

**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.)

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Prepared By: The Professional Staff of the Committee on Banking and Insurance

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BILL: SB 358

INTRODUCER: Senator Stargel

SUBJECT: Health Insurance Coverage for Enteral Formulas

DATE: March 15, 2019

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

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Knudson	BI	<b>Favorable</b>
2.			GO	
3.			AP	

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**I. Summary:**

SB 358 requires the state group insurance program to cover prescription and nonprescription enteral formulas and amino-acid-based elemental formulas, regardless of the method of delivery or intake, for home use when ordered or prescribed by a licensed physician as medically necessary for the treatment of eosinophilic disorders, food protein-induced enterocolitis syndrome, inherited diseases of amino acid, organic acid, carbohydrate, or fat metabolism as well as malabsorption originating from congenital defects present at birth or acquired during the neonatal period. There are no annual dollar limits or age restrictions on such coverage.

Currently, Florida law requires coverage for the treatment of inherited diseases of amino acid, organic acid, carbohydrate, or fat metabolism, as well as malabsorption originating from congenital defects present at birth or acquired during the neonatal period. Coverage for inherited diseases of amino acids and organic acids must include food products modified to be low-protein in an amount not to exceed \$2,500 annually for any insured individual, through the age of 24.

Enteral formula can be a life-saving and life sustaining food for individuals that are unable to obtain adequate nutrition due to certain disorders. Enteral feeding can be achieved by oral intake or by tube. The costs of such formula can be significant and present a real financial hardship for families if they need to cover the expense of medical foods, and there can be medical consequences for children who require a specialized formula if that formula is no longer available to them for financial reasons.

The fiscal impact on the State Group Insurance program is estimated to be \$2,862,925.

## II. Present Situation:

### Enteral Formulas

Enteral formulas are medical foods<sup>1</sup> 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. These enteral feedings should not be confused with parenteral (or intravenous) nutrient formulations.<sup>2</sup>

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 6 to 8 percent of children under the age of three suffer from general food allergies.<sup>3</sup>

### 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.<sup>4</sup> 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.<sup>5</sup> 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 children who have eosinophilic

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<sup>1</sup> 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."

<sup>2</sup> 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 viewed Mar. 13, 2019).

<sup>3</sup> See "Food Allergy, An Overview," National Institute of Allergy and Infectious Diseases, Publication No. 07-5518 (July 2007), available at <http://www.niaid.nih.gov/publications/pdf/foodallergy.pdf> (last visited on April 9, 2008).

<sup>4</sup> International Foundation for Functional Gastrointestinal Disorders (IFFGD). Eosinophilic Gastroenteritis. Updated 17 January 2013; accessed 8 March 2016: <http://www.iffgd.org/site/gi-disorders/other/gastroenteritis> (last viewed Mar. 13, 2019)

<sup>5</sup> International Foundation for Gastrointestinal Disorders (IFFGD), available at <https://iffgd.org/other-disorders/eosinophilic-gastroenteritis.html> (last viewed Mar. 13, 2019).

esophagitis (EE) or EGID are highly allergic to certain foods and susceptible to recurrent episodes of the disorders.<sup>6</sup> 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. Phenylketonuria (PKU) is a disorder of amino acid metabolism that causes a clinical syndrome of intellectual disability with cognitive and behavioral abnormalities caused by elevated serum phenylalanine. The primary cause is deficient phenylalanine hydroxylase activity and treatment is lifelong dietary phenylalanine restriction.<sup>7</sup> 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 prenatal<sup>8</sup> or newborn screenings; early diagnosis is essential to prevent damage caused by these disorders, and most patients will require lifelong management of their condition.<sup>9</sup> 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.<sup>10</sup> Reactions typically occur 2 or more hours after ingesting certain foods.<sup>11</sup>

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

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<sup>6</sup> OLR Research Report, Insurance Coverage for Specialized Formula, 2012, available at <https://www.cga.ct.gov/2012/rpt/2012-R-0304.htm> (last viewed Mar. 13, 2019).

