Kentucky Board of Pharmacy

Emergency Regulation: Ordering and Administering Vaccinations

Frequently Asked Questions and Board Guidance

February 24, 2021

The Kentucky Board of Pharmacy approved an amendment to emergency regulation 201 KAR 2:410E. Ordering and Administering Vaccinations in a Special Called Meeting on February 8, 2021. The regulation is in response to federal laws and guidance enacted during the COVID-19 pandemic.

These questions and answers will be monitored and updated as new information becomes available.

Questions:

1. What is an emergency regulation? When did the emergency regulation become effective? How long is it effective?

2. What does this emergency regulation address?

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6. What is required for a pharmacist administering a COVID-19 vaccine?

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11. Which immunizations must be reported to the Kentucky Immunization Registry (KYIR)?

12. What is the Kentucky Immunization Registry (KYIR)? How do I report vaccinations to the KYIR?

13. What resources are available that address vaccination, including administration and <u>storage?</u>

14. May a pharmacy technician administer medications, such as Vitamin B12, pursuant to a prescription drug order?

1. What is an emergency regulation? When did the emergency regulation become effective? How long is it effective?

A: An emergency regulation is a regulation that has been adopted on an expedited, temporary basis because it has been determined to be necessary to protect public health, safety and welfare.

This regulation went into effect November 23, 2020, the amendment went into effect February 22, 2021 and the emergency regulation will expire on August 20, 2021.

2. What does this emergency regulation address?

A: This emergency regulation, 201 KAR 2:410E Ordering and Administering Vaccinations, conforms state law to federal law during the public health emergency resulting from the coronavirus (COVID-19) pandemic; specifically, the requirements under the Department of Health and Human Services Declaration under the PREP Act. The Declaration under the PREP Act and the emergency regulation expands how a pharmacist may provide a vaccination and expands who may administer vaccines. The PREP Act Declaration and emergency regulation have additional requirements in order to practice under these expansions.

Expansion to allow:

- Pharmacists to prescribe for administration:
 - Standard childhood vaccines to children aged three (3) to eighteen (18)
 - COVID-19 vaccines to all ages
- Pharmacists to administer:
 - Vaccines pursuant to prescription drug order
 - Vaccines pursuant to prescriber-approved protocol
 - Vaccines prescribed by a pharmacist
- Supervised pharmacist interns to administer:
 - o Vaccines pursuant to prescription drug order
 - Vaccines pursuant to prescriber-approved protocol
 - Vaccines prescribed by a pharmacist
- Supervised pharmacy technicians to administer:
 - o Vaccines pursuant to prescription drug order
 - Vaccines pursuant to prescriber-approved protocol
 - Vaccines prescribed by a pharmacist

3. What is the PREP Act?

A. The Public Readiness and Emergency Preparedness (PREP) Act is a federal law that authorizes the Secretary of the Department of Health and Human Services (HHS) to issue a declaration that provides immunity from liability for covered persons in instances of public health emergencies and pre-empts state laws in order to address a public health emergency.

There was a declaration under the PREP Act issued March 17, 2020 to address the COVID-19 pandemic. <u>PREP Act</u>

Several amendments to the HHS declaration address vaccinations by pharmacists and other covered persons.

4. What is required for a pharmacist to prescribe?

A. Prescribe means a pharmacist may issue an original or new order for either:

- A FDA-approved or authorized vaccination; or
- A medication to treat emergency reactions to vaccines.

A pharmacist may prescribe:

- A vaccine for a child aged three (3) to eighteen (18) pursuant to the ACIP standard immunization schedule; or
- A COVID-19 vaccine to any individual, pursuant to the ACIP recommendations.

In order to prescribe, a pharmacist must:

- Complete or has completed practical training on administering vaccinations
- Possess a current certificate in basic cardiopulmonary resuscitation (CPR)
- Complete a minimum of two (2) hours of immunization-related ACPE CE per renewal period
- Report vaccination to the Kentucky Immunization Registry
- Notify primary care provider, when available, of vaccination
- Inform parents or guardians of importance of well child visits
- Comply with requirements of CDC's COVID-19 vaccination provider agreement

5. What is required for a pharmacist administering <u>a non-COVID-19 vaccine</u>? A.

Scenario 1: Pursuant to a prescription drug order:

• No additional requirements covered under KRS 315.010 (22)

Scenario 2: Pursuant to a prescriber-approved protocol for ages nine (9) and older:

• No additional requirements covered under KRS 315.010 (22)

Scenario 3: Pursuant to a prescriber-approved protocol for ages three (3) to eight (8):

- Pharmacist must:
 - Complete or has completed practical training on administering vaccinations
 - Possess a current certificate in basic cardiopulmonary resuscitation (CPR)
 - Complete a minimum of two (2) hours of immunization-related ACPE CE per renewal period
 - Report vaccination to the Kentucky Immunization Registry
 - Notify primary care provider, when available, of vaccination
 - Inform parents or guardians of importance of well child visits

