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 Banking and Insurance Committee

BILL: CS/SB 1598

INTRODUCER: Committee on Banking and Insurance and Senator Peaden

SUBJECT: Mandated Offer of Health Insurance Coverage for Amino-acid-based Formulas

DATE: April 1, 2008 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Mays	Deffenbaugh	BI	**Fav/CS**
2.			HP	
3.			GA	
4.				
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	X	Statement of Substantial Changes
B. AMENDMENTS.....		Technical amendments were recommended
		Amendments were recommended
		Significant amendments were recommended

I. Summary:

This bill amends s. 627.42395, F.S., to require that health insurers make available to policyholders of individual, group, blanket, or franchise health insurance policies and all medically necessary amino-acid-based elemental formulas for the treatment of medically diagnosed conditions of severe multiple food protein allergies, gastroesophageal reflux, eosinophilic disorders, and short bowel syndrome, so long as such formulas are ordered by a licensed physician. Medically necessary treatments are further described. Experimental and investigational services are expressly not required to be covered. Pursuant to existing provisions in s. 627.42395, F.S., this mandated offering applies to all covered individuals, and allows for an appropriate additional premium to be charged to the policyholder.

This bill amends s. 641.31, F.S., to require health maintenance organizations (HMOs) contracts to make available similar coverage of amino-acid based elemental formulas as previously described for group and individual policies, however without any specificity on conditions to be covered.

This bill amends s. 627.6741, F.S., to require insurers issuing Medicare supplement policies to guaranty-issue coverage to an individual within 6 months after they become eligible for

Medicare due to having end stage renal disease, or until January 1, 2009, whichever is later. Such persons must also be enrolled in Medicare Part B to be entitled to this coverage.

The effective date of the bill is October 1, 2008.

This bill amends ss. 627.42395, 641.31, and 627.6741 of the Florida Statutes.

II. Present Situation:

Amino-acid Based Formulas

Amino-acid-based formulas are made of the simplest compositional units. These formulas, composed of specially engineered simplified proteins or 100 percent free amino-acids, are more easily digestible. Neocate (manufactured by Nutricia North America) and Elecare (manufactured by Abbott Laboratories) are two of the more widely known brands of amino-acid-based formulas.

Amino-acid-based formulas provide nutrition to those who suffer from malabsorptive and maldigestive medical conditions ranging from food protein allergies or gastroesophageal reflux to cerebral palsy or cystic fibrosis. Advocates claim the majority of use occurs in younger children with severe multiple allergies, short bowel syndrome, eosinophilic esophigitis (EE), and gastroesophageal reflux disease (GERD), and these conditions affect less than 1 percent of children 5 years of age or younger. The majority (98 percent) of children who use amino-acid-based formulas outgrow the reliance according to advocates study.[1] The National Institute of Allergy and Infectious Diseases estimate six to eight percent of children under the age of three suffer from general food allergies.[2]

Physicians typically order these formulas only as a treatment of last resort after attempting other specialized formulas. Amino-acid-based formulas are not only composed of the most basic digestible units, but are the more expensive and more unpleasant tasting option.[3]

Current law requires a mandated offering of coverage for prescription and nonprescription enteral formulas. Enteral feeding provides sustenance and nutrition to the patient directly through a tube into the stomach. Amino-acid-based formulas are covered under the current mandate in s. 627.42395, F.S. if delivered through the enteral tube as prescribed by a physician as medically necessary. There is an annual cap of $2,500 to cover a specific list of conditions through the age of 24 for enteral feeding. The weighted national estimated mean cost for enteral nutrition (tube feeding) and parenteral nutrition (intravenous feeding) (principle procedure only) based on 2003 data is $16,093.[4]

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[1] Children's MAGIC Inc. Report to the Legislature of the State of Florida and Florida Agency for Health Care Administration. March 2008.

[2] *See* "Food Allergy, An Overview," National Institute of Allergy and Infectious Diseases, Publication No. 07-5518 (July 2007); located on March 2, 2008 at http://www.niaid.nih.gov/publications/pdf/foodallergy.pdf

[3] Based on conversations between staff and advocates, physicians, and parents of children's using the amino-acid-based formulas.

[4] United States Department of Health and Human Services, Agency for Healthcare Research and Quality, HCUP.net Kids' Inpatient Database (for children aged 0-17); located on March 2, 2008 at http://hcupnet.ahrq.gov/HCUPnet.jsp.

The Women, Infants, and Children (WIC) and Nutrition program administered by the Department of Health covers the amino-acid-based formulas regardless of method of intake for eligible recipients. This coverage only extends for children up to the age of 5 with monthly limits for medically necessary conditions as ordered by a physician.

