

Clinical Pharmacy Considerations: A Review of Ohio Law

Donald L. Sullivan, R.Ph., Ph.D.
Professor of Pharmacy Practice
Ohio Northern University

Objectives:

- 1) Discuss the concept of corresponding liability when dispensing a prescription
- 2) Discuss the requirements of prospective drug utilization review
- 3) Discuss the appropriate use of DEA number suffixes in a hospital
- 4) Discuss the requirements for dispensing medication when the patient is out of refills
- 5) Discuss compounding drugs for physician use (in-office)
- 6) Discuss recent changes to pharmacy law and how they impact the practice of pharmacy in Ohio

I. Corresponding Liability and the Pharmacist

The pharmacist who fills any prescription has a corresponding responsibility with the physician to make sure that the prescription has been issued for a **Legitimate Medical Purpose**. The responsibility to ensure that a prescription is for a legitimate medical purpose in the usual course of a prescriber's professional practice is equal for both the physician and the pharmacist. (Fifty percent of this responsibility is on the pharmacist and 50% is on the physician). The argument that "Just because a physician wrote the prescription, I can legally fill it" is no excuse.

The following text is an excerpt from the DEA's Pharmacist's Manual 2010:

"A pharmacist also needs to know there is a corresponding responsibility for 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 an invalid prescription within the meaning and intent of the CSA (21 U.S.C. § 829). 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. A pharmacist is required to exercise sound professional judgment when making a determination about the legitimacy of a controlled substance prescription. Such a determination is made before the prescription is dispensed. The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin. To the contrary, the pharmacist who deliberately ignores a questionable prescription when there is reason to believe it was not issued for a legitimate medical purpose may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances. Such action is a felony

offense, which may result in the loss of one's business or professional license (see United States v. Kershman, 555 F.2d 198 [United States Court Of Appeals, Eighth Circuit, 1977])."

Let's discuss a few cases on how to handle some of these situations:

Case: A patient brings you a prescription for Percocet 5/325, #240, one tablet every two hours. How should you handle this prescription? What types of questions should you be asking the patient? the physician?

Case: A patient brings you the following prescriptions

- 1) Valium 10mg, #120, one tablet three times daily and at bedtime.
- 2) Ambien CR 12.5mg, #90, one tablet at bedtime.

You call the doctor to obtain more information and to ask a few questions. The doctor tells you "That's the way I want it." I am the doctor, you are the pharmacist. If you won't fill it, some else will." How should you handle this situation?

Case: You are working at a local pharmacy. Ninety percent of the prescriptions you see from Dr. X are for the following three drugs. In fact, 90% of patients receive the same three drugs:

- 1) Vicodin ES, #60, one tablet twice daily
- 2) Xanax 2mg, #30, ½ tab BID
- 3) Phenergan with codeine cough syrup, 180mL, one teaspoonful QID

How would you handle this situation? Are there any "red flags" you should be concerned with?

Case: A patient has been taking Hycodan cough syrup from April to November. They have been receiving a prescription every two weeks for 180mL. The patient never has it filled early. How should you handle this situation?

What are some examples of similar situations you have seen in your practice? Let's discuss them.

II. Drug Utilization Review

Case: What is the difference between prospective DUR and retrospective DUR?

Case: Pharmacists are required by law to conduct prospective, retrospective or both.

Prior to dispensing any prescription, the pharmacist shall review the patient profile for the following:

- a) over-utilization or under-utilization
- b) therapeutic duplication
- c) drug-disease state contraindications
- d) drug-drug interactions
- e) incorrect drug dose
- f) drug-allergy interaction

- g) abuse/misuse
- h) inappropriate duration of treatment
- i) documented food/nutritional supplements-drug interactions

Upon recognizing any of the above, a pharmacist, using professional judgment shall take appropriate steps to avoid or resolve the potential problem. These steps may include consulting with the prescriber and/or counseling the patient.

Case: Should a pharmacist document regular use of OTCs and herbal products in the patient's profile?

Case: Can other prescription drugs that are **not** controlled substances be the target of abuse by patients? What are they?

