



**Board of
Pharmacy**

2024 Fall Law Review

OPA Mid-Year Conference

Makoy Center

5462 Center Street

Hillard, Ohio 43026

November 3, 2024



2024 FALL LAW REVIEW

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LEGAL DISCLAIMER

The following presentation was accompanied by an oral presentation and does not purport to establish legal standards that are not contained in statutes, regulations, or other competent law. Statements contained in this presentation that are not embodied in the law are not binding on the Ohio Board of Pharmacy. Summaries of statutory and regulatory provisions that are summarized in this presentation do not purport to state the full extent of the statutory and regulatory requirements of the cited statutes and regulations.

I have no financial relationships to disclose.



LEARNING OBJECTIVES

1. Identify recent changes in state and federal laws and rules which impact pharmacy practice in Ohio.
2. Describe the effect of recent law and rule changes on the practice of pharmacy.
3. Discuss implementation strategies for law and rule compliance
4. Review relevant board notices and publications.





LAW AND RULE UPDATES

AUTHORITY TO ADMINISTER IMMUNIZATIONS

ORC 4729.41 - EFFECTIVE 10/24/2024

- **Who:** Pharmacist, Intern, Certified Pharmacy Technician, Registered Pharmacy Technician.
- **What:** May administer for any disease, including immunizations for influenza and COVID-19 to individuals 5 years of age or older, without a prescription.
- **How:** Technicians and interns must be working under a pharmacist.
 - A protocol must be in place.
 - If under 18: Must inform the parent/legal guardian of the importance of well-child visits with a pediatrician or other primary care provider, referring when appropriate.

* RULE UPDATES PENDING



RECALL PROCEDURES

OAC 4729:5-3-18 – EFFECTIVE 11/11/2024

Effective: November 11, 2024

- TDDD must develop and implement a WRITTEN procedure for the management of recalls
- Applies to all TDDDs
- Must include:
 - Contacting patients affected by the recall
 - Removal of the affected drug no later than the next business day
 - Quarantined until disposal/ return
 - No lot number? = must include in the recall
 - Records of actions taken
- Update written procedures as necessary
- Keep recall records for 3 years
- Procedures and records must be readily retrievable

RECALL PROCEDURES OAC 4729:5-3-18 EFFECTIVE 11-11-2024



Drug Recall Resources:

- The FDA currently lists all active drug recalls here:
<https://www.fda.gov/drugs/drugsafety-and-availability/drug-recalls>
- Licensees are encouraged to sign up for FDA's MedWatch Safety Alert:
<https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reportingprogram/subscribe-medwatch-safety-alerts>
- Best Practices for Drug Product Recalls (Video Presentation)
<https://www.youtube.com/watch?v=2shQ1tBdL-&t=76s>
- Industry Guidance For Recalls
<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls>



CONTINUOUS QUALITY IMPROVEMENT PROGRAMS IN PHARMACY SERVICES OAC 4729:5-3-22- EFFECTIVE 3/1/2025

Error in dispensing:

- Variation from the prescriber's prescription or drug order, unless otherwise modified by the pharmacist in accordance with agency 4729 of the Administrative Code, including:
- Failure to exercise professional judgment in identifying and managing DUR.
- Sale of a drug to the incorrect patient.
- Variation in bulk repackaging or filling of automated devices, including: (a) Incorrect drug;
- A dispensing error does not include the delivery of an incorrect drug to a patient by a pharmacy delivery agent as defined in rule 4729:5-5-22 of the Administrative Code.