Florida Medicaid reimburses for amino-acid-based formulas regardless of the method of intake for eligible recipients under the age of 21. Medicaid has a service limit of 930 units (100 calories of formula per unit) per recipient per month. However, the coding system did not allow the Agency for Health Care Administration staff to determine the exact fiscal or total population impact of specifically the amino-acid-based formulas.[5]

The State Employees' PPO Plan administered by Blue Cross/Blue Shield of Florida (BCBSFL) covers the mandated benefit in accordance with s. 627.42395, F.S., but no orally administered formulas are included. Aetna, carrying over 1 million health insurance policies in the State of Florida, does not cover food supplements, specialized infant formulas, banked breast milk, vitamins or minerals taken orally unless mandated by state law.[6]

Children's MAGIC Inc. submitted the study required by s. 624.215, F.S. The report was prepared by the Collins Center for Public Policy, Inc., and by Dr. Christopher Douglas Jolley, M.D., University of Florida Department of Pediatrics. Children's MAGIC Inc. is a non-profit organization based out of Washington D.C. that is committed to coverage and reimbursement of amino-acid-based formulas. The organization is seed funded by Nutricia North America, the manufacturer of the amino-acid-based formula Neocate.[7]

According to the Children's MAGIC Inc. study, projected annual costs for a diet of amino-acid-based formulas were $5,075 per child. This is in comparison to normal formulas for a child that may range between $1,000 and $3,000 per year depending on the child's age, weight, and other factors. This study did not address the estimated costs for other populations who may receive amino-acid-based formula, such as those suffering from cerebral palsy.

Multiple states have enacted laws of varying degrees of specificity to cover amino-acid-based formulas. Additional states have currently pending legislation similar to this bill. Other state laws include annual dollar limits, age limitations, and specified medical conditions as some of the limiting and cost-containment provisions.

The 2008 Health Insurance Mandates in the States report issued by the Council for Affordable Health Insurance (CAHI) indicates the State of Florida currently has over 48 health insurance mandates, ranking Florida 13th highest in the nation.[8] However, the CAHI report does not have a specific category comparing coverage for amino-acid-based formulas regardless of method of intake between states.

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[5] Based on correspondence between staff and the Agency for Health Care Administration
[6] Aetna Clinical Policy Bulletin: Nutritional Support. Available online at www.aetna.com/cpb/medical/data/1_99/0061.html
[7] Children's MAGIC Inc. Website. www.childrensMAGIC.org
[8] "Health Insurance Mandates in the States 2008," Council for Affordable Health Insurance; located on March 2, 2008 at http://www.cahi.org/cahi_contents/resources/pdf/HealthInsuranceMandates2008.pdf.

Medicare Supplement Insurance

Medicare beneficiaries age 65 and older have the right under federal law to an open enrollment period in which to buy Medicare supplemental coverage. Those eligible for Medicare under the age of 65, who qualify based on disability or end-stage renal disease, do not have the same federal right. Medicare supplement coverage is commonly known as Medigap. According to the Florida Renal Coalition, only 8 percent of Americans with disabilities who are under the age 65 with Medicare have a Medigap policy, compared to 28 percent of those 65 or older with Medicare. A number of states have enacted legislation requiring insurers to offer enrollment in Medicare supplemental policies to varying degrees. Current Florida law requires Medicare supplemental polices be available to any individual eligible for Medicare who is 65 year of age and is enrolled in Medicare part B, either within 6 months of eligibility or within 2 months following termination of coverage under a group health insurance policy.

III. Effect of Proposed Changes:

Section 1 amends s. 627.42395, F.S. to revise the mandatory offering of coverage for certain prescription and nonprescription formulas, to require that health insurers make available to policyholders of individual, group, blanket, or franchise health insurance policies all medically necessary amino-acid-based elemental formulas for the treatment of medically diagnosed conditions of severe multiple food protein allergies, gastroesophageal reflux, eosinophilic disorders, and short bowel syndrome, so long as such formulas are ordered by a licensed physician. Medically necessary treatments are further described. Experimental and investigational services are expressly not required to be covered. Pursuant to existing provisions in s. 627.42395, F.S., this mandated offering allows for an appropriate additional premium to be charged to the policyholder.

Section 2 amends s. 641.31, F.S. to revise the mandatory offering of coverage for certain prescription and nonprescription formulas, to require that health maintenance contracts offer coverage for all medically necessary amino-acid-based elemental formulas for the treatment of medically diagnosed conditions *such as* (see Technical Errors, below) severe multiple food protein allergies, gastroesophageal reflux, eosinophilic disorders, and short bowel syndrome, so long as such formulas are ordered by a licensed physician. Medically necessary treatments are further described. Experimental and investigational services are expressly not required to be covered. Pursuant to existing provisions in s. 627.42395, F.S., this mandated offering allows for an appropriate additional premium to be charged to the policyholder.

