



OHIO LEGISLATIVE SERVICE COMMISSION

Bill Analysis

Audra Tidball

Am. H.B. 101

132nd General Assembly
(As Reported by H. Health)

Reps. Merrin, Becker, Thompson, Seitz, Stein, West, Roegner, Sheehy, Sprague, Hood, R. Smith

BILL SUMMARY

- Authorizes a pharmacist to dispense epinephrine pursuant to a physician-established protocol, rather than a prescription, to certain individuals experiencing or likely to experience anaphylaxis and certain entities located where allergens capable of causing anaphylaxis may be present.
- Authorizes a pharmacist filling a prescription for an epinephrine autoinjector identified by a specific name to substitute another autoinjector if the drugs they contain are equivalent and certain other conditions are met.
- Specifies that the act is to be known as the "Epinephrine Accessibility Act."

CONTENT AND OPERATION

Dispensing epinephrine without a prescription

Epinephrine is a prescription drug used to treat anaphylaxis, a life-threatening allergic reaction.¹ Since the late 1980s, epinephrine has been available in the form of an autoinjector that facilitates self-administration of the drug.² One type of autoinjector is commonly known by the brand name "Epi-pen"®.

¹ National Institutes of Health, U.S. National Library of Medicine, MedlinePlus, *Epinephrine Injection*, available at <www.nlm.nih.gov/medlineplus/druginfo/meds/a603002.html>.

² Brice Labuzzo Mohundro, PharmD, and Michael Marlan Mohundro, PharmD, *Important Considerations When Dispensing Epinephrine Auto-injector Devices*, PHARMACY TIMES (September 23, 2010), available at <www.pharmacytimes.com/p2p/P2PEpinephrine-0910>.

Current law permits an elementary or secondary school or children's camp to obtain epinephrine from a wholesale distributor of dangerous drugs after obtaining a prescriber-issued protocol or from a pharmacy after obtaining a nonpatient specific prescription from a prescriber.³ Current law also permits locations where allergens capable of causing anaphylaxis may be present, known as "qualified entities," to obtain epinephrine autoinjectors from a prescriber who agrees to personally furnish them or from a pharmacy after obtaining a nonpatient specific prescription from a prescriber.⁴ The prescribers are physicians and certain advanced practice nurses and physician assistants.⁵

The bill, to be known as the "Epinephrine Accessibility Act,"⁶ further expands access to epinephrine by authorizing a pharmacist or pharmacy intern to dispense epinephrine without a prescription. For this to occur, a physician or a local board of health must have authorized the use of a protocol that meets requirements to be established by the State Board of Pharmacy (see below).⁷ In accordance with the protocol, the pharmacist or pharmacy intern may dispense epinephrine without a prescription to either of the following individuals, so long as the individual is age 18 or older:

(1) An individual who there is reason to believe is experiencing or at risk of experiencing anaphylaxis if the individual was previously issued a prescription for epinephrine and the pharmacy has a record of the prescription;

(2) An individual acting on behalf of a qualified entity, which is defined in current law to mean any public or private entity associated with a location where allergens capable of causing anaphylaxis may be present, such as child day-care centers, colleges and universities, places of employment, restaurants, amusement parks, recreation camps, sports playing fields and arenas, and other similar locations.⁸ Primary and secondary schools and certain residential and child day camps are excluded from the definition, but as noted above, are permitted by current law to obtain epinephrine.

³ R.C. 3313.7110, 3313.7111, 3314.143, 3326.28, 3328.29, and 5101.76, not in the bill.

⁴ R.C. 3728.03, not in the bill.

⁵ R.C. 3728.01, 4723.483, 4730.433, and 4731.96, not in the bill.

⁶ Section 3.

⁷ R.C. 3707.60 and 4731.961.

⁸ R.C. 4729.46(B); R.C. 3728.01(C), not in the bill.

Regarding dispensing to qualified entities, the bill amends existing law, which permits a qualified entity to acquire and maintain a supply of autoinjectors pursuant to a prescription or directly from a prescriber, to specify that a qualified entity is also authorized to acquire and maintain a supply of autoinjectors pursuant to the bill's protocol provisions. By adding this reference, the bill makes a qualified entity that obtains epinephrine autoinjectors through a protocol subject to the same requirements in existing law that are applicable if the entity obtains the autoinjectors from a prescription or directly from a prescriber. Those requirements include storage, training, and reporting requirements.⁹

The bill also extends civil immunity protections to qualified entities and their employees associated with administering epinephrine or acquiring, maintaining, accessing, or using epinephrine obtained pursuant to the bill's protocol provisions.¹⁰

Instruction and notice requirements

A pharmacist or pharmacy intern who dispenses epinephrine under the bill must instruct the individual to whom it is dispensed to contact emergency services as soon as practicable when it is administered. If the dispensing is to an individual, the pharmacist or pharmacy intern also must provide notice to the individual's primary care provider, if known, or to the prescriber who issued the initial prescription.¹¹

The dispensing may be documented on a prescription form, which may be assigned a number for record-keeping purposes.¹² The bill specifies that it does not affect the authority of a pharmacist or pharmacy intern to fill or refill a prescription for epinephrine.¹³

Pharmacy Board rules and protocol

The bill requires the Board to adopt rules implementing its provisions authorizing the dispensing of epinephrine without a prescription. The rules must specify minimum requirements for physician-established protocols that authorize pharmacists and pharmacy interns to dispense epinephrine without a prescription. Before adopting the rules, the Board must consult with the State Medical Board. The

⁹ R.C. 3728.03; R.C. 3728.04 and 3728.10, not in the bill.

