



e-News July 2024

REMINDER: Outpatient Pharmacy Minimum Standards Rules Effective 5/1/2024

The Board would like to remind licensees that Ohio's new rules on outpatient pharmacy minimum standards went into effect on May 1, 2024.

These rules, intended to promote improved patient safety, are the result of the work of the Ohio Pharmacist Workload Advisory Committee and feedback provided by pharmacy professionals through various surveys.

The Board's minimum standards are listed below with a link to the full rule text.

- [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.

To ensure compliance with the new rules, the Board issued a guidance document, which can be accessed here: www.pharmacy.ohio.gov/minstandard.

Please be advised these rules also prohibit retaliation against employees who comply with the requirements of the rule or who report violations of these rules to the Board.

For any questions regarding these rules, the most expedient way to have them answered will be to e-mail the Board office by visiting: <https://www.pharmacy.ohio.gov/contact>.

Reporting Violations

Any violations of these rules should be reported using the Board's online complaint form, which can be found here: <https://www.pharmacy.ohio.gov/complaint>.

Per section [4729.23 of the Ohio Revised Code](#), the identity of an individual submitting a complaint to the Ohio Board of Pharmacy is confidential.

New Rules Effective 7/1/2024

Effective 7/1/2024, amendments to the following rules for pharmacists, pharmacy interns, and terminal distributors of dangerous drugs went into effect.

- [4729:1-5-03](#) - Veteran and military family provisions related to continuing education.
- [4729:2-2-05](#) - Internship credit.
- [4729:2-3-01](#) - Practice as a pharmacy intern.
- [4729:2-3-02](#) - Therapeutic diabetic shoes.
- [4729:5-1-02](#) - Licensed health professional authorized to prescribe drugs.
- [4729:5-3-01](#) - Disposal of controlled substances.
- [4729:5-3-03](#) - Inspections and corrective actions.
- [4729:5-3-05](#) - Confidentiality of patient records.
- [4729:5-3-06](#) - Storage of adulterated drugs.
- [4729:5-3-08](#) - Sales of dangerous drugs on-line.
- [4729:5-3-10](#) - Employment of individuals with felony convictions.
- [4729:5-7-02](#) - Licensure, compliance, and support personnel.
- [4729:5-7-03](#) - Persons eligible to transfer sample drugs to a charitable pharmacy.
- [4729:5-12-01](#) - Medication therapy management - definitions.
- [4729:5-12-02](#) - Medication therapy management.

(Click on the rule number to access the full text of the rule)

For questions regarding the rules, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: <http://www.pharmacy.ohio.gov/contact.aspx>.

New Rules Effective 8/31/2024

Effective 8/31/2024, amendments to the following rules for distributors of dangerous drugs will go into effect.

- [4729:6-2-03](#) - Criminal records checks.
- [4729:6-2-04](#) - Drug distributor applications.
- [4729:6-2-06](#) - Procedure for discontinuing business as a distributor of dangerous drugs.
- [4729:6-3-01](#) - Disposal of controlled substances.
- [4729:6-3-03](#) - Inspections and corrective actions.
- [4729:6-3-04](#) - Verification of licensure prior to sale or purchase.
- [4729:6-3-06](#) - Controlled substances inventory requirements.
- [4729:6-3-07](#) - Sales of dangerous drugs on-line.
- [4729:6-3-08](#) - Distributor of dangerous drugs samples and complimentary supplies.
- [4729:6-5-01](#) - Wholesale distributors - general operations.
- [4729:6-5-02](#) - Wholesale distributors - recordkeeping.
- [4729:6-6-01](#) - Virtual wholesalers - general operations.
- [4729:6-7-01](#) - Brokers - general operations.
- [4729:6-8-01](#) - Manufacturers - general operations.
- [4729:6-8-02](#) - Manufacturers - recordkeeping.
- [4729:6-9-01](#) - Repackagers - general operations.
- [4729:6-9-02](#) - Repackagers - recordkeeping.
- [4729:6-10-01](#) - Outsourcing facilities - general operations.
- [4729:6-10-02](#) - Outsourcing facilities - recordkeeping.
- [4729:6-11-01](#) - Third-party logistics providers - general operations.
- [4729:6-11-02](#) - Third-party logistics providers - recordkeeping.

(Click on the rule number to access the full text of the rule)

For questions regarding the rules, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: <http://www.pharmacy.ohio.gov/contact.aspx>.

Licensure Verification for Institutional Pharmacies Restocking EMS Medications

To ensure compliance with the licensure verification requirements of OAC 4729:5-3-04 and to

reduce operational burden, the Ohio Board of Pharmacy adopted the following resolution for institutional pharmacies owned or operated by Ohio hospitals:

An institutional pharmacy that is owned or operated by a hospital for purposes of restocking an emergency medical services vehicle may satisfy the licensure verification requirements of OAC 4729:5-3-04 by conducting an annual query to ensure the EMS organization is properly licensed as a terminal distributor of dangerous drugs. This resolution shall remain in effect until rescinded by the Board or upon amendment of OAC 4729:5-3-04.

This resolution went into effect on 7/9/2024. The Board will be incorporating this language into a permanent rule, which is open for [public comment](#).

Submit to the APhA Pharmacy Workplace and Well-Being Reporting Portal

Pharmacists and pharmacy personnel workplace factors and well-being continue to be a critical, complex issue for the profession and patient safety. In recent decades, considerable work has been done to identify and understand medication errors, including near misses, and characterize the root causes. What is lacking in the research is to critically examine workplace factors to determine how they affect pharmacy personnel well-being and patient safety.

This is why pharmacists and pharmacy personnel are invited to submit their pharmacy workplace experiences – positive and negative – to Pharmacy Workplace and Well-being Reporting (PWWR). Your individual reports are confidential and anonymous. PWWR is free to use and you do not need to be an APhA or state pharmacy association member.

For more information and to submit to the Pharmacy Workplace & Well-being Reporting portal, visit: <https://www.pharmacist.com/Advocacy/Well-Being-and-Resiliency/pwwr>

Ohio's SPF RX 2021 Community Prevention Funding Opportunity

Ohio's SPF Rx Initiative Community Prevention Project is now accepting requests for funding. They focused on helping communities use evidence-based strategies to create environmental changes that promote healthy decision-making. These environmental changes have been proven to reduce statewide substance use indicators and adverse consequences, therefore impacting the prescription drug epidemic in Ohio.

The goal of this project is to implement targeted activities that address prescription drug misuse and promote safe medication storage and disposal within the target populations of youth, young adults, parents, and older adults. This opportunity will provide up to \$10,000 for the implementation of approved strategies and activities. Additionally, grantees will be provided access to technical assistance and training opportunities, as needed.

For more information on the required deliverables and a link to apply, [click here](#).

FDA Grants DSCSA Exemption to Small Dispensers

FDA is issuing [exemptions](#) from certain requirements of section 582 of the Food, Drug and Cosmetic Act to small dispensers (pharmacies), and where applicable, their trading partners, until November 27, 2026. This provides small dispensers additional time to stabilize their operations to fully implement the enhanced drug distribution security requirements of DSCSA.

Additionally, FDA is reminding trading partners the Drug Supply Chain Security Act (DSCSA)

[one-year stabilization period](#) ends on November 27, 2024. The agency is not extending the stabilization period beyond this date.

Trading partners that do not qualify for the small dispenser exemptions and are unable to meet the enhanced drug distribution security requirements by November 27, 2024, may request a waiver or exemption from those requirements. The agency expects the trading partner to continue their efforts to meet the requirements until FDA has approved or denied the request.

FDA also reopened a [request for information](#) to better understand the status of trading partners' interoperable systems and processes for enhanced drug distribution security.

Licensee Scam Warning

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

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 of Pharmacy 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 of Pharmacy 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, personal service, or electronic registered mail.

If you are contacted by a scammer, please report this information using the Board's online complaint form: www.pharmacy.ohio.gov/complaint. 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 of Pharmacy, we encourage you to call (614-466-4143) or email (contact@pharmacy.ohio.gov) the Board to confirm its legitimacy.



People call, text, and chat the 988 Lifeline to talk about a lot of emotional needs—not just thoughts of suicide. Whatever your reason, the #988Lifeline is there to help. There is hope.

Ohio Board of Pharmacy
Mike DeWine, Governor | Steven W. Schierholt, Executive Director

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