

**JOINT LEGISLATIVE AUDIT AND REVIEW COMMISSION
OF THE VIRGINIA GENERAL ASSEMBLY**

**EVALUATION OF PROPOSED
MANDATED HEALTH INSURANCE BENEFITS**

**Evaluation of House Bill 615
and House Bill 669: Mandated
Coverage of Amino Acid-Based
Formulas**

September 2008

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JLARC provides evaluations of proposed health insurance mandates in accordance with Sections 2.2-2503 and 30-58.1 of the *Code of Virginia*.

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Evaluation of House Bill 615 and House Bill 669: Mandated Coverage of Amino Acid-Based Formulas

JLARC SUMMARY

House Bill 615 of the 2008 General Assembly would mandate health insurance coverage for amino acid-based elemental formulas for various gastrointestinal (GI) and hypersensitivity diseases and disorders, and HB 669 of the 2008 Session would mandate coverage for amino acid-based formulas for inborn errors of metabolism (IEM) and certain GI conditions. The type of amino acid-based formula and the length of time used are specific to the disease or disorder. However, the precise conditions covered by the bills are unclear, as they would cover broad categories of GI and hypersensitivity conditions. Four similar mandates have been proposed in Virginia since 1999. The majority of states have mandates covering formulas for IEM. However, fewer states cover formulas for GI and hypersensitivity disorders.

MEDICAL EFFICACY AND EFFECTIVENESS

The medical efficacy and effectiveness of amino acid-based formulas are well established for certain conditions listed in HB 615 and HB 669; however, the bills also cover conditions for which the use is not standard medical practice. Few clinical trials exist for the use of metabolic formulas in IEM disorders, given the dire consequences of withholding treatment, but there is strong medical evidence for their use. Clinical trials show positive outcomes for the use of elemental formulas in treating eosinophilic esophagitis and Crohn's disease, and their use is standard medical practice for

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children. However, the use of amino acid-based elemental formulas is not primary treatment for other conditions covered by the bill.

SOCIAL IMPACT

Conditions requiring the use of amino acid-based formulas are relatively rare. Most individuals diagnosed with IEM treated with amino acid-based metabolic formulas are likely using them. An estimated less than one percent of those diagnosed with the hypersensitivity and GI conditions utilize amino acid-based formulas. Most health insurance companies do not provide coverage of the formulas. This may be a financial hardship because the formulas' cost could range from three to ten percent of median household income in 2008. Therefore, some individuals, including some adults with IEM, may not be receiving the necessary formula due to cost.

FINANCIAL IMPACT

The impact of HB 615 and HB 669 on premiums is expected to be in the range of other health insurance mandates. Overall, the proposed mandates may increase the total cost of health care in Virginia, primarily due to the inclusion of certain GI and hypersensitivity conditions for which amino acid-based formulas are not standard medical practice. Likewise, this may inappropriately increase the utilization rate of these formulas. Focusing the mandates on increasing the availability of formulas for those disorders for which amino acid-based formulas are medically necessary may modestly reduce the total cost of health care due to the reduction in adverse medical consequences.

BALANCING MEDICAL, SOCIAL, AND FINANCIAL CONSIDERATIONS

Amino acid-based metabolic formulas are the primary medical treatment for ten IEM disorders screened in Virginia, and amino acid-based elemental formulas are the primary treatment for certain severe GI and hypersensitivity conditions. HB 615 would mandate coverage of elemental formulas for GI and hypersensitivity conditions, but does not include coverage for IEMs. HB 669 would mandate coverage of amino acid-based formulas for IEMs as well as certain GI conditions, but does not include hypersensitivity conditions. Mandated coverage would help relieve financial hardship of those self-paying. However, both bills include coverage for conditions for which amino acid-based formulas are not standard medical practice. Limiting the mandates to coverage of conditions that medical practice guidelines recommend be treated with amino acid-based formulas would more directly meet patients' needs and would reduce the impact on insurance premiums.



Evaluation of House Bill 615 and House Bill 669: Mandated Coverage of Amino Acid- Based Formulas

This evaluation covers House Bill 615 (HB 615) and House Bill 669 (HB 669) from the 2008 General Assembly Session. HB 615 would mandate health insurance coverage for amino acid-based elemental formulas for various gastrointestinal (GI) and hypersensitivity diseases and disorders. HB 669 would mandate health insurance coverage for amino acid-based formulas for inborn errors of metabolism and certain GI diseases or disorders, including elemental and metabolic amino acid-based formulas.

BACKGROUND

Amino acid-based formulas are used to treat various conditions including inborn errors of metabolism (IEM) and certain hypersensitivity and GI diseases and disorders. The type of amino acid-based formula and the length of time it is used are specific to the condition. However, the precise conditions covered by HB 615 and HB 669 are unclear because the bills would cover broad categories of GI and hypersensitivity diseases and disorders. Four similar mandates have been proposed in Virginia since 1999. The majority of states currently have a mandate covering formulas for IEM, but fewer have mandates covering formulas for GI and hypersensitivity disorders.

a. Description of Medical Condition and Proposed Treatment

Several categories of medical conditions may require the use of amino acid-based formulas for treatment and nutrition. These conditions include IEM, GI, and hypersensitivity diseases and disorders. Two distinct types of amino acid-based formula are used to treat these conditions. Metabolic formulas are used to treat IEM disorders and elemental formulas are used for GI and hypersensitivity conditions. Both types of formula are referred to as amino acid-based formulas; however, they contain different ingredients, serve distinct medical purposes, and cannot be used interchangeably.

Inborn Errors of Metabolism. An IEM is an inherited metabolic disorder caused by a defect in a single gene that results in a missing or defective enzyme. The missing enzyme usually helps convert

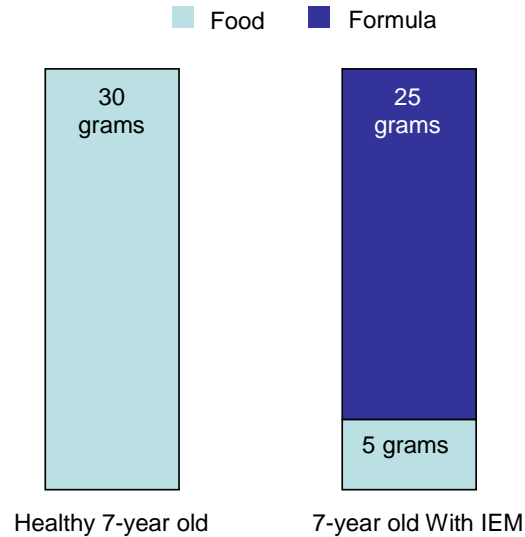
various substances, called substrates, into other substances, called products, some of which are used for protein synthesis or other biochemical processes. In an individual with IEM, the enzyme is not available to convert the substrate, so the substrate accumulates in the body where it becomes toxic to the system and impedes normal function. In some cases, an IEM can cause death.

The primary treatment for many IEMs is nutrition therapy based on a diet that severely restricts the substrate that is found to be toxic. Typically, meat, fish, eggs, dairy, and grains cannot be consumed; therefore, patients get most of their nutrition from medical foods, including formulas that are manufactured without the relevant substrate. Some IEM disorders, including organic acid disorders, may also require pharmaceuticals to prevent or reduce damage to the body. For these IEMs, pharmaceuticals are used in combination with formulas and a tailored diet.

Phenylketonuria (PKU) is the most common IEM disorder treated by nutrition therapy. In an individual with PKU, the body cannot process the substrate (an essential amino acid, in this case) called phenylalanine, commonly present in foods. If an individual with PKU consumes a typical diet, phenylalanine accumulates in the blood. The build-up of phenylalanine is toxic to the body, and can cause mental retardation, seizures, small head size, and other symptoms. An individual with PKU requires a diet very low in phenylalanine (the toxic substrate). Therefore, a small proportion of the diet consists of foods low in phenylalanine, while the majority consists of an amino acid-based metabolic formula manufactured without phenylalanine. This ratio is needed for complete nutrition and the exact ratio depends upon the individual's enzyme needs. Thus, an individual with PKU and other IEMs need chronic medical attention and monitoring. Figure 1 shows how formula is combined with food to achieve complete nutrition for a 7-year-old.

Many IEMs, including PKU, are identified shortly after birth through newborn screening. The Virginia Newborn Screening Services is a program of the Virginia Department of Health (VDH) that screens every infant born in the State for IEM as defined by §32.1-65 in the *Code of Virginia*. Newborn screening has been conducted since 1966 in Virginia, and in 2006 was expanded to include 28 disorders. Although there are more than 300 types of IEM, the *Code* dictates that the Virginia newborn screening panel be consistent with the screening panel recommended by the American College of Medical Genetics. The 28 disorders included in the newborn screening panel, which are screened by dried blood-spot through VDH, are listed in Appendix E.

Figure 1: Sources and Amounts of Protein Needed by Healthy 7-Year-Old Versus 7-Year-Old With Inborn Error of Metabolism



Source: Virginia Commonwealth University Metabolic Treatment Center.

Twenty-one of the 28 screened disorders are metabolic disorders, and 17 of these commonly are treated with formulas. Ten of the disorders, including PKU, are treated with amino acid-based formulas. Several other IEM disorders may be treated with amino acid-based formula on a case-by-case basis. IEM disorders are categorized based on the aspect of metabolism that is impaired. Types of IEM disorders included in the newborn screening panel are amino acid, fatty acid oxidation, organic acid, and other metabolic disorders. Amino acid disorders, including PKU and maple syrup urine disease, and most organic acid disorders are treated with amino acid-based formulas. Other IEMs are treated with fat-based or protein-free formulas. Fat-based or protein-free formulas would not be covered by either HB 615 or HB 669, both of which are restricted to amino acid-based formulas.

Importantly, an IEM is a lifelong condition. In order to function normally, individuals with IEM remain on formula for life. According to medical experts, the risk of mental retardation is a concern for all IEM disorders, but a greater risk for those with PKU and maple syrup urine disease. Although the risk of mental retardation decreases with age, after brain development is complete, medical professionals have noted symptoms such as behavioral issues (including abuse of self and others) in individuals with IEM who do not remain on formula. Also, formulas are important for pregnant women with IEM, especially those with amino acid IEMs and essential for those with PKU. Infants born to women with PKU who do not adhere to their special diet before and during pregnancy

have a 93 percent chance of mental retardation. Heart defects and other adverse consequences, such as death, are also possible.

