

OHIO BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

From the Director's Desk

Dear Ohio Pharmacists,

On May 1, 2024, the following rules on outpatient pharmacy minimum standards went into effect:

- 4729:5-5-02: Minimum Standards for the Operation of an Outpatient Pharmacy.
- 4729:5-5-02.1: Provision of Ancillary Services in an Outpatient Pharmacy.
- 4729:5-5-02.2: Mandatory Rest Breaks for Pharmacy Personnel.
- 4729:5-5-02.3: Requests for Additional Staff and Reports of Staffing Concerns in an Outpatient Pharmacy.
- 4729:5-5-02.4: Significant Delays in the Provision of Pharmacy Services.
- 4729:5-5-02.5: Outpatient Pharmacy Access Points.

These rules are the result of the work of the Ohio Pharmacist Workload Advisory Committee and feedback provided by pharmacy professionals through various surveys conducted. For more information on the Pharmacist Workload Advisory Committee, visit www.pharmacy.ohio.gov/PWAC.

To assist licensees in complying with these new regulations, we developed a frequently asked questions document that can be accessed here. If you have questions regarding the rules, please review this document. If you need additional information, the quickest way to have your questions answered is to email the Ohio Board of Pharmacy office by visiting http://www.pharmacy.ohio.gov/contact.aspx.

National Pharmacy Compliance News

A Service of the National Association of Boards of Pharmacy Foundation (NABPF)

Visit NABP's website for the latest regulatory updates and news from FDA, USP, NABP, and more.

Read National News

Any violations of these rules should be reported using the Board's online complaint form at https://www.pharmacy.ohio.gov/complaint. Remember that under Section 4729.23 of the Ohio Revised Code (ORC), the identity of an individual submitting a complaint to the Board is confidential.

Ohio rules (specifically Ohio Administrative Code 4729:5-4-01 (B)(25)) also prohibit a licensed pharmacy from retaliating against or disciplining an employee for filing a complaint with the Board or other licensing body, or for reporting a violation of state or federal statute or any ordinance or regulation of a political subdivision that the employee's employer has the authority to correct. Retaliation or discipline of an employee includes, but is not limited to, the following:

- Removing or suspending the employee from employment;
- Withholding from the employee salary increases or employee benefits to which the employee is otherwise entitled;
- Transferring or reassigning the employee;
- Denying the employee a promotion that otherwise would have been received; and
- Reducing the employee in pay or position.

On behalf of the Board, thank you for all that you do to help keep Ohioans safe and healthy.

Sincerely,

Steven W. Schierholt, Esq Executive Director Ohio Board of Pharmacy

New Rules Adopted in March and April

The Board filed 27 rules that went into effect in March and April 2024. See the rules listed below with their number, effective date, and a link to the rule text.

- 4729:5-5-06 Amend Labeling of drugs dispensed on prescription. Effective date: April 1, 2024.
- 4729:6-2-02 Rescind Distributor of dangerous drugs licensing and renewal. Rescinded in favor of the below rule. Effective date: March 7, 2024.
- 4729:6-2-02 New Distributor of dangerous drugs licensing and renewal. Effective date:
 March 7, 2024.
- 4729-6-01 Amend Continuing education providers definitions. Effective date: March 7, 2024.
- 4729-6-02 Amend Criteria for in-state approved providers of pharmacy jurisprudence continuing education. Effective date: March 7, 2024.
- 4729:2-2-01 Amend Licensure as a pharmacy intern. Effective date: March 7, 2024.

- 4729:2-2-02 Amend Application for licensure as a pharmacy intern. Effective date:
 March 7, 2024.
- 4729:2-2-04 Rescind Pharmacy intern license renewal and expiration. Rescinded in favor of the below rule. Effective date: March 7, 2024.
- 4729:2-2-04 New Pharmacy intern license renewal and expiration. Effective date:
 March 7, 2024.
- 4729:2-2-06 Amend Statement of preceptor and practical experience affidavit.
 Effective date: March 7, 2024.
- 4729:2-2-08 Amend Pharmacy intern change of name, address, or employment.
 Effective date: March 7, 2024.
- 4729:2-2-09 Rescind Pharmacy intern licensure and renewal. Being rescinded because provisions in this rule are being incorporated into rule 4729:2-2-04. Effective date: March 7, 2024.
- 4729:1-2-01 Amend Criteria for licensure by examination. Effective date: March 4, 2024.
- 4729:1-2-02 Amend Criteria for licensure by reciprocity. Effective date: March 4, 2024.
- 4729:1-2-03 Amend Examination application for licensure as a pharmacist. Effective date: March 4, 2024.
- 4729:1-2-06 Amend Pharmacist change of name, address or employment. Effective date: March 4, 2024.
- 4729:1-2-07 Rescind Pharmacist licensure and renewal. Rescinded in favor of the below rule. Effective date: March 4, 2024.
- 4729:1-2-07 New Pharmacist licensure and renewal. Effective Date: March 4, 2024.
- 4729:1-5-01 Amend Pharmacist continuing education definitions. Effective date:
 March 4, 2024.
- 4729:1-5-02 Amend Continuing education requirements for pharmacists. Effective date: March 4, 2024.
- 4729:3-2-01 Amend Registration procedures. Effective date: April 19, 2024.
- 4729:3-3-02 Amend Approved pharmacy technician training programs. Effective date:
 March 7, 2024.
- 4729:3-3-03 Amend Registered pharmacy technicians. Effective date: March 7, 2024.

