(continued)

(4) a violation of sections 4301, subdivision (o) and 4115, subdivision (h) for failing to properly supervise the technician and allowing her to steal the Norco;

(5) a violation of sections 4301, subdivision (o) and 4005 and California Code of Regulations, title 16, section 1714, subdivision (b) for failing to secure and maintain the facilities, space, fixtures, and equipment from theft; and

and (6) a violation of sections 4301, subdivision (o) and 4005 and California Code of Regulations, title 16, section 1714, subdivision (d), for failing to provide effective controls to prevent the theft of the Norco® and maintain records for the drug.

The Appeal

Sternberg contended that the Board had erred in three ways:

(1) it improperly found he had a duty to randomly audit invoices and keep scheduled drugs locked in a secured area, given the technician destroyed invoices and hid the Norco® so no one else knew it was in the pharmacy;

(2) it improperly found the pharmacist-in-charge's duties included performing random audits of drug deliveries, checking staff work, and participating in checking inventory delivered to the pharmacy because neither side's expert testified that the pharmacist-in-charge had those duties; and

(3) the Board incorrectly interpreted Business and Professions Code section 4081 to apply to him when he did not know the technician was stealing the Norco®

The Judgment

The court of appeals affirmed the judgment of the lower trial court

A pharmacist-in-charge has a responsibility to monitor and control all of the activities that occur in the pharmacy

A pharmacist-in-charge is responsible for developing inventory control procedures to prevent theft and to monitor/audit the inventory of controlled substances

Physician Convicted of Murder for Recklessly Prescribing Drugs

Dr. Hsiu-Ying “Lisa” Tseng of Rowland Heights was convicted for three counts of second degree murder for the deaths of three of her patients for whom she recklessly prescribed controlled substances

She was accused of ignoring “red flags” about her prescribing habits, including the overdose of a patient in her clinic and nine phone calls in less than three years from authorities informing her that patients had died with drugs in their system.

Tseng was charged with murder for the deaths of:

- Vu Nguyen, 28, of Lake Forest
- Steven Ogle, 25, of Palm Desert
- Joey Rovero, 21, of Tempe Arizona

Red Flags in the Murder Case

Student traveled over 300 miles with friends from another state to get the prescriptions

Prescribing drugs to persons with no legitimate need for medications

Fraudulent prescribing for writing a man's name on prescriptions so his wife could double her pill count

At least eight of Tseng's patients died of overdoses from the same type of drug she prescribed to them

At least three of her patients had been charged with dealing drugs and a fourth was suspected by police of doing so

What is the Connection to Pharmacy?

Several of Dr. Tseng's prescriptions were among those filled at the Pacifica Pharmacy in Huntington Beach (see earlier slides)

Prescriptions were written for no legitimate medical purpose

The Doctrine of Corresponding Responsibility assigns the pharmacist with a corresponding responsibility to ascertain that the prescription being filled is for a legitimate medical purpose

It doesn't take too much of a stretch of the imagination to foresee a pharmacist who recklessly fills excessive quantities of controlled substances being charged with murder where the patient dies of an overdose from the prescription using the Doctrine of Corresponding Responsibility

New Proposed Regulations for CII Inventory in California

Proposed California Code of Regulations §1715.65 Reconciliation and Inventory Report of Controlled Substances

Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances

The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all inventory and inventory reconciliation reports taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the inventory reconciliation reports required by this section.

Proposed CII Inventory & Reconciliation Regulations (continued)

A pharmacy or clinic shall compile an Inventory Reconciliation Report of all Schedule II controlled substances at least every three months. This compilation shall require:

1) A physical count, not an estimate, of all quantities of Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section;

2) A review of all acquisitions and dispositions of Schedule II controlled substances since the last Inventory Reconciliation Report;

3) A comparison of (1) and (2) to determine if there are any variances; and

4) All records used to compile each Inventory Reconciliation Report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form.

Proposed CII Inventory & Reconciliation Regulations (continued)

Losses shall be identified in writing and reported to the board and, when appropriate, to the Drug Enforcement Administration. Likely causes of overages shall be identified in writing and incorporated into the Inventory Reconciliation Report.

The Inventory Reconciliation Report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge, and be readily retrievable in the pharmacy or clinic for three years.

A new pharmacist-in-charge of a pharmacy shall complete an inventory within 30 days of becoming pharmacist-in-charge as identified in subdivision (c). Whenever possible an outgoing pharmacist-in-charge should complete an inventory

For inpatient hospital pharmacies, a separate Inventory Reconciliation Report shall be required for Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location.

Proposed CII Inventory & Reconciliation Regulations (continued)

The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that:

1) All controlled substances added to an automated drug delivery system are accounted for;

2) Access to automated drug delivery systems is limited to authorized facility personnel;

3) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed;

4) Confirmed losses of controlled substances are reported to the board; and

5) A pharmacy or clinic identifying losses of controlled drugs but unable to identify the cause within 30 days shall take additional steps to identify the origin of the losses and improve security of controlled substance access to prevent losses.

Self Assessment

(pharmacists)

What is the Doctrine of Corresponding Responsibility?

A corresponding responsibility rests with the pharmacist who fills the prescription must determine that the drug prescribed is for a legitimate medical purpose

Self Assessment

(pharmacists and technicians)

What are the “Red Flags” to watch for when filling prescriptions for controlled substances?

Common sense signs:

- Long distance between pharmacy, prescriber, and/or patient
- Suspicious combinations of controlled substances
- Large quantities of controlled substances
- Cash payments
- Early refills/multiple prescribers

Self Assessment

(pharmacists)

What is Strict Liability for the Pharmacist-In-Charge (PIC)?

The PIC is responsible for all activities occurring within the pharmacy and to take measures to assure the security of the drugs therein

Self Assessment

(pharmacists)

How might a pharmacist face second degree murder charges by merely filling prescriptions?

Through the Doctrine of Corresponding Responsibility, the pharmacist has a duty to determine that a substance is being prescribed for a legitimate medical purpose. If the pharmacist recklessly fills controlled substances and a patient subsequently dies from an overdose of such, the pharmacist may face liability for such reckless behavior

Self Assessment

(pharmacists and technicians)

What are the new requirements for Schedule II inventories in California?

A pharmacy or clinic must perform a physical inventory and reconciliation of all Schedule II Controlled Substances at least every 3 months, and the transactions from the last inventory must be reconciled with the current inventory. Discrepancies must be investigated and resolved. Unresolved discrepancies must be reported to the Board.

References

21 Code of Federal Regulations §1306.04 Purpose of issue of prescription

California Health & Safety Code §11153. Responsibility for Legitimacy of Prescription; Corresponding Responsibility of Pharmacist

Board of Pharmacy Corresponding Responsibility video
https://www.youtube.com/watch?v=jdeQ0GeJjAM&sns=em

In the Matter of the Accusation Against Pacifica Pharmacy; Thang Tran, Board of Pharmacy Case No. 3802; OAH No. 2011010644; Precedential Decision No. 2013-01, Made precedential by the Board of Pharmacy effective August 9, 2013; Available at
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http://www.pharmacy.ca.gov/enforcement/fy1516/sternberg_lexis.pdf

Doctor convicted of murder for patients' drug overdoses gets 30 years to life in prison; Los Angeles Times, 2/5/16. Available at http://www.latimes.com/local/lanow/la-me-ln-doctor-murder-overdose-drugs-sentencing-20160205-story.html

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