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DPH Numbered Memo EMS 23-01

To: Pharmacies licensed in Wisconsin

From: Wisconsin Department of Health Services (DHS)

Statewide Epinephrine Standing Order for Pharmacists

Background

Under Wisconsin law (<u>Wis. Stat. § 255.07</u>), 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. (<u>4</u>) by authorized individuals or by employees or agents of authorized entities who have completed the training required by sub. (<u>5</u>).

Definition

A standing order is defined in <u>Wis. Stat. § 450.01(21p)</u> 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This order is effective as of the date signed and shall remain effective until withdrawn by Dr.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

www.dhs.wisconsin.gov

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.

Procedures

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

1. Standing order compliance requirements

- a. **Participant training**: 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 four years of completion.
- b. **Public posting**: 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: <u>https://dhs.wisconsin.gov/dph/memos/ems/index.htm</u>.
- c. **Order copy maintenance**: 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. **Participant authority**: All registered pharmacists at the pharmacy must be familiar with epinephrine and the patient education materials.
- e. **Patient education**: The pharmacist must educate the patient and distribute the patient education materials at the time of dispensing.
- f. **Record maintenance**: Pharmacists must maintain dispensing records according to Wis. Admin. Code § Phar 7.11 requirements (pharmacy records).

2. Consultation with patient

- a. Offer education on:
 - Anaphylaxis recognition and epinephrine administration.
 - The importance of establishing an anaphylaxis response plan.
 - The importance of others in their residence learning 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.
 - Proper procedure to respond to anaphylaxis with the use of epinephrine.
 - Contraindications

- Side effects
- e. Discuss how to safely dispose of epinephrine.
- f. After Epinephrine administration
 - Call 911. Tell emergency dispatcher the person is having anaphylaxis and may need epinephrine when emergency responders arrive.
 - 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.
 - If symptoms do not improve, or symptoms return, more doses of epinephrine can be given about 5 minutes or more after the last dose.
 - Alert emergency contacts.
 - Encourage transport to ER, even if symptoms resolve; symptoms may reoccur.

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 fulfilled¹:

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

Acute onset of hypotension, or bronchospasm, or laryngeal involvement, after exposure to a known or highly probable allergen for that patient (minutes to several hours), even in the absence of typical skin involvement (https://www.worldallergyorganizationjournal.org/article/S1939-4551(20)30375-6/fulltext#secsectitle0030).

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.

*"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.

** "Authorized individual" means an individual who has successfully completed the training program and for sub. (5).

¹ 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 the following requirements have been met:

- (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:

	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: Uncap the epinephrine syringe. 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 auto-injector 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: Uncap the epinephrine syringe. 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.

Product, quantity and instructions for epinephrine to be dispensed

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
 - Dispensed per standing order; and
 - Use as directed.

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.

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. Rugardo Colla DO, Mput

1.6.2023

DATE

SIGNATURE: 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

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one hour of training on epinephrine and have read and understand both the epinephrine standing order and the epinephrine patient education materials.