



Rules November 2023

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4729:5-2-05 - Notification of Accessible Services. (NEW)

(A) Every outpatient pharmacy providing pharmacy services in this state shall report to the state board of pharmacy, in a manner determined by the board, the following information on accessible services provided by the pharmacy within ninety days of the effective date of this rule:

- (1) The type of language translation services, including translated prescription labels, for patients who are of limited English proficiency;
- (2) The type of services available for patients who are hard of hearing; and
- (3) The type of services available for patients with low vision.

(B) As part of the licensure and renewal process established in rule 4729:5-2-02 of the Administrative Code, an outpatient pharmacy providing pharmacy services in this state shall submit information on the accessible services listed in paragraph (A) of this rule that are provided by the pharmacy.

(C) An outpatient pharmacy required to submit notification to the board in accordance with this rule shall notify the board within thirty days of any change in the accessible services provided by the pharmacy.

(D) **Except as provided in paragraph (E) of this rule,** a pharmacy that reports it offers accessible services shall be required to provide those services to patients upon request.

(E) Paragraph (D) does not apply if the pharmacy experiences a temporary software or equipment failure of the accessible service offered.



**4729:5-5-02 - Minimum Standards for the Operation of an Outpatient Pharmacy
(RESCIND CURRENT RULE AND FILE NEW)**

(A) As used in this rule, "pharmacy personnel" means any of the following licensed or registered in accordance with Chapter 4729. of the Revised Code:

- (1) Pharmacist;
- (2) Pharmacy intern;
- (3) Certified pharmacy technician;
- (4) Registered pharmacy technician;
- (5) Pharmacy technician trainee.

(B) In accordance with division (D) of section 4729.55 of the Revised Code, an outpatient pharmacy licensed as a terminal distributor of dangerous drugs shall:

(1) Ensure sufficient personnel are scheduled to work at all times in order to prevent fatigue, distraction, or other conditions which interfere with a pharmacist's ability to practice with reasonable competence and safety. Staffing levels shall not be solely based on prescription volume but shall consider any other requirements of the practice of pharmacy by pharmacy personnel during working hours.

(2) Provide sufficient tools and equipment in updated and good repair and minimize excessive distractions to support a safe workflow for a pharmacist to practice with reasonable competence and safety to address patient needs in a timely manner. All tools and equipment shall be housed in a suitable, well-lit, and well-ventilated room or department and maintained in a clean, sanitary, and orderly condition.

(3) Provide pharmacy personnel with access to the following:

(a) All current federal and state laws, regulations, and rules governing the practice of pharmacy and legal distribution of drugs in Ohio, including internet access to:

(i) The board's website (www.pharmacy.ohio.gov);

(ii) LAWriter Ohio laws and rules (<http://codes.ohio.gov/>);

(iii) The code of laws of the United States of America (variously abbreviated to Code of Laws of the United States, United States Code, U.S. Code, U.S.C., or USC); and

(iv) The code of federal regulations.

(b) References necessary to conduct a pharmacy in a manner that is in the best interest of the patients served and to comply with all state and federal laws, this shall include hard copy or internet access to appropriate pharmacy reference materials.

(c) The telephone number of a poison control center.

