

Pharmacists' Prescriptive Authority for Epinephrine Auto-injectors

Continuing Pharmacy Education (CPE) Information:

- This CPE program is approved for 0.5 hours of home study CPE in Pharmacy Law for Idaho pharmacists.
- To satisfactorily complete this program, a pharmacist must:
 - Fully read the CPE monograph and complete the accompanying post-test evaluation
 - Mail the post-test answer sheet, postmarked no later than December 31, 2016 to:
 - Idaho State Board of Pharmacy
Home Study CPE Program
1199 Shoreline Lane, Suite 303
Boise, Idaho 83720-0067
 - Pass the post-test with a score of at least 80%; and
 - Include a self-addressed stamped envelope (SASE) for the return of a statement of credit. No statement of credit will be awarded unless a SASE is provided by the pharmacist.

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 CPE program will:

- Describe the parameters of pharmacist prescriptive authority for epinephrine auto-injectors as articulated in [Idaho Senate Bill 1322a](#);
- Review key counseling points for epinephrine auto-injectors; and
- Review signs and symptoms of anaphylaxis.

To Whom May an Idaho Pharmacist Prescribe Epinephrine Auto-Injectors?

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 pharmacist, 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, 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 may occur may similarly stock epinephrine auto-injectors.

Pharmacists should also be aware that a prescription is traditionally only valid if it is issued for a legitimate medical purpose arising from a 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. Further, pharmacists who prescribe epinephrine within the specifications of the bill are granted liability protection against injuries or other damages that result from the actions of an authorized entity to whom they prescribe.

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 for educational purposes (**Appendix A**).

Is a Collaborative Practice Agreement Necessary to Prescribe An Epinephrine Auto-Injector?

Idaho Senate Bill 1322a grants unrestricted prescriptive authority to pharmacists for epinephrine auto-injectors. Thus, no collaborative practice agreement is necessary, and there is no statewide protocol to follow. Instead, pharmacists can serve as the prescriber of record in a manner similar to what Idaho pharmacists currently enjoy for immunizations, opioid antagonists, and dietary fluoride supplements.

Is Training Required of a Pharmacist Prior to Prescribing?

Idaho Senate Bill 1322a did not require any specific training or other requirements of pharmacists prior to being eligible to prescribe epinephrine auto-injectors.

Is There Any Notification Requirements Following Issuance of a Prescription?

While Idaho Senate Bill 1322a did not require any specific notification to be provided to a patient's primary care provider, pharmacists who prescribe for a specific individual patient are encouraged to provide notification to ensure collaborative, team-based care is provided.

Can Pharmacists Prescribe Other Forms of Epinephrine?

The autonomous prescriptive authority granted in Idaho Senate Bill 1322a is specific to epinephrine auto-injectors, and thus would not encompass other forms of epinephrine.

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.

Pharmacist Counseling on Epinephrine Auto-Injectors

Given that individual patients, caregivers, or even authorized entities may be picking up an epinephrine auto-injector, the pharmacist should tailor the counseling appropriately. The remainder of this CPE module will review key counseling pearls related to anaphylaxis and epinephrine auto-injectors, which is likely to be a well-known to pharmacists.

What is anaphylaxis?

Anaphylaxis is a rapidly progressing, systemic 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 incident to incident. 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
Cutaneous	90%
Urticaria and angioedema	85 - 90%
Flushing	45 - 55%
Pruritis without rash	2-5%
Respiratory	40-60%
Dyspnea, wheeze	45-50%
Upper airway angioedema	50-60%
Rhinitis	15-20%
Dizziness, syncope, hypotension	30-35%
Abdominal	
Nausea, vomiting, diarrhea, cramping	25-30%
Miscellaneous	
Headache	5-8 %
Substernal 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 systemic 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 pruritus, urticaria, gastrointestinal symptoms and angioedema 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 edema of the airways, respiratory constriction, hypotension 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

What Epinephrine Auto-Injectors Are Currently on the Market?

Products available on the market include:

Product	Website	Mfr./Dist.	Generic available?	NDCs
Epi-Pen™ and Epi-Pen Jr.	www.epipen.com	Mylan, Inc.	Yes	49502-501-02 (0.15mg) 49502-500-02 (0.3mg)
AdrenaClick™	www.adrenaClick.com	Amedra Pharmaceuticals, LLC	Yes	52054-803-02 (0.15mg) 52054-804-02 (0.3mg)
Epinephrine injector, USP auto-inject	www.epinephrineautoinject.com	Lineage Therapeutics	N/A	54505-101-02 (0.15mg) 54505-102-02 (0.3mg)

*As of 6/2016

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

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 reported absolute contraindications to the use of epinephrine for a life-threatening allergic reaction.^{4,5} Common adverse reactions to administration of epinephrine can include tachycardia, hypertension, nausea, vomiting, nervousness, anxiety, tremor, headache, sweating and pallor.

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 hypertension, 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 may be considered.

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 may be 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.

Conclusion

Idaho Senate Bill 1322 (effective July 1, 2016) provides new authority to pharmacists with the hopes of reducing barriers and time to treatment of allergic reactions. The bill grants pharmacists the ability to prescribe epinephrine auto-injectors to patients, caregivers, and authorized entities that may encounter a person experiencing anaphylaxis. In order to provide effective medication counseling, pharmacists must be aware of the clinical aspects of anaphylaxis and should counsel patients, caregivers, and authorized entities on its appropriate use.

