FLORIDA HOUSE OF REPRESENTATIVES FINAL BILL ANALYSIS

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BILL #: <u>CS/CS/CS/HB 597</u> COMPANION BILL: <u>CS/SB 772</u> (Calatayud)

TITLE: Diabetes Management in Schools
SPONSOR(S): Smith

LINKED BILLS: None
RELATED BILLS: None

FINAL HOUSE FLOOR ACTION: 110 Y's 0 N's GOVERNOR'S ACTION: Approved

SUMMARY

Effect of the Bill:

The bill expands diabetes management in public schools by authorizing school districts or public schools to acquire and maintain a supply of undesignated glucagon for use on students with diabetes experiencing hypoglycemic emergencies. School districts or public schools are authorized to obtain the glucagon through a prescription from a county health department or an authorized healthcare practitioner, or through arrangements with manufacturers or suppliers.

The bill outlines storage, maintenance, and administration requirements for the acquired glucagon and provides immunity to the school district and its employees along with the glucagon supplier, provided that any injury is not the result of gross negligence or deliberate misconduct.

Fiscal or Economic Impact:

Public schools that choose to act under the authority granted by the bill may incur costs associated with implementing provisions of the bill.

IUMP TO SUMMARY ANALYSIS RELEVANT INFORMATION

ANALYSIS

EFFECT OF THE BILL:

The bill revises current law regulating <u>diabetic management services in public schools</u> for students with diabetes by authorizing school districts or public schools to acquire and maintain a supply of undesignated <u>glucagon</u> to treat a student with diabetes who experiences a <u>hypoglycemic emergency</u>.

The undesignated glucagon must be a rescue therapy approved by the U.S. Food and Drug Administration that does not require reconstitution for the treatment of severe hypoglycemia in a dosage form that can be rapidly administered to a patient in an emergency; this includes both prefilled injectable and nasally administered glucagon. The undesignated glucagon must be stored according to the manufacturer's instructions in a secure location that is immediately accessible to the school nurse or other school personnel who have been trained to administer glucagon.

Licensed physicians,¹ physician assistants,² and advanced practice registered nurse practitioners³ are authorized to prescribe glucagon in the name of a school district or public school. A licensed pharmacist may dispense undesignated glucagon pursuant to a prescription issued in the name of a school district or public school. Additionally, a school district or public school may request a prescription for glucagon from a county health department.

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¹ Licensed under Chs. 458 or 459, F.S.

² *Id*.

³ Licensed under Ch. 464, F.S. STOPACE NAME: b05977

A school district or public school may acquire and stock a supply of glucagon from a wholesale distributor⁴ to enter into an arrangement with a wholesale distributor or manufacturer,⁵ for glucagon at fair-market, free, or reduced prices pursuant to the issued prescription. A school district or public school may also accept glucagon as a donation or transfer if it is new, unexpired, manufacturer-sealed, not subject to recall, unadulterated, and in compliance with relevant regulations adopted by the U.S. Food and Drug Administration. A school district or public school may obtain monetary donations or apply for grants to purchase glucagon.

A participating school must make available undesignated glucagon that is able to be administered as ordered in a student's <u>diabetes medical management plan</u> or health care practitioner's orders.

A school nurse or trained school personnel must administer glucagon to the student only if the school nurse or trained personnel has successfully completed the training and believe in good faith that the student is experiencing a hypoglycemic emergency. After the undesignated glucagon has been administered to a student, an employee of the school must immediately call for emergency assistance, notify a school nurse, and notify the student's parent, guardian, or emergency contact.

A school nurse and other appropriately trained school personnel who administers, or attempts to administer, glucagon in compliance with the provisions of the bill and the <u>Good Samaritan Act</u>,⁶ as well as the school district that employs such individual, are immune from civil or criminal liability resulting from such action. Immunity from civil and criminal liability is also granted to any authorized health care practitioner who prescribes, or pharmacist who fills, a prescription for glucagon to a school district or public school under the provisions of this bill, and acts in good faith and exercises reasonable care. Similarly, immunity from licensure discipline is granted on the same basis. (Section <u>1</u>).

The bill was approved by the Governor on April 29, 2025, ch. 2025-15, L.O.F., and will become effective on July 1, 2025. (Section $\underline{2}$).

