HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1105 Cystic Fibrosis Treatment
SPONSOR(S): Patronis
TIED BILLS: **IDEN./SIM. BILLS:** SB 274

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Jobs & Entrepreneurship Council		Davis	Thorn
2) Policy & Budget Council			
3)			
4)			
5)			

SUMMARY ANALYSIS

This bill addresses health care coverage of cystic fibrosis, a progressive genetic disease that causes a range of symptoms primarily affecting the lungs and digestive system. This bill mandates certain health care coverage for cystic fibrosis.

Currently, some symptoms of cystic fibrosis are treated by most insurers, except where contractually excluded. There is disagreement about what types of services should be covered. This bill mandates that group health insurance policies and group health maintenance organization (HMO) contracts sold in this state provide all medically necessary chest physiotherapy provided by a license respiratory therapist, and certain other services and supplies if deemed medically necessary by the patient's treating physician or an insurer-authorized physician who specializes in the treatment of cystic fibrosis.

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 states that "the Legislature finds that this act fulfills an important state interest."

The fiscal impact of this bill to all insurance policies issued in this state is not known because there is a wide range of possible costs tied to frequency of the utilization of cystic fibrosis treatments. The increased frequency of treatment is expected to increase once cystic fibrosis treatments are mandated by statute, but the amount and costs associated with such a mandate is not adequately known at this time.

The bill applies to policies or contracts issued or renewed on or after the effective date of the bill, October 1, 2007.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government – This bill mandates certain insurance companies and HMOs to offer coverage for cystic fibrosis. The cost for this type of coverage would be spread among insurance providers and paid by policyholders.

B. EFFECT OF PROPOSED CHANGES:

BACKGROUND

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.[1] This 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 Cystic Fibrosis Foundation approximates that 30,000 people in the United States have cystic fibrosis. An additional ten million more people, which equals about 1 in every 31 Americans, are carriers of the defective CF gene; but, they do not have the disease. Cystic fibrosis is most common in Caucasian people, but it can affect all races. Approximately 40 percent of children with cystic fibrosis live beyond age 18; in 2005, the median age of survival was 36.5 years.

In Florida, Medicaid reports that claims have been paid for 4,081 recipients with cystic fibrosis as a primary or secondary diagnosis, as of January 31, 2007.

Medical Care for Cystic Fibrosis

The treatment of cystic fibrosis requires a comprehensive approach comprised of drugs, dietary supplements, and airway clearance techniques. 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 (2004) and the Cystic Fibrosis Foundation Website.[2] Of the almost 23,000 patients documented in the 2004 registry, 1,081, or 4.8% were from Florida. Only California, New York, Ohio, and Pennsylvania had higher percentages of patients in the registry, ranging from 5.3% to 8.2%.

Drugs -- An estimated 72.4 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 67.5 percent of all patients use TOBI, an antibiotic specifically designed for cystic fibrosis patients to minimize the frequency of infection. About 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, such as enteral formulas and prescription vitamins. In regards to the enteral

[1] Cystic Fibrosis Foundation website, available at http://www.cff.org/AboutCF/Faqs/#What_is_cystic_fibrosis?
[2] Report available at: http://www.cff.org/ID=4573/TYPE=2676/2004%20Patient%20Registry%20Report.pdf

formula benefit, data for three individuals provided by the Cystic Fibrosis Foundation indicated that the annual cost of such formulas ranges from $607 - $884. About 40 percent of patients with cystic fibrosis use supplemental feeding.

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 almost anyone. Older kids and adults can do their own ACTs."[3] 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, an HMO.[4] 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.[5]

The majority of these 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.

Cystic Fibrosis-Related Statutory Coverage

Currently, there is no specific health insurance mandate that requires the coverage of cystic fibrosis. Section 627.42395, Florida Statutes, 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 this coverage to apply, the formula must be for home use and prescribed by a physician as medically necessary. Such coverage is capped at $2,500 annually. In addition, the Florida 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.[6] Under the provisions applicable to group insurers, s. 627.6617, Florida Statutes, 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 2005-06, issued by the Agency for

[3] Cystic Fibrosis Foundation website, available at: http://www.cff.org/treatments/Therapies/Respiratory/AirwayClearance/

[4] 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.

[5] Lieu, Tracy, et. al., The Cost of Medical Care for Patients with Cystic Fibrosis in a Health Maintenance Organization, Pediatrics. 1999:103; 72-76.

[6] Section 627.6408, F.S.

Health Care Administration (AHCA or agency), Medicaid served over 2 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, age, and disability status.

Medicaid provides coverage for inpatient and outpatient hospital and physician services. Medicaid generally does not reimburse for over-the-counter (OTC) drugs, although some Medicaid managed care plans offer limited OTC coverage. 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 6 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. For fiscal year 2005-06, there were two adults in the program.

According to the AHCA, for fiscal year 2005-06, there were 4,081 recipients with Medicaid claims coded with a primary or secondary diagnosis of cystic fibrosis. The average cost per person for cystic fibrosis diagnosed recipients was $12,528 for the fiscal year. However, the number of cystic fibrosis recipients could be understated. The agency stated that they were unable to confirm that all the Medicaid recipients with a cystic fibrosis diagnosis have been identified because not all claim types require a diagnosis and for those claims that require a diagnosis, there might have been a reason other than cystic fibrosis for the visit or service. Also, the agency noted that data has only been pulled for primary and secondary diagnoses. Claims such as hospital claims can list more than one diagnosis, so more individuals might be included if all the diagnoses were included.

The Florida KidCare Program

The Florida KidCare Program was established in 1998 as a combination of Medicaid expansions and public/private partnerships, with a wrap-around delivery system serving children with special health care needs. The Florida KidCare Program is primarily targeted to uninsured children under age 19 whose family income is at or below 200 percent of the federal poverty level ($40,000 for a family of four in 2006). The Florida KidCare Program is outlined in sections 409.810 through 409.821, Florida Statutes.

As structured, Florida KidCare is an "umbrella" program that currently includes the following four components: Medicaid for children; Medikids; the Florida Healthy Kids Program; and the

Children's Medical Services Network (CMSN), which serves children with special health care needs. Family income level, age of the child, and whether the child has a serious health condition are the eligibility criteria that determine which component serves a particular child. Children with cystic fibrosis would be served through the CMSN, although funding may come through Title XIX (Medicare or Medicaid) or Title XXI (State Children's Health Insurance Program) of the Social Security Act.

Enrollment in the Florida KidCare Program was initiated on October 1, 1998, and 1,394,083 children were enrolled in the various components of the Florida KidCare Program as of February 2007. Of this total, 204,021 children are Title XXI eligible, 26,249 children are non-Title XXI eligible, and 1,163,813 children are eligible under the Medicaid Title XIX program.

State Employees Insurance Coverage

The Division of State Group Insurance of the Department of Management Services (DMS) contracts with Blue Cross Blue Shield of Florida to administer the state employees' Preferred Provider Organization (PPO) plan. The state also contracts with 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 agency must provide weekly reports to the treating physician and must provide detailed invoices for reimbursement, and providers of service must be licensed.

PROPOSED CHANGES

The bill creates a new section 627.6614, Florida Statutes, which requires that group health insurance policies sold in Florida provide coverage for all medically necessary chest physiotherapy provided by a respiratory therapist licensed under Part V of chapter 468, Florida Statutes. Coverage must also be provided for home health care, equipment, supplies, and enteral formulas described in section 627.42395 which are used to treat cystic fibrosis. These coverages are required if deemed medically necessary by the patient's treating physician or a physician authorized by the insurer who specializes in the treatment of cystic fibrosis. The group health insurer may require the policyholder to be responsible for any deductible or copayment that generally applies under the policy.

The bill also creates a new subsection (36), which applies to group HMO contracts sold in Florida, and requires the same coverage as that required under the new section 627.6614. The group HMO may require the subscriber to be responsible for any deductible or copayment that generally applies under the contract.

The bill amends section 627.6515(2)(c), Florida Statutes, which applies to out-of-state group health insurers who issue or deliver policies to Florida residents. The bill includes the new section 627.6614 (requiring group health insurance coverage of medically necessary chest physiotherapy and other medically necessary cystic fibrosis services and supplies) in the list of required coverages. Some of the other coverages included are: maternity[7] and newborn care;[8] surgical procedures and devices

[7] Section 627.6574, F.S.
[8] Section 627.6575, F.S.

incident to mastectomy;[9] mammograms;[10] osteoporosis screening, diagnosis, treatment and management;[11] and cleft lip and cleft palate.[12]

The bill provides a statement that the act satisfies an important state interest. The bill also states that the act shall take effect on October 1, 2007, and it applies to policies and contracts issued or renewed on or after that date.

C. SECTION DIRECTORY:

Section 1: Creates section 627.6614, Florida Statutes; requires that group health insurance policies sold in Florida provide coverage for all medically necessary chest physiotherapy and other medically necessary services and supplies.

Section 2: Amends section 641.31, Florida Statutes; redesignates present subsections (36), (37), (38), (39), and (40) as subsections (37), (38), (39), (40), and (41), respectively; creates a new subsection (36) which requires group HMOs to provide coverage for all medically necessary chest physiotherapy and other medically necessary services and supplies.

Section 3: Amends section 627.6515, Florida Statutes; includes new section 627.6614 in list of benefits of group health insurance policies issued or delivered outside this state under which a Florida resident is provided coverage.

Section 4: Provides that the act fulfills an important state interest.

Section 5: Provides an effective date of October 1, 2007; applies to policies renewed on or after that date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   This bill would impact the cost of state-provided group health insurance and require that cystic fibrosis be included in any such offered or renewed policy. As a result, the cost for state provided insurance could increase. However, the amount of the increase is indeterminate.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   This bill would impact the cost of local government-provided group health insurance and require that cystic fibrosis be included in any such offered or renewed policy. As a result, the cost for state provided insurance could increase. However, the amount of the increase is indeterminate.

[9] Section 627.6612, F.S.
[10] Section 627.6613, F.S.
[11] Section 627.6691, F.S.
[12] Section 627.66911, F.S.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The cost for private sector health insurance may increase by an indeterminate amount.

D. FISCAL COMMENTS:

AHCA reports that this legislation will have no fiscal impact on the agency.

DMS indicates that the cost of the legislation is indeterminate, but that it would incur a $67,860 cost for a mailout to all State Group Health Insurance Program enrollees in order to advise them of benefit changes.

The amount of increase to health policy premiums remains indeterminate. The increase in coverage of treatments may be offset by a decrease in hospitalizations.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

The mandates provision appears to apply because to this bill because it requires counties or municipalities to spend funds or to take an action requiring the expenditure of funds; however, an exemption applies if a bill contains a statement of important state interest and the provisions of the bill apply to all persons similarly situated. State government and all local governments, not just counties and municipalities, are subject to the screening coverage requirement, thereby satisfying one part of the exemption. Additionally, the bill contains a statement of important state interest; therefore, the bill does not require a two-thirds vote of the membership of each house.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

D. STATEMENT OF THE SPONSOR:

No statement submitted.

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES