



Ohio Legislative Service Commission

Bill Analysis

Lisa Musielewicz

Sub. H.B. 296*

130th General Assembly

(As Reported by S. Medicaid, Health and Human Services)

Reps. Johnson and Duffey, Grossman, Butler, Hackett, Beck, Blessing, Scherer, Derickson, Milkovich, Sprague, Antonio, Becker, Barborak, Stinziano, Roegner, Sears, Amstutz, Phillips, Terhar, R. Hagan, Buchy, Stebelton, Perales, Smith, Blair, Rosenberger, Cera, Brenner, Fedor, Bishoff, Driehaus, R. Adams, Anielski, Ashford, Baker, Barnes, Boose, Boyce, Brown, Budish, Carney, Celebrezze, Curtin, DeVitis, Dovilla, Foley, Gerberry, Green, Hall, Hayes, Heard, Henne, Hottinger, Kunze, Landis, Lynch, Maag, Mallory, McClain, O'Brien, Patmon, Patterson, Pillich, Ramos, Reece, Retherford, Rogers, Ruhl, Schuring, Sheehy, Slaby, Slesnick, Strahorn, Thompson, Winburn, Young, Batchelder

BILL SUMMARY

- Permits public and chartered and nonchartered nonpublic (private) schools and camps to procure epinephrine autoinjectors without a license for use in specified emergency situations, and specifies procedures for those that do so.
- Permits a school district to deliver epinephrine autoinjectors it receives to a school under its operation.
- Grants public and private schools and camps, as well as and their employees and contractors, qualified immunity from liability in civil actions for damages allegedly arising from the procurement, maintenance, accessing, or use of an epinephrine autoinjector.
- Permits drug manufacturers to donate epinephrine autoinjectors to public and private schools and explicitly authorizes schools and camps to receive financial donations from individuals for the purpose of purchasing epinephrine autoinjectors.
- Declares an emergency.

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

CONTENT AND OPERATION

Procurement of epinephrine autoinjectors by schools and camps

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

Ohio law generally prohibits the sale, donation, and possession of prescription drugs (referred to as "dangerous drugs" in the Revised Code³) by individuals or entities except when the individual or entity is (1) exempted from the prohibition under law, or (2) possesses the applicable terminal distributor of dangerous drugs license from the Ohio State Board of Pharmacy to possess, sell, or have custody or control over prescription drugs.⁴ According to Pharmacy Board staff, some school districts have been procuring epinephrine autoinjectors by obtaining that license.⁵ The bill authorizes a school governing authority (i.e., the board of education of a school district, governing authority of a community school, governing body of a STEM school, board of trustees of a college-preparatory boarding school, or governing authority of a chartered or nonchartered nonpublic school), a residential camp, child day camp, or camp operated by a specified political subdivision⁶ to procure epinephrine autoinjectors for use in emergency situations without possessing the otherwise required license.⁷ Associated with this authorization, the bill exempts from the prohibition on the sale, donation, and

¹ National Institutes of Health, U.S. National Library of Medicine, MedlinePlus, *Epinephrine Injection* (last visited March 26, 2014), available at <<http://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 <<http://www.pharmacytimes.com/p2p/P2PEpinephrine-0910>>.

³ R.C. 4729.01(F).

⁴ R.C. 4729.51.

⁵ Interview with Ohio State Board of Pharmacy staff (July 2012).

⁶ Specifically, a camp operated by a county, township, municipal corporation, township park district, park district, or joint recreation district (R.C. 5101.76(A)).

⁷ R.C. 3313.7110(A), 3313.7111(A), 3314.143(A), 3326.28(A), 3328.29(A), and 5101.76(A).



possession of dangerous drugs school governing authorities or camps that procure epinephrine autoinjectors in accordance with the bill.⁸

Procedures for maintenance and use of epinephrine autoinjectors

If a school governing authority or a camp elects to procure epinephrine autoinjectors, the bill requires that it adopt a policy authorizing their maintenance and use.⁹ In the case of a public school district, the district's board of education must require the district's superintendent to adopt the policy.¹⁰ The governing authority, superintendent, or camp must consult with a licensed health professional who is authorized to prescribe drugs (a "prescriber") to develop a policy composed of procedures for the maintenance and use of epinephrine autoinjectors.¹¹ One component of the policy must be a prescriber-issued protocol, specifying definitive orders for epinephrine autoinjectors and the dosages of epinephrine to be administered through the autoinjectors. The policy must also do the following:¹²

(1) Identify one or more locations in which an epinephrine autoinjector must be stored;

(2) Specify the conditions under which an epinephrine autoinjector must be stored, replaced, and disposed;

(3) Specify the employees or individuals under contract who may access and use an epinephrine autoinjector to provide a dosage of epinephrine to an individual in specified emergency situations. Under the bill, a licensed school nurse or athletic trainer is designated as a school employee or contractor who may administer epinephrine. Other employees or contractors also may be designated.

