Pharmacy Laws on Epinephrine Autoinjectors

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Ohio has several laws intended to promote the accessibility of epinephrine autoinjectors. This document will provide a general overview of the following laws:

- Section 4729.382 - Pharmacist's authority to dispense an epinephrine autoinjector by substitution.
- Section 4729.47 - Authority to dispense epinephrine without a prescription (FAQ starts on page 5 of this document).

For questions regarding either provision, please review the following frequently asked questions. If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: http://www.pharmacy.ohio.gov/contact.aspx.

Section 4729.382 - Pharmacist's authority to dispense an epinephrine autoinjector by substitution.

Section 4729.382 of the Ohio Revised Code expands a pharmacist's ability to substitute epinephrine autoinjectors.

NOTE: Nothing in this provision applies to the following:

- Generic substitution of products deemed as being therapeutically equivalent in the FDA Orange Book and in accordance with section 4729.38 of the Revised Code; or
- Obtaining a new verbal prescription from a prescriber for a different epinephrine autoinjector.

Q1) Under what circumstances am I permitted to substitute the prescribed autoinjector?

In addition to generic substitution (i.e. an AB rating in the Orange Book), epinephrine autoinjector substitution may occur if the form of epinephrine in the dispensed autoinjector, when compared to the form of the drug in the prescribed autoinjector, complies with all the following:

1. *Is a pharmaceutical equivalent of the form of epinephrine in the type of autoinjector that was prescribed in that it contains identical amounts of the identical active ingredients, but not necessarily the same inactive ingredients.*
2. *Has been approved by the United States Food and Drug Administration; and*
3. *Has not been excluded from recognition as a pharmaceutical equivalent form of epinephrine by rules adopted by the Board of Pharmacy (see Q2 and Q3 of this section for more information).*

This essentially allows the substitution of an epinephrine autoinjector that contains the same active ingredient but not the same inactive ingredient even if it has not been identified in the FDA Orange Book as being a therapeutic equivalent (i.e., an A rating). Therefore, it would be permissible to substitute an epinephrine autoinjector that has a BX rating in the Orange Book (see Q2 of this section for additional information).

IMPORTANT: This **does not** authorize the substitution of an epinephrine autoinjector with another epinephrine product that is not administered via autoinjector (ex. vial and syringe). Additionally, the Board does consider the substitution of an epinephrine autoinjector with another product that has known or potential bioequivalence problems (i.e. a BD or BP rating) to be a departure from prevailing standards of care and may subject a pharmacist to administrative discipline.

Q2) Has the Board excluded any products from being recognized as pharmaceutical equivalents?

At this time, the Board has not adopted any rule prohibiting an FDA-approved epinephrine autoinjector product from being considered a pharmaceutical equivalent.

However, the Board does consider the substitution of an epinephrine autoinjector with another product that has known or potential bioequivalence problems (i.e. a BD or BP rating) to be a departure from prevailing standards of care and may subject a pharmacist to administrative discipline.

IMPORTANT: A pharmacist is still responsible for determining if the substituted autoinjector meets the requirements specified in Q1 of this document. If a pharmacist is uncomfortable making this determination, the pharmacist or pharmacy staff can call the prescriber's office to ask for a new prescription.

Q3) How does a pharmacist determine if an FDA-approved epinephrine autoinjector product meets the requirements outlined in Q1 of this document?

A pharmacist should use the product's labeling to make this determination.

NOTE: If a pharmacist is uncomfortable making this determination, the pharmacist or pharmacy staff can call the prescriber's office to ask for a new prescription.

Q4) If I make a substitution of an epinephrine autoinjector in accordance with section 4729.382 of the Ohio Revised Code, what am I required to do?

Labeling: In addition to the requirements of product labeling required, the label for every epinephrine autoinjector dispensed by substitution must include the epinephrine autoinjector's name, if any, and the distributor of the autoinjector. Abbreviations for the distributor name may be used as necessary.

The autoinjector's label must also indicate that a substitution was made. An auxiliary label may be added to the container indicating a substitution has been made.

Patient Counseling: A pharmacist or a pharmacy intern shall provide to the person receiving the device instruction on the proper method of administering epinephrine with the device, except that the instruction does not have to be provided if the person is receiving the same device that was dispensed when the person last received the device by having a prescription filled or refilled.

