



# Ohio Legislative Service Commission

## Final Analysis

Audra Tidball

### Sub. H.B. 200

131st General Assembly  
(As Passed by the General Assembly)

- 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
- Sens.** Tavares, Brown, Balderson, Beagle, Burke, Coley, Eklund, Faber, Gardner, Hite, Hottinger, Hughes, Jones, LaRose, Lehner, Manning, Obhof, Oelslager, Patton, Peterson, Schiavoni, Seitz, Thomas, Uecker, Yuko

**Effective date:** September 8, 2016

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## ACT SUMMARY

- Authorizes certain entities where allergens capable of causing anaphylaxis may be present ("qualified entities") to (1) acquire and maintain epinephrine autoinjectors without being licensed to distribute drugs and (2) authorize their employees or agents to provide or administer epinephrine during emergencies.
- Specifies training requirements for individuals authorized by qualified entities to administer epinephrine.
- Provides immunity from civil or criminal liability for actions associated with procurement of epinephrine autoinjectors by qualified entities.
- Permits school districts, schools, and camps, which are authorized to procure epinephrine autoinjectors pursuant to prescriber protocols, to procure them directly from a prescriber or pursuant to a prescription.
- Extends to prescribers who personally furnish or prescribe, 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

### Qualified entities

The act permits qualified entities to procure epinephrine autoinjectors for use in emergencies directly from or pursuant to a prescription from any of the following prescribers:

- (1) A clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner who holds a certificate to prescribe under Ohio law;
- (2) A physician assistant with physician-delegated prescriptive authority;
- (3) A physician.<sup>1</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 a child day-care center, college or university, place of employment, restaurant, amusement park, recreation camp, sports playing field or arena, or similar location. However, "qualified entity" does not include the school districts, schools, and camps that are authorized by other laws to procure epinephrine.<sup>2</sup>

Epinephrine autoinjectors must be prescribed or furnished under the act so they may be administered only in a manufactured dosage form.<sup>3</sup> A qualified entity may procure epinephrine without first obtaining a license to act as a terminal distributor of dangerous drugs.<sup>4</sup> A terminal distributor of dangerous drugs is a pharmacy, nursing home, hospital, or other entity that sells prescription drugs directly to consumers.<sup>5</sup>

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<sup>1</sup> R.C. 4723.483(A)(1), 4730.433(A)(1), and 4731.96(B)(1). (R.C. 4730.433 was originally numbered R.C. 4730.432 in the act. The LSC Director changed the number under R.C. 103.131.)

<sup>2</sup> R.C. 3728.01(C).

<sup>3</sup> R.C. 4723.483(A)(2), 4730.433(A)(2), and 4731.96(A)(2).

<sup>4</sup> R.C. 4729.51 and 4729.60.

<sup>5</sup> R.C. 4729.01.



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

The act requires qualified entities to store epinephrine autoinjectors in a location that is readily accessible in an emergency and to maintain them 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 act to be responsible for oversight of autoinjectors, including storage, maintenance, and control.<sup>6</sup>

The act authorizes ODH to adopt rules in accordance with the Administrative Procedure Act specifying standards and procedures for storage and maintenance of epinephrine autoinjectors.<sup>7</sup>

### **Epinephrine administration**

The act permits a qualified entity to authorize individuals who have successfully completed an anaphylaxis training program to administer epinephrine through an autoinjector.<sup>8</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 that individual has an epinephrine prescription or has previously been diagnosed with an allergy:<sup>9</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**

An individual must complete training prior to being authorized by a qualified entity to administer epinephrine, and every two years thereafter. Successful completion of the training must be evidenced by a certificate from the trainer on a form developed by ODH.<sup>10</sup> The training may be conducted by a nationally recognized organization with experience providing emergency health care training to individuals who are not health

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<sup>6</sup> R.C. 3728.03(B) and (C).

<sup>7</sup> R.C. 3728.11(B)(2).

<sup>8</sup> R.C. 3728.03(C).

<sup>9</sup> R.C. 3728.01(A) and 3728.05.

<sup>10</sup> R.C. 3728.04 and 3728.11.



professionals. Alternatively, it may be by an ODH-approved individual or organization or in an ODH-approved class.

