An Update of Ohio Pharmacy Laws for PRO 2025

Donnie Sullivan, R.Ph.,Ph.D.
Professor of Clinical Pharmacy
The Ohio State University

Objectives

- Describe the new laws regarding continuous quality improvement and medication errors
- Describe the duty to report laws for Ohio pharmacists
- Describe other new and common Ohio pharmacy laws and rules

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Continuous Quality Improvement

- Any pharmacy licensed as a terminal distributor must implement a continuous quality improvement (CQI) program for pharmacy services. This program must document and assess dispensing errors to determine the cause and appropriate response to improve the quality of pharmacy services and to prevent errors. This is only required for pharmacies that dispense prescription drugs.
- Effective: 3/1/25
- Reference: 4729:5-3-22 and 5-4-02

Continuous Quality Improvement

Each CQI must include:

1) Written policies and procedures of the CQI program which must be readily available if requested by the Board

2) Necessary documentation, internal reporting, and assessment of dispensing errors to determine the cause and appropriate response to prevent future dispensing errors

3) All records must be maintained for 3 years

4) Quality assurance review may be conducted by a quality assurance committee

Continuous Quality Improvement

Dispensing Errors means any of the following listed below discovered after final verification by the pharmacist.

1) Variation from the prescriber's prescription or drug order:

a) incorrect drug

b) incorrect strength

c) incorrect dosage form

d) incorrect patient

e) inadequate or incorrect packaging, labeling, or directions

Continuous Quality Improvement

2) Failure to exercise professional judgment in identifying and managing:
a) known therapeutic duplication
b) known drug-disease contraindications
c) known drug-drug interactions
d) incorrect drug dosage or duration of treatment

Continuous Quality Improvement

e) known drug-allergy interactions
f) any product quality issue from a compounded product
g) a clinically significant, avoidable delay in therapy
h) any other significant, actual, or potential problem with a patient's drug therapy related to the practice of pharmacy

Continuous Quality Improvement

3) Sale of a drug to the wrong patient

4) Variation in bulk repackaging or filling of automated devices including:
a) incorrect drug
b) incorrect strength
c) incorrect dosage form
d) inadequate or incorrect packaging or labeling

Continuous Quality Improvement

Reporting of Dispensing Errors to the Board of Pharmacy

A pharmacy is required to report to the Ohio Board of Pharmacy within 10 days any of the following:

1) Any error in dispensing which is the result of reckless behavior

Continuous Quality Improvement

2) Any error which results in any of the following per NCCMERP Error Index:

a) Category G: Error that resulted in permanent patient harm

b) Category H: Error that resulted in near-death event (anaphylaxis, cardiac arrest, etc.)

c) Category I: Error that resulted in patient death

Other CQI Information

1) When a dispensing error has occurred, the following should be done:

a) Communicate to the patient or patient's caregiver the fact that an error in dispensing has occurred and the steps required to avoid harm or mitigate the error.

b) Communicate to the prescriber an error has occurred, but only if the error could result in potential or actual harm to the patient.

c) Document all of this communication and retain it for 3 years

Other CQI Information

2) The pharmacy shall inform pharmacy personnel of the changes to pharmacy policy, procedures, systems, and/or processes made as a result of recommendations generated by the quality assurance program.

Other CQI Information

3) Pharmacies are required to report to the Board the termination or resignation of an individual licensed by the Board (pharmacist, intern, or tech) that was based on an error or errors in dispensing, even if error(s) were only part of the reason.

Other CQI Information

4) All required reporting must be done to the Board within 10 days.

5) This rule does not apply to the delivery of an incorrect drug to a patient by a pharmacy delivery agent.

Other CQI Information

6) Nothing in this law prohibits a pharmacy from instituting a proactive error reduction program (near misses) to catch those errors prior to final verification by the pharmacist.

7) The reporting of errors now falls on the "pharmacy" through its CQI program not the individual pharmacist.

Other CQI Information

8) How often the CQI program must be reviewed and updated is at the discretion of the pharmacy.

9) The pharmacy's CQI program can be contracted to a third party or administrative offices. However, the pharmacy, not the contracted third party is ultimately responsible for ensuring compliance with this rule.