RULEMAKING:

Current law authorizes the State Board of Education (SBE), in cooperation with the Department of Health, to adopt rules relating to the management and care of diabetes by students in school. The bill further directs the SBE to adopt rules relating to the use of undesignated glucagon by public schools.

Lawmaking is a legislative power; however, the Legislature may delegate a portion of such power to executive branch agencies to create rules that have the force of law. To exercise this delegated power, an agency must have a grant of rulemaking authority and a law to implement.

FISCAL OR ECONOMIC IMPACT:

LOCAL GOVERNMENT:

The bill may have an insignificant, indeterminate, negative fiscal impact on school districts. Schools that choose to exercise this authority may incur costs related to acquiring and storing glucagon to treat students with diabetes.

RELEVANT INFORMATION

SUBJECT OVERVIEW:

Diabetic Management Services in Public Schools

⁶ S. <u>768.13, F.S.</u>

⁴ S. <u>499.003(49)</u>, F.S. Wholesale distributor means a person, other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or a repackager, who is engaged in wholesale distribution.

⁵ S. <u>499.003(29)</u>, F.S. Manufacturer means a person who holds a New Drug Application, an Abbreviated New Drug Application, a Biologics License Application, or a New Animal Drug Application approved under the federal act or license issued under s. 351 of the Public Health Ser vice Act, 42 U.S.C. s. 262, for such drug or biologics, or if such drug or biologics are not the subject of an approved application or license, the person who manufactured the drug or biologics, a co-licensed partner or affiliates, and those manufacturing devices or cosmetics.

Diabetes is a disease that impairs the body's ability to produce or properly use insulin, a hormone that is needed to convert food into energy. This causes blood sugar, also known as blood glucose, to be too high, which over time can cause other health problems, such as heart disease, nerve damage, eye problems, and kidney disease.8

In Florida's public schools, 7,006 students were reported to have type 1 diabetes and 917 had type 2 diabetes during the 2020–2021 school year, totaling 7,923 students managing diabetes in a school setting. Of these, 3,588 required glucose monitoring, 3,060 required carbohydrate counting, and 3,304 required insulin administration while at school.9

In Florida, students with diabetes, with written consent from their healthcare provider and parent, are permitted to self-manage their medication, supplies, and equipment based on the student's diabetes medical management plan¹⁰ without additional assistance or supervision.¹¹ Students may manage and care for their diabetes while in school, participating in school-sponsored activities, or in transit to or from school or school sponsored activities to the extent authorized by the parent and physician.¹²

School districts are required to have personnel, whether licensed nurses or trained school staff, assigned to each school a student with diabetes would otherwise attend if he or she did not have diabetes. These personnel must be available to provide necessary diabetes care throughout the school day and during school-sponsored activities. 13

Current law requires the SBE, in collaboration with the Department of Health, to develop rules regarding the safe management and care of diabetes by students, as well as rules to encourage school personnel to be trained in routine and emergency diabetes care. 14 Pursuant to these rules, the Department of Education provides sources for school districts for training school personnel to ensure proper management and care of diabetic students in schools.15

Severe Hypoglycemia Treatment

Living with diabetes causes a person's blood sugar levels to fluctuate. Hypoglycemia, or low blood sugar, is common among people with diabetes. Most episodes of hypoglycemia are mild and easily treated if caught and addressed early in the episode. 16 When hypoglycemia isn't treated efficiently, or isn't responding to first-level treatments, it can quickly develop into severe hypoglycemia, sometimes referred to as an insulin reaction or insulin shock, which is a life-threatening condition.

Severe hypoglycemia is an emergency. If left untreated for too long, severe hypoglycemia can lead to brain or organ damage, or even death. A person experiencing severe hypoglycemia may become confused or lose consciousness, rendering them unable to self-administer medication.¹⁷

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⁷ Rule 6A-6.0253, F.A.C.

⁸ National Institute of Diabetes and Digestive and Kidney Disease, Health Information, https://www.niddk.nih.gov/healthinformation/health-statistics/diabetes-statistics (last visited Apr. 23, 2025).

⁹ Florida Diabetes Advisory Council, 2023 Florida Diabetes Report, at 17, available at https://www.floridahealth.gov/providerand-partner-resources/dac/ documents/2023-dac-report.pdf.

