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Bill Analysis

Version: As Introduced

Primary Sponsors: Reps. Rogers and Richardson

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SUMMARY

- Permits public and private schools and camps to procure injectable or nasally administered glucagon without a license for use in emergency situations for individuals with diabetes, and specifies procedures for those that do so.
- Permits a school district to deliver injectable or nasally administered glucagon it receives to a school under its operation.
- Grants schools and camps, and their employees, contractors, and volunteers, qualified immunity from liability in civil actions for damages allegedly arising from the procurement, maintenance, access, or use of injectable or nasally administered glucagon.
- Permits drug manufacturers and wholesalers to donate injectable and nasally administered glucagon to schools or camps and allows schools and camps to receive financial donations from individuals for their purchase.

DETAILED ANALYSIS

Procurement of glucagon by schools and camps

Synthetic glucagon is an emergency medicine, dispensed only by prescription, that may be administered to treat severe low blood sugar in persons with diabetes (see "**Background**, **Glucagon**," below). Currently, synthetic glucagon is available in forms that may be injected or administered nasally.¹ Ohio law generally prohibits the sale, donation, and possession of prescription drugs (referred to as "dangerous drugs" in the Revised Code²) by individuals or

¹ Healthline, *How Does Glucagon Work to Treat Hypoglycemia? Facts and Tips*, available at https://www.healthline.com/health/severe-hypoglycemia/how-glucagon-works.

² R.C. 4729.01(F).

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 (TDDD) license from the Ohio State Board of Pharmacy to possess, sell, or have custody or control over prescription drugs.³ A wholesale distributor of dangerous drugs that sells, donates, or otherwise transfers possession of dangerous drugs to an individual or entity that is not exempt from the prohibition or does not possess the TDDD license is guilty of a misdemeanor of the first degree.⁴

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 subdivision⁵ to procure a supply of injectable or nasally administered glucagon for use in emergency situations without processing the otherwise required license.⁶ Associated with this authorization, the bill exempts school governing authorities and camps that procure glucagon in accordance with the bill from the prohibition regarding the sale, donation, or transfer of possession of dangerous drugs.⁷

Under the bill, a school or camp has two options for procuring injectable or nasally administered glucagon:⁸

- 1. Have a licensed health professional authorized to prescribe drugs (a "prescriber") personally furnish the glucagon to the school, school district, or camp or issue a prescription for the drug in the name of the school, school district, or camp; or
- 2. Have the school district superintendent, school governing authority, or camp obtain a prescriber-issued protocol that includes definitive orders for injectable or nasally administered glucagon and the dosages to be administered.

Donations from manufacturers; monetary donations

The bill permits a wholesale distributor of dangerous drugs or manufacturer of dangerous drugs to donate injectable or nasally administered glucagon to schools or camps. It also allows schools and camps to accept monetary donations to purchase the drug.⁹

Procedures for maintenance and use of glucagon

If a school or camp elects to procure injectable or nasally administered glucagon, the bill requires that it adopt a policy authorizing their maintenance and use. In the case of a public

³ R.C. 4729.51.

⁴ R.C. 4729.99(D), not in the bill.

⁵ Specifically, a camp operated by a county, township, municipal corporation, township park district, park district, or joint recreation district (R.C. 5101.78(B)).

⁶ R.C. 3313.7115(B), 3313.7116, 3314.147(A), 3326.60(A), and 3328.38(A).

⁷ R.C. 4729.51(I). A corrective amendment will be needed to R.C. 4729.51(E)(2)(b)(ii).

⁸ R.C. 3313.7115(A), 3313.7116(A), 3314.147(A), 3326.60(A), 3328.38(A), and 5101.78(B).

⁹ R.C. 3313.7115(F), 3313.7116(C), 3314.147(C), 3326.60(C), 3328.38(C), and 5101.78(F).

school district, the district's board of education must require the district's superintendent to adopt the policy. The superintendent, governing authority, or camp must consult with a licensed health professional who is authorized to prescribe drugs (a "prescriber") to develop a policy containing procedures for the maintenance and use of injectable or nasally administered glucagon.¹⁰ The policy must do all of the following:¹¹

--Identify the one or more locations in each school or at camp in which injectable or nasally administered glucagon must be stored;

--Specify the conditions under which injectable or nasally administered glucagon must be stored, replaced, and disposed;

--Specify the individuals employed by or under contract with a school (in addition to a school nurse or athletic trainer) or, if a camp, the employees, contractors, or volunteers, who may access and use injectable or nasally administered glucagon in an emergency situation;

--Specify any training that individuals (other than a school nurse or athletic trainer) must complete before being authorized to access and use injectable or nasally administered glucagon;

--Specify that assistance from an emergency medical services provider must be requested immediately after a dose of glucagon is administered; and

--Specify the individuals to whom a dosage of glucagon may be administered in an emergency situation.

