

AUTHENTICATED, OHIO LEGISLATIVE SERVICE COMMISSION DOCUMENT #249692

## Ohio Administrative Code

Rule 4729:1-3-06 Dispensing of epinephrine autoinjectors by pharmacists. Effective: January 18, 2020

(A) A pharmacist may dispense an epinephrine autoinjector without a prescription to either of the following in accordance with a protocol specified in paragraph (B) of this rule:

(1) An individual who there is reason to believe is experiencing or at risk of experiencing anaphylaxis if the pharmacy affiliated with the pharmacist has a record of previously dispensing epinephrine to the individual in accordance with a prescription issued by a licensed health professional authorized to prescribe drugs; or

(2) An individual acting on behalf of a qualified entity, as defined in section 3728.01 of the Revised Code.

(B) A physician-established protocol for the dispensing of epinephrine autoinjectors by a pharmacist or pharmacy intern under the direct supervision of a pharmacist shall include, but is not limited to, the following:

(1) Indications for use of epinephrine autoinjectors, including criteria for identifying persons eligible to receive an autoinjector under the protocol.

(2) Precautions and contraindications related to the dispensing of epinephrine autoinjectors.

(3) Epinephrine autoinjectors authorized to be dispensed, including all the following information:

(a) Name of product;

(b) Dose;

(c) Quantity to be dispensed; and



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(d) Directions for use.

(4) Any patient instructions in addition to the training specified in this rule and rule 4729:2-3-06 of the Administrative Code.

(1) A pharmacist who dispenses an epinephrine autoinjector pursuant to this rule shall instruct the individual to whom the epinephrine autoinjector is dispensed, either verbally or in writing, to summon emergency services as soon as practicable either before or after administering epinephrine.

(2) A pharmacist who dispenses an epinephrine autoinjector to an individual identified in paragraph (A) of this rule shall provide notification of the dispensing to the individual's primary care provider, if known, or to the prescriber who issued the individual the initial prescription for an epinephrine autoinjector. Notification shall be conducted using one of the following methods that is capable of confirming delivery of the required notification:

(a) Electronic mail;

(b) Interoperable electronic medical records system;

(c) Facsimile;

- (d) Electronic prescribing system;
- (e) Electronic pharmacy record system;
- (f) Documented verbal communication;

(g) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.

(D) When a pharmacist dispenses an epinephrine autoinjector pursuant to this rule, the pharmacist, or pharmacy intern under the direct supervision of a pharmacist, shall provide to the person receiving the device instruction on the proper method of administering epinephrine with the device.



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(E) A terminal distributor of dangerous drugs shall ensure that all pharmacists that dispense epinephrine autoinjectors pursuant to this rule are trained on the use of epinephrine and can meet the training requirements listed in paragraphs (C) and (D) of this rule.

(F) A pharmacist may document the dispensing of an epinephrine autoinjector by the pharmacist or pharmacy intern under the direct supervision of the pharmacist on a prescription form. The form may be assigned a number for record-keeping purposes.

(G) This rule does not affect the authority of a pharmacist to:

(1) Dispense a new prescription or refill for epinephrine; or

(2) Contact a prescriber to obtain a new oral prescription for an epinephrine autoinjector in accordance with the applicable provisions of division 4729:5 of the Administrative Code.

(H) All physician-established protocols must be signed and dated by the physician prior to implementation and maintained by the terminal distributor of dangerous drugs. The protocols shall be renewed by a physician on a biennial basis.

(1) A physician may sign one protocol for multiple locations licensed as terminal distributors of dangerous drugs.

(2) Each location licensed as a terminal distributor of dangerous drugs shall maintain a copy of the protocol on-site for inspection by an agent, inspector or employee of the state board of pharmacy.