# Sample Pharmacy Dispensing Protocol for Epinephrine Autoinjectors

**Updated 5/7/2025**

**This sample protocol should be modified or expanded, in accordance with Ohio law, to fit the description of each pharmacy's operations.**

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# Pharmacy Protocol for Dispensing Epinephrine Autoinjectors to Individuals At-Risk of Experiencing Anaphylaxis and Qualified Entities

| Pharmacy Name | Pharmacy TDDD License No. |
|---|---|
| Pharmacy Address | |

**Definitions**

- **"Individual at risk of experiencing anaphylaxis"** means a person who the pharmacy affiliated with the pharmacist or intern has a record of previously dispensing epinephrine to the individual in accordance with a prescription issued by a licensed health professional authorized to prescribe drugs.

- **"Qualified entity"** means a public or private entity that is associated with a location where allergens capable of causing anaphylaxis may be present, including childcare centers, colleges and universities, law enforcement agencies, places of employment, restaurants, amusement parks, recreation camps, sports playing fields and arenas, and other similar locations, except that "qualified entity" does not include either of the following:

  (1) A chartered or nonchartered nonpublic school; community school; science, technology, engineering, and mathematics school; college-preparatory boarding school; or a school operated by the board of education of a city, local, exempted village, or joint vocational school district, as those entities are otherwise authorized to procure epinephrine autoinjectors pursuant to sections 3313.7110, 3313.7111, 3314.143, 3326.28, or 3328.29 of the Revised Code; or

  (2) A camp described in section 5101.76 of the Revised Code that is authorized to procure epinephrine autoinjectors pursuant to that section.

**Purpose**

This protocol specifies the criteria and procedures for pharmacists and pharmacy interns to initiate the dispensing of epinephrine autoinjectors to the following persons, who are at least eighteen years of age, in accordance with ORC 4729.47:

(1) An individual at risk of experiencing anaphylaxis; or

(2) An individual acting on behalf of a qualified entity, as defined in section 3728.01 of the Revised Code.

**Policy**

This protocol authorizes pharmacists and pharmacy interns practicing in an Ohio pharmacy to maintain supplies of epinephrine autoinjectors for the purposes stated herein and does not prevent the use of patient-specific or third-party prescriptions for epinephrine autoinjectors written by prescribers.

**IMPORTANT:** ORC 4729.47 does not permit the dispensation of epinephrine vials or nasal formulations. The law specifically limits the use of protocols for dispensing epinephrine autoinjectors.

**Procedures**

This protocol authorizes pharmacists to dispense epinephrine pursuant to the following procedures outlined herein. Unlimited refills are authorized.

Prior to dispensing, a pharmacist or pharmacy intern must verify that the individual meets the requirements of ORC 4729.47.

1. Verify the date of birth of the patient or requestor to confirm they are at least eighteen years old.

2. Confirm either:

a. The patient had previously received an epinephrine autoinjector pursuant to a prescription issued by a licensed health professional authorized to prescribe drugs. The record of dispensing must be on-file with the dispensing pharmacy.

**OR**

b. The individual requesting the epinephrine autoinjector is acting on behalf of a qualified entity and has successfully completed the required training from the Ohio Department of Health. The representative of the qualified entity should present a copy of a certificate of completion of ODH's Training Course: *Anaphylaxis Training for Qualified Entities (Course ID: 1072343)*

**Indication for Use of Epinephrine Autoinjectors**

An epinephrine autoinjector is indicated in the emergency treatment of severe allergic reactions (Type 1) including anaphylaxis to stinging insects (e.g., order Hymenoptera, which includes bees, wasps, hornets, yellow jackets and fire ants), biting insects (e.g., triatoma, mosquitoes), allergen immunotherapy, foods (e.g., peanuts, tree nuts, shellfish, fish, milk, eggs, and wheat), medications, diagnostic testing substances (e.g., radiocontrast media), and other allergens, as well as idiopathic anaphylaxis (anaphylaxis to unknown substances) or exercise-induced anaphylaxis. An epinephrine autoinjector is intended for immediate administration in patients with a history of anaphylactic reactions.