The bill encourages a school governing authority or camp that elects to procure injectable or nasally administered glucagon to maintain at least two doses of the drug.¹²

Reporting of procurement and use

The bill requires a school district or public or private school that elects to procure injectable or nasally administered glucagon as permitted by the bill to report to the Ohio Department of Education each procurement and each occurrence in which a dose of the drug is used from the school's supply.¹³

Similarly, the bill requires a camp that elects to procure injectable or nasally administered glucagon as permitted by the bill to report to the Ohio Department of Job and Family Services (ODJFS) each procurement and each occurrence in which a dose of the drug is used from the camp's supply.¹⁴

¹⁴ R.C. 5101.78(G).

¹⁰ R.C. 3313.7115(C), 3313.7116(A), 3314.147(A), 3326.60(A), 3328.38(A), and 5101.78(C).

¹¹ R.C. 3313.7115(D), 3313.7116(A), 3313.147(A), 3326.60(A), 3328.38(A), and 5101.78(D).

¹² R.C. 3313.7115(B), 3313.7116(A), 3314.147(A), 3326.60(A), 3328.38(A), and 5101.78(B).

 $^{^{13}}$ R.C. 3313.7115(G), 3313.7116(D), 3314.147(D), 3326.60(D), and 3328.38(D).

Delivery of glucagon to individual schools

The bill permits the board of education of a school district to deliver injectable or nasally administered glucagon to a school under its control if the purpose of the delivery is to give possession of glucagon to the school for use in emergency situations in accordance with the bill.¹⁵

Qualified civil immunity

The bill specifies that all school districts, public and private schools, and camps that elect to procure injectable and nasally administered glucagon, as well as their governing authorities, employees, contractors, and volunteers, as applicable, and any prescriber who personally furnishes or prescribes the glucagon, are not liable in damages in a civil action arising from an act or omission associated with procuring, maintaining, accessing, or using injectable or nasally administered glucagon under the bill unless the act or omission constitutes willful or wanton misconduct. The bill also specifies that its provisions do not eliminate, limit, or reduce any other immunity or defense that those persons or entities may be entitled to under the existing Political Subdivision Sovereign Immunity (PSSI) Law (R.C. Chapter 2744), any other provision of the Revised Code, or Ohio common law.¹⁶

Under the PSSI Law, not modified by the 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 an act or omission of the political subdivision or an employee of the political subdivision in connection with a government function or proprietary function. (School districts, counties, townships, municipal corporations, township park districts, parks districts, and joint recreation districts are political subdivisions. The provision of a system of 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.)¹⁷

--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 on the employee by a section of the Revised Code.¹⁸

Background

Glucagon

In individuals with a fully functional pancreas, insulin and glucagon, both naturally occurring hormones, work in tandem to keep blood sugars stable. Insulin lowers blood sugar,

¹⁵ R.C. 4729.51(I).

¹⁶ R.C. 3313.7115(E), 3313.7116(B), 3314.147(B), 3326.60(B), 3328.38(B), and 5101.78(E).

¹⁷ R.C. 2744.01(C)(1), (C)(2)(c), and (F), not in the bill.

¹⁸ R.C. 2744.03(A)(6), not in the bill.

while glucagon releases the body's glucose reserves from the liver to raise blood sugars. When a person has type 1 diabetes, this does not happen because the beta cells in the pancreas produce little or no insulin.¹⁹ A person with type 1 diabetes must therefore take synthetic insulin either by injection or insulin pump every day, but maintaining the right balance of synthetic insulin and glucagon in the body can be challenging because at least 42 factors affect blood sugar levels. These factors include the type and quantity of carbohydrates consumed, exercise intensity, lack of sleep, allergies, illness, puberty, stress, insulin pump infusion issues, and even outside temperature.²⁰ Any person with diabetes, but especially one with type 1 diabetes, can experience low blood sugar for a variety of reasons.²¹ Mild to moderate low blood sugar must be treated quickly with a source of fast-acting sugar, like fruit juice or candy. If a person's blood sugar drops so low that they are unable to treat it themselves, they are having severe low blood sugar (severe hypoglycemia). Symptoms of severe low blood sugar include unresponsiveness, acute drowsiness, unconsciousness, and seizures.²² Severe low blood sugar can even result in death.²³ To treat severe hypoglycemia, the person with diabetes will need to have someone administer glucagon via syringe, nasal spray, or auto-injector pen to him or her.24

Continuing law

Ohio law

Schools

The diabetes care in schools statute outlines public and private schools' obligations with respect to a student with any type of diabetes.²⁵ It was enacted in 2014 through Sub. H.B. 264 of the 130th General Assembly.

