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MEMORANDUM

TO: Eden S. Davis, General Counsel, Kentucky Board of Pharmacy

FROM: Emily Caudill, Regulations Compiler

RE: Proposed Amendment or New Regulation – 201 KAR 002:420

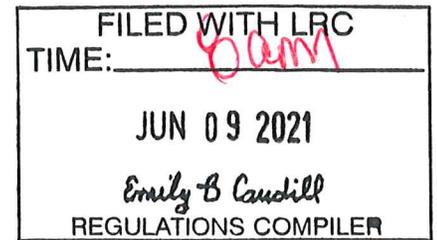
DATE: June 9, 2021

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 or (502) 564-8100.

Enclosures



1 BOARDS AND COMMISSIONS

2 Kentucky Board of Pharmacy

3 (New Ordinary Regulation)

4 201 KAR 002:420. Administration of Vaccines.

5 RELATES TO: KRS 315.010, KRS 315.136, KRS 315.050

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

7 NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the

8 board to promulgate administrative regulations relating to pharmacists, pharmacist

9 interns, and pharmacy technicians. This administrative regulation authorizes pharmacist

10 interns, and pharmacy technicians to administer vaccinations pursuant to requirements.

11 This regulation does not change the authorization for pharmacist to administer

12 vaccinations pursuant to KRS 315.010(22).

13

14 Section 1. Definitions.

15 (1) "Administer" is defined by KRS 315.010(1).

16 (2) "Pharmacist" is defined by KRS 315.010(17).

17 (3) "Pharmacist intern" is defined by KRS 315.010(18).

18 (4) "Pharmacy technician" is defined by KRS 315.010(21).

1 Section 2. Pharmacist Requirements. A pharmacist may administer a vaccine to an
2 individual pursuant to the Advisory Committee on Immunization Practices (ACIP)
3 standard immunization schedule in accordance with KRS 315.010(22).

4

5 Section 3. Pharmacist Intern Requirements. A pharmacist intern under the general
6 supervision of a pharmacist may administer a vaccine to an individual if the pharmacist
7 intern:

8 (1) Completes, or has completed as part of pharmacy school curriculum, a practical
9 training program accredited by the Accreditation Council for Pharmacy Education
10 (ACPE) that includes hands-on injection technique and the recognition and treatment of
11 emergency reactions to vaccines; and

12 (2) Possesses a current certificate in basic cardiopulmonary resuscitation.

13

14 Section 4. Pharmacy Technician Requirements. A pharmacy technician may administer
15 a vaccine under the general supervision of a pharmacist to an individual if the pharmacy
16 technician:

- 1 (1) Completes a minimum of two (2) hours of immunization-related continuing education
- 2 accredited by the Accreditation Council for Pharmacy Education (ACPE) per each state
- 3 registration period;
- 4 (2) Completes, or has completed, a practical training program accredited by the
- 5 Accreditation Council for Pharmacy Education (ACPE) that includes hands-on injection
- 6 technique and the recognition and treatment of emergency reactions to vaccines; and
- 7 (3) Possesses a current certificate in basic cardiopulmonary resuscitation.



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

June 8, 2021

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.

REGULATORY IMPACT ANALYSIS
AND TIERING STATEMENT

201 KAR 002:420, Administration of Vaccines

Contact person: Larry Hadley

Contact Phone No.: 502-564-7910

Contact email: larry.hadley@ky.gov

1. Provide a brief summary of:

a. What this administrative regulation does:

- This administrative regulation establishes that pharmacists, pharmacist interns, and pharmacy technicians may administer vaccinations pursuant to specific requirements.

b. The necessity of this administrative regulation: KRS 315.191(1)(a) authorizes the Board of Pharmacy to promulgate administrative regulations and control all matters relating to pharmacists, pharmacist interns, and pharmacy technicians. This administrative regulation establishes that pharmacists, pharmacist interns, and pharmacy technicians may administer vaccinations pursuant to specific requirements.

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

- KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations necessary to regulate and control all matters relating to pharmacists, pharmacist interns, and pharmacy technicians. This new administrative regulation establishes that pharmacists, pharmacist interns, and pharmacy technicians may administer vaccinations pursuant to specific requirements.

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

- This new administrative regulation, authorized by KRS 315.191(1)(a), identifies the appropriate curriculum, training, and certification required to administer vaccinations.

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 government affected by this administrative regulation:

- The board anticipates pharmacies, pharmacists, pharmacist interns, and pharmacy technicians will be impacted by this regulation, but this regulation does not force any licensee or registrant to administer vaccinations, it simply authorizes the practice pursuant to specific requirements for those interested in administering vaccinations.

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, pharmacist interns, and pharmacy technicians will have to familiarize themselves with new administrative regulation.
- The entities identified will have to complete the required curriculum, training, and certification in accordance with new administrative regulation if they seek to administer vaccinations.
- The board will assist in educating pharmacies, pharmacists, pharmacist interns, and pharmacy technicians of this new administrative regulation.

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 new regulation will provide pharmacist interns and pharmacy technicians the ability to administer vaccinations by completing the required curriculum, training, and certification identified.

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 the regulation is applicable to all pharmacists, pharmacist interns, and pharmacy technicians who wish to administer vaccinations.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

201 KAR 002:420, Administration of Vaccines

Contact person: Larry Hadley

Contact Phone No.: 502-564-7910

Contact email: 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?

- Pharmacists, pharmacist interns, and pharmacy technicians will be affected minimally by this new regulation.

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

- 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