



# Outpatient Pharmacy Minimum Standards

**Updated: 4/26/2024**

All updates are notated in red (i.e. **UPDATED 4.26.2024**)

Effective 5/1/2024, the following rules on outpatient pharmacy minimum standards go into effect. These rules are the result of the work of the Ohio Pharmacist Workload Advisory Committee and feedback provided by pharmacy professionals through various surveys. For more information on the Pharmacist Workload Advisory Committee, please visit:

[www.pharmacy.ohio.gov/PWAC](http://www.pharmacy.ohio.gov/PWAC).

Rule No.	Title
<a href="#">4729:5-5-02</a>	Minimum Standards for the Operation of an Outpatient Pharmacy.
<a href="#">4729:5-5-02.1</a>	Provision of Ancillary Services in an Outpatient Pharmacy.
<a href="#">4729:5-5-02.2</a>	Mandatory Rest Breaks for Pharmacy Personnel.
<a href="#">4729:5-5-02.3</a>	Requests for Additional Staff and Reports of Staffing Concerns in an Outpatient Pharmacy.
<a href="#">4729:5-5-02.4</a>	Significant Delays in the Provision of Pharmacy Services.
<a href="#">4729:5-5-02.5</a>	Outpatient Pharmacy Access Points.

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

To assist licensees in complying with these new regulations, the Board developed this frequently asked questions document. This document is divided into sections for each rule:

[Minimum Standards for the Operation of an Outpatient Pharmacy](#)

[Provision of Ancillary Services in an Outpatient Pharmacy](#)

[Mandatory Rest Breaks for Pharmacy Personnel](#)

[Requests for Additional Staff and Reports of Staffing Concerns in an Outpatient Pharmacy](#)

[Significant Delays in the Provision of Pharmacy Services](#)

[Outpatient Pharmacy Access Points](#)



## **Additional Questions**

For questions regarding the rules, please review this document. If you need additional information, 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>.

## **To Report Any Violations**

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

**REMINDER:** 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.

## **Anti-Retaliation Provisions**

Ohio rules (OAC 4729:5-4-01 [B]{25}) prohibit a licensed pharmacy from retaliating against or disciplining an employee for filing a complaint with the Board or other licensing body or reporting a violation of state or federal statute or any ordinance or regulation of a political subdivision that the employee's employer has authority to correct.

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; and
5. Reducing the employee in pay or position.

Further, the following rules have specific employee anti-retaliation provisions:

- 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.

**OAC 4729:5-5-02 - Minimum Standards for the Operation of an Outpatient Pharmacy**

**Q1) What are the significant changes/additions to this rule?**

**A1)** OAC 4729:5-5-02 is being replaced with an updated version of the rule. The table below provides an overview of the substantive changes made to the rule:

<b>OAC 4729:5-5-02 (prior to 5/1/24)</b>	<b>OAC 4729:5-5-02 (on or after 5/1/24)</b>
The pharmacy shall be appropriately staffed to operate in a safe and effective manner pursuant to section <a href="#">4729.55</a> of the Revised Code.	Ensure sufficient personnel are scheduled to work at all times in order to minimize 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.
N/A	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.
N/A	Ensure pharmacy personnel are sufficiently trained to safely and adequately perform their assigned duties.

**IMPORTANT:** The rule defines pharmacy personnel to include pharmacists, pharmacy interns, and pharmacy technicians (certified, registered, and trainees).

**Q2) Do these rules apply to all pharmacies?**

**A2)** These rules apply to all outpatient pharmacies that are licensed and regulated under [OAC 4729:5-5](#). This includes all outpatient pharmacies operated by hospitals.

**REMINDER:** There are some exceptions in the rules for closed-door pharmacies. Please refer to each rule for more information.

## **OAC 4729:5-5-02.1 - Provision of Ancillary Services in an Outpatient Pharmacy.**

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

### **Q3) This rule bans the use of quotas for ancillary services. How is quota defined in the rule?**

**A3)** 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.

"Quota" does not mean any of the following:

1. 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.
2. 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.
3. Any performance metric required by state or federal regulators.

### **Q4) What is considered an ancillary service under this rule?**

**A4)** The rule defines an ancillary service as any service performed by pharmacy personnel that are performed in addition to, or outside of, the dispensation of dangerous drugs. They include, but are not limited to, the following:

- Immunizations
- Drug administration
- Medication therapy management
- Disease state management
- Refill reminders

Ancillary services DO NOT include services provided by an outpatient pharmacy to patients upon discharge from an institutional facility (hospital, nursing home, etc.). An example of this includes a hospital's "Meds to Beds" program.

### **Q5) Can quotas for ancillary services be implemented at the pharmacy-level?**

**A5)** A licensee may have goals or metrics for each pharmacy as it relates to the provision of ancillary services. However, any goals or metrics related to ancillary services that are applied at the pharmacy-level cannot include fixed numbers or formulas for pharmacy personnel.

**Example:** Pharmacy A, which employs Pharmacist A and Pharmacist B, has a vaccination goal of 20 people per week. The pharmacy cannot require Pharmacist A and B to administer 10 vaccines per week. Pharmacy A may offer incentives to meet such goals but cannot penalize Pharmacist A or B for failing to meet the 10 vaccine per week goal (as this would be considered a quota under the rule). **(UPDATED 4.26.2024)**

**OAC 4729:5-5-02.2 - Mandatory Rest Breaks for Pharmacy Personnel**

**Q6) What are the requirements for mandatory rest breaks for pharmacy personnel?**

**A6)** The rule requires all pharmacy personnel working longer than six continuous hours per workday to be allowed during that time to take a thirty-minute, uninterrupted rest break. The following provides a summary of the rest break requirements:

<b>Break Type*</b>	<b>Requirements</b>
<b>Pharmacy Stays Open</b>	<p>1) Another pharmacist provides coverage for the pharmacist on break.</p> <p style="text-align: center;"><b>-OR-</b></p> <p>2) If no pharmacist coverage is provided:</p> <ul style="list-style-type: none"><li>▪ The pharmacist must remain on the premises of the pharmacy and shall be available for emergencies.</li><li>▪ Prescriptions may be sold when the pharmacist is on break. The pharmacy must provide an offer to counsel. 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 returning from break.</li><li>▪ Pharmacists returning from break shall immediately attempt to contact persons who requested counseling.</li></ul>
<b>Pharmacy Closes for Required Break</b>	<ul style="list-style-type: none"><li>▪ 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.</li><li>▪ Prescriptions cannot be sold when the pharmacy is closed.</li></ul>

**\*IMPORTANT:** The requirements listed above 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 is still required to allow all pharmacy personnel working longer than six continuous hours to take a thirty-minute, uninterrupted rest break.

**Q7) Are pharmacy personnel required to work longer than thirteen hours in any workday?**

**A7)** No. The rule prohibits an outpatient pharmacy from requiring pharmacy personnel to work longer than thirteen hours in any workday. The rule also requires eight hours of time off between consecutive shifts.

**REMINDER:**

- The rule defines pharmacy personnel to include pharmacists, pharmacy interns, and pharmacy technicians (certified, registered, and trainees).
- Outpatient pharmacies that are not open to the public (e.g., closed door pharmacies) are still required to adhere to this requirement.
- This only applies to actual hours worked in a pharmacy or engaged in the practice of pharmacy (e.g., remote processing). It does not apply to pharmacists that may be “on-call.”

**Q8) Can pharmacy personnel volunteer to work longer than thirteen hours in any workday?**

**A8) ONLY Pharmacists may volunteer to work longer than thirteen continuous hours.** If this occurs, the pharmacy must document and date the amount of time worked beyond the thirteen-hour limit along with the reason and make it available in the pharmacy for immediate inspection for at least three years from the date it was created.

As a reminder, OAC 4729:5-5-02.2 prohibits a pharmacy from retaliating or disciplining a pharmacist for refusing to work longer than thirteen hours or pharmacy personnel that opt to take breaks in accordance with this rule.

