# 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 St	taff of the Health Re	gulation Commit	tee
BILL:	SB 166				
INTRODUCER:	Senator Wise				
SUBJECT:	SUBJECT: Prescribed Pancreatic Enzyme Supplements/Use				
DATE:	DATE: February 12, 2010 REVISED:				
ANALYST		STAFF DIRECTOR	REFERENCE		ACTION
l. Harkey		Matthews	ED	<b>Favorable</b>	
2. Munroe		Wilson	HR	Favorable	
3.			EA		
4.					
5.	<del></del> -				
5.	<del>-</del>			-	

# I. Summary:

The bill authorizes 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 a prescribing practitioner have 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 section 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 or transport enough digestive enzymes to break down food in the intestine and to allow its absorption. The condition 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, pancreatic insufficiency is most frequently associated

<sup>&</sup>lt;sup>1</sup> See "Pancreatic Insufficiency" at <<u>http://www.labtestsonline.org/understanding/conditions/pancreatic\_insuf.html</u>>. (Last visited on February 11, 2010).

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with cystic fibrosis.<sup>2</sup> 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.<sup>3</sup> 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.<sup>4</sup> 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 belownormal growth and development. 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.<sup>5</sup> 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.

## **Pancreatic Enzyme Supplements**

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

## **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 a procedure for licensed medical personnel to train the school personnel 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. Students may carry and use an inhaler in the treatment of asthma<sup>9</sup> and

 $<sup>^{2}</sup>$  Id.

 $<sup>^{3}</sup>Id$ .

<sup>&</sup>lt;sup>4</sup> See D. Golonka, "Cystic Fibrosis," on WebMD (Last Updated June 23, 2009) at: <a href="http://children.webmd.com/tc/cystic-fibrosis-topic-overview">http://children.webmd.com/tc/cystic-fibrosis-topic-overview</a>> (Last visited on February 11, 2010).

<sup>&</sup>lt;sup>5</sup> See the website for the Cystic Fibrosis Foundation, "Nutrition: School, Enzymes, and Sports for the Child with Cystic Fibrosis", at: < <a href="http://www.cff.org/UploadedFiles/LivingWithCF/AtSchool/SchoolEnzymes/Nutrition%20-%20School%20Enzymes%20Sports.pdf">http://www.cff.org/UploadedFiles/LivingWithCF/AtSchool/SchoolEnzymes/Nutrition%20-%20School%20Enzymes%20Sports.pdf</a> (Last visited on February 11, 2010).

<sup>&</sup>lt;sup>6</sup> *Id*.

 $<sup>^{7}</sup>$  Id.

<sup>&</sup>lt;sup>8</sup> *Id*.

<sup>&</sup>lt;sup>9</sup> See s. 1002.20(3)(h), F.S.

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epinephrine auto-injectors in the treatment of a life-threatening allergic reaction. <sup>10</sup> Authorization by a student's parent and physician is required before a student can carry or use either medication.

## **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.<sup>11</sup>

# III. Effect of Proposed Changes:

Students with, or at risk of, pancreatic insufficiency or students with cystic fibrosis, who need the enzymes to grow and develop appropriately, would be authorized to carry and administer enzyme supplements at school or school-sponsored activities with parental and medical authorization. This authorization would permit the student to take the enzymes in a timely manner when they are food containing fat, protein, or complex carbohydrates.

The State Board of Education, in cooperation with the Department of Health, would adopt rules for the use of the supplements. The bill provides an affirmative right to carry and use the supplements. Since s. 1006.062, F.S., requires school districts to adopt policies governing the administration of medication on their campuses and at events, the requirement for the state board to adopt rules may be superfluous.

Parents who grant the authorization would be required to indemnify the school district, county health department, public-private partners and their employees or volunteers for any liabilities arising from the use of the supplements. Indemnity clauses do not eliminate a party's liability; rather, they operate to allow the party to seek restitution from another. In a school setting, a parent's ability to indemnify the school district or another party may be quite limited.

The effective date of the bill is July 1, 2010.

#### 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.

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<sup>&</sup>lt;sup>10</sup> See s. 1002.20(3)(i), F.S.

<sup>&</sup>lt;sup>11</sup> See Black's Law Dictionary, 8th ed., 2004.

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#### 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. 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.)

None.

B. Amendments:

None.