¹⁰ A Diabetes Medical Management Plan is a medical authorization for diabetes treatment that includes medication orders from student's healthcare provider for routine and emergency care.

¹¹ Rule 6A-6.0253(3), F.A.C.

¹² S. <u>1002.20(3)(j)</u>, F.S.

¹³ Rule 6A-6.0253(2), F.A.C.

¹⁴ S. 1002.20(3)(j), F.S.

¹⁵ Rule 6A-6.0253(4), F.A.C.; see, Florida Department of Education, School Health Services: Health Issues - Guidelines, Resources and Training, https://www.fldoe.org/schools/k-12-public-schools/sss/sch-health-serv.stml (last visited Apr. 23, 2025). ¹⁶ Treatment for mild hypoglycemia usually involves consuming glucose tablets or gel, or a food or beverage that contains fastacting carbohydrates such as candy or regular soda, and continuing to monitor blood sugar levels until they have returned to a normal level, per a health care provider's directives. See, American Diabetes Association, Signs, Symptoms, and Treatment for Hypoglycemia (Low Blood Glucose), https://diabetes.org/living-with-diabetes/hypoglycemia-low-blood-glucose/symptomstreatment (last visited Apr. 23, 2025).

¹⁷ American Diabetes Association, Severe Hypoglycemia (Severe Low Blood Glucose), https://diabetes.org/living-withdiabetes/hypoglycemia-low-blood-glucose/severe (last visited Apr. 23, 2025). RELEVANT INFORMATION

Glucagon has been approved by the U.S. Food and Drug Administration for the treatment of severe hypoglycemia. Glucagon quickly raises blood sugar levels by causing the liver to release stores of glucose into the bloodstream. Glucagon can be administered through various routes and as such is produced in several different formulations, including a prefilled injector, an intranasal spray, and a powder which must be reconstituted with sterile water before being injected. The powder formulation of glucagon is commonly found in medical settings; however, the prefilled injector and intranasal spray are ready-to-use formulations able to be easily administered by a layperson.¹⁸

Glucagon is safe for use in all ages; the American Diabetes Association advises that all children who take insulin require access to glucagon for treatment of severe hypoglycemia. Side effects from glucagon are mild, with nausea being the most commonly reported adverse effect. Other, more serious, potential side effects are very rare, but include hypertension, severe allergic reactions, and rebound hypoglycemia. After glucagon has been administered, a person should receive further medical treatment and may need to be hospitalized for further monitoring. On the contraction of t

Florida's Good Samaritan Act

The <u>Good Samaritan Act</u> (the Act) provides civil immunity to any person, including those licensed to practice medicine, who gratuitously and in good faith renders emergency care or treatment in direct response to an emergency situation.²¹ Under the Act, a person may not be held liable for any civil damages resulting from such care or treatment, or from failure to act in providing further medical treatment, where the person acted as a reasonable person would.

OTHER RESOURCES:

Florida Department of Education School Health Services

UMP TO <u>SUMMARY</u> <u>ANALYSIS</u> <u>RELEVANT INFORMATION</u>

¹⁸ Morris C.H. & Baker J., *Glucagon*. (2025), StatPearls Publishing, https://www.ncbi.nlm.nih.gov/books/NBK559195/ (last visited Apr. 23, 2025). For more information on how to administer glucagon, see, American Diabetes Association, https://diabetes.org/living-with-diabetes/hypoglycemia-low-blood-glucose/how-use-glucagon (last visited Apr. 23, 2025).

¹⁹ Cogen, F., et al. *Diabetes Care in the School Setting: A Statement of the American Diabetes Association* (2024), Diabetes Care, 47(12):2050-2061, https://diabetesjournals.org/care/article/47/12/2050/157411/Diabetes-Care-in-the-School-Setting-A-Statement-of (last visited Apr. 23, 2025).

²⁰ Morris C.H. & Baker J., *Glucagon*, (2025), StatPearls Publishing, *Glucagon*, https://www.ncbi.nlm.nih.gov/books/NBK559195/ (last visited Apr. 23, 2025).

²¹ S. <u>768.13(2)(a)</u> and (b), F.S., in this context, an emergency situation includes those arising out of a public health emergency declared pursuant to s. <u>381.00315</u>, F.S., a state of emergency which has been declared pursuant to s. <u>252.36</u>, F.S., or at the scene of an emergency outside of a medical facility.