A pharmacist, pharmacy intern, or agent of the pharmacist must inform the patient or the patient's representative of the person's right to refuse substitution of the prescribed epinephrine autoinjector. While not specifically required, **the Board strongly encourages a pharmacist or pharmacy intern to personally instruct a patient or caregiver that a substitution has been made.**

A pharmacist, pharmacy intern, or agent of the pharmacist must make a reasonable attempt to inform the patient or the patient's representative if a type of epinephrine autoinjector is available at a lower or equal cost. **NOTE:** This is the same provision required for generic substitution in accordance with section 4729.38 of the Revised Code.

Recordkeeping: A pharmacist should maintain the same records as required for generic substitution if making a substitution of an epinephrine autoinjector in accordance with section 4729.38 of the Revised Code.

Q5) Can a pharmacist substitute an epinephrine autoinjector if the cost of the autoinjector is more expensive than the prescribed autoinjector?

The law specifically states the following:

The pharmacist shall not make the substitution unless its price to the patient is less than or equal to the price of the prescribed epinephrine autoinjector, except that a pharmacist may substitute an epinephrine autoinjector with a price to the patient that is greater than the prescribed autoinjector if the patient specifically requests the more expensive autoinjector.

Q6) Does the inclusion of "dispense as written" or another indication prohibit the substitution of an epinephrine autoinjector?

Yes. The law states the following:

The pharmacist shall not make the substitution if either of the following applies to the prescription:

> *(a) In the case of a written or electronic prescription, including a computer-generated prescription, the prescriber handwrites or actively causes to display on the prescription "dispense as written," "D.A.W.," "do not substitute," "medically necessary*

as prescribed," or any other statement or numerical code that indicates the prescriber's intent to prevent substitution. Such a designation shall not be preprinted or stamped on the prescription, but a reminder to the prescriber of the designation procedure may be preprinted or displayed on the prescription form or electronic system the prescriber uses to issue the prescription.

(b) *In the case of an oral prescription, the prescriber specifies that the epinephrine autoinjector as prescribed is medically necessary or otherwise indicates the prescriber's intent to prevent substitution.*

Q7) Are there any liability protections for pharmacists that are included in the law?

Yes. As with generic substitution, a pharmacist who dispenses an epinephrine autoinjector pursuant to section 4729.382 of the Revised Code assumes no greater liability for dispensing the autoinjector by substitution than would be incurred for dispensing the autoinjector identified on the prescription.

Section 4729.47 - Authority to dispense epinephrine autoinjectors without a prescription.

Section 4729.47 of the Ohio Revised Code authorizes a pharmacist or pharmacy intern to dispense epinephrine autoinjectors without a prescription pursuant to a physician protocol. To implement this section of law, the Board has adopted the following rules:

- 4729:1-3-06 - Dispensing of epinephrine autoinjectors by pharmacists
- 4729:2-3-06 - Dispensing of epinephrine autoinjectors by pharmacy interns.

NOTE: Nothing in this provision prohibits the emergency dispensing of an epinephrine autoinjector pursuant to section 4729.281 of the Ohio Revised Code. For more information on this law, visit: www.pharmacy.ohio.gov/emergency.

Q1) Who is eligible to receive epinephrine pursuant to a physician-approved protocol?

A pharmacist or pharmacy intern may dispense an epinephrine autoinjector without a prescription to either of the following in accordance with a physician-approved protocol:

1) An individual who there is reason to believe is experiencing or at risk of experiencing anaphylaxis if the pharmacy has a record* of previously dispensing epinephrine to the individual in accordance with a prescription issued by a licensed health professional authorized to prescribe drugs; or
2) An individual acting on behalf of a qualified entity, as defined in section 3728.01 of the Revised Code.

REMINDER: A pharmacist or pharmacy intern should use their professional judgement to make the determination that a patient meets the criteria specified above.

***NOTE:** The record of dispensing must be on-file with the dispensing pharmacy.

Q2) What are the requirements of the physician protocol?