Scenario 4: Prescribed by a pharmacist for ages three (3) to eighteen (18):

- Pharmacist must:
 - Complete or has completed practical training on administering vaccinations
 - Possess a current certificate in basic cardiopulmonary resuscitation (CPR)
 - Complete a minimum of two (2) hours of immunization-related ACPE CE per renewal period
 - Report vaccination to the Kentucky Immunization Registry
 - Notify primary care provider, when available, of vaccination

• Inform parents or guardians of importance of well child visits

6. What is required for a pharmacist administering a <u>COVID-19 vaccine</u>? A.

Scenario 1: Pursuant to a prescription drug order:

• Pharmacist must comply with requirements of CDC's COVID-19 vaccination provider agreement <u>CDC COVID-19 Provider Requirements</u>

Scenario 2: Pursuant to a prescriber-approved protocol for ages nine (9) and older:

• Pharmacist must comply with requirements of CDC's COVID-19 vaccination provider agreement <u>CDC COVID-19 Provider Requirements</u>

Scenario 3: Pursuant to a prescriber-approved protocol for ages three (3) to eight (8): Pharmacist must:

- Complete or has completed practical training on administering vaccinations
- Possess a current certificate in basic cardiopulmonary resuscitation (CPR)
- Complete a minimum of two (2) hours of immunization-related ACPE CE per renewal period
- Report vaccination to the Kentucky Immunization Registry
- Comply with requirements of CDC's COVID-19 vaccination provider agreement <u>CDC COVID-19 Provider Requirements</u>

Scenario 4: Prescribed by a pharmacist for any age:

- Pharmacist must:
 - Complete or has completed practical training on administering vaccinations
 - Possess a current certificate in basic cardiopulmonary resuscitation (CPR)
 - Complete a minimum of two (2) hours of immunization-related ACPE CE per renewal period
 - Report vaccination to the Kentucky Immunization Registry
 - Comply with requirements of CDC's COVID-19 vaccination provider agreement <u>CDC COVID-19 Provider Requirements</u>

7. What is required for a pharmacist intern administering a vaccine?

A.

Scenario 1: Pursuant to a prescription drug order:

- Pharmacist intern must:
 - Be under general supervision of a pharmacist
 - Complete or has completed ACPE approved practical training on administering vaccinations, as part of pharmacy school curriculum
 - Possess a current certificate in basic cardiopulmonary resuscitation (CPR)
- If COVID-19 vaccine, pharmacist must comply with requirements of CDC's COVID-19 vaccination provider agreement. <u>CDC COVID-19 Provider Requirements</u>

Scenario 2: Pursuant to a prescriber-approved protocol for ages nine (9) and older:

- Pharmacist intern must:
 - Be under general supervision of a pharmacist

- Complete or has completed ACPE approved practical training on administering vaccinations, as part of pharmacy school curriculum
- Possess a current certificate in basic cardiopulmonary resuscitation (CPR)
- If COVID-19 vaccine, pharmacist must comply with requirements of CDC's COVID-19 vaccination provider agreement. <u>CDC COVID-19 Provider Requirements</u>

Scenario 3: Pursuant to a prescriber-approved protocol for ages three (3) to eight (8):

- Pharmacist intern must:
 - Be under general supervision of a pharmacist
 - Complete or has completed ACPE approved practical training on administering vaccinations, as part of pharmacy school curriculum
 - Possess a current certificate in basic cardiopulmonary resuscitation (CPR)
- Supervising Pharmacist must ensure:
 - Vaccination reported to the Kentucky Immunization Registry
 - o Primary care provider, when available, notified of vaccination
 - Parents or guardians informed of importance of well child visits
 - If COVID-19 vaccine, compliance with requirements of CDC's COVID-19 vaccination provider agreement. CDC COVID-19 Provider Requirements

Scenario 4: Prescribed by a pharmacist for ages three (3) to eighteen (18):

- Pharmacist intern must:
 - Be under general supervision of a pharmacist
 - Complete or has completed ACPE approved practical training on administering vaccinations, as part of pharmacy school curriculum
 - Possess a current certificate in basic cardiopulmonary resuscitation (CPR)
- Supervising Pharmacist must ensure:
 - Vaccination reported to the Kentucky Immunization Registry
 - Primary care provider, when available, notified of vaccination
 - Parents or guardians informed of importance of well child visits
 - If COVID-19 vaccine, compliance with requirements of CDC's COVID-19 vaccination provider agreement. <u>CDC COVID-19 Provider Requirements</u>

8. What is required for a registered pharmacy technician administering a vaccine?

A.

