



Institutional Pharmacy & Facility Rules

Effective December 1, 2021

Effective December 1, 2021, new rules for institutional pharmacies and facilities (Chapter 4729:5-9 of the Administrative Code) go into effect. This guide applies only to locations licensed as terminal distributor of dangerous drugs that meet the following definition of an "institutional pharmacy" or "institutional facility" in rule [4729:5-9-01](#) of the Ohio Administrative Code:

"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 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 short link: www.pharmacy.ohio.gov/IPFinspect. It is also accessible via the Board's TDDD licensing page: <https://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 comment/question period for the inspection guide. This comment period will be 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/questions on the institutional pharmacy/facility inspection guide may be sent to: RuleComments@pharmacy.ohio.gov
