



Ohio Administrative Code

Rule 4729:1-3-04 Dispensing of naloxone by pharmacists.

Effective: December 1, 2020

(A) A pharmacist may dispense naloxone 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 an opioid-related overdose;

(2) A family member, friend, or other person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.

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

(1) A description of the clinical pharmacology of naloxone.

(2) Indications for use of naloxone as rescue therapy, including criteria for identifying persons eligible to receive naloxone under the protocol.

(3) Precautions and contraindications concerning dispensing naloxone.

(4) Naloxone products authorized to be dispensed, including all of the following information:

(a) Name of product;

(b) Dose;

(c) Route of administration and required delivery device; and

(d) Directions for use.



(5) Any patient instructions in addition to the patient training specified in this rule and rule 4729:2-3-04 of the Administrative Code.

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

(D) Except as provided in paragraph (E) this rule, a pharmacist or a pharmacist's designee that is appropriately trained shall provide in-person training, unless the in-person training requirement is waived by the board, and written educational materials to the individual to whom naloxone is dispensed that includes all the following:

- (1) Risk factors of opioid overdose;
- (2) Strategies to prevent opioid overdose;
- (3) Signs of opioid overdose;
- (4) Steps in responding to an overdose;
- (5) Information on the naloxone dispensed;
- (6) Procedures for administering the naloxone dispensed;
- (7) Proper storage and expiration of the naloxone dispensed; and
- (8) Information on where to obtain a referral for substance abuse treatment.

(E) Patient training as required by paragraph (D) of this rule is not required if the patient has previously received training and all the following apply:

- (1) The patient is offered training and refuses;



- (2) The pharmacist or pharmacist designee has documentation confirming training pursuant to this rule has been provided within the previous twelve months;
- (3) A pharmacist who dispenses naloxone pursuant to this rule shall still instruct the individual to whom naloxone is dispensed verbally or in writing to summon emergency services as soon as practicable either before or after administering naloxone.
- (F) If training conducted pursuant to paragraph (D) of this rule is offered by a pharmacist's designee, the pharmacist shall not be required to counsel a patient or caregiver pursuant to rule 4729:5-5-09 of the Administrative Code if the patient or caregiver refuses the offer of counseling or does not respond to the written offer to counsel.
- (G) A terminal distributor of dangerous drugs shall ensure that all pharmacists that dispense naloxone pursuant to this rule are trained on the use of naloxone and can meet the training requirements listed in paragraphs (C) and (D) of this rule.
- (H) A terminal distributor of dangerous drugs shall ensure that all pharmacist designees are trained on the use of naloxone and can meet the training requirements listed in paragraph (D) of this rule.
- (I) A pharmacist may document on a prescription form the dispensing of naloxone by the pharmacist or a pharmacy intern supervised by the pharmacist. The form may be assigned a number for record-keeping purposes.
- (J) 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.



(K) Any pharmacy that dispenses naloxone pursuant to section 4729.44 of the Revised Code shall notify the board, in a manner determined by the board, within thirty days of establishing a protocol. A pharmacy that no longer dispenses naloxone pursuant to section 4729.44 of the Revised Code shall notify the board, in a manner determined by the board, within thirty days of discontinuation.

(1) Except in the event of a drug shortage, a pharmacy submitting notification of naloxone dispensing shall ensure naloxone is made available in accordance with this rule.

(2) A pharmacy that has submitted notification of naloxone dispensing shall provide initial training to all new employees and annual training to existing employees on the availability of naloxone dispensing pursuant to a protocol. Employees requiring training in accordance with this paragraph shall include: pharmacists, pharmacy interns, certified pharmacy technicians, registered pharmacy technicians, pharmacy technician trainees, and support personnel, as defined in rule 4729:3-1-01 of the Administrative Code, that have direct contact with the public. Training documentation records shall be maintained for a period of three years and shall be made readily retrievable.

(L) Paragraph (K) of this rule does not apply to institutional pharmacies that provide naloxone to inpatients or patients upon discharge.