Gastrointestinal and Hypersensitivity Disorders. HB 615 seeks coverage for amino acid-based elemental formulas for various GI and hypersensitivity diseases and disorders, while HB 669 seeks coverage for amino acid-based formulas primarily for IEM disorders, discussed above, and certain GI conditions. Medical experts noted that the language in both bills covers a broad array of disorders and identified some of the diseases and disorders that would be covered by the mandates. However, the list of conditions provided by medical experts is not exhaustive. Table 1 shows examples of GI and hypersensitivity conditions that may be covered by the language found in HB 615 and HB 669. One physician stated that nearly 100 diseases and disorders could be covered by the language

Table 1: Examples of Gastrointestinal and Hypersensitivity Diseases and Disorders Covered by HB 615 and HB 669

Disease or Disorder (Language from Bill)	Description of Disease or Disorder	Common Examples
House Bill 615		
Immunoglobulin-E (IgE) mediated allergy to multiple food proteins	Immediate allergic reaction, typically involves the skin, including swelling, hives, vomiting, and anaphylaxis.	-Type-I immediate hypersensitivity reaction -Anaphylaxis
Non-Immunoglobulin-E (non-IgE) mediated allergy to multiple food proteins	Hypersensitivity reactions occur hours to days after ingestion. Primarily involve the GI tract. Most disorders involve multiple foods.	-Milk-soy protein intolerance (MSPI) -Heiner Syndrome
Food protein-induced enterocolitis syndrome	A non-IgE mediated hypersensitivity reaction that causes inflammation of the small and large intestines. Symptoms include vomiting, diarrhea, and dehydration.	
Eosinophilic disorders	May be associated with food allergy, though the precise cause is often uncertain. Symptoms include chest pain, heartburn, abdominal pain, vomiting, and failure to thrive.	-Eosinophilic esophagitis -Eosinophilic gastroenteritis
Impaired absorption of nutrients caused by disorders affecting the absorptive surface, functional length, and motility of the GI tract	Disorders that affect the absorption function of the GI tract	-Short bowel syndrome -Crohn's disease -Severe celiac disease -Inflammatory bowel disease -Radiation enteritis
House Bill 669		
Disease or disorder of the GI tract that leads to malnutrition or malabsorption due to inflammation, protein sensitivity, or inborn errors of digestion	Diseases and disorders of the GI tract that lead to malnutrition or malabsorption issues	-Short bowel syndrome -Crohn's disease -Severe celiac disease -Inflammatory bowel disease -Radiation enteritis

Source: 2008 General Assembly, Virginia Commonwealth University physicians, and medical literature review.

in HB 615. Further, medical experts noted that some language in the bill is unclear. For example, they were not familiar with the term “inborn errors of digestion” found in HB 669.

A food hypersensitivity disorder results in an abnormal reaction to an ingested food protein or carbohydrate. A wide range of symptoms follows ingestion of the implicated food that can affect several organ systems including the skin, respiratory tract, cardiovascular system, and GI tract. Conditions caused by food hypersensitivities are classified into three groups based on the immunologic pathway involved: immunoglobulin-E mediated (IgE), non-immunoglobulin-E mediated (non-IgE), and mixed IgE/non-IgE mediated. IgE mediated food allergies typically result in an immediate allergic reaction that can involve the skin, GI tract, respiratory system, and cardiovascular system. Non-IgE mediated food allergies involve the GI tract and skin and occur hours to days after ingesting the food allergen.

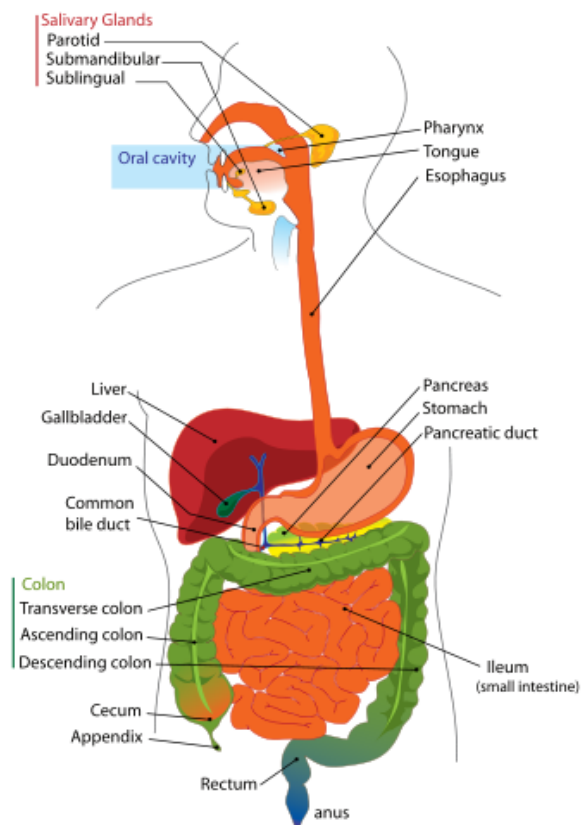
Although HB 615 would cover formulas for both IgE and non-IgE mediated hypersensitivities and related disorders, the impetus behind the bill appears to be non-IgE and mixed IgE/non-IgE disorders. IgE mediated allergies do not appear to utilize formulas in treatment. Food protein-induced enterocolitis syndrome is an example of a disorder affecting infants and young children that results from a non-IgE mediated hypersensitivity. It occurs shortly after consuming the food antigen, most commonly milk and soy formulas. Symptoms typically include vomiting, diarrhea, dehydration, and low blood pressure. The syndrome typically resolves by two to three years of age.

Eosinophilic disorders included in HB 615 can be associated with mixed IgE/non-IgE mediated food allergies and include eosinophilic esophagitis and gastroenteritis. Recognition of eosinophilic esophagitis has increased sharply during the last decade. It is an inflammatory condition in which the esophagus narrows and becomes rigid and tight, making swallowing difficult. The cause of eosinophilic esophagitis is not well understood, though the condition can be diagnosed by a biopsy of the esophagus. Its classification as a hypersensitivity rather than autoimmune disorder is based upon the improvement observed in many infants with the disorder after they are placed on elemental formula. However, in many cases, particularly in older children and adults, the cause is less clear.

Eosinophilic gastroenteritis is an infiltration of white blood cells from the immune system (called eosinophils) into the GI tract. Symptoms include abdominal pain, diarrhea, vomiting, and failure to thrive (poor weight gain and physical growth in infancy). The cause of eosinophilic gastroenteritis, in most cases, is not known.

Both HB 615 and HB 669 would cover amino acid-based formulas for certain GI conditions. The GI tract is the organ system that processes the foods that we eat through ingestion, digestion, absorption, and defecation. Organs in the GI tract include the tongue, esophagus, stomach, large and small intestines, and others (Figure 2). HB 615 would provide amino acid-based elemental formulas for GI disorders related to impaired absorption. HB 669 would provide amino acid-based formulas for diseases or disorders of the GI tract resulting in malnutrition or malabsorption caused by inflammation or protein sensitivity. The GI conditions covered by both bills are similar.

Figure 2: Human Gastrointestinal Tract



Source: Wikimedia Commons, <http://wikimediafoundation.org/wiki/Home>.

HB 615 and HB 669 would cover amino acid-based elemental formulas that are used for GI conditions such as Crohn's disease and short bowel syndrome. Crohn's disease is a chronic inflammation in the GI tract that causes diarrhea, abdominal pain, fever, weight loss, fatigue, and problems with the eyes, skin, and liver. Short bowel syndrome (SBS) or short gut syndrome is a malabsorption disorder caused by a shortened small intestine. SBS is usually

caused by surgical removal of the small intestine, but may be congenital, and usually develops when more than two thirds of the small intestine is lost.

Amino acid-based elemental formulas are used for treatment or nutrition primarily for children with the previously mentioned GI and hypersensitivity conditions. According to medical experts, the use of amino acid-based elemental formulas for certain hypersensitivity conditions depends in part upon the severity of the hypersensitivity and may be medically necessary on a case-by-case basis. For GI disorders, especially when digestion and absorption are compromised, amino acid-based formulas are used orally and other types of formula are used intravenously.

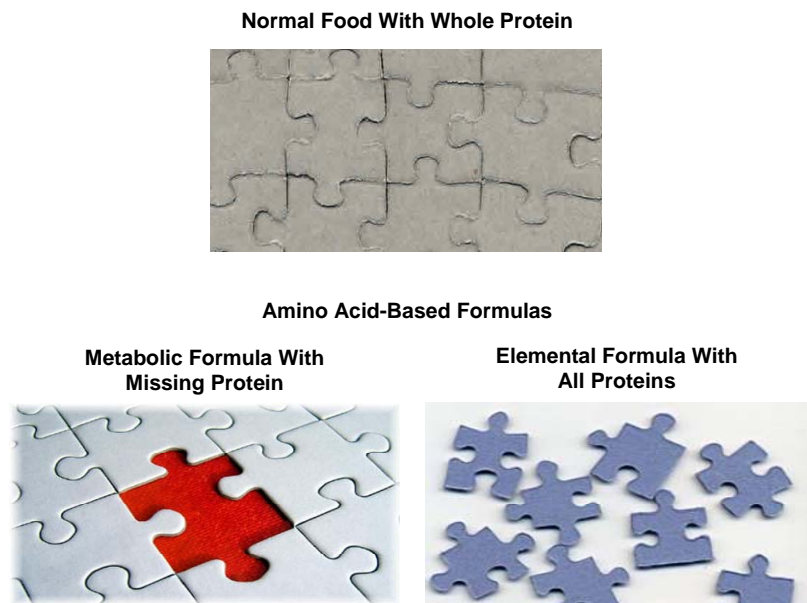
Certain hypersensitivity and GI conditions may result in adverse health consequences when elemental formulas are not utilized. Adverse consequences for children may include deteriorating overall health, poor nutrition, failure to thrive, physical growth failure, and poor weight gain. For example, GI disorders may result in small intestine failure in which the body cannot digest food. Elemental formulas are predigested so that the work required by the small intestine is minimal and, in many cases, the formulas are delivered through a feeding tube. According to a GI specialist, an individual with a failing small intestine may die without elemental formula. Health insurance coverage for elemental formulas via feeding tube is more common than by oral consumption.

In the case of the hypersensitivity conditions, elemental formulas are used primarily for infants and young children, and not adults. According to Children's Milk Allergy and Gastrointestinal Coalition (MAGIC), children typically need the formulas for a period of two years or less, and the majority of children outgrow their allergies or conditions by age five. However, GI conditions with impaired digestion and absorption, such as SBS, may affect individuals of any age. Both children and adults may use amino acid-based elemental formulas to treat these conditions, but according to medical practice guidelines, the formulas are only recommended as primary treatment for children. The duration of the formulas' use is uncertain and varies from weeks to years depending on the conditions and the individual.