(4) Specify any training that designated employees or contractors, other than a licensed school nurse or athletic trainer, must complete before being authorized to access or use an epinephrine autoinjector;

⁸ R.C. 4729.51(B)(1)(l) and (m) and (C)(4).

⁹ R.C. 3313.7110(B), 3313.7111(A), 3314.143(A), 3326.28(A), 3326.29(A), and 5101.76(B).

¹⁰ R.C. 3313.7110(B).

¹¹ R.C. 3313.7110(B), 3313.7111(A), 3314.143(A), 3326.28(A), 3328.29(A), and 5101.76(B).

¹² R.C. 3313.7110(C) and 5101.76(C).

(5) Identify the emergency situations, including when an individual exhibits signs and symptoms of anaphylaxis, in which an epinephrine autoinjector may be administered;

(6) Specify that assistance from an emergency medical service provider must be requested immediately after an epinephrine autoinjector is used; and

(7) Specify the individuals, in addition to students, school employees or contractors, and school visitors, to whom a dosage of epinephrine may be administered through an epinephrine autoinjector in specified emergency conditions.

The bill encourages a school governing authority or camp that elects to procure epinephrine autoinjectors to maintain at least two autoinjectors at all times.¹³

Reporting of procurement and use

The bill requires a school district or public or private school that maintains a supply of epinephrine autoinjectors as permitted by the bill to report to the Department of Education each procurement of epinephrine autoinjectors and each occurrence in which an epinephrine autoinjector is used from a school's supply.¹⁴

Similarly, the bill requires a camp that maintains a supply of epinephrine autoinjectors as permitted by the bill to report to the Department of Job and Family Services each procurement of epinephrine autoinjectors and each occurrence in which an epinephrine autoinjector is used from a camp's supply.¹⁵

Delivery of epinephrine autoinjectors to individual schools

The bill permits the board of education of a city, local, exempted village, or joint vocational school district to deliver epinephrine autoinjectors to a school under its control if the purpose of the delivery is to give possession of autoinjectors to the school for use in emergency situations in accordance with the bill.¹⁶

¹³ R.C. 3313.7110(A), 3313.7111(A), 3314.143(A), 3326.28(A), 3328.29(A), and 5101.76(A).

¹⁴ R.C. 3313.7110(F), 3313.7111(D), 3314.143(D), 3326.28(D), and 3328.29(D).

¹⁵ R.C. 5101.76(F).

¹⁶ R.C. 4729.51(G).

Donations from manufacturers; monetary donations

The bill permits a manufacturer of dangerous drugs to donate epinephrine autoinjectors to a public or private school.¹⁷ Under current law, a donation of drugs is considered a sale of drugs which, on a wholesale basis, is generally limited to registered wholesale distributors of dangerous drugs.¹⁸

The bill also expressly authorizes a school district, public or private school, or camp to accept financial donations from individuals for the purpose of purchasing epinephrine autoinjectors.¹⁹

Qualified civil immunity

The bill specifies that all school districts, public and private schools, and camps that elect to procure epinephrine autoinjectors, as well as their 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 bill unless the act or omission constitutes willful or wanton misconduct.²⁰ The bill also specifies that its provisions do not eliminate, limit, or reduce any other immunity or defense that such persons or entities may be entitled to under the existing Political Subdivision Sovereign Immunity Law (R.C. Chapter 2744.), any other provision of the Revised Code, or Ohio common law.²¹

Under the Political Subdivision Sovereign Immunity (PSSI) Law, not modified by bill, both of the following are the case:

--A political subdivision is generally not liable in damages in a civil action for injury, death, or loss to person or property allegedly caused by any act or omission of the political subdivision or an employee of the political subdivision in connection with a governmental function or proprietary function.²² (School districts, counties, townships, municipal corporations, township park districts, parks districts, and joint recreation districts are, among other entities, political subdivisions.²³ The provision of a system of

¹⁷ R.C. 4729.51(A)(2).

¹⁸ R.C. 4729.01(J) and 4729.51(A).

¹⁹ R.C. 3313.7110(E), 3313.7111(C), 3314.143(C), 3326.28(C), 3328.29(C), and 5101.76(E).

²⁰ R.C. 3313.7110(D), 3313.7111(B), 3314.143(B), 3326.28(B), 3328.29(B), and 5101.76(D).