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 training may include any other material the trainer or ODH considers appropriate.<sup>11</sup>

### **Reporting**

Qualified entities that maintain epinephrine autoinjectors and make them available in accordance with the act must annually report to ODH each administration of epinephrine or provision of an epinephrine autoinjector by the qualified entity. The report must be on a form developed by ODH, and ODH must publish an annual report summarizing and analyzing the reports.<sup>12</sup>

### **Schools and camps**

Law largely unchanged by the act authorizes a school district, school, or camp that adopts a policy governing the maintenance and use of epinephrine autoinjectors to procure them without being licensed as a terminal distributor of dangerous drugs. The policy must contain a prescriber-issued protocol specifying definitive orders for the epinephrine autoinjectors and the dosages to be administered through them.<sup>13</sup> This authority extends to school districts, nonpublic schools, community schools, STEM schools, public college preparatory boarding schools, residential camps, and child day camps.

The act establishes an additional method for a school district, school, or camp to procure epinephrine autoinjectors. As with qualified entities, it authorizes a school

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<sup>11</sup> R.C. 3728.04(B).

<sup>12</sup> R.C. 3728.10 and 3728.11(A).

<sup>13</sup> R.C. 3313.7110, 3313.7111, 3314.143, 3326.28, 3328.29, and 5101.76.



district, school, or camp to obtain epinephrine autoinjectors directly from a prescriber or pursuant to a prescription issued by a prescriber.<sup>14</sup> The prescriber may be a physician or one of the following who has authority to prescribe: a physician assistant, clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner.

## **Prescribers and pharmacists**

The act authorizes a prescriber to personally furnish epinephrine autoinjectors for use in accordance with the act or to issue a prescription. The prescriber may do this without having examined an individual to whom epinephrine may be furnished.<sup>15</sup> It also authorizes a pharmacist to dispense epinephrine autoinjectors pursuant to a prescription issued by a prescriber. The act 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>16</sup>

## **Immunities**

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

The act 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 act, except where the conduct constitutes willful or wanton misconduct:<sup>17</sup>

- Qualified entities and their employees or agents;
- Trained individuals authorized by qualified entities;
- Individuals and organizations that conduct anaphylaxis training.

The act also provides immunity for a person located in Ohio concerning 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

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<sup>14</sup> R.C. 3313.7110(A), 3313.7111(A), 3314.143(A), 3326.28(A), 3328.29(A), and 5101.76(A).

<sup>15</sup> R.C. 4723.483, 4730.433, and 4731.96.

<sup>16</sup> R.C. 4729.01(H)(4) and (5).

<sup>17</sup> R.C. 3728.09(A).



(2) the person is not liable under the law of the state in which the act or omission occurred.<sup>18</sup>

The act 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 law.<sup>19</sup>

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

Law unchanged by the act provides that school districts, public and private schools, 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, except where the conduct constitutes willful or wanton misconduct. The act extends this qualified civil immunity to these individuals and entities for either of the following:<sup>20</sup>

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

--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 act maintains law providing 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 law and extends this to nonpublic schools.<sup>21</sup>

### **Immunity from criminal prosecution**

The act 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 to an individual or qualified entity acting in good faith and in accordance with the act in administering epinephrine or furnishing an epinephrine autoinjector to (1) an

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<sup>18</sup> R.C. 3728.09(C).

<sup>19</sup> R.C. 3728.09(B).

<sup>20</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>21</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).



individual who appears to be experiencing or at risk of experiencing anaphylaxis or (2) the parent, guardian, or custodian of the individual.<sup>22</sup>

### **Immunity for prescribers and pharmacists**

The act provides that a prescriber who acts in good faith in prescribing or furnishing epinephrine autoinjectors to qualified entities, school districts, schools, and camps is not liable for or subject to damages in a civil action, criminal prosecution, or professional disciplinary action.<sup>23</sup> It also extends qualified immunity from civil liability associated with procuring, maintaining, accessing, or using an epinephrine autoinjector to prescribers who consult with or provide protocols to school districts, schools, and camps related to epinephrine procurement and administration.<sup>24</sup>

A pharmacist who acts in good faith in dispensing epinephrine autoinjectors as authorized by the act is not liable for or subject to damages in a civil action or subject to criminal prosecution or professional disciplinary action for any action or omission of an entity to which an epinephrine autoinjector is dispensed.<sup>25</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	05-25-16
Passed Senate (33-0)	05-25-16
House concurred in Senate amendments (96-0)	05-25-16

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<sup>22</sup> R.C. 2925.64.

<sup>23</sup> R.C. 4723.483(B), 4730.96(C), and 4731.96(C).

<sup>24</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).

<sup>25</sup> R.C. 4729.88.

