

Instruction for Authorized Entities Seeking Prescriptions for Epinephrine Auto-Injectors from Pharmacists

Background

Starting July 1, 2016, Idaho licensed pharmacists will have prescriptive authority for epinephrine auto-injectors, not just for individual patients, but also for *authorized entities* such as schools, day care centers, restaurants, and gyms, among others. Idaho is the first state in the country that will grant pharmacists such broad autonomous prescriptive authority for epinephrine auto-injectors. This module will:

- Describe the parameters of authorized entities obtaining epinephrine auto-injectors from pharmacists as articulated in [Idaho Senate Bill 1322a](#); and
- Review key clinical points for epinephrine auto-injectors
- Review signs and symptoms of anaphylaxis.

Who May Possess an Epinephrine Auto-Injector?

Under Idaho Senate Bill 1322a, a pharmacist acting in good faith and exercising reasonable care may prescribe an epinephrine auto-injector to the following categories of individuals:

- A person at risk of experiencing anaphylaxis;
- A person in a position to assist a person at risk of experiencing anaphylaxis;
- A person who, in the course of the person's official duties or business, may encounter a person experiencing anaphylaxis; and
- A person who, in the opinion of the prescriber or pharmacists, has a valid reason to be in possession of an epinephrine auto-injector

In addition, pharmacists can both prescribe and dispense an epinephrine auto-injector in the name of an *authorized entity*. The bill defined authorized entities broadly as any organization at which allergens capable of causing anaphylaxis may be present. Pre-positioning epinephrine auto-injectors at locations in which individuals may experience anaphylaxis has proven beneficial. Many patients are unaware of their allergy status, and studies have demonstrated nearly 25% of epinephrine administrations are to patients with no prior allergy history.

A sample list of authorized entities was included in the bill: recreational camps, colleges, day care facilities, youth sports leagues, amusement parks, restaurants, places of employment, law enforcement and sports arenas. This list is intended to be non-exhaustive, and any other entity that may be a venue in which an allergic reaction occurs may similarly stock epinephrine auto-injectors.

Authorized entities should be aware that traditionally pharmacists are only able to fill prescriptions pursuant to a valid prescriber-patient relationship. There are several exemptions to the requirement of a prescriber-patient relationship, and Idaho Senate Bill 1322a added such an exemption for epinephrine auto-injectors written in the name of an authorized entity.

To obtain an epinephrine auto-injector from a pharmacist, an authorized entity must provide proof that at least one individual at the entity has completed a training program covering the statutorily required

elements (described later). At the pharmacy level, this may be accomplished by having the entity sign a form of attestation. A sample form is attached to this CPE home study module (**Appendix A**).

What Are the Requirements for Authorized Entities Who Stock Epinephrine Auto-Injectors?

As described previously, pharmacists may prescribe epinephrine auto-injectors to *authorized entities* such as schools, day care centers, restaurants, and gyms, among other venues at which allergens capable of causing anaphylaxis may be present. Under Idaho Senate Bill 1322a, an authorized entity must meet the following requirements in order to maintain epinephrine auto-injector supply:

- Epinephrine auto-injectors must be stored in a location readily accessible in an emergency and in accordance with proper instructions for use.
- The authorized entity must contact emergency medical services as soon as possible following an administration.
- An authorized entity shall take effort to remove outdated product and dispose of it properly.

In addition, an employee or agent of the authorized entity must complete a training program by a “nationally recognized organization experienced in training laypersons in emergency health treatment” in order to administer the product. The bill delineated certain required topics that a training must cover, including:

- How to recognize signs and symptoms of severe allergic reactions, including anaphylaxis
- Standard procedures for storage, administration, and disposal
- Emergency follow-up procedures

Several training programs are available online or in person that satisfy this training requirement. A few representative programs may include, but are not limited to the following:

<http://www.redcross.org>

<http://www.allergyready.com/>

<http://medicine.edu/ashottolive>

<http://mylan.com/en/mylan-on-location-featuring-epipen>

The training program must be completed in advance by an employee or agent in order for the authorized entity to stock product.