Amino Acid-Based Metabolic Formulas Versus Amino Acid-Based Elemental Formulas. HB 615 and HB 669 seek to mandate coverage for two distinct types of amino acid-based formulas. HB 669 seeks coverage for amino acid-based formulas. As interpreted by JLARC staff and medical experts consulted for this study, this would include both amino acid-based metabolic and amino acid-based elemental formulas. HB 615 seeks coverage for amino acid-based elemental formulas. Amino acid-based metabolic formulas are used

for IEM disorders. Elemental formulas are used for certain food hypersensitivity and GI conditions. In metabolic formulas, a particular amino acid protein is removed from the formula, depending upon the type of IEM. In elemental formulas, the proteins are pre-digested and broken down into smaller pieces for easier digestion and absorption. Figure 3 presents a visual representation of the proteins in normal food compared to amino acid-based formulas. The complete puzzle shows the whole protein in normal food. Metabolic formulas are depicted as a puzzle with one piece removed, where the missing puzzle piece is the amino acid that cannot be processed by the body. Elemental formulas include all of the proteins, but they are broken into individual pieces for easier digestion.

Figure 3: Food Proteins in Normal Food and Amino Acid-Based Formulas: Elemental versus Metabolic Formulas



Source: VCU Metabolic Treatment Center.

Another difference between amino acid-based metabolic and amino acid-based elemental formulas is the need for a prescription to purchase the formulas. The use of amino acid-based metabolic formulas to treat IEM requires a prescription. Pharmacies and manufacturers cannot sell metabolic formulas without a prescription. Amino acid-based elemental formulas used for GI and certain hypersensitivity disorders are available for purchase through the manufacturers and pharmacies, but a prescription is not required. In order to gain health insurance coverage of the formulas, HB 615 would require a physician's written order stating medical necessity while HB 669 would require a prescription.

b. History of Proposed Mandate

Both HB 615 and HB 669 were introduced in the 2008 General Assembly. HB 615 would cover amino acid-based elemental formulas for GI and hypersensitivity disorders, while HB 669 would provide amino acid-based formulas primarily for inborn errors of metabolism and some GI disorders. The language in HB 615 appears to be derived from a model bill developed by Children's MAGIC, a national advocacy group. HB 669 is similar to legislation previously introduced in the Virginia General Assembly in 2002.

Four proposed mandates similar to HB 669 were previously considered by the Special Advisory Commission on Mandated Health Insurance Benefits (Advisory Commission). In all four cases the Advisory Commission voted against recommending adoption of the mandates, but rather recommended the expansion of existing programs offered through the Virginia Department of Health.

- In 1999, HB 2197 and HB 2199 were introduced to mandate coverage of low protein foods and medical formulas, respectively, prescribed for the treatment of individuals diagnosed with an IEM.
- In 2002, HB 84 mandated coverage for polypeptide-based or amino acid-based formulas prescribed for the treatment of an inborn error of amino acid or organic acid metabolism, GI/malabsorption disorders, or inborn errors of digestion.
- In 2004, HB 1216 mandated coverage for treatment of inborn errors of metabolism for which medically standard methods exist, primarily metabolic formulas.

There is some concern that the current mandates do not exclude nutritional supplements or naturally low protein foods purchased commercially and not developed for treatment purposes. Similar versions of the bill in 1999 and 2004 include an exclusion; however, this exclusion was not found in HB 84 (2002). HB 669 specifies that a prescription is required and HB 615 says that the formula must be medically necessary and ordered by a physician. While nutritional supplements or naturally low protein foods could be prescribed or ordered, HB 615 and HB 669 specify that coverage is for amino acid-based formulas.

Most states mandate coverage of amino acid-based formulas for inborn errors of metabolism; fewer states mandate coverage for GI and/or hypersensitivity disorders. Thirty-one states, including the District of Columbia, have mandated some insurance coverage of formulas or foods for disorders identified through newborn screening, although in seven states, statutes mention only medical foods. According to medical experts, metabolic formulas are considered

medical foods. The coverage varies based on the disorder, type of formula, age limits, and annual dollar amount of benefit. Unlike HB 669, most states cover all metabolic formulas used to treat IEMs, as opposed to only amino acid-based metabolic formulas. The eight states that cover elemental formulas for various GI and/or hypersensitivity disorders are Arizona, Connecticut, Illinois, Massachusetts, Minnesota, New Hampshire, New Jersey, and New York. The formulas must be medically necessary and require a physician's order.

c. Proponents and Opponents of Proposed Mandate

Proponents and opponents of HB 615 and HB 669 will have the opportunity to express their views at the Special Advisory Commission on Mandated Health Insurance Benefits public hearing on September 29, 2008. Proponents of HB 615 appear to be advocates for children with GI and hypersensitivity disorders who benefit from amino-acid based elemental formulas, such as Children's MAGIC. Proponents of HB 615 argue that the need for elemental formulas is rare and children who need them typically use them for two years or less. Further, children who do not receive the formula may face deteriorating health as a result, which may lead to surgery to insert a feeding tube. Proponents argue that health insurance often pays for elemental formulas in the case of a feeding tube and that surgery is much more expensive and invasive than providing formulas orally.

Proponents of HB 669 indicate that amino acid-based metabolic formulas for IEM disorders are the primary treatment, medically necessary, and not a regular foodstuff but a medical food. Further, formulas required for individuals with IEM are available through prescription only, and their use is monitored by physicians and registered dietitians. Children who do not maintain this diet are at risk for mental retardation and in some cases, death. Nationally, the American Academy of Pediatrics and American Public Health Association support mandated coverage of IEM formulas.

The main opposition to the mandates appears to be from the health insurance industry. The health insurance industry points out that Virginians have access to the formula distribution and purchase program through VDH. Although the program is limited to those with inborn errors of metabolism, the purchase program could be extended to those with conditions for which use of the formulas is deemed medically necessary. Additionally, industry representatives have expressed concern that the formulas serve as nutritional supplements for those with allergies, and are not medically necessary. Further, there is concern that the number of individuals covered by the mandates would be a large group of individuals due to the broad list of GI and hypersensitivity conditions

included in the mandates. Coverage of formulas for IEM has encountered less resistance from the health insurance industry in other states than coverage of formulas for GI and hypersensitivity conditions.

MEDICAL EFFICACY AND EFFECTIVENESS

The medical efficacy and effectiveness of amino acid-based formulas are well established for treating certain conditions listed in HB 615 and HB 669; however, the bills also cover certain conditions for which the use of formulas is not standard medical practice. HB 615 would mandate coverage for amino acid-based elemental formulas for GI and hypersensitivity diseases and disorders. HB 669 would mandate coverage for amino acid-based metabolic formulas for IEMs as well as elemental formulas for certain GI conditions. Few clinical trials have been conducted for the use of metabolic formulas in treating IEM disorders given the dire consequences of withholding treatment, but there is strong medical evidence for their use. Clinical trials show positive outcomes for the use of amino acid-based elemental formulas in treating multiple food protein allergies, eosinophilic esophagitis, and Crohn's disease. The use of elemental formulas is standard medical practice for treating these hypersensitivity and GI disorders in children, though alternative treatments also may be considered. However, the use of an amino acid-based elemental formula is not standard practice and may be considered an alternative treatment for other conditions covered by the bill, such as eosinophilic gastroenteritis and multiple food protein allergies.

a. Medical Efficacy of Benefit

For medical ethics reasons, there have been no randomized clinical trials on the use of amino acid-based formulas for individuals with IEM. However, clinical trials have demonstrated the efficacy of amino acid-based elemental formulas for some GI and hypersensitivity disorders.

Medical Efficacy

Assessments of medical efficacy are typically based on clinical research, particularly randomized clinical trials, demonstrating the success of a particular treatment compared to alternative treatments or no treatment at all.

Inborn Errors of Metabolism. Given the rarity of IEM and the potentially dire outcome of withholding treatment, no controlled, randomized clinical studies have been published on the efficacy of amino acid-based formulas for treatment of IEM. Most studies on the treatment of IEM are case studies. According to a report by the California Health Benefits Review Program, the lack of clinical trials studies for IEM disorders is not a concern because there is a single cause for the disorders, and the medical evidence and rationale for treatment are strong.

Gastrointestinal and Hypersensitivity Disorders. Clinical trials for the use of amino acid-based elemental formulas with GI and hy-

persensitivity disorders were identified for multiple food protein allergies, eosinophilic esophagitis, and Crohn's disease. JLARC staff did not identify clinical trials related to these formulas for food protein-induced enterocolitis syndrome, eosinophilic gastroenteritis, and the enteral use of formulas for short bowel syndrome.

A 1999 clinical trial of the use of elemental formula with 18 infants having multiple food protein intolerance, both an IgE and non-IgE hypersensitivity, and a hypersensitivity to extensively hydrolyzed formulas, supports the use of amino acid-based elemental formulas in treating multiple food protein allergies. All 18 infants showed improvement of symptoms within two weeks of beginning the amino acid-based formula. After treatment with the formula, a majority of the infants were able to resume consumption of cow's milk, soy milk, or extensively hydrolyzed formulas. Only three of the 18 infants required ongoing use of elemental formula after three years of age.

A clinical trial published in 1995 assessing the efficacy of amino acid-based elemental formulas in treating eosinophilic esophagitis (EE) showed resolution or improvement of symptoms in ten children. The ten children, with a mean age of five years, received the formula for six to 58 weeks. During the trial, eight patients became free from long-term symptoms and two showed substantial improvement. Upon completion of the formula trial, patients participated in an open food challenge to identify the offending food(s). After the food allergen was identified and eliminated from the patients' diets, all ten patients discontinued the use of amino acid-based formula and maintained a regular diet, other than offending food(s).

During a 2003 clinical trial of 51 children and adolescents diagnosed with EE, all but two of the patients improved on an amino acid-based elemental diet. Improvement was measured by the number of eosinophils found in the esophagus and a reduction in symptoms including vomiting, abdominal pain, and chest pain. The physicians who conducted the trial concluded that an elemental diet is an effective treatment for eosinophilic esophagitis, and in many cases may be the best of the available treatment options.

Various clinical trials have been conducted on the use of formulas for Crohn's disease; however, many trials have investigated the efficacy of other types of formulas (including polymeric formulas) and the effect of the formulas' fat content. A 1991 prospective randomized clinical trial of 30 patients with Crohn's disease investigated the effectiveness of an amino acid-based elemental versus polymeric formulas diet. Remission of symptoms occurred in 10 of the 15 patients on elemental formula and in 11 of the 15 patients on polymeric formula. Most patients relapsed during the year after

terminating the use of both formulas. The physicians concluded that oral administration of formulas, in general, is an effective therapy for promoting remission, but does not affect long-term outcomes for patients with Crohn's disease.

