

I. Training Standards for the Administration of Epinephrine Auto-injectors

It is recommended that all school personnel responsible for the storage and emergency use of an epinephrine auto-injector be trained annually, that the training be conducted by a physician or school nurse and that the training include the following information.

A. Techniques for recognizing symptoms of anaphylaxis.

The signs and symptoms of anaphylaxis usually appear rapidly, within seconds or minutes, after an exposure to an allergen, although, in some cases the reaction can be delayed for up to one to three hours depending on the substance causing the reaction. The Utah Health Code definition of **ANAPHYLAXIS IS " POTENTIALLY LIFE-THREATENING HYPERSENSITIVITY TO A SUBSTANCE."** Common symptoms, according to the American Academy of Allergy, Asthma and Immunology's (AAAAI) *Position Statement 34*, may include:

Hives	Coughing
Itching (of any part of the body)	Wheezing
Swelling (of any body parts)	Throat tightness or closing
Red, watery eyes	Difficulty swallowing
Runny nose	Difficulty breathing
Vomiting	Sense of doom
Diarrhea	Dizziness
Stomach cramps	Fainting or loss of consciousness
Change of voice	Change of color

Some individuals have an anaphylactic reaction and the symptoms go away only to return a few hours later. This is called a bi-phasic reaction. Often the symptoms of the bi-phasic reaction occur in the respiratory system and take the individual by surprise. Therefore, according to the AAAAI, after a serious reaction "observation in a hospital setting is necessary for at least four hours after initial symptoms subside because delayed and prolonged reactions may occur even after proper initial treatment."

Once anaphylaxis has begun, the treatment of choice is an immediate intramuscular injection of epinephrine, which is effective for 10 to 15 minutes (according to the manufacturer of epinephrine auto-injectors, Dey Labs), followed by emergency medical attention.

Common causes of anaphylaxis include:

- **Food**
- **Insect stings**
- **Medication (e.g. antibiotics, aspirin, and non-steroidal anti-inflammatory drugs)**
- **Latex**
- Less common causes of anaphylaxis include:
- **Food-dependent exercise induced anaphylaxis** (rare — occurs when an individual eats a specific food and exercises within three to four hours after eating)
- **Idiopathic anaphylaxis** (Unknown cause)

Severe allergic reactions may be at times unavoidable because foods may contain unknown or unreported allergy producing ingredients, insects range widely, latex can be found almost anywhere, and some individuals do not know that they are severely allergic to one or more allergens.

B. Standards and procedures for the storage and emergency use of epinephrine auto-injectors.

An epinephrine auto-injector is a disposable drug delivery system that contains the proper dose of epinephrine and is used to treat anaphylaxis. It is supplied as a spring-loaded syringe that can be easily transported. The disposable system is designed to treat a single anaphylactic episode and must be properly discarded (in compliance with applicable state and federal laws) after its use. It is generally recommended that two epinephrine auto-injectors be kept on-hand as back-up. The following information on the emergency use of an epinephrine auto-injector is based on the manufacturer's instructions/

Steps in the Emergency Use of an Epinephrine Auto-Injector (EpiPen):

1. Determine if anaphylaxis is suspected. Anaphylaxis usually, but not always, occurs right after exposure to an allergen. Frequently anaphylaxis occurs in individuals who have a history of a previous reaction. **If there is uncertainty about the diagnosis, but there is a reasonable probability that it is anaphylaxis, then treat as anaphylaxis.**
2. **If anaphylaxis symptoms occur, call 911 or activate the emergency medical system (EMS). Stay with the victim.** Have others notify the paramedics, school nurse, parents and school administrator immediately.
3. **Prepare to administer EpiPen.**
4. For students in second grade or below, or if less than 66 lbs, use the **Green label** EpiPen Jr (0.15 mg).
5. For adults and students in third grade or above, or if more than 66 lbs, use **Yellow label** EpiPen (0.3 mg). The EpiPen acts immediately; however the effects last only 10—15 minutes. *Make sure someone has called 911.*
6. EpiPen Administration Procedure:
 - a. **Pull of the blue safety release cap**
 - b. **Swing and firmly push the orange tip against the outer thigh so it 'clicks.'** **HOLD on thigh for approximately 3 seconds to deliver the drug.**
 - i. Please note: As soon as you release pressure from the thigh, the protective cover will extend.
 - ii. Each EpiPen Auto-Injector contains a single dose of a medicine called epinephrine, which you inject into your outer thigh. **DO NOT INJECT INTRAVENOUSLY. DO NOT INJECT INTO YOUR BUTTOCK,** as this may not be effective for a severe allergic reaction. In case of accidental injection, please seek immediate medical treatment.

