

# SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

---

Prepared By: Banking and Insurance Committee

---

BILL: SB 376

INTRODUCER: Senator Margolis

SUBJECT: Cystic Fibrosis Treatment

DATE: February 15, 2006

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Deffenbaugh	BI	<b>Favorable</b>
2.	_____	_____	HE	_____
3.	_____	_____	WM	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

---

## I. Summary:

The bill requires group health insurance policies and group health maintenance organization (HMO) contracts to provide coverage for all medically necessary chest physiotherapy provided by a licensed respiratory therapist, home health care, equipment, supplies, and enteral formulas used to treat cystic fibrosis if the patient's treating physician or a physician authorized by the insurer or HMO who specializes in the treatment of cystic fibrosis certifies that such services are medically necessary. The insurer may require that the policyholder or subscriber is responsible for any deductible or copayment that generally applies under the policy or contract.

The bill would not apply to any individual health insurance policy or individual HMO contract. It would also not apply to the standard policy, basic policy, or limited benefit policy sold to a small employer since a mandated benefit does not apply without a specific reference to such small group policies. The bill applies to policies or contracts issued or renewed on or after the effective date of the bill, October 1, 2006.

This bill amends ss. 641.31, and 627.6515, F.S. The bill creates s. 627.6614, F.S.

## II. Present Situation:

### Background on Cystic Fibrosis

Cystic fibrosis is a progressive genetic disease that causes a range of symptoms primarily affecting the lungs and the digestive system. According to the Cystic Fibrosis Foundation, "the basic problem in cystic fibrosis is an error in the salt and water exchange in some cells. This causes the body to make thick, sticky mucous, which clogs the lungs and the pancreas."<sup>1</sup> This

---

<sup>1</sup> Website: [www.cff.org](http://www.cff.org)

mucous can also prevent pancreatic enzymes from reaching the intestines to digest food and absorb food which results in malnutrition, slow growth, and poor weight gain. Approximately 10-20 percent of cystic fibrosis patients also have cystic fibrosis-related diabetes which usually begins in their teens or young adult years.

The disease is the most common life-shortening genetic disorder among Caucasian individuals worldwide. Approximately 40 percent of children with cystic fibrosis live beyond age 18. The average life expectancy for those who live to adulthood is 30-33 years of age. The incident rate for cystic fibrosis in the United States is approximately one out of every 2,500 infants. Nationwide, approximately 30,000 adults and children have this disorder. According to the Cystic Fibrosis Foundation Patient Registry Annual Data Report 2003, an estimated 1,006 Floridians were reported to have cystic fibrosis in 2003.

However, according to the Agency for Health Care Administration, there were 1,653 individuals with Medicaid claims where there was a primary or secondary diagnosis of cystic fibrosis for fiscal year 2003-2004. If the incident rate reported by the Cystic Fibrosis Foundation (foundation) is adjusted upward to reflect the actual number of Medicaid individuals with cystic fibrosis, the actual number of Floridians with cystic fibrosis appears to be at least 2,299.

### **Medical Care for Cystic Fibrosis**

The treatment of cystic fibrosis requires a comprehensive approach comprised of drugs, dietary supplements, and airway clearance techniques. The treatment of the disease is contingent upon the severity of the disease and the organs affected.<sup>2</sup> The following is a breakdown and summary of typical treatment components based upon information obtained from the Cystic Fibrosis Foundation Patient Registry Annual Data Report (2003) and the Cystic Fibrosis Foundation website.<sup>3</sup>

*Drugs* -- An estimated 67.4 percent of all cystic fibrosis patients use Pulmozyme; a medication designed to break down the viscosity of the mucous. If not removed, the mucous can cause significant reduction in lung function and creates an environment where infections can easily grow. Approximately 6.1 percent of all patients use TOBI, an antibiotic specifically designed for cystic fibrosis patients to minimize the frequency of infection. Over 90 percent of the patients use pancreatic enzymes that enable them to digest food. Without this enzyme, patients are unable to digest food and nutrients.

