

1 GENERAL GOVERNMENT CABINET

2 KENTUCKY BOARD OF PHARMACY

3 (New Administrative Regulation)

4 201 KAR 2:360. Naloxone Dispensing.

5 RELATES TO: KRS 217.186

6 STATUTORY AUTHORITY: KRS 315.191, 217.186

7 NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.186 authorizes the Board
8 of Pharmacy to promulgate administrative regulations governing dispensing of naloxone
9 by a pharmacist pursuant to a physician-approved protocol. This administrative
10 regulation establishes the minimum requirements for the pharmacist to be able to
11 dispense naloxone pursuant to a physician-approval protocol.

12 Section 1. Certification. (1) A pharmacist desiring to achieve certification to initiate the
13 dispensing of naloxone shall complete and submit an "Application for Pharmacist
14 Certification for Naloxone Dispensing", Form 1, with the Board and provide the
15 following:

16 (a) Name;

17 (b) Address;

18 (c) Phone number;

19 (d) Pharmacist license number;

- 1 (e) Employer;
- 2 (f) Employer address; and
- 3 (g) Proof of education and training in the use and dispensing of naloxone for treatment of
- 4 opioid overdose pursuant to the requirements set forth in Section 5 of this administrative
- 5 regulation.
- 6 (2) The board shall issue the certification to a pharmacist who meets the requirements of
- 7 Section (1) of this section within thirty (30) days of the receipt of the application.
- 8 Section 2. Procedures for dispensing of naloxone. (1) A pharmacist is authorized to
- 9 initiate the dispensing of naloxone under the following conditions:
- 10 (a) The pharmacist has met the requirements of Section 1 of this administrative
- 11 regulation;
- 12 (b) The pharmacist has received his or her certification;
- 13 (c) The pharmacist has a physician-approved protocol that meets the minimum
- 14 requirements of Section 3 of this administrative regulation; and
- 15 (d) The pharmacist documents the dispensing event in the pharmacy management system
- 16 including:
- 17 1. Documentation as required in 201 KAR 2:170 for the dispensing of prescription
- 18 medication; and
- 19 2. Documentation that the individual receiving naloxone was provided with the required
- 20 training and education pursuant to Section 4 of this administrative regulation.
- 21 Section 3. Protocol minimum requirements. (1) A physician-approved protocol
- 22 authorizing a pharmacist to initiate the dispensing of naloxone shall contain:
- 23 (a) Criteria for identifying persons eligible to receive naloxone under the protocol;

1 (b) Naloxone products authorized to be dispensed shall include:

2 1. Name of product;

3 2. Dose; and

4 3. Route of administration.

5 (c) Specific education to be provided to the person whom the naloxone is dispensed;

6 (d) Procedures for documentation of naloxone dispensation, including:

7 1. Procedures for notification of the physician authorizing the protocol.

8 (e) The length of time the protocol is in effect;

9 (f) The date and signature of physician approving protocol; and

10 (g) The names and work addresses of pharmacist(s) authorized to initiate dispensing of
11 naloxone under the protocol.

12 Section 4. Education to be provided to person receiving naloxone prescription under
13 protocol. (1) A pharmacist dispensing naloxone to a person shall provide verbal
14 counseling and written educational materials, appropriate to the dosage form of naloxone
15 dispensed, including:

16 (a) Risk factors of opioid overdose;

17 (b) Strategies to prevent opioid overdose;

18 (c) Signs of opioid overdose;

19 (d) Steps in responding to an overdose;

20 (e) Information on naloxone;

21 (f) Procedures for administering naloxone; and

22 (g) Proper storage and expiration of naloxone product dispensed.

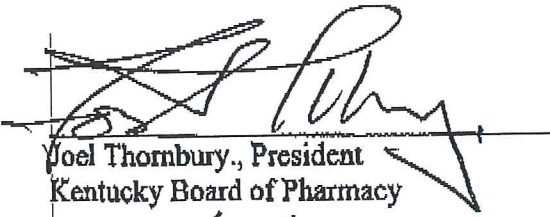
1 Section 5. Pharmacist education and training required for certification. (1) A pharmacist
2 who applies for certification to initiate dispensing of naloxone shall have received
3 education and training related to the safe dispensing of opioids and use of naloxone as
4 rescue therapy for opioid overdose, including:

- 5 (a) Risk factors for opioid abuse and overdose;
- 6 (b) Opioid overdose prevention;
- 7 (c) Recognizing and responding to opioid overdoses;
- 8 (d) Indications for use of naloxone as rescue therapy;
- 9 (e) Contraindications for use of naloxone;
- 10 (f) Administration of naloxone;
- 11 (g) Adverse effects associated with naloxone rescue therapy;
- 12 (h) Identification of a patient who meets the criteria for provision of naloxone;
- 13 (i) Required education to provide to persons receiving naloxone;
- 14 (j) Required elements of protocol to initiate dispensing of naloxone, and
- 15 (k) Required documentation when initiating dispensing of naloxone.