- c. **Call 911 and be sure to take the EpiPen Auto-Injector with you to emergency room.**
7. Monitor the victim's airway and breathing. Begin CPR immediately if the victim stops breathing.
8. Follow-up medical care should be obtained at the emergency room or from the victim's physician. A second delayed reaction may occur up to 6 hours after the initial anaphylaxis.
9. Document the incident. Include in the documentation the date and time EpiPen was administered, the victim's response, and additional pertinent information. Send a copy of the report to the school nurse.

Storage:

According to the manufacturer, epinephrine auto-injectors should be **stored at room temperature** until the marked expiration date, at which time the unit must be replaced. Auto-injectors should not be refrigerated as this could cause the device to malfunction. Auto-injectors should not be exposed to extreme heat, such as in the glove compartment or trunk of a car during the summer and they should not be exposed to direct sunlight. Heat and light shorten the life of the product and can cause the epinephrine to degrade. To be effective, the solution in the auto-injector should be clear and colorless. If the solution is brown, replace the unit immediately.

C. Emergency follow-up procedures, including calling the emergency 911 phone number and contacting, if possible, the pupil's parent and physician.

When it is determined, based on the symptoms, that an anaphylactic reaction is occurring, it is important to act quickly. Administer epinephrine via an epinephrine auto-injector and have an assistant call 911 and request emergency response. Then contact the school nurse, school administrator, pupil's parent and physician and inform them of the actions taken. Stay with the pupil until the paramedics arrive.

Even after epinephrine has been administered, emergency medical care should be obtained immediately because severely allergic individuals who have experienced anaphylaxis may need emergency respiratory or cardiac care, or even to be resuscitated if they stop breathing altogether. At the very least, these individuals will need professional care to determine whether additional epinephrine, steroids, antihistamines, or other treatment is required. Follow-up diagnosis and care by medical professionals after the administration of epinephrine is important for recovery. A delayed or secondary reaction may occur. Therefore the individual needs to remain under medical supervision for at least four hours after an episode of anaphylaxis.

How to use an EpiPen[®] (epinephrine injection, USP) Auto-Injector



1 PREPARE

Remove the Auto-Injector from the clear carrier tube.

Flip open the yellow cap of your EpiPen[®] or the green cap of your EpiPen Jr[®] carrier tube. Tip and slide the auto-injector out of the carrier tube.

Hold the auto-injector in your fist with the orange tip pointing downward.

Blue to the sky, orange to the thigh[®].

With your other hand, remove the blue safety release by pulling straight up without bending or twisting it.



NEVER-SEE-NEEDLE[®] helps with protection. Protects against needle exposure before and after use.

NOTE:

- The needle comes out of the orange tip.
- To avoid an accidental injection, never put your thumb, fingers or hand over the orange tip. If an accidental injection happens, get medical help right away.

2 ADMINISTER

If you are administering to a young child, hold the leg firmly in place while administering an injection.

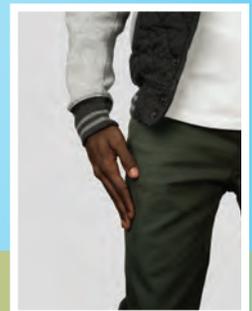
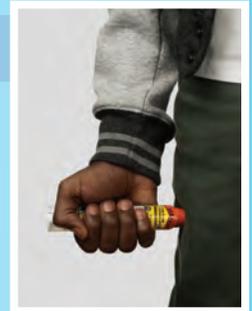
Place the orange tip against the middle of the outer thigh (upper leg) at a right angle (perpendicular) to the thigh.

Swing and push the auto-injector firmly until it “clicks.” The click signals that the injection has started.

Hold firmly in place for 3 seconds (count slowly 1, 2, 3).

Remove the auto-injector from the thigh. The orange tip will extend to cover the needle. If the needle is still visible, do not attempt to reuse it.

Massage the injection area for 10 seconds.



3 GET EMERGENCY MEDICAL HELP RIGHT AWAY

You may need further medical attention.

If symptoms continue or recur, you may need to use a second EpiPen[®] or EpiPen Jr[®] Auto-Injector.