Severe allergic reactions may occur within minutes after exposure and consist of flushing, apprehension, syncope, tachycardia, thready or unobtainable pulse associated with a fall in blood pressure, convulsions, vomiting, diarrhea and abdominal cramps, involuntary voiding, wheezing, dyspnea due to laryngeal spasm, pruritus, rashes, urticaria, and/or angioedema. An epinephrine autoinjector is designed as emergency supportive therapy only and is not a replacement or substitute for immediate medical care.

## Precautions and Contraindications

### *Precautions*

An epinephrine autoinjector is not intended to be a substitute for immediate medical care. Appropriate medical care should be sought by or for the patient including the activation of emergency services (911). In most patients, epinephrine is effective after one injection. However, symptoms may recur, and further injections may be required to control the reaction. Epinephrine can be re-injected every 5 to 15 minutes until there is resolution of the anaphylaxis or signs of adrenaline excess (such as palpitations, tremors, and anxiety). More than two sequential doses of epinephrine should only be administered under direct medical supervision.

Epinephrine should be used with caution in patients with cardiac arrhythmias, coronary artery or organic heart disease, hypertension, or in patients who are on medications that may sensitize the heart to arrhythmias (e.g., digitalis, diuretics, or anti-arrhythmic medications). In such patients, epinephrine may precipitate or aggravate angina pectoris as well as produce ventricular arrhythmias. Tricyclic antidepressants (ex., amitriptyline, desipramine, nortriptyline, etc.), monoamine oxidase inhibitors (ex. phenelzine, tranylcypromine, isocarboxazid, etc.), levothyroxine sodium, and certain antihistamines may potentiate the effects of epinephrine.

Some patients may be at greater risk of developing adverse reactions after epinephrine administration. These include patients with hyperthyroidism, cardiovascular disease, hypertension, and diabetes; elderly individuals; and pregnant women. It must be noted that, despite these concerns, epinephrine is essential for the treatment of anaphylaxis. Therefore, patients with these conditions, or any other person who might be in a position to administer epinephrine to a patient with these conditions experiencing anaphylaxis, should be instructed about the circumstances under which epinephrine should be used.

Epinephrine autoinjectors should ONLY be injected into the anterolateral aspect of the thigh. Do not inject intravenously or into the buttock, digits, hands, or feet. Ensure the leg is held firmly during injection as lacerations, bent needles, and embedded needles have been reported when epinephrine autoinjectors have been injected into the thigh of young children who are uncooperative and kick or move during an injection.

Accidental injection into fingers, hands or feet may result in decrease or loss of blood flow to these areas. The patient should be advised to go immediately to the nearest emergency department and to inform the healthcare professional in the emergency department of the location of the accidental injection.

Rare cases of serious skin and soft tissue infections have been reported following epinephrine injection. Advise patients to seek medical care if they develop symptoms of infection such as persistent redness, warmth, swelling, or tenderness at the injection site.

***Pregnancy: Category C***

There are no adequate and well controlled studies of the acute effect of epinephrine in pregnant women. In animal reproductive studies, epinephrine administered by the subcutaneous route to rabbits, mice, and hamsters during the period of organogenesis was teratogenic at doses 7 times and higher than the maximum recommended human intramuscular and subcutaneous dose on a mg/m2 basis. Epinephrine is the first-line medication of choice for the treatment of anaphylaxis during pregnancy in humans. Epinephrine should be used for treatment of anaphylaxis during pregnancy in the same manner as it is used in non-pregnant patients. For more information, consult the epinephrine autoinjector's package insert.

***Contraindications***

There are no absolute contraindications to the use of epinephrine in a life-threatening allergic reaction.