*Dietary Supplements* -- A serious symptom of cystic fibrosis is the inability to gain or maintain proper weight. This, in and of itself, can reduce the ability of the patient to fight infection and maintain the rigorous treatments required for survival. Dietary treatments can include any of a number of high-calorie supplements as well as prescription vitamins.

*Airway Clearance Techniques (ACTs)* -- Clearing mucous from the lungs is an integral part of the daily treatment regimen to reduce lung infection and improve the functionality of the lungs. According to the Cystic Fibrosis Foundation, "For infants and toddlers, ACTs can be done by

---

<sup>2</sup> Reach for the Stars Foundation to Benefit Individuals with Cystic Fibrosis. *Legislative Study*. February 24, 2005.

<sup>3</sup> Website: [www.cff.org](http://www.cff.org)

almost anyone. Older kids and adults can do their own ACTs.”<sup>4</sup> The types of ACTs include chest physiotherapy, oscillating positive expiratory pressure, high-frequency wall oscillation, and positive expiratory therapy. Chest physiotherapy is a technique that includes postural drainage and chest percussions. Chest percussions consist of clapping and vibrating the chest to dislodge mucous. Oscillating positive expiratory pressure is a procedure where the person blows out of a specialized device numerous times to open the airways. High-frequency chest wall oscillation is a method where an inflatable vest is attached to a machine that vibrates at a very high frequency to open up the airways.

*Costs* -- In 1999, a study was released which evaluated the medical costs of 136 cystic fibrosis patients enrolled in the Kaiser Permanente Medical Care Plan, a health maintenance organization (HMO).<sup>5</sup> The results of the study indicated that the annual cost of medical care in 1996 averaged \$13,300 and ranged from \$6,200 among patients with mild disease to \$43,300 among patients with severe disease.<sup>6</sup>

If these observed costs were used to extrapolate the costs of medical care for the cystic fibrosis population in the United States, these total costs were estimated to be \$314 million per year in 1996 dollars. Of these total costs, 47 percent were attributable to hospitalization, 18 percent from Pulmozyme, 12 percent from clinic visits, and 10 percent were from outpatient antibiotics. The study included the cost of hospital, laboratory, radiology, outpatient, and pharmaceutical services. The study excluded the home health nursing visits for intravenous antibiotic administration because these services were not covered by the health plan since parents or patients could either administer the medication themselves or visit the outpatient clinic for such services. Another study estimated that the average cost of home health care was approximately 20 percent of the total annual cost.<sup>7</sup> If the results of the 1999 study were adjusted for the personal consumption deflator for medical services (which increased 28% over this period), the 1996 average cost would result in a 2005 average of \$17,060. The 1999 range of costs would result in a 2005 range from \$7,953 to \$55,543. If 20 percent was added to address home health care, the 2005 average cost would be \$20,472, and the range of costs, expressed in 2005 dollars would increase to \$9,544 to \$66,652.

### **Cystic Fibrosis-Related Statutory Coverage**

Currently, there is no specific health insurance mandate that requires the coverage of cystic fibrosis. Section 627.42395, F.S., requires insurers to make available to any policyholder, for an additional premium, coverage for certain prescription and nonprescription enteral formulas for any insured individual through the age of 24 for the treatment of certain inherited diseases of amino acid, organic acid, carbohydrate, or fat metabolism, and malabsorption, which would generally cover cystic fibrosis. For coverage to apply, the formula must be for home use and prescribed by a physician as medically necessary. Such coverage is capped at \$2,400 annually. In

---

<sup>4</sup> Cystic Fibrosis Foundation website. *An Introduction to Airway Clearance Techniques*. 2004.

<sup>5</sup> The age of the patients included in this study ranged from 9 months to 56 years of age. The breakout of the clinical characteristics of this population of patients was 41 percent had mild disease, 31 percent had moderate disease, and 15 percent had severe disease.

<sup>6</sup> Lieu, Tracy, et. al., *The Cost of Medical Care for Patients with Cystic Fibrosis in a Health Maintenance Organization*, *Pediatrics*. 1999:103:72-76.

