

**STATEMENT OF EMERGENCY
201 KAR 002:410E**

This emergency administrative regulation is being promulgated to establish requirements that the Board of Pharmacy shall implement in order to comply with 85 Fed. Reg. 15198, 52136 (Third Amendment to the PREP Act Declaration) promulgated by the Department of Health and Human Services (HHS) as a federal emergency regulation to be in effect while a declaration of a public health emergency exists under 42 U.S.C. 247d..

The Third Amendment clarified that “covered countermeasures” include products that limit the harm that COVID19 might cause, and it amended the category of disease, health condition, and threat for which the HHS secretary recommends the administration or use of covered countermeasures to include the decrease in the rate of childhood immunizations during the pandemic. The Third Amendment included pharmacists as “qualified persons” to order and administer vaccinations to children ages three (3) and seventeen (17) pursuant to certain requirements, and for pharmacist interns to be “qualified persons” to administer vaccinations to children ages three (3) through seventeen (17) pursuant to certain requirements. The Third Amendment preempts narrower state scope-of-practice laws for pharmacists and pharmacy interns who meet the requirements set forth in the Third Amendment. The Third Amendment does not affect broader scope-of-practice laws.

This emergency administrative regulation is necessary, pursuant to KRS 13A.190(1)(a)3. and 4., to ensure state regulation meets federal floor requirements authorizing pharmacists to order and administer vaccines to children between the ages of three (3) and seventeen (17) and for pharmacist interns to be authorized to administer vaccinations to children between the ages of three (3) and seventeen (17) for the duration of the state of public health emergency. An ordinary administrative regulation is not a sufficient avenue to address the current emergency due to the time constraints of promulgating an ordinary administrative regulation. The federal regulation became effective on August 24, 2020, and without a change in state law, Kentucky does not comply with federal regulation. 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, Executive Director

**BOARDS AND COMMISSIONS
Board of Pharmacy
(New Emergency Administrative Regulation)**

201 KAR 002:410E. Ordering and administering vaccinations.

EFFECTIVE: November 23, 2020

RELATES TO: KRS 39A.180, 315.010, 315.020, 315.050, 315.065, 315.135, 315.205, 315.500, 42 U.S.C. 247d-6d, 85 Fed. Reg. 15198, 52136

STATUTORY AUTHORITY: KRS 315.500, 315.505

NECESSITY, FUNCTION, AND CONFORMITY: The Third Amendment to the Department of Health and Human Services Declaration under the PREP Act, 85 Fed. Reg. 15198, 85 Fed. Reg. 52136, requires the Board of Pharmacy to promulgate an administrative regulation to conform state law to federal law during the period of this public health emergency. KRS 315.010(22) does not authorize pharmacists to order vaccinations. KRS 315.010(22) also does

not authorize the use of prescriber-approved protocols for pharmacists or pharmacist interns to administer vaccinations to children under the age of nine (9). The third amendment of 85 C.F.R. 15198, 85 Fed. Reg. 52136, requires that state-licensed pharmacists be authorized to order and administer vaccinations to children between the ages of three (3) and seventeen (17) and that state-registered pharmacist interns and pharmacy technicians be authorized to administer vaccinations to children between the ages of three (3) and seventeen (17). Department of Health & Human Services Guidance issued on October 20, 2020 authorizes pharmacy technicians to administer vaccinations if they meet specific federal requirements listed in the federal guidance. The Prep Act (42 U.S.C. 247d-6d(8)) preempts any state law that would prohibit or effectively prohibit activities authorized by the Secretary in a PREP Act Declaration, including pharmacists ordering and administering vaccinations and pharmacist interns administering vaccinations to children between the ages of three (3) and seventeen (17). According to Department of Health and Human Services Advisory Opinion 20-03, issued on October 22, 2020, state law does not need to mirror federal requirements; however, state law shall allow for pharmacists to be able to order and to administer vaccinations to children between the ages of three (3) and seventeen (17), and pharmacist interns shall be able to administer vaccinations to children between the ages of three (3) and seventeen (17). This administrative regulation establishes requirements for Kentucky to comply with 85 Fed. Reg. 52136.

Section 1. Definitions. (1) "Administer" is defined by KRS 315:010(1).

(2) "Certified Pharmacy Technician" is an individual who:

(a) Has successfully completed the Pharmacy Technician Certification Exam administered by the Pharmacy Technician Certification Board (PTCB) or the examination for the Certification of Pharmacy Technicians by the National Healthcareer Association (NHA);

(b) The certificate issued by the PTCB or NHA is current.

(3) "Order" means an original or new order from a pharmacist for an FDA approved or authorized vaccination or medication to treat emergency reactions to vaccines, including epinephrine.

(4) "Pharmacist" is defined by KRS 315.010(17).

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

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

Section 2. Pharmacist Requirements. A pharmacist may order and administer a vaccine to an individual, age three (3) or older, pursuant to the Advisory Committee on Immunization Practices' (ACIP) standard immunization schedule, if the pharmacist:

(1) Reports the administration of each vaccination by the pharmacist, pharmacist intern, or pharmacy technician to the Kentucky Immunization Registry administered by the Cabinet for Health and Family Services;

(2) Completes, or has completed, a practical training program accredited by the Accreditation Council for Pharmacy Education (ACPE) that includes hands-on injection technique and the recognition and treatment of emergency reactions to vaccines;

(3) Completes a minimum of two (2) hours of immunization-related continuing education accredited by ACPE per each licensing period;

(4) Provides notification of the immunization to the individual's primary care provider upon the request of the individual or the individual's parent or guardian, if the individual:

(a) Is under eighteen (18) years of age; or

(b) Has a court-appointed guardian; and

(5) Possesses a current certificate in basic cardiopulmonary resuscitation.

Section 3. Pharmacist Intern Requirements. A pharmacist intern may administer a vaccine ordered by a pharmacist, or pursuant to a prescriber-approved protocol or prescription drug order, to an individual, aged three (3) or older, if the pharmacist intern:

- (1) Completes, or has completed, a practical training program accredited by the Accreditation Council for Pharmacy Education (ACPE) that includes hands-on injection technique and the recognition and treatment of emergency reactions to vaccines; and
- (2) Possesses a current certificate in basic cardiopulmonary resuscitation.

Section 4. Pharmacy Technician Requirements. A pharmacy technician may administer a vaccine ordered by a pharmacist or pursuant to prescriber-approved protocol or prescription drug order to an individual, aged three (3) or older, if the pharmacy technician:

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

Section 5. Prescriber-approved Protocols. (1) A pharmacist may utilize prescriber-approved protocols or a prescription drug order as a means to provide a vaccine for individuals aged nine (9) and older pursuant to KRS 315.010 (22), while the vaccine may be administered by a pharmacist, pharmacist intern or pharmacy technician. The pharmacy technician shall meet the conditions established in Section 4 of this administrative regulation, if administering a vaccination that has been provided by prescription drug order or prescriber-approved protocol.

(2) A pharmacist may utilize prescriber approved protocols or a prescription drug order as a means to provide a vaccine for individuals aged three (3) to eight (8), while the vaccine may be administered by a pharmacist, pharmacist intern or pharmacy technician. The pharmacist, pharmacist intern or pharmacy technician shall meet the conditions established in section 2, 3 or 4, respectively, of this administrative regulation.

Section 6. Effective Date. (1) This administrative regulation shall become effective at 5 p.m. on the date it is filed.

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

- (a) Expiration of the time period established by KRS 13A.190; or
- (b) Withdrawn in accordance with KRS 13A.190(12).

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

LARRY HADLEY, Executive Director

APPROVED BY AGENCY: November 23, 2020

FILED WITH LRC: November 23, 2020 at 1:45 p.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held on February 23, 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 February 28, 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

Contact Person: Larry Hadley

(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 to be ordered and administered by a greater number of individuals. This will allow for an increase in childhood immunizations that are currently in decline.

(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 completing an accredited training program, 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? 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.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

(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, 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

(1) Federal statute or regulation constituting the federal mandate. 42 U.S.C. 247d-6d, 85 Fed. Reg. 15198, 85 Fed. Reg. 52136. 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 children ages three (3) through seventeen (17) and that pharmacist interns be authorized to administer vaccinations to children ages three (3) through seventeen (17).

(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 to administer vaccinations are fewer in this administrative regulation than the federal mandate. Also, pursuant to non-binding federal guidance, this administrative regulation will authorize technicians that comply with specific requirements to administer vaccinations to individuals three and up.

(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.