***Adverse Reactions***

Adverse reactions of epinephrine include transient, moderate anxiety; feelings of over stimulation; apprehensiveness; restlessness; tremor; weakness; shakiness; dizziness; sweating; tachycardia; palpitations; pallor; nausea and vomiting; headache; and/or respiratory difficulties. Ventricular arrhythmias may follow administration of epinephrine. While these symptoms occur in some patients treated with epinephrine, they are likely to be more pronounced in patients with hypertension or hyperthyroidism. These signs and symptoms usually subside rapidly, especially with bed rest.

**Authorization to Dispense Epinephrine Autoinjectors**

Pursuant to ORC 4729.47 and OAC 4729:1-3-06 and 4729:2-3-06, this protocol authorizes pharmacists and pharmacy interns employed at the location on Page 1 of this protocol to dispense epinephrine autoinjectors without a prescription to either of the following so long as the individual is at least 18 years of age:

- An individual who there is reason to believe is experiencing[1] or at risk of experiencing anaphylaxis if the pharmacy affiliated with the pharmacist has a record of previously dispensing epinephrine to the individual in accordance with a prescription issued by a licensed health professional authorized to prescribe drugs; or

- An individual acting on behalf of a qualified entity, as defined in section 3728.01 of the Ohio Revised Code.

Upon dispensing of an epinephrine autoinjector without a prescription, a pharmacist or pharmacy intern under direct supervision of a pharmacist shall do all of the following:

***Pharmacy (TDDD) Responsibility***

The Ohio pharmacy licensed as a terminal distributor of dangerous drugs (TDDD) listed on Page 1 of this protocol shall ensure that all pharmacists and pharmacy interns who dispense epinephrine autoinjectors pursuant to this protocol are trained on the use of epinephrine autoinjectors and can meet the training requirements for patient counseling listed below.

***Required Patient Counseling***

The dispensing pharmacist or pharmacy intern shall provide the following patient counseling:

[1] If a patient is currently experiencing anaphylaxis, pharmacy personnel must call emergency services immediately.

1. Instruct the individual to whom the epinephrine autoinjector is dispensed, either verbally or in writing, to summon emergency services as soon as practicable either before or after administering epinephrine.

2. Provide the person receiving the device instructions on the proper method of administering epinephrine with the device.

While not required by law or rule, patients should also be counseled on the proper method of disposing of used epinephrine autoinjectors. For more information on safe sharp disposal visit: https://www.fda.gov/medical-devices/consumer-products/safely-using-sharps-needles-and-syringes-home-work-and-travel

***Required Physician/Prescriber Notification***

***NOTE:*** *This notification requirement only applies to dispensing an epinephrine autoinjector to an individual who there is reason to believe is experiencing or at risk of experiencing anaphylaxis if the pharmacy affiliated with the pharmacist has a record of previously dispensing epinephrine to the individual in accordance with a prescription issued by a licensed health professional authorized to prescribe drugs. This requirement* ***does not apply*** *when dispensing an epinephrine autoinjector to a qualified entity.*

Provide notice of the dispensing to the individual's primary care provider, if known, or to the prescriber who issued the individual the initial prescription for epinephrine. Notification shall be conducted using one of the following methods that is capable of confirming delivery of the required notification:

1. Electronic mail;
2. Interoperable electronic medical records system
3. Facsimile;
4. Electronic prescribing system;
5. Electronic pharmacy record system;
6. Documented verbal communication;
7. Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.

**Type of Epinephrine Autoinjectors Authorized and Directions for Use**

A pharmacist or pharmacy intern under the direct supervision of a pharmacist may dispense any of the following formulations of epinephrine autoinjectors and the specified drug delivery devices without a prescription (only selected formulations are authorized):

| Epinephrine Autoinjector | Authorized |
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| Epinephrine Injection, authorized generic of Adrenaclick® | ☐ |
| EpiPen® and EpiPen Jr® | ☐ |
| Epinephrine Injection, authorized generic of EpiPen® (Mylan) | ☐ |
| Epinephrine Injection, authorized generic of EpiPen® (Teva) | ☐ |
| AUVI-Q® | ☐ |