<sup>7</sup> Wildhagen MF, Hilderink, HB, et al., *Costs, Effects, and Savings of Screening for Cystic Fibrosis Gene Carriers*, *Journal of Epidemiology and Community Health*. 1998: 52; 459-467.

addition, the insurance code mandates individual and group coverage for all medically necessary equipment, supplies, and diabetes outpatient self-management training and educational services used to treat diabetes.<sup>8</sup> Under the provisions applicable to group insurers, s. 627.6617, F.S., coverage for home health care is required. Such coverage must provide for at least \$1,000 in reimbursements per policy year. Generally, policyholders and subscribers of health maintenance organizations are responsible for co-payments and deductibles associated with coverage, including mandated benefits.

### **Medicaid Coverage**

According to the Florida Medicaid Summary of Services, FY 2004-2005, issued by the Agency for Health Care Administration, Medicaid serves 2.1 million people in Florida with about half of those being children under the age of 21. Medicaid is a medical assistance program that provides access to health care for low-income families and individuals and provides assistance for the payment of nursing care facilities and other medical expenses for the elderly and disabled population. Eligibility is generally based on a family or individual's income.

Medicaid provides coverage for inpatient and outpatient hospital and physician services. Medicaid generally does not reimburse for over-the-counter drugs. Food supplements, if authorized for medical necessity, are reimbursable through the prescribed drug program. Medicaid provides coverage for respiratory therapy which includes chest physiotherapy in the home or other appropriate setting. For Medicaid recipients under the age of 21, Medicaid reimburses for medically necessary respiratory therapy services. For recipients age 21 and older, respiratory therapy is provided under the outpatient hospital services program. Medicaid reimbursement is limited to one initial evaluation per recipient, per provider, and one re-evaluation every six months per recipient, per provider. A respiratory therapy treatment must have a minimum duration of 15 minutes with a maximum of 14 units-of-service per week. Daily treatments may not exceed four units-of-service. These services must be prescribed by the patient's primary physician and be provided by a licensed registered respiratory therapist.

Home health services deemed medically necessary are provided in a recipient's home or other authorized setting to promote, maintain, or restore health or to minimize the effects of illness and disability when either leaving the home is medically contraindicated or the recipient is unable to leave home without the assistance of another person. Medicaid reimbursement for home health services are subject to a limit of 60 visits by nurses or aides per lifetime, per recipient. Any exceptions to the 60-day limit for children and adults must be authorized prior to the provision of the services.

The Medicaid Waiver for Adult Cystic Fibrosis program will provide an array of services, such as nutritional counseling, respiratory therapy, personal care, personal emergency response service, skilled nursing, specialized medical equipment, transportation, vitamins, and nutritional supplements. This program targets cystic fibrosis patients, age 18 or older, who are determined to be at risk of hospitalization and meet certain disability and income tests. This program is designed to provide services for approximately 150 individuals at a cost of approximately \$10,000 per recipient per year when fully implemented.

---

<sup>8</sup> Sections 627.6408 and 627.4754, F.S.

According to the Agency for Health Care Administration, for fiscal year 2003-2004, there were 1,653 individuals with Medicaid claims where there was a primary or secondary diagnosis of cystic fibrosis. Those 1,653 individuals averaged \$17,830 each in total claims for that year.

### **Florida Kidcare**

Florida Kidcare is a program that provides comprehensive health coverage for previously uninsured children and is broken into the following components:

- Medicaid – entitlement program for children under age 21 whose family income qualifies them for services. Children receive all medically necessary services under Medicaid.
- Medikids – insurance for children ages 1 – 5 years. Enrollees receive most of Medicaid services, including immunizations, dental, and transportation.
- Florida Healthy Kids – insurance for children ages 4 to 19 years. Children receive services according to the benefits required under the Healthy Kids Program.
- Children’s Medical Services (CMS) Network – for children ages 1 to 19 years with special health care needs. CMS clients with cystic fibrosis who are eligible for Medicaid or Title XXI receive the Medicaid benefit package; CMS clients with cystic fibrosis who are not eligible for Medicaid or Title XXI receive services according to their needs and the resources available in the program.

### **State Employees Insurance Coverage**

The Division of State Group Insurance of the Department of Management Services contracts with Blue Cross Blue Shield of Florida to administer the state employees’ Preferred Provider Organization (PPO) plan. The State also contracts with health maintenance organizations (HMOs) to provide health care services to state employees. These plans do not have a specific dollar or number limitation for chest physiotherapy treatments or home respiratory chest percussion treatments per year. The services and treatment for cystic fibrosis, as well as all other services and conditions, are subject to medical necessity and medical policy guidelines.

The plans do have specific circumstances and provisions for home health care services, not specific to services or conditions, but for all home health care. For example, for home health care services to be covered, the following requirements must be met: the patient must be confined to home, the physician must provide a detailed written plan of treatment, the costs must be less expensive than for in-patient care, the services must all be approved in advance, the home health care agency must provide weekly reports to the treating physician and must provide detailed invoices for reimbursement, and providers of service must be licensed.

### **Coverage Issues**

Advocates for the bill were asked about current coverage gaps or issues related to equipment, supplies, and supplements which are benefits mandated by the bill. The results of a 2004 survey conducted by the Reach for the Stars Foundation indicated that individuals with cystic fibrosis have been denied coverage for durable medical equipment, brand name medications, nutritional supplements, and access to a cystic fibrosis specialist. The individuals with cystic fibrosis also report that some policies will cover lung transplantation but not the drugs needed after the surgery. According to advocates for the bill, most cystic fibrosis patients do not attempt to obtain coverage for nutritional supplements and vitamins because they always are denied despite the law that makes coverage for enteral formulas for persons under age 24 required under certain

circumstances. The advocates provided documentation related to one parent who appealed the denial of coverage for liquid supplements and ultimately prevailed in obtaining the coverage. Commonly used over-the-counter drugs for indigestion include Prilosec, Xantax, and Maalox.

According to the advocates, medical equipment is generally covered, but there have been cases where insurance companies will not provide the exact equipment prescribed; and instead, they will provide the most cost-effective equipment instead. The advocates cited an example of this situation involving one cystic fibrosis patient who had been prescribed nebulizers and an oxygen tank. The advocates of the bill indicated that, based on recent conversations with cystic fibrosis patients, there did not appear to be a problem obtaining coverage for diabetes equipment and diabetes related-drugs covered. However, generic drugs are frequently substituted for brand name drugs.

According to advocates for the bill, typical policies offer limited home health care benefits. According to The Reach for the Stars Foundation's survey, 55 percent of the population surveyed had a limit on the number of home health care visits allowed by their insurance company. Staff of the Banking and Insurance Committee contacted representatives of insurers who indicated that a limitation of 60 visits per policy year was typical.

According to advocates for the bill, insurers routinely deny coverage for in-home chest physiotherapy by a licensed respiratory therapist because the service does not meet the definition of medical necessity for the particular insurance plan. According to the Reach for the Stars Foundation's survey, 59 percent of the population surveyed had been denied coverage for chest physiotherapy provided by a licensed respiratory therapist. Based on conversations staff of the Banking and Insurance Committee had with representatives of insurers in Florida, coverage for chest physiotherapy or home respiratory chest percussion treatments provided by a licensed respiratory therapist is generally covered by an insurer if such service is medically necessary to stabilize the patient or service is needed when the patient's pulmonary condition is unstable. Some plans limit the number of such services to 60 - 120 treatments per benefit year.

Copies of letters supplied by advocates of the bill document that some insurers have stated that family caregivers can be instructed to perform chest physiotherapy on the family member and therefore the request for licensed professional in-home physiotherapy is not considered medically necessary. Advocates also have stated that many insurers will provide a mechanical vest that performs limited chest physiotherapy.