CONTINUOUS QUALITY IMPROVEMENT PROGRAMS IN PHARMACY SERVICES OAC 4729:5-3-22- EFFECTIVE 3/1/2025



Quality Assurance Program:

- Written policies and procedures
- Documentation of internal reporting and assessment of errors
- Determine the cause of the error
- Formulate a response to the error to prevent future errors
- Provide training to staff as needed
- Records maintained x 3 years, readily retrievable
- Records are confidential and not public records subject to discovery in civil action
- Review may be conducted by a quality assurance committee (ORC 2305.24)

CONTINUOUS QUALITY IMPROVEMENT PROGRAMS IN PHARMACY SERVICES

OAC 4729:5-3-22- EFFECTIVE 3/1/2025

- When a dispensing error is identified:
 - Communicate to patient/caregiver with steps to avoid harm and mitigate the error
 - Communicate to the prescriber **IF** the error could result in potential or actual patient harm
 - Document communication and retain x 3 years
- Communication is only required if the error poses harm.
 - Harm = physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.



CONTINUOUS QUALITY IMPROVEMENT PROGRAMS IN PHARMACY SERVICES

OAC 4729:5-3-22- EFFECTIVE 3/1/2025

- To encourage internal reporting pursuant to OAC 4729:5-3-22, the Board updated its disciplinary rules (also effective 3/1/2025) for pharmacists, pharmacy interns, and pharmacy technicians that prohibits the Board from taking disciplinary action against an individual licensee/registrant for an error in dispensing, **UNLESS** the error is the result of reckless behavior.
- This also applies to any product quality issue for any compounded drug preparation as defined in rule 4729:7-2-03 of the Administrative Code.
- More information available: www.pharmacy.ohio.gov/CQI



DUTY TO REPORT – TERMINAL DISTRIBUTORS

OAC 4729:5-4-02 – EFFECTIVE 3/1/2025

- A pharmacy must report, from direct observation or objective evidence, the following to the board:
 - Any error in dispensing resulting from reckless behavior.
 - Any error in dispensing where the error results in any of the following per the National Coordinating Council for Medication Error Reporting and Prevention Medication Error Index:
 - Category G: Permanent patient harm.
 - Category H: A near-death event (e.g., anaphylaxis, cardiac arrest).
 - Category I: Patient death.



DUTY TO REPORT – TERMINAL DISTRIBUTORS

OAC 4729:5-4-02 – EFFECTIVE 3/1/2025

- Pharmacies must report, from direct observation or objective evidence, the termination of a board licensed employee if termination was based in whole or in part on:
 - An an error or errors in dispensing.
 - Engaging in unprofessional conduct, dishonesty, or reckless behavior.
 - Practicing pharmacy while physically or mentally impaired by alcohol, drugs or other chemical substances, or impaired physically or mentally to such a degree as to render the individual unfit to carry out their professional duties



DUTY TO REPORT – TERMINAL DISTRIBUTORS

OAC 4729:5-4-02 – EFFECTIVE 3/1/2025



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- Report by mail, online or by telephone:
 - Errors in dispensing- within 10 days of the date the quality assurance program review was completed.
 - Termination/Resignation- within 10 days from the date of termination/resignation.
 - Information submitted is not a public record and is not subject to discovery in any civil action.
 - Identity of the reporting person and contents of the report are confidential

DUTY TO REPORT- PHARMACIST, INTERN, TECHNICIAN OAC 4729:1-4-02, OAC 4729:2-4-02, OAC 4729:3-4-02 EFFECTIVE 3/1/2025

A licensee must report no later than 10 days from discovery, from direct observation or objective evidence, the following to the board:

- Conduct indicating a licensed individual is practicing pharmacy while physically or mentally impaired by alcohol, drugs or other chemical substances, or impaired physically or mentally to such a degree as to render the individual unfit to carry out their professional duties.
 - Unless the licensee is treating the individual for the condition.
 - Unless the licensee learned through PHI
 - Unless licensee voluntarily seeks treatment for a mental health or substance use disorder and there are no other violations of law/rule.
- Unprofessional conduct or dishonesty



DUTY TO REPORT- PHARMACIST, INTERN, TECHNICIAN OAC 4729:1-4-02, OAC 4729:2-4-02, OAC 4729:3-4-02 EFFECTIVE 3/1/2025

A licensee must report no later than 10 days from discovery, from direct observation or objective evidence, if a board licensed employee or entity:

- Violates, attempts to violate, aids and abets in the violation of any provisions of ORC 4729, 4752, 3719, 3796, 2913,
- Violates OAC 4729

Report by mail, online, or telephone:

- Reports are confidential.
- Pharmacist may be required to testify in disciplinary proceedings.



