



Guidance Document HB 296 - Procurement of epinephrine autoinjectors by schools and camps

About the Law

HB 296 (130th General Assembly) was signed into law and took effect on April 21, 2014. The law authorizes a school governing authority (i.e., the board of education of a school district, governing authority of a community school, governing body of a STEM school, board of trustees of a college-preparatory boarding school, or governing authority of a chartered or nonchartered nonpublic school), a residential camp, child day camp, or camp operated by a specified political subdivision to procure epinephrine autoinjectors for use in emergency situations **without possessing a terminal distributor of dangerous drugs license.**

Where do I obtain a supply of epinephrine autoinjectors?

The law permits wholesale distributors of dangerous drugs to sell or donate epinephrine autoinjectors to school governing authorities or camps for use in emergency situations. Wholesalers of dangerous drugs are licensed by the Ohio State Board of Pharmacy. To ensure the license status of a potential wholesaler, please visit: <https://license.ohio.gov/lookup/default.asp?division=96>.

In addition, a manufacturer of a dangerous drug is also permitted to donate epinephrine autoinjectors to school governing authorities for use in emergency situations.

Developing a Policy

Please be advised, if a school or a camp elects to procure epinephrine autoinjectors, the law requires that it adopt a policy authorizing their maintenance and use. One component of the policy must be a prescriber-issued protocol, specifying definitive orders for epinephrine autoinjectors and the dosages of epinephrine to be administered through the autoinjectors. The policy also must do the following:

- (1) Identify the one or more locations in which an epinephrine autoinjector must be stored;
- (2) Specify the conditions under which an epinephrine autoinjector must be stored, replaced, and disposed;
- (3) Specify the individuals who may access and use an epinephrine autoinjector to provide a dosage of epinephrine to an individual in an emergency situation;
- (4) Specify any training that must be completed before being authorized to access and



use an epinephrine autoinjector;

(5) Identify the emergency situations, including when an individual exhibits signs and symptoms of anaphylaxis, in which authorized personnel may access and use an epinephrine autoinjector;

(6) Specify that assistance from an emergency medical service provider must be requested immediately after an epinephrine autoinjector is used;

(7) Specify the individuals to whom a dosage of epinephrine may be administered through an epinephrine autoinjector in an emergency situation.

To assist schools and camps with developing item (1) and (2) of their policy, the Ohio State Board of Pharmacy has developed the following guidance information.

Section I: Locations for Safe Storage

The following locations are recommended for the safe storage of epinephrine autoinjectors:

For schools:

- a. School main office;
- b. School nurse or health aide's office, if available on-site;
- c. Physical education department or athletic training facility, if available on-site; and
- d. Other locations as outlined per school policy that meet the requirements in Section II of this document.

For camps:

- a. Camp main office;
- b. Nurse or other licensed health care professional, if available on-site; and
- c. Other locations as outlined per camp policy that meet the requirements in Section II of this document.

Section II: Storing, Replacing and Disposing of Epinephrine Autoinjectors

The following are the conditions under which an epinephrine autoinjector must be stored, replaced, and disposed:

- I. Storage of epinephrine autoinjectors must meet the following requirements:
 - a. In a temperature controlled environment between 68° to 77° F (20° to 25° C) with brief excursions not to exceed 59° to 86° F (15° to 30° C);
 - b. A tamper-evident container that can be accessed immediately by authorized personnel; and
 - c. Any other requirement in the manufacturer's or distributor's labeling.
- II. All doses should be checked periodically to ensure that the epinephrine autoinjector is not adulterated. An epinephrine autoinjector shall be considered adulterated when:
 - a. It is beyond the manufacturer's or distributor's expiration date; and/or

- b. There are signs of discoloration or particulate matter in the epinephrine solution.

III. Adulterated epinephrine autoinjectors shall be stored in a separate and secure area apart from active drug stock to prevent its use.

IV. Adulterated epinephrine autoinjectors shall be destroyed within one year from the date of adulteration or expiration utilizing a proper method of disposal and maintaining a record of such disposal for three years. The disposal method shall prevent the possession of the epinephrine autoinjector by unauthorized persons.

Tamper Evident Containers

A tamper evident container is one that makes unauthorized access to the epinephrine autoinjectors easily detectable. This could be a small, inexpensive (approx. \$15-\$20) medical storage box (similar to tackle box) with pull through tags or security seals (approx. \$10-\$20 per bag of 100) that break easily.



Example of a tamper evident container

Questions or Additional Information

For more information on the new law, including additional requirements such as reporting, please visit: http://archives.legislature.state.oh.us/bills.cfm?ID=130_HB_296 or contact your school or camp's legal representation.

The Ohio State Board of Pharmacy is committed to the safe storage and disposal of medications. If you have any questions regarding your organization's policy on epinephrine autoinjectors, please call us at 614-466-4143 or email us by visiting <http://www.pharmacy.ohio.gov/Contact.aspx> and we will do everything we can to assist you.

