



California Medical & Pharmacy Boards' Joint Forum to Promote Appropriate Prescribing & Dispensing



PHARMACIST CORRESPONDING RESPONSIBILITY

BY

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Before We Begin Discussion Let's All Agree



- **Prescriptions for legitimate pain patients, written for a legitimate medical purpose will be dispensed promptly with pharmacist consultation, when required, and appropriate pharmacist monitoring.**

Pharmacist Corresponding Responsibility



CA Health & Safety Code Section 11153

- 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 & dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fill the prescription.

Examples of prescriptions the code section considers not to be legal prescription:

1. prescription issued not in usual course of professional treatment or in legitimate and authorized research
2. prescription for an addict not in the course of professional treatment or not as a part of an authorized narcotic treatment program

* Code of Federal Regulations (DEA) section 1306.04(a) contains virtually the same language as CA H&SC 11153

Additional Code Section

Erroneous or Uncertain Prescriptions



- **California Code of Regulations section 1761**
 - A.** No pharmacist shall dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.
 - B.** Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose.

BEFORE WE CONTINUE, LETS ALL UNDERSTAND



- **99% of concerns and inquiries by pharmacist are not a challenge to appropriateness of the prescription written by the prescriber**
- **Pharmacies have unique challenges as do prescribers and at times the only way to deal with an issue is for pharmacy to contact prescriber.**

The World Has Changed



- **H&SC 11153 enacted and 1761 was promulgated implemented in 1982**
 - 1990's -2009 – Board of Pharmacy investigate only 1-2 complaints yearly statewide.
 - Currently - 39 open investigations in Southern California only. That means 39 pharmacies are being investigated.
- **CA Board of Pharmacy investigates complaints related to this matter reported by any source:**
 - Member of the public, patient, former patient, pharmacy employee, another agency investigating pharmacy, law enforcement agency, Board of Pharmacy inspection related to other matters, insurance carriers , anonymous complaints, newspaper reports identifying our licensees.

THE WORLD HAS CHANGED



- ARE WE PART OF THE SOLUTION
 - THESE DRUGS KILL OUR CHILDREN WHO DON'T UNDERSTAND ALWAYS WHAT THEY ARE DOING
 - OR.... ARE WE PART OF THE PROBLEM BECAUSE WE TURN AWAY OR DO NOTHING
-
- Similar to TSA at airport. Everyone hates it, but the world has changed and had to change

The World Has Changed



- **Current favorite substances of abuse**
 - Prescription controlled substances
 - Not a schedule I substance that is made in someone's kitchen or illegally
 - Highly regulated by DEA and plus additional regulation at the state level
 - From manufacturer until dispensed to patient per prescription these drugs are always held by a licensed entity
 - Uncontrolled internet sales for a number of years caused increased demand for these items. When Ryan Haight Act implemented the internet patients either had to buy foreign drugs, go to the street, or back to the doctor.

The World Has Changed



- **Criminal element an integral part of prescription controlled substance diversion. Never previously a part of our industry. Criminal strategies used to obtain prescription controlled substances for street sale:**

Individual patient consumes a portion of prescription & sells remainder to support addiction (Oxycontin 30mg #90 cash paying patient \$818.00)

Individual drug dealers- usually a source in some type of pharmacy

Organized diversion rings- cappers (drivers) take patients to prescriber, then to pharmacy. Patient paid \$100 for the day. Drugs collected and sold on street.

Gang participation in diversion and street sale of controlled substances-increased pharmacy burglaries and robberies, 1st pharmacy technician death during robbery in Sacramento area, pharmacy ancillary staff intimidated forcing them to steal from pharmacy.

* Note – ancillary staff steal to sell and also self use. Pharmacists usually steal for self use

The World Has Changed



- **Physician and pharmacy practice changes**

- Physician

- pain agreement,
 - urine testing,
 - CURES review,
 - rarely store controlled substances in your office and very careful about security of your prescription documents.

- Pharmacy

- inordinate amount of time currently required to monitor & secure pharmacy inventory (skyrocketing internal theft)
 - increased awareness of all controlled substances dispensed
 - increased documentation and recordkeeping.