III. Hospital DEA Numbers

Practitioners (interns, residents, staff physicians, mid-level practitioners) who are agents or employees of a hospital or other institution, may, when acting in the usual course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution in which he or she is employed, in lieu of individual registration, provided that:

1. The dispensing, administering, or prescribing is in the usual course of professional practice.
2. The practitioner is authorized to do so by the state in which they practice.
3. The hospital or institution has verified that the practitioner is permitted to administer, dispense, or prescribe controlled substances within the state.
4. The practitioner acts only within the scope of employment in the hospital or institution.
5. The hospital or institution authorizes the practitioner to administer, dispense, or prescribe under its registration and assigns a specific internal code number for each practitioner.

An example of a specific internal code number for Riverside Hospital is:

Hospital DEA # \Rightarrow AR4618510-1890 \Leftarrow Physician's hospital code number

A current list of internal codes and the corresponding individual practitioners is to be maintained by the hospital or other institution. This list is to be available at all times to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the prescribing individual practitioner. Pharmacists should contact the hospital or other institution for verification if they have any doubts in filling such a prescription.

Case: An ED physician is employed by the hospital. Can he use the hospital's DEA number with a suffix to write controlled substances in the ED department?

Case: An APN with a CTP number is employed by the hospital. Can she use the hospital's DEA number with a suffix to write controlled substances for patients being discharged from the hospital?

Case: Can a resident moonlighting at another physician's office on Saturdays use the hospital's DEA number with a suffix and write controlled substance prescriptions?

IV. Dispensing when a patient is out of refills

Case: A patient comes into your pharmacy on a Saturday night. He is out of his Lipitor 20mg. The physician's office is closed. How much Lipitor could you dispense to this patient?

Case: When a patient is out of refills and the pharmacist dispenses a 24 hour supply to the patient, How long does a pharmacist have to notify the physician?

Key points with this rule: Always do what's best for the patient. Always take care of the patient first. Be sure to document what you do.

A pharmacist may dispense or sell a dangerous drug, other than a schedule II controlled substance, without a written or oral prescription from a licensed health care professional authorized to prescribe drugs if all of the following conditions are met:

- 1) Pharmacy has a record of a prescription for the drug in the name of the patient who is requesting it and the prescription has no refills.
- 2) R.Ph. is unable to contact the physician for refill authorization.
- 3) In the pharmacist's judgement, the drug is essential to sustain life, continues therapy for a chronic condition, or failure to dispense the drug could result in harm to the health of the patient.
- 4) Dispense only a 72-hour supply.
- 5) Record the dispensing and notify the physician within 72 hours of the dispensing.
- 6) R.Ph. may dispense 72-hour supply once for each prescription on file.
- 7) Recordkeeping: For one year after the sale or dispensing the pharmacist must keep records of the following:
 - a) name and address of patient
 - b) name and address of the individual receiving the drug (if different from the patient)
 - c) amount dispensed
 - d) original prescription number

Partial Refilling of Controlled Substances for Schedules III and IV drugs

Consider this example: A patient brings you a prescription for Darvocet N-100, one tablet QID, prn #100 with 4 refills. The patient only wants to get 50 tablets at a time. How many times can the pharmacist fill this prescription with a quantity of 50?

Answer: The prescription was written for a total of 500 tablets. The pharmacist can dispense the entire 500 tablets as long as they are dispensed within 6 months of the date the prescription was written.

- 1) These are considered partial fillings.
- 2) The patient is entitled to the entire quantity prescribed, even if this means the number of “partial fillings” exceeds five. The total quantity dispensed in all partial fillings cannot exceed the total quantity prescribed.
- 3) However, all partial fills must be dispensed within 6 months of the date the prescription was written.
- 4) Each partial filling is recorded in the same manner as a refill.
- 5) If the computer system does not permit “partial refilling” of a schedule III or IV drug, a new prescription number for the partial refilling must be assigned. In the computer database, a notation must be included that identifies this new prescription number as a partial refilling. A prescription bearing the new prescription number must be placed in the Schedule III, IV and V prescription files.