***(Authorizing physician must select one or more)***

| Epinephrine Injection, authorized generic of Adrenaclick® | |
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| **Dose** | • Injection, 0.3 mg/0.3 mL epinephrine injection, USP, pre-filled auto-injector for patients ≥ 30 kg (66 lbs) (NDC No. 0115-1694-49)<br><br>• Injection, 0.15 mg/0.15 mL epinephrine injection, USP, pre-filled autoinjector for patients 15 to 30 kg (33 to 66 lbs) (NDC No. 0115-1695-49) |
| **Quantity to be Dispensed** | Carton containing two autoinjectors |
| **Directions for Use** | 1. Activate emergency services (Call 9-1-1).<br>2. Remove epinephrine injection from its protective carrying case.<br>3. Pull off blue end caps; you will now see a red tip.<br>4. Grasp the autoinjector in your fist with the red tip pointing downward.<br>5. Place the red tip against the middle of the outer thigh (upper leg) at a 90° angle (perpendicular) to the thigh. NOTE: If you are administering epinephrine injection to a young child, hold the leg firmly in place and limit movement prior to and while administering an injection.<br>6. Press down hard and hold firmly against the thigh for approximately 10 seconds to deliver the medicine.<br>7. Only inject into the middle of the outer thigh. Do not inject into any other part of the body.<br>8. Remove autoinjector from the thigh.<br>9. Massage the area for 10 seconds.<br>10. Check the red tip. The injection is complete and you have received the correct dose of the medicine if you see the needle sticking out of the red tip. If you do not see the needle, repeat the injection.<br>11. Carefully cover the needle with the carrying case.<br>12. You may need to use a second autoinjector if symptoms continue or recur. |

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| | 13. Take the used autoinjector with you when seeing a healthcare provider and dispose of properly. |
| **Storage Requirements** | • Store epinephrine injection at room temperature between 68°F to 77° F (20°C to 25° C).<br><br>• Protect from light.<br><br>• Do not expose to extreme heat or cold. For example, do not store in your vehicle's glove box and do not store in the refrigerator or freezer.<br><br>• Always keep your epinephrine injection in the carrying case to protect it from damage. The carrying case is not waterproof.<br><br>• Examine the contents in the viewing window of your epinephrine autoinjector periodically. The solution should be clear. If the solution is discolored (pinkish or brown), cloudy or contains solid particles, replace the unit. |

| EpiPen® and EpiPen Jr® | |
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| **Dose** | • EpiPen®: Injection, 0.3 mg/0.3 mL epinephrine injection, USP, pre-filled autoinjector for patients ≥ 30 kg (66 lbs) (NDC No. 49502-500-02)<br><br>• EpiPen Jr®: Injection, 0.15 mg/0.3 mL epinephrine injection, USP, pre-filled autoinjector for patients 15 to 30 kg (33 to 66 lbs) (NDC No. 49502-501-02) |
| **Quantity to be Dispensed** | Carton containing two autoinjectors |
| **Directions for Use** | 1. Activate emergency services (Call 9-1-1).<br>2. Remove the autoinjector from the protective case.<br>3. Grip the autoinjector with one hand and with the orange needle end pointing down. Use the other hand to remove the blue safety top. Pull it straight up and away.<br>4. Place the orange needle end against the outer thigh, through clothing if needed.<br>5. Push down firmly and hold in place for 3 seconds. The autoinjector will make a distinct pop sound when pushed against the thigh.<br>6. Lift the auto-injector straight out from the thigh. The orange needle end will extend to cover the needle. If the needle is visible, do not reuse it. Use a new auto-injector. Throw away the blue safety top.<br>7. You may need to use a second autoinjector if symptoms continue or recur.<br>8. Take the used autoinjector with you when seeing a healthcare provider and dispose of properly. |
| **Storage Requirements** | • Store at room temperature between 68°F to 77° F (20°C to 25° C).<br><br>• Keep protective case in the outer carton to protect from light. |

