

# **KENTUCKY BOARD OF PHARMACY**

via teleconference

<https://us02web.zoom.us/j/81000621940?pwd=ZzFyQ0piV0kyVIFTaEttZXdlLa0djZz09>

Meeting ID: 810 0062 1940      Passcode: 8ZMvdH

Dial by your location

+1 646 558 8656 US (New York)      +1 312 626 6799 US (Chicago)

Meeting ID: 810 0062 1940      Passcode: 776270

## **Special Called Board Meeting**

**November 17, 2020**

**1:00 p.m.**

### **Agenda**

- I. Call to Order
- II. Emergency Regulation on Vaccinations [attached]
- III. Adjournment

# Working Draft for 11/17/2020

## 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). 85 Fed. Reg. 52136 (Third Amendment) was promulgated to address a nationwide decline in childhood vaccination rates. This emergency administrative regulation is necessary, pursuant to KRS 13A.190(1)(a)3. and 4., to meet a deadline for the promulgation of the administrative regulation established by federal law and to protect human health. This emergency administrative regulation will make state law congruent with emergency federal regulations, and responds to the current COVID-19 public health emergency that necessitates having pharmacists available to order and administer the COVID-19 vaccination and Advisory Committee on Immunization Practices (ACIP) recommended vaccinations and having pharmacy technicians and pharmacist interns available to administer the COVID-19 vaccination and ACIP recommended vaccinations.

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  
Board of Pharmacy

1 BOARDS AND COMMISSIONS

2 Board of Pharmacy

3 (New Emergency Administrative Regulation)

4 201 KAR 002:410E. Ordering and Administering Vaccinations.

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

7 STATUTORY AUTHORITY: KRS 315.500, 315.505

8 NECESSITY, FUNCTION, AND CONFORMITY: The Third Amendment to 85  
9 Fed. Reg. 15198, 85 Fed. Reg. 52136, requires the Board of Pharmacy to promulgate an  
10 administrative regulation to conform state law to federal law during the period of this  
11 public health emergency. KRS 315.010(22) does not authorize pharmacists to order  
12 vaccinations. KRS 315.010(22) also does not authorize the use of prescriber-approved  
13 protocols for pharmacists or pharmacist interns to administer vaccinations to children  
14 under the age of nine (9). The third amendment of 85 CFR 15198, 85 Fed. Reg. 52136,  
15 requires that state-licensed pharmacists be authorized to order and administer  
16 vaccinations to children between the ages of three (3) and seventeen (17) and that state-  
17 registered pharmacist interns and pharmacy technicians be authorized to administer  
18 vaccinations to children between the ages of three (3) and seventeen (17). Department  
19 of Health & Human Services Guidance issued on October 20, 2020 authorizes pharmacy  
20 technicians to administer vaccinations if they meet specific federal requirements listed in  
21 the federal guidance. The Prep Act (42 U.S.C. 247d-6d(8)) preempts any state law that

1 would prohibit or effectively prohibit activities authorized by the Secretary in a PREP Act  
2 Declaration, including pharmacists ordering and administering vaccinations and  
3 pharmacist interns administering vaccinations to children between the ages of three (3)  
4 and seventeen (17). According to Department of Health and Human Services Advisory  
5 Opinion 20-03, issued on October 22, 2020, state law does not need to mirror federal  
6 requirements; however, state law shall allow for pharmacists to be able to order and to  
7 administer vaccinations to children between the ages of three (3) and seventeen (17),  
8 and pharmacist interns shall be able to administer vaccinations to children between the  
9 ages of three (3) and seventeen (17). This administrative regulation establishes  
10 requirements for Kentucky to comply with 85 Fed. Reg. 52136.

11 Section 1. Definitions. (1) "Administer" means the direct application of a drug to a  
12 patient by injection or intranasal application.

13 (2) "Certified Pharmacy Technician" is an individual who: (a) Has successfully  
14 completed the Pharmacy Technician Certification Exam administered by the Pharmacy  
15 Technician Certification Board (PTCB) or the examination for the Certification of  
16 Pharmacy Technicians by the National Healthcareer Association (NHA);

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

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

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

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

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

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

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

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

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

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

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

16 (b) Has a court-appointed guardian; and

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

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

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

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

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

6 (1) Is a certified pharmacy technician;

7 (2) Completes a minimum of two (2) hours of immunization-related continuing  
8 education accredited by the Accreditation Council for Pharmacy Education (ACPE) per  
9 each state registration period;

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

13 (4) Possesses a current certificate in basic cardiopulmonary resuscitation.

14 Section 5. Prescriber-approved Protocols. (1) Except as provided by subsection  
15 (2) of this section, a pharmacist may utilize prescriber-approved protocols or a  
16 prescription drug order as a means to obtain a vaccine for individuals aged three (3) or  
17 older.

18 (2) If a vaccine is obtained via a prescriber-approved protocol or prescription  
19 drug order, but administered by a pharmacist, pharmacist intern or pharmacy technician  
20 the pharmacist, pharmacist intern or pharmacy technician shall meet the conditions  
21 established in section 2, 3 or 4, respectively, of this administrative regulation.

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

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

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

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

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

DRAFT

---

Larry Hadley, Executive Director  
Board of Pharmacy

DRAFT



PUBLIC HEARING AND PUBLIC COMMENT PERIOD:

A public hearing on this administrative regulation shall be held on \_\_\_\_\_ at \_\_\_\_\_ Eastern Time at \_\_\_\_\_. 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 \_\_\_\_\_. 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](mailto:Larry.Hadley@ky.gov).