A 2007 controlled clinical trial studied the impact of long-term use of amino acid-based elemental formula on patients with Crohn's disease. The trial compared the use of an elemental formula diet versus non-elemental diet among 40 patients with Crohn's disease who recently underwent bowel obstruction surgery. One year after surgery the study found that the use of an amino acid-based elemental diet had significantly reduced recurrence of Crohn's disease.

b. Medical Effectiveness of Benefit

Medical treatment guidelines support the use of amino acid-based elemental formulas for some, but not all of the conditions covered by HB 615 and HB 669. Amino acid-based metabolic formulas are indicated for patients with IEM disorders, and elemental formulas are suggested for some GI and hypersensitivity conditions, particularly when they occur in children. However, amino acid-based elemental formulas are not recommended for all of the GI and hypersensitivity conditions covered by HB 615 and HB 669, particularly when they occur in adults.

Medical Effectiveness

Medical effectiveness refers to the success of a particular treatment in a normal clinical setting as opposed to ideal or laboratory conditions.

Inborn Errors of Metabolism. Medical experts consulted for this study indicated that amino acid-based metabolic formulas are very effective and medically necessary for individuals with any of ten specified IEM disorders. When patients diagnosed with an IEM do not adhere to the prescribed diet, including formulas, the consequences include mental retardation, a range of illnesses often leading to hospitalization, and, in some cases, death. According to medical experts, the daily intake of amino acid-based metabolic formulas combined with a restriction on whole protein (normal food) consumption has been the standard treatment for IEM disorders for decades. The amount of formula and whole protein depends upon the particular IEM disorder and the patient's age and body weight, and is prescribed by the physician.

Many IEM disorders utilize a combination of amino acid-based metabolic formulas and pharmaceuticals in treatment. Pharmaceuticals include high doses of specific vitamins that serve to supplement the body's missing enzyme. According to medical experts, the combination of formulas, whole protein, and pharmaceuticals produces the best outcomes for individuals with these IEM disorders. The proportions of each are prescribed and monitored by physicians and dietitians.

Lifelong management of IEM disorders and the use of amino acid-based metabolic formulas are monitored by physicians and are especially important for children and pregnant women. Strict adherence to the prescribed diet is important during brain development, or children face brain damage and mental retardation. According to a medical literature review, children with PKU who discontinued the prescribed formula diet showed a decreased developmental age and increased behavioral difficulties. Formula intake is also crucial for women with PKU before and during pregnancy. Elevated levels of phenylalanine in a pregnant woman with PKU who does not maintain the prescribed diet of amino acid-based metabolic formula cause mental and growth retardation and congenital heart disease in infants. Medical experts have also anecdotally noted that discontinuation of the prescribed formula diet impacts the social and behavioral function in adults with IEM disorders. Therefore, continued lifelong use of prescribed amounts of amino acid-based formulas is the medically recommended course of treatment for patients with IEM disorders.

Gastrointestinal and Hypersensitivity Disorders. For certain hypersensitivity and GI disorders, the medical literature reports that amino acid-based elemental formulas are not the first choice in treatment; however, elemental formulas are the mainstay treatment for other disorders (Table 2, which also indicates which disorders are included in which bill). Overall, the mainstay treatment for food allergies is prevention through avoidance of the foods identified as allergens. In rare cases of multiple food protein allergies among infants and children (as discussed in the previous section), there may be a need for elemental formulas when cow milk, soy milk, and extensively hydrolyzed formulas are attempted and are not effective.

According to the medical literature, the primary treatment for food protein-induced enterocolitis syndrome is avoidance of the food antigens. Since onset typically occurs in early infancy as a hypersensitivity reaction to cow or soy milk, formulas may be needed for children not old enough to consume solid foods. Extensively hydrolyzed formulas are recommended as the first choice for treating food protein-induced enterocolitis syndrome in children. Amino acid-based formulas are the recommended second choice, in the event that the child is not able to tolerate the hydrolyzed formulas.

Amino acid-based elemental formulas are used to treat eosinophilic esophagitis (EE) in children (and have been demonstrated as being effective in the previously discussed clinical studies), but are not considered a primary treatment for adults. According to 2007 medical practice guidelines, developing a treatment plan for EE is difficult due to the lack of evidence regarding the cause and long-

Table 2: Use of Amino Acid-Based Elemental Formulas to Treat Gastrointestinal and Hypersensitivity Diseases and Disorders in Children and Adults

Condition and House Bill	Child		Adult	
	Standard Treatment	Alternative Treatment	Standard Treatment	Alternative Treatment
Multiple food protein allergy, HB 615	X	✓	X	X
Food protein-induced enterocolitis syndrome, HB 615	X	✓	X	X
Eosinophilic esophagitis, HB 615	✓	✓	X	X
Eosinophilic gastroenteritis, HB 615	X	✓	X	X
Crohn's disease, HB 615 & HB 669	✓	X	X	X
Short bowel syndrome, HB 615 & HB 669	X	✓	X	X

✓= Indicates the recommendations of medical practice guidelines. X= Not supported by medical practice guidelines.

Note: Determination of formulas as standard or alternative treatment is based on medical literature and medical expert reviews; however, treatment with amino acid-based formulas should be made on an individual basis by a physician.

Source: Medical literature and medical expert review.

term impact of treatments. Studies have reported successful use of esophageal dilation in adults and topical and systemic corticosteroids in adults and children, although recurrence after discontinuation of treatment is common and the long-term use of systemic corticosteroids is not recommended. Long-term treatment with topical corticosteroids is a consideration. Nevertheless, medical practice guidelines indicate that the use of elemental formulas is an effective therapy for children. The use of elemental formulas has been shown to be extremely effective in 92 to 98 percent of children with EE. The effect of amino acid-based elemental formulas for adults with EE has not been studied.

The efficacy and long-term use of amino acid-based elemental formulas in treating eosinophilic gastroenteritis (EG) has not been well studied. Favorable outcomes have been observed for the use of corticosteroids and an elemental diet with EG. Elemental formulas have been useful for those with multiple food allergies, and patients showed improvement of symptoms in four to nine weeks. One study reported positive outcomes with the use of amino acid-based formulas in treatment for children with both eosinophilic gastroenteritis and an anemic disorder.

According to medical professionals, elemental formulas may be critical for certain GI disorders involving the small intestines. Elemental formulas are easier to digest and absorb since the proteins are broken down into the most basic elements. GI conditions

such as Crohn's disease and short bowel syndrome utilize amino acid-based elemental formulas under certain circumstances.

Amino acid-based elemental formulas are a primary treatment of Crohn's disease in children, but not adults. Treatment depends largely on the disease's stage, since it is not curable. The main goal of treatment is to control symptoms and improve the quality of life. The formulas are used to prevent and treat under-nutrition, improve growth and development, and improve quality of life. Corticosteroids are frequently used for adults with Crohn's disease; however, their long-term use has adverse effects on the physical and mental growth in children. Therefore, elemental formulas are the primary treatment for children during onset and the active stage of Crohn's disease.

There is also no cure for short bowel syndrome (SBS), and symptoms are treated with medications, vitamins and supplements, surgery, and formulas. The use of formulas, though not necessarily amino acid-based elemental formulas, is important to the medical management of individuals with SBS in order to provide adequate nutrition, and especially important for infants and children. However, formula feeding is most often delivered intravenously. Most patients with SBS require parenteral nutrition (intravenous feeding), especially initially, after surgery. Elemental formulas may be effective in shortening the duration of parenteral nutrition, and facilitating the transition to oral consumption by reducing symptoms such as diarrhea and vomiting.

According to U.S. medical practice guidelines, both elemental and semi-elemental formulas may be used to provide dietary protein in patients with SBS. Peptide-based formulas rather than amino acid-based formulas are often recommended for adults. Feeding recommendations for infants with SBS currently suggest extensively hydrolyzed formulas, but some studies of SBS in infants and children suggest that amino acid-based formulas may be more effective in severe cases. According to the medical literature, there is generally insufficient evidence that elemental formulas are preferred over other types of formulas for patients with SBS.

SOCIAL IMPACT

Conditions that require the use of amino acid-based formulas are relatively rare; PKU is the most common. Most, but not all, of those diagnosed with an IEM treated with amino acid-based metabolic formulas are likely using it. An estimated less than one percent of individuals diagnosed with the hypersensitivity and GI conditions listed in HB 615 and HB 669 utilize amino acid-based elemental formulas. The majority of health insurance companies do not provide coverage of amino acid-based elemental or meta-

bolic formulas. This may present a financial hardship because the cost of formulas could range from three to ten percent of median household income in 2008. Therefore, some individuals, including some adults with IEM, may not be receiving the necessary formula due to the cost.

a. Utilization of Treatment

The level of utilization of amino acid-based formulas depends on the condition for which it is used. The majority of patients with IEM receive metabolic formula although it appears that some adults do not have access to formulas due to cost. Also, it appears that only a subset of individuals, largely children, with the GI and hypersensitivity conditions covered by the mandates use amino acid-based elemental formulas. Estimates of the number of Virginia children using the formulas for GI or hypersensitivity conditions range from 327 to 503 (less than one percent of those diagnosed). Analysis of the number of children and adults using amino acid-based formulas is significantly less than one percent of Virginia's population.

Inborn Errors of Metabolism. IEM disorders are rare, but treatment of these disorders is medically necessary. Individuals who do not receive treatment risk serious adverse consequences such as mental retardation or death. Since newborn screening for IEM disorders began in Virginia in 1966, 136 newborns have been diagnosed with one of the ten IEM disorders which require treatment with amino acid-based formulas. However, this number probably underreports Virginians diagnosed with an IEM because newborn screening for seven of the ten disorders began in 2006. Other data sources indicate that the number is higher. For example, data from the State employee health plan indicate 200 individuals diagnosed with one of the ten IEMs that require amino acid-based metabolic formula receiving health insurance coverage through the plan in FY 2008. Amino acid-based metabolic formulas must be used throughout the patient's life; however, the number of Virginians requiring the formula may also vary from 136 as a result of individuals having died or moved in or out of State.