²¹ R.C. 3313.7110(D), 3314.143(B), 3326.28(B), 3328.29(B), and 5101.76(D).

²² R.C. 2744.02(A)(1).

²³ R.C. 2744.01(F).



public education is explicitly identified as a governmental function, and it appears that operation of a camp by a political subdivision would also be a governmental function.²⁴)

--An employee of a political subdivision is immune from liability unless (1) the employee's acts or omissions were manifestly outside the scope of the employee's employment or official responsibilities, (2) the employee's acts or omissions were with malicious purpose, in bad faith, or in a wanton or reckless manner, or (3) civil liability is expressly imposed upon the employee by a section of the Revised Code.²⁵ The PSSI Law specifies that civil liability is not to be construed to exist under another Revised Code section merely because that section imposes a responsibility or mandatory duty on an employee, provides for a criminal penalty, or uses the term "shall" in a provision pertaining to an employee or because of a general authorization in that section that an employee may sue and be sued.²⁶

Background – current law

School administration of drugs in general

Current law requires each school district board of education to have a general policy on the administration of drugs that have been prescribed for its students. That policy must either (1) prohibit the district's employees from administering prescription drugs or (2) authorize designated employees to do so. A district board that permits administration of prescription drugs must adopt a policy designating the employees authorized to administer them. Those employees must be licensed health professionals or individuals who have completed a drug administration training program conducted by a licensed health professional and considered appropriate by the district board. Conversely, a district that does not permit administration of prescription drugs must adopt a policy stating that no employee may do so, except as required by federal special education law.²⁷

Self-administration of epinephrine by students

Current law also includes a separate provision pertaining to self-administration of epinephrine in schools. Under that provision, a student of a school district, public community school, public STEM school, or chartered nonpublic school is permitted to possess and use an epinephrine autoinjector to treat anaphylaxis under certain

²⁴ R.C. 2744.01(C)(2)(c).

²⁵ R.C. 2744.03(A)(6).

²⁶ R.C. 2744.03(A)(6)(c).

²⁷ R.C. 3313.713.



conditions.²⁸ However, possession of an epinephrine autoinjector is permitted only if (1) the student has written approval from the prescriber of the medication and, if the student is a minor, from the student's parent, (2) the required written approval is on file with the principal of the student's school and, if one is assigned, the school's nurse, and (3) the principal or nurse has received a back-up dose of the medication from the parent or the student.

School possession and administration of epinephrine

Although not explicitly provided for in the Revised Code, school districts, community schools, STEM schools, and chartered and nonchartered nonpublic schools may possess a supply of epinephrine autoinjectors for administration to students in emergency situations, provided certain requirements are met. They may do so by obtaining a terminal distributor of dangerous drugs license from the State Board of Pharmacy.²⁹ To obtain epinephrine or other dangerous drugs, a district or school that is a licensed terminal distributor must purchase those drugs at wholesale from a wholesale distributor or at retail from another terminal distributor, or receive the drugs from licensed individuals or entities in other manners, such as by gift or exchange. Examples of terminal distributors of dangerous drugs include pharmacies, hospitals, nursing homes, and laboratories.³⁰

Administration of epinephrine from a supply is a matter distinct from maintenance of a supply. That is, merely holding a terminal distributor license to possess dangerous drugs does not, in and of itself, qualify a school district or school to administer an epinephrine autoinjector to an individual without a prescription. Current administrative law provides that a licensed health professional may not administer a drug from a supply unless acting pursuant to an order from a prescriber.³¹ Therefore, a school district or public or private school must obtain a standing order or protocol from an authorized prescriber in order to administer epinephrine from its supply.

Such an order or protocol is also required under the bill. However, a school district or public or private school is exempted from the licensing requirements if it complies with the bill's procedures.

²⁸ R.C. 3313.718, 3314.03(A)(11)(d), and 3326.11, latter two sections not in the bill.

²⁹ Interview with Ohio State Board of Pharmacy staff (June 6, 2012).

³⁰ R.C. 4729.01(J) and (Q) and 4729.51(B).

³¹ See Ohio Administrative Code (O.A.C.) 4729-5-01(L)(1).



