

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 539 Health Insurance Coverage for Enteral Formulas
SPONSOR(S): Health Market Reform Subcommittee, Zika
TIED BILLS: IDEN./SIM. **BILLS:** SB 358

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Market Reform Subcommittee	14 Y, 0 N, As CS	Grabowski	Crosier
2) Appropriations Committee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Enteral formulas are medical foods used to replace or supplement the nutrition of patients unable to consume sufficient nutrients through a normal oral diet. Enteral feeding can be achieved by oral intake or by tube. Enteral feeding by tube refers to a tube or catheter that delivers nutrients beyond the oral cavity directly into the stomach or small intestine. Enteral tube nutrition is indicated for patients who have a functioning GI tract but cannot ingest enough nutrients orally because they are unable or unwilling to take oral feedings.

Florida law currently requires a mandated offering of coverage for prescription and nonprescription enteral formulas. 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.

HB 539 amends section 627.42395, F.S., clarifying that health insurance policies must make available coverage for prescription and nonprescription enteral formulas that are ordered or prescribed by physicians licensed pursuant to chapters 458 or 459, F.S., as medically necessary. The bill specifies that coverage for inherited diseases of amino acid and organic acid metabolism must include food products modified to be low-protein, in an amount not to exceed \$5,000 annually per individual, for insureds through the age of 30.

The bill specifies that these modified requirements apply to health insurance policies beginning on or after January 1, 2020.

The bill has an indeterminate negative fiscal impact on the Department of State Group Insurance and an indeterminate negative fiscal impact on local governments.

The bill has an effective date of July 1, 2019.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Enteral Formulas

Enteral formulas are medical foods¹ used to replace or supplement the nutrition of patients unable to consume sufficient nutrients through a normal oral diet. Enteral feeding can be achieved by oral intake or by tube. Enteral feeding by tube refers to a tube or catheter that delivers nutrients beyond the oral cavity directly into the stomach or small intestine. Enteral tube nutrition is indicated for patients who have a functioning GI tract but cannot ingest enough nutrients orally because they are unable or unwilling to take oral feedings.² These enteral feedings should not be confused with parenteral (or intravenous) nutrient formulations.³

Amino-acid-based formulas or elemental formulas are made of the simplest compositional units, and are easily digestible. 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. The National Institute of Allergy and Infectious Diseases estimates about 5 percent of children and about 4 percent of adults suffer from general food allergies.⁴

Enteral Formulas for the Treatment of Specific Diseases

Many conditions are associated with digestive deficiency or malabsorption, such as patients who rely on tube feeding for nutrition. Nutrition support therapy using enteral formulas and medical foods plays an important role in treating a host of conditions. Formulas are used for oral or tube feedings. Physicians typically order these formulas only as a treatment of last resort after attempting other specialized formulas.

Eosinophilic Disorders

These disorders are the result of a disorder of the immune system. Eosinophilic gastrointestinal disorders (EGIDs) are rare chronic diseases in which white blood cells, known as eosinophils, infiltrate the gastrointestinal tract and increase in number in the blood in reaction to food.⁵ Eosinophil-associated diseases are chronic and require long-term management. The symptoms may be debilitating, and may greatly impact a patient's quality of life. Treatment varies by the type of EGID and can include enteral formulas.⁶ Eosinophilic esophagitis (EE) is a chronic disorder of the digestive system in which large numbers of a particular type of white blood cell (called eosinophils) are present in the esophagus Some

¹ A medical food, as defined in section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)), is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."

² Merck Manual, Enteral Tube Nutrition, available at <https://www.merckmanuals.com/professional/nutritional-disorders/nutritional-support/enteral-tube-nutrition> (last visited on March 23, 2019).

³ U.S. Department of Health and Human Services Food and Drug Administration, *Food Guidance*, (May 2016) <https://www.fda.gov/downloads/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm500094.pdf> (last visited on March 23, 2019).