16 Section 6. (1) Incorporated by Reference. The following is incorporated by reference:

- 17 (a) “Application for Pharmacist Certification for Naloxone Dispensing”, Form 1 5/2015.

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


Joel Thornbury., President
Kentucky Board of Pharmacy
Date: 5/13/2015

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held on Monday June 22, 2015 at 9:30 a.m. at the Board's office located at State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601. Individuals interested in attending this hearing shall notify this agency in writing by five workdays prior to this hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be cancelled.

This hearing is open to the public. Any person 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 attend the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted until 11:59 p.m. Tuesday June 30, 2015.

Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to: Michael Burleson, Executive Director, Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky, 40601; Telephone No. (502) 564-7910; Facsimile No. (502) 696-3806.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

201 KAR 2:360. Naloxone Dispensing
Contact person: Michael Burleson

(1) Provide a brief summary of:

- (a) What this administrative regulation does: This administrative regulation allows a pharmacist that has received certification from the Board of Pharmacy to dispense naloxone pursuant to a physician-approved protocol.
- (b) The necessity of this administrative regulation: This regulation is necessary to comply with SB192.
- (c) How this administrative regulation conforms to the content of the authorizing statutes: The regulation is in conformity with the authorizing statute that authorizes the board to promulgate administrative regulations that establishes the requirements for a pharmacist to dispense naloxone pursuant to a physician-approved protocol.
- (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This regulation will set the requirements for a pharmacist to dispense naloxone pursuant to a physician-approved protocol.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

- (a) How the amendment will change this existing administrative regulation: *N/A*
- (b) The necessity of the amendment to this administrative regulation: *N/A*
- (c) How the amendment conforms to the content of the authorizing statutes: *N/A*
- (d) How the amendment will assist in the effective administration of the statutes: *N/A*

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The board anticipates 500 pharmacists annually will be affected by this administrative regulation.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

- (a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: A pharmacist will apply to receive certification from the Board to dispense naloxone pursuant to a physician-approved protocol. (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): None.
- (c) As a result of compliance, what benefits will accrue to the entities identified in question (3): A pharmacist will be able to dispense naloxone

pursuant to a physician-approved protocol to assist those individuals that have an opioid overdose.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:

(a) Initially: None

(b) On a continuing basis: None

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: None required.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: None.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: No fees will be established.

(9) TIERING: Is tiering applied? (Explain why tiering was or was not used) Tiering was not applied as the regulation is applicable any pharmacist applying for certification to dispense naloxone pursuant to a physician-approved protocol.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 201 KAR 2:360

Contact Person: Michael Burleson
(502) 564-7910

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Board of Pharmacy will be impacted by this administrative regulation.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. 2015 RS SB 192 and KRS 315.191 requires or authorizes the action taken by this administrative regulation.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? None

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? None

(c) How much will it cost to administer this program for the first year? None

(d) How much will it cost to administer this program for subsequent years? None

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

Revenues: The Board anticipates no revenues.

Expenditures: The Board anticipates no expenditures.

SUMMARY OF MATERIAL INCORPORATED BY REFERENCE

201 KAR 2:360. Pharmacist Certification for Dispensing Naloxone

“APPLICATION FOR PHARMACIST DISPENSING NALOXONE” (5-2015)

This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky, 40601, 8:00 a.m. to 4:30 p.m. This material may also be inspected or copied on the Board’s website: www.pharmacy.ky.gov. If you have questions, please contact the Board at 502-564-7985.

“Application for Pharmacist for Dispensing Naloxone Pursuant to a Physician-Approved Protocol” Form 1 (7/2012)

- (a) This application is for certification for a pharmacist to dispense naloxone pursuant to a physician-approved protocol. This application requires the name, address, phone number, pharmacist license number, employer name, employer address, and proof of education and training in the use and dispensing of naloxone for treatment of opioid overdose pursuant to the requirements set forth in Section 5 of this administrative regulation.
- (b) 2015 RS SB 192 and KRS 315.191 provide the board authorization to promulgate this regulation.
- (c) This application is one (1) page.

Kentucky Board of Pharmacy
State Office Building Annex, Suite 300
125 Holmes Street
Frankfort, KY 40601
Phone 502-564-7910 Fax 502-696-3806



APPLICATION FOR PHARMACIST CERTIFICATION FOR NALOXONE DISPENSING

Incomplete or illegible applications will be returned to applicant for correction.

Name _____ RPh License No _____

Street _____ Home Phone _____

City _____ County _____ State _____ Zip _____

E-mail Address _____ Birthdate _____ Social Security Number XXX-XX-_____

Primary Place of Employment: [Please provide secondary places of employment on additional sheet and attach.]

Pharmacy/Business Name _____

Kentucky Pharmacy Permit Number _____ Phone No. _____

INCLUDE WITH YOUR APPLICATION IS PROOF OF EDUCATION AND TRAINING IN THE USE AND DISPENSING OF NALOXONE SET FORTH IN 201 KAR 2:360.

THE APPLICATION MUST BE DATED AND SIGNED.

DATE

SIGNATURE