Camps and drug policies

The Ohio Department of Job and Family Services (ODJFS) has adopted rules governing medication administration to children attending child day camps that provide publicly funded child care or that voluntarily register with ODJFS.³² In general, a child day camp is a program (1) in which only school-age children (enrolled in or eligible to be enrolled in a grade of kindergarten or above but are less than age 15) attend, (2) that operates not longer than seven hours per day, (3) that operates only during one or more public school district's regular vacation periods or for not more than 15 weeks during the summer, and that offers outdoor activities that last for a minimum of 50% of each day.³³ A child day camp that provides publicly funded child care must register with ODJFS, unless it is exempted by statute or is operated by a county, township, municipal corporation, township park district, park district, or joint recreation district.³⁴ Current law exempts (1) child day camps that operate for two or less consecutive weeks and for no more than a total of two weeks during each calendar year, (2) supervised training, instruction, or activities conducted on an organized or periodic basis no more than one day a week and for no more than six hours' duration in areas such as art, drama, music, sports, or an educational subject, (3) programs in which a parent of each child is on the child day camp activity site and readily accessible at all times (unless the premises is the parent's place of employment), and (4) child day camps funded and regulated or operated and regulated by another state department, if ODJFS has determined that the rules governing such camps are equivalent to ODJFS rules governing child day camps.

Under ODJFS rules, a child attending a registered child day camp who may need epinephrine in situations in which the child cannot self-administer the medication must have a medical/physical care plan.³⁵ That plan must include written instructions from the child's parent or guardian containing information similar to that in the medical/physical care plans for children in day care settings.³⁶ For example, the plan must include the amount of each dose and when the medication is to be administered.³⁷ In addition, the medication must be stored in a safe location that is inaccessible to

³² R.C. 5104.21(C); O.A.C. 5101:2-18-15.

³³ R.C. 5104.01(I), not in the bill, and O.A.C. 5101:2-18-01(A).

³⁴ R.C. 5104.20 and 5104.21(A) and (B).

³⁵ Electronic correspondence from ODJFS staff (March 8, 2013).

³⁶ O.A.C. 5101:2-18-15(F)(4).

³⁷ O.A.C. 5101:2-18-15(F)(4)(d) and (e).



children and the camp must maintain a written record of the date, time, and amount of each medication given to each child.³⁸

Despite having a medical/physical care plan, the parent or guardian of a child who may need epinephrine must consider that each child day camp establishes its own policy regarding whether it will administer medication.³⁹ If a camp adopts a policy of not administering that drug or drugs of that type, the child must still have a medical/physical care plan. But, the parent or guardian must arrange for the child to have prescribed epinephrine administered by someone other than camp staff or instruct camp staff to call emergency medical services personnel if the child experiences anaphylaxis.⁴⁰

In general, residential camps are not regulated by ODJFS. A "residential camp" is a program in which the care, physical custody, or control of children is accepted overnight for recreational or for both recreational and educational purposes.⁴¹ The Director of Health has adopted rules governing residential camps that largely address sanitation issues; the rules do not address medication administration.⁴² In the absence of rules governing medication administration, it appears that medication administration at residential camps must be consistent with Pharmacy Board policy and practitioner scope of practice laws. The Pharmacy Board has taken the position that once drugs are dispensed to a patient by a pharmacist, the drugs become the patient's property and may be stored in a secure place with the patient's consent.⁴³ Since a child is legally below the age of consent,⁴⁴ a residential camp may store epinephrine prescribed for a child with consent from the child's parents or someone legally authorized to consent on the child's behalf. If a child is not able to self-administer epinephrine, it appears that it could be administered only by a person specifically authorized by the Revised Code to administer drugs, because a person administering a drug without specific statutory

³⁸ O.A.C. 5101:2-18-15(F)(8) and (9).

³⁹ O.A.C. 5101:2-18-15(F)(2).

⁴⁰ Electronic correspondence from ODJFS staff (March 8, 2013).

⁴¹ R.C. 2151.011(B)(45), not in the bill.

⁴² O.A.C. Chapter 3701-25.

⁴³ The Athletic Trainers Section of the Ohio Occupational Therapy, Physical Therapy, and Athletic Trainers Board, *Guidelines for the Storage and Use of Emergency Inhalers and Epi-pens* (last visited March 28, 2014) available at <<http://otptat.ohio.gov/Portals/0/Pdfs/Guidelines%20for%20the%20Storage%20and%20Use%20of%20Emergency%20Inhalers%20and%20EpiPens.pdf>>.

⁴⁴ In Ohio, the age of majority is 18 years "for all purposes." (R.C. 3109.01.)



authorization would be subject to the statutory prohibition on the authorized practice of medicine.⁴⁵

HISTORY

ACTION	DATE
Introduced	10-10-13
Reported, H. Education	11-14-13
Passed House (92-0)	11-20-13
Reported, S. Medicaid, Health & Human Services	---

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⁴⁵ See Ohio Attorney General Opinion No. 2000-023, available at <<http://www.ohioattorneygeneral.gov/OhioAttorneyGeneral/files/8f/8f9b9a9f-edd5-4ac4-9c6b-2a9bba8f0962.pdf>>.