⁴ National Institute of Allergy and Infectious Diseases, *Food Allergy*, available at <https://www.niaid.nih.gov/diseases-conditions/food-allergy> (last visited on March 23, 2019).

⁵ International Foundation for Functional Gastrointestinal Disorders (IFFGD). Eosinophilic Gastroenteritis. Updated 17 January 2013; available at <http://www.iffgd.org/site/gi-disorders/other/gastroenteritis> (last visited March 23, 2019).

⁶ International Foundation for Gastrointestinal Disorders (IFGD), available at <https://iffgd.org/other-disorders/eosinophilic-gastroenteritis.html> (last visited March 23, 2019).

children who have eosinophilic esophagitis (EE) or EGID are highly allergic to certain foods and susceptible to recurrent episodes of the disorders.⁷ The nutritional quality of the foods they are permitted to eat is too limited to meet the needs for normal growth. As such, they remain dependent on specialized formulas to meet their nutritional requirements. For eosinophilic colitis, elemental diets and enteral formulas have been found to provide symptomatic relief for many patients.

Amino Acid and Organic Acid Metabolism Disorders and Other Disorders

Amino acid and organic acid metabolism disorders are genetic diseases that affect a body's metabolism, or ability to change food into energy. These disorders result from the body's inability to break down or use specific amino acids, ketones, proteins, vitamins, or carbohydrates, leading to a buildup of toxic chemicals and a shortage of other vital chemicals essential to normal body functioning. Untreated, these disorders may lead to brain, heart, liver or kidney damage, eye problems or vision loss, osteoporosis, intellectual or developmental disabilities, coma, seizures, or death. Infants are most often diagnosed with these disorders, through prenatal⁸ or newborn screenings; early diagnosis is essential to prevent damage caused by these disorders, and most patients will require lifelong management of their condition.⁹ Patients must eliminate and avoid certain foods, often including those high in protein, and many rely on enteral elemental or disease-specific formulas to meet their nutritional needs.

Food protein-induced enterocolitis syndrome is a rare type of food allergy that affects the gastrointestinal tract. It is a non-immunoglobulin E (IgE)-mediated gastrointestinal food hypersensitivity that manifests as profuse, repetitive vomiting, leading to dehydration and lethargy in the acute setting, or weight loss and failure to thrive in a chronic form. This disease primarily affects infants.¹⁰ Reactions typically occur 2 or more hours after ingesting certain foods.¹¹

Because of a lack of adequate pancreatic digestive enzymes, patients with exocrine pancreatic insufficiency have clinical symptoms related to malabsorption of fat. Exocrine pancreatic insufficiency is associated with diseases and conditions that affect the pancreas, including hereditary conditions, such as cystic fibrosis, or acquired conditions, such as chronic pancreatitis. For many of these patients, enteral nutrition is necessary to avoid malnourishment.¹²

Demand for Enteral Formulas

In 2013, an estimated 189,036 pediatric patients and 248,846 adult patients were receiving home enteral nutrition.¹³ One study in the United States reported the cost of home enteral nutrition, including feeds, supplies, and care, and one hospitalization stay range from \$5,000 to \$50,000. This cost is likely to have increased in recent years, although it is generally difficult to obtain expenditure information due to differences in insurance coverage and reimbursement.¹⁴

⁷ OLR Research Report, Insurance Coverage for Specialized Formula, 2012, available at <https://www.cga.ct.gov/2012/rpt/2012-R-0304.htm> (last visited March 23, 2019).

⁸ For example, phenylketonuria (PKU) and lipidoses. See Merck Manual, Consumer Version available at <https://www.merckmanuals.com/home/children-s-health-issues/hereditary-metabolic-disorders/disorders-of-amino-acid-metabolism> (last visited March 23, 2019).

⁹ Merck Manual, Phenylketonuria (PKU), available at <https://www.merckmanuals.com/home/children-s-health-issues/hereditary-metabolic-disorders/phenylketonuria-pku> (last visited March 23, 2019).