- (4) Ensure pharmacy personnel are sufficiently trained to safely and adequately perform their assigned duties.
- (5) Maintain a stock of drugs sufficient to compound and prepare the types of prescriptions offered by the pharmacy.
- (6) Maintain a stock of prescription containers necessary to dispense drugs in accordance with federal and state laws, including the provisions of the federal Poison Prevention Act of 1970 and compendial standards, or as recommended by the manufacturer or distributor for non-compendial drug products.
- (7) Ensure all areas where drugs and devices are stored and prepared are dry, well-lit, well-ventilated, and maintained in a clean, sanitary, and orderly condition. Storage areas shall be maintained at temperatures and conditions which will ensure the integrity of the drugs prior to their dispensing or administering as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.
- (8) For outpatient pharmacies open to the public, publicly post the operating hours of the pharmacy department.
- (9) Ensure all employees of the pharmacy are identified by a name tag that includes the employee's job title and, if a pharmacy technician, the technician's registration type pursuant to Chapter 4729:3-3 of the Administrative Code.
- (10) Provide adequate security for all dangerous drugs in accordance with the requirements of agency 4729 of the Administrative Code. A pharmacy shall maintain the current contact information for the pharmacy's security system vendor and shall immediately provide this information upon the request of an agent, inspector, or employee of the board.
- (11) Provide sufficient time for pharmacists to complete professional duties and responsibilities, including:
 - (a) Drug utilization review;
 - (b) Immunization;
 - (c) Patient counseling;
 - (d) Dispensing of prescriptions;
 - (e) Patient testing; and
 - (f) All other duties of a pharmacist as authorized by Chapter 4729. of the Revised Code.

4729:5-5-02.1 - Provision of Ancillary Services in an Outpatient Pharmacy. (NEW)

(A) As used in this rule, "ancillary services" are those services performed by pharmacy personnel that are not directly involved in the dispensation of dangerous drugs as set forth in this chapter of the Revised Code. Examples of such services include, but are not limited to, immunizations, drug administration, medication therapy management, disease state management, and refill reminders.

(B) In accordance with division (D) of section 4729.55 of the Revised Code, an outpatient pharmacy licensed as a terminal distributor of dangerous drugs shall not establish any productivity or production quotas relating to the provision of ancillary services.

(1) For purposes of this rule, "quota" means a fixed number or formula related to the duties of pharmacy personnel, against which the pharmacy or its agent measures or evaluates the number of times either an individual performs tasks or provides services while on duty.

(2) For purposes of this rule, "quota" does not mean any of the following:

(a) A measurement of the revenue earned by a pharmacy not calculated in relation to, or measured by, the tasks performed, or services provided by pharmacy personnel.

(b) Any evaluation or measurement of the competence, performance, or quality of care provided to patients of pharmacy personnel if the evaluation does not use quotas.

(c) Any performance metric required by state or federal regulators.

(C) This rule does not apply to outpatient pharmacies that are not open to the public (e.g., closed door pharmacies).

4729:5-5-02.2 - Mandatory Rest Breaks for Pharmacy Personnel. (NEW)

(A) Except in a documented emergency, as deemed by the professional judgement of the pharmacist, that would endanger the health and safety of patients, an outpatient pharmacy licensed as a terminal distributor of dangerous drugs shall not require pharmacy personnel to work longer than twelve continuous hours in any workday and shall allow at least eight hours of off time between consecutive shifts.

(1) A pharmacist may volunteer to work longer than twelve continuous hours.

(2) In the case of an emergency, the pharmacist must document and date the amount of time worked beyond the twelve hours limit along with the reason and make it available for immediate inspection for at least three years from the date it was created.

(B) Pharmacy personnel working longer than six continuous hours per workday shall be allowed during that time to take a thirty-minute, uninterrupted rest break.

(1) Unless as provided in paragraph (B)(2) of this rule, a pharmacist that takes a break in accordance with this rule shall remain on the premises of the pharmacy during the meal/rest break and shall be available for emergencies.

(2) The requirement in paragraph (B)(1) of this rule does not apply in either case:

(a) There are two or more pharmacists working in the pharmacy and the pharmacists stagger their rest breaks so that the pharmacy is not left without a pharmacist on duty.

(b) The pharmacy closes for the required rest break. If a pharmacy closes for a required rest break, The pharmacy shall implement a regular break schedule and communicate the break schedule to customers wherever pharmacy hours are publicly posted or communicated.

(C) The requirements of paragraph (B) of this rule do not apply to outpatient pharmacies that are not open to the public (e.g., closed door pharmacies). An outpatient pharmacy that is not open to the public shall still be required to allow all pharmacy personnel working longer than six continuous hours to take a thirty-minute, uninterrupted rest period and meal break.