The Reach for the Stars Foundation provided actual weekly cost data for a 13-year old healthy child with cystic fibrosis that was used by staff of the Banking and Insurance Committee to estimate annual costs for services. For this child, annual out-of-pocket costs were estimated to be \$60,288. Insurance provided 120 chest physiotherapy treatments per year for the child. However, this individual receives at least one daily chest physiotherapy treatment (or 365 visits per year) provided at home by a licensed registered respiratory therapist. The parents pay for the remaining 245 days of daily treatments, at \$40 per treatment that are not covered by insurance. The cost of chest physiotherapy provided in the home by a licensed registered respiratory therapist comprised 23 percent or \$14,000 of these annual costs. Doctor visits, medical equipment, and hospitalizations totaled \$3,388 or 6 percent of the total costs for the year. However, the foundation indicated that hospitalization would generally cost in the range of

\$20,000 - \$75,000 per stay depending on the length of stay. The annual costs for high-calorie liquid supplements were \$780 which was not covered by insurance. The weekly cost for this child did not include any home health visits. Staff of the Banking and Insurance Committee estimated the annual costs for a 14-year old sick child and a 29-year healthy adult to be \$169,563 and \$104,033, respectively, based on foundation data.

According to the United States Census Bureau, 54.2 percent of all residents of Florida obtained health insurance through an employer-based insurance plan.<sup>9</sup> Therefore, staff assumed that at least 545 of the 1,006 individuals registered with the Cystic Fibrosis Patient Registry had insurance coverage through an employer group plan. Based on the limited data, it appears that limitations or exclusions on the provision of chest physiotherapy provided by a licensed respiratory therapist resulted in a range of additional annual costs of \$9,800 (one treatment per day) to \$19,600 (two treatments per day). The estimated additional cost of providing such treatments, once or twice daily would be in the range of \$5,341,000 – \$10,682,000 for these 545 individuals. An additional administrative cost associated with such claims of 20 percent was added to arrive at an adjusted estimated range of \$6,409,200 – \$12,818,400. According to the Office of Insurance Regulation, there are 1,612,288 insureds in the large group market.<sup>10</sup> These insureds may experience an increase in premiums in the range of \$3.98 – \$7.95 per year associated with the cost of mandating this chest physiotherapy benefit. Staff was unable to estimate the additional costs associated with the home health care benefit. In regards to the enteral formula benefit, data for three individuals provided by the Cystic Fibrosis Foundation indicated that the annual costs of such formulas ranges from \$607- \$884. The estimated total cost of providing this benefit to 545 individuals was estimated to be in the range of \$396,978 – \$578,136 per year, after adjusting upward for administrative costs of 20 percent. This would result in an estimated increase in annual premiums in the large group market of \$0.25 - \$0.36 per policyholder in the large group market.

Staff of the Banking and Insurance Committee contacted the Department of Financial Services and the Agency for Health Care Administration to determine the extent of coverage issues and disputes regarding coverage. As of January 14, 2005, the Division of Consumer Assistance of the Department of Financial Services had not received any complaints from consumers regarding cystic fibrosis coverage issues. The Subscriber Assistance Panel (panel) of the Agency for Health Care Administration, which handles coverage disputes between subscribers and health maintenance organizations, reported four disputes related to cystic fibrosis coverage (equipment and services) for the period of 2000 - 2004. In all four cases, the panel recommended that the Office of Insurance Regulation order the HMO to cover the cost of such equipment or services. Two cases involved coverage for The Vest Airways Clearance System and two cases involved chest physiotherapy. In one of the chest physiotherapy cases, the panel determined that the health plan was required to cover the cost of respiratory therapy administered at home, until it was no longer deemed medically necessary. In the remaining chest physiotherapy case, the panel found that the definition of home health care did not include chest physiotherapy under the terms of that coverage; and therefore, the chest physiotherapy was not subject to the home health limitations and chest physiotherapy was not specifically excluded or limited by the agreement.

---

<sup>9</sup> U.S. Census Bureau, Current Population Survey, 2004 Annual Social and Economic Supplement.

<sup>10</sup> Office of Insurance Regulation, *Summary of Enrollment Information, Calendar Year 2002*. November 24, 2003.

### III. Effect of Proposed Changes:

**Section 1.** Creates s. 627.6614, F.S., to require a group health insurance policy sold in Florida to provide coverage for all medically necessary chest physiotherapy provided by a licensed respiratory therapist, home health care, equipment, supplies, and enteral formulas described in s. 627.42395, F.S., used to treat cystic fibrosis, if the patient's treating physician or a physician authorized by the insurer who specializes in the treatment of cystic fibrosis certifies that such services are medically necessary. The insurer may require the policyholder to be responsible for any deductible or copayment that generally applies under the policy.

