OHIO LEGISLATIVE SERVICE COMMISSION

Final Analysis

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Sub. H.B. 101

132nd General Assembly
(As Passed by the General Assembly)

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, T. 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

Sens. Beagle, Bacon, Brown, Coley, Hackett, Hoagland, Hottinger, Jordan, Kunze, LaRose, Obhof, Peterson, Uecker, Wilson, Yuko

Effective date: April 8, 2019

ACT SUMMARY

- Authorizes a pharmacist to dispense epinephrine under a physician-established protocol, rather than a prescription, to (1) individuals experiencing or likely to experience anaphylaxis and (2) entities 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 the prescribed autoinjector with another autoinjector if the drugs in each are equivalent.

- Designates investigatory information and certain disciplinary information received or maintained by the State Board of Pharmacy as not being a public record.

- Clarifies that the authority to dispense drugs is generally limited to pharmacists, but continues the authority of pharmacy interns to dispense drugs in limited circumstances while also permitting them to dispense epinephrine under a protocol.

- Names the act's epinephrine provision the "Epinephrine Accessibility Act."

- Permits the Board to approve basic life-support training courses for pharmacists and pharmacy interns seeking authority to administer immunizations and drugs by injection.

- Exempts the following facilities from the licensing requirement that must be met to provide office-based opioid treatment: federally qualified health centers and their look-alikes, state or local correctional facilities, and other facilities specified by the Board in rule.

- Allows an office-based opioid treatment facility to employ a person with a criminal record if (1) the disqualifying offense was committed more than ten years before the person applied or (2) the Board grants the facility a waiver permitting the person to be employed despite having a disqualifying offense within the preceding ten years.

CONTENT AND OPERATION

EPINEPHRINE

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"®.

The act, to be known as the "Epinephrine Accessibility Act,"[3] authorizes a pharmacist or pharmacy intern to dispense epinephrine without a prescription. For this to occur, a physician or board of health must have authorized the use of a protocol that meets requirements to be established by the State Board of Pharmacy.[4] In accordance with the protocol, the pharmacist or pharmacy intern may dispense epinephrine without a prescription to an individual age 18 or older if either of the following applies:

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[1] National Institutes of Health, U.S. National Library of Medicine, MedlinePlus, *Epinephrine Injection*, available at https://medlineplus.gov/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 22, 2010), available at https://www.pharmacytimes.com/p2p/p2pepinephrine-0910.

[3] Section 3.

[4] R.C. 3707.60 and 4731.961.

(1) The pharmacist has reason to believe that the individual is experiencing or at risk of experiencing anaphylaxis, the individual was previously issued a prescription for epinephrine, and the pharmacy has a record of the prescription;

(2) The individual is acting on behalf of a "qualified entity," which is defined by continuing law as 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 similar locations.[5] Primary and secondary schools and certain residential and child day camps are excluded from the definition, but are permitted by continuing law to obtain epinephrine through a prescription that does not specify a particular patient.[6]

Regarding qualified entities, continuing law already permits a qualified entity to acquire and maintain a supply of autoinjectors through a prescription or directly from a prescriber. The requirements that must be met to do so are extended by the act to a qualified entity when it obtains epinephrine autoinjectors through the act's protocol provisions. Storage, training, and reporting are among the matters addressed by those requirements.[7]

The act also extends civil liability protections to qualified entities and their employees associated with administering epinephrine or acquiring, maintaining, accessing, or using epinephrine obtained under the act's protocol provisions.[8]

Instruction and notice requirements

A pharmacist or pharmacy intern who dispenses epinephrine under the act must instruct the individual receiving it to contact emergency services as soon as practicable when it is administered. If the drug is dispensed to an individual, the pharmacist or pharmacy intern must notify the individual's primary care provider, if known, or the prescriber who issued the initial prescription.[9]

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[5] R.C. 4729.47(B); R.C. 3728.01(C), not in the act.

[6] R.C. 3313.7110, 3313.7111, 3314.143, 3326.28, 3328.29, and 5101.76, not in the act.

