

STATEMENT OF EMERGENCY

201 KAR 2:413E.

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 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 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 will 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. This emergency administrative regulation will ensure that state law remains congruent with emergency federal regulations and responds to the current COVID-19 federal public health emergency. 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 with regard to pharmacist authority 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 federal public health emergency.

ANDY BESHEAR, Governor

CHRISTOPHER HARLOW, PharmD., Executive Director

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

201 KAR 2:413E. Ordering and administering vaccinations.

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

STATUTORY AUTHORITY: KRS 315.191

NECESSITY, FUNCTION, AND CONFORMITY: 85 Fed. Reg. 15198, 85 Fed. Reg. 52136 and 86 Fed. Reg. 9516, 10588 and 41977 require the Board of Pharmacy to promulgate an administrative regulation to conform state law to federal law during the period of this national public health emergency resulting from the coronavirus (COVID-19) pandemic. KRS 315.010(22) does not authorize pharmacists to order vaccinations nor does KRS 315.010(22) authorize the use of prescriber-approved protocols for pharmacists or pharmacist interns to administer vaccinations to children under the age of nine (9). 85 Fed. Reg. 52136, requires that state-licensed pharmacists be authorized to order and to 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). 85 Fed. Reg. 79190 requires that technicians be authorized to administer childhood vaccinations and COVID-19 vaccinations and requires that state law establish a training requirement for all pharmacists, technicians, and interns that will be ordering or administering vaccinations pursuant to the declaration. 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. This administrative regulation establishes requirements for Kentucky to comply with 85 Fed. Reg. 15198, 52136, 79190 and 86 Fed. Reg. 7872, 9516, 10588, 14462 and 41977 and ensures a robust pool of pharmacist for ordering and administering vaccines.

Section 1. Definitions.

- (1) "Administer" is defined by KRS 315.010(1).
- (2) "Pharmacist" is defined by KRS 315.010(17).
- (3) "Pharmacist intern" is defined by KRS 315.010(18).
- (4) "Pharmacy technician" is defined by KRS 315.010(21).
- (5) "Prescribe" means to issue an original or new order from a pharmacist for an FDA-approved or authorized vaccination or medication, including but not limited to, epinephrine, diphenhydramine and corticosteroids to treat emergency reactions to vaccines.

Section 2. Pharmacist Requirements.

- (1) A pharmacist may administer a vaccine to an individual pursuant to the Advisory Committee on Immunization Practices (ACIP) standard immunization schedule in accordance with KRS 315.010(22).
- (2) A pharmacist may administer a vaccine to a child, age three (3) through eight (8), pursuant to a prescriber-approved protocol.
- (3) A pharmacist may prescribe and administer a vaccine to an individual eighteen (18) and under, pursuant to the ACIP standard immunization schedule, a seasonal flu vaccine to any individual aged nineteen and over, a COVID-19 vaccine to any individual, and medications necessary for the emergency treatment of vaccine reactions, if the pharmacist:

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

1. Completion of a practical training program from an education provider 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;
2. Graduation from an ACPE accredited pharmacy school in which hands-on immunization training was part of the curriculum; or
3. Training via hands-on experience immunizing in current or previous pharmacy practice; and

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

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

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

- (1) Completes, or has completed as part of pharmacy school curriculum, 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 under the general supervision of a pharmacist to an individual, if the pharmacy technician:

- (1) 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;
- (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; and
- (3) Possesses a current certificate in basic cardiopulmonary resuscitation.

Section 5. 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.

CHRISTOPHER P. HARLOW, PharmD., R.Ph., Executive Director

APPROVED BY AGENCY: June 27, 2022

FILED WITH LRC: June 27, 2022 at 3:35 p.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall be held on August 31, 2022 at 10:00 a.m. Eastern Time at the Kentucky Department of Transportation Auditorium, 200 Mero Street, 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, 2022. 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.