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Procurement of Epinephrine Autoinjectors by Schools, Camps, and Qualified Entities

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Over the past several years, changes to Ohio law have permitted schools, camps, and "qualified entities" to obtain epinephrine autoinjectors for emergency use without needing a license as a terminal distributor of dangerous drugs from the Ohio Board of Pharmacy (referred to in this guidance document as exempted entities). The purpose of these laws is to equip and train personnel to quickly and effectively respond to an individual who may be experiencing anaphylaxis (e.g., a severe, life-threatening allergic reaction).

Please be advised that these laws are limited to epinephrine autoinjectors only. It does not apply to epinephrine administered in other formulations (ex., nasal or injections that do not utilize an autoinjector).

These exempted entities include the following:

- **Schools:** A board of education of a city, local, exempted village, or joint vocational school district; a chartered or nonchartered nonpublic school; a community school established under Chapter 3314. of the Revised Code; a STEM school established under Chapter 3326. of the Revised Code; or a college-preparatory boarding school established under Chapter 3328. of the Revised Code.
- Camps: A residential camp, as defined in section <u>2151.011</u> of the Revised Code; a child day camp, as defined in section <u>5104.01</u> of the Revised Code; or a child day camp operated by any county, township, municipal corporation, township park district created under section <u>511.18</u> of the Revised Code, park district created under

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section <u>1545.04</u> of the Revised Code, or joint recreation district established under section <u>755.14</u> of the Revised Code.

- Qualified Entities: Any 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*, 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:
 - 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;
 - A camp described in section 5101.76 of the Revised Code that is authorized to procure epinephrine autoinjectors pursuant to that section.

*Per ORC 3728.01, law enforcement is included in the definition of a qualified entity. It includes either of the following served by a peace officer: a law enforcement agency or other entity described in division (A) of section 109.71 of the Revised Code.

To assist those listed above in procuring epinephrine autoinjectors the Ohio Board of Pharmacy developed this guidance document. It is broken down into the following sections based upon the type of exempted entity:

- Section 1 Schools
- Section 2 Camps
- Section 3 Qualified Entities

For additional information on pharmacy laws on epinephrine autoinjectors, visit: www.pharmacy.ohio.gov/EPI

Section 1 - Schools

The law authorizes a school governing authority to procure epinephrine autoinjectors for each school operated by that authority to have on the school premises for use in emergency situations without needing a license from the Ohio Board of Pharmacy. Below is an overview of what is required to procure and utilize epinephrine autoinjectors in a school:

- 1. Obtain a prescriber-issued protocol that includes definitive orders for epinephrine autoinjectors and the dosages of epinephrine to be administered through them. For the purposes of the law, a prescriber must be any of the following: physician (MD/DO), physician assistant (PA), or APRN.
- 2. Adopt a policy governing the maintenance and use of epinephrine autoinjectors. Before adopting the policy, the superintendent/school governing authority shall consult with a licensed health professional authorized to prescribe drugs (i.e., physician, physician assistant, or APRN). The policy must include all of the following:
 - a. Identify one or more locations in each school operated by the district in which an epinephrine autoinjector must be stored. REMINDER: A school that elects to procure epinephrine autoinjectors is encouraged to maintain, at all times, at least two epinephrine autoinjectors at each school.
 - b. Specify the conditions under which an epinephrine autoinjector must be stored, replaced, and disposed.
 - c. Specify the individuals employed by or under contract with the school, in addition to a school nurse or an athletic trainer, licensed under Chapter 4755. of the Revised Code, who may access and use an epinephrine autoinjector to provide a dosage of epinephrine to an individual in an emergency situation identified in the policy.
 - d. Specify any training that employees or contractors identified in the policy, other than a school nurse or athletic trainer, must complete before being authorized to access and use an epinephrine autoinjector.
 - e. Identify the emergency situations, including when an individual exhibits signs and symptoms of anaphylaxis, in which a school nurse, athletic trainer, or

- other employees or contractors specified in the policy may access and use an epinephrine autoinjector.
- f. Specify that assistance from an emergency medical service provider must be requested immediately after an epinephrine autoinjector is used.
- g. Specify the individuals, in addition to students, school employees or contractors, and school visitors, to whom a dosage of epinephrine may be administered through an epinephrine autoinjector in an emergency situation specified in the policy.

NOTE: Per ORC 3728.01, colleges and universities are considered <u>qualified entities</u>.

Where do I obtain a supply of epinephrine autoinjectors?

Schools who meet the requirements of the law listed above are exempt from Ohio Board of Pharmacy licensure as a terminal distributor of dangerous drugs (for the purposes of obtaining epinephrine autoinjectors). As an exempted entity, a school may purchase epinephrine autoinjectors from the following suppliers:

Wholesale Distributors & Manufacturers

Wholesale distributors and manufacturers are companies that sell non-patient specific medications directly to healthcare facilities and pharmacies. All wholesale distributors and manufacturers selling drugs in this state must be licensed with the Ohio Board of Pharmacy.

