

Staying Current: A Review and Update of Ohio Pharmacy Practice Laws

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Pharmacy Forward: Advancing Practice for a Healthier Tomorrow!

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Disclosure Statement

- Donnie Sullivan has no relevant financial relationship(s) with ineligible companies to disclose.
and
- None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.





Learning Objectives

At the completion of this activity, the participant will be able to:

1. Describe the requirements of remote dispensing pharmacies
2. Describe new Ohio pharmacy practice laws and rules
3. Describe commonly misunderstood Ohio pharmacy laws and how they affect the day-to-day practice of pharmacy

Remote Pharmacy

- Definition: A pharmacy where drugs are dispensed, patient counseling occurs, and other pharmacist care is provided through a telepharmacy system. There is no pharmacist physically present.
- Passed Ohio legislature 5/9/2025
- Board of Pharmacy is still working on the rules to go along with the law



Remote Pharmacy

- Shall not dispense more than an average of 150 prescriptions per day over a 90-day period (Board can waive this)
- Cannot be located within 10 miles of another pharmacy except:
 - It is located in an FQHC
 - It is located in an underserved area as defined by the Board
- If it dispenses controlled substances, it must maintain a perpetual inventory of all controlled substances



Remote Pharmacy - Staffing

- No pharmacist on-site
- Supervising pharmacist located in Ohio responsible for monitoring
- 2 or more pharmacy interns or certified technicians
 - Certified techs: 1,000 hours of experience and 1 year working in a pharmacy in the last 3 years
 - Interns: 1,000 hours working in a pharmacy during the last 3 years and no more than 500 of these hours can be from an academic rotation (IPPE or APPE)



Remote Dispensing - Staffing

- No more than 3 certified tech or interns working at the same time
- Interns and Techs cannot:
 - Counsel a patient
 - Recommend drugs
 - Provide drug therapy advice
 - Compound
 - Repackage drugs
 - Administer immunizations
 - Perform diagnostic testing



Remote Pharmacy

Supervising Pharmacist

- Can only oversee the activities of one remote pharmacy*
 - Visit the remote pharmacy at least once a quarter
 - Oversee all techs and interns through a telepharmacy and surveillance system
 - Verify each prescription and drug dispensed through visual review, barcoding, and any other technology
 - Offer to provide patient counseling
 - Cannot be located more than 50 miles from the remote pharmacy
- *May increase to a maximum of two with Board approval



New Pharmacist Administered Injectables

- Addiction treatment drug in long-acting or extended–release form
- HIV treatment or prevention drug in long-acting or extended – release form
- Antibiotics
- Denosumab or romosozumab
- Methotrexate for non-emergent conditions
- Heparin, low molecular weight heparin, and factor Xa inhibitors



Outpatient Delivery Services

- 1) Before delivering a drug, the pharmacy must contact the patient or patient's caregiver for consent before billing or delivery of any medication, unless the patient has provided general consent for delivery services.
- 2) Communicate with the patient or patient's caregiver the date shipped, method of delivery, and expected arrival.



Outpatient Delivery Services

3) Take appropriate measures to ensure that temperature sensitive drugs will be maintained within the temperature ranges recommended by the manufacturer until the delivery has been completed. The pharmacy must also provide notification to the patient of the timeliness in addressing proper storage of the medication.



Outpatient Delivery Services

- 4) If the prescription is a controlled substance, proof of delivery is required. This may include the signature of the patient.
- 5) Assist the patient with arranging access to the medication from a local pharmacy if unable to deliver the medications in the expected timeframe.



Outpatient Delivery Services

- 6) Provide a method for the patient or caregiver to notify the pharmacy as to an irregularity in the delivery of the medication including: timeliness of the delivery, condition of the drug upon delivery, or failure to receive the proper drug.

- 7) Have a process to inform the patient or caregiver within 2 business days of being notified of a delay in the scheduled delivery if it will be interrupted or late.



Outpatient Delivery Services

- 8) If the prescription is compromised or lost, the pharmacy must replace it at no additional cost to the patient.

- 9) Any drug that has been delivered to a patient or is no longer in possession of the delivery agent shall not be returned to stock.



Outpatient Delivery Services

10) Recording keeping for prescriptions that are delivered must include:

- a) Patient name
- b) Patient address
- c) Prescription number
- d) Name and dosage of the drug
- e) Name of the pharmacy delivery agent (This may be USPS or other common carrier as well)
- f) For contract carriers it must include: name of the contract carrier and individual conducting the delivery on behalf of the contract carrier.
- g) If employee of the pharmacy, full name of the employee must be documented



Outpatient Delivery Services

11) All records must be kept for three years.

12) Significant theft or loss of any prescription drug(s) must be reported to the Board of Pharmacy.



Compounding Clarifications

Under the Federal Food Drug and Cosmetic Act (FD&C Act), compounding drug products that are essentially copies of a commercially available drug product is prohibited unless either of the following exceptions occur. The prescriber needs to document the specific reason that the compounded drug would produce a significant difference from the commercially available drug product. This must be documented on the prescription.



Compounding Clarifications

- a) The drug is not commercially available, including the drug product has been discontinued, on the FDA shortage list, or is no longer marketed.

- b) The compounded drug includes a change made for an identified individual patient, which produces for that patient a significant difference as determined by the prescriber.