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| | • Do not expose to extreme cold or heat. For example, do not store in your vehicle's glove box or trunk. Do not store in the refrigerator or freezer.<br><br>• Always keep your epinephrine autoinjector in the carrying case to protect it from damage. The protective case is not waterproof.<br><br>• Examine the contents in the medicine viewing window of your autoinjector regularly. The medicine should be clear. If the medicine is discolored (pinkish or brown color) or contains solid particles, replace the autoinjector. |

| Epinephrine Injection, authorized generic of EpiPen® (Mylan) | |
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| **Dose** | • Injection, 0.3 mg/0.3 mL epinephrine injection, USP, pre-filled autoinjector for patients ≥ 39 kg (66 lbs) (NDC No. 49502-102-02)<br><br>• Injection, 0.15 mg/0.3 mL epinephrine injection, USP, pre-filled autoinjector for patients 15 to 30 kg (33 to 66 lbs) (NDC No. 49502-101-02) |
| **Quantity to be Dispensed** | Carton containing two autoinjectors |
| **Directions for Use** | 1. Activate emergency services (Call 9-1-1).<br>2. Remove the auto-injector from the protective case.<br>3. Grip the autoinjector with one hand and with the orange needle end pointing down. Use the other hand to remove the blue safety top. Pull it straight up and away.<br>4. Place the orange needle end against the outer thigh, through clothing if needed.<br>5. Push down firmly and hold in place for 3 seconds. The autoinjector will make a distinct pop sound when pushed against the thigh.<br>6. Lift the auto-injector straight out from the thigh. The orange needle end will extend to cover the needle. If the needle is visible, do not reuse it. Use a new auto-injector. Throw away the blue safety top.<br>7. You may need to use a second autoinjector if symptoms continue or recur.<br>8. Take the used autoinjector with you when seeing a healthcare provider and dispose of properly. |
| **Storage Requirements** | • Store at room temperature between 68°F to 77° F (20°C to 25° C).<br><br>• Keep protective case in the outer carton to protect from light. When exposed to air or light epinephrine changes quickly to a pinkish or brown color and should not be used. |

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| | • Do not expose to extreme cold or heat. For example, do not store in your vehicle's glove box or trunk. Do not store in the refrigerator or freezer.<br><br>• Always keep your epinephrine autoinjector in the carrying case to protect it from damage. The protective case is not waterproof.<br><br>• Examine the contents in the medicine viewing window of your epinephrine autoinjector regularly. The medicine should be clear. If the medicine is discolored (pinkish or brown color) or contains solid particles, replace the autoinjector. |

| Epinephrine Injection, authorized generic of EpiPen® (Teva) | |
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| **Dose** | • Epinephrine: Injection, 0.3 mg/0.3 mL epinephrine injection USP, pre-filled autoinjector for patients ≥ 30 kg (≥ 66 lbs) (NDC No. 0093-5986-27)<br><br>• Epinephrine: Injection, USP 0.15 mg/0.3 mL epinephrine injection USP, prefilled autoinjector for patients 15 to 30 kg (33 to 66 lbs) (NDC No. 0093-5985-27) |
| **Quantity to be Dispensed** | Carton containing two autoinjectors |
| **Directions for Use** | 1. Activate emergency services (Call 9-1-1).<br>2. Quickly twist the yellow cap off the epinephrine injection, 0.3 mg auto-injector or the green cap off the epinephrine injection, 0.15 mg auto-injector in the direction of the “twist arrow” to remove it.<br>3. Grasp the auto-injector in your fist with the orange tip (needle end) pointing downward. With your other hand, pull off the blue safety release.<br>4. Place the orange tip against the middle of the outer thigh (upper leg) at a right angle (perpendicular) to the thigh.<br>5. Swing and push the auto-injector firmly until it ‘clicks’. The click signals that the injection has started.<br>6. Hold firmly in place for 3 seconds (count slowly 1,2,3).<br>7. 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.<br>8. Massage the area for 10 seconds.<br>9. You may need to use a second autoinjector if symptoms continue or recur.<br>10. Take the used autoinjector with you when seeing a healthcare provider and dispose of properly. |
| **Storage Requirements** | • Store at room temperature between 68°F to 77° F (20°C to 25° C).<br><br>• Protect from light. |

