

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Health Regulation Committee

BILL: CS/SB 552

INTRODUCER: Health Regulation Committee and Senator Wise

SUBJECT: Prescribed Pancreatic Enzyme Supplements

DATE: March 4, 2009 REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Harkey	Matthews	ED	Favorable
2.	Munroe	Wilson	HR	Fav/CS
3.			EA	
4.				
5.				
6.				

Please see Section VIII. for Additional Information:	
A. COMMITTEE SUBSTITUTE.....	<input checked="" type="checkbox"/> Statement of Substantial Changes
B. AMENDMENTS.....	<input type="checkbox"/> Technical amendments were recommended
	<input type="checkbox"/> Amendments were recommended
	<input type="checkbox"/> Significant amendments were recommended

I. Summary:

This bill would permit a student to carry and self-administer prescribed pancreatic enzyme supplements while in school, at a school-sponsored activity, or while in transit to or from school or a school-sponsored activity, if the student's parent and physician had provided the school with authorization for the student's use of the supplement. The State Board of Education, in cooperation with the Department of Health, would be required to adopt rules for the use of the supplements. The bill requires the parents of a student who uses prescribed pancreatic enzyme supplements to indemnify the school district, county health department, public-private partners, and their employees or volunteers for any and all liabilities arising from the student's use of the supplements.

This bill amends s. 1002.20, Florida Statutes.

II. Present Situation:

Pancreatic Insufficiency/Cystic Fibrosis

The pancreas is an organ that produces enzymes that are involved in digestion as well as hormones, including insulin, that regulate metabolism. Pancreatic insufficiency is the inability of the pancreas to produce and/or transport enough digestive enzymes to break down food in the intestine and to allow its absorption. It typically occurs as a result of progressive pancreatic damage that may be caused by recurrent acute pancreatitis or by chronic pancreatitis due to a variety of conditions. In children, it is most frequently associated with cystic fibrosis. Shwachman-Diamond Syndrome is the second most common cause of inherited pancreatic insufficiency. Pancreatic insufficiency can also be associated with type 1 or autoimmune diabetes. It is less frequently but sometimes associated with pancreatic cancer.¹

Cystic fibrosis is a chronic and progressive disease causing mucus in the body to become thick and sticky. The mucus builds up in the body and clogs passages in the lungs, interfering with respiration. In the pancreas, the mucus blockage can interfere with normal digestive processes. Children who have cystic fibrosis often cannot absorb nutrients from food and may have below-normal growth and development. Children with cystic fibrosis need a high-calorie, high-protein diet and enzymes in order to gain weight and grow. There is no cure for cystic fibrosis. Management of the disease varies from person to person and generally focuses on treating respiratory and digestive problems to prevent infection and complications.²

Pancreatic Enzyme Supplements

Individuals with pancreatic insufficiency or with cystic fibrosis take pancreatic enzymes to help digestion and food absorption. According to the Cystic Fibrosis Foundation, children with cystic fibrosis need a high-calorie, high-protein diet and enzymes in order to gain weight and grow.³ They take oral pancreatic enzyme medicine with all meals and snacks that contain fat, protein, or complex carbohydrates.⁴ According to the Foundation, the pancreatic enzymes do not cause a problem if taken by another child.⁵ Most children with cystic fibrosis have been taking pancreatic enzymes since infancy and can take them on their own.⁶

Administration of Medication by District School Board Personnel

Section 1006.062, F.S., requires each district school board to adopt policies governing the administration of prescription medication by district school board personnel. Each school district must have in its policies a procedure for licensed medical personnel to train the school personnel

¹ See "Pancreatic Insufficiency" at < http://www.labtestsonline.org/understanding/conditions/pancreatic_insuf.html > (Last visited on February 26, 2009).

² See D. Golonka, "Cystic Fibrosis," on WebMD (Last Updated June 26, 2007) at <<http://www.webmd.com/hw-popup/cystic-fibrosis>> (Last visited on February 26, 2009).

³ See the website for the Cystic Fibrosis Foundation, "Nutrition: School, Enzymes, and Sports for the Child with Cystic Fibrosis", at <<http://www.cff.org/LivingWithCF/AtSchool/>> (Last visited on February 26, 2009).

⁴ *Id.*

⁵ *Id.* See also "Pancrelipase" as discussed on Drug Information Online at <<http://www.drugs.com/MTM/pancrelipase.html>> (Last visited on February 26, 2009).

⁶ *Id.*

who are designated by the school principal to assist students in the administration of prescribed medication. Each prescribed medication to be administered by district school board personnel must be received, counted, and stored in its original container. Under s. 1006.062(4), F.S., non-medical assistive personnel may perform health-related services after completing child-specific training taught by licensed medical personnel. Such procedures as intermittent clean catheterization, gastronomy tube feeding, monitoring blood glucose, and administering emergency injectable medication must be monitored periodically by a licensed nurse or physician.

