



STATE OF OHIO BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

From the Director's Desk

Dear Ohio Pharmacist,

The State of Ohio Board of Pharmacy recently announced that effective December 1, 2021, new rules for institutional pharmacies and facilities (Chapter 4729:5-9 of the Ohio Administrative Code (OAC)) go into effect. These rules only apply to locations licensed as terminal distributor of dangerous drugs (TDDD) that meet the following definition of an “institutional pharmacy” or “institutional facility” in rule 4729:5-9-01 of the OAC.

“Institutional pharmacy” means a pharmacy that primarily provides inpatient pharmacy services to an institutional facility in accordance with this chapter.

“Institutional facility” means any of the following:

- (1) A public hospital or hospital as defined in section 3701.01 or 5122.01 of the Revised Code.
- (2) A freestanding emergency department.
- (3) A freestanding inpatient rehabilitation facility or inpatient rehabilitation facility as defined in rule 3701-83-25 of the Administrative Code.
- (4) An ambulatory surgical facility as defined in rule 3701-83-15 of the Administrative Code.
- (5) A nursing home or residential care facility licensed under Chapter 3721. of the Revised Code;
- (6) An inpatient psychiatric service provider as defined in rule 5122-14-01 of the Administrative Code;
- (7) A facility that provides medically supervised detoxification services that meets the following requirements:
 - (a) Patients are administered dangerous drugs to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of drugs or alcohol;

- (b) Patients are under the care of a licensed prescriber and are provided continuous onsite monitoring by nurses licensed in accordance with Chapter 4723 of the Revised Code;
 - (c) If the period of detoxification is less than twenty-four hours, patients shall be transitioned to an inpatient, residential, or outpatient treatment program; and
 - (d) The facility holds the appropriate license or certification by the Ohio department of mental health and addiction services.
- (8) A state or local correctional facility, as defined in section 5163.45 of the Revised Code;
- (9) A juvenile correctional facility that is under the management and control of the department of youth services or a private entity with which the department of youth services has contracted for the institutional care; and
- (10) Any other facility as determined by the board.

To assist licensees in complying with the new rule chapter, the Board recently published an institutional inspection guide that can be accessed using the following link: www.pharmacy.ohio.gov/IPFinspect. It is also accessible via the Board's TDDD licensing page at www.pharmacy.ohio.gov/Licensing/TDDD.aspx.

The inspection guide aligns with internal guidance used by Board inspectors and allows licensees to conduct self-inspections to ensure compliance. The guide also includes links to the new rules, important definitions, and reminders of when a licensee is required to submit notification or additional information to the Board.

To provide further guidance to licensees, the Board has opened a comment/question period for the inspection guide. This comment period will remain open until **August 20, 2021**. Following the conclusion of this comment period, the Board will review all comments and attempt to address or clarify any issues within the guide.

Comments and questions on the institutional pharmacy/facility inspection guide may be sent to RuleComments@pharmacy.ohio.gov.

Board staff continues to work remotely. If you have any questions, please do not hesitate to contact the Board via email at contact@pharmacy.ohio.gov or by phone at 614/466-4143. For the latest information on the Board's coronavirus disease 2019 (COVID-19) updates, visit www.pharmacy.ohio.gov/COVID.

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
State of Ohio Board of Pharmacy

Pharmacy Compounding Rules – Now Effective as of July 1, 2021

On July 1, 2021, the Board's updated pharmacy compounding rules went into effect. These rules apply to both in-state and nonresident pharmacies. For more information about these rule updates, the Board has developed the following guidance documents:

- In-state compounding pharmacies: www.pharmacy.ohio.gov/PharmCompound
- Nonresident compounding pharmacies: www.pharmacy.ohio.gov/NRPcompound

Reminder: New Automated Pharmacy Systems Rule Now Effective

To promote uniform review and approval of automated pharmacy systems, the Board implemented rule [4729:5-3-17](#) of the OAC on June 4, 2021. This rule provides a process by which automated pharmacy systems are approved by the Board. This rule replaces the previous automated systems rule, [4729-5-35](#).

(A) As used in this rule:

- (1) 'Automated pharmacy system' means a mechanical system that performs operations or activities, other than administration, relative to storage, packaging, compounding, dispensing, or distribution of dangerous drugs that collects, controls, and maintains transaction information and records. [It] does not include an 'automated drug storage system' [eg, Pyxis] utilized by institutional facilities . . . or other locations licensed as terminal distributors of dangerous drugs.

For questions regarding automated pharmacy systems, the Board created a [frequently asked questions document](#).

Important Reminders

- This rule applies to in-state automated pharmacy systems only.
- Systems that were approved under the previous rule ([OAC 4729-5-35](#)) do not need to be reapproved. However, there are new requirements for quality assurance plans for approved systems (see [OAC 4729:5-3-17\(F\)](#)).

Use of Contingency Stock License by Institutional Facilities

To promote vaccination storage and administration at long-term care facilities and other institutional facilities, the Board hereby authorizes the following policy:

A long-term care facility or other institutional facility, as defined under agency 4729 of the Ohio Administrative Code, may possess and administer vaccines and other biologics to patients and staff under the terminal distributor of dangerous drugs license issued to the facility's servicing pharmacy (e.g., contingency stock license). This policy shall also permit the use of the servicing pharmacy's contingency stock

license to maintain dangerous drugs used to treat adverse reactions to vaccines and biologics stored at the facility.

For more information on this policy, visit www.pharmacy.ohio.gov/ConStock.

Reminder: 2021 Virtual Law Reviews and Responsible Person Roundtables

Join the Board for a presentation to learn about the latest developments in pharmacy law and rules.

Law Review topics will include:

- New requirements for TDDD
- New outpatient pharmacy rules and inspection guide
- Board COVID-19 response efforts
- Pharmacy compounding rules and implementation plan

Responsible Person Roundtable topics will include:

- Duties of a responsible person
- General provisions applicable to a TDDD
- Duty to report requirements
- Additional compliance resources

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Who should attend?

- Pharmacists, pharmacy interns, registered or certified pharmacy technicians, and pharmacy compliance staff employed in outpatient/community-based pharmacies.

More information can be found [here](#).

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Steven W. Schierholt, Esq - State News Editor

Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor & Executive Editor

Amy Sanchez - Publications and Editorial Manager

77 S High St, 17th Floor | Columbus, OH 43215-6126 | Tel: 614/466-4143 Fax: 614/752-4836 | www.pharmacy.ohio.gov