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| | • Do not expose to extreme cold or heat. For example, do not store in your vehicle's glove box or trunk. Do not store in the refrigerator or freezer.<br><br>• Always protect your epinephrine autoinjector from damage and water.<br><br>• Examine the contents in the clear window of your epinephrine autoinjector periodically. The solution should be clear. If the solution is discolored (pinkish or darker than slightly yellow) or contains solid particles, replace the unit. |

| AUVI-Q® | |
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| **Dose** | • Injection, 0.3 mg/0.3 mL epinephrine injection, USP, pre-filled autoinjector for patients > 30 kg (> 66 lbs) (NDC No. 60842-023-02)<br><br>• Injection, 0.15 mg/0.15 mL epinephrine injection, USP, pre-filled autoinjector for patients 15 to 30 kg (33 to 66 lbs) (NDC No. 60842-022-02)<br><br>• Injection, 0.1 mg/0.1 mL epinephrine injection, USP, pre-filled autoinjector for patients 7.5 to 15 kg (16.5 to 33 lbs) (NDC No. 60842-021-02) |
| **Quantity to be Dispensed** | Carton containing two autoinjectors |
| **Directions for Use** | 1. Activate emergency services (Call 9-1-1).<br>2. Pull AUVI-Q® up from the outer case.<br>3. Pull red safety guard down and off of AUVI-Q® (pull firmly to remove).<br>4. Place black end of AUVI-Q® against the middle of the outer thigh (through clothing, if needed), then push firmly until you hear a click and hiss sound, and hold in place for 2 seconds. Only inject into the middle of the outer thigh. Do not inject into any other part of the body.<br>5. If you are administering AUVI-Q® to a young child or infant, hold the leg firmly in place while administering an injection.<br>6. The needle automatically retracts after the injection is complete, so the needle will not be visible after the injection. AUVI-Q® includes a 2-second countdown after it is activated, then the voice instruction will indicate the injection is complete, and to seek emergency medical attention, AUVI-Q will beep, and the lights will blink red.<br>7. You may need to use a second autoinjector if symptoms continue or recur.<br>8. Take the used autoinjector with you when seeing a healthcare provider and dispose of properly. |

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| **Storage Requirements** | • Store at room temperature between 68°F to 77° F (20°C to 25° C).<br><br>• Keep in the outer case it comes in to protect it from light.<br><br>• Do not freeze. Do not expose to extreme heat or cold. For example, do not store in your vehicle's glove box.<br><br>• Examine contents in the viewing window periodically. Solution should be clear. If the solution is discolored (pinkish color or darker than slightly yellow), cloudy or contains solid particles, replace the unit. |

## Additional Patient Instructions

## Any Additional Requirements or Limitations

**Physician Authorization**

| I HEREBY AUTHORIZE THE PHARMACISTS AND PHARMACY INTERNS PRACTICING AT THE LOCATION LISTED IN THIS PROTOCOL TO DISPENSE EPINEPHRINE AUTOINJECTORS IN ACCORDANCE WITH SECTION 4729.47 OF THE OHIO REVISED CODE. | |
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| Physician Signature | License Number |
| Physician Name (print) | Date |

*(Not Valid without Physician Authorization)*

***REMINDER: THIS PROTOCOL MUST BE REVIEWED AND AUTHORIZED ON A BIENNIAL BASIS (E.G., ONCE EVERY TWO YEARS).***

**Pharmacy Responsible Person Authorization**

| Responsible Person Signature | License Number |
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| Responsible Person Name (print) | Date |