Normally a wholesaler or manufacturer would be required to verify the purchaser's Board of Pharmacy license (TDDD). However, the exemption for epinephrine allows them to sell directly to schools. A school may order from a wholesaler or manufacturer, if the school provides a signed attestation stating the school is exempted from Ohio Board of Pharmacy licensure. This attestation is still required even if the manufacturer or wholesaler is providing the epinephrine autoinjectors at no cost (this would be considered a no-cost sale).

To assist in this process, the Board developed a sample attestation form that can be used by schools: www.pharmacy.ohio.gov/WSattest. The school would be considered an "Exempted Non-Prescriber Practice."

For Local Government and Non-Profits: The Ohio Department of Mental Health and Addiction Service's Pharmacy Service Center (PSC) is a licensed Ohio wholesaler and can supply epinephrine autoinjectors to government and non-profit entities. For more information, contact them directly at 888-471-5632 or operation.com.

Pharmacies

Ohio licensed pharmacies are also permitted to provide epinephrine autoinjectors to schools. This can be achieved in one of two ways:

Occasional wholesale sale conducted by the pharmacy. Here a pharmacy acts as a
wholesaler by providing the school with non-patient specific epinephrine
autoinjectors, much like they were purchasing from a wholesaler. The pharmacy,
acting as the wholesaler, would still need to verify the school's exemption status. As
with a wholesaler or manufacturer the school may utilize this form:
www.pharmacy.ohio.gov/WSattest.

REMINDER: The pharmacy must maintain a record of sale that includes all of the following: name, strength, dosage form, national drug code, and quantity of the epinephrine autoinjectors sold, the address of the location where the autoinjectors were transferred or sold, and the date of transfer or sale. A sample form to capture this information is available here: www.pharmacy.ohio.gov/SampleSale.

2. The law permits a school to obtain a prescription in the name of the school or district to be dispensed by a pharmacy. Please be advised that pharmacies do not normally "dispense" prescriptions for buildings or other non-patient entities. Therefore, schools that choose this option are encouraged to reach out to their local pharmacy prior to presenting a prescription.

Are there any state reporting requirements for schools?

Yes. A school that elects to procure epinephrine autoinjectors must report to the Ohio Department of Education and Workforce each procurement and occurrence in which an epinephrine autoinjector is used from a school's supply of epinephrine autoinjectors. For more information on reporting to the Ohio Department of Education and Workforce, visit: https://education.ohio.gov/Topics/Student-Health/Supporting-Students-With-Food-Allergies

Section 2 - Camps

The law authorizes a camp to procure epinephrine autoinjectors for use in emergency situations without needing a license from the Ohio Board of Pharmacy. Below is an overview of what is required to procure and utilize epinephrine autoinjectors at a camp:

- Obtain a prescriber-issued protocol that includes definitive orders for epinephrine autoinjectors and the dosages of epinephrine to be administered through them. For the purposes of the law, a prescriber must be any of the following: physician (MD/DO), physician assistant (PA), or APRN.
- 2. Adopt a policy governing the maintenance and use of epinephrine autoinjectors. Before adopting the policy, the camp shall consult with a licensed health professional authorized to prescribe drugs (i.e., physician, physician assistant, or APRN). The policy must include all of the following:
 - a. Identify one or more locations in which an epinephrine autoinjector must be stored. REMINDER: A camp that elects to procure epinephrine autoinjectors is encouraged to maintain, at all times, at least two epinephrine autoinjectors.
 - b. Specify the conditions under which an epinephrine autoinjector must be stored, replaced, and disposed.
 - c. Specify the individuals employed by or under contract with the camp who may access and use an epinephrine autoinjector to provide a dosage of epinephrine to an individual in an emergency situation identified in the policy.
 - d. Specify any training that employees or contractors identified in the policy must complete before being authorized to access and use an epinephrine autoinjector.
 - e. Identify the emergency situations, including when an individual exhibits signs and symptoms of anaphylaxis, in which employees or contractors specified in the policy may access and use an epinephrine autoinjector.
 - f. Specify that assistance from an emergency medical service provider must be requested immediately after an epinephrine autoinjector is used.

g. Specify the individuals to whom a dosage of epinephrine may be administered through an epinephrine autoinjector in an emergency situation specified in the policy.

Where do I obtain a supply of epinephrine autoinjectors?

Camps who meet the requirements of the law listed above are exempt from Ohio Board of Pharmacy licensure as a terminal distributor of dangerous drugs (for the purposes of obtaining epinephrine autoinjectors). As an exempted entity, a camp may purchase epinephrine autoinjectors from the following suppliers:

Wholesale Distributors & Manufacturers

Wholesale distributors and manufacturers are companies that sell non-patient specific medications directly to healthcare facilities and pharmacies. All wholesale distributors and manufacturers selling drugs in this state must be licensed with the Ohio Board of Pharmacy.

