BOARDS AND COMMISSIONER
Board of Pharmacy
(Amendment)

201 KAR 2:360. Naloxone dispensing.

RELATES TO: KRS 217.186
STATUTORY AUTHORITY: KRS 217.186, KRS 315.191(1)(a)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.186 requires the Board of Pharmacy to promulgate administrative regulations governing dispensing of 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 naloxone pursuant to a physician-approved protocol. This administrative regulation also provides the requirements for a pharmacy to stock naloxone to an emergency department.

Section 1. Certification.
(1) A pharmacist desiring to achieve certification to initiate the dispensing of naloxone shall complete and submit an Application for Pharmacist Certification for 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 Naloxone. A pharmacist may initiate the dispensing of 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 naloxone was provided with the required training and education pursuant to Section 4 of this administrative regulation, unless the recipient of the Naloxone is a person or agency operating a harm reduction program.
(5) A pharmacist may dispense naloxone to any person or agency who provides training on the mechanism and circumstances for the administration of naloxone to the public as part of a harm reduction program, regardless of whom the ultimate user of the naloxone may be. The documentation of the dispensing of 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 naloxone shall contain:
(1) Criteria for identifying persons or agencies eligible to receive naloxone under the protocol;
(2) 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 naloxone is dispensed;
(4) Procedures for documentation of 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);
(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 naloxone under the protocol.
(8) Authorization for naloxone to be supplied to an emergency department for dispensing under the protocol.

Section 4. Education to be Provided to Person Receiving Naloxone Prescription Under Protocol. Except as described in Section 5(e), a pharmacist dispensing 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 naloxone dispensed.

Section 5.
(1) Nothing shall prohibit a pharmacist from supplying naloxone to an emergency department to be dispensed per the physician approved protocol provided that:
(a) If the pharmacist is providing the 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 naloxone is stored in a locked drug storage area or automated pharmacy system;
(c) Access to the naloxone storage area is monitored and approved per a service agreement or hospital policy;
(d) There is a monthly documented check of the naloxone storage area for proper storage, labeling, education material, and expiration dating;
(e) With the exception of patient name, the pharmacist labels the naloxone in accordance with KRS 217.065 prior to supplying to the emergency department;
(f) 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 education materials appropriate to the dosage form of 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. Incorporation by Reference.
(1) "Application for Pharmacist Certification for Naloxone Dispensing", Form 1, 6/2021, 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/Documents/APPLICATION%20FOR%20PHARMACIST%20CERTIFICATION%20FOR%20NALOXONE%20I

CHRISTOPHER HARLOW, Pharm.D., Executive Director

APPROVED BY AGENCY: September 14, 2022

FILED WITH LRC: September 14, 2022 at 3:15 p.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall be held on November 30, 2022, at 9:00 a.m. Eastern Time via zoom teleconference and at the Kentucky Transportation Cabinet Auditorium, 200 Mero Street, Frankfort, Kentucky 40601. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through November 30, 2022. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

CONTACT PERSON: Christopher Harlow, Executive Director, Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, Frankfort, Kentucky 40601, phone (502) 564-7910, fax (502) 696-3806, email Christopher.harlow@ky.gov.