Other CQI Information

10) The Board is prohibited from taking disciplinary action for medication errors against pharmacists, interns, or techs unless the error is the result of reckless behavior.

Continuous Quality Improvement - Cases

Case: CQI issues must be reported to the Board of Pharmacy within _____ days

Case: A pharmacist puts the wrong name on a prescription label. Does this have to be reported to the Board of Pharmacy?

Case: A pharmacist makes a medication error. It was the result of human error. Can the Board discipline the pharmacist?

Continuous Quality Improvement - Cases

Case: Whose responsibility is it to make sure medication errors are reported to the Board?

Case: A delivery driver gives the prescription to the wrong patient. Is this considered an error?

Case: A medication error occurs. There is no harm to the patient. Does the prescriber have to be notified?

Duty to Report

- New Rules Effective 3/1/25
- OAC 4729:1-4-02
- Conduct issues must be reported no later than 10 days from discovery
- Guidance Document: www.pharmacy.ohio.gov/PharmReport
- Evidence: Direct observation or objective evidence

Duty to Report

- Conduct indicating that an individual licensed by the Board (pharmacist, tech or intern) is practicing pharmacy while physically or mentally impaired by alcohol, drugs, or other chemical substances or impaired to such a degree as to render the individual unfit to carry out their professional duties.
- There are exceptions for those receiving treatment.

Duty to Report

- Conduct by a pharmacist, tech or intern that constitutes unprofessional conduct or dishonesty
- Unprofessional Conduct: Conduct that endangers the health, safety, and welfare of a patient or client. Examples: coercion, intimidation, harassment, sexual harassment, improper use of private information, threats, degradation of character, indecent or obscene conduct, and theft.

Duty to Report

- Dishonesty: Making any statement that deceives, misrepresents or misleads, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in the practice of pharmacy or operation or conduct of a pharmacy
- Self-report - Pharmacists, interns, and techs must self-report within 10 days any of the following: criminal convictions, entry into a diversion program or deferred prosecution, any felony arrest, disciplinary action by another state, etc.

Outpatient Minimum Standards

- Effective: 5/1/24
- References: OAC 4729:5-5-02 thru OAC 4729:5-5-02.5
- Violations can reported to: www.pharmacy.ohio.gov/complaint

Outpatient Minimum Standards

- Definition of Pharmacy Personnel: pharmacist, intern, and all classifications of pharmacy technicians
- Definition of Ancillary Services: These include, but are not limited to, immunizations, drug administration, MTM, disease state management, and refill reminders

Outpatient Minimum Standards

- Definition of a Quota: A fixed number or formula related to the duties of pharmacy personnel, against which the pharmacy measures or evaluates the number of times either an individual performs tasks or provides services while on duty. Quota does not mean a measurement of revenue, competence, performance, or quality of care.
- Goals are considered OK and can have incentives tied to them, but cannot have punitive actions for not meeting them.

Outpatient Minimum Standards

1) Must schedule a sufficient number of pharmacy personnel to minimize fatigue, distraction, or other conditions which interfere with a pharmacist's ability to practice with reasonable competence and safety. Staffing levels cannot solely be based on prescription volume. Sufficient time must be provided to complete professional duties and responsibilities such as:

Outpatient Minimum Standards

a) DUR immunizations

b) patient counseling

c) dispensing of prescriptions

d) patient testing

e) any other duties of a pharmacist.

Outpatient Minimum Standards

2) An outpatient pharmacy shall not establish any quotas related to the provision of ancillary services. This does not apply to outpatient pharmacies that are not open to the public (closed door pharmacies).

3) Pharmacy personnel cannot work more than 13 continuous hours in any workday and must have at least 8 hours off between consecutive shifts. However, a pharmacist may volunteer to work longer than 13 continuous hours.

Outpatient Minimum Standards

4) Pharmacy personnel working longer than 6 continuous hours per workday shall be allowed during that time to take a 30-minute uninterrupted rest break. If the pharmacy remains open during this rest break, a thru d apply during this rest break.