[7] R.C. 3728.03; R.C. 3728.04 and 3728.10, not in the act.

[8] R.C. 3728.09, not in the act.

[9] R.C. 4729.47(C).

The dispensing may be documented on a prescription form, which may be assigned a number for record-keeping purposes.[10] The act specifies that it does not affect the authority of a pharmacist or pharmacy intern to fill or refill an epinephrine prescription.[11]

Rules for protocols

The act requires the Board to adopt rules implementing the protocol provisions. 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 July 7, 2019.[12]

Authorizations under protocols

The act permits both of the following methods to be used to authorize pharmacists and pharmacy interns to dispense epinephrine without a prescription under a protocol:

(1) A physician, including a podiatrist, may authorize pharmacists and pharmacy interns to use a protocol that the physician has established;[13]

(2) A board of health may authorize pharmacists and pharmacy interns practicing pharmacy in any county that includes territory within the health district the board represents to use a protocol developed by a physician serving as the board's health commissioner or medical director.[14]

Immunity from liability

Each of the following who acts in good faith and in accordance with the act 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

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

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

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

[13] R.C. 4731.96 and 4731.961.

[14] R.C. 3707.60.

epinephrine is dispensed: (1) a board of health, (2) a physician, and (3) a pharmacist or pharmacy intern.[15]

Substitution of epinephrine autoinjectors

The act 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. The process to be used is similar to the process that applies under continuing law to the substitution of generic drugs.[16]

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, is either (1) identical or (2) a federally approved pharmaceutical equivalent. The act does not address the issue of substitution based on generic versions of devices.[17]

The act describes a drug as being the pharmaceutical equivalent of another if the drug contains identical amounts of the identical active ingredients, but not necessarily the same inactive ingredients.[18] 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.[19]

Instruction on administration

When a pharmacist dispenses an epinephrine autoinjector by substitution, the act requires the pharmacist or a pharmacy intern to provide instruction on proper administration. However, instruction is not required if the person is receiving the same device that was last received.[20]

Conditions on substitution

As under continuing law for generic drug substitution, the act establishes a number of conditions that apply to epinephrine autoinjector substitution. The conditions include adhering to prescriber or patient instructions not to substitute,

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

[16] R.C. 4729.38, not in the act.

[17] *See* U.S. Food & Drug Administration, FDA approves first generic version of EpiPen, August 16, 2018, https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm617173.htm.

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

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

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

informing the patient of the right to refuse substitution, providing specified labeling information, and limiting the cost the patient incurs. Regarding cost, the act differs from the generic drug substitution law by permitting substitution to occur when a patient requests a more expensive autoinjector than the one that was prescribed.[21]

The act prohibits a pharmacist from knowingly engaging in conduct in violation of its conditions on epinephrine autoinjector substitution. Violation is a minor misdemeanor.[22]

Limits on liability

Similar to continuing law for generic drug substitution, the act establishes limits on the liability of pharmacists and prescribers with respect to epinephrine autoinjector substitution.[23] It specifies that (1) a pharmacist assumes no greater liability for making the substitution than would be incurred for dispensing the prescribed autoinjector, (2) 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 autoinjector, and (3) a prescriber is not liable for civil damages or subject to criminal prosecution arising from the substitution unless the prescribed autoinjector would have reasonably caused the same loss, damage, injury, or death.

PHARMACY LAW CHANGES

Confidential investigation and discipline information

The act specifies that information received by the Board pursuant to an investigation is not a public record, in addition to continuing law specifying that the information is confidential and not subject to discovery in civil actions. This provision, which applies to investigatory information in general, replaces a provision of prior law that excluded the following specific types of information from being considered a public record: any record that identified a patient, confidential informant, or individual who filed a complaint with the Board and any record that could have reasonably lead to the identification of any of those persons.[24]

The act also specifies that information received or maintained by the Board regarding monitoring an individual for treatment or recovery as part of a disciplinary

[21] R.C. 4729.382(D) and (E).

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

[23] R.C. 4729.382(F) and (G).

