

**ANAPHYLAXIS TREATMENT PROTOCOL FOR EMERGENCY EPINEPHRINE INJECTION  
DEVICES v3  
Approved 12/11/2019**

**PURPOSE**

This protocol specifies the criteria and procedures for pharmacist(s) to initiate the dispensing of emergency epinephrine injection devices for emergency treatment of anaphylaxis in the community.

**PHARMACIST EDUCATION AND TRAINING**

Prior to initiating the dispensing of emergency epinephrine injection devices under this protocol, pharmacist(s) must have received education and training in the recognition and management of anaphylaxis and the use of emergency epinephrine injection devices for the emergency treatment of anaphylaxis in the community.

The education of pharmacist(s) must be conducted by a provider accredited by the Accreditation Council for Pharmacy Education, or by a comparable provider approved by the Kentucky Board of Pharmacy.

Provider of Training: \_\_\_\_\_

Date Training Completed: \_\_\_\_\_

**CRITERIA**

Pharmacist(s) authorized to initiate the dispensing of emergency epinephrine injection devices will follow the most current guidelines from the American Academy of Pediatrics Guidance on Epinephrine for First-Aid Management of Anaphylaxis<sup>1</sup> and standard adult dosing.

Inclusion criteria:

- Any person at risk for experiencing anaphylaxis
- Any person in a position to assist a person at risk for experiencing anaphylaxis and wishes to become certified pursuant to KRS 311.646 (Emergency Allergy Treatment Act)
- A person, who in the course of their official duties or business, may encounter a person experiencing anaphylaxis (e.g., school officials, day care workers, etc.) and wishes to become certified pursuant to KRS 311.646 (Emergency Allergy Treatment Act)

Exclusion criteria:

- There are no absolute contraindications to treatment with epinephrine in a person experiencing anaphylaxis

---

<sup>1</sup>Sicherer SH, Simons FER, AAP Section on Allergy and Immunology. Epinephrine for First-aid Management of Anaphylaxis. *Pediatrics*. 2017;139(3):e20164006.  
<https://pediatrics.aappublications.org/content/pediatrics/early/2017/02/09/peds.2016-4006.full.pdf>.  
Accessed March 2019.

## MEDICATIONS

This protocol authorizes pharmacist(s) to initiate the dispensing of the following medications\*

Product	Mfr./Dist.	Device	NDCs
EpiPen® and EpiPen Jr®	Mylan	auto-injector	49502-501-02 (0.15mg) 49502-500-02 (0.3mg)
Adrenaclick®	Amedra Pharmaceuticals, LLC	auto-injector	52054-803-02 (0.15mg) 52054-804-02 (0.3mg)
Epinephrine Injection, USP, Auto-Injector	Lineage Therapeutics	auto-injector	00115-1695-49 (0.15mg) 00115-1694-49 (0.3mg)
Auvi Q®	Kaleo, Inc.	auto-injector	60842-0022-01 (0.15mg) 60842-0023-01 (0.3mg)
Symjepi™	Adamis Pharmaceuticals Corporation	pre-filled syringe	38739-100-01 (0.15 mg) 38739-200-01 (0.3 mg)

\*or any other FDA-approved emergency epinephrine injection device.

*Recommended dosing per Academy of Pediatrics Guidance on Epinephrine for First-Aid Management of Anaphylaxis<sup>1</sup>*

- Infants and children up to 25 kg (55 lb): 0.15 mg emergency epinephrine injection device
- Children weighing more than 25 kg (55 lb), teens and adults: 0.3 mg emergency epinephrine injection device
- Obese persons and those with severe allergies may need two doses

*Recommended dosing per FDA product labeling:*

- Patients 15 to 30 kg (33 lbs–66 lbs): 0.15 mg emergency epinephrine injection device
- Patients greater than or equal to 30 kg (66 lbs): 0.3 mg emergency epinephrine injection device

## PROCEDURES FOR INITIATING THERAPY

Individuals identified by the pharmacist as meeting the inclusion criteria may receive a prescription for the number of emergency epinephrine injection devices needed to meet the specific circumstances of the individual as determined by the pharmacist's professional judgement. Prescriptions may be refilled as needed for a 12-month period from the original date of the initial prescription if the previously dispensed emergency epinephrine injection devices have been utilized.

## EDUCATION REQUIREMENTS

Individuals or their parent/guardian/caregiver receiving emergency epinephrine injection devices under protocol will receive education regarding:

- Common anaphylaxis triggers and allergen avoidance
- Signs and symptoms of anaphylaxis
- General treatment of anaphylaxis
- When and how to use emergency epinephrine injection devices, including administration, storage, and adverse effects, expiration, disposal and how to get more
- Importance of calling 911

## PHARMACIST ISSUED CERTIFICATE OF EMERGENCY EPINEPHRINE DEVICE TRAINING

For individuals receiving emergency epinephrine devices under this protocol who are not the patient or

patient's parent/guardian/caregiver who wish to become certified pursuant to KRS 311.646 (Emergency Allergy Treatment Act), a pharmacist may conduct training and issue a certificate. The training shall include instructions for recognizing the symptoms of anaphylaxis and administering an emergency epinephrine injection device.

Once an individual has received a certificate of training from a pharmacist the individual may:

- Receive and possess an emergency epinephrine injection device from the pharmacist
- Administer an emergency epinephrine injection device to a person or provide an emergency epinephrine injection device to a person for immediate self-administration

**DOCUMENTATION**

Pharmacists will document via prescription record each person who receives an emergency epinephrine injection device under this protocol, including:

- Documentation as required in 201 KAR 2:170 for the dispensing of prescription medication; and
- Documentation that the individual receiving the emergency epinephrine injection device was provided with the required education pursuant to 201 KAR 2:380 and, if applicable, issued a certificate of training pursuant to KRS 311.646.

**NOTIFICATION**

Pharmacist(s) shall ask all individuals receiving emergency epinephrine injection devices under this protocol for the name and contact information of the individual's primary care provider and shall provide notification of the emergency epinephrine injection devices dispensed under the protocol to the identified primary care provider within two (2) business days. Any individual affirmatively stating that the individual does not have a primary care provider may still receive an emergency epinephrine injection device under this protocol provided all other applicable requirements of the protocol are met.

[If directed by the authorizing prescriber, the pharmacist(s) shall provide written notification via fax or other secure electronic means to the authorizing prescriber of persons receiving emergency epinephrine injection devices under this protocol within 7 days of initiating dispensing.]

**TERMS**

This protocol is effective as of the date all parties execute the document. It shall remain in effect for a period of one year and shall automatically renew for successive one-year periods unless otherwise terminated by any party, with or without cause. Any termination without cause shall require prior notice to all parties of no less than sixty days.

**SIGNATURES**

\_\_\_\_\_  
Prescriber Name

\_\_\_\_\_  
Prescriber Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Pharmacist Name

\_\_\_\_\_  
Pharmacist Signature

\_\_\_\_\_  
Date