Gastrointestinal and Hypersensitivity Disorders. The number of individuals using amino acid-based formulas as treatment for GI and hypersensitivity disorders is not tracked at the State level; however, the level of utilization can be gleaned from other sources. For the majority of the GI and hypersensitivity disorders for which amino acid-based formulas are recommended by medical practice guidelines, the use of formulas is standard practice in children with the relevant disorder, but not adults. A report by Children's MAGIC estimates that between 327 and 503 children under five years old in Virginia rely on amino acid-based elemental formulas

for the treatment of GI and hypersensitivity disorders listed in HB 615 and HB 669 that utilize the formulas in treatment. The low end of this range (327) is based on a projected utilization rate using data from Virginia's Women, Infants, and Children (WIC) program. In December 2007, the WIC program provided elemental formulas to 68 infants and children. The high end of the range (503) is derived from an estimate from a specialist at Johns Hopkins School of Medicine that one to two percent of the 2.5 percent of children with milk allergies require amino acid-based elemental formulas.

Data from the Department of Medical Assistance Services (DMAS) and the State employee health plan indicate that the utilization rate of amino acid-based elemental formulas for the conditions covered in HB 615 and HB 669 is less than one percent for adults diagnosed with the conditions listed. Neither the State Medicaid nor employee health plan is typically subject to health insurance mandates. However, because both plans cover amino acid-based formulas for certain GI and hypersensitivity disorders when medically necessary, these data provide insight on the potential utilization of these formulas when covered. Even though utilization is low, the adult utilization rate for these formulas may be overstated because the analysis to determine the rate includes other types of formulas in addition to elemental formulas. Medical procedure codes used to identify formulas do not distinguish between elemental formulas and several other types of formula, like extensively hydrolyzed formula. As mentioned in the Medical Efficacy section, extensively hydrolyzed formulas are often the first choice in treatment for some GI and hypersensitivity conditions, and elemental formulas are used as an alternative treatment for severe cases.

Approximately 2,900 to 4,000 Virginia adults may use extensively hydrolyzed or elemental formula for treatment of GI and hypersensitivity conditions covered by HB 615 and HB 669, based on analysis of Medicaid utilization. According to data from DMAS, approximately 22,000 to 23,000 adults on Medicaid in State fiscal years (SFY) 2007 and 2008 were diagnosed with one or more GI or hypersensitivity conditions covered by HB 615 and HB 669. Among these adults, 16 in SFY 2007 and 11 in SFY 2008 received elemental or extensively hydrolyzed formula. Therefore, the utilization rate of these formulas for adults with the relevant conditions is 0.07 percent in SFY 2007 and 0.05 percent in SFY 2008, significantly less than one percent.

The State employee health plan provided coverage of either elemental or extensively hydrolyzed formulas for one adult and two children in FY 2007 and two adults and four children in FY 2008. In both FY 2007 and FY 2008, there were approximately 28,000 diagnoses of GI or hypersensitivity conditions in individuals re-

ceiving coverage through the State employee plan. (Individuals may be diagnosed with more than one condition.) Approximately 5,000 of these diagnoses fall in the category of conditions covered by HB 615 and HB 669. A portion of the remaining 23,000 diagnoses may be covered depending on how the language in the proposed mandates is interpreted.

b. Availability of Coverage

Among the top 50 insurance carriers in Virginia surveyed by the Bureau of Insurance (BOI), seven provide coverage of amino acid-based formulas as in HB 669 and four provide coverage of amino acid-based elemental formulas as in HB 615 as part of their standard benefit package. Four additional carriers indicated that coverage may be available for IEM and certain severe allergies with a physician's prescription, but did not consider the benefits listed in HB 615 or HB 669 as part of the standard benefit package.

Inborn Errors of Metabolism. Among the top 50 insurance carriers surveyed by BOI, seven of the responding carriers indicated that coverage of the benefits in HB 669 is available as part of the standard insurance package. However, two of these insurers qualified their responses. Representatives for these insurance companies indicated that patients with IEM for whom it is medically necessary to have treatment would have coverage for it; however, individuals with the GI conditions listed in HB 669 would not have coverage. In addition, four of the responding carriers indicated that coverage of conditions listed in HB 669 is not a standard benefit, but amino acid-based metabolic formulas for IEMs is a covered benefit.

Although the majority of insurance carriers report that they do not provide coverage for amino acid-based formulas for IEM disorders, medical professionals report that a proportion of patients with private health insurance are able to gain coverage for metabolic formulas after going through the carrier's appeals process. According to two of Virginia's metabolic treatment centers, approximately 50 to 70 percent of patients with an IEM have received coverage for the formulas through health insurance. They also report that mandating coverage would streamline the process by reducing staff time and the amount of paperwork involved in gaining coverage.

Gastrointestinal and Hypersensitivity Disorders. Among the top 50 insurance carriers surveyed by BOI, four of the responding carriers indicated that the benefit called for by HB 615 is available as part of the standard insurance package. However, four insurers who indicated that the benefit is not part of the standard package qualified their responses. Representatives for these insurance compa-

nies indicated that patients with severe soy and protein allergies for whom it is medically necessary to have treatment would have coverage for it.

c. Availability of Treatment/Benefit

The availability of amino acid-based formulas does not appear to be a problem, and JLARC staff did not identify any incidents in which individuals seeking to purchase the formulas were unable to purchase them. Amino acid-based metabolic formulas and amino acid-based elemental formulas are available for purchase from at least three sources: certain pharmacies, durable medical equipment (DME) providers, and directly from the manufacturer. Pharmacies do not stock metabolic formulas, but certain pharmacies may order them for customers. In addition, the manufacturer, and in some cases, the DME provider will ship the formulas to the individual's home. Elemental formulas are also available for purchase through pharmacies, DME providers, and the manufacturer.

d. Availability of Treatment Without Coverage

As previously discussed, amino acid-based formulas are widely available for purchase; however, the cost may be prohibitive for individuals and families in some cases, and insurance coverage of the formulas is not widely available. Those individuals enrolled in the 74 percent of responding health-care plans which indicated that they do not provide coverage for amino acid-based metabolic formulas and 90 percent that do not provide coverage for amino acid-based elemental formulas are required to pay out-of-pocket for needed formulas unless they are at or below 300 percent of the federal poverty level (FPL) and therefore qualify for a State program.

As mentioned, with IEM disorders, formulas are essential or individuals risk mental retardation or death. According to medical experts, most individuals with IEM have access to formulas, even without health insurance coverage. However, cases have been reported in which families cannot afford the formulas for their child or adult. Children with IEM who do not have access to formulas may suffer intellectual and developmental delays.

In the case of GI and hypersensitivity conditions, individuals may go without the formulas or the desired amount of formulas depending on the severity of the disease and cost of the formulas. This may result in adverse health consequences, such as failure to thrive, in some situations. According to medical experts, for certain conditions, such as GI disorders involving small intestinal failure, the consequences are more severe, and individuals likely obtain the formulas without coverage. Anecdotally, some parents have re-

ported having a feeding tube inserted in their child to obtain coverage because their health insurance covered enteral consumption of elemental formulas, but not oral consumption.

Two Virginia Department of Health (VDH) programs—the metabolic formula program and Care Connection for Children—provide free amino acid-based formulas for low-income children and individuals. One of these also offers a formula purchase program for those without health insurance coverage. The metabolic formula program has two tracks: (1) the formula distribution program provides free formula to individuals or families at or below 300 percent of the FPL and (2) the formula purchase program sells formulas at cost to individuals and families above 300 percent FPL who are uninsured or whose health insurance company has denied coverage. In 2007, three adults received free formula, five adults and two children received formula through the program that was paid for by Medicaid, and 13 individuals purchased at least one order of formula through the program.

The number of participants in the metabolic formula program decreased since the screening panel was expanded in March 2006. In March 2006, approximately 100 individuals participated compared to 23 in 2007. When the newborn screening panel was expanded in 2006, the metabolic formula program eligibility requirements also changed. Staff worked with program participants to transition them to existing formula programs (such as WIC, Medicaid, and Care Connection) or gain coverage for formula through private insurance. Staff at VDH also cite other reasons for the decline. First, VDH is a payer of last resort and refers children to Medicaid or Care Connection for Children (discussed below), if they are eligible for these programs. Second, several participants moved out of the State or chose to go off the formulas. Third, some participants found that the State's bulk purchase price for certain formulas was more expensive than ordering directly from the manufacturer.

Expansion of the VDH metabolic formula program was previously recommended by the Special Advisory Commission on Mandated Health Insurance Benefits. Expansion could include increased support to individuals with IEM and formulas for other disorders, such as GI and/or hypersensitivity conditions, that require amino acid-based formulas. However, expansion may not be feasible or desirable. First, as the Advisory Commission recognized with regard to its recommended expansion in 2002, increased State funding may not be available due to the current economic environment. Current funding for the metabolic formula program comes from federal dollars and revenue from the sale of newborn screening equipment. Second, there is no clear benefit for individuals to purchase formulas through VDH, because, as mentioned, the cost of amino acid-based metabolic formulas offered through VDH is often

more expensive than ordering directly from the manufacturer. Third, individuals with health insurance coverage must first apply for coverage for amino acid-based metabolic formulas and receive a denial letter in order to qualify for the formula purchase program. Medical professionals who work with these patients argue that eliminating this extra paperwork would leave substantially more time for treating patients.

Another VDH program, Care Connection for Children, also provides free formula for children at or below 300 percent FPL with a physical condition lasting longer than 12 months. The formulas must be medically necessary and have a physician's prescription. In 2007-2008, Care Connection provided metabolic formulas to 11 children statewide. Children with GI or hypersensitivity disorders may qualify for the program; however, no amino acid-based elemental formulas are currently distributed through this program.

e. Financial Hardship

The cost of amino acid-based formulas may be problematic for some individuals and is substantially more expensive than traditional baby formulas. Generally, the monthly cost of amino acid-based metabolic formulas appears to be comparable to the cost of elemental formulas; however, individuals with IEM remain on the formulas for life. Therefore, on average, lifetime costs for metabolic formulas would far exceed the cost of formulas for an individual with a GI or hypersensitivity condition. Also, because IEM disorders are hereditary, some families have more than one child that requires metabolic formulas. This may or may not be true of the various GI and hypersensitivity disorders.

Table 3 provides sample formula costs for a child, teenager, and adult with PKU. These costs may vary greatly since the amino acid-based formulas most commonly ordered by the VDH formula purchase program range from \$121 to \$446 per case. As shown in Table 3, annual costs for an individual using an amino acid-based metabolic formula at \$238 per case may range from approximately \$1,900 to \$4,750 for a child to approximately \$5,700 for an adult. These estimates may be low for individuals who require more expensive metabolic formulas.

The cost of elemental formulas is also significant and considerably more than the cost of traditional baby formulas. According to Children's MAGIC, children who use elemental formulas tend to stay on the formula for two years or less. Table 4 shows sample formula costs for a five-month-old baby with a hypersensitivity disorder versus formula costs for a healthy five-month-old. The monthly cost of elemental formulas is more than double the cost of tradi-

tional baby formulas and may be greater depending on the child’s age and medical condition.