Student and Parental Rights

Section 1002.20, F.S., establishes a number of rights for students in kindergarten through 12th grade and their parents. This statute gives students the right to carry and use an inhaler in the treatment of asthma⁷ and epinephrine auto-injectors in the treatment of a life-threatening allergic reaction⁸. Authorization by a student's parent and physician is required before a student can carry and use either of those medications.

Indemnity Clause

An indemnity clause is a contractual provision in which one party agrees to answer for any specified or unspecified liability or harm that the other party might incur.⁹

Sovereign Immunity

Article X, s. 13, of the State Constitution, authorized the Florida Legislature in 1868 to waive sovereign immunity by stating that, "Provision may be made by general law for bringing suit against the state as to all liabilities now existing or hereafter originating." The doctrine of sovereign immunity prohibits lawsuits in state court against a state government, and its agencies and subdivisions without the government's consent. Section 768.28, F.S., provides that sovereign immunity for tort liability is waived for the state, and its agencies and subdivisions, but imposes a \$100,000 limit on the government's liability to a single person and for claims arising out of a single incident, the limit is \$200,000. Section 768.28, F.S., outlines requirements for claimants alleging an injury by the state or its agencies. Section 11.066, F.S., requires a claimant to petition the Legislature, in accordance with its rules, to seek an appropriation to enforce a judgment against the state or state agency. The exclusive remedy to enforce damage awards that exceed the recovery cap is by an act of the Legislature through the claims bill process. A claim bill is a bill that compensates an individual or entity for injuries or losses occasioned by the negligence or error of a public officer or agency.

Section 768.28(9), F.S., defines "officer, employee, or agent" to include, but not be limited to, any health care provider when providing services pursuant to s. 766.1115, F.S., any member of the Florida Health Services Corps, as defined in s. 381.0302, F.S., who provides uncompensated care to medically indigent persons referred by the Department of Health, and any public defender

⁷ See s. 1002.20(3)(h), F.S.

⁸ See s. 1002.20(3)(i), F.S.

⁹ See BLACK'S LAW DICTIONARY, 8th ed., 2004.

or her or his employee or agent, including among others, an assistant public defender and an investigator.

The second form of sovereign immunity potentially available to private entities under contract with the government is set forth in s. 768.28(9), F.S. It states that agents of the state or its subdivisions are not personally liable in tort; instead, the government entity is held liable for its agent's torts. The factors required to establish an agency relationship are: (1) acknowledgment by the principal that the agent will act for him; (2) the agent's acceptance of the undertaking; and (3) control by the principal over the actions of the agent.¹⁰ The existence of an agency relationship is generally a question of fact to be resolved by the fact finder based on the facts and circumstances of a particular case. In the event, however, that the evidence of agency is susceptible of only one interpretation the court may decide the issue as a matter of law.¹¹

III. Effect of Proposed Changes:

This bill allows kindergarten through 12th grade students who have experienced or who are at risk of pancreatic insufficiency or who have been diagnosed with cystic fibrosis, to carry and self-administer prescribed pancreatic enzyme supplements while in school, at a school-sponsored activity, or while in transit to or from school or a school-sponsored activity, if the student's parent and physician provided the school with authorization for the student's use of the supplement. The State Board of Education, in cooperation with the Department of Health, would be required to adopt rules for the use of the supplements.

The parents of a student who used prescribed pancreatic enzyme supplements under the provisions of the bill would have to indemnify the school district, county health department, public-private partners, and their employees or volunteers for any and all liabilities arising from the student's use of the supplements.

The bill would take effect July 1, 2009.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

¹⁰ *Goldschmidt v. Holman*, 571 So.2d 422 (Fla. 1990).

¹¹ *Campbell v. Osmond*, 917 F. Supp. 1574, 1583 (M.D. Fla. 1996). See also *Stoll v. Noel*, 694 So.2d 701 (Fla. 1997).

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The indemnity provision shifts the risk of loss for any potential litigation to the parents of a student who used prescribed pancreatic enzyme supplements under the provisions of the bill. The parents would have to indemnify the school district, county health department, public-private partners, and their employees or volunteers for any and all liabilities arising from the student's use of the supplements.

C. Government Sector Impact:

To the extent that a party could obtain a judgment against the school district or other government entity and the parents do not have sufficient assets to satisfy the judgment, the State of Florida or local school districts may bear the risk of loss. To some extent this potential risk of loss is mitigated to the extent that the school district or other government entity may assert immunity from civil liability under s. 768.28, F.S. Section 768.28, F.S., extends immunity from civil liability to governmental agents and officers under specified circumstances.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Regulation on March 4, 2009:

Authorizes a student to “carry and self-administer,” rather than “use” a prescribed pancreatic enzyme supplement. Changes the term “pancreatic enzyme prescription supplements” to “prescribed pancreatic enzyme supplements.”

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.
