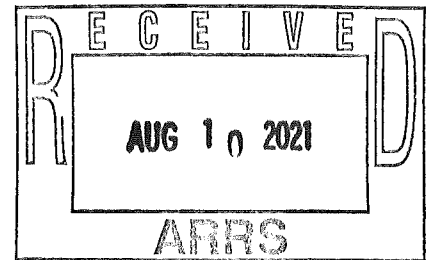




ANDY BESHEAR
GOVERNOR

KENTUCKY BOARD OF PHARMACY

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pharmacy.ky.gov



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EXECUTIVE DIRECTOR

LARRY A. HADLEY, R.PH.

August 10, 2021

Legislative Research Commission
Emily Caudill, Regulation Compiler
702 Capitol Avenue
Capitol Annex, 029
Frankfort, Kentucky 40601

RE: 201 KAR2:410E

Dear Ms. Caudill:

Due to changes in federal regulations that require state compliance, the Kentucky Board of Pharmacy respectfully requests the withdrawal of Emergency Regulation, 201 KAR 2:410E. The Board of Pharmacy is simultaneously filing 201 KAR 2:411E with this withdrawal letter to properly address the federal requirements.

Sincerely,

A handwritten signature in black ink, appearing to read "Larry A. Hadley".

Larry A. Hadley, R.Ph.
Executive Director
Kentucky Board of Pharmacy

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MEMORANDUM

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

FROM: Emily Caudill, Regulations Compiler

RE: Acknowledgement of Emergency Regulation – 201 KAR 002:411E

DATE: August 10, 2021

A copy of the above listed emergency administrative regulation is enclosed for your files. This emergency administrative regulation became effective on **August 10, 2021** and will expire in 270 days on **May 7, 2022** or when replaced by an ordinary administrative regulation, whichever occurs first.

The emergency administrative regulation is scheduled to be reviewed by the Administrative Regulation Review Subcommittee at its **October 2021**, meeting.

Pursuant to KRS 13A.280, **if** a public hearing is held or you receive written comments on the emergency administrative regulation, the Statement of Consideration for this ordinary administrative regulations is due by noon on **October 15, 2021**. Please reference KRS 13A.270 and 13A.280 for other requirements relating to public hearings and the Statement of Consideration.

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


Enclosure

FILED WITH LRC
TIME: 12:15pm
AUG 10 2021
Emily B Caudill
REGULATIONS COMPILER

STATEMENT OF EMERGENCY
201 KAR 002:411E

This emergency administrative regulation establishes requirements that the Board of Pharmacy shall implement in order to comply with 42 U.S.C. 247d-6d, 85 Fed. Reg. 15198, 52136 and 86 Fed. Reg. 9516, 10588 and 14462. 85 Fed. Reg. 15198, 52136 and 86 Fed. Reg. 9516, 10588, 14462 and 41977 have been promulgated in response to the public health emergency invoked by 42 U.S.C. 247d-6d to address COVID-19. 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 protect human health. This emergency administrative regulation will ensure that state law remains congruent with emergency federal regulations, and responds to the current COVID-19 public health emergency.

An ordinary administrative regulation is not a sufficient avenue to address the current emergency due to the emergency being temporary. This emergency administrative regulation will not be replaced by an ordinary administrative regulation due to the scope of the administrative regulation only existing and being needed for the duration of the state of emergency.



Andy Beshear,
Governor



Larry Hadley, R.Ph.
Executive Director

1 BOARDS AND COMMISSIONS
2 Kentucky Board of Pharmacy
3 Board of Pharmacy

4 (New Emergency Administrative Regulation)

5 201 KAR 002:411E Ordering and administering vaccinations.

6 RELATES TO: KRS 39A.180, 315.010, 315.020, 315.050, 315.065, 315.135, 315.205, 315.500,
7 42 U.S.C. 247d-6d, 85 Fed. Reg. 15198, 52136, 79190, 86 Fed. Reg. 7872, 9516, 10588,
8 14462 and 41977.

9 STATUTORY AUTHORITY: KRS 315.500, 315.505

10 NECESSITY, FUNCTION, AND CONFORMITY: 85 Fed. Reg. 15198, 85 Fed. Reg. 52136 and
11 86 Fed. Reg 9516, 10588 and 41977 require the Board of Pharmacy to promulgate an admin-
12 istrative regulation to conform state law to federal law during the period of this public health
13 emergency resulting from the coronavirus (COVID-19) pandemic. KRS 315.010(22) does not au-
14 thorize pharmacists to order vaccinations nor does KRS 315.010(22) authorize the use of pre-
15 scriber-approved protocols for pharmacists or pharmacist interns to administer vaccinations to
16 children under the age of nine (9). 85 Fed. Reg. 52136, requires that state-licensed pharmacists
17 be authorized to order and to administer vaccinations to children between the ages of three (3)
18 and seventeen (17) and that state-registered pharmacist interns and pharmacy technicians be
19 authorized to administer vaccinations to children between the ages of three (3) and seventeen
20 (17). 85 Fed. Reg. 79190, published on December 3, 2020 and effective on February 4, 2021,
21 requires that technicians be authorized to administer childhood vaccinations and COVID-19 vac-
22 cinations and requires that state law establish a training requirement for all pharmacists, techni-
23 cians, and interns that will be ordering or administering vaccinations pursuant to the declaration.
24 Moreover, on August 4, 2021, 86 FR 41977 was released requiring that pharmacists be author

1 zed to order the seasonal flu vaccine for individuals aged nineteen and over and that interns and
2 technicians be authorized to administer the seasonal flu vaccine. The Prep Act (42 U.S.C. 247d-
3 6d(8)) preempts any state law that would prohibit or effectively prohibit activities authorized by
4 the secretary in a PREP Act Declaration. This administrative regulation establishes requirements
5 for Kentucky to comply with 85 Fed. Reg. 15198, 52136, 79190 and 86 Fed. Reg. 7872, 9516,
6 10588, 14462 and 41977.

7 Section 1. Definitions. (1) "Administer" is defined by KRS 315.010(1)

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

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

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

11 (5) "Prescribe" means to issue an original or new order from a pharmacist for an FDA-approved
12 or authorized vaccination or medication to treat emergency reactions to vaccines.

13 Section 2. Pharmacist Requirements. (1) A pharmacist may administer a vaccine to an individu-
14 al pursuant to the Advisory Committee on Immunization Practices (ACIP) standard immuniza-
15 tion schedule in accordance with KRS 315.010(22).

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

18 (3) A pharmacist may prescribe and administer a vaccine to an individual eighteen (18) and un-
19 der, pursuant to the ACIP standard immunization schedule or a seasonal flu vaccine to any indi-
20 vidual aged nineteen and over or a COVID-19 vaccine to any individual, if the pharmacist:

21 (a) Completes, or has completed practical training on administering vaccinations. This may in-
22 clude:

23 1. Completion of a practical training program accredited by the Accreditation Council for Phar-
24 macy Education (ACPE) that includes hands-on injection technique and the recognition and
25 treatment of emergency reactions to vaccines;

- 1 2. Graduation from an ACPE-approved pharmacy school in which hands-on immunization train-
2 ing was part of the curriculum; or
- 3 3. Training via hands-on experience immunizing in current or previous pharmacy practice; and
- 4 (b) Possesses a current certificate in basic cardiopulmonary resuscitation.

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

- 7 (1) Completes, or has completed as part of pharmacy school curriculum, a practical training
8 program accredited by the Accreditation Council for Pharmacy Education (ACPE) that includes
9 hands-on injection technique and the recognition and treatment of emergency reactions to vac-
10 cines; and
- 11 (2) Possesses a current certificate in basic cardiopulmonary resuscitation.

12 Section 4. Pharmacy Technician Requirements. A pharmacy technician may administer a vac-
13 cine under the general supervision of a pharmacist to an individual, if the pharmacy technician:

- 14 (1) Completes a minimum of two (2) hours of immunization-related continuing education accred-
15 ited by the Accreditation Council for Pharmacy Education (ACPE) per each state registration pe-
16 riod;
- 17 (2) Completes, or has completed, a practical training program accredited by the Accreditation
18 Council for Pharmacy Education (ACPE) that includes hands-on injection technique and the
19 recognition and treatment of emergency reactions to vaccines; and
- 20 (3) Possesses a current certificate in basic cardiopulmonary resuscitation.

21 Section 5. Effective Date. (1) This administrative regulation shall become effective at 5 p.m. on
22 the date it is filed.

- 23 (2) In accordance with KRS 13A.190, this administrative regulation shall remain in effect until:
 - 24 (a) Expiration of the time period established by KRS 13A.190; or
 - 25 (b) Withdrawn in accordance with KRS 13A.190(12).

