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**LEGISLATIVE RESEARCH COMMISSION**

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**MEMORANDUM**

TO: Larry Hadley, Executive Director, Kentucky Board of Pharmacy

FROM: Emily Caudill, Regulations Compiler

RE: Proposed Amendment or New Regulation – 201 KAR 002:360

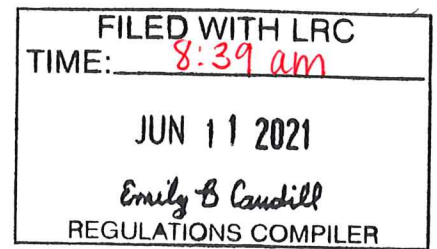
DATE: June 11, 2021

A copy of the administrative regulation listed above is enclosed for your files. This regulation is **tentatively** scheduled for review by the Administrative Regulation Review Subcommittee at its **September 2021** meeting. We will notify you of the date and time of this meeting once it has been scheduled.

Pursuant to KRS 13A.280, **if** comments are received during the public comment period, a Statement of Consideration or a one-month extension request for this regulation is due **by noon on September 15, 2021**. Please reference KRS 13A.270 and 13A.280 for other requirements relating to the public hearing and public comment period and Statements of Consideration.

If you have questions, please contact us at [RegsCompiler@LRC.ky.gov](mailto:RegsCompiler@LRC.ky.gov) or (502) 564-8100.

Enclosures



1 BOARDS AND COMMISSIONS

2 Kentucky Board of Pharmacy

3 (Amendment)

4 201 KAR 2:360. Naloxone dispensing.

5 RELATES TO: KRS 217.186

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

7 NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.186 requires the Board of  
8 Pharmacy to promulgate administrative regulations governing dispensing of naloxone  
9 by a pharmacist pursuant to a physician-approved protocol. This administrative regula-  
10 tion establishes the minimum requirements for the pharmacist to be able to dispense  
11 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 Certifi-  
14 cation for Naloxone Dispensing, Form 1, with the board and provide the following:

15 (a) Name;

16 (b) Address;

17 (c) Phone number; and

18 (d) Pharmacist license number.

19 ~~(e) Proof of education and training in the use and dispensing of naloxone for treatment~~  
20 ~~of opioid overdose pursuant to Section 5 of this administrative regulation.~~

1 (2) The board shall issue the certification to a pharmacist ~~who meets the requirements~~  
2 ~~of subsection (1) of this section~~ within thirty (30) days of the receipt of the application.

3  
4 Section 2. Procedures for Dispensing of Naloxone. A pharmacist may initiate the dis-  
5 pensing of naloxone under the following conditions:

6 (1) The pharmacist has met the requirements of Section 1 of this administrative regula-  
7 tion;

8 (2) The pharmacist has received his or her certification;

9 (3) The pharmacist has a physician-approved protocol that meets the minimum re-  
10 quirements of Section 3 of this administrative regulation; and

11 (4) The pharmacist documents the dispensing event in the pharmacy management sys-  
12 tem including:

13 (a) Documentation as required in 201 KAR 2:~~1711470~~ for the dispensing of prescription  
14 medication; and

15 (b) Documentation that the individual receiving naloxone was provided with the required  
16 training and education pursuant to Section 4 of this administrative regulation, unless the  
17 recipient of the Naloxone is a person or agency operating a harm reduction program.

18 (5) The pharmacist may dispense naloxone to any person or agency who provides train-  
19 ing on the mechanism and circumstances for the administration of naloxone to the pub-  
20 lic as part of a harm reduction program, regardless of whom the ultimate user of the na-  
21 loxone may be. The documentation of the dispensing of naloxone to any person or  
22 agency operating a harm reduction program shall satisfy any general documentation or  
23 recording requirements.

1 Section 3. Protocol Minimum Requirements. A physician-approved protocol authorizing  
2 a pharmacist to initiate the dispensing of naloxone shall contain:

3 (1) Criteria for identifying persons or agencies eligible to receive naloxone under the  
4 protocol;

5 (2) Naloxone products authorized to be dispensed, including:

6 (a) Name of product;

7 (b) Dose; and

8 (c) Route of administration;

9 (3) Specific education to be provided to the person whom the naloxone is dispensed;

10 (4) Procedures for documentation of naloxone dispensation, including procedures for  
11 notification of the physician authorizing the protocol, if desired by the physician in ac-  
12 cordance with KRS 217.186(5)(b)3;

13 (5) The length of time the protocol is in effect;

14 (6) The date and signature of the physician approving the protocol; and

15 (7) The names and work addresses of pharmacists authorized to initiate dispensing of  
16 naloxone under the protocol.

