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MEMORANDUM

To: Christopher Harlow, Executive Director, Kentucky Board of Pharmacy

FROM: Emily Caudill, Regulations Compiler

RE: Acknowledgement of Emergency Regulation – 201 KAR 002:414E.

DATE: March 22, 2023

A copy of the above listed emergency administrative regulation is enclosed for your files. This emergency administrative regulation became effective on **March 22, 2023** and will expire in 270 days on **December 17, 2023** or when replaced by an ordinary administrative regulation, whichever occurs first.

This emergency administrative regulation is scheduled to be reviewed by the Administrative Regulation Review Subcommittee at its **June 2023**, meeting.

Pursuant to KRS 13A.280, **if** a public hearing is held or you receive written comments on this emergency administrative regulation, the Statement of Consideration for this emergency regulation is due by noon on **June 15, 2022**. Please reference KRS 13A.270 and 13A.280 for other requirements relating to public comment periods and Statements of Consideration.

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

Enclosure


FILED WITH LRC
TIME: 11:20 AM
MAR 22 2023
Emily B. Conhill
REGULATIONS COMPILER

STATEMENT OF EMERGENCY
201 KAR 002:414E

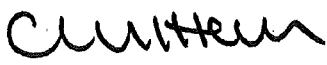
This emergency administrative regulation establishes requirements that the Board of Pharmacy shall implement to comply with 42 U.S.C. 247d-6d, 85 Fed. Reg. 15198, 52136 and 86 Fed. Reg. 9516, 10588, 14462 and 41977. These provisions of federal law preempt state law during the public health emergency (PHE). Since March 18, 2020, ten (10) amendments to the Prep Act declaration have been issued, including amendments authorizing pharmacists to prescribe and administer COVID-19 vaccines for individuals as young as three (3). The PHE for COVID-19 is scheduled to end on May 11, 2023, and under section V(d) and (f) and under section VII(b) of the PREP Act declaration, the expanded authority for pharmacists will expire at that point. This statement of emergency is limited from filing until the end of the federal public health emergency.

This emergency administrative regulation is necessary, pursuant to KRS 13A.190(1)(a)3 and 4, to ensure continued compliance with federal law and to ensure that Kentucky continues to have an ample pool of pharmacists available to order and administer the COVID-19 vaccine. Without this emergency regulation, many Kentucky-licensed pharmacists would become ineligible to order and to administer the COVID-19 vaccine because they do not meet federal training requirements. So long as the state has a training requirement, compliance with the state training requirement is sufficient to comply with federal law. Without this emergency administrative regulation, there is no state training requirement.

An ordinary administrative regulation is not a sufficient avenue to address the current emergency due to the COVID-19 pandemic being temporary. This emergency administrative regulation will not be replaced by an ordinary administrative regulation.



Andy Beshear, Governor



Christopher Harlow, PharmD
Executive Director

1 BOARDS AND COMMISSIONS

2 Kentucky Board of Pharmacy

3 Board of Pharmacy

4 (New Emergency Administrative Regulation)

5 201 KAR 002:414E. Ordering and administering vaccinations.

6 RELATES TO: KRS 315.010, 315.020, 315.050, 315.065, 315.135, 315.205, 42 U.S.C.

7 247d-6d, 85 Fed. Reg. 15198, 52136, 79190, 86 Fed. Reg. 7872, 9516, 10588, 14462,

8 and 41977.

9 STATUTORY AUTHORITY: KRS 315.191

10 NECESSITY, FUNCTION, AND CONFORMITY: 85 Fed. Reg. 15198, 85 Fed. Reg.

11 52136 and 6 Fed. Reg. 9516, 10588, and 41977, require the Board of Pharmacy to

12 promulgate an administrative regulation to conform state law to federal law while the

13 PREP Act declaration remains in effect for COVID-19. KRS 315.010(22) does not

14 authorize pharmacists to prescribe vaccinations, nor does KRS 315.010(22) authorize

15 the use of prescriber-approved protocols for pharmacists or pharmacist interns to

16 administer vaccinations to children under the age of nine (9). 85 Fed. Reg. 52136

17 requires that state-licensed pharmacists be authorized to prescribe and to administer

18 vaccinations to children between the ages of three (3) and seventeen (17). 85 Fed. Reg.

19 79190 requires that state law establish a training requirement for all pharmacists that

1 will be ordering or administering vaccinations pursuant to the declaration. The Prep Act
2 (42 U.S.C. 247d-6d(8)) preempts any state law that would prohibit or effectively prohibit
3 activities authorized by the secretary in a PREP Act Declaration. This administrative
4 regulation establishes requirements for Kentucky to comply with 85 Fed. Reg. 15198,
5 52136, 79190 and 86 Fed. Reg. 7872, 9516, 10588, 14462, and 41977 and ensures a
6 robust pool of pharmacist for prescribing and administering vaccines.

7 Section 1. Definitions.

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

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

10 (3) "Prescribe" means to issue an original or new order from a pharmacist for an FDA-
11 approved or authorized vaccination or medication, including but not limited to,
12 epinephrine, diphenhydramine, and corticosteroids for the emergency treatment of
13 acute vaccine reactions.

14 Section 2. Pharmacist Requirements.

15 (1) A pharmacist may administer a vaccine to an individual pursuant to the Advisory
16 Committee on Immunization Practices (ACIP) standard immunization schedule in
17 accordance with KRS 315.010(22).

18 (2) A pharmacist may administer a vaccine to a child, age three (3) through eight (8),
19 pursuant to a prescriber-approved protocol.

20 (3) A pharmacist may prescribe and administer a vaccine to an individual eighteen (18)
21 and under, pursuant to the ACIP standard immunization schedule, a seasonal flu
22 vaccine to any individual aged nineteen and over, a COVID-19 vaccine to any

1 individual, and medications necessary for the emergency treatment of acute vaccine
2 reactions, if the pharmacist:

3 (a) Completes or has completed practical training on administering vaccinations. This
4 may include:

5 1. Completion of a practical training program from an education provider accredited by
6 the Accreditation Council for Pharmacy Education (ACPE) that includes hands-on
7 injection technique and the recognition and emergency treatment of acute reactions;

8 2. Graduation from an ACPE accredited pharmacy school in which hands-on
9 immunization training was part of the curriculum; or

10 3. Training via hands-on experience immunizing in current or previous pharmacy
11 practice; and

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

13 (4) No provision in this regulation affects the ability of a pharmacist to administer a
14 vaccination to any individual pursuant to a prescription drug order.

15 Section 3. Effective Date.

16 (1) This administrative regulation shall become effective at 5 p.m. on the date it is filed.

17 (2) In accordance with KRS 13A.190, this administrative regulation shall remain in effect
18 until:

19 (a) Expiration of the time period established by KRS 13A.190; or

20 (b) Withdrawn in accordance with KRS 13A.190(12).

21 (3) The Board of Pharmacy shall regularly consult with the Governor's Office, the

22 Centers for Disease Control and Prevention, and other public health authorities to

- 1 determine if this administrative regulation shall be withdrawn prior to its expiration under
- 2 KRS 13A.190.

Christopher P. Harlow

March 16, 2023

CHRISTOPHER P. HARLOW,
Executive Director
Kentucky Board of Pharmacy

DATE

PUBLIC HEARING AND PUBLIC COMMENT PERIOD

A public hearing on this administrative regulation shall be held on May 24, 2023, at 10:00 a.m. Eastern Time at the Kentucky Board of Pharmacy's conference room, 125 Holmes St., Third Floor, 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. 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 May 31, 2023. 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.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

201 KAR 2:414E. Ordering and administering vaccinations.

Contact person: Christopher Harlow

Contact Phone No.: 502-564-7910

Contact email: Christopher.harlow@ky.gov

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation authorizes pharmacists to order and to administer vaccinations to individual three (3) and older, pursuant to specific requirements.

(b) The necessity of this administrative regulation: The administrative regulation is necessary to comply with federal regulation and to ensure the health and safety of the citizens of the Commonwealth. This administrative regulation is necessary to limit the training requirements for pharmacists so that the federal default training requirement is not imputed to Kentucky pharmacists. If that were to occur, the majority of Kentucky pharmacists would not be authorized to administer the COVID-19 vaccine.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 315.191 authorizes the Board of Pharmacy to promulgate regulations to regulate and control all matters relating to pharmacists, pharmacies, pharmacist interns and pharmacy technicians. This emergency regulation relates to pharmacist authority to order and administer vaccinations.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation will allow for vaccinations that are recommended by the Advisory Committee on Immunization Practices' (ACIP) standard immunization schedule, including COVID-19 vaccinations and seasonal flu vaccinations to be ordered and administered by a greater number of individuals.

(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 is a new emergency administrative regulation.

(b) The necessity of the amendment to this administrative regulation: This is a new emergency administrative regulation.

(c) How the amendment conforms to the content of the authorizing statutes: This is a new emergency administrative regulation.

(d) How the amendment will assist in the effective administration of the statutes: This is a new emergency administrative regulation.

(3) List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation: This regulation impacts any pharmacist that desires to order or administer vaccinations to individuals three (3) and up.

(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: There is no requirement for pharmacists to prescribe or to administer vaccinations; however, this administrative regulation provides pharmacists with an authorization to prescribe and to administer vaccinations pursuant to this administrative regulation's requirements. Should the pharmacist choose to order or to administer vaccinations, the pharmacist shall meet the conditions set forth in this regulation, including completing a training, being CPR certified and other conditions specifically enumerated.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): This administrative regulation does not require pharmacists to prescribe or to administer vaccinations and therefore this administrative regulation does not create any cost to the potentially impacted individuals. However, should the pharmacist choose to prescribe or to administer vaccinations, those individuals will have the cost of training and the cost of becoming CPR certified, if they are not already.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3). The ability to vaccinate more individuals aged three (3) and up. This will improve vaccination rates.

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

- a. Initially: No cost to the administrative body.
- b. On a continuing basis: No cost to the administrative body.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The Board of Pharmacy will inspect pharmacies and pharmacist practice to ensure compliance with this emergency administrative regulation. The Board of Pharmacy already employs inspectors, and this regulation will not increase any cost of enforcement for the Board of Pharmacy.

(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: There will be no increase in fees or funding necessary to implement this 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 any fees directly or indirectly.

(9) TIERING: Is tiering applied? (Explain why tiering was or was not used)
Tiering is not applied, as this administrative regulation does not mandate that any pharmacist prescribe or administer vaccines, it simply provides an opportunity for those qualified individuals to do so if they choose.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

201 KAR 2:414E. Ordering and administering vaccinations.

Contact person: Christopher Harlow

Contact Phone No.: 502-564-7910

Contact email: Christopher.harlow@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?

There will be no impact on local or state government outside of the Board of Pharmacy's enforcement of the regulation.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. 42 U.S.C. 247d-6d, 85 Fed. Reg. 15198, 85 Fed. Reg. 52136, 86 Fed. Reg. 9516, 10588, 14462 and 41977.

(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. There will be no effect on the expenditures and revenue of a state or local government agency.

(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 any revenue for the state or local government.

(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 regulation will not generate revenue.

(c) How much will it cost to administer this program for the first year? There will be no cost to administer this regulation.

(d) How much will it cost to administer this program for subsequent years? This regulation will not generate costs.

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

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect? There will be no impact on the expenditures or cost savings of regulated entities. The Board does not require any action in this regulation, it only permits action.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year? There will be no impact on the expenditures or cost savings of regulated entities. The Board does not require any action in this regulation, it only permits action.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years? There will be no impact on the expenditures or cost savings of regulated entities. The Board does not require any action in this regulation, it only permits action.

(c) How much will it cost the regulated entities for the first year? There will be no impact on the expenditures or cost savings of regulated entities. The Board does not require any action in this regulation, it only permits action.

(d) How much will it cost the regulated entities for subsequent years? There will be no impact on the expenditures or cost savings of regulated entities. The Board does not require any action in this regulation, it only permits action.

Cost Savings (+/-): 0

Expenditures (+/-): 0

(5) Explain whether this administrative regulation will have a major economic impact, as defined below. "Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars (\$500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)] This administrative regulation will not have a major economic impact.

FEDERAL MANDATE ANALYSIS COMPARISON

201 KAR 2:414E Ordering and administering vaccinations.

Contact Person: Christopher Harlow, phone (502) 564-7910, email christpher.harlow@ky.gov.

(1) Federal statute or regulation constituting the federal mandate. 42 U.S.C. 247d-6d, 85 Fed. Reg. 15198, 85 Fed. Reg. 52136, 86 Fed. Reg. 9516, 10588, 14462 and 41977. This is an emergency federal mandate only in effect during the federal declaration under the PREP Act and during the federal Public Health Emergency (PHE) for COVID-19 and is scheduled to expire on May 11, 2023. At the expiration of the PHE, the Board will withdraw this emergency administrative regulation.

(2) State compliance standards. Without this administrative regulation, the Commonwealth is not in compliance with the federal mandate. The federal regulation requires a training program if the state does not have training requirements for the prescribing and administration of vaccinations by pharmacists. This regulation sets forth the training requirements that are less stringent than the federal standards, ensuring that Kentucky licensed pharmacists remain eligible vaccinators.

(3) Minimum or uniform standards contained in the federal mandate. That pharmacists shall be authorized to prescribe and to administer vaccinations to individuals ages three (3) and up.

(4) Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? This administrative regulation will not impose stricter requirements than the federal mandate. Rather, this administrative regulation will be more permissive than the federal mandate in that it allows for pharmacists to prescribe and to administer vaccinations to all individuals three and older. The conditions for pharmacists to be authorized to prescribe and to administer vaccinations are fewer in this administrative regulation than the federal mandate.

(5) Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. If this regulation were to mirror the federal regulations, or if this regulation was not promulgated at all, it would have the effect of severely limiting the number of pharmacists that could prescribe and administer vaccinations due to the majority of Kentucky pharmacists not having completed a twenty-hour training program on immunizing.