Authorized Entity Review of Anaphylaxis and Epinephrine Auto-Injectors

Given that only one agent or employee of an authorized entity is required to complete a formal training program on anaphylaxis and epinephrine auto-injectors the rest of this module will review the clinical aspects of anaphylaxis and its treatment.

What is anaphylaxis?

Anaphylaxis is a rapidly progressing, general immune response to an allergen. The onset most commonly occurs within seconds or minutes, up to two hours from exposure to the offending allergen.¹ Common triggers include but are not limited to: insect stings, foods (The top eight food allergens being peanuts, milk, eggs, wheat, tree nuts, soy, fish and shellfish), natural latex rubber, medications and exercise.^{1,2}

What are Common Signs and Symptoms of Anaphylaxis?

Presentation of anaphylaxis varies greatly from incidence to incidence. Symptoms often affect the skin, and the respiratory, circulatory and gastrointestinal systems.

Table 1: Signs and Symptoms of Anaphylaxis and their Occurrence²

Signs and Symptoms	Occurrence
Skin	90%
Hives and Swelling	85 - 90%
Flushing	45 - 55%
Itching without rash	2-5%
Respiratory	40-60%
difficulty breathing, wheezing	45-50%
Upper airway constriction	50-60%
irritation and swelling of nasal passage	15-20%
Dizziness, Fainting, Low Blood Pressure	30-35%
Abdominal	
Nausea, vomiting, diarrhea, cramping	25-30%
Miscellaneous	
Headache	5-8 %
Chest & Abdominal pain	4-6 %
Seizure	1-2 %

Be aware that other symptoms, such as repeated sneezing, repeated coughing, hoarseness, difficulty swallowing, and a sense of anxiety and/or impending doom may occur.

The key to recognizing anaphylaxis is determining whether it is a general allergic reaction (two or more body systems involved mild-moderately, or one body system involved severely). Consideration should also be given to how rapidly the reaction is progressing.

Treatment of Anaphylaxis

Epinephrine is the first-line agent in treating anaphylaxis, and delays in treatment have been shown to be a factor in mortalities.^{1,3} Epinephrine works rapidly by acting on alpha and beta-adrenergic receptors to reduce vasodilation and vascular permeability as well as increasing bronchial smooth muscle relaxation. It also alleviates itching, hives, gastrointestinal symptoms and swelling by relaxing various other smooth muscles.^{4,5} Antihistamines may be used as secondary treatment after the administration of epinephrine, to reduce itching and to increase the patient's comfort level.¹ Antihistamines do NOT ameliorate the life-threatening effects of anaphylaxis, such as swelling of the airways, respiratory constriction, low blood pressure, and loss of consciousness. As antihistamines can have the potential to mask outward symptoms of an inwardly progressing reaction, the use of antihistamines alone may increase the risk of progression towards a life-threatening event.¹

Written allergy action plans can be extremely helpful in deciding how to treat individual allergic reactions. A popular allergy action plan form can be found at the Food Allergy Research and Education (FARE) website: www.foodallergy.org/file/emergency-care-plan.pdf

What Epinephrine Auto-Injectors Are Currently on the Market?

Product	Website	Mfr./Dist.	Generic available?	Dose	Price
Epi-Pen™ and Epi-Pen Jr.	www.epipen.com	Mylan, Inc.	Yes	(0.15mg) (0.3mg)	\$745 \$760
Adrenaclick™	www.adrenaclick.com	Amedra Pharmaceutical s, LLC	YES	(0.15mg) (0.3mg)	\$500
Epinephrine injector, USP auto-inject	www.epinephrineautoinject.com	Lineage Therapeutics	N/A	(0.15mg) (0.3mg)	\$450

*As of 6/2016. Prices from GoodRX.com

Discount programs, manufacturer coupons, and individual pharmacy discounts are available to help authorized entities afford the cost of epinephrine auto-injectors. For more information on pricing check with your local pharmacy or visit product websites for manufacturer coupons.