How Do These Controlled Substances Make Their Way to the Street Dealers



- **Steal it from:**
 - Manufacturer
 - Drug wholesaler
 - Pharmacy
 - Prescriber
- **Presenting various types of prescriptions to the pharmacy that are not written for a legitimate medical purpose by a practitioner acting in their usual course of professional practice.**

Board of Pharmacy Recommendation to Pharmacists



- **1. Once you order a controlled substance for your pharmacy, don't let anyone steal it from you.**
 - 6700 pharmacies in CA, if 1000 HPAP lost from each in 1 year that is 6.7 million HPAP on the street
- **2. Only dispense prescriptions written for a legitimate medical purpose.**

In an ideal world if these two recommendations were followed there would not be prescription controlled substances for sale on the street.

Prescriptions Inappropriately Dispensed by Pharmacists



- Stolen prescription documents
- Altered prescriptions
- Fraudulent telephonic or fax prescriptions- CA requires pharmacist ID patient if not known to pharmacist if telephonic or fax prescription
- Fraudulent CA security prescription document – usually MD phone number connects to a cell phone
- Unknown patient and/or prescriber, both located significant distance from pharmacy without any reasonable reason
- Pharmacy staff in an effort to steal drug enter prescriptions for non existent patients or add refills to existing valid prescriptions and then steal the drugs
- Unauthorized refills
- Dispensing controlled substances without a valid prescription

Note: these prescriptions need to be verified by prescriber, but these violations appear to occur without prescriber knowledge

Pharmacy/Physician Issues



- Pharmacy in Los Angeles older ethnic area, small family owned pharmacy. About 1800 prescriptions dispensed written by one doctor, out of area, and suspect patients out of area.
 - Pharmacist corresponding responsibility criteria
 - ✦ Only fills between 4-6 of these prescriptions per day
 - ✦ Only fills prescriptions for small quantities – only 120 tablets
 - ✦ Business plan – filling 5-7 prescriptions per day will increase revenue by \$80,000

Pharmacy/Physician Issues



- Prescriber in San Fernando Valley, pharmacy in Los Angeles, patients all over southern CA. Empty prescription containers dispensed by one pharmacy, for 45 patients found all at the same time in a trash can in Oceanside. Drugs were poured out of patient labeled containers and sold on the street. This diverter group was providing the vast majority of HPAP in northern San Diego county and Mexico.
- Pharmacist corresponding responsibility criteria
 - If the doctor orders it, he/she should make the decision, and I fill it

Pharmacy/Physician Issues



- Central valley pharmacy purchases and dispenses 15 cases of Phenergan & Codeine weekly. All prescriptions written by a few prescribers in central valley. Prescriptions for 240ml or 480ml. Specific brands preferred. Patients in central valley, Los Angeles and all of southern California. Up to 10 prescriptions for different patients filled all that the at same time written by the same prescriber
 - Many prescriptions obviously altered quantity
 - Pharmacist corresponding responsibility criteria
 - ✦ feels doctor writes the prescription and he fills the prescription

How Does a Pharmacist Determine if a Prescriptions is Written for a Legitimate Medical Purpose



- **Usually no access to the patient's medical record**
 - Unless in a closed setting like an acute hospital, other health care facility, managed care or clinic
- **Pharmacist must form an opinion by relying on information obtained from:**
 - Patient profile created & maintained in the pharmacy
 - Information provided by the patient
 - Any diagnostic or indication of use information written on the prescription document itself
 - Communication with prescriber
 - CURES data

Chain Pharmacies



- Most do not regularly access CURES
- Most have inter-store dispensing data available, many times not accessed before dispensing a prescription
- Larger number of pharmacists work the store. Problem patients target “easy pharmacist” for early refills
- Continually electronically request refill until the refill program will allow dispensing.

Pharmacist Responsibilities



- **Patient/ pharmacy relationship**
 - How much does pharmacy know or interact with patient
- **Patient/prescriber relationship**
 - Does pharmacy have any certainty that a patient/physician relationship exists. Is this really a patient of the prescriber
- **Pharmacy/prescriber relationship**
 - What is the pharmacy knowledge of the prescriber

Should I Dispense This Prescription?