(D) Only prescriptions dispensed by a pharmacist pursuant to this chapter of the Administrative Code may be sold when the pharmacist is on break. An offer to counsel any person filling a prescription shall be offered pursuant rule 4729:5-5-09 of the Administrative Code. Persons who request to speak to the pharmacist shall be told that the pharmacist is on break and that they may wait to speak with the pharmacist or provide a telephone number for the pharmacist to contact them upon return from break. Pharmacists returning from break shall immediately attempt to contact persons who requested counseling.

(E) An outpatient pharmacy shall not retaliate or discipline a pharmacist for refusing to work longer than twelve continuous hours or pharmacy personnel that opt to take breaks in accordance with paragraph (B) of this rule. As used in this rule, retaliation or discipline of an employee includes, but is not limited to, the following:

(1) Removing or suspending the employee from employment;

- (2) Withholding from the employee salary increases or employee benefits to which the employee is otherwise entitled;
- (3) Transferring or reassigning the employee;
- (4) Denying the employee a promotion that otherwise would have been received;
- (5) Reducing the employee in pay or position.

4729:5-5-02.3 - Staffing Requests or Concerns in an Outpatient Pharmacy. (NEW)

(A) Staffing requests or concerns shall be communicated by the responsible person or pharmacist on duty to the terminal distributor in writing.

(B) Executed staffing requests or reports of concern shall be provided to the immediate supervisor of the responsible person or pharmacist on duty, with one copy maintained in the pharmacy for three years for immediate inspection by an agent, inspector, or employee of the board.

(C) Outpatient pharmacies licensed as terminal distributors of dangerous drugs shall review all requests and reports of concern submitted in accordance with this rule and shall resolve any issues listed in a timely manner to ensure a safe working environment for pharmacy staff as required by section 4729.55 of the Revised Code. A written response to the request or concern shall occur within fourteen business days of submission and be communicated to the responsible person or pharmacy staff who submitted the staffing request or report of concern. A copy of this response shall be maintained in the pharmacy for three years for immediate inspection by an agent, inspector, or employee of the board.

(D) An outpatient pharmacy shall not retaliate or discipline a pharmacist who, in good faith, reports staffing concerns in accordance with this rule. As used in this rule, retaliation or discipline of an employee includes, but is not limited to, the following:

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

4729:5-5-02.4 - Significant Delays in the Provision of Pharmacy Services. (NEW)

(A) An outpatient pharmacy has a duty to properly dispense lawful prescriptions for dangerous drugs or devices without significant delay.

(1) For purposes of this rule, "significant delay" means a prescription that was submitted to the pharmacy for processing by a prescriber, patient, or caregiver and has yet to be dispensed (e.g., final verification) by a pharmacist within three business days of receiving the prescription.

(2) Receipt of the prescription as described in paragraph (A)(1) of this rule is said to occur:

(a) For new prescriptions, receipt occurs on the day when the prescription is transmitted or submitted to the pharmacy.

(b) For refills on existing prescription, receipt occurs on the day when a refill request is submitted to the pharmacy by a patient or caregiver or when a refill request is generated by the pharmacy as part of an auto-refill program.

(3) For purposes of this rule, "significant delay" does not mean any of the following:

(a) A prescription that has been submitted to the pharmacy but where there is a documented drug shortage, or the pharmacy documents the drug is not available from the pharmacy's drug distributor.

(b) A prescription that has been submitted to the pharmacy that requires clarification or consultation by the issuing prescriber.

(c) A prescription that has been submitted to the pharmacy that requires a prior-authorization or is otherwise delayed because of the patient's prescription insurance coverage.

(d) A prescription that is for a compounded drug product.

(e) A prescription that the pharmacist, using their professional judgement, determines is of doubtful, questionable, or suspicious origin.

(f) A prescription where the prescriber indicates a "do not fill until" date or similar designation.

