OHIO LEGISLATIVE SERVICE COMMISSION

Bill Analysis

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Sub. H.B. 101*

132nd General Assembly
(As Reported by S. Health, Human Services & Medicaid)

Reps. Merrin, Becker, Thompson, Seitz, Stein, West, Roegner, Sheehy, Sprague, Hood, R. Smith, Anielski, Antani, Antonio, Arndt, Boyd, Brenner, Brinkman, Butler, Carfagna, Celebrezze, Clyde, Conditt, Craig, Cupp, Dever, DeVitis, Duffey, Edwards, Galonski, Gavarone, Ginter, Goodman, Greenspan, Hagan, Hambley, Hill, Holmes, Hughes, Johnson, Keller, Kick, Koehler, Landis, Leland, Lepore-Hagan, Lipps, Manning, McColley, O'Brien, Patterson, Patton, Pelanda, Perales, Ramos, Reineke, Retherford, Rogers, Ryan, Schaffer, Slaby, K. Smith, Strahorn, Sweeney, Wiggam, Young

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 in each autoinjector are equivalent and certain other conditions are met.

- Generally prohibits pharmacy interns from dispensing dangerous drugs except for (1) naloxone or epinephrine, pursuant to a protocol, and (2) when the Governor declares an emergency.

- Adds exceptions to the office-based opioid treatment (OBOT) licensure requirement for federally qualified health centers, federally qualified health center look-alikes, state or local correctional facilities, and other facilities specified in rule.

* This analysis was prepared before the report of the Senate Health, Human Services, and Medicaid Committee appeared in the Senate Journal. Note that the list of co-sponsors and the legislative history may be incomplete.

- Makes changes to the OBOT employee background check requirements, including limiting the lookback period for disqualifying offenses to ten years.

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"®.

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

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[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>.

[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.

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.

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. A qualified entity that obtains epinephrine autoinjectors through a protocol is subject to the same requirements in existing law applicable when the autoinjectors are obtained 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]

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[8] R.C. 4729.47(B); R.C. 3728.01(C), not in the bill.

[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. 4729.47(C).

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 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]

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[12] R.C. 4729.47(D).

[13] R.C. 4729.47(E).

[14] R.C. 4729.47(G).

[15] R.C. 3707.60.

[16] R.C. 4731.961.

[17] R.C. 4731.96.

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]

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 epinephrine autoinjectors. 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 State Board of Pharmacy, 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]

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[18] R.C. 4729.47(F).

[19] R.C. 4729.382(B).

[20] R.C. 4729.382(H).

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."

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 make a reasonable attempt to 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]

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[21] R.C. 4729.382(C).

[22] R.C. 4729.382(E).

[23] R.C. 4729.382(D).

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 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]

Other Pharmacy Law changes

Certain Pharmacy Board information not a public record

The bill specifies that information received by the Board pursuant to an investigation is not a public record. Current law specifies only the following as not a public record: any record that identifies a patient, confidential informant, or individual who files a complaint with the Board and any record that may reasonably lead to the identification of any of those persons.[27]

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[24] R.C. 4729.382(F).

[25] R.C. 4729.382(G).

[26] R.C. 4729.382(I) and 4729.99(A).

[27] R.C. 4729.23(A).

The bill also specifies that information received or maintained by the Board regarding monitoring an individual for treatment or recovery as part of a disciplinary action is not a public record.[28]

Pharmacy interns

The bill generally prohibits pharmacy interns from dispensing dangerous drugs.[29] However, it maintains current authority for pharmacy interns to dispense naloxone pursuant to a protocol or to dispense dangerous drugs when the Governor declares an emergency.[30] It also authorizes a pharmacy intern to dispense epinephrine pursuant to a protocol (see "**Dispensing epinephrine with a prescription**," above).[31]

The bill defines "dispense" by reference to rules adopted by the Board. A current rule of the Board defines "dispense" as the "final association of a drug with a particular patient pursuant to the prescription, drug order, or other lawful order of a prescriber and the professional judgment of and the responsibility for interpreting, preparing, compounding, labeling, and packaging a specific drug."[32]

Pharmacist and pharmacy intern administration of immunizations and drugs

The bill permits the Board to approve the basic life-support training course that is a requirement for pharmacist or pharmacy intern immunization and drug administration. Under current law, pharmacists and pharmacy interns are authorized to administer certain immunizations and drugs if certain conditions are met. One condition is that the pharmacist or intern must be certified to perform basic life-support procedures. Current law requires completion of a basic life-support training course certified by the American Red Cross or the American Heart Association. The bill permits the Board to approve the course as well.[33]

Office-based opioid treatment

With some exceptions, current law requires a facility where a physician or other prescriber provides office-based opioid treatment (OBOT) to more than 30 patients to hold a category III terminal distributor of dangerous drugs license with an office-based

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[28] R.C. 4729.23(C).

[29] R.C. 4729.28 and 4729.43.

[30] R.C. 3701.048 and 4729.44, not in the bill.

[31] R.C. 4729.28(B)(2) and 4729.47.

[32] Ohio Administrative Code 4729-5-01.

[33] R.C. 4729.41(B)(2) and 4729.45(B)(2).

opioid treatment classification. "Office-based opioid treatment" is defined by current law as the treatment of opioid dependence or addiction using a controlled substance.[34] The bill makes changes to licensure exceptions and employee criminal records checks.

Exceptions to licensure

One of the current exceptions to the OBOT licensing requirement applies to a program or facility that is licensed or certified by the Ohio Department of Mental Health and Addiction Services. Under the bill, a program or facility comes within this exception only if the license or certification issued by the Department is also approved by the Board.[35]

The bill creates three new exceptions to the OBOT licensing requirement. The new exceptions apply to federally qualified health centers and federally qualified health center look-alikes, state or local correctional facilities, and any other facilities specified in rules adopted by the Board.[36]

Criminal records checks

Current law requires OBOT licensees to require all employees of the facility to submit to a criminal records check. The bill adds that persons seeking employment also must submit the criminal records check.

Under the bill, a felony theft offense or felony drug offense disqualifies a person from employment by the facility only if the person was convicted of or pleaded guilty to the offense within the ten years immediately preceding the date the person applied for employment. Currently, the disqualification applies regardless of when the offense was committed. Even under the bill's ten-year lookback period, however, the bill grants the Board authority to waive an individual's disqualification from employment. This means that the Board could permit a facility to employ a person who was convicted of or pleaded guilty to a felony theft offense or felony drug offense within the ten-year period.[37]

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[34] R.C. 4729.553(A) and (B).

[35] R.C. 4729.553(B)(2)(f).

[36] R.C. 4729.553(B)(2)(g), (h), and (i).

[37] R.C. 4729.553(D)(4) and (5).

HISTORY

ACTION	DATE
Introduced	02-28-17
Reported, H. Health	05-03-17
Passed House (96-0)	05-10-17
Reported, S. Health, Human Services & Medicaid	---

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