



# Ohio Legislative Service Commission

## Bill Analysis

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### Sub. H.B. 200\*

131st General Assembly

(As Reported by S. Health and Human Services)

**Reps.** Hagan, Duffey, Becker, Roegner, Blessing, Hackett, Gonzales, Huffman, Antonio, Barnes, Bishoff, Brown, Butler, Ginter, T. Johnson, Kuhns, LaTourette, Lepore-Hagan, Schuring, Sears, Sprague, Amstutz, Anielski, Arndt, Ashford, Baker, Boose, Boyd, Buchy, Burkley, Celebrezze, Cera, Conditt, Cupp, Derickson, Dever, DeVitis, Dovilla, Driehaus, Fedor, Green, Grossman, Hall, Hambley, Hayes, Henne, Hill, Howse, Koehler, Kunze, Landis, Leland, Maag, Manning, McClain, McColley, M. O'Brien, S. O'Brien, Patterson, Pelanda, Perales, Phillips, Ramos, Reece, Reineke, Retherford, Rezabek, Rogers, Ruhl, Ryan, Schaffer, Scherer, Sheehy, K. Smith, R. Smith, Stinziano, Strahorn, Sweeney, Terhar, Thompson, Young

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## BILL SUMMARY

- Authorizes certain entities located where allergens capable of causing anaphylaxis may be present to acquire and maintain epinephrine autoinjectors without a license and to administer the epinephrine during an emergency.
- Provides school districts, schools, and camps that are currently authorized to procure epinephrine autoinjectors with an alternative means for doing so by authorizing a prescriber to personally furnish the epinephrine autoinjectors or to issue a prescription for them in the name of the school, school district, or camp.
- Specifies training requirements for individuals authorized by qualified entities to administer epinephrine during an emergency.
- Provides certain immunities associated with the procurement of epinephrine autoinjectors.

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

- Extends to prescribers who consult with, or issue protocols to, school districts, schools, or camps qualified immunity from civil liability arising from procuring, maintaining, accessing, or using epinephrine autoinjectors in the schools or camps.

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## CONTENT AND OPERATION

### Overview

Epinephrine is a prescription drug used to treat life-threatening allergic reactions caused by insect bites or stings, foods, medications, latex, and other causes.<sup>1</sup> Since the late 1980s, epinephrine has been available in the form of an autoinjector that facilitates self-administration of the drug.<sup>2</sup>

Ohio law generally prohibits the sale, donation, and possession of prescription drugs (referred to as "dangerous drugs" in the Revised Code<sup>3</sup>) by individuals or entities except when the individual or entity is (1) exempt from the prohibition under law or (2) possesses the applicable terminal distributor of dangerous drugs license from the State Board of Pharmacy to possess, sell, or have custody or control over prescription drugs.<sup>4</sup> One of the current exemptions applies to schools and camps, which are permitted by current law to procure epinephrine autoinjectors for use in emergencies.

In addition to the current authority of schools, the bill authorizes "qualified entities" associated with locations where allergens capable of causing anaphylaxis may be present to procure epinephrine autoinjectors for use in emergencies without possessing the otherwise required license. The bill also provides school districts, schools, and camps an alternative means by which to procure epinephrine autoinjectors for use in emergencies. It does so by permitting a prescriber to personally furnish epinephrine autoinjectors to the school district, school, or camp, or issue a prescription for the epinephrine autoinjectors in the name of the school, school district, or camp. (Current law restricts schools, school districts, and camps to procuring and administering epinephrine autoinjectors pursuant to a prescriber-issued protocol.) Further, the bill grants certain immunities associated with the procurement and maintenance of epinephrine autoinjectors by qualified entities, schools, school districts,

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

<sup>2</sup> 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](http://www.pharmacytimes.com/p2p/P2PEpinephrine-0910).

<sup>3</sup> R.C. 4729.01(F), not in the bill.

<sup>4</sup> R.C. 4729.51.



and camps. It also expands to prescribers who issue protocols related to epinephrine procurement and administration by schools and camps qualified immunity from civil liability arising from procuring, maintaining, accessing, and using epinephrine autoinjectors.

### **Procurement of epinephrine autoinjectors by qualified entities**

The bill permits qualified entities to procure epinephrine autoinjectors for use in emergencies by being personally furnished with them or by receiving a prescription for them from any of the following licensed health professionals:

- (1) A clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner who holds a certificate to prescribe under Ohio law;<sup>5</sup>
- (2) A physician assistant with physician-delegated prescriptive authority;<sup>6</sup>
- (3) A physician.<sup>7</sup>

A "qualified entity" is any public or private entity that is associated with a location where allergens capable of causing anaphylaxis may be present, including child day-care centers, colleges and universities, places of employment, restaurants, amusement parks, recreation camps, sports playing fields and arenas, and other similar locations. It is not any of the following: a chartered or nonchartered nonpublic school; a community school; a science, technology, engineering, and mathematics (STEM) school; or a school operated by a board of education of a city, local, exempted village, or joint vocational school district.<sup>8</sup>

Associated with this authority, the bill expands the definition of "prescription" in the pharmacy law to include a written, electronic, or oral order for an epinephrine autoinjector issued to and in the name of a qualified entity, school district, school, or camp.<sup>9</sup> Epinephrine autoinjectors prescribed or furnished by a health professional under the bill must be prescribed or furnished in such a manner that they may be administered only in a manufactured dosage form.<sup>10</sup>

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<sup>5</sup> R.C. 4723.483(A)(1).