INDICATIONS

EpiPen[®] (epinephrine injection, USP) 0.3 mg or EpiPen Jr[®] (epinephrine injection, USP) 0.15 mg Auto-Injectors are for the emergency treatment of life-threatening allergic reactions (anaphylaxis) caused by allergens, exercise, or unknown triggers; and for people who are at increased risk for these reactions. EpiPen[®] or EpiPen Jr[®] are intended for immediate administration as emergency supportive therapy only. Seek immediate emergency medical help right away.

IMPORTANT SAFETY INFORMATION

Use EpiPen[®] or EpiPen Jr[®] Auto-Injectors right away when you have an allergic emergency (anaphylaxis). **Get emergency medical help right away.** You may need further medical attention. Only a healthcare professional should give additional doses of epinephrine if you need more than two injections for a single anaphylactic episode. EpiPen[®] or EpiPen Jr[®] should **only** be injected into the middle of your outer thigh (upper leg), through clothing if necessary. Do not inject into your veins, buttocks, fingers, toes, hands or feet. Hold the leg of young children firmly in place before and during injection to prevent injuries. In case of accidental injection, please seek immediate medical treatment.

Not actual patient.

**Please see additional Important Safety Information and Indications on the back.
Please see accompanying Full Prescribing Information and Patient Information.**

Every EpiPen 2-Pak[®] (epinephrine injection, USP) and Mylan's Authorized Generic For EpiPen Two-Pack comes with an EpiPen[®] Trainer

Practice with your Trainer repeatedly to become familiar with it.

The EpiPen[®] Auto-Injector and Mylan's Authorized Generic For EpiPen[®]



or

Identify the EpiPen[®] Trainer by:

Label

The EpiPen[®] Trainer is clearly labeled TRAINER or TRAINING DEVICE.

Color

The EpiPen[®] Trainer is shaded grey

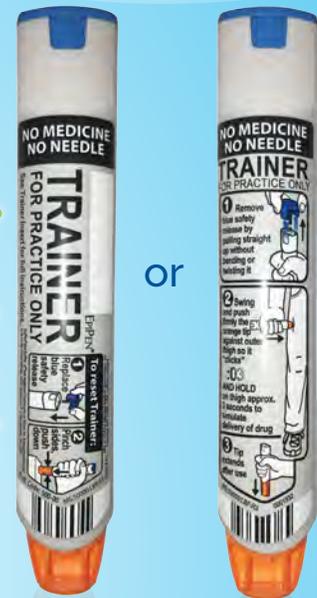
EpiPen[®] and Mylan's Authorized Generic For EpiPen[®] are yellow

EpiPen Jr[®] and Mylan's Authorized Generic For EpiPen Jr[®] are green

No Window or Liquid

Reset after each use

The EpiPen[®] Trainer



or

The grey EpiPen[®] Trainer contains no medicine and no needle, and **SHOULD NOT BE USED** during an anaphylactic reaction.

Always have access to two Auto-Injectors in all the places you may need them because some people require a second dose. More than two sequential doses should be administered only under direct medical supervision.

Visit epipen.com to watch our *How to Use* video and more.

IMPORTANT SAFETY INFORMATION (Continued)

Rarely, patients who have used EpiPen[®] or EpiPen Jr[®] may develop an infection at the injection site within a few days. Some of these infections can be serious. Call your healthcare professional right away if you have any of the following at an injection site: redness that does not go away, swelling, tenderness, or the area feels warm to the touch.

Tell your healthcare professional about all of your medical conditions, especially if you have asthma, a history of depression, thyroid problems, Parkinson's disease, diabetes, high blood pressure or heart problems, have any other medical conditions, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed. Be sure to also tell your healthcare professional all the medicines you take, especially medicines for asthma. **If you have certain medical conditions, or take certain medicines, your condition may get worse or you may have longer lasting side effects when you use EpiPen[®] or EpiPen Jr[®].**

Common side effects include fast, irregular or "pounding" heartbeat, sweating, nausea or vomiting, breathing problems, paleness, dizziness, weakness, shakiness, headache, feelings of over excitement, nervousness or anxiety. These side effects usually go away quickly if you lie down and rest. **Tell your healthcare professional if you have any side effect that bothers you or that does not go away.**

Please see accompanying Full Prescribing Information and Patient Information.

For additional information, please contact us at 800-395-3376.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088

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Better Health
for a Better World[™]

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