Ohio Legislative Service Commission

Bill Analysis

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Sub. H.B. 296

130th General Assembly
(As Passed by the House)

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 schools (school districts, community schools, STEM schools, and college-preparatory boarding schools), residential camps, and child day 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 schools, residential camps, and child day camps and their employees immunity from liability in civil actions for damages allegedly arising from the use of an epinephrine autoinjector in accordance with the bill's provisions.

- Permits drug manufacturers to donate epinephrine autoinjectors to public schools, residential camps, and child day camps, and explicitly authorizes such schools and camps to receive financial donations from individuals for the purpose of purchasing epinephrine autoinjectors.

CONTENT AND OPERATION

Procurement of epinephrine autoinjectors by public schools and certain 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 Code[3]) by individuals or entities except when the individual or entity is (1) exempted from the prohibition under law, or (2) possesses the applicable 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, or board of trustees of a college-preparatory boarding school) or a residential camp or child day camp to procure epinephrine autoinjectors for use in emergency situations without possessing the otherwise required terminal distributor of dangerous drugs license from the Pharmacy Board.[6] Associated with this authorization, the bill exempts from the prohibition on the sale, donation, and possession of dangerous drugs school governing authorities or camps that procure epinephrine autoinjectors in accordance with the bill.[7]

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[1] National Institutes of Health, U.S. National Library of Medicine, MedlinePlus, *Epinephrine Injection* (last visited February 4, 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] R.C. 3313.7110(A), 3314.143(A), 3326.28(A), 3328.29(A), and 5104.60(A).

[7] R.C. 4729.51(B)(1)(l) and (m) and (C)(4).

Procedures for maintenance and use of epinephrine autoinjectors

If a school governing authority, residential camp, or child day camp elects to procure epinephrine autoinjectors, the bill requires that it adopt a policy authorizing their maintenance and use. The governing authority 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.[8] One component of the policy must be a prescriber-issued protocol, approved by the Pharmacy Board, specifying definitive orders for epinephrine autoinjectors and the dosages of epinephrine to be administered through the autoinjectors. The policy must also do the following:[9]

(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 individuals 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 is designated as a school employee who may administer epinephrine. Other school employees also may be designated.

(4) Specify any training that designated employees, other than a licensed school nurse, must complete before accessing or using an epinephrine autoinjector;

(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 who may receive a dosage of epinephrine 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.[10]

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[8] R.C. 3313.7110(B), 3314.143(A), 3326.28(A), 3328.29(A), and 5104.60(B).

[9] R.C. 3313.7110(C) and 5104.60(C).

[10] R.C. 3313.7110(A), 3314.143(A), 3326.28(A), 3328.29(A), and 5104.60(A).

Reporting of procurement and use

The bill requires a school district, community school, STEM school, or college-preparatory boarding 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.[11]

Similarly, the bill requires a residential camp or child day camp that maintains a supply of epinephrine autoinjectors 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.[12]

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.[13]

Donations from manufacturers; monetary donations

The bill permits a manufacturer of dangerous drugs to donate epinephrine autoinjectors to a public school, residential camp, or child day camp.[14] 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.[15] The bill also explicitly authorizes a school district, community school, STEM school, college-preparatory boarding school, residential camp, and child day camp to accept financial donations from individuals for the purpose of purchasing epinephrine autoinjectors.[16]

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[11] R.C. 3313.7110(G), 3314.143(D), 3326.28(D), and 3328.29(D).

[12] R.C. 5104.60(F).

[13] R.C. 4729.51(G).

[14] R.C. 4729.51(A)(2).

[15] R.C. 4729.01(J) and 4729.51(A).

[16] R.C. 3313.7110(F), 3314.143(C), 3326.28(C), 3328.29(C), and 5104.60(E).

Civil immunity

For schools and school employees

Public schools and their employees acting within the scope of employment generally have immunity from civil liability for damages in the performance of governmental functions under the state Political Subdivision Sovereign Immunity Law.[17] Under that law, unchanged by the bill, the provision of a system of public education is explicitly included as a governmental function and, accordingly, public schools have a qualified immunity from tort liability while providing public education.

Nonetheless, the bill explicitly provides that a school or school district, a member of its board, governing authority, or governing body, or an employee is not liable in damages in a civil action for injury, death, or loss to person or property allegedly arising from the use of an epinephrine autoinjector under the bill's provisions. The bill does not provide any qualifications or conditions on that civil immunity. It does state, however, that its provisions do not eliminate, limit, or reduce any other immunity or defense that may be available under the Sovereign Immunity Law, any other provision of the Revised Code, or the common law of Ohio.[18]

For camps and camp employees

Similar to the provisions regarding civil immunity for public schools and their employees, the bill explicitly provides that a residential camp, child day camp, or an employee of a residential camp or child day camp is not liable in damages in a civil action for injury, death, or loss to person or property allegedly arising from the use of an epinephrine autoinjector. The bill does not provide any qualifications or conditions on that civil immunity.[19]

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

[17] R.C. Chapter 2744.

[18] R.C. 3313.7110(D), 3314.143(B), 3326.28(B), and 3328.29(B).

[19] R.C. 5104.60(D).

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.[20]

Self-administration of epinephrine by students

Current law also includes a separate provision pertaining to self-administration of epinephrine in schools. The statute provides that 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 conditions.[21] 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 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.[22] 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 a gift or an exchange. Examples of terminal distributors of dangerous drugs include pharmacies, hospitals, nursing homes, and laboratories.[23]

Administration of epinephrine from a supply is a matter distinct from maintenance of a supply. That is, merely holding a terminal distributor license to

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[20] R.C. 3313.713.

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

[22] Interview with Ohio State Board of Pharmacy staff (June 6, 2012).

[23] R.C. 4729.01(J) and (Q) and 4729.51(B).

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.[24] Therefore, a school district or 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 public school is exempted from the licensing requirements if it complies with the bill's procedures.

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.[25] In general, a 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.[26] 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.[27] 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.

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

[25] R.C. 5104.21(C); O.A.C. 5101:2-18-15.

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

[27] R.C. 5104.20 and 5104.21(A) and (B).

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.[28] 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.[29] For example, the plan must include the amount of each dose and when the medication is to be administered.[30] In addition, the medication must be stored in a safe location that is inaccessible to children and the camp must maintain a written record of the date, time, and amount of each medication given to each child.[31]

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.[32] 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.[33]

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 recreational and educational purposes.[34] The Director of Health has adopted rules governing residential camps that largely address sanitation issues; the rules do not address medication administration.[35] 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

[28] Electronic correspondence from ODJFS staff (March 8, 2013).

[29] O.A.C. 5101:2-18-15(F)(4).

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

[31] O.A.C. 5101:2-18-15(F)(8) and (9).

[32] O.A.C. 5101:2-18-15(F)(2).

[33] Electronic correspondence from ODJFS staff (March 8, 2013).

[34] R.C. 2151.011(B)(45), not in the bill.

[35] O.A.C. Chapter 3701-25.

may be stored in a secure place with the patient's consent.[36] Since a child is legally below the age of consent,[37] 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 authorization would be subject to the statutory prohibition on the authorized practice of medicine.[38]

HISTORY

ACTION	DATE
Introduced	10-10-13
Reported, H. Education	11-14-13
Passed House (92-0)	11-20-13

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[36] 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 January 31, 2014) available at <http://otptat.ohio.gov/Portals/0/Pdfs/Guidelines%20for%20the%20Storage%20and%20Use%20of%20Emergency%20Inhalers%20and%20EpiPens.pdf>.

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

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