DUTY TO REPORT- PHARMACIST, INTERN, TECHNICIAN OAC 4729:1-4-02, OAC 4729:2-4-02, OAC 4729:3-4-02 EFFECTIVE 3/1/2025

A licensee shall notify the board of any of the following:

- Any criminal conviction for, judicial finding of guilt of, or plea of guilty to a disqualifying offense within ten days after the date of conviction.
- The licensee is convicted of, plead guilty to, is subject to a judicial finding of eligibility for intervention in lieu of conviction in this state under section 2951.041 of the Revised Code or the equivalent thereof in another jurisdiction within ten days after the individual is deemed eligible.



DUTY TO REPORT- PHARMACIST, INTERN, TECHNICIAN OAC 4729:1-4-02, OAC 4729:2-4-02, OAC 4729:3-4-02 EFFECTIVE 3/1/2025

A licensee shall notify the board of any of the following:

- The licensee is granted entry into a diversion program, deferred prosecution program, or the equivalent thereof within ten days after the individual is granted entry into a program.
- Any arrest for a felony within ten days after the arrest.
- For a Certified Pharmacy Technician:
 - Failure to maintain a current pharmacy technician certification from a board approved organization.



DUTY TO REPORT- PHARMACIST, INTERN, TECHNICIAN OAC 4729:1-4-02, OAC 4729:2-4-02, OAC 4729:3-4-02 EFFECTIVE 3/1/2025

A licensee shall notify the board of any of the following:

- Any disciplinary licensing or registration action taken by another state within ten days of the notice action. This includes disciplinary action that is stayed pending appeal.
- Pursuant to section 4729.10 of the Revised Code, in the absence of fraud or bad faith, a person who reports in accordance with this rule or testifies in any adjudication conducted under Chapter 119. of the Revised Code is not liable to any person for damages in a civil action as a result of the report or testimony.



DUTY TO REPORT- PHARMACIST, INTERN, TECHNICIAN OAC 4729:1-4-02, OAC 4729:2-4-02, OAC 4729:3-4-02 EFFECTIVE 3/1/2025

IMPORTANT: A licensee is not required to report an error in dispensing or prescription error. Error reporting is the responsibility of the terminal distributor of dangerous drugs (i.e., the pharmacy) per OAC 4729:5-4-02 (effective 3.1.2025). For more information on error reporting, visit:

www.pharmacy.ohio.gov/PharmacyReport.



ACCESSIBLE SERVICES RULE – OAC 4729:5-2-05

- Effective August 23, 2024, OAC 4729:5-2-05 requires all outpatient pharmacies located in Ohio to submit notification to the Ohio Board of Pharmacy of the types of language translation services, hearing impairment services, and vision impairment services they offer to patients using the Board’s accessible services reporting webpage.
- The requirement to submit notification of accessible services does not take effect until November 21, 2024 (90 days from the effective date of the rule).
- Outpatient pharmacies in Ohio will have until November 21, 2024, to submit initial notification of accessible services to the Board.



ACCESSIBLE SERVICES RULE – OAC 4729:5-2-05

- This information is also required to be reviewed and updated during the licensure renewal process for all Ohio pharmacies.
- Except in the instance of a temporary software or equipment failure, a pharmacy that reports it offers accessible services shall be required to provide those services to patients upon request.
- This information will be reported to a public website where patients can search for accessible services. This public website will be deployed closer to the November 21st submission deadline.
- For more information, visit: www.pharmacy.ohio.gov/accessreport



PROPOSED RULE: OAC 4729:5-5-26 OUTPATIENT PHARMACY DELIVERY SERVICES

Contact the patient/caregiver for approval prior to billing and/or delivery (general consent is permitted).