Section 3 amends s. 627.6741, F.S. to require Medicare supplement insurers to guaranty-issue coverage to an individual within 6 months after they become eligible for Medicare due to having end stage renal disease, or until January 1, 2009, whichever is later. The individual must also be enrolled in Medicare Part B (which covers office visits) as a condition of being entitled to guaranty-issue. This effectively allows persons who are already covered by Medicare due to having end-stage renal disease as of the bill's effective date of October 1, 2008, to have a 3-month open enrollment period until January 1, 2009, to purchase a Medicare supplement policy on a guaranty-issue basis. The insurer may not discriminate in the premium for coverage issued to such persons.

Section 4 establishes an effective date of October 1, 2008.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The health insurance benefit required by this bill applies to local government health insurance plans.

Section 18(a), Art. VII of the State Constitution provides that a city or county is not bound by any general law requiring the city or county to spend funds or to take an action to expend funds unless the Legislature has determined that the law fulfills an important state interest and unless, for purposes relevant to this bill, the expenditure is required to comply with a law that applies to all persons similarly situated or the law requiring the expenditure is approved by two-thirds of the membership of each house of the Legislature.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

There will be a fiscal impact to health insurers and their policyholders from this mandated offer of coverage. The study done by Children's MAGIC Inc. estimated an increase in premiums of $0.02 per insured person in a health maintenance organization (HMO) or exclusive provider organization (EPO) per month. This estimate may be low for two reasons. The estimate is based on an increase in HMO premiums, not a preferred provider organization (PPO) or individual policy premium. Also, there are no age limitations in the bill, which make numbers from the study less significant, which were extrapolated from a WIC population of 5 years old or less.

An actuarial analysis from Blue Cross/Blue Shield of Florida (BCBSFL) estimated an increase of $0.47 per policyholder per month. The estimate from the BCBSFL actuary differs from that of Children's MAGIC based on assumptions included in their formula. The BCBSFL actuary used a prevalence rate of 3 children per 1000 with an annual cost

of $9,575. The prevalence rate and estimation of annual cost were taken from the Children's MAGIC Inc., website, Guidebook to Enacting Legislation.[9]

Persons who are covered by health insurance who suffer from severe multiple food protein allergies, gastroesophageal reflux, eosinophilic disorders, and short bowel syndrome, and other conditions that require amino-acid-based elemental formulas will be subject to lower out of pocket costs for such formulas that are not currently covered.

C. Government Sector Impact:

The expanded mandate will affect the State Employees' PPO Plan by increasing premiums to cover new services. Using the range of $0.02 to $0.47 increase per policyholder premium per month, the estimated fiscal impact for the State Employees' PPO Plan would be an increase of $49,200 to $1,156,200 per year for the approximately 205,000 policyholders.

Staff from the Division of State Group Insurance estimated the annual cost of this mandate to range from $58,000 to $336,000 for the $1.3 billion health insurance program. The estimates assume a plateau in utilization in populations covered to range from 5 years of age to 10 years of age based on manufacturer's recommendations. This bill does not provide any age limitations.

The Department of Management Services (DMS) noted other effects in their analysis of Senate Bill 1598, which cannot be determined:
Does not provide for age or dollar limitations;

- May require State Employees' PPO Plan to provide coverage for otherwise excluded food, medical food products or substitutes;
- The State Employees' Group Health Insurance Program may be required to remove or modify existing covered benefits, benefit limitations, exclusions, and inpatient day limitations.[10]

VI. Technical Deficiencies:

The CS for the bill changed the language of the conditions covered to a specific list of four conditions rather than coverage for conditions "such as" for specified conditions, in order to limit the scope of the coverage. The CS made this change to Section 1 for health insurers, but failed to make this change in Section 2 for HMO coverage.

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,

[9] Children's MAGIC Inc. website. Guidebook to Enacting Legislation. Available online at: http://www.childrensMAGIC.org/pages/pdfs/How percent 20To percent 20Guide percent 202008.pdf - Page 32 (Accessed on 3/20/08)
[10] Analysis prepared by the Department of Financial Services on HB 709.

which assesses the social and financial impacts of the proposed coverage. A report was filed addressing the specific items listed in this statute by Children's MAGIC Inc.

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 Banking and Insurance on April 1, 2008.

The CS changes the term, "such as" to "of" to limit the scope of the covered conditions to those listed in the bill.

The CS defined more clearly how the treatment must be medically necessary and appropriate, consistent with the person's symptoms, diagnosis, and condition, and may not be furnished primarily for the convenience of the person or provider.

The CS states that experimental or investigational services do not meet the criterion of medically necessary.

The CS broadens the mandated offering to include health maintenance organizations contracts, under the same requirements as all the other policies (individual, group, etc.). The conditions that may be covered by this bill are listed, "such as" meaning no specificity in conditions that will be covered, inconsistent with individual and group policies from section 1.

The CS expands the mandated population to be offered Medicare supplemental policies to include those eligible for Medicare due to end-stage renal disease who are enrolled in Medicare part B.

B. Amendments:

None.