Case: Patient comes into the pharmacy with a prescription for methylphenidate 10mg, #60. They only want 30 tablets. They want to get the other thirty tablets in two weeks. Can the pharmacist fill the remaining 30 tablets in two weeks?

V. Compounding Drugs for Physician Use (in-office)

- 1) A pharmacist may compound a drug if requested by the prescriber or agent of prescriber to be used for direct administration to patients.

Examples:

- 2) The total amount supplied cannot exceed 5% of total dollar sales (5% rule)
- 3) Pharmacies can only do this for products that are not commercially available.
- 4) These drugs should only be provided in the following situations:
 - a) to treat an emergency situation
 - b) unanticipated procedure for which a time delay would negatively affect patient outcomes.
 - c) for diagnostic purposes

- 5) 72 hour supply limit (prescriber should have no more than 72 hour supply on hand)
- 6) topical products (compounded) shall be supplied in a single container in which quantity does not exceed 60 grams or 60 mL. (Prescribers can only have only one container at one time.)
- 7) Pharmacies cannot sell compounded drugs to other pharmacies or wholesalers.
- 8) Prescribers can only administer these drugs to their own patients.
- 9) Each product must have a “Beyond Use Date” on it
 - a) Low risk compounds: 48 hours at controlled room temperature (20-25 degree Celsius), 14 days when refrigerated (2-8 degree Celsius), and 45 days in solid frozen state (-10 to -25 degrees Celsius).
 - b) Medium risk compounds: 30 hours at controlled room temperatures temperature (20-25 degree Celsius), 9 days when refrigerated, (2-8 degree Celsius), and 45 days in solid frozen state (-10 to -25 degrees Celsius).
 - c) High risk compounds: 24 hours at controlled room temperature (20-25 degree Celsius), 3 days when refrigerated (2-8 degree Celsius), and 45 days in solid frozen state (-10 to -25 degrees Celsius).
- 10) Labeling of these compounded products must include:
 - a) statement: “For direct patient administration only”
 - b) statement: “Not for resale”
 - c) storage conditions
 - d) beyond use date
 - e) name of active and inactive ingredients
 - f) amount or percentage of active drug ingredients
 - g) quantity
 - h) route of administration
 - i) pharmacy name, address, and phone
 - j) pharmacy control number (lot number)

VI. Discuss recent changes to Ohio pharmacy law and how they impact the practice of pharmacy in Ohio

- 1) The prescription transfer rule reverted back to its original form in the summer of 2011. Prescriptions for non-controlled substances can be transferred an unlimited number of times. Controlled substance prescriptions can only be transferred once. Exception: If a company has a shared database where several stores use the same computer database (centralized records like Walgreen’s) controlled substance prescriptions can be transferred an unlimited number of times.

2) Once electronic controlled substance prescribing software has been approved, the prescriber may send the written prescription electronically for an emergency C-II prescription instead of sending the written prescription. The pharmacist must document on the electronic prescription that it's for "Emergency Dispensing".

3) The DEA has changed their policy to recognize nurses in long-term care (LTC) facilities as agents of the prescriber for schedule III thru V controlled substances. This means they can fax prescriptions and call-in oral prescriptions for these drugs.

4) All controlled substances for weight reduction have a 12 week therapy limit. After this time, there must be a 6-month controlled substance free period before a controlled substance for weight reduction can be re-started. (Meridia is gone from the market.)

5) FDA has ruled that they will not enforce the MedGuide requirements for inpatients.

6) Zoster vaccine requirements:

- Pharmacists may administer the zoster vaccine.
- Before administering the zoster vaccine, the pharmacist must have an updated immunization course or "bridge" course approved by the Board of Pharmacy.
- The pharmacist must receive a patient specific prescription for the zoster vaccine.
- The prescription for the zoster vaccine is valid for 30 days.
- The patient must meet the age criteria specified in the FDA approved labeling of the zoster vaccine.
- Pharmacist must be able to document the training required to administer the zoster vaccine.