¹⁰ R.C. 3728.09, not in the bill.

¹¹ R.C. 4729.46(C).

¹² R.C. 4729.46(D).

¹³ R.C. 4729.46(E).

rules must be adopted in accordance with the Administrative Procedure Act (R.C. Chapter 119.) not later than 90 days after the bill's effective date.¹⁴

Authorization by boards of health

Under the bill, a board of health may authorize pharmacists and pharmacy interns practicing pharmacy in any county that includes territory within the health district represented by the board to dispense epinephrine without a prescription in accordance with a protocol developed by a physician serving as the board's health commissioner or medical director. The bill applies to a board of health of a city or general health district and to an authority having the duties of a board of health under a city's charter.¹⁵

Authorization by physicians

The bill permits a physician who has established a protocol to authorize pharmacists and pharmacy interns to use the protocol for purposes of dispensing epinephrine without a prescription.¹⁶ For purposes of the bill, "physician" means an individual authorized to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery.¹⁷

Immunity

Each of the following who acts in good faith and in accordance with the bill is not liable for or subject to damages in any civil action, prosecution in any criminal proceeding, or professional discipline for any action or omission of the person to whom epinephrine is dispensed:

- (1) A board of health;
- (2) A physician;
- (3) A pharmacist or pharmacy intern.¹⁸

¹⁴ R.C. 4729.46(G).

¹⁵ R.C. 3707.60.

¹⁶ R.C. 4731.961.

¹⁷ R.C. 4731.96.

¹⁸ R.C. 4729.46(F).



Substitution of epinephrine autoinjectors

The bill allows a pharmacist, when dispensing an epinephrine autoinjector pursuant to a prescription that identifies a specific type of autoinjector, to substitute a different epinephrine autoinjector in a manner similar to existing substitution of generic drugs. Current law authorizes a pharmacist to substitute a generic drug for a drug prescribed by its brand name, but does not address the substitution of medical devices that may dispense drugs, such as an epinephrine autoinjector. While epinephrine autoinjectors are commonly referred to as simply "epi-pens," EpiPen® is a brand name that is a trademark of the drug manufacturer. According to a representative of the Pharmacy Board, when "EpiPen" is prescribed, current law does not permit substitution of another epinephrine autoinjector without first contacting the prescriber.

The bill permits substitution if the form of epinephrine contained in the dispensed autoinjector is either (1) identical to the form of epinephrine in the prescribed autoinjector or (2) a United States Food and Drug Administration-approved pharmaceutical equivalent to the form of epinephrine in the prescribed autoinjector.

The bill describes pharmaceutical equivalent as containing identical amounts of the identical active ingredients, but not necessarily the same inactive ingredients.¹⁹ It permits the Board to adopt rules specifying forms of epinephrine that are not to be recognized as pharmaceutical equivalents for purposes of autoinjector substitution.²⁰

Conditions

The bill specifies that the following conditions apply to a pharmacist's authority to substitute an epinephrine autoinjector:²¹

Patient instruction. A pharmacist cannot substitute if the person receiving the autoinjector instructs otherwise.

Prescriber instruction. A pharmacist cannot substitute if the prescriber indicates an intent to prevent substitution, such as by writing "dispense as written" or "D.A.W." on a written or electronic prescription or, for an oral prescription, specifying the prescribed autoinjector is "medically necessary."

¹⁹ R.C. 4729.382(B).

²⁰ R.C. 4729.382(H).

²¹ R.C. 4729.382(C).



Price. A pharmacist cannot substitute if the substituted autoinjector will cost the patient more than the prescribed autoinjector unless the patient specifically requests a more expensive autoinjector.

Right to refuse. A pharmacist, or a pharmacy intern or agent of the pharmacist, must inform the patient if a lower or equal cost autoinjector is available and of the patient's right to refuse substitution.

Instruction on administration

When a pharmacist dispenses an epinephrine autoinjector by substitution, the bill requires the pharmacist or a pharmacy intern to provide instruction on the proper method of administration. However, the instruction does not have to be provided if the person is receiving a device that is the same as the device that was last received.²²

Labeling

As under current law for substitution of generic drugs, the bill requires that the label for every dispensed epinephrine autoinjector include the epinephrine autoinjector's name, if any, and the distributor. Abbreviations may be used if necessary. When dispensing by substitution at retail, a pharmacist must indicate on the autoinjector's label or container that a substitution was made. The labeling requirements are in addition to all other labeling requirements adopted by the Board.²³

Liability

Also similar to current law for the substitution of generic drugs, the bill provides the following:

-- A pharmacist who dispenses an epinephrine autoinjector by substitution assumes no greater liability than would be incurred for dispensing the autoinjector identified on the prescription.²⁴

-- It is not evidence of negligence for a prescriber to fail to prevent substitution unless the prescriber had reasonable cause to believe the patient's health condition required a specific type of epinephrine autoinjector and no other.

-- A prescriber is not liable for civil damages or subject to criminal prosecution arising from a pharmacist's substitution of an epinephrine autoinjector unless the type

²² R.C. 4729.382(E).

²³ R.C. 4729.382(D).

²⁴ R.C. 4729.382(F).

of autoinjector prescribed would have reasonably caused the same loss, damage, injury, or death.²⁵

Prohibition

The bill prohibits a pharmacist from knowingly engaging in conduct concerning autoinjector substitution that is prohibited by the bill. Violation is a minor misdemeanor.²⁶

HISTORY

ACTION	DATE
Introduced	02-28-17
Reported, H. Health	05-03-17

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²⁵ R.C. 4729.382(G).

²⁶ R.C. 4729.382(I) and 4729.99(A).

