



Ohio Administrative Code

Rule 4729:5-5-02.4 Significant Delays in the Provision of Pharmacy Services.

Effective: May 1, 2024

(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 as follows:

(a) For new prescriptions: within three business days of receiving the prescription.

(b) For refill prescriptions not generated by a pharmacy auto-refill program: within three business days of receiving the prescription.

(c) For refill prescriptions generated by a pharmacy auto-refill program: within five 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 prescriptions: receipt occurs on the day when a refill request is submitted to the pharmacy by a patient, caregiver, or prescriber or when a refill request is generated as part of a pharmacy's 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 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 questionable, doubtful, or suspicious origin.
- (f) A prescription that, in the pharmacist's professional judgment, if dispensed, cannot be safely provided or may negatively impact patient care.
- (g) A prescription where the prescriber indicates a "do not fill until" date or similar designation.
- (h) 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.
- (i) A prescription where the patient, caregiver, or issuing prescriber has requested a transfer to another pharmacy.
- (j) 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.



(k) 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, excluding holidays, where the pharmacy is open for business.

(F) An outpatient pharmacy shall only provide auto-refills of a prescription upon the authorization of the patient or the patient's caregiver.

(1) The pharmacy shall maintain documentation indicating the patient or the patient's caregiver has enrolled in the pharmacy's auto-refill program.



(2) Consent for enrollment in the pharmacy's auto-refill program may be captured electronically, verbally by pharmacy staff, or in writing.

(3) The pharmacy shall 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.

(4) The pharmacy shall discontinue enrollment in an auto-refill program upon the request of the patient or the patient's caregiver.