1 (3) The Board of Pharmacy shall regularly consult with the Governor's Office, the Centers for
2 Disease Control and Prevention, and other public health authorities to determine if this adminis-
3 trative regulation shall be withdrawn prior to its expiration under KRS 13A.190.

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

FILED

201 KAR 2:411E



Larry Hadley, R.Ph.
Executive Director
Kentucky Board of Pharmacy

August 10, 2021
Date

FILLED

PUBLIC HEARING AND PUBLIC COMMENT PERIOD:

A public hearing on this administrative regulation shall be held on September 28, 2021 at 9 a.m. Eastern Time via zoom teleconference. A link to the public hearing shall be provided on the Board's website no fewer than (5) days before the hearing. Individuals interested in being heard at this hearing shall notify this agency in writing by five (5) 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 is received. 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 September 30, 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 2:411E

Contact Person: Larry Hadley, phone (502) 564-7910, email Larry.Hadley@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 individuals three (3) and older, pursuant to specific requirements. This administrative regulation also authorizes pharmacy technicians and pharmacist interns to administer vaccinations to individuals 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 during the current national and state public health emergency.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 315.500 and KRS 315.505 authorize the Board of Pharmacy to promulgate regulations during a state of emergency pursuant to KRS 39A.100 within the scope of the enumerated reasons listed in KRS 315.500, including administering immunizations to children pursuant to protocols established by the Centers for Disease Control and Prevention, the National Institutes of Health, or the National Advisory Committee on Immunization Practices or determined to be appropriate by the commissioner of public health or his or her designee.

(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 administrative regulation.

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

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

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

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This regulation impacts any pharmacist, pharmacist intern or pharmacy technician that desires to order or to administer vaccinations to individuals three 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, pharmacy technicians or pharmacist interns to order or to administer vaccinations; however, this administrative regulation provides pharmacists with an authorization to order and to administer vaccinations pursuant to this administrative regulation's requirements and for pharmacy technicians and pharmacist interns with an authorization to administer vaccinations pursuant to this administrative regulation's requirements. Should the pharmacist, pharmacist intern or pharmacy technician choose to order or to administer vaccinations, the pharmacist, pharmacist intern or pharmacy technician 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, pharmacist interns or pharmacy technicians to order 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 order or to administer vaccinations or the pharmacist intern or pharmacy technician choose to administer vaccinations, those individuals will have the cost of training, potential yearly continuing education requirements and the cost of becoming CPR certified.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The ability to vaccinate more individuals age three and up. Not only will this improve vaccination rates, ensuring a healthier Commonwealth, but the qualified individuals ordering or administering the vaccination will potentially garner greater business as well as increased revenue streams for the companies or organizations in which they are employed.

(5) Provide an estimate of how much it will cost the administrative body 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, pharmacist practice and pharmacist intern and pharmacy technician practices to ensure compliance with this 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 established any fees or directly or indirectly increased any fees: This administrative regulation does not establish any fees directly or indirectly.

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

FULLER D

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

201 KAR 2:411E

Contact Person: Larry Hadley, phone (502) 564-7910, 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? 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, KRS 315.500, KRS 315.505.

(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 the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

FEDERAL MANDATE ANALYSIS COMPARISON

201 KAR 2:411E

Contact Person: Larry Hadley, phone (502) 564-7910, email Larry.Hadley@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 national state of emergency.

(2) State compliance standards. Without this administrative regulation, the Commonwealth is not in compliance with the federal mandate.

(3) Minimum or uniform standards contained in the federal mandate. That pharmacists shall be authorized to order and to administer vaccinations to individuals ages three (3) and up and that pharmacist interns and technicians be authorized 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 order and to administer vaccinations to all individuals three and older. It allows for pharmacists to order vaccines or to use prescription drug orders or prescriber-approved protocols. The conditions for pharmacists to be authorized to order and administer vaccinations are fewer in this administrative regulation than the federal mandate. Moreover, pharmacist interns have been authorized to administer vaccinations to individuals three and older. The conditions for pharmacist interns and technicians 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, it would have the effect of severely limiting the number of pharmacists that could order and administer vaccinations due to the majority of Kentucky pharmacists not having completed a twenty-hour training program on immunizing. Therefore, it was critical that federal floor standards be adopted, but with fewer conditions than the federal regulation.