### DEPARTMENT OF HEALTH SERVICES

STATE OF WISCONSIN Effective 01/19/23

Division of Public Health

## STATEWIDE EPINEPHRINE STANDING ORDER FOR PHARMACISTS

### **BACKGROUND:**

Under Wisconsin law (Wis. Stat. § 255.07), a health care provider with prescribing authority who is employed by or under contract with the department may issue a statewide standing order for the dispensing of epinephrine auto-injectors or prefilled syringes for use under sub. (4) by authorized individuals or by employees or agents of authorized entities who have completed the training required by sub. (5).

### STATEWIDE STANDING ORDER:

A standing order is defined in Wis. Stat. § 450.01(21p) as an order transmitted electronically or in writing by a practitioner for a drug or device for multiple patients or for one or more groups of patients. A centralized, statewide epinephrine standing order for pharmacists outlines predetermined conditions and criteria that, when met, enables pharmacists across Wisconsin to dispense epinephrine without a patient-specific prescription order. A health care provider with prescribing authority who is licensed in Wisconsin and employed by or under contract with the Department of Health Services (DHS) may issue standing orders for epinephrine that delegate authority to pharmacists practicing and licensed in Wisconsin to dispense epinephrine to those authorized in the standing order.

### **SUBJECT:**

Statewide Standing Order for Pharmacies—Epinephrine Dispensing for Anaphylaxis Treatment

### **EFFECTIVE DATE:**

01/19/2023 (supersedes all previous versions)

### **EXPIRATION OF STANDING ORDER:**

This Order is effective as of the date signed and shall remain effective until withdrawn by Dr. Colella, DHS Secretary, or either's designee. Dr. Colella retains the right to modify or supplement this Order as needed.

# APPROVED FOR USE AS A POPULATION-BASED STANDING ORDER BY:

Wisconsin Department of Health Services (DHS)

### **PURPOSE:**

This statewide epinephrine standing order delegates authority to pharmacists and outlines the policies and procedures necessary for dispensing epinephrine without a patient-specific prescription to authorized individuals or to employees or agents of authorized entities who have completed the required training.

### **POLICY:**

This standing order authorizes pharmacists located, and licensed in Wisconsin, to maintain supplies of epinephrine for the purposes stated herein and does not prevent the use of patient-specific or third-party prescriptions for epinephrine written by prescribers.

# **AUTHORITY:**

This standing order is issued pursuant to Wis. Stat. § 255.07, which permits a physician with prescribing authority who is employed by or under contract with DHS to issue a statewide standing order to one or more persons authorizing the dispensing of epinephrine.

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

### **PROCEDURES:**

# 1. Standing order compliance requirements:

- a. Before dispensing epinephrine under the standing order to an authorized employee, agent, or individual, the pharmacy must verify completion of an anaphylaxis training program conducted by a nationally recognized organization experienced in training laypersons in emergency health treatment or an organization approved by DHS. The authorized employee, agent, or individual shall provide the pharmacy a certificate of training from a nationally recognized organization or an organization approved by DHS that must be current within 4 years of completion.
- b. The standing order signed by a health care provider with prescribing authority who is licensed in Wisconsin and employed by or under contract with DHS, can be found at the following DHS website: www.dhs.wisconsin.gov.
- c. A copy of the standing order signed by a DHS State EMS Medical Director, who is also a licensed physician in Wisconsin, must be maintained on file and be readily retrievable at each participating pharmacy site.
- d. All registered pharmacists at the pharmacy must be familiar with epinephrine and the patient educationmaterials.
- e. The pharmacist must educate the patient and distribute the patient education materials at the time of dispensing.
- f. Pharmacists must maintain dispensing records according to Wis. Admin. Code § Phar 7.11 requirements (pharmacy records).

# 2. Consultation

- a. Offer education on anaphylaxis recognition and epinephrine administration. Emphasize the importance of establishing an anaphylaxis response plan; ensure others in their residence learn this plan in case of emergency.
- b. Provide client with information about the epinephrine delivery options and insurance coverage.
- c. Review questions about anaphylaxis and epinephrine administration.
- d. Provide overview of how to recognize anaphylaxis and proper procedure to respond to anaphylaxis with the use of epinephrine.
- e. Discuss how to safely dispose of epinephrine.