¹⁰ UpToDate, Food protein-induced enterocolitis syndrome, available at <https://www.uptodate.com/contents/food-protein-induced> (last visited March 23, 2019).

¹¹ *Id.*

¹² American Health and Drug Benefits, Is adequate nutrition cost-effective? (Mar. 15, 2019) available at <http://www.ahdbonline.com/issues/2018/may-2018-vol-11-no-3/2574-is-adequate-nutrition-cost-effective> (last visited March 23, 2019).

¹³ Nutr Clin Pract. 2017 Dec; 32(6):799-805.

¹⁴ *Nutrients*. 2018 Feb; 10(2): 214.

In the United States, approximately 11 percent of patients with cystic fibrosis (approximately 3300 individuals) required supplemental enteral nutrition in 2014.¹⁵ The direct costs of a new treatment for cystic fibrosis associated with enteral nutrition can range from \$80 to \$200 daily, considering the cost of the formula, tube-feeding supplies, and oral pancreatic enzymes.

The costs of formula to sustain a patient with phenylketonuria (PKU) is approximately \$86 per can and the can may only last for 4 days. Some of these formulas are required during an individual's entire lifespan.¹⁶

The availability and amount of insurance coverage, however, varies greatly among the states. In the United States, some studies estimate that 21 states mandate coverage for some type of elemental formula or coverage for specific conditions.¹⁷ Another study indicated that 38 states have enacted legislation that requires insurers to provide coverage for medical foods for at least PKU; over a third of these states require coverage for all inborn errors of metabolism.¹⁸ States generally provide coverage beyond age 18.¹⁹

Regulation of Insurers and Health Maintenance Organizations in Florida

The Office of Insurance Regulation (OIR) licenses and regulates the activities of insurers, HMOs, and other risk-bearing entities.²⁰ The Agency for Health Care Administration (agency) regulates the quality of care by HMOs under part III of ch. 641, F.S. Before receiving a certificate of authority from the OIR, an HMO must receive a Health Care Provider Certificate from the agency.²¹ As part of the certification process used by the agency, an HMO must provide information to demonstrate that the HMO has the ability to provide quality of care consistent with the prevailing standards of care.²²

All persons who transact insurance in the state must comply with the Code.²³ OIR has the power to collect, propose, publish, and disseminate any information relating to the subject matter of the Code,²⁴ and may investigate any matter relating to insurance.²⁵

Current State Law on Enteral Formulas

Florida law currently mandates an offer of coverage for prescription and nonprescription enteral formulas. 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.

Florida State Employee Group Insurance Program

Under the authority of s. 110.123, F.S., the Department of Management Services (DMS), through the Division of State Group Insurance (DSGI), administers the state group insurance program by providing employee benefits such as health, life, dental, and vision insurance products under a cafeteria plan consistent with s. 125, Internal Revenue Code. To administer the state group health insurance program, DMS contracts with third part administrators, HMOs, and a PBM for the state employees' prescription drug program pursuant to s. 110.12315, F.S.

¹⁵ Cystic Fibrosis Foundation. Patient Registry: 2014 Annual Data Report. www.cff.org/2014_CFF_Annual_Data_Report_to_the_Center_Directors.pdf/ (last visited March 23, 2019).

¹⁶ Correspondence from Department of Health, September 7, 2017 (on file with Senate Banking and Insurance Committee).

¹⁷ Approximately 20 states have enacted legislation mandating coverage for elemental formula, which is used to treat eosinophilic associated disorders, available at <https://apfed.org/> (last visited March 23, 2019).

¹⁸ Mol Genet Meta. 2012 September; 107(1-2):3-9.

¹⁹ *Id.*

²⁰ S. 20.121(3)(a), F.S.

²¹ S. 641.21(1), F.S.

²² S. 641.495, F.S.

²³ S. 624.11, F.S.

²⁴ S. 624.307(4), F.S.

²⁵ S. 624.307(3), F.S.