Physician protocol requirements are set forth in rule 4729:1-3-06 of the Administrative Code, which states:

A physician-established protocol for the dispensing of epinephrine autoinjectors by a pharmacist or pharmacy intern under the direct supervision of a pharmacist shall include, but is not limited to, the following:

(1) Indications for use of epinephrine autoinjectors, including criteria for identifying persons eligible to receive an autoinjector under the protocol.

(2) Precautions and contraindications related to the dispensing of epinephrine autoinjectors.

(3) Epinephrine autoinjectors authorized to be dispensed, including all the following information: (a) Name of product; (b) Dose; (c) Quantity to be dispensed; and (d) Directions for use.

(4) Any patient instructions in addition to the required training (see Q4 of this section).

All physician-established protocols must be signed and dated by the physician prior to implementation and maintained by the terminal distributor of dangerous drugs. The protocols shall be renewed by a physician on a biennial basis.

A physician may sign one protocol for multiple locations licensed as terminal distributors of dangerous drugs. Each location licensed as a terminal distributor of dangerous drugs shall maintain a copy of the protocol on-site for inspection by an agent, inspector or employee of the Board of Pharmacy.

Q3) Can any Ohio-licensed physician approve an epinephrine dispensing protocol?

Yes. The law authorizes the any of the following to approve 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 pharmacy 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 under section 4729.47 of the Revised Code. (ORC 3707.60)

- A physician may authorize one or more pharmacists and any of the pharmacy interns supervised by the pharmacist or pharmacists to use the protocol for the purpose of dispensing epinephrine under section 4729.47 of the Revised Code. (ORC 4731.961)

NOTE: As with other types of pharmacist dispensing protocols, there is no limit on the number of protocols that can be authorized by an Ohio-licensed physician.

Q4) What are the training requirements for patients receiving an epinephrine autoinjector via a protocol?

The training requirements are as follows:

- A pharmacist or pharmacy intern who dispenses an epinephrine autoinjector pursuant to a protocol is required to instruct the individual to whom the epinephrine autoinjector is dispensed, either verbally or in writing, to summon emergency services as soon as practicable either before or after administering epinephrine.

- A pharmacist, or pharmacy intern under the direct supervision of a pharmacist, shall provide to the person receiving the device instruction on the proper method of administering epinephrine with the device.

Q5) Am I required to notify a patient's healthcare provider?

Yes. The law and rules require a pharmacist or pharmacy intern who dispenses an epinephrine autoinjector to a patient pursuant to a protocol to notify either:

1. To patient's primary care provider, if known; or
2. The prescriber who issued the individual the initial prescription for an epinephrine autoinjector.

Notification shall be conducted using one of the following methods that is capable of confirming delivery of the required notification: (a) Electronic mail; (b) Interoperable electronic medical records system; (c) Facsimile; (d) Electronic prescribing system; (e) Electronic pharmacy record system; (f) Documented verbal communication; (g) Any other

method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.

NOTE: While there is no specific timeframe to submit notification, it is the Board's policy that notification takes place no later than thirty days after the autoinjector is dispensed.

Q6) Are there any liability protections included in the law?

Yes. There are liability protections for all the following:

A pharmacist or pharmacy intern authorized under this section to dispense epinephrine without a prescription who does so in good faith is not liable for or subject to any of the following for any action or omission of the individual to whom the epinephrine is dispensed: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

A physician who in good faith authorizes a pharmacist or pharmacy intern to dispense epinephrine without a prescription in accordance with a protocol is not liable for or subject to any of the following for any action or omission of the individual to whom the epinephrine is dispensed: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

A board of health that in good faith authorizes a pharmacist or pharmacy intern to dispense epinephrine without a prescription in accordance with a protocol is not liable for or subject to any of the following for any action or omission of the individual to whom the epinephrine is dispensed: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

Q7) Can I dispense other formulations of epinephrine per physician protocol?

No. ORC 4729.47 does not permit the dispensation of epinephrine vials or nasal formulations. The law specifically limits the use of protocols for dispensing epinephrine autoinjectors.

Q8) How do I confirm the person is requesting an epinephrine autoinjector on behalf of a qualified entity?

The representative of the qualified entity should present a copy of a certificate of completion of the Ohio Department of Health's Training Course: Anaphylaxis Training for Qualified Entities (Course ID 1072343).