# **Epinephrine Pharmacist Dispensing Protocol**

# **Clinical Pharmacology Description**

Epinephrine is indicated for the treatment of anaphylaxis induced by an allergen. Anaphylaxis is highly likely when any one of the following two criteria are fulfilled<sup>1</sup>:

- 1. Acute onset of an illness (minutes to several hours) with simultaneous involvement of the skin, mucosal tissue, or both (e.g., generalized hives, pruritus or flushing, swollen lips-tongue-uvula) *AND AT LEAST ONE OF THE FOLLOWING:* 
  - Respiratory compromise (e.g., dyspnea, wheeze-bronchospasm, stridor, reduced PEF, hypoxemia)
  - Reduced BP or associated symptoms of end-organ dysfunction (e.g., hypotonia [collapse], syncope, incontinence)
  - Severe gastrointestinal symptoms (e.g., severe crampy abdominal pain, repetitive vomiting), especially after exposure to non-food allergens.
- 2. Acute onset of hypotension<sup>a</sup>, or bronchospasm<sup>b</sup>, or laryngeal involvement<sup>c</sup>, after exposure to a known or highly probable allergen<sup>d</sup> for that patient (minutes to several hours), even in the absence of typical skin involvement.

PEF, Peak expiratory flow; BP, blood pressure.

- <sup>a</sup> Hypotension defined as a decrease in systolic BP greater than 30% from that person's baseline, OR i. Infants and children under 10 years: systolic BP less than (70 mmHg + [2 x age in years]) ii. Adults and children over 10 years: systolic BP less than <90 mmHg.
- <sup>b</sup> Excluding lower respiratory symptoms triggered by common inhalant allergens or food allergens perceived to cause "inhalational" reactions in the absence of ingestion.
- <sup>c</sup> Laryngeal symptoms include: stridor, vocal changes, odynophagia.
- <sup>d</sup> An allergen is a substance (usually a protein) capable of triggering an immune response that can result in an allergic reaction. Most allergens act through an IgE-mediated pathway, but some non-allergen triggers can act independent of IgE (for example, via direct activation of mast cells).

# **Eligible Candidates**

An employee or agent of an authorized entity who has completed the training required by sub. (5) or an authorized individual may use an epinephrine auto-injector or prefilled syringe prescribed under sub. (2) to do any of the following: (a) Provide one or more epinephrine auto-injectors or prefilled syringes to any individual who the employee, agent, or authorized individual believes in good faith is experiencing anaphylaxis, or to the parent, guardian, or caregiver of that individual for immediate administration, regardless of whether the individual has a prescription for an epinephrine auto-injector or prefilled syringe or has previously been diagnosed with an allergy.

(b) Administer an epinephrine auto-injector or prefilled syringe to any individual who the employee, agent, or authorized individual believes in good faith is experiencing anaphylaxis, regardless of whether the individual has a prescription for an epinephrine auto-injector or prefilled syringe or has previously been diagnosed with an allergy.

### Definitions:

- (b) "Authorized entity" means any entity or organization, other than a school described in s. <u>118.2925</u>, operating or participating in a business, activity, or event at which allergens capable of causing anaphylaxis may be present, including a recreational and educational camp, college, university, day care facility, youth sports league, amusement park, restaurant, place of employment, and sports arena.
- (bg) "Authorized individual" means an individual who has successfully completed the training program under sub. (5).

<sup>&</sup>lt;sup>1</sup> Cardona V, Ansotegui IJ, Ebisawa M, El-Gamal Y, Fernandez Rivas M, Fineman S, Geller M, Gonzalez-Estrada A, Greenberger PA, Sanchez Borges M, Senna G, Sheikh A, Tanno LK, Thong BY, Turner PJ, Worm M. World allergy organization anaphylaxis guidance 2020. World

Allergy Organ J. 2020 Oct 30;13(10):100472. doi: 10.1016/j.waojou.2020.100472. PMID: 33204386; PMCID: PMC7607509.

