

BOARDS AND COMMISSIONS
Board of Pharmacy
(Amended at ARRS Committee)

201 KAR 2:360. *Opioid antagonist* ~~*Naloxone*~~ dispensing.

RELATES TO: KRS 217.186

STATUTORY AUTHORITY: KRS 217.186, KRS 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.186(6) requires the Board of Pharmacy to promulgate administrative regulations governing dispensing of *an opioid antagonist* ~~*naloxone*~~ by a pharmacist pursuant to a physician-approved protocol. This administrative regulation establishes the minimum requirements for the pharmacist to be able to dispense *an opioid antagonist* ~~*naloxone*~~ pursuant to a physician-approved ~~[approval]~~ protocol; ~~and~~ ~~*This administrative regulation also*~~ provides the requirements for a pharmacy to stock *an opioid antagonist* ~~*naloxone*~~ to an emergency department.

Section 1. Certification.

(1) A pharmacist desiring to achieve certification to initiate the dispensing of *an opioid antagonist* ~~*naloxone*~~ shall complete and submit an Application for Pharmacist Certification for *Opioid Antagonist* ~~*Naloxone*~~ Dispensing, Form 1, with the board and provide the following:

- (a) Name;
- (b) Address;
- (c) Phone number; and
- (d) Pharmacist license number.

(2) The board shall issue the certification to a pharmacist within thirty (30) days of the receipt of the application.

Section 2. Procedures for Dispensing of *an Opioid Antagonist* ~~*Naloxone*~~. A pharmacist may initiate the dispensing of *an opioid antagonist* ~~*naloxone*~~ under the following conditions:

- (1) The pharmacist has met the requirements of Section 1 of this administrative regulation;
- (2) The pharmacist has received his or her certification;
- (3) The pharmacist has a physician-approved protocol that meets the minimum requirements of Section 3 of this administrative regulation; and
- (4) The pharmacist documents the dispensing event in the pharmacy management system including:
 - (a) Documentation as required in 201 KAR 2:171 for the dispensing of prescription medication; and
 - (b) Documentation that the individual receiving *an opioid antagonist* ~~*naloxone*~~ was provided with the required training and education pursuant to Section 4 of this administrative regulation, unless the recipient of the *opioid antagonist* ~~*Naloxone*~~ is a person or agency operating a harm reduction program.
- (5) A pharmacist may dispense *an opioid antagonist* ~~*naloxone*~~ to any person or agency who provides training on the mechanism and circumstances for the administration of *an opioid antagonist* ~~*naloxone*~~ to the public as part of a harm reduction program, regardless of whom the ultimate user of the *opioid antagonist* ~~*naloxone*~~ may be. The documentation of the dispensing of *an opioid antagonist* ~~*naloxone*~~ to any person or agency operating a harm reduction program shall satisfy any general documentation or recording requirements.

Section 3. Protocol Minimum Requirements. A physician-approved protocol authorizing a pharmacist to initiate the dispensing of *an opioid antagonist* ~~*naloxone*~~ shall contain:

- (1) Criteria for identifying persons or agencies eligible to receive *an opioid antagonist* ~~*naloxone*~~ under the protocol;
- (2) *Opioid antagonist* ~~*Naloxone*~~ products authorized to be dispensed, including:
 - (a) Name of product;
 - (b) Dose; and
 - (c) Route of administration;
- (3) Specific education to be provided to the person whom the *opioid antagonist* ~~*naloxone*~~ is dispensed;
- (4) Procedures for documentation of *opioid antagonist* ~~*naloxone*~~ dispensation, including procedures for notification of the physician authorizing the protocol, if desired by the physician in accordance with KRS 217.186(6)(b)3, (2) ~~[KRS 217.186(5)(b)3]~~;
- (5) The length of time the protocol is in effect;
- (6) The date and signature of the physician approving the protocol; ~~and~~
- (7) The names and work addresses of pharmacists authorized to initiate dispensing of *an opioid antagonist* ~~*naloxone*~~ under the protocol; ~~and~~
- (8) Authorization for *an opioid antagonist* ~~*naloxone*~~ to be supplied to an emergency department for dispensing under the protocol.

Section 4. Education to be Provided to Person Receiving *an Opioid Antagonist* ~~*Naloxone*~~ Prescription Under Protocol. Except as described in Section 2(5) of this administrative regulation ~~(5)(c)~~, a pharmacist dispensing *an opioid antagonist* ~~*naloxone*~~ to a person or agency not operating a harm reduction program shall provide verbal counseling and written educational materials appropriate to the dosage form of *an opioid antagonist* ~~*naloxone*~~ dispensed.

Section 5.

(1) ~~*Nothing shall prohibit*~~ A pharmacist may supply an opioid antagonist ~~*from supplying naloxone*~~ to an emergency department to be dispensed per the physician approved protocol ~~if~~ provided that :

- (a) ~~*If*~~ The pharmacist is providing the *opioid antagonist* ~~*naloxone*~~ from a pharmacy other than the institutional pharmacy, the pharmacy is under common ownership, or has a written service agreement with the hospital;
- (b) The *opioid antagonist* ~~*naloxone*~~ is stored in a locked drug storage area or automated pharmacy system;
- (c) Access to the *opioid antagonist* ~~*naloxone*~~ storage area is monitored and approved per a service agreement or hospital policy;
- (d) There is a monthly documented check of the *opioid antagonist* ~~*naloxone*~~ storage area for proper storage, labeling, educational ~~*education*~~ material, and expiration dating;
- (e) With the exception of patient name, the pharmacist labels the *opioid antagonist* ~~*naloxone*~~ in accordance with KRS 217.065 prior to supplying to the emergency department;
- (f) *An opioid antagonist* ~~*Naloxone*~~ from this supply is provided to the patient by a licensed health care provider as described in KRS 217.186(2);
- (g) The patient is provided written educational ~~*education*~~ materials appropriate to the dosage form of the opioid antagonist ~~*naloxone*~~ which includes the telephone number of the supplying pharmacy;
- (h) A record of each provision to a patient is communicated to the providing pharmacy and documented in the pharmacy management system; and
- (i) The dispensing record is reviewed by a pharmacist at the supplying pharmacy within one (1) pharmacy business day.

(2) Dispensing from an emergency drug stock shall not require a prospective drug use review.

Section 6. ~~{Section 5.}~~ Incorporation by Reference.

(1) "Application for Pharmacist Certification for Opioid Antagonist~~Naloxone~~ Dispensing", Form 1, ~~12/2022~~~~6/2024~~, is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m. or on the Web site at:

~~<https://pharmacy.ky.gov/Forms/Documents/Application%20for%20Pharmacist%20Certification%20for%20OPIOID%20ANTAGONIS>~~
~~<https://pharmacy.ky.gov/Documents/APPLICATION%20FOR%20PHARMACIST%20CERTIFICATION%20FOR%20A>~~

(41 Ky.R. 2691; Am. 42 Ky.R. 273 eff. 9-4-2015; 48 Ky.R. 101, 1112; eff. 10-20-2021; 49 Ky.R. 862, 1754; eff. 3-9-2023.)

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