**Q9) How are rest break hours calculated? Based upon schedule or upon hours worked?**

**A9)** The rule references “hours worked.” Therefore, rest breaks should be calculated based upon actual hours worked. (**UPDATED 4.26.2024**)

**Q10) If the pharmacy is closed for the required rest break and it is published, is further documentation needed stating the break was taken?**

**A10)** No. The rule does not require additional documentation. (**UPDATED 4.26.2024**)

**Q11) If a pharmacist works a thirteen-hour shift, are they allowed to take two rest breaks?**

**A11)** The rule requires the offer of only one 30-minute rest-break per shift. Nothing prohibits a pharmacy from offering additional request breaks to pharmacy personnel. (**UPDATED 4.26.2024**)

**Q12) Are pharmacy personnel required to take a rest break?**

**A12)** No. The rule only requires a pharmacy to offer a rest break. (**UPDATED 4.26.2024**)



**OAC 4729:5-5-02.3 - Requests for Additional Staff and Reports of Staffing Concerns in an Outpatient Pharmacy**

**Q13) What are the requirements for developing a process to communicate requests for additional staff or reports of staffing concerns?**

**A13)** The rule requires all outpatient pharmacies to develop a process for pharmacy staff to communicate requests for additional staff or reports of staffing concerns (excludes requests for time off). The rule does not require the use of a specific form. Rather, it requires requests for additional staff or reports of staffing concerns to be communicated and documented as follows:

- 1) Executed requests for additional staffing or reports of staffing concerns shall be provided to the immediate supervisor of the pharmacy personnel submitting a request or report, with one copy maintained in the pharmacy for three years for immediate inspection by an agent, inspector, or employee of the Board.
- 2) The pharmacy (e.g., management) shall review all requests and reports of concern submitted and shall resolve any issues listed in a timely manner to ensure a safe working environment for pharmacy staff. A written response to the request or report of concern shall occur within **fourteen business days** of submission and be communicated to the responsible person or pharmacy staff who submitted the request for additional staffing 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.

**IMPORTANT:**

- Pharmacies may use existing communication systems/processes to meet the requirements of this rule as long as such information can be documented for compliance purposes.
- "Business day" means any day, excluding holidays, where the pharmacy is open for business.
- This rule specifically prohibits a pharmacy from retaliating or disciplining a pharmacist who, in good faith, makes a request for additional staff or reports staffing concerns in accordance with the rule.

## **OAC 4729:5-5-02.4 - Significant Delays in the Provision of Pharmacy Services**

### **Q14) How is a significant delay defined in the rule?**

**A14)** The rule requires an outpatient pharmacy to dispense lawful prescriptions for drugs or devices without significant delay. Significant delay means any 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 as follows:

- **For new prescriptions:** within three business days of receiving the prescription.
- **For refill prescriptions not generated by a pharmacy auto-refill program:** within three business days of receiving the prescription.
- **For refill prescriptions generated by a pharmacy auto-refill program:** within five business days of receiving the prescription.

**IMPORTANT:** Business day means any day, excluding holidays, where the pharmacy is open for business.

A significant delay **DOES NOT** include any of the following:

- 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.
- A prescription that has been submitted to the pharmacy that requires clarification or consultation by the issuing prescriber.
- A prescription that has been submitted to the pharmacy that requires prior authorization or is otherwise delayed because of the patient's prescription insurance coverage.
- A prescription that is for a compounded drug product.
- A prescription that the pharmacist, using their professional judgement, determines is of questionable, doubtful, or of suspicious origin.
- A prescription that, in the pharmacist's professional judgment, if dispensed, cannot be safely provided or may negatively impact patient care.

- A prescription where the prescriber indicates a "do not fill until" date or similar designation.
- A prescription where the patient, caregiver, or issuing prescriber has communicated to the pharmacy that dispensing may occur beyond the three- or five-day period required by the rule.
- A prescription where the patient, caregiver, or issuing prescriber has requested a transfer to another pharmacy.
- A prescription where the pharmacy has experienced any of the following:
  - A natural disaster (fire, flood, etc.), civil unrest, or human made disaster;
  - An outbreak of a pandemic illness or the declaration of a state or federal public health emergency;
  - A loss of power; or
  - An unplanned information technology system outage.