The prescription drug program has three cost-share categories for members: generic drugs, preferred brand name drugs, which are those brand name drugs on the preferred drug list, and non-preferred brand name drugs, which are those brand name drugs not on the preferred drug list.²⁶ The PBM for the prescription drug program updates the preferred drug list quarterly as brand drugs enter the market and as the PBM negotiates pricing, including rebates, with manufacturers.²⁷

The prescription drug program covers all federal legend drugs²⁸ for covered medical conditions, and employs very limited utilization review and clinical review for traditional or specialty prescription drugs.²⁹ Copayments and coinsurance for high deductible plans for each drug tier are the same for all members, as follows:³⁰

State Group Health Prescription Drug Co-payments		
Drug Tier	Retail Up to 30-Day Supply	Retail and Mail Up to 90-Day Supply and Specialty Medications
Generic	\$7	\$14
Preferred Brand	\$30	\$60
Non-Preferred Brand	\$50	\$100

Effect of Proposed Changes

HB 539 amends section 627.42395, F.S., clarifying that health insurance policies must make available coverage for prescription and nonprescription enteral formulas that are ordered or prescribed by physicians licensed pursuant to chapters 458 or 459, F.S., as medically necessary. The bill removes specific applicability of coverage for the following conditions, relying instead on the medical necessity criteria:

- Inherited diseases of amino acid, organic acid, carbohydrate, or fat metabolism; and,
- Malabsorption originating from congenital defects present at birth or acquired during the neonatal period.

The bill specifies that coverage of enteral formulas for inherited diseases of amino acid and organic acid metabolism must include food products modified to be low-protein, in an amount not to exceed \$5,000 annually per individual, for insureds through the age of 30.

The bill specifies that these new requirements apply to health insurance policies beginning on or after January 1, 2020.

The bill provides an effective date of July 1, 2019.

B. SECTION DIRECTORY:

Section 1: Amends s. 627.42395, F.S., relating to coverage for certain prescription and nonprescription enteral formulas.

²⁶ S. 110.12315(a), F.S.

²⁷ Department of Management Services, *2019 Agency Analysis of Senate Bill 358*, pg. 2, (March 6, 2019).

²⁸ "Legend drug" means a drug that is approved by the FDA and is available by prescription only. These drugs historically contained an inscription, or legend, denoting them as prescribed. Today, they typically state "Rx Only."

²⁹ Supra, FN 28.

³⁰ Id.

- Section 2:** Specifies that the bill applies to health insurance policies beginning on or after January 1, 2020.
- Section 3:** Provides an effective date of July 1, 2019.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill would have an indeterminate negative fiscal impact on the DSGI. The Department's contracted medical and pharmacy vendors would each incur additional costs due to the revised coverage requirements. The estimated impacts would vary by vendor based upon enrollment count and current utilization of enteral formulas.³¹

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

The bill would have an indeterminate negative fiscal impact on local governments, due to the expanded mandates for coverage of enteral formulas.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

The county/municipality mandates provision of Art. VII, section 18, of the Florida Constitution may apply if the bill requires local governments to spend funds. The bill requires health insurers and HMOs to cover enteral formulas when medically necessary and increases annual coverage limits for certain diseases, both of which could lead to spending by local governments; however, an exemption may apply because the bill applies to all persons or entities similarly situated (state, counties, and municipalities).

³¹ Supra, FN 27.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Current law provides OIR and DSGI with sufficient rule-making authority to execute the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 26, 2019, the Health Market Reform Subcommittee adopted an amendment to the bill. The amendment deletes specific directives to the Department of State Group Insurance (DSGI) for coverage of enteral formulas. The amendment also:

- Deletes the current law list of diseases for which coverage of enteral formulas is required, instead mandating coverage of the formulas when “medically necessary”; and,
- Increases the mandated annual dollar limit and age limit applicable to coverage of enteral formulas for diseases of amino acid and organic acid metabolism.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute as passed by the Health Market Reform Subcommittee