The statute specifies that schools must ensure that each student who has diabetes receives "appropriate and needed diabetes care in accordance with an order signed by the

¹⁹ U.S. National Library of Medicine, MedlinePlus, *Type 1 Diabetes*, available at https://medlineplus.gov/ency/article/000305.htm.

²⁰ Adam Brown, diaTribe, 42 Factors that Affect Blood Glucose?! – A Surprising Update, available at https://diatribe.org/42factors.

²¹ Insulin is required for person with type 1 diabetes and is sometimes necessary for persons with type 2 diabetes. American Diabetes Association, *Insulin Routines*, available at https://www.diabetes.org/diabetes/medication-management/insulin-other-injectables/insulin-routines.

²² Beyond Type 1, All About Glucagon, available at https://beyondtype1.org/glucagon/; Diabetes@school, Glucagon: What available it is, and how to use it, at https://www.diabetesatschool.ca/schools/glucagon; Healthline, Glucose disorders, available at https://www.healthline.com/health/diabetes/insulin-and-glucagon#glucose-disorders.

²³ Endocrine Society, *Severe Hypoglycemia*, available at https://www.hormone.org/diseases-and-conditions/diabetes/severe-hypoglycemia.

²⁴ JDRF, *Hypoglycemia: Symptoms, Causes, and Treatment for Low Blood Sugar*, available at https://www.jdrf.org/t1d-resources/about/symptoms/blood-sugar/low/.

²⁵ R.C. 3313.7112, not in the bill.

student's treating practitioner."²⁶ Accordingly, the treating practitioner's orders govern the treatment a student is to receive while at school. Also, each student's order will be unique to the individual. Some students with type 1 diabetes, for example, use an insulin pump, while others take multiple daily injections of insulin. Some students check their blood glucose levels with a glucometer (through finger-sticking), while others rely on a continuous glucose monitor. Even for those with pumps, variations exist in how the pumps operate. As diabetes technology advances, orders are often modified from school year to school year and sometimes even during a single school year to reflect these advances and evolving methods of treating diabetes.²⁷

The law provides examples of the diabetes care activities that a treating practitioner's order will cover: $^{\rm 28}$

--Checking and recording blood glucose and ketone levels or assisting the student with checking and recording these levels;

--Responding to blood glucose levels that are outside of the student's target range;

--In the case of severe hypoglycemia, administering glucagon and other emergency treatments as prescribed;

--Administering insulin or assisting the student in self-administering insulin through the insulin delivery system the student uses;

--Providing oral diabetes medications;

--Understanding recommended schedules and food intake for meals and snacks in order to calculate medication dosages pursuant to the order of the student's treatment practitioner;

--Following the treating practitioner's instructions regarding meals, snacks, and physical activity; and

--Delivering diabetes medication.

The statute limits who (other than the student to himself or herself) may administer diabetes medication in the school setting to a school nurse or a school employee who has been trained to provide diabetes care.²⁹ Some schools do not have a school nurse, or only a school nurse who works part-time; that fact does not nullify the school's obligation to provide diabetes care in accordance with the treating practitioner's order. For this reason, the statute authorizes

²⁶ R.C. 3313.7112(B)(1), not in the bill.

²⁷ National Institute of Diabetes and Digestive and Kidney Diseases, *How to Help Students Implement Effective Diabetes Management*, available at https://www.niddk.nih.gov/health-information /professionals/clinical-tools-patient-management/diabetes/helping-student-diabetes-succeed-guide-school-personnel/diabetes-overview/help-students-implement-effective-diabetes-management.

²⁸ R.C. 3313.7112(B)(1), not in the bill.

²⁹ R.C. 3313.7112(C), not in the bill.

schools to provide training to school employees so that the school may fulfill this obligation (including the administration of medication) even if it does not have a full-time nurse.³⁰

The statute also authorizes a school to provide training in the recognition of hypoglycemia and hyperglycemia and the responsive emergency measures to certain persons who interact with the student but who have not received the diabetes care training described above. These are school employees who have the primary responsibility for supervising a student with diabetes during some portion of the school day and bus drivers.³¹

Day camps

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 Such camps are referred to as "approved child day camps."³³

Under those rules, all of the following apply with respect to the administration of prescription medication: $^{\rm 34}$

--The camp must ensure that the medication is stored in the original container with the prescription label that includes the child's full name, a current dispensing date within the previous 12 months, and exact dosage and directions for use;

--The camp must not administer the medication for any period of time beyond the date indicated by the prescriber on the prescription label, for 12 months from the date on the form, or after the expiration date on the medication, whichever comes first;

--Prior to administering the medication, the camp must have written permission from the parent for each medication to be administered; and

--The camp must document each administration of medication on a form with specified information.