17

18 Section 4. Education to be Provided to Person Receiving Naloxone Prescription Under  
19 Protocol. A pharmacist dispensing naloxone to a person or agency not operating a harm  
20 reduction program shall provide verbal counseling and written educational materials,  
21 appropriate to the dosage form of naloxone dispensed, including:

22 —(1) ~~Risk factors of opioid overdose;~~

23 —(2) ~~Strategies to prevent opioid overdose;~~

- 1    ~~—(3) Signs of opioid overdose;~~
- 2    ~~—(4) Steps in responding to an overdose;~~
- 3    ~~—(5) Information on naloxone;~~
- 4    ~~—(6) Procedures for administering naloxone; and~~
- 5    ~~—(7) Proper storage and expiration of naloxone product dispensed.~~

6

7    ~~Section 5. Pharmacist Education and Training Required for Certification. A pharmacist~~  
8    ~~who applies for certification to initiate dispensing of naloxone shall have received edu-~~  
9    ~~cation and training related to the safe dispensing of opioids and use of naloxone as res-~~  
10   ~~cue therapy for opioid overdose, including:~~

- 11   ~~—(1) Risk factors for opioid abuse and overdose;~~
- 12   ~~—(2) Opioid overdose prevention;~~
- 13   ~~—(3) Recognizing and responding to opioid overdoses;~~
- 14   ~~—(4) Indications for use of naloxone as rescue therapy;~~
- 15   ~~—(5) Contraindications for use of naloxone;~~
- 16   ~~—(6) Administration of naloxone;~~
- 17   ~~—(7) Adverse effects associated with naloxone rescue therapy;~~
- 18   ~~—(8) Identification of a patient who meets the criteria for provision of naloxone;~~
- 19   ~~—(9) Required education to provide to persons receiving naloxone;~~
- 20   ~~—(10) Required elements of protocol to initiate dispensing of naloxone; and~~
- 21   ~~—(11) Required documentation when initiating dispensing of naloxone.~~

22

23   ~~Section 6. Incorporation by Reference. (1) "Application for Pharmacist Certification for~~

1 Naloxone Dispensing", Form 1, 6//2021 ~~7/2015~~, is incorporated by reference.

2 (2) This material may be inspected, copied, or obtained, subject to applicable copy-  
3 right law, at the Kentucky Board of Pharmacy, 125 Holmes Street, , Suite 300, State  
4 Office Building Annex, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to  
5 4:30 p.m. or on the website at:

6 [https://pharmacy.ky.gov/Documents/APPLICATION%20FOR%20PHARMACIST%20CE](https://pharmacy.ky.gov/Documents/APPLICATION%20FOR%20PHARMACIST%20CERTIFICATION%20FOR%20NALOXONE%20DISPENSING.pdf)  
7 [RTIFICATION%20FOR%20NALOXONE%20DISPENSING.pdf](https://pharmacy.ky.gov/Documents/APPLICATION%20FOR%20PHARMACIST%20CERTIFICATION%20FOR%20NALOXONE%20DISPENSING.pdf)



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LARRY A. HADLEY, R.Ph.  
Executive Director  
Kentucky Board of Pharmacy

June 11, 2021

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DATE

## PUBLIC HEARING AND PUBLIC COMMENT PERIOD

A public hearing on this administrative regulation shall be held on August 31, 2021 at 9:00 a.m. Eastern Time at the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, 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 August 31, 2021. 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: Larry Hadley, 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 [Larry.Hadley@ky.gov](mailto:Larry.Hadley@ky.gov).



