Guidelines for the Storage and Use of Emergency Inhalers and Epi-Pens

The Athletic Trainers Section of the Ohio Occupational Therapy, Physical Therapy, and Athletic Trainer Board receives many questions about the use and storage of inhalers and epi-pens that are not prescribed to a specific individual. The answer to the question differs based on setting. Due to ORC 3313.7110, Procurement of epinephrine auto-injectors by schools and camps, went into effect April 2014, which allows public and nonpublic K-12 schools to obtain and use epi-pens in emergency situations with a prescriber issued protocol. Please reference the Guidance document from the Ohio State Board of Pharmacy which can be found at the following link to guide your policy development related to obtaining, storing, and using an epipen in an emergency situation.

http://pharmacy.ohio.gov/Documents/Pubs/Special/DangerousDrugs/Procurement%20of%20Epinephrine%20Autoinjectors%20by%20Schools%20and%20Camps.pdf

However, if you work in any other setting pursuant to the Pharmacy Board’s laws and rules, athletic trainers, may legally hold specifically prescribed inhalers and epi-pens for an athlete to use when needed, in accordance with established protocols for use of such emergency medications.

Athletic training facilities are prohibited to store and use emergency inhalers and/or epi-pens that are not specifically prescribed to an individual unless the athletic training facility holds a Terminal Distributor of Dangerous Drugs license from the Pharmacy Board. If the facility does hold a Terminal Distributor license, the athletic trainer must still follow the established protocols for use of such emergency medications.

Ohio Revised Code section 4729.01 defines a “dangerous drug” as:

- Any substance labeled “Caution: Federal law prohibits dispensing without prescription”, “Rx Only”, or any other similar restrictive statement;
- The drug may be dispensed only upon a prescription; or
- Any drug intended for administration into the human body other than through a natural orifice of the human body (e.g.: injectables).

“Dangerous drugs” include, but are not limited to:

- Epi-Pens
- Short-Acting Beta-Agonist Inhalers

Storage of “dangerous drugs”:

- For athletic training sites located within a hospital, “dangerous drugs” must be stored in accordance with policies and procedures established by the Director of the Hospital Pharmacy under the hospital’s license as a Terminal Distributor of Dangerous Drugs. (A separate Terminal Distributor of Dangerous Drugs license is not required if there is common ownership and control.)
- For athletic training sites located outside of a hospital setting (even if owned by a hospital), “dangerous drugs” must be stored in an area secured by either a physical barrier with suitable locks and/or an electronic barrier to deter and detect unauthorized access.
For more information on managing prescriptions and non-prescription medication, see the NATA’s *Consensus Statement: Managing Prescriptions and Non-Prescription Medication in the Athletic Training Facility* (January 2009).

*The following information was provided by the Ohio State Pharmacy Board.*

**Storage of patients’ emergency inhalers and/or epi-pens:**

- Drugs, once dispensed by a pharmacist, are the patient’s property and as such can be stored in a secure place with the patient’s permission.
- It is **STRONGLY** recommended that the athletic trainer request a signed release from the patient to securely and properly store the patients’ drugs.
- It is **STRONGLY** recommended that included on the form for the patient to sign is the information about what will happen to the drug(s) following the end of treatment. (ex: On the patient’s last day of treatment, any leftover drug will be destroyed (wasted) in the patient’s presence with the patient’s permission, or if the patient cancels or does not show up for the last treatment or is unable to be present for any reason, the athletic trainer will hold the drug for 30 days. At the end of that time, the drug will be destroyed by the athletic trainer and witnessed by another licensed individual.)
- **EITHER** situation must be completely documented.
- Under no circumstances can a stored drug be used on any other person than the one to whom it was dispensed.

**Applying for a Limited Category Two Terminal Distributor of Dangerous Drugs license:**

- A Terminal Distributor of Dangerous Drugs license (Limited Category Two) is required only if the athletic training site desires to purchase and possess “dangerous drugs” for administration directly to patients pursuant to a prescriber’s order.
- A Terminal Distributor of Dangerous Drugs license is not required if the athletic training site only stores “dangerous drugs” that were dispensed by a pharmacy to a specific patient.
- An application packet for a Terminal Distributor of Dangerous Drugs license may be obtained from the Ohio State Board of Pharmacy by calling (614) 466-4143 or sending an email request to licensing@bop.ohio.gov.
- A completed application consists of:
  1. Completely filling out the two-page application;
  2. The signature of a physician licensed in Ohio to serve as the Responsible Person pursuant to Ohio Revised Code section 4729.55;
  3. A list of personnel having access to and administering “dangerous drugs” (name & SSN or professional license number and expiration date);
  4. A signed and notarized letter (by the Medical Advisory) specifying a list of “dangerous drugs” and their intended use. The list of “dangerous drugs” must include the name, strength, and dosage form of the drug;
  5. A check for $112.50 for the original application (made payable to “Treasurer, State of Ohio”); and
  6. A copy of the corporation or LLC papers.
A new application must be completed and submitted with the required fee each time there is a change of business name, change of ownership, or change of address.

Delivery of a new license will be done by an inspector of the Ohio State Board of Pharmacy will check for:

1. Security (including sharps disposable, if applicable);
2. Accountability (documentation of receipt, administration, use, and disposal of i. “dangerous drugs”); and
3. Control (storage conditions, including temperature control and sanitary conditions).

Terminal Distributor of Dangerous Drugs licenses are issued on a calendar year basis and expire on December 31 of each year. A renewal application is sent each year at the end of September. The renewal application must be completed and returned to the State Board of Pharmacy along with a list of current personnel and a check for $112.50.

Questions regarding licensure should be directed to:

Licensing Administrator
Ohio State Board of Pharmacy
77 South High Street, Room 1702
Columbus, Ohio 43215-6126
(614) 466-4143
licensing@bop.ohio.gov