Also, a child attending an approved child day camp who has diabetes must have a written medical care plan. The written medical care plan must include all of the following:³⁵

--The symptoms the staff should monitor which may require staff to take action;

--Administering procedures which require staff to be trained on those procedures;³⁶

³⁰ R.C. 3313.7112(E)(1), not in the bill.

³¹ R.C. 3313.7112(F), not in the bill.

³² R.C. 5104.21(C), not in the bill, and Ohio Administrative Code (O.A.C.) 5101:2-18-11.

³³ O.A.C. 5101:2-18-01(C).

³⁴ O.A.C. 5101:2-18-11(A).

³⁵ O.A.C. 5101:2-18-11(C)(1).

 $^{^{36}}$ Only staff members trained by the parent or a certified professional are permitted to perform medical procedures. (O.A.C. 5101:2-18-11(C)(5).)

--Whether the child needs to avoid specific foods, environmental conditions, or activities; and

--Permission for the child to carry and administer their own emergency medication (i.e., glucagon), if applicable.

The approved child day camp must:³⁷

--Ensure the child's parent completes and signs the written medical care plan;

--Review the plan for completeness and ensure it is signed by an administrator or designee;

--Implement and follow all requirements of the plan;

--Ensure the plan is signed by any trained child day camp staff member who is providing care to the child; and

--Maintain the plan in a location that can be easily and quickly accessed at all times, including on field trips and when the child is off-site.

The camp may require a physician's statement within a designated timeframe. There must be a trained staff member on-site at all times whenever a child with diabetes is present.³⁸

Residential camps

In general, residential (or overnight) camps are not regulated by ODJFS. The Director of Health has adopted rules governing residential camps that largely address sanitarian issues; the rules do not address medication administration.³⁹ 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.⁴⁰ Since a child is legally below the age of consent,⁴¹ a residential camp may store glucagon prescribed for a child with consent from the child's parents or someone legally authorized to consent on the child's behalf.

Federal law

Two federal laws protect students with diabetes from discrimination, ensuring that children with diabetes receive the care they need while at school or camp, including glucagon administration should they need it.

³⁸ O.A.C. 5101:2-18-11(C)(4) and (6).

⁴¹ In Ohio, the age of majority is 18 years "for all purposes." (R.C. 3109.01, not in the bill.)

³⁷ O.A.C. 5101:2-18-11(C)(2).

³⁹ O.A.C. Chapter 3701-25.

⁴⁰ 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*, available at https://otptat.ohio.gov/Portals/0/Pubs/Guidelines%20for%20the%20Storage%20and%20Use%20of%20 Emergency%20Inhalers%20and%20Epi%202015.pdf.

Section 504 of the Rehabilitation Act of 1973

Section 504 of the Rehabilitation Act of 1973 ("Section 504") is a federal civil rights law that prohibits discrimination on the basis of disability. A disability under Section 504 is a "physical or mental impairment that substantially limits one or more major life activities." Individuals with diabetes are considered to have a Section 504 disability, because their endocrine system, a major life activity that helps regulate bodily functions, is substantially limited.⁴²

All schools and camps, including private and religious camps, that receive federal funding must comply with Section 504. The obligations of private and religious schools and camps, however, are somewhat different.⁴³

Americans with Disabilities Act

The Americans with Disabilities Act (ADA) prohibits most schools and camps from discriminating against children with diabetes. Public schools and camps qualify as "public programs" under Title II, while private schools and camps are usually "public accommodations" under Title III. Religious schools and camps are excluded under this law.⁴⁴ Otherwise, the protections for children under the ADA are similar to Section 504.⁴⁵

HISTORY

| Action | Date |
|------------|----------|
| Introduced | 02-18-20 |
| | |

H0511-I-133/ar

⁴⁴ Id.

⁴² American Diabetes Association, *Section 504 of the Rehabilitation Act of 1973*, available at https://www.diabetes.org/resources/know-your-rights/section-504-rehabilitation-act-1973.

 ⁴³ *Id.*; American Diabetes Association, *The Rights of Children with Diabetes at Camp* (last edited April 27, 2016), on file with the drafter.

⁴⁵ American Diabetes Association, *Fact Sheet: The Legal Rights of Students with Diabetes on Field Trips and in Extracurricular Activities*, available at http://www.diabetesnd.org/image/cache/ADA.Fact.Sheet.Extracurriculars.pdf.