How Do You Administer an Epinephrine Auto-injector?

1. Have patient sit or lie down.
2. Select proper strength of auto-injector (Per the manufacturer(s) guidelines, 33-65 lbs uses the “junior” strength of 0.15mg, 66 pounds or greater uses the “adult” strength of 0.3mg. However, recommendations from the National Institute of Allergy and Infectious Diseases (NIAID), The American Academy of Pediatrics (AAP), and the National Association of School Nurses (NASN) are to upsize from the 0.15mg dose to the 0.3mg dose for persons who weigh equal to or greater than 55 pounds. When in doubt, choose the higher strength).
3. Remove auto-injector from protective case
4. Remove safety cap(s) (varies by product)
5. Grasp barrel firmly, keeping fingers away from the tip of auto-injector
6. Holding auto-injector at a 90 degree angle to the anterolateral aspect of the thigh (in front, away from midline; slightly towards outer side of thigh), jab and press firmly into the thigh until a click or other activation sound can be heard. **may be given through one light layer of clothing if needed**
7. Hold in place for 5 to 10 seconds (timing depends on device)
8. Massage injection site to enhance rate of absorption
9. Call 9-1-1 for patient to be transported to hospital (note time of administration and give info to emergency responders). DO NOT LEAVE PATIENT. If needed, assign someone to make the call.
10. Monitor patient. If there is no change in patient’s status or if the symptoms return prior to emergency responders’ arrival, a second dose may be administered after 5 minutes.

What Contraindications and Adverse Reactions Can Be Expected?

There are no absolute contraindications to the use of epinephrine for a life-threatening allergic reaction.^{4,5} Common adverse reactions to administration of epinephrine can include rapid heart rate, high blood pressure, nausea, vomiting, nervousness, anxiety, tremor, headache, sweating and paleness.

Extra caution should be exercised to monitor patients who may be at increased risk for such adverse reactions, such as those with heart conditions, pre-existing high blood pressure, thyroid conditions and those on beta-blockers. Note: patients on beta-blockers may be 1.) at an increased risk for the development of anaphylaxis, and 2.) resistant to the use of epinephrine.⁶ If a person is currently on beta-blockers and is suspected to be at risk of anaphylaxis, consider contacting the patient's health care provider to see if a therapeutic change away from beta-blockers can be made.

Epinephrine has a very short half-life. As a result, adverse reactions tend to abate quickly. Unfortunately, this also means that the therapeutic effects wane quickly as well. It is important to contact emergency responders as soon as possible following the administration of epinephrine so that the patient can be escorted for immediate, extended medical supervision. Up to 20% of patients will experience a second, bi-phasic anaphylactic reaction hours later (most commonly occurring up to 8 hours after the initial episode), which further accentuates the need for continued monitoring.^{7,8}

How Should Epinephrine Be Stored?

- Store epinephrine at room temperature between 68° to 77° F (20° to 25° C). Brief excursions permitted.
- Protect from light.
- Do not expose to extreme cold or heat. (no refrigerator or glove box, etc.)
- It is recommended to inspect the auto-injector periodically. If the device seems damaged in any way, if the solution changes color (pink or brown) or has particulate matter, replace immediately.
- Expired or used products should not be discarded in the normal trash. Disposal of these products should be into a sharps container (local hospital or pharmacy)

Conclusion

Idaho Senate Bill 1322 (effective July 1, 2016) provides new prescriptive authority to pharmacists granting them the ability to prescribe epinephrine auto-injectors to patients, caregivers, and authorized entities that may encounter a person experiencing anaphylaxis. In order to effectively identify and treat anyone experiencing anaphylaxis all entities must be aware of the clinical aspects of anaphylaxis and should regularly review the information presented in this module.

References

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