Outpatient Minimum Standards

a) The pharmacist shall remain on the premise and available for emergencies.

b) Prescriptions dispensed by the pharmacist may be sold when the pharmacist is on break.

c) Patients who request to speak to the pharmacist who is on break should be told when the pharmacist will return or provide the staff with their phone number for the pharmacist to call.

Outpatient Minimum Standards

d) Pharmacists must immediately contact patients requesting counseling after their break.

Note: If the pharmacy closes for a required rest break, the pharmacy must implement a regular break schedule and publish this where the pharmacy's hours are posted.

Outpatient Minimum Standards

5) New and refill (not auto-refill) prescriptions must be dispensed to the patient within 3 business days. Refill prescriptions generated by auto-refill programs must be dispensed within 5 days.

Note: These time constraints do not apply to prescriptions that require clarification, prior authorization, drug shortages, compounds, suspicious prescriptions, "do not fill until dated Rxs", prescription transfers, natural disasters, technology issues, etc.

Outpatient Minimum Standards

6) A pharmacy shall develop and implement an effective policy that permits the pharmacists to do all of the following. This does not apply to a closed-door pharmacy.

a) Limit ancillary services if such services cannot be safely provided or may negatively impact patient access to medications. The policy shall include an offer to make an appointment for the patient or refer the patient to another location offering ancillary services.

Outpatient Minimum Standards

b) Limit pharmacy access points if this will minimize fatigue, distraction, or other conditions which interfere with the pharmacist's ability to practice with reasonable safety and competence.

c) In the absence of such as "policy", the pharmacy shall not override the control of the pharmacist on duty to not provide ancillary services.

Outpatient Minimum Standards

7) A pharmacy cannot retaliate or discipline any pharmacy personnel for any part of these rules. This includes removing or suspending pharmacy personnel, withholding salary/benefits, transferring/reassignment, deny a promotion, or reduce their pay or position.

Outpatient Minimum Standards

8) An outpatient pharmacy shall only provide auto-refills of a prescription upon authorization of the patient or patient's caregiver. The pharmacy must maintain documentation of this authorization.

9) Pharmacies must ensure that pharmacy personnel are sufficiently trained to safely and adequately perform their assigned duties.

Outpatient Minimum Standards

10) Outpatient pharmacies must develop a process for pharmacy personnel to communicate requests for additional staff or report staffing concerns. These concerns and requests must be provided to the immediate supervisor and maintained for 3 years. A written response to the concern or request must occur within 14 business days and be communicated to the person making the request or concern.

Other Ohio Laws and Rules

Immunizations

1) Pharmacists, interns, registered techs, and certified techs can give an immunization for any disease for any patient 5 years old and older without a prescription.

2) For each immunization for a person under 18, the pharmacist, intern or technician shall inform the parent or legal guardian of the importance of well child visits with a pediatrician or other primary care provider and shall refer when appropriate.

Other Ohio Laws and Rules

Registered pharmacy technicians can now do sterile compounding if all of the following are met:

1) The registered technician must complete all the same training as a certified technician to do this type of compounding.
2) The registered technician must be in the process of studying to become a Certified Pharmacy Technician. This "studying" time period can be no longer than 18 months. The 18-month time period begins after all the training is complete.

Other Ohio Laws and Rules

Notification of Accessible Services

- Any changes must be reported within 30 days
- Reference: OAC 4729:5-2-05

All outpatient pharmacies in Ohio are required to notify the Ohio Board of Pharmacy which of the following they offer:

i) types of language translation services

ii) hearing impairment services

iii) vision impairment services

b) This notification must be done on the Board's webpage at www.pharmacy.ohio.gov/ASreport

USP Beyond Use Dates for Compounds

USP 795 Compounds

Non-preserved aqueous = 14 days

Preserved aqueous = 35 days

Nonaqueous dosage forms = 90 days

Solid dosage forms = 180 days

Other Ohio Laws and Rules

Mobile Clinics (Medication Units) 4729:5-3-23

The following may operate a mobile unit to dispense or administer medications:

i) a non-profit organization or association

ii) a for-profit entity who provides services to patients needing treatment for substance use disorder, mental health condition, and any related medical issue

The mobile clinic must register with a satellite license that is affiliated with an existing terminal distributor's license. There is no cost for this.

Questions???