REGULATORY IMPACT ANALYSIS  
AND TIERING STATEMENT

1 **201 KAR 2:360. Naloxone dispensing**

Contact person: Larry Hadley

Contact Phone No.: 502-564-7910

Contact email: [larry.hadley@ky.gov](mailto:larry.hadley@ky.gov)

1. Provide a brief summary of:

a. What this administrative regulation does:

- This administrative regulation amendment establishes the minimum requirements for the pharmacist to be able to dispense naloxone pursuant to a physician-approval protocol to an individual or an agency.

b. The necessity of this administrative regulation:

- This administrative regulation amendment is necessary pursuant to changes made in KRS 217.186 allowing for the dispensing of naloxone to agencies.
- This administrative regulation amendment enables the dispensing of naloxone as part of a harm reduction program.

c. How this administrative regulation conforms to the content of the authorizing statutes:

- This administrative regulation amendment, authorized by KRS 217.186, establishes the minimum requirements for the pharmacist to dispense naloxone pursuant to a physician-approval protocol.

d. How this administrative regulation currently assists or will assist in the effective administration of the statutes:

- KRS 217.186 enables the Board of Pharmacy to promulgate an administrative regulation to identify the appropriate certification and procedures for the dispensing of naloxone by a pharmacist to an individual or an agency.

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:

- This amendment authorizes a pharmacist to dispense naloxone to any person or agency for administration to the public as part of a harm reduction program. Moreover, this amendment removes the educational requirement for pharmacist certification to dispense naloxone.

b. The necessity of the amendment to this administrative regulation:

- This amendment is necessary to conform to the language in KRS 217.186 regarding the ability for a pharmacy to dispense to an agency.

- c. How the amendment conforms to the content of the authorizing statutes:
    - 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.
  - d. How the amendment will assist in the effective administration of the statutes:
    - The amendment will further promote, preserve, and protect public health through effective regulation of pharmacists and pharmacies by identifying the minimum requirements to dispense naloxone pursuant to a physician-approval protocol.
3. List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation:
- The board anticipates pharmacists, individual persons, and agencies will be minimally impacted by this regulation amendment. This amendment removes the educational requirements necessary for a pharmacist to become naloxone certified.
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:
    - Pharmacists, individual persons, and agencies will have to familiarize themselves with the amended language.
    - This regulation amendment provides greater authorization to pharmacists by removing the educational requirement for pharmacist certification and allowing for the dispensing of naloxone to agencies.
    - The board will help educate identified entities of these changes.
  - b. In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):
    - There are no expected costs for the entities identified to comply with the amendment.
  - c. As a result of compliance, what benefits will accrue to the entities identified in question (3).
    - This amendment will provide pharmacists with a heightened ability to combat the opioid epidemic by authorizing pharmacists to dispense naloxone to agencies as part of a harm reduction program.
5. Provide an estimate of how much it will cost to implement this administrative regulation:

- a. Initially: No costs will be incurred.
- b. On a continuing basis: No costs will be incurred.

6. What is the source of the funding to be used for the implementation and enforcement of this administrative regulation:

- Board revenues from pre-existing fees provide the funding to enforce the regulation.

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:

- No increase in fees or funding will be required because of this new regulation.

8. State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

- This administrative regulation does not establish fees or directly or indirectly increase any fees.

9. TIERING: Is tiering applied? (Explain why tiering was or was not used)

- Tiering is not applied because this regulation is applicable to all pharmacists, individual persons, and agencies which seek to dispense naloxone as part of a harm reduction program.

## FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

### **201 KAR 2:360. Naloxone dispensing**

Contact person: Larry Hadley

Contact Phone No.: 502-564-7910

Contact email: [larry.hadley@ky.gov](mailto:larry.hadley@ky.gov)

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?

- Pharmacies and private and public agencies will be impacted by this administrative regulation amendment.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation.

- KRS 217.186, KRS 315.191(1)(a).

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?

- This administrative regulation will not generate revenue for the Board in the first year.

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?

- This administrative regulation will not generate revenue for the Board in subsequent years.

c. How much will it cost to administer this program for the first year?

- No costs are required to administer this program for the first year.

d. How much will it cost to administer this program for subsequent years?

- No costs are required to administer this program for subsequent years.

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

Revenues (+/-): 0

Expenditures (+/-): 0

## SUMMARY OF MATERIAL INCORPORATED BY REFERENCE

The "Application for Naloxone Certification", Form 5-2021, is the 1-page form that pharmacists need to file with the Board of Pharmacy if they are seeking certification to dispense naloxone pursuant to a prescriber-approved protocol. KRS 217.186 requires pharmacists that dispense naloxone pursuant to a prescriber-approved protocol to be certified.

## SUMMARY OF CHANGES TO MATERIAL INCORPORATED BY REFERENCE

The only change made is to remove the proof of education and training in the use and dispensing of naloxone as set forth in 201 KAR 2:360 statement.