Notification: date shipped, method of delivery, expected arrival.

Take precautions for temperature sensitive drugs.

Notify patient of timeliness for proper storage of temperature sensitive drugs.

Proof of Delivery for controlled substances

Assist with medication access if delivery does not occur in the expected timeframe.

Provide a notification method for irregularities in drug delivery

- Timeliness
- Condition of drug
- Failure to receive drug

Notification within 48-hours if scheduled delivery is interrupted or delayed.

PROPOSED RULE: OAC 4729:5-5-26

OUTPATIENT PHARMACY DELIVERY SERVICES

- Compromised or Lost Deliveries:
 - Replace at no cost to the patient
 - If replacement cause an interruption in therapy – must mitigate patient harm
- Drugs delivered – i.e., no longer in possession of the delivery agent
 - May NOT be returned to stock.
- Report theft or significant loss to the Board, as is required by OAC 4729:5-3-02

PROPOSED RULE: OAC 4729:5-5-26

OUTPATIENT PHARMACY DELIVERY SERVICES

Delivery Records

- Patient name and address
- Rx number
- Drug name & dosage
- Name and contact info of delivery agent

Must enter a contract with third party carriers (except: USPS or common carrier [FedEx, UPS])

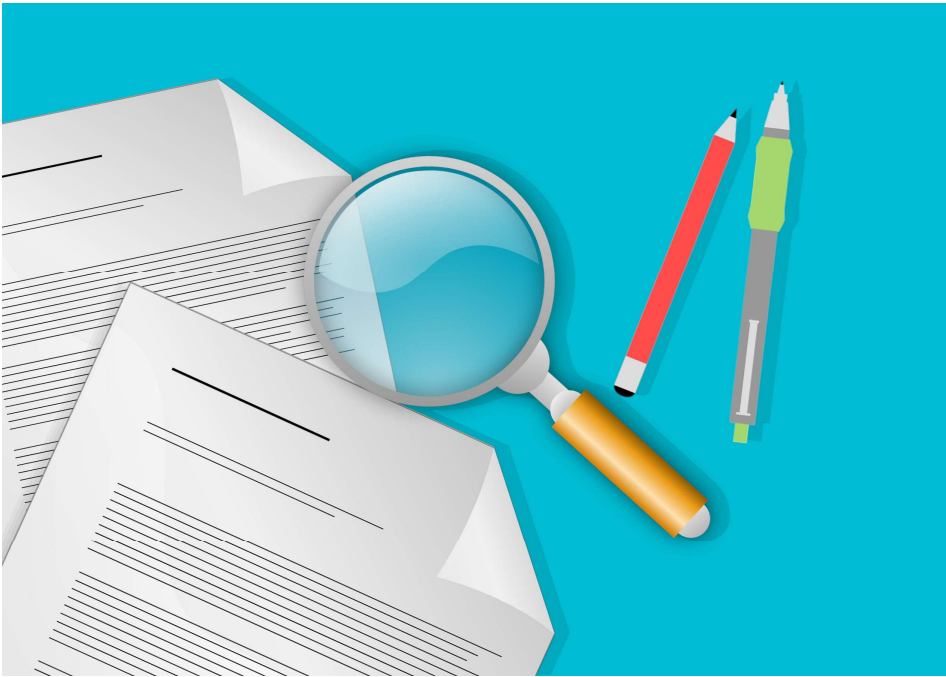
- Contract company must provide delivery records to the pharmacy
- Contract company agrees to cooperate with all investigations regarding theft or loss of drugs/devices, including producing records within 3 business days.

CERTIFIED PHARMACY TECHNICIANS RESTRICTED STATUS

- Certified Pharmacy Technicians must hold a **CURRENT** certification from an approved organization (PTCB, ExCPT)
- If certification lapses:
 - Technician registration is placed on “Restricted” status.
 - Not eligible to renew.
 - Cannot perform the job duties of a certified technician.
 - May perform the job duties of a registered technician.
- To do:
 - Renew certification and upload to their eLicense dashboard – Submit Additional Documentation
 - Reapply as a Registered Pharmacy Technician
 - Inactivate their registration.