<sup>7</sup> Merck Manual, PKU, available at <https://www.merckmanuals.com/professional/pediatrics/inherited-disorders-of-metabolism/phenylketonuria-pku> (last viewed Mar. 13, 2019). Incidence rate is about 1/10,000 births among Caucasians.

<sup>8</sup> 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 viewed Mar. 13, 2019).

<sup>9</sup> Merck Manual, Phenylketonuria (PKU), available at <https://www.merckmanuals.com/home/children-s-health-issues/hereditary-metabolic-disorders/phenylketonuria-pku> (last viewed Mar. 13, 2019).

<sup>10</sup> UpToDate, Food protein-induced enterocolitis syndrome, available at <https://www.uptodate.com/contents/food-protein-induced> (last viewed Mar. 13, 2019).

<sup>11</sup> *Id.*

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.<sup>12</sup>

### **Insurance Coverage, Costs, and Demand for Enteral Formulas**

In 2013, an estimated 189,036 pediatric patients and 248,846 adult patients were receiving home enteral nutrition.<sup>13</sup> 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.<sup>14</sup>

In the United States, approximately 11 percent of patients with cystic fibrosis (approximately 3300 individuals) required supplemental enteral nutrition in 2014.<sup>15</sup> 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.<sup>16</sup>

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.<sup>17</sup> 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.<sup>18</sup> States generally provide coverage beyond age 18.<sup>19</sup>

### **Regulation of Insurance in Florida**

The Office of Insurance Regulation (OIR) licenses and regulates the activities of insurers, health maintenance organizations (HMOs), and other risk-bearing entities.<sup>20</sup> The Agency for Health Care Administration (agency) regulates the quality of care provided 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.<sup>21</sup>

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<sup>12</sup> 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 viewed Mar. 13, 2019).

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

<sup>14</sup> [Nutrients](#). 2018 Feb; 10(2): 214.

<sup>15</sup> Cystic Fibrosis Foundation. Patient Registry: 2014 Annual Data Report.

[www.cff.org/2014\\_CFF\\_Annual\\_Data\\_Report\\_to\\_the\\_Center\\_Directors.pdf/](http://www.cff.org/2014_CFF_Annual_Data_Report_to_the_Center_Directors.pdf/). Accessed April 27, 2018.

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

<sup>17</sup> 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 viewed Mar. 12, 2019).

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

<sup>19</sup> *Id.*

<sup>20</sup> Section 20.121(3)(a), F.S.

<sup>21</sup> Section 641.21(1), F.S.

### ***Current Insurance coverage for Enteral Formulas***

Florida law currently 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.

### **Coverage by the Women, Infants, and Children and Nutrition Program**

The Women, Infants, and Children (WIC) and Nutrition program administered by the Department of Health covers a wide variety of formulas that are available with an approved medical diagnosis and for specific health care conditions. Formula approvals will be considered for one or more of the following qualifying medical conditions:

- Premature birth will be considered a qualifying medical condition for children under 12 months of age (adjusted age) to receive a premature formula.
- Low birth weight will be considered a qualifying medical condition for infants under 6 months of age (adjusted age) to receive a high calorie formula.
- Inborn errors of metabolism and metabolic disorders.
- GER or GERD only with an additional qualifying medical condition.
- Immune system disorders.<sup>22</sup>

### **Division of State Group Insurance**

Under the authority of s. 110.123, F.S., the Department of Management Services, through the Division of State Group Insurance (DSGI), administers the state group health insurance program (program) under a cafeteria plan consistent with section 125, Internal Revenue Code. To administer the state group health insurance program, the Department contracts with third party administrators for self-insured health plans, a fully insured health maintenance organization (HMO), and a pharmacy benefits manager (PBM) for the state employees' self-insured prescription drug program pursuant to s. 110.12315, F.S.

The state employees' self-insured prescription drug program has three cost-share categories for members: generic drugs, preferred brand name drugs (those brand name drugs on the preferred drug list), and non-preferred brand name drugs (those brand name drugs not on the preferred drug list). Contractually, the PBM for the state employees' self-insured 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.