Normally a wholesaler or manufacturer would be required to verify the purchaser's Board of Pharmacy license (TDDD). However, the exemption for epinephrine allows them to sell directly to camps. A camp may order from a wholesaler or manufacturer, if the camp provides a signed attestation stating the camp is exempted from Ohio Board of Pharmacy licensure. This attestation is still required even if the manufacturer or wholesaler is providing the epinephrine autoinjectors at no cost (this would be considered a no-cost sale).

To assist in this process, the Board developed a sample attestation form that can be used by camps: www.pharmacy.ohio.gov/WSattest. The school would be considered an "Exempted Non-Prescriber Practice."

For Local Government and Non-Profits: The Ohio Department of Mental Health and Addiction Service's Pharmacy Service Center (PSC) is a licensed Ohio wholesaler and can supply epinephrine autoinjectors to government and non-profit entities. For more information, contact them directly at 888-471-5632 or operation.com.

Pharmacies

Ohio licensed pharmacies are also permitted to provide epinephrine autoinjectors to camps. This can be achieved in one of two ways:

Occasional wholesale sale conducted by the pharmacy. Here a pharmacy acts as a
wholesaler by providing the camp with non-patient specific epinephrine
autoinjectors, much like they were purchasing from a wholesaler. The pharmacy,
acting as the wholesaler, would still need to verify the camp's exemption status. As
with a wholesaler or manufacturer the camp may utilize this form:
www.pharmacy.ohio.gov/WSattest.

REMINDER: The pharmacy must maintain a record of sale that includes all of the following: name, strength, dosage form, national drug code, and quantity of the epinephrine autoinjectors sold, the address of the location where the autoinjectors were transferred or sold, and the date of transfer or sale. A sample form to capture this information is available here: www.pharmacy.ohio.gov/SampleSale.

2. The law permits a camp to obtain a prescription in the name of the camp to be dispensed by a pharmacy. Please be advised that pharmacies do not normally "dispense" prescriptions for buildings or other non-patient entities. Therefore, camps that choose this option are encouraged to reach out to their local pharmacy prior to presenting a prescription.

Are there any state reporting requirements for schools?

Yes. A camp that elects to procure epinephrine autoinjectors under this section shall report to the Ohio Department of Children and Youth each procurement and occurrence in which an epinephrine autoinjector is used from a camp's supply of epinephrine autoinjectors. For more information, visit: https://childrenandyouth.ohio.gov/help-center.

Section 3 - Qualified Entities

The law authorizes a qualified entity to procure epinephrine autoinjectors for use in emergency situations without needing a license from the Ohio Board of Pharmacy. For more information on the training, storage, and reporting requirements for qualified entities, visit: https://odh.ohio.gov/know-our-programs/epinephrine-autoinjector-use

Where do I obtain a supply of epinephrine autoinjectors?

Unlike schools and camps, qualified entities must obtain epinephrine autoinjectors from the following:

- 1. Personally furnished by a prescriber (physician (MD/DO), physician assistant (PA), or APRN): This would require a prescriber to personally furnish the medication from their own office stock (sometimes referred to as prescriber dispensing). For example, if a local physician maintains a supply of autoinjectors, the physician may personally furnish those medications directly to qualified entities. Unless the physician is offering the medication for free, the qualified entity would reimburse the physician. REMINDER: If the prescriber holds a terminal distributor of dangerous drugs license from the Ohio Board of Pharmacy, they must comply with all applicable rules on personally furnishing medications: https://codes.ohio.gov/ohio-administrative-code/rule-4729:5-19-02
- 2. Dispensed by a pharmacy pursuant to a prescription: The law also permits a qualified entity to obtain epinephrine autoinjectors from a pharmacy in the name of the qualified entity pursuant to a prescription issued by a prescriber (MD/DO, PA, or APRN). Please be advised that pharmacies do not normally "dispense" prescriptions for buildings or other non-patient entities. Therefore, qualified entities that choose this option are encouraged to reach out to their local pharmacy prior to presenting a prescription.
- 3. **Dispensed by a pharmacy pursuant to a dispensing protocol:** Ohio law permits a pharmacy to maintain an epinephrine autoinjector dispensing protocol. This means

that pharmacies who have this protocol are permitted to dispense epinephrine autoinjectors to qualified entities without needing a prescription. The Board is currently unable to track the number of pharmacies who have this protocol in place, as there is no reporting requirement in the rule. Therefore, it is strongly encouraged to reach out to your local pharmacy to see if such a protocol exists.

For more information on the requirements for epinephrine dispensing protocols, visit: www.pharmacy.ohio.gov/epi.

For a sample epinephrine autoinjector dispensing protocol, visit: www.pharmacy.ohio.gov/SampleEpi

For Local Health Departments: If a local pharmacy cannot find a prescriber to authorize an epinephrine dispensing protocol, a Board of Health, through a physician serving as the Board's Health Commissioner or Medical Director, may authorize pharmacists and pharmacy interns practicing in a county that includes all or part of the health district represented by the Board to use the protocol for the purpose of dispensing epinephrine autoinjectors. For more information on the requirements for epinephrine dispensing protocols, visit: www.pharmacy.ohio.gov/epi.

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