References

1. EpiPen/EpiPen Jr. Auto-injector [prescribing information]. Morgantown, WV: Mylan Specialty LP; Apr 2014.
2. Toogood, J. H. (1987). Beta-blocker therapy and the risk of anaphylaxis. *CMAJ: Canadian Medical Association Journal*, 136(9), 929–933.
3. Lieberman P. Biphasic anaphylactic reactions. *Ann Allergy Asthma Immunol*. 2005; 95(3): 217-226

4. Stark BJ, Sullivan TJ. Biphasic and protracted anaphylaxis. *J Allergy Clin Immunol.* 1986; 78 (1pt1):76-83
5. EpiPen/EpiPen Jr. Auto-injector [prescribing information]. Morgantown, WV: Mylan Specialty LP; Apr 2014.
6. Adrenaclick Auto-injector [prescribing information] Horsham, PA: Amedra Pharmaceuticalls LLC; Apr 2013
7. Toogood, J. H. (1987). Beta-blocker therapy and the risk of anaphylaxis. *CMAJ: Canadian Medical Association Journal*, 136(9), 929–933.
8. Lieberman P. Biphasic anaphylactic reactions. *Ann Allergy Asthma Immunol.* 2005; 95(3): 217-226
9. Stark BJ, Sullivan TJ. Biphasic and protracted anaphylaxis. *J Allergy Clin Immunol.* 1986; 78 (1pt1):76-83
10. Mylan on location- EpiPen Auto-Injector Training Course. Morgantown, WV: Mylan Specialty LP; Sept. 2015

Acknowledgments

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Appendix A. Sample Form of Attestation.

Authorized Entity Epinephrine Auto-Injector Training Completion
Attestation Statement

(Pharmacy Name)

(Address)

(Phone Number)

I, _____ understand that by signing this statement of attestation I am acknowledging the successful completion of a qualifying epinephrine auto-injector training program by an agent or member of my organization. I certify that the training program completed was offered by a nationally recognized organization experienced in training laypersons in emergency health treatment. Training provided instruction on recognition of allergic reactions and anaphylaxis, standard procedures for product storage, administration, disposal, and emergency follow-up procedures.

Name: _____

Signature: _____

Date: _____

Post-Test Questions

1. An Idaho pharmacist may legally prescribe an epinephrine auto-injector in which of the following cases?
 - A. A mother of a 7 year old boy with a documented peanut allergy who doesn't have time to make a doctor's appointment for a new prescription
 - B. A 25 year old man with a mild seafood allergy that has been getting worse with each exposure
 - C. A youth summer camp counselor who doesn't know of any children with allergies but wants to have the medication on hand just in case
 - D. All of the above

2. It is illegal for a school nurse to possess an epinephrine auto-injector that is not prescribed directly to a specific patient.
 - A. True
 - B. False

3. Pharmacists who prescribe an epinephrine auto-injector in good faith to an authorized entity are provided liability protections in Idaho law.
 - A. True
 - B. False

4. Pharmacists who wish to exercise their epinephrine auto-injector prescribing authority must do so under a collaborative practice agreement and follow a statewide protocol.
 - A. True
 - B. False

5. Pharmacists can legally prescribe and dispense epinephrine auto-injectors to an agent of an authorized entity as long as they _____
 - A. Sign a form of attestation that the risk of exposure to allergens is documented by a physician as being present
 - B. Have previously received the medication from a doctor in this state
 - C. Intend to complete training on recognizing and treating anaphylaxis in the near future
 - D. Work in an industry requiring regular interactions with children
 - E. All of the above
 - F. None of the above

6. To obtain an epinephrine auto-injector, an authorized entity must have at least one employee or agent complete a nationally recognized training program.
 - A. True
 - B. False

7. Which of the following is not one of the top eight food allergens?

- A. Milk
 - B. Egg
 - C. Peanuts
 - D. Soy
 - E. All of the above are major allergens
8. What medication is the first-line treatment for anaphylaxis?
- A. Epinephrine
 - B. Antihistamines
 - C. Albuterol
 - D. Acetaminophen
 - E. All of the above
9. A caregiver asks whether or not they need to call 911 after they administer the epinephrine auto-injector to someone experiencing anaphylaxis and the person's symptoms start to subside? As the pharmacist you respond_____.
- A. Yes. You should always call 911 when anyone is experiencing anaphylaxis
 - B. No. You do not need to call 911 unless the person is unconscious
10. Pharmacists should counsel anyone receiving an epinephrine auto-injector on all of the following **except**?
- A. Side effects of epinephrine may include tachycardia, nausea, anxiety, headache, and sweating
 - B. Never administer a second dose of the medication
 - C. The epinephrine auto-injector can be disposed of in the trash after use
 - D. B and C only
 - E. All of the above are correct

Pharmacists' Prescriptive Authority for Epinephrine Auto-injectors

Post-Test Answer Sheet

- Mail the post-test answer sheet, postmarked no later than December 31st, 2016 to:
 - Idaho State Board of Pharmacy
Home Study CPE Program
1199 Shoreline Lane, Suite 303
Boise, Idaho 83720-0067
- Include a self-addressed stamped envelope (SASE) for the return of a statement of credit. No statement of credit will be awarded unless a SASE is provided by the pharmacist.

Pharmacists Name: _____

Idaho License Number: _____

Answers:

1. _____

2. _____

3. _____

4. _____

5. _____

6. _____

7. _____

8. _____

9. _____

10. _____

Feedback on this CPE Program:

Ideas for future Board-approved Home Study CPE Programs: