



# Ohio Legislative Service Commission

## Bill Analysis

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### Sub. H.B. 200

131st General Assembly  
(As Reported by H. Health and Aging)

**Reps.** Hagan, Duffey, Becker, Roegner, Blessing, Hackett, Gonzales, Huffman, Antonio, Barnes, Bishoff, Brown, Butler, Ginter, T. Johnson, Kuhns, LaTourette, Lepore-Hagan, Schuring, Sears, Sprague

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## BILL SUMMARY

- Permits 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.
- Authorizes certain health professionals who are authorized by law to prescribe drugs to furnish or prescribe epinephrine autoinjectors to qualified entities.
- Specifies training requirements for individuals authorized by qualified entities to administer epinephrine during an emergency.
- Provides certain immunities to qualified entities, authorized individuals, training providers, health professionals, and pharmacists.
- Grants health professionals who consult with, or issue protocols to, schools or camps pursuant to existing law 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

### Procurement of epinephrine autoinjectors for emergency administration

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

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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).

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>

The bill authorizes "qualified entities" associated with locations where allergens capable of causing anaphylaxis may be present to procure epinephrine autoinjectors for use in emergency situations without possessing the license that would otherwise be required.<sup>5</sup> Additionally, regarding existing law that permits schools and camps to procure epinephrine autoinjectors, the bill grants health professionals who consult with, or issue protocols to, schools or camps qualified immunity from civil liability.

### **Qualified entities**

Under the bill, "qualified entities" are public and private entities associated with locations 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.

The bill specifies that the following are not included as "qualified entities": public schools, chartered or nonchartered nonpublic schools, community schools, STEM schools, or residential and child day camps.<sup>6</sup> Procurement and administration of epinephrine autoinjectors in those locations is governed by current law that is largely unchanged by the bill.<sup>7</sup>

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<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.

<sup>5</sup> R.C. 3728.03, 3728.05, and 4729.51.

<sup>6</sup> R.C. 3728.01(C).

<sup>7</sup> R.C. 3313.7110, 3313.7111, 3313.718, 3314.143, 3326.28, and 3326.29, not in the bill.

## Health professional prescribing and furnishing of epinephrine autoinjectors

The bill provides that the definition of "prescription" includes a written, electronic, or oral order for an epinephrine autoinjector issued to and in the name of a qualified entity.<sup>8</sup> The bill permits the following licensed health professionals to issue a prescription for epinephrine autoinjectors to a qualified entity or to personally furnish a supply of epinephrine autoinjectors to a qualified entity:

(1) A clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner who holds a certificate to prescribe under Ohio law;<sup>9</sup>

(2) A physician assistant who holds a certificate to prescribe under Ohio law;<sup>10</sup>

(3) A physician.<sup>11</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>12</sup>

A health professional who acts in good faith in prescribing or furnishing epinephrine autoinjectors as authorized by the bill is not liable for or subject to damages in a civil action, criminal prosecution, or professional disciplinary action.<sup>13</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, criminal prosecution, or professional disciplinary action.<sup>14</sup>

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<sup>8</sup> R.C. 4729.01(H)(3).

<sup>9</sup> R.C. 4723.489(B)(1).

<sup>10</sup> R.C. 4730.432(B)(1). This section will need to be updated to reflect recent changes in the law governing physician assistants.

<sup>11</sup> R.C. 4731.96(B)(1).

<sup>12</sup> R.C. 4723.489(B)(2), 4730.432(B)(2), and 4731.96(B)(2).

<sup>13</sup> R.C. 4723.489(C), 4730.432(C), and 4731.96(C).

<sup>14</sup> R.C. 4729.88.

## **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. 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>15</sup>

The bill authorizes the Department 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>16</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>17</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:

(1) Administer epinephrine using an autoinjector;

(2) Provide an autoinjector to the individual or the individual's parent, guardian, or caregiver for immediate administration.<sup>18</sup>

## **Training to administer epinephrine via an 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 and prescribed by the Ohio Department of Health.<sup>19</sup>

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<sup>15</sup> R.C. 3728.03(B) and (C).

<sup>16</sup> R.C. 3728.11(B)(2).

<sup>17</sup> R.C. 3728.03(C).

<sup>18</sup> R.C. 3728.01(A) and 3728.05.

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

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 Department-approved individuals and organizations or in Department-approved classes.<sup>20</sup>

The training may be completed in person or online and must cover all of the following:

(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 Department 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 the Ohio Department of Health each administration of epinephrine or provision of an epinephrine autoinjector from the qualified entity's supply. The report must be on a form developed by the Department.<sup>22</sup> The bill requires the Department to publish an annual report summarizing and analyzing the reports from qualified entities.<sup>23</sup>

## **Immunity**

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

The bill provides 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. The immunity is provided to qualified entities and their employees or agents, trained individuals, and individuals or organizations that conduct

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<sup>20</sup> R.C. 3728.04(A) and 3728.11(B)(1).

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

<sup>22</sup> R.C. 3728.10 and 3728.11(A)(2).

<sup>23</sup> R.C. 3728.11(A)(3).

anaphylaxis training.<sup>24</sup> 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>25</sup>

The bill provides that its 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>26</sup>

### **Criminal immunity for qualified entities and authorized individuals**

The bill provides that certain individuals and qualified entities that administer epinephrine or furnish autoinjectors are not subject to criminal prosecution for drug 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>27</sup>

### **Epinephrine autoinjectors in schools and camps**

The bill provides qualified immunity in civil actions to health professionals who consult with, or provide protocols to, schools and camps that elect to procure epinephrine autoinjectors under existing law. Current law permits public and private schools and camps to procure epinephrine autoinjectors without a license for use in specified emergency situations. A school governing authority or camp that elects to procure epinephrine autoinjectors must adopt a policy authorizing their maintenance and use. The governing authority, superintendent, or camp must consult with a licensed health professional who is authorized to prescribe drugs to develop a policy composed of procedures for the maintenance and use of the epinephrine autoinjectors. One component of the policy must be a prescriber-issued protocol specifying definitive orders for epinephrine autoinjectors and the dosages to be administered.<sup>28</sup>

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<sup>24</sup> R.C. 3728.09(A).

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

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

<sup>27</sup> R.C. 2925.64.

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



Under current law, all school districts, public and private schools, and camps that elect to procure epinephrine autoinjectors, as well as governing authorities, employees, and contractors, are not liable for damages in a civil action arising from an act or omission associated with procuring, maintaining, accessing, or using an epinephrine autoinjector under the law, unless the act or omission constitutes willful or wanton misconduct. The bill extends this protection to health professionals who consult with, or provide protocols to, schools or camps.<sup>29</sup>

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## HISTORY

ACTION	DATE
Introduced	05-12-15
Reported, H. Health & Aging	10-07-15

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