Considerations:

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

Evaluation of Prescription Document



- Is prescription written on CA Security Prescription document, or written on normal prescription document and each order must be reduced to writing.
- If elements of security document missing rph required to call and validate the prescription
- Prescription II-V must be dated and signed in ink (11164(a)(1))
- If prescription computer generated with digital signature, if it is faxed to pharmacy it must have a handwritten signature.
- Is prescriber information correct- DEA number, telephone number and address
- Evaluate document for signs of alteration or forgery
- Telephone orders – does pharmacy know the authorized agent calling in prescriptions
- Fax source
- Electronic prescriptions received thru approved vendor
- Drug therapy consistent with any diagnosis or indication documented on the prescription

Prescriber Information



- Is prescriber within your normal trade area
- Status of CA license to practice medicine
- Status of DEA registration
- Specialty
- Any restrictions of Medi-cal or Medicare priveleges
- Any prior discipline with CA Medical Board or out of state boards
- What percent of your pharmacy's controlled substances are written by one prescriber. If so, is there a logical reason – ie. Located in the same building
- What percent of prescribers patients pay cash – Is there a logical reason for all or a high percentage of cash patients. How expensive are drugs
- Prescriber practices
 - Do you fill a variety of dangerous drugs and controlled substance prescriptions or only controlled substances (consider prescriber specialty)
 - Does prescriber write for the same combination of drugs for all patients

Evaluation of Patient Information



- Does pharmacy know or identify the patient
- Does pharmacy access CURES report for new patients or questionable patients
- Does CURE report show multiple doctors and or multiple pharmacies
- Does patient live in the normal trade area of pharmacy
- Distance patient lives from prescriber
- Does patient have addiction or abuse history
- Does patient visit pharmacy and pick up prescriptions. Do you see the patient or is there a runner or a relative that picks up prescriptions
- Patient age
- Diagnosis
- What other medication do you dispense for this patient

Evaluation of Patient (cont)



- Method of payment
- Frequent early refills
- Frequent address changes – address on profile never matches prescription address – if Google address does the address exist
- Patient appearance
 - Diagnosis appear to fit the patient
 - Any adverse affects – sedation, confused, dizzy, nauseated
 - Does patient appear at times to be in pain

Evaluation of the Drug



- Does indication for drug seem appropriate
- Length of therapy and quantity ordered
- Narcotic naïve
- Does patient take medication per directions or request early refills frequently
- Same drug, strength and directions for all patients of a single prescriber, if so does RPH understand the prescriber's practice
- Time release pain medication ordered without short acting drug for break thru pain
- Are only most popular drugs on the street ordered repeatedly
 - Oxycontin, Vicodin, Xanax, Soma

Pharmacist Evaluation of Their Own Practice



- What would cause you to refuse to fill a controlled substance prescription?
- What do you do when there are red flags or your gut tells you not to fill a prescription
- How would you react if a large number of patients arrived all at once, all with controlled substance prescriptions written by the same prescriber unknown to you
- What special training do you, the pharmacist, have to assist you to make making the right decisions when dispensing for large numbers of chronic pain patients?
- PHARMACIST -DO YOU THOUGHTFULLY AND PROFESSIONALLY EMBRACE THE ISSUE OF CORRESPONDING RESPONSIBILITY, OR DO YOU AVOID, TURN AWAY BECAUSE THAT IS EASIER, OR JUST TAKE THE MONEY FOR THE PRESCRIPTION THAT MAY BE THE ONE THAT KILLS A PERSON.
- What documentation does pharmacy keep when dispensing medications for chronic pain patients
 - CURES reports
 - Copy of patient “pain agreement” with prescriber
 - Notes documenting communication with prescriber or patient
 - How does RPH document when either fill or refuse to fill an unusual prescription
 - Some exceptional pharmacies generate their own patient record and document all interactions and pharmacy related pain management information

CURES



Real time access to CURES data valuable for all pharmacists, but most valuable for emergency room prescribers, urgent care prescribers, and pharmacists working in 24 hour pharmacies who are often times presented with difficult decisions surrounding prescribing of controlled substances.

- When reviewing CURES data for one patient, look for :
 - multiple dates of birth
 - multiple addresses
 - multiple doctors



Questions?



Visit our Web site at www.pharmacy.ca.gov

Or call us at (916) 574-7900