Table 3: Sample Formula Costs for an Individual with PKU

Age	# Cans/Month	Monthly Cost	Annual Cost
Child	4-10	\$159-397	\$1,908-4,764
Teen	8-10	317-397	\$3,804-4,764
Adult	12	476	\$5,712

Note: Based on \$238 per case of six cans for Phenex-2 unflavored when purchased from the manufacturer. Type of formula varies based on IEM disorder, age, and physician prescription. Also, this table does not reflect the price mark-up of formulas purchased through a pharmacy.

Source: VCU Metabolic Treatment Center and Abbott Nutrition.

Table 4: Sample Formula Cost for a Five-Month-Old With a Hypersensitivity Disorder Requiring Amino Acid-Based Elemental Formula Versus an Infant Using Standard Baby Formula

	Elemental Formula ^a	Baby Formula ^b
Price per can	\$31.5	\$14.17
Reconstituted ounces per can	96 oz	96 oz
Feeding guideline, ounces per day / ounces per month	25-48 / 750-1440 oz	25-48 / 750-1440 oz
Number of cans per month	8-15	8 -15
Estimated monthly cost	\$252-473	\$113-213
Estimated annual cost	\$3,024-5,676	\$1,356-2,556

^a EleCare unflavored powder, at the manufacturer’s price of \$189 per case of six.

^b Similac Advance, at the manufacturer’s price of \$85 per case of six.

Note: Feeding guidelines for infants with GI and hypersensitivity conditions on elemental formula vary, and the amount is determined by the physician. In the absence of a standard guideline for these infants, the healthy infant guideline is used. However, the quantity of formula consumed by an infant with GI and hypersensitivity conditions is sometimes greater due to vomiting and diarrhea.

Source: Virginia Department of Health, Women, Infant, and Children program; Ross Laboratories; www.EleCare.com.

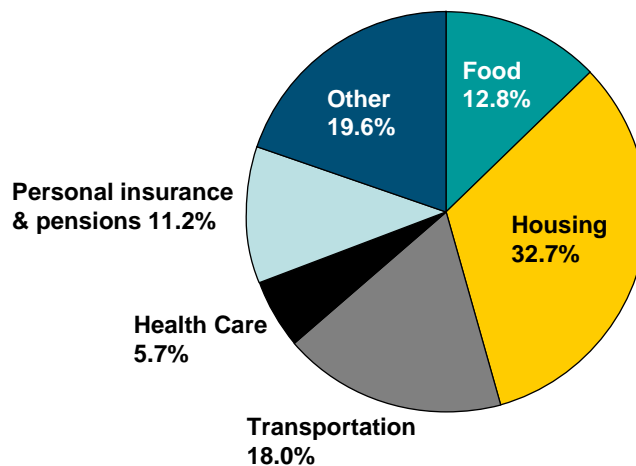
The financial hardship would be greatest for those above 300 percent of the FPL who do not have coverage for amino acid-based formulas. As mentioned, two State programs provide formulas to individuals who are at or below 300 percent FPL, in addition to Medicaid and WIC. According to medical experts working with IEM patients, middle-income families struggle the most with the cost of formulas.

Based on a median household income of \$58,607 in Virginia in 2008, the annual cost could range from 3.3 to 9.7 percent of median income for metabolic formulas and 5.2 to 9.7 percent for elemental

formulas. This is higher than the cost of traditional baby formulas, which takes up from 2.3 to 4.4 percent of median household income. These cost figures reflect only the cost of the formulas and do not include other medical treatments that may be necessary as a result of the disorders. For example, amino acid-based metabolic formulas are taken in combination with other foods and/or pharmaceuticals (see Figure 1).

As shown in Figure 4, health-care costs are estimated to be approximately 5.7 percent of total annual U.S. household expenditures. Therefore, the cost of amino acid-based formulas could be nearly double what households typically spend on health-care costs nationally. These costs would persist throughout an individual's lifetime for IEM disorders. In the case of GI and hypersensitivity disorders, these costs would persist for two years or less.

Figure 4: Distribution of Total Annual U.S. Household Expenditures by Major Category, 2005



Source: Bureau of Labor Statistics, Consumer Expenditure Survey, 2005.

Surprisingly, health insurance coverage may not provide a significant benefit for individuals needing amino acid-based formulas. Both medical experts and advocates note that costs remain high for those with insurance coverage of formulas. Providers of amino acid-based formulas available through health insurance companies' networks may mark up the price of formulas. For example, one patient used a metabolic formula that cost approximately \$160 per case when ordered directly from the manufacturer. However, the DME provider, which accepted the patient's insurance, charged \$380 per case for the same formula. Since the insurance pays for only a portion of the formula's cost, the patient's portion was similar to the manufacturer's price (\$160). Further investigation into this issue may be warranted, including whether there is a need for a maximum allowable charge of which the patient pays a portion.

f. Prevalence/ Incidence of Condition

IEMs are rare conditions, with PKU being the most common. The prevalence of GI and hypersensitivity conditions varies from extremely rare to much more common, depending on the condition. However, not all GI and hypersensitivity conditions use amino acid-based formulas as part of their treatment.

Incidence Rate
 The incidence rate is the number of new cases of a condition within a specified period of time.

Inborn Errors of Metabolism. National incidence rates for the general population are available for inborn errors of metabolism. Table 5 shows incidence rates for the ten IEM disorders screened by Virginia’s newborn screening program that use amino acid-based metabolic formulas in treatment. PKU is the most common IEM among these, with a rate of one in every 25,000 births. Homocystinuria is the least common nationally with a rate of one in every 150,000 births. Due to the genetic nature of IEM, certain IEM disorders may be more common among certain populations. For example, maple syrup urine disorder is more prevalent among Old Order Mennonites at a rate of one for every 150 to 176 births.

Table 5: Incidence Rates in the General Population for Inborn Errors of Metabolism That Utilize Amino Acid-Based Metabolic Formulas

Disorder	Incidence Rate
Phenylketonuria (PKU)	1:25,000
Citrullinemia (CIT)	1:57,000
Argininosuccinic Aciduria (ASA)	1:70,000
Glutaric Aciduria Type I (GA I)	1:75,000
Propionic Acidemia (PPA)	1:75,000
Methylmalonyl-CoA Mutase Deficiency (MUT)	1:75,000
Maple Syrup Urine Disease (MSUD)	1:100,000
Tyrosinemia Type I (TYR 1)	1:100,000
Isovaleric Acidemia (IVA)	1:100,000
Homocystinuria (HYC)	1:150,000

Source: Virginia Department of Health, Newborn Screening Services.

According to the VDH newborn screening program, 136 Virginia newborns from 1966 to 2007 were diagnosed with an IEM that requires amino acid-based formulas (Table 6). PKU is the most common IEM, with 118 Virginians diagnosed with PKU since 1966. Low numbers of infants in Virginia have been diagnosed with several of the other IEMs that require amino acid-based metabolic formulas. However, screening for most of these disorders was added to the panel in March 2006; therefore, statewide historical data are not available. Medical experts indicate that prior to the expansion of newborn screening some individuals were diagnosed with the newly screened IEMs when they became severely

ill. Other sources of data indicate that Virginians have been diagnosed with the newly screened IEMs.

Table 6: Newborns Diagnosed With Inborn Errors of Metabolism That Utilize Amino Acid-Based Metabolic Formulas Through Virginia’s Newborn Screening Program, 1966-2007

Disorder	Newborns Diagnosed in Virginia	
	Screened since 1966	
Phenylketonuria	118	
Maple Syrup Urine Disease	10	
Homocystinuria	2	
Screening began in 2006		
Citrullinemia	2	
Propionic Acidemia	2	
Isovaleric Acidemia	2	
Argininosuccinic Aciduria	0	
Methylmalonyl-CoA Mutase Deficiency	0	
Glutaric Aciduria Type I	0	
Tyrosinemia Type I	0	
Total	136	

Source: Virginia Department of Health, Newborn Screening Services.

Prevalence

The prevalence rate is defined as the total number of cases of the condition in the population in a specific time.

Gastrointestinal and Hypersensitivity Disorders. National prevalence rates for the GI and hypersensitivity disorders listed in HB 615 and HB 669 exist, but do not accurately reflect the number of individuals who would use amino acid-based elemental formulas for treatment of these conditions. National prevalence rates range from 50 per 100,000 individuals for eosinophilic esophagitis and Crohn’s disease to 8,000 per 100,000 children under five years of age for food allergies (Table 7). However, these conditions do not all necessarily utilize amino acid-based elemental formulas in treatment, and some conditions utilize formulas only for severe cases. For example, formulas for treating eosinophilic esophagitis are recommended for children, but not adults. As mentioned previously, Children’s MAGIC estimated 327 to 503 children under five years old may need amino acid-based elemental formulas in Virginia. In addition, an estimated 2,900 to 4,000 adults in Virginia may use extensively hydrolyzed or elemental formulas for GI and hypersensitivity conditions, based on data from the State employee health plan.

Table 7: Estimated Prevalence of Gastrointestinal and Hypersensitivity Disorders in Virginia, 2006

Disorder	National Prevalence Rate	Estimated Prevalence in Virginia
Food allergy, children under 5 years	8,000:100,000	40,717
Food allergy, adults	2,500:100,000	145,901
Food protein-induced enterocolitis syndrome	Unknown ^a	Unknown
Eosinophilic esophagitis	50:100,000	3,821
Eosinophilic gastroenteritis	Unknown ^a	Unknown
Short bowel syndrome	Unknown ^b	Unknown
Crohn's disease	50:100,000	3,821

^a According to medical literature, no prevalence rate has been established because of the rarity of the condition.

^b According to medical literature, prevalence is not available for all short bowel syndrome patients but is limited to those on home parenteral support.