- 4729:7-2-03 Amend Drugs compounded in a pharmacy. Effective date: March 7, 2024.
- 4729:5-2-02 Rescind Terminal distributor of dangerous drugs licensing and renewal.
 Rescinded in favor of the below rule. Effective date: March 7, 2024.
- 4729:5-2-02 New Terminal distributor of dangerous drugs licensing and renewal.
 Effective date: March 7, 2024.

2024 Law and Responsible Person Review Virtual Presentations

Join the Board for presentations throughout 2024 to learn about the latest developments in pharmacy laws and rules.

2024 Law Review topics will include:

- Minimum standard rules for an outpatient pharmacy
- Updates to state and federal laws and rules
- Scams and drug diversion trends

Responsible Person Roundtable topics will include:

- Minimum standard rules and terminal distributor of dangerous drugs (TDDD) responsibility
- Drug diversion trends and safeguard practices
- Updates to state and federal laws and rules what responsible persons (RPs) need to do

Responsible Person 101 topics will include:

- Duties and responsibilities of an RP
- General requirements of a TDDD
- · An overview of resources available for an RP

For presentation dates and times and a link to sign up, visit https://www.pharmacy.ohio. gov/2024lawreview.

Fentanyl Test Strip Handouts Now Available in Spanish

The Board has translated the "How to Test Your Drugs – Using Fentanyl Test Strips" educational handout into Spanish and is offering licensees the opportunity to place orders for these handouts using the following link: https://www.pharmacy.ohio.gov/FTSorder.

Licensees can also use that link to request the educational handout in English and a maximum of two packs of fentanyl test strips per order (200 strips in total). Please allow seven to 10 business days for delivery.

New Distributor of Dangerous Drugs Inspection Guide Available

The Board has posted a new inspection guide for distributors of dangerous drugs. The guide can be found here.

The guide applies only to locations licensed as drug distributors in accordance with **Section 4729.52** of the ORC, which includes the following license types:

- · Wholesale distributors of dangerous drugs, including brokers and virtual wholesalers
- Manufacturers of dangerous drugs
- Outsourcing facilities
- Third-party logistics providers
- Repackagers of dangerous drugs

Certified Pharmacy Technicians With Restricted Status

The Board actively monitors certified pharmacy technicians' certification status with the Pharmacy Technician Certification Board and National Healthcareer Association. Any certified technician who does not maintain their national certification will receive a sub-status of Restricted on their registration and communication from the Board on how to remedy their registration status. Any technician with a Restricted status will not be eligible to renew. More information on the Restricted status can be found on the Board's website: www.pharmacy.ohio.gov/TechStatus.

Updated Regulatory Guidance: Hospitals Reporting Sales to EMS

In light of pending Drug Enforcement Administration (DEA) regulations for emergency medical services (EMS), the Board is issuing updated guidance related to hospitals that sell or transfer Ohio Automated Rx Reporting System (OARRS) reportable drugs to EMS agencies.

Hospitals that sell or transfer controlled substances and other OARRS-reportable drugs to an EMS agency are not required to report these transactions to OARRS.

The OARRS wholesale guide has been updated to reflect this policy change.

Licensee Scam Warning

The Board continues to learn that licensees are being targeted by scammers who claim to work for various governmental agencies (Board of Pharmacy, DEA, Federal Bureau of Investigation, Department of Justice, etc) to obtain money from the target. The Board strongly encourages licensees to be alert to avoid scammers.

USA Today recently published this article detailing an elaborate scam targeting a pharmacist from Ohio: https://www.usatoday.com/story/money/2024/03/24/professionals-with-licenses-targeted-scams-online-phone/72094706007/.

Scammers may try to initiate contact via phone calls, emails, faxes, and letters purporting to originate from various state and federal agencies that include allegations of drug trafficking and threats of suspension against the target's license.

Board investigators will not ask for fine payment or personal/sensitive information over the phone and will never contact licensees via fax. As a reminder, administrative fines issued by the Board are not paid via gift cards or cryptocurrency. If the Board is conducting an investigation and that individual faces action against their license, they will receive an official notice of opportunity for a hearing either via certified mail or by personal service.

If you are contacted by a scammer, please report this information using the Board's online complaint form. Additionally, reports should be made to your local law enforcement agency.

If you receive any suspicious calls or correspondence purporting to be from the Board, you are encouraged to call (614/466-4143) or email the Board (contact@pharmacy.ohio.gov) to confirm its legitimacy.

The Ohio Board of Pharmacy News is published by the Ohio Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

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