(g) A prescription where the patient, caregiver, or issuing prescriber has communicated to the pharmacy that dispensing may occur beyond the period described in paragraph (A)(1) of this rule.

(h) A prescription where the pharmacy has experienced any of the following:

(i) A natural disaster (fire, flood, etc.), civil unrest, or human made disaster;

(ii) An outbreak of a pandemic illness or the declaration of a state or federal public health emergency;

(iii) A loss of power; or

(iv) An unplanned information technology system outage.

(j) Any other circumstance as determined by the board.

(B) Each prescription that experiences a significant delay, as defined in paragraph (A) of this rule, shall be considered a violation of this rule and shall subject the outpatient pharmacy to disciplinary action in accordance with rule 4729:5-4-01 of the Administrative Code.

(C) Immediately upon discovery or at the request of an agent, inspector, or employee of the board, a pharmacy experiencing a significant delay shall implement one or more of the following remediation measures to dispense all prescriptions that are experiencing a significant delay:

(1) Limiting pharmacy hours (e.g., dark hours);

(2) Transferring prescriptions to another pharmacy, upon patient consent;

(3) Increasing pharmacy staff; or

(4) Any other strategy that is mutually agreed upon by the outpatient pharmacy and the agent, inspector, or employee of the board.

(D) As part of the remediation process required in paragraph (C) of this rule, the outpatient pharmacy shall implement a process that triages lifesaving and life-sustaining medications that are experiencing a significant delay.

(E) As used in this rule, "business day" means any day, including holidays, where the pharmacy is not open for business.

4729:5-5-02.5 - Outpatient Pharmacy Access Points. (NEW)

(A) As used in this rule, "ancillary services" are those services performed by pharmacy personnel that are not directly involved in the dispensation of dangerous drugs as set forth in this chapter of the Revised Code. Examples of such services include, but are not limited to, immunizations, drug administration, medication therapy management, disease state management, and refill reminders.

(B) Except as provided for in paragraph (C) of this rule, a pharmacy shall develop and implement an effective organizational policy that permits a pharmacist to do all the following:

(1) Limit the provision of ancillary services if, in the pharmacist's professional judgment, the provision of such services cannot be safely provided or may negatively impact patient access to medications; and

(2) Limit pharmacy access points, if, in the pharmacist's professional judgment, limiting such access points will prevent fatigue, distraction, or other conditions which interfere with a pharmacist's ability to practice with reasonable safety and competence.

(C) In the absence of an organizational policy in paragraph (B), an outpatient pharmacy shall not override the control of the pharmacist on duty as follows:

(a) A pharmacist's decision not to administer or supervise immunizations or provide other ancillary services if, in the pharmacist's professional judgment, the provision of such services cannot be provided safely or may negatively impact patient access to medications. The pharmacy shall offer to make an appointment for the patient or may refer the patient to another location offering immunizations.

(b) A pharmacist's decision to limit pharmacy access points if, in the pharmacist's professional judgment, limiting such access points will prevent fatigue, distraction, or other conditions which interfere with a pharmacist's ability to practice with reasonable safety and competence. Such limitations shall not interfere with a patient's ability to drop off or receive dispensed prescriptions during the pharmacy's posted hours of operation.

(D) Organizational policies developed in accordance with paragraph (A) of this rule shall be maintained in the pharmacy for immediate inspection by an agent, inspector, or employee of the board.

(E) The requirements in this rule do not apply to outpatient pharmacies that are not open to the public (e.g., closed door pharmacies).

(F) An outpatient pharmacy shall not retaliate or discipline a pharmacist who, in good faith, acts in accordance with this rule. As used in this rule, retaliation or discipline of an employee includes, but is not limited to, the following:

(1) Removing or suspending the employee from employment;

(2) Withholding from the employee salary increases or employee benefits to which the employee is otherwise entitled;

(3) Transferring or reassigning the employee;

- (4) Denying the employee a promotion that otherwise would have been received;
- (5) Reducing the employee in pay or position.