OAC 4729:3-2-08 VERIFICATION OF REGISTRATION AND CERTIFICATION



Prior to commencing employment



At least every 24 months



Certification from organization at least every 24 months

R-2024-0291

Enforcement of USP 795 and USP 797

To permit licensees to begin the transition to the newly published Chapters of USP 795 and USP 797 (effective November 1, 2023), the Board will not take administrative action against a licensee if the licensee is found to be in compliance with the latest version of USP 795 and USP 797.

This authorization shall remain in effect until the rules enforcing these new chapters are made effective.



BOARD COMMUNICATIONS

ELECTRONIC REGISTERED MAIL

- Official electronic registered mail from the board will sometimes have a banner across the top stating:

Registered Mail | Certified Delivery

 REGISTERED EMAIL™ | CERTIFIED DELIVERY

This is a Registered Email™ message from Jennifer.Nelson@pharmacy.ohio.gov.

Good Afternoon,

The State of Ohio Board of Pharmacy (Board) is contacting you regarding your scheduled June 3, 2024, probation appearance. The June Board Meeting will be held at the offices of the **State Board of Pharmacy, 77 South High Street, Columbus, Ohio 43215-6126**; however, you will have the option of participating in your Probation Appearance in-person or remotely.



VERIFY MESSAGES

The screenshot shows the website for the State of Ohio Board of Pharmacy. At the top left is the board's logo, which features a landscape with a sun and the text "STATE OF OHIO BOARD OF PHARMACY". To the right of the logo is the text "STATE OF OHIO BOARD OF PHARMACY". Further right is a search bar with the word "Search" and a magnifying glass icon, and a dark red button labeled "CONTACT" with an envelope icon. Below the logo and text is a dark blue navigation bar with several menu items: "ABOUT", "VERIFY LICENSE", "PUBLICATIONS", "LICENSING / CE", "LAWS & RULES", and "COMPLIANCE / ENFORCEMENT". The "PUBLICATIONS" menu item is circled in red. A dropdown menu is open under "PUBLICATIONS", listing several options: "BOARD ACTIONS", "BOARD MINUTES", "BOARD PUBLICATIONS", "GUIDANCE DOCUMENTS", "NEWS RELEASES", "NEWSLETTERS", "REPORTS", "SEND TO US", and "VERIFY MESSAGES". The "VERIFY MESSAGES" option at the bottom of the dropdown is also circled in red. The background of the page features a large image of a man and a woman in white lab coats, with the text "Protecting Ohio Since - 1884 -" overlaid. At the bottom left, there is a section titled "MEDICAL MARIJUANA RESOURCES" with a question mark icon. At the bottom right, there is a dark red button labeled "FILE A COMPLAINT" with a document icon and a link to "> LEARN MORE".



PHARMACY.OHIO.GOV

The screenshot shows a web browser window with the URL `pharmacy.ohio.gov`. The browser's address bar and tabs are visible at the top. The website header features the State of Ohio Board of Pharmacy logo on the left and the text "STATE OF OHIO BOARD OF PHARMACY" in the center. A search bar is located in the top right corner, and a "CONTACT" button with an envelope icon is positioned directly below it. This "CONTACT" button is circled in red. Below the header is a navigation menu with links for "ABOUT", "VERIFY LICENSE", "PUBLICATIONS", "LICENSING / CE", "LAWS & RULES", and "ENFORCEMENT". The main content area has a background image of a pharmacist and a banner that reads "Protecting Ohio Since - 1884 -". Below this banner are three promotional tiles: "MEDICAL MARIJUANA RESOURCES" with a question mark icon, "OARXRS OHIO AUTOMATED RX REPORTING SYSTEM", and "FILE A COMPLAINT" with a document icon and a "LEARN MORE" link.



QUESTIONS?

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THANK YOU

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OF IT ALL™**

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