<sup>6</sup> R.C. 4730.432(A)(1).

<sup>7</sup> R.C. 4731.96(B)(1).

<sup>8</sup> R.C. 3728.01(C).

<sup>9</sup> R.C. 4729.01(H)(4) and (5).

<sup>10</sup> R.C. 4723.483(A)(2), 4730.433(A)(2), and 4731.96(A)(2).

## **School districts, schools, and camps**

The current law authorizing schools and camps to procure epinephrine autoinjectors without a license requires that a school district, school, or camp have a policy governing the maintenance and use of epinephrine autoinjectors. The policy must contain a prescriber-issued protocol specifying definitive orders for the epinephrine autoinjectors and the dosages to be administered through them.<sup>11</sup> The bill maintains with slight modification this authority for school districts, schools, and camps to maintain and use epinephrine autoinjectors for emergencies through the use of a protocol. Specifically, the bill permits a school district's superintendent, school's governing authority, or camp to obtain a prescriber-issued protocol that includes definitive orders for epinephrine autoinjectors and the dosages of epinephrine to be administered through them. In addition, the bill authorizes a school district, school, or camp to procure epinephrine autoinjectors in the same manner the bill authorizes for qualified entities: by permitting a prescriber to personally furnish epinephrine autoinjectors to the school, school district, or camp, or issue a prescription for them in the name of the school, district, or camp.<sup>12</sup>

## **Pharmacist dispensing of epinephrine autoinjectors**

The bill authorizes pharmacists to dispense epinephrine autoinjectors pursuant to prescriptions issued by health professionals specified in the bill. A pharmacist who acts in good faith in dispensing epinephrine autoinjectors as authorized by the bill is not liable for or subject to damages in a civil action or subject to criminal prosecution or professional disciplinary action.<sup>13</sup>

## **Storage, maintenance, and control of epinephrine autoinjectors**

The bill requires qualified entities to store any acquired epinephrine autoinjectors in a location that is readily accessible in an emergency, and to maintain the autoinjectors in accordance with manufacturer instructions and any additional requirements established by the Ohio Department of Health (ODH). The qualified entity must designate one or more employees or agents who have been trained as specified in the bill to be responsible for oversight of the autoinjectors, including storage, maintenance, and control.<sup>14</sup>

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<sup>11</sup> R.C. 3313.7110(A) to (C), 3313.7111(A), 3314.143(A), 3326.28(A), 3328.29(A), and 5101.76(A) to (C).

<sup>12</sup> R.C. 3313.7110(A), 3313.7111(A), 3314.143(A), 3326.28(A), 3328.29(A), and 5101.76(A).

<sup>13</sup> R.C. 4729.88.

<sup>14</sup> R.C. 3728.03(B) and (C).



The bill authorizes ODH to adopt rules specifying standards and procedures for storage and maintenance of supplies of epinephrine autoinjectors. If any rules are adopted, the bill requires that they be adopted in accordance with the Administrative Procedure Act (R.C. Chapter 119.).<sup>15</sup>

### **Administration of epinephrine**

The bill permits a qualified entity to authorize individuals who have successfully completed an anaphylaxis training program to administer epinephrine through an autoinjector.<sup>16</sup> A trained and authorized individual may do either of the following to an individual believed in good faith to be experiencing anaphylaxis, regardless of whether the individual believed to be experiencing anaphylaxis has a prescription for an epinephrine autoinjector or has previously been diagnosed with an allergy:<sup>17</sup>

(1) Administer epinephrine using an autoinjector;

(2) Provide an autoinjector to the individual or the individual's parent, guardian, or caregiver for immediate administration.

### **Training to administer epinephrine by autoinjector**

Prior to being authorized by a qualified entity to administer epinephrine, and every two years thereafter, an individual must complete training. Successful completion of the training must be evidenced by a certificate from the trainer on a form developed by ODH.<sup>18</sup>

The training may be conducted by a nationally recognized organization with experience providing emergency health care training to individuals who are not health professionals. Alternatively, the training may be by ODH-approved individuals and organizations or in ODH-approved classes.<sup>19</sup>

The training may be completed in person or online and must cover all of the following:<sup>20</sup>

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<sup>15</sup> R.C. 3728.11(B)(2).

<sup>16</sup> R.C. 3728.03(C).

<sup>17</sup> R.C. 3728.01(A) and 3728.05.

<sup>18</sup> R.C. 3728.04(C) and 3728.11(A)(1).

<sup>19</sup> R.C. 3728.04(A) and 3728.11(B)(1).

<sup>20</sup> R.C. 3728.04(B).

(1) Recognition of the signs and symptoms of severe allergic reactions, including anaphylaxis;

(2) Standards and procedures for administration of epinephrine and storage of epinephrine autoinjectors;

(3) Emergency follow-up procedures.