**Q15) Does this rule mean that I have three days to fill any new prescriptions?**

**A15)** No. The requirements of this rule represent the floor rather than the ceiling. Pharmacists must still ensure patients have access to life-sustaining medications in a timely manner as part of their required standard of care.

**Q16) Is a pharmacy that is experiencing a significant delay in processing prescriptions required to implement remediation measures?**

**A16)** Pharmacies that are experiencing significant delays are, immediately upon discovery, required to implement remediation measures. Each prescription that is deemed to be significantly delayed is considered a separate violation of Ohio law.

If such prescriptions are identified by Board staff, the rule requires pharmacies to implement one of the following solutions:

- (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.

**IMPORTANT:** As part of this remediation, the pharmacy is required to implement a process that triages lifesaving and life-sustaining medications that are experiencing a significant delay.

**Q17) Does this rule establish standards for pharmacy auto-refill programs?**

**A17)** Yes. The rule requires auto-refills of a prescription upon the authorization of the patient or the patient's caregiver. It requires the pharmacy to:

- Maintain documentation indicating the patient or the patient's caregiver has enrolled in the pharmacy's auto-refill program. Consent for enrollment in the pharmacy's auto-refill program may be captured electronically, verbally by pharmacy staff, or in writing.
- Maintain a record of consent in the patient's profile, or another system maintained by the pharmacy, in a readily retrievable manner. As part of this record, the pharmacy shall document the date the patient or caregiver consented to enrollment in the pharmacy's auto-refill program.
- Discontinue enrollment in an auto-refill program upon the request of the patient or the patient's caregiver.
- If the patient has previously documented consent, including the date of consent, for enrollment in an auto-refill program, that meets the requirement of the rule. If the pharmacy does not have this documentation on file, it will need to obtain additional consent for the pharmacy's auto-refill program. **(UPDATED 4.26.2024)**

**IMPORANT:** Consent for auto-refill is patient-specific and not prescription-specific. Therefore, consent for auto-refill is only required once and not for every prescription dispensed.

**OAC 4729:5-5-02.5 - Outpatient Pharmacy Access Points**

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

**Q18) What policies are outpatient pharmacies required to develop under this rule?**

**A18)** The rule requires pharmacies to either:

- 1) Develop and implement effective organizational policies that address the following:
  - a. Limits on 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.  
  
**IMPORTANT:** The pharmacy's policy shall include an offer by pharmacy staff to make an appointment for a patient or refer a patient to another location offering immunizations and other ancillary services.
  - b. Limits on pharmacy access points, if, in the pharmacist's professional judgment, limiting such access points will minimize fatigue, distraction, or other conditions which interfere with a pharmacist's ability to practice with reasonable safety and competence.

**-OR-**

- 2) In the absence of policies, not override the control of the pharmacist on duty as it relates to the following:
  - 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.  
  
**IMPORTANT:** The pharmacy staff shall offer to make an appointment for the patient or may refer the patient to another location offering immunizations and other ancillary services.
  - b. A pharmacist's decision to limit pharmacy access points if, in the pharmacist's professional judgment, limiting such access points will minimize 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.

**Q19) What does the Board consider an “effective” organizational policy?**

**A19)** The Board considers an effective organizational policy to be one that can address the needs of pharmacy staff that may be experiencing potentially unsafe working conditions. For example, an organizational policy that offers no guidance to the pharmacist on duty would not be considered “effective” under this rule. Such policies must include concrete actions pharmacy personnel can take for managing ancillary services and access points amid staffing shortages.

**REMINDER:** All organizational policies required by the rule must be maintained in the pharmacy for immediate inspection by an agent, inspector, or employee of the Board.

**Q20) What are considered ancillary services under this rule?**

**A20)** As used in the rule, “ancillary services” are those services performed by pharmacy personnel that are not directly involved in the dispensation of dangerous drugs. Examples of such services include, but are not limited to, immunizations, drug administration, medication therapy management, disease state management, and refill reminders.