**Section 2.** Adds a new subsection (36) to s. 641.31, F.S., to require a group health maintenance contract sold in Florida to provide coverage for all medically necessary chest physiotherapy provided by a licensed respiratory therapist, home health care, equipment, supplies, and enteral formulas described in s. 627.42395, F.S., used to treat cystic fibrosis if the patient's treating physician or a physician authorized by the health maintenance organization who specializes in the treatment of cystic fibrosis certifies that such services are medically necessary. The health maintenance organization may require the subscriber to be responsible for any deductible or copayment that generally applies under the contract.

**Section 3.** Amends s. 627.6515, F.S., to include the newly created s. 627.6614, F.S., as one of the mandated benefits that would apply to a group policy issued by an out-of-state insurer.

**Section 4.** States that the Legislature finds that this bill fulfills an important state interest.

**Section 5.** Provides that the bill will take effect October 1, 2006, and will apply to policies and contracts issued or renewed on or after that date.

### IV. Constitutional Issues:

#### A. Municipality/County Mandates Restrictions:

Inasmuch as this bill requires local governments to incur expenses to pay additional health insurance costs, the bill falls within the purview of s. 18, Art. VII of the State Constitution, which provides that cities and counties are not bound by general laws requiring them to spend funds or to take an action which requires the expenditure of funds unless certain specified conditions are met. One condition that must be met is that the Legislature has determined that the law fulfills an important state interest. The bill contains an express legislative determination to this effect. In addition, one of various other conditions must be met, including (among others), approval by a two-thirds vote of the membership of each house of the Legislature for passage; or that the expenditure is required to comply with a law that applies to all persons similarly situated, including the state and local government.

#### B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

In 2005, staff of the Banking and Insurance Committee estimated the fiscal impact of the bill on the large group market that is comprised of employers with more than 50 employees. According to the United States Census Bureau, 54.2 percent of all residents of Florida obtained health insurance through an employer-based insurance plan. Therefore, staff assumed that at least 545 of the 1,006 individuals registered with the Cystic Fibrosis Patient Registry had insurance coverage through an employer group plan. Based on the limited data, it appears that limitations or exclusions on the provision of chest physiotherapy provided by a licensed respiratory therapist resulted in a range of additional annual costs of \$9,800 (one treatment per day) to \$19,600 (two treatments per day), based on an annual coverage limit of 120 treatments. The estimated additional cost of providing such treatments, once or twice daily would be in the range of \$5,341,000 – \$10,682,000 for these 545 individuals. An additional administrative cost associated with such claims of 20 percent was added to arrive at an adjusted estimated range of \$6,409,200 – \$12,818,400. According to the Office of Insurance Regulation, there were 1,612,288 insureds in the large group market in 2002. These insureds may experience an increase in premiums in the range of \$3.98 – \$7.95 per year associated with the cost of mandating this chest physiotherapy benefit. Staff was unable to estimate the additional costs associated with the home health care benefit. In regards to the enteral formula benefit, data for three individuals provided by the Cystic Fibrosis Foundation indicated that the annual cost of such formulas ranges from \$607 - \$884. The estimated total cost of providing this benefit to 545 individuals was estimated to be in the range of \$396,978 – \$578,136 per year, after adjusting upward for administrative costs of 20 percent. This would result in an estimated increase in annual premiums in the large group market of \$0.25 - \$0.36 per policyholder in the large group market.

C. Government Sector Impact:

Representatives of the Division of State Group Insurance are not aware of any appeal denials regarding treatment for cystic fibrosis under the PPO Plan in recent years. Since the current number of insureds with cystic fibrosis in the State PPO Plan or State HMOs is indeterminate, the cost of this mandated benefit to the State is unknown.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

Pursuant to s. 624.215, F.S., every person seeking consideration of a legislative proposal, which would mandate health coverage by an insurer, health care service contractor, or health maintenance organization, shall submit to the legislative committees having jurisdiction a report, which assesses the social and financial impacts of the proposed coverage. Such a report was filed with the Banking and Insurance Committee.

---

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

---

## **VIII. Summary of Amendments:**

None.

---

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

---