The bill specifies that the training may include any other material the trainer or ODH considers appropriate.<sup>21</sup>

## **Reporting requirement**

The bill requires qualified entities that maintain epinephrine autoinjectors and make them available in accordance with the bill's provisions to annually report to ODH each administration of epinephrine or provision of an epinephrine autoinjector from the qualified entity's supply.<sup>22</sup> The report must be on a form developed by ODH.<sup>23</sup> The bill requires ODH to publish an annual report summarizing and analyzing the reports from qualified entities.<sup>24</sup>

## **Immunity**

### **Civil immunity for qualified entities, authorized individuals, and trainers**

The bill provides to all of the following immunity in civil actions for damages arising from administration of epinephrine or acquiring, maintaining, accessing, or using an epinephrine autoinjector as authorized by the bill, except where the conduct constitutes willful or wanton misconduct:<sup>25</sup>

--Qualified entities and their employees or agents;

--Trained individuals;

--Individuals or organizations that conduct anaphylaxis training.

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<sup>21</sup> R.C. 3728.04(B).

<sup>22</sup> R.C. 3728.10.

<sup>23</sup> R.C. 3728.11(A)(2).

<sup>24</sup> R.C. 3728.11(A)(3).

<sup>25</sup> R.C. 3728.09(A).

The bill also provides immunity for persons located in Ohio with regard to acquiring, maintaining, accessing, or using an epinephrine autoinjector outside of Ohio if (1) the person would not have been liable had the act or omission occurred in Ohio or (2) the person is not liable under the law of the state in which the act or omission occurred.<sup>26</sup>

The bill provides that these immunity provisions do not eliminate, limit, or reduce any other immunity or defense a person may be entitled to under any other provision of Ohio statutory or common law.<sup>27</sup>

### **Civil immunity for schools, school districts, and camps**

Current law provides that public and private schools, school districts, and camps, as well as their governing authorities, employees, and contractors, are not liable in civil actions arising from procuring, maintaining, accessing, or using an epinephrine autoinjector in accordance with a prescriber-issued protocol authorized under current law, except where the conduct constitutes willful or wanton misconduct. The bill, extends this qualified civil immunity to these individuals and entities for either of the following:<sup>28</sup>

--Having an authorized prescriber personally furnish the epinephrine autoinjectors to the school, school district, or camp, or issue a prescription for them in the name of the school, district, or camp; or

--Having the district's superintendent, school's governing authority, or camp obtain a prescriber-issued protocol that includes definitive orders for epinephrine autoinjectors and the dosages of epinephrine to be administered through them.

The bill maintains current law that provides that the immunity provisions do not eliminate, limit, or reduce any other immunity or defense an individual or entity may be entitled to under any other provision of Ohio statutory or common law.<sup>29</sup>

### **Immunity from criminal prosecution**

The bill provides that certain individuals and qualified entities that administer epinephrine or furnish autoinjectors are not subject to criminal prosecution for drug

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<sup>26</sup> R.C. 3728.09(C).

<sup>27</sup> R.C. 3728.09(B).

<sup>28</sup> R.C. 3313.7110(A) and (D), 3313.7111(A) and (B), 3314.143(A) and (B), 3326.28(A) and (B), 3328.29(A) and (B), and 5101.76(D).

<sup>29</sup> R.C. 3313.7110(D)(2), 3313.7111(B)(2), 3314.143(B)(2), 3326.28(B)(2), 3328.29(B)(2), and 5101.76(D)(2).



offenses or the unauthorized practice of medicine. The immunity applies if the individual or qualified entity acts in good faith and in accordance with the bill's requirements in administering epinephrine or furnishing an epinephrine autoinjector to (1) an individual who appears to be experiencing, or is at risk of experiencing, anaphylaxis or (2) the parent, guardian, or custodian of the individual.<sup>30</sup>

### **Immunity for prescribers**

The bill provides that a prescriber who acts in good faith in prescribing or furnishing epinephrine autoinjectors to qualified entities, schools, school districts, and camps is not liable for or subject to damages in a civil action, criminal prosecution, or professional disciplinary action.<sup>31</sup>

The bill also extends qualified immunity from civil immunity associated with procuring, maintaining, accessing, or using an epinephrine autoinjector to prescribers who consult with, or provide protocols to, schools, school districts, and camps related to epinephrine procurement and administration. This immunity applies under existing law to schools, school districts, and camps, as well as their governing authorities, employees, and contractors.<sup>32</sup>

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## **HISTORY**

<b>ACTION</b>	<b>DATE</b>
Introduced	05-12-15
Reported, H. Health & Aging	10-07-15
Passed House (94-0)	12-01-15
Reported, S. Health & Human Services	---

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<sup>30</sup> R.C. 2925.64.

<sup>31</sup> R.C. 4723.483(B), 4730.96(C), and 4731.96(C).

<sup>32</sup> R.C. 3313.7110(D)(1)(d), 3313.7111(B)(1)(d), 3314.143(B)(1)(d), 3326.28(B)(1)(d), 3328.29(B)(1)(d), and 5101.76(D)(1)(c).