Source: U.S. Census Bureau and medical literature review.

g. Demand for Proposed Coverage

The number of patients demanding coverage of amino acid-based metabolic formulas for IEMs is low due to the relatively low number of individuals diagnosed with this disorder. However, there have been multiple bills similar to HB 669 previously introduced seeking coverage for these disorders, and the metabolic treatment centers, as well as VDH, report actively working with patients' insurance companies to obtain coverage. Assessing the demand for coverage for individuals with GI and hypersensitivity disorders is difficult due to the broad range of disorders covered in the bills. However, mandated coverage could result in increased levels of demand, as a result of the inclusion of conditions for which amino acid-based elemental formulas are not standard medical practice.

h. Labor Union Coverage

Labor unions do not appear to have advocated specifically for the inclusion of this benefit in their health benefit packages. Typically, labor unions advocate for broader benefits, rather than a benefit as specific as the proposed mandate.

i. State Agency Findings

There do not appear to be any State agency reports or findings on the use of amino acid-based formulas as treatment for the diseases and disorders listed in HB 615 or HB 669. As previously mentioned, the BOI reported to the Advisory Commission in 2000, 2003, and 2005 on mandated coverage for formulas used in the

treatment of IEM and/or GI disorders. In all cases, the Advisory Commission recommended expansion of the VDH formula program rather than mandated coverage.

j. Public Payer Coverage

One VDH program offers amino acid-based metabolic formulas, and another VDH program as well as Medicaid and WIC cover amino acid-based formulas for both IEM and GI and hypersensitivity disorders. As previously discussed, the metabolic formula program offers amino acid-based metabolic formulas for children and adults, while Care Connection for Children offers both types of amino acid-based formulas for children at or below 300 percent FPL. The metabolic formula program also offers a purchase program for those above 300 percent FPL who are unable to gain health insurance coverage for the formulas.

In addition to the VDH programs, both Medicaid and WIC provide amino acid-based formulas for certain conditions. Medicaid provides amino acid-based formulas for individuals with IEM disorders, and for GI and hypersensitivity conditions when the use is adequately justified by a physician. In SFY 2007, Medicaid provided coverage for amino acid-based formulas for 41 children with IEM disorders and either amino acid-based or extensively hydrolyzed formulas for approximately 3,750 children with GI and hypersensitivity disorders through the Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) program. Medicaid coverage of amino acid-based formulas for adults is through the HIV/AIDS waiver and Durable Medical Equipment programs. In SFY 2007, four adults received amino acid-based formulas for IEM, and 16 adults received either amino acid-based or extensively hydrolyzed formulas for GI and hypersensitivity conditions.

Children under five years of age with GI and hypersensitivity disorders may be eligible to receive amino acid-based elemental formulas from the WIC program through VDH. In December 2007, 68 children received amino acid-based elemental formulas through WIC. Infants and children at or below 185 percent FPL are eligible for WIC.

k. Public Health Impact

The overall public health impact of mandating coverage in HB 615 and HB 669 would be small in terms of Virginia's population due to the low incidence and prevalence of these disorders that utilize amino acid-based formulas. Further, the benefits of the proposed legislation would be received primarily by the patients diagnosed with IEM and certain GI and hypersensitivity diseases and disorders. For individuals with these disorders, a lack of access to

Public Health

The role of public health is to protect and improve the health of a community through preventive medicine, health education, and control of communicable diseases.

needed formulas would create a significant need for services due to adverse consequences like mental retardation. As mentioned previously, some individuals with IEM may not have access to formula; however, these individuals appear to be adults. To the extent that the proposed mandate may increase the cost of health insurance, and thereby increase the number of uninsured patients, there could be a negative public health impact. However, as described in the next section, the financial impact of the proposed mandate would likely be modest.

FINANCIAL IMPACT

The impact of HB 615 and HB 669 on premiums is expected to be in the range of other health insurance mandates, which is estimated to range from 0.02 to 5.30 percent depending on the mandate and type of contract. However, overall the proposed mandates may increase the total cost of health care in Virginia, primarily due to the inclusion of certain GI and hypersensitivity conditions for which amino acid-based formulas are not standard medical practice. Likewise, the inclusion of certain disorders may inappropriately increase the utilization rate of these formulas. If the conditions for which amino acid-based formulas serve as an alternative or are not standard medical practice were eliminated, the impact on premiums could be minimized and utilization of the formulas would decrease. In addition, focusing the mandates on increasing the availability of formulas for those disorders for which amino acid-based formulas are medically necessary may modestly reduce the total cost of health care as a result of the reduction in adverse medical consequences. The proposed mandates would not change the cost of metabolic formulas used to treat IEM, and utilization may increase slightly.

a. Effect on Cost of Treatment

The potential impact of the proposed mandates on the cost of amino acid-based formulas is unknown, but no increase is expected. In the case of metabolic formulas, the majority of patients, especially children, are likely already utilizing the formulas. According to medical experts at two of Virginia's metabolic treatment centers, from five to 17 percent of their patients currently pay out-of-pocket for formulas, although most have private health insurance coverage. In the case of children with IEM, establishing a mandate largely will likely only change the payer. The same is true for amino acid-based elemental formulas for children with certain severe GI and hypersensitivity disorders because individuals face dire adverse consequences in the absence of use.

b. Change in Utilization

Mandating coverage of amino acid-based formulas will not increase the number of patients with IEM, GI, and hypersensitivity diseases and disorders for which the formulas would be deemed medically necessary. However, mandating coverage could increase the number of individuals that have access to amino acid-based formulas covered by private insurance, thereby perhaps increasing the utilization rate when prescribed or ordered as a course of treatment. In some cases, families who could not afford the recommended level of amino acid-based formulas may increase their utilization as a result of the mandates. However, one concern with HB 615 and HB 669 is that amino acid-based formulas would be prescribed or ordered by physicians for GI and hypersensitivity disorders for which they are not standard medical treatment. If this were to occur, the utilization rate may increase proportionately to the over-prescribing of the formulas.

Utilization of amino acid-based formula for individuals with IEM disorders may increase slightly, although in most cases, a mandate will only change the payer. According to medical experts at two of Virginia's metabolic treatment centers, approximately five to 17 percent of their patients currently pay out-of-pocket for the formula, although, most have private health insurance coverage. The majority of patients with IEM, especially children, are likely already utilizing the formulas due to the severe adverse consequences. However, the metabolic treatment centers also report that, in each case, a small number of adult patients choose not to purchase the formula due to cost.

c. Serves as an Alternative

According to metabolic medical experts, formulas are the primary and most effective treatment for IEM. For IEM, any alternative to the formulas is mismanagement of the disease. As of December 2007, a new drug, sapropterin (Kuvan), is approved for individuals with PKU. It is estimated that Kuvan may be effective for 25-33 percent of patients with PKU. Kuvan would not be a "stand-alone" treatment for PKU, but used in conjunction with amino acid-based metabolic formulas.

The alternative to amino acid-based elemental formulas is other types of formulas, steroids, or surgery for certain GI and hypersensitivity conditions. Families and Children's MAGIC also report anecdotally that mandating coverage would allow some children to consume elemental formulas orally rather than through a feeding tube. In some cases, amino acid-based elemental formulas are used as a second or alternative treatment to other formulas:

- Extensively hydrolyzed formulas are the first choice for children with food protein-induced enterocolitis syndrome, and amino acid-based elemental formulas are used for children with severe cases who are not able to tolerate the hydrolyzed formulas.
- Extensively hydrolyzed formulas are the first choice for children with short bowel syndrome, and amino acid-based elemental formulas are recommended for severe cases.
- Amino acid-based elemental formulas are a primary treatment for children with eosinophilic esophagitis and Crohn's disease, but not for adults with the conditions.

With some conditions, elemental formulas would be an alternative that is not currently recommended as the primary treatment by medical practice guidelines such as multiple food protein allergies, food protein-induced enterocolitis syndrome, eosinophilic gastroenteritis, and short bowel syndrome when diagnosed in children (Table 2). Importantly, for certain severe cases of these conditions, elemental formulas may be the only treatment for children, when other formulas have failed. However, in the case of GI and hypersensitivity conditions included in this study, elemental formulas are not commonly used in the treatment of adults.

The use of amino acid-based formulas, when recommended by medical practice guidelines, serves as a primary medical treatment. Examples include IEM disorders, eosinophilic esophagitis and Crohn's disease in children, and certain severe cases of GI and hypersensitivity conditions. According to medical experts, amino acid-based formulas, when medically necessary, are not foodstuff, but a medical food used in treatment.

d. Effect on Providers

Mandating insurance coverage of amino acid-based formulas is not expected to impact the availability of the formulas. At least 167 DME providers throughout the State order formulas, certain pharmacies will special-order formulas, and individuals can order directly from the manufacturer. In some cases, particularly IEM disorders, mandating coverage may only slightly increase the utilization of amino acid-based formula.

e. Administrative and Premium Costs

Administrative costs of the proposed mandate would likely be similar to other mandates. Premium estimates were gathered by the Bureau of Insurance through a survey of health insurers. Median monthly premium estimates for coverage of HB 615 range from \$0.34 to \$2.61. For coverage of HB 669, median monthly premium

Impact of Premiums on Employers' Decisions to Offer Health Insurance

“Elasticity of offer” indicates how sensitive employers are to changes in premiums in their decisions to offer health insurance. The Congressional Budget Office and others have reported an elasticity of offer of approximately -0.25 across all employers, meaning that a 10 percent increase in the average premium is predicted to decrease the likelihood of an employer offering health insurance by about 2.5 percent. Small employers are more sensitive to price and have a higher elasticity of offer. In addition to premiums, other factors affect employer decisions to offer health insurance including the availability of public coverage such as Medicaid, non-group coverage alternatives for employees, the industry, and the employer’s location.

estimates range from \$0.34 to \$1.61. A low response rate may limit the usefulness of estimates of premium costs. This is particularly true of individual optional coverage estimates because they were only provided by two insurers. The median premium estimates at the low end of the range appear to be similar to existing mandates.

Administrative Expenses of Insurance Companies. The administrative expenses for insurance companies would likely be similar to other mandates. Insurance companies do not provide estimates on the administrative expenses separately in their responses to the BOI survey.

Premium and Administrative Expenses of Policyholders. BOI annually surveys a sample of Virginia health insurers on the premium impact of proposed mandates. In 2008, the top 50 health insurance providers in Virginia were surveyed. While an overall response rate to the survey of 84 percent (42 companies) was achieved, a relatively small number of insurance companies provided estimated monthly premiums costs for HB 615 and HB 669, which may limit the usefulness of the estimates. In addition, the estimates varied widely with considerable differences between individual and group policyholders (Table 8).

Table 8: Estimated Monthly Premium Impact of HB 615 and HB 669

	# of Responses	Median Estimate	Highest Estimate	Lowest Estimate
HB 615				
Individual (standard)	4	\$0.60	\$1.00	\$0.21
Individual (optional)	2	2.61	5.00	0.21
Group (standard)	15	0.40	1.46	0.05
Group (optional)	15	0.34	3.00	0.05
HB669				
Individual (standard)	5	1.00	9.90	0.14
Individual (optional)	2	1.61	3.00	0.21
Group (standard)	16	0.40	12.40	0.05
Group (optional)	15	0.34	2.00	0.05

Source: Bureau of Insurance, Survey of Insurance Providers, 2008.