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

action is not a public record. As with investigatory information, this exclusion from being a public record is in addition to continuing law specifying that the information is confidential and not subject to discovery in civil actions.[25]

Dispensing drugs and pharmacy interns

The act clarifies that the authority to dispense dangerous drugs is generally limited to licensed pharmacists. It defines "dispense" by reference to rules adopted by the Board. Under rules adopted prior to the act, "dispense" is defined 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."[26] The Board's rules on the proper processing of prescriptions refer only to the duties of pharmacists when drugs are dispensed.[27]

In clarifying that only pharmacists are authorized to dispense dangerous drugs, the act eliminates a number of provisions that refer to drugs being dispensed by pharmacy interns.[28] During a pharmacy internship, an individual gains the practical experience necessary to become licensed, but must practice under the supervision of a pharmacist.[29] Under Board rules adopted prior to the act, the professional functions of a pharmacy intern do not include the authority to dispense drugs.[30]

Although pharmacy interns are generally not authorized to dispense drugs, the act retains provisions that permit them to dispense the following: (1) naloxone pursuant to a protocol and (2) certain dangerous drugs pursuant to a protocol when the Governor declares a public health emergency.[31] The act also authorizes a pharmacy intern to dispense epinephrine pursuant to a protocol, as described above.[32]

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

[26] Ohio Administrative Code (O.A.C.) 4729-5-01.

[27] O.A.C. 4729-5-21(C).

[28] R.C. 4729.28 and 4729.43.

[29] R.C. 4729.28; O.A.C. 4729:2-01 and 4729-5-22(E).

[30] O.A.C. 4729-5-08.

[31] R.C. 3701.048 and 4729.44, not in the act.

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

Administration of immunizations and drugs – basic life-support training

The act establishes an additional method for pharmacists and pharmacy interns to obtain basic life-support certification, which is one of the requirements they must meet to be authorized under continuing law to administer immunizations and other drugs by injection. Under the act, they may complete a basic life-support training course that is approved by the Board. The act retains the options of completing a training course certified by the American Red Cross or the American Heart Association.[33]

Office-based opioid treatment

Ohio law generally requires a facility where a physician or other prescriber provides office-based opioid treatment to more than 30 patients to be licensed by the Board, specifically by obtaining a category III terminal distributor of dangerous drugs license with an office-based opioid treatment classification. "Office-based opioid treatment" is defined by continuing law as the treatment of opioid dependence or addiction using a controlled substance.[34]

Licensure exemptions

Several types of facilities are exempt under continuing law from the office-based opioid treatment licensing requirement, including hospitals, hospital-operated treatment facilities, and clinical research facilities. The act creates exemptions for the following:

(1) Federally qualified health centers;

(2) Federally qualified health center look-alikes, which are community health organizations that do not receive the federal grants that federally qualified health centers receive, but meet all of the eligibility requirements for the funding;[35]

(3) State or local correctional facilities;

(4) Any other facilities specified in rules adopted by the Board.[36]

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

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

[35] FQHC.org. *What Is an FQHC Look-Alike and What Benefits Does One Receive?*, available at https://www.fqhc.org/fqhc-look-alike-info.

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

The act also limits an exemption that applies to programs and facilities licensed or certified by the Ohio Department of Mental Health and Addiction Services. Under the act, a program or facility is exempt only if its license or certification from the Department is also approved by the Board.[37]

Criminal records checks

Continuing law requires all employees of a licensed office-based opioid treatment facility to submit to a criminal records check. The act also requires persons seeking employment to submit a criminal records check.[38]

Under the act, 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. Prior to the act, the disqualification applied regardless of when the offense was committed.[39]

Even under the act's ten-year period of consideration, a person with a disqualifying offense may be employed. For this to occur, the Board must authorize the employment by waiving the disqualification requirement for the facility.[40]

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	11-28-18
Passed Senate (32-0)	12-27-18
House concurred in Senate amendments (88-0)	12-27-18

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

[38] R.C. 4729.553(D)(4).

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

[40] R.C. 4729.553(D)(5).