# Order to dispense

Upon satisfactory assessment that

- (a) An employee or agent described in sub. (3) or (4) or an individual seeking to be an authorized individual completed an anaphylaxis training program and at least every 4 years thereafter conducted by a nationally recognized organization experienced in training laypersons in emergency health treatment or an organization approved by the department.
- **(b)** The organization that conducts the training under par. (a) shall issue a certificate, on a form approved by the department, to each person who successfully completes the anaphylaxis training program.

and upon providing consultation to that individual regarding recognizing and responding to suspected anaphylaxis, deliver one epinephrine kit. The specific epinephrine formulation shall be selected from the list below in accordance with the recipient's preference and training to administer a particular formulation:

Product, quantity and instructions for epinephrine to be dispensed

	Auto-injector	Pre-filled syringe
Adult 66 pounds or more/30 kilograms or more	Dispense Two single-use auto-injectors of epinephrine 1:1,000; 0.3 to 0.5 mg/ml depending on manufacturer availability.	Dispense Two single-use pre-filled syringes of epinephrine 1:1,000; 0.5 mg/ml
	Sig: Place one auto-injector against the middle of the outer thigh (through clothing, if needed), then push firmly until you hear a click sound, and hold in place for 3 seconds to allow drug administration.  If there is no improvement after 5 minutes, repeat the injection.	Sig: 1) Uncap the epinephrine syringe. 2) Insert the needle into the muscle of the middle of the outer thigh of the patient, through clothing if needed, and push on the plunger to inject the epinephrine. If there is no improvement after 5 minutes, repeat the injection.
Pediatric 33 to 66 pounds/15 to 30 kilograms for prefilled syringes or as specified by autoinjector manufacturer.  Do not dispense pediatric epinephrine for patients below 33 pounds/15 kg or as specified by autoinjector manufacturer.	Dispense Two single-use auto-injectors of epinephrine 1:1,000; 0.15 mg/ml.  Sig: Place one auto-injector against the middle of the outer thigh (through clothing, if needed), then push firmly until you hear a click sound, and hold in place for 3 seconds to allow drug administration.  If there is no improvement after 5 minutes, repeat the injection.	Dispense Two single-use pre-filled syringes of epinephrine 1:1,000; 0.15 mg/ml. Sig: 1) Uncap the epinephrine syringe. 2) Insert the needle into the muscle of the middle of the outer thigh of the patient, through clothing if needed, and push on the plunger to inject the epinephrine. If there is no improvement after 5 minutes, repeat the injection.

# **Prescription label**

Should include the following:

- Name of the recipient or patient (prescribed or using)
- Prescriber name on the standing order
- Epinephrine formulation and concentration
- Date dispensed
- Refills: PRN, as needed for a year
- Patient instructions
  - o Dispensed per standing order; and
  - Use as directed.

#### Consultation

- Ask if ever used epinephrine before. Offer education on anaphylaxis recognition and epinephrine administration. Emphasize the importance of establishing an anaphylaxis response plan; ensure others in their residence learn this plan in case of emergency.
- Provide client with information about epinephrine delivery options and insurance coverage.

### **Patient Education**

- Review common questions about anaphylaxis and epinephrine administration.
- Provide an overview of how to recognize anaphylaxis and proper procedure to respond with epinephrine.
- Discuss how to administer epinephrine and when.
- Discuss how to safely dispose of epinephrine.
- Additional information and resources are available on https://www.foodallergy.org/resources.

# After Epinephrine administration

- 1. **Call 911.** Tell emergency dispatcher the person is having anaphylaxis and may need epinephrine when emergency responders arrive.
- 2. Lay the person flat, raise legs and keep warm. If breathing is difficult or they are vomiting, let them sit up or lie on their side.
- 3. If symptoms do not improve, or symptoms return, more doses of epinephrine can be given about 5 minutes or more after the last dose.
- 4. Alert emergency contacts.
- 5. Encourage transport to ER, even if symptoms resolve; symptoms may reoccur.

### **Contraindications**

Patients know to be hypersensitive to epinephrine or any components of the preparation.

### **Precautions**

Common side effects of epinephrine include:

- Fast, irregular or "pounding" heartbeat
- Sweating
- Shakiness
- Headache
- Feeling nervous
- Weakness
- Dizziness
- Nausea and vomiting
- Breathing problems

# **Statewide Epinephrine Standing Order Signature:**

M. Ricardo Colella Do, Mpri

Dr. Mario Riccardo Colella, DHS EMS Medical Director

Wisconsin Medical License: 50358-21

NPI #: 1336106277

By dispensing epinephrine under this Statewide Epinephrine Standing Order for Pharmacists, the managing pharmacist attests that all registered pharmacists at this location have received one hour of training on epinephrine and have read and understand both the epinephrine standing order and the epinephrine patient education materials.