Compounding Clarifications

When pharmacies obtain active pharmaceutical ingredients (APIs) for compounding, they must ensure that:

- a) It is a pharmaceutical grade product
- b) It comes with a valid certificate of analysis
- c) It is sources from an establishment registered with the FDA



Mobile Clinics

The following may operate a mobile unit to dispense without a fixed location:

- a) Non-profit organization or association
- b) A for-profit entity whose purpose is to provide services to patients needing treatment for substance use disorder, a mental health condition, and any related medical issue



Mobile Clinics

- 1) If no health care professional is present when transporting drugs, all drugs must be secured with physical locks.
- 2) When dispensing drugs, a pharmacist must be present on the premises and the mobile must be under their control. When personally furnishing drugs, a prescriber must be present on the premises and the mobile must be under their control.



Mobile Clinics

3) Unless the mobile unit is stored in a locked garage with access control, no drugs can be left in the mobile unit during the hours it is not in operation.

4) If the drugs have already been dispensed, they must be in full and actual charge of a licensed or registered health care professional.



Destruction of Non-Controls

Most pharmacists are very familiar with how to document and destroy controlled substances. In fact, most pharmacies use reverse distributors. However, pharmacists may not be sure how to properly document the destruction of non-controlled substances.



Destruction of Non-Controls

- The law requires all pharmacies to dispose of non-controlled drugs from inventory using a method that prevents the possession or use of the drugs by unauthorized persons.
- Outdated and adulterated drugs must be destroyed within one year and must be stored in a separate and secure area apart from the pharmacy's other inventory to ensure they will not be accidentally dispensed.



Destruction of Non-Controls

The following records are required of all non-controlled substance prescription drugs that are disposed of from a pharmacy's inventory:

- a) Name, strength, dosage form, and quantity of the prescription drugs disposed
- b) Date of disposal
- c) Method of disposal
- d) ID of the pharmacist that performed the disposal



Destruction of Non-Controls

- The Board has created a form which can be used by the pharmacy. Here is the link:

<https://www.pharmacy.ohio.gov/Documents/Compliance/InspectionGuides/Compliance%20Forms/Non-Controlled%20Drug%20Destruction%20Form.pdf>



Partially Dispensing C-IIs

Pharmacists may partially dispense a prescription for a schedule II drug in two circumstances for up to 60 days:

- 1) A patient who is terminally ill
- 2) A patient in a long-term care facility or nursing home

You can partially dispense a schedule II drug for any patient for up to 30 days.



Partially Dispensing C-IIs

- Partial dispensing can only occur at the pharmacy where the original prescription is on file.
- The total quantity dispensed through all partial fills cannot exceed the total quantity on the written prescription.
- Partial dispensing of the prescription can only occur for 60 days from the date the prescription was written. Any quantity “left-over” after 60 days cannot be partially filled.



Partially Dispensing C-IIs

At the time of each partial dispensing, the following information must be recorded on the back of the original prescription or within the computerized recordkeeping system:

- Date dispensed
- Quantity dispensed
- Remaining quantity
- The “new” prescription number of each partial dispensing if different from the original prescription number.
- Written initials of the dispensing pharmacist



Partially Dispensing C-IIs

- If the computer system does not permit “refilling” of a schedule II drug, a new prescription number for the partial dispensing must be assigned. In the computer database, a notation must be included that identifies this new prescription number as a partial dispensing. A prescription bearing the new prescription number must be placed in the Schedule II file. The prescription for each partial filling must also show the prescription number of the original prescription.



The Law vs. Corporate Policy

Example: Transferring an unfilled electronic schedule II prescription



Computer Generated Faxes for TPNs

- On 11/3/25, the Ohio Board of Pharmacy approved a resolution permitting the transmission of prescriptions for compounded TPNs for dispensing by a pharmacy via an electronic system that converts the prescription into a computer-generated fax or scanned image.



Cases

- Case: A nurse returns a partially used vial of hydromorphone injectable from the floor of the hospital to the pharmacy. Can the pharmacy “waste it”?
- Case: Can a dentist write a prescription for oxycodone 5mg/acetaminophen 325mg for her husband for dental pain?



Cases

- Case: A patient's physician dies and the patient still has 5 refills of lisinopril 10mg, one daily on a prescription. How much can the pharmacist dispense?
- Case: A patient's physician dies and the patient still has 3 refills of lorazepam 0.5mg, BID, #30 on a prescription. How much can the pharmacist dispense?



Cases

- Case: Patient has a new prescription for amoxicillin 875mg, BID, #14 written by a physician on Friday, April 3rd. The physician is killed in a car crash on Sunday, April 5th. The patient brings you the prescription on Monday, April 6. Can you fill it?



Cases

- Case: A patient brings you a prescription for dextroamphetamine/amphetamine XR 10mg, 1 daily, #120. The patient is 12 years old and has been taking the medication for 4 years. Can you fill this prescription as written?



Cases

- Case: A patient brings you a prescription for methylphenidate 10mg, 1 daily, #30 on 9/1/25. The patient is 10 years old and has been taking the medication for 1 year. The prescription is dated 6/2/25. Can you fill it?



Cases

- Can a pharmacy dispose of broken tabs in its drug takeback kiosk?
- Can a pharmacy dispose of outdated drugs in its drug takeback kiosk?
- How long do pharmacies have to dispose of outdated drugs?



References

ORC 4729.554

OAC 4729:5-18-04

OAC 4729:1-3-03

OAC 4729:5-5-26

OAC 4729:5-3-23

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Need More Information?

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