

COMMITTEE AMENDMENT

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BOARDS AND COMMISSIONS

Board of Pharmacy

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, **79190, 86 Fed. Reg. 7872**

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 ***resulting from the coronavirus (COVID-19) pandemic***. KRS 315.010(22) does not authorize pharmacists to order vaccinations ***nor does[-]*** 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 ***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). ***The Fourth Amendment to the Department of Health and Human Services Declaration under the PREP Act, 85 Fed. Reg. 79190, published on December 3, 2020 and effective on February 4, 2021, 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, and if the state does not have a training requirement, a twenty (20) hour requirement shall be enforced by 85 Fed. Reg. 79190 for immunity from liability to attach[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 ***and 79190***.

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

~~(3)[(5)] "Pharmacist intern" is defined by KRS 315.010(18).~~

~~(4)[(6)] "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 to treat emergency reactions to vaccines.~~

Section 2. Pharmacist Requirements. ~~(1)~~ 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 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, or a COVID-19 vaccine to any individual,~~ if the pharmacist:

~~(a)[(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 on administering vaccinations. This may include:~~

~~1. Completion of 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;

~~2. Graduation from an ACPE-approved 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)[(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 **under the general supervision of a pharmacist** 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 **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** ~~[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;
- ~~(2)](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
- ~~(3)](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).

~~(2)](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.

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.