Generic drugs are the least expensive and have the lowest member cost share, preferred brand name drugs have the middle cost share, and non-preferred brand name drugs are the most expensive and have the highest member cost share. Generally, prescriptions written for a brand name drug, preferred or non-preferred, are substituted with a generic drug when available. If the

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<sup>22</sup> Florida Department of Health WIC Program Medical Documentation for Formula and Food, available at <http://www.floridahealth.gov/programs-and-services/wic/health-providers/documents/medical-documentation-formula-food.pdf> (last viewed Mar. 13, 2019).

prescribing provider states on the prescription that the brand name drug is “medically necessary” over the generic equivalent, the member will pay only the brand name (preferred or non-preferred) cost share. If the member requests the brand name drug over the generic equivalent, then the member will pay the brand name (preferred or non-preferred) cost share plus the difference between the cost of the generic drug and the brand name drug.

The program covers all federal legend drugs (open formulary) for covered medical conditions and employs very limited utilization review and clinical review for traditional or specialty prescription drugs. Specialty drugs are high-cost prescription medications used to treat complex, chronic conditions such as cancer, rheumatoid arthritis, and multiple sclerosis. Specialty drugs often require special handling (e.g., refrigeration during shipping) and administration (such as injection or infusion).

### III. Effect of Proposed Changes:

**Section 1** amends s. 627.42395, F.S., to revise the mandatory offer of coverage for prescription and nonprescription enteral formulas. The section clarifies that health insurance policies must make available coverage for prescription and nonprescription enteral formulas that are ordered or prescribed by physicians licensed pursuant to chs. 458 or 459, F.S., and 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 \$2,500 annually per individual.

The bill requires the state group insurance program to provide the following coverage:

- Prescription and nonprescription enteral formulas and amino-acid-based elemental formulas, regardless of the method of delivery or intake, for home use which are prescribed by a physician licensed under ch. 458 or ch. 459, F.S., as medically necessary for the treatment of:
  - Eosinophilic disorders;
  - Food protein-induced enterocolitis syndrome;
  - Inherited diseases of amino acid, organic acid, carbohydrate, or fat metabolism, or
  - Malabsorption originating from congenital defects present at birth, acquired during the neonatal period, or diagnosed later in life.

The coverage requirement for the state group insurance program does not provide an annual dollar cap on benefits or an age cap on insured individuals.

**Section 2** provides that the amendment to s. 627.42395, F.S., apply to health insurance policies and state group health insurance plans beginning on or after January 1, 2020.

**Section 3** provides an effective date of July 1, 2019.

### IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

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

None.

**C. Trust Funds Restrictions:**

None.

**D. State Tax or Fee Increases:**

None.

**E. Other Constitutional Issues:**

None.

**V. Fiscal Impact Statement:****A. Tax/Fee Issues:**

None.

**B. Private Sector Impact:**

Persons who are covered by the state group health insurance program, and who have from severe food allergies, eosinophilic disorders, and other conditions that require amino-acid-or elemental formulas will be subject to lower out of pocket costs for such formulas that are not currently covered or are subject to a \$2,500 annual limit or age 24eligibility limit. The reduction in costs and increase in coverage may result in better health outcomes for affected individuals.

**C. Government Sector Impact:**

The Division of State Group Insurance contacted its pharmacy benefit manager, CVS/caremark, its fully-insured vendor, and its third-party administrators for its self-insured plan. These vendors estimated the following fiscal impact of the bill:

- CVS: \$1,409,000 estimated annual average.
- Florida Blue: \$360,000 annually.
- Capital Health Plan: indeterminate.
- AvMed: \$104,028 annually.
- UnitedHealthCare: \$199,904.

The estimated total fiscal impact on the State Group Insurance program is \$2,862,925.

The estimated impacts by vendor vary based upon enrollment count and current utilization of enteral formulas.<sup>23</sup>

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<sup>23</sup> Department of Management Services, *Analysis of SB 358* (Jan. 23, 2019) (on file with Senate Committee on Banking and Insurance).

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Statutes Affected:**

This bill substantially amends section 627.42395 of the Florida Statutes.

**IX. Additional Information:**

**A. Committee Substitute – Statement of Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

**B. Amendments:**

None.