Scenario 1: Pursuant to a prescription drug order:

- Registered pharmacy technician must:
 - Be under general supervision of a pharmacist
 - Complete or has completed ACPE approved practical training on administering vaccinations
 - Complete a minimum of two (2) hours of immunization-related ACPE CE per renewal period
 - Possess a current certificate in basic cardiopulmonary resuscitation (CPR)
- If COVID-19 vaccine, pharmacist must comply with requirements of CDC's COVID-19 vaccination provider agreement. <u>CDC COVID-19 Provider Requirements</u>

Scenario 2: Pursuant to a prescriber-approved protocol for ages nine (9) and older:

- Registered pharmacy technician must:
 - Be under general supervision of a pharmacist
 - Complete or has completed ACPE approved practical training on administering vaccinations
 - Complete a minimum of two (2) hours of immunization-related ACPE CE per renewal period
 - Possess a current certificate in basic cardiopulmonary resuscitation (CPR)
- If COVID-19 vaccine, pharmacist must comply with requirements of CDC's COVID-19 vaccination provider agreement. <u>CDC COVID-19 Provider Requirements</u>

Scenario 3: Pursuant to a prescriber-approved protocol for ages three (3) to eight (8):

- Registered pharmacy technician must:
 - Be under general supervision of a pharmacist
 - Complete or has completed ACPE approved practical training on administering vaccinations
 - Complete a minimum of two (2) hours of immunization-related ACPE CE per renewal period
 - Possess a current certificate in basic cardiopulmonary resuscitation (CPR)
- Supervising Pharmacist must ensure:
 - Vaccination reported to the Kentucky Immunization Registry
 - Primary care provider, when available, notified of vaccination
 - Parents or guardians informed of importance of well child visits
 - If COVID-19 vaccine, compliance with requirements of CDC's COVID-19 vaccination provider agreement. <u>CDC COVID-19 Provider Requirements</u>

Scenario 4: Prescribed by a pharmacist for ages three (3) to eighteen (18):

- Registered pharmacy technician must:
 - Be under general supervision of a pharmacist
 - Complete or has completed ACPE approved practical training on administering vaccinations
 - Complete a minimum of two (2) hours of immunization-related ACPE CE per renewal period
 - Possess a current certificate in basic cardiopulmonary resuscitation (CPR)
- Supervising Pharmacist must ensure:
 - Vaccination reported to the Kentucky Immunization Registry
 - Primary care provider, when available, notified of vaccination
 - Parents or guardians informed of importance of well child visits
 - If COVID-19 vaccine, compliance with requirements of CDC's COVID-19 vaccination provider agreement. CDC COVID-19 Provider Requirements

9. What meets the requirement for the practical training on administering vaccinations for a pharmacist?

A. The practical training on administering vaccinations may include:

- Completion of practical training program accredited by the ACPE that includes hands-on injection technique and the recognition and treatment of emergency reactions to vaccines; or
- Graduation from an ACPE-approved pharmacy school in which hands-on immunization training was part of the curriculum; or
- Training via hands-on experience immunizing in current or previous pharmacy practice.

10. Does the basic cardiopulmonary resuscitation (CPR) training for pharmacists, pharmacist interns, and pharmacy technician have to be completed in person?

A. No, it may be completed in person or online. If completed online, the course must be accredited by ACPE, the American Nurses Credentialing Center or the Accreditation for Continuing Medical Education.

11. Which immunizations must be reported to the Kentucky Immunization Registry (KYIR)?

A. A pharmacist must report administration of vaccines by pharmacists, pharmacist interns or pharmacy technicians:

- To any individual age three (3) to eight (8) vaccinated via prescriber-approved protocol;
- To any individual vaccinated via pharmacist prescribing; and
- To any individual administered a COVID-19 vaccine.

The Kentucky Department for Public Health (DPH) strongly recommends all vaccinations be reported to the KYIR.

12. What is the Kentucky Immunization Registry (KYIR)? How do I report vaccinations to the KYIR?

A. Please read the September 2020 Board of Pharmacy Newsletter or visit the KYIR website for details on the KYIR and how to report immunizations. September 2020 Board of Pharmacy Newsletter

KYIR website

13. What resources are available that address vaccination, including administration and storage?

A. Epidemiology and Prevention of Vaccine –Preventable Diseases <u>The Pink Book</u> ACIP Vaccine Recommendations and Guidelines <u>ACIP</u> ACIP Vaccine Administration Best Practice Guidelines <u>Vaccine Administration</u> CDC Vaccine Storage and Handling Toolkit <u>Vaccine Toolkit</u> CDC's COVID-19 vaccination provider agreement. <u>CDC COVID-19 Provider Requirements</u>

14. May a pharmacy technician administer medications, such as Vitamin B12, pursuant to a prescription drug order?

A. No. This emergency regulation only allows pharmacy technicians to administer vaccinations or medications to treat emergency reactions to vaccines.