Estimates reported by insurance companies may be high, in some cases. A public health expert consulted for this evaluation stated that the estimates of monthly premium impact appear to be high given the prevalence of the disorders that utilize amino acid-based formulas. Further, reports by the California Health Benefits Review Program estimate a premium increase of 0.0042 percent in the group market and 0.0045 percent in the individual market for coverage of amino acid-based formulas for IEMs. Coverage of amino acid-based elemental formulas for eosinophilic esophagitis and short bowel syndrome are estimated to raise premiums by 0.0147 percent to 0.0181 percent in the group market and 0.0152 percent in the individual market. Based on these percentages, a plan in the individual market with an existing premium of \$244 per month might increase by \$0.04 per month.

Five insurance companies indicated that coverage was available as part of either standard or optional packages for the diseases and disorders listed in HB 615; however, not all provided an estimate of monthly premium costs. Four companies provided an estimate for individual policyholders and 15 companies provided an estimate for group certificate-holders; currently, not all offer coverage in the standard or optional packages. Contributing to the low response rate for individual coverage are those companies that do not serve the individual market and companies that no longer provide services in Virginia.

The median monthly premium estimates for the coverage in HB 615 as part of a standard individual option is around \$0.60 per month and the estimate for standard group coverage is approximately \$0.40. One company provided an estimated total monthly premium cost of \$313.50. Optional group coverage is estimated at \$0.34. Only two providers indicated that individual coverage is available as optional at a median \$2.61 per month.

For the conditions listed in HB 669, eight insurance companies indicated that coverage was available as part of either standard or optional packages; however, not all provided an estimate of monthly premium costs. Although they may not offer coverage, five companies provided an estimate for individual standard policyholders and 16 companies provided an estimate for group standard certificate-holders.

The median monthly premium estimates for coverage of HB 669 as part of a standard individual coverage option is around \$1.00 per month and the estimate for standard group coverage is approximately \$0.40. One company provided an estimated total monthly premium cost of \$313.50. Optional group coverage is estimated at \$0.34. Only two providers indicated that optional individual coverage is available at a median \$1.61 per month.

Average Individual Insurance Premiums

In October 2007, the Virginia Bureau of Insurance reported an average annual health insurance premium (with current mandated benefits) for an individual contract, single coverage, of \$2,929.58 or approximately \$244 per month.

For HB 615, an individual premium increase of \$0.21 to \$1 would result in a monthly premium increase between 0.09 percent and 0.4 percent based on the estimated average monthly premium cost for a single coverage, individual contract, as defined in BOI's 2007 report on the financial impact of mandated health insurance benefits. For HB 669, an individual premium increase of \$0.14 to \$9.90 would result in a monthly premium increase between 0.06 percent and four percent based on the estimated average monthly premium cost for a single coverage. These compare to the premium impacts of existing mandates, which range from 0.07 to 5.3 percent for single coverage individual contracts. Data are not available on the monthly premium estimate for group plans, so it is not possible to calculate the percent increase in premium costs resulting from this mandate. The BOI estimates that mandates currently contribute approximately \$410.96 (14 percent) to average annual premium costs. However, health insurance would likely cover many of the conditions and treatments required by mandates, so some of these premium costs would occur even in the absence of mandates.

It is interesting to note that the median group standard cost is higher than the median group optional cost for both HB 615 and HB 669. This is not typical, as optional coverage is usually more expensive than standard coverage due to fewer policy holders over which to spread costs.

f. Total Cost of Health Care

Mandated coverage of amino acid-based formulas may modestly reduce total health care cost in Virginia for conditions that utilize the formulas as a primary treatment. As mentioned, newborns diagnosed with IEM in Virginia have access to formulas through State VDH programs, public health insurance coverage, or self pay. Therefore, a large cost reduction may not be seen, but a shift to private insurance could occur. In the event that a child does not have consistent access to the necessary formulas, mental retardation or other costly adverse consequences would occur.

Mandated coverage of amino acid-based formulas used to treat severe GI and hypersensitivity conditions may reduce the total cost of health care. Left untreated, certain severe GI and hypersensitivity conditions may result in increased long-term costs resulting from adverse health consequences.

However, the proposed mandates may impact the total cost of health care in Virginia for other conditions, and may increase total overall costs. A concern with HB 615 and HB 669 is the inclusion of GI and hypersensitivity conditions for which amino acid-based formulas is not standard medical practice. As written, both man-

dates may include coverage for formulas for certain disorders for which the evidence for their use is inconclusive. While these cases should be mitigated by the requirement for a physician's written order or prescription, the mandates could increase the total cost of health care with little or no health benefits for some conditions. If the conditions for which amino acid-based formulas are not standard medical practice were eliminated from the bills, then as discussed above, increasing the use of amino acid-based formulas may modestly reduce total cost of health care as a result of the reduction in adverse medical consequences and a decrease in the utilization rate.

BALANCING MEDICAL, SOCIAL, AND FINANCIAL CONSIDERATIONS

For certain medical conditions listed in HB 615 and HB 669 health insurance coverage appears consistent with the role of insurance. Amino acid-based metabolic formulas are the primary medical treatment for ten IEM disorders screened in Virginia, and amino acid-based elemental formulas are the primary treatment for certain severe GI and hypersensitivity conditions. HB 615 would mandate coverage of amino acid-based elemental formulas for GI and hypersensitivity diseases and disorders, including eosinophilic esophagitis and Crohn's disease, but does not include coverage of IEMs. HB 669 would mandate coverage of amino acid-based formulas for IEMs that utilize metabolic formulas as well as certain GI conditions that utilize elemental formulas, like Crohn's disease, but does not include hypersensitivity conditions. Mandated coverage of the formulas would help to relieve financial hardship of those self-paying. However, both HB 615 and HB 669 include coverage for conditions for which amino acid-based formula is not standard medical practice. Limiting the mandates to coverage of conditions that medical practice guidelines recommend be treated with amino acid-based formulas would more directly meet patients' needs and would reduce the impact on insurance premiums.

a. Social Need/Consistent With Role of Insurance

Based on the premise that the role of health insurance is to promote public health, encourage the use of preventive care, and provide protection from catastrophic financial expenses for unexpected illness or injury, HB 615 and HB 669 appear consistent with the role of insurance for certain medical conditions. The use of amino acid-based formulas is the primary medical treatment for IEM disorders (covered by HB 669) and its use prevents catastrophic consequences, such as mental retardation and/or death. Amino acid-based elemental formulas are used as medical treatment for certain severe GI and hypersensitivity disorders for chil-

dren and, in some cases, for adults (covered primarily by HB 615). For certain severe GI conditions, such as Crohn's, its use may sustain the lives of patients (covered by HB 615 and HB 669).

Further evidence that the mandates, particularly coverage of amino acid-based formulas for IEM disorders, are consistent with insurance is that Medicaid and the State employee health plan cover formulas for this purpose. Thirty-one other states also mandate coverage of metabolic formulas for IEM disorders, including but not limited to amino acid-based metabolic formulas. Medicaid also covers amino acid-based elemental formulas for GI and hypersensitivity conditions, and eight other states mandate coverage of elemental formulas for this purpose. However, coverage of formulas for IEM has encountered less resistance from the health insurance industry in other states than coverage of formulas for GI and hypersensitivity conditions.

However, HB 615 and HB 669 include a broad range of GI and hypersensitivity conditions for which the use of amino acid-based formulas is not standard medical practice. The mandates each specify that the use of amino acid-based formulas to treat the listed conditions must be medically necessary. For certain conditions, amino acid-based formulas are recommended as an alternative formula or treatment, and for other conditions their use is not standard medical practice. Mandating their coverage could promote the utilization of ineffective treatment as opposed to the most effective or recommended treatment. The mandates would more directly meet the needs of consumers of health insurance if the covered conditions were more clearly defined as opposed to including broad categories of GI and hypersensitivity conditions.

b. Need Versus Cost

The population that requires the use of amino acid-based formulas is relatively small, but the formulas are medically necessary for the treatment of certain disorders. As discussed above, IEM and certain GI and hypersensitivity conditions utilize amino acid-based formulas as the primary treatment and in some cases for a lifetime. Also, four mandates similar to HB 669 have been previously introduced.

Due to the adverse consequences associated with IEM disorders, most individuals with IEM currently utilize the metabolic formulas. This may also be true for some elemental formulas. However, the financial hardship due to the cost of amino acid-based formulas may be significant, from three percent to almost 10 percent of median household income. In comparison, mandating coverage is estimated to have a modest impact on premiums. The impact could be lessened further, however, by limiting the bills to those condi-

tions for which amino acid-based formulas are a recommended treatment according to medical practice guidelines.

c. Mandated Offer

Mandated Offer

A mandated offer requires health insurers to offer for purchase the coverage described in the mandate for an additional fee.

Mandating that health insurers offer coverage of amino acid-based formulas would likely not meet the need for coverage of the formulas. The proposed mandate addresses relatively rare conditions, and most purchasers of health insurance will probably not view coverage of amino acid-based formulas as a critical need leaving only those with the disorders to purchase coverage.

ACKNOWLEDGMENTS

JLARC staff would like to acknowledge the expertise, assistance, and information provided by staff at Virginia Commonwealth University and University of Virginia Health System. JLARC staff would also like to thank Dr. Robert Valdez, Executive Director, Robert Wood Johnson Foundation Center for Health Policy and Professor of Family and Community Medicine and Economics at the University of New Mexico, for his suggestions and expertise as a public health consultant. In addition, JLARC would like to thank the Virginia State Corporation Commission Bureau of Insurance, the Virginia Association of Health Plans, the Department of Human Resource Management, the Department of Medical Assistance Services, and the Department of Health for their assistance.

Statutory Authority for JLARC Evaluation of Proposed Mandated Health Insurance Benefits

§ [2.2-2503](#). Special Advisory Commission on Mandated Health Insurance Benefits; membership; terms; meetings; compensation and expenses; staff; chairman's executive summary.

A. The Special Advisory Commission on Mandated Health Insurance Benefits (the Commission) is established as an advisory commission within the meaning of § [2.2-2100](#), in the executive branch of state government. The purpose of the Commission shall be to advise the Governor and the General Assembly on the social and financial impact of current and proposed mandated benefits and providers, in the manner set forth in this article.

B. The Commission shall consist of 18 members that include six legislative members, 10 nonlegislative citizen members, and two ex officio members as follows: one member of the Senate Committee on Education and Health and one member of the Senate Committee on Commerce and Labor appointed by the Senate Committee on Rules; two members of the House Committee on Health, Welfare and Institutions and two members of the House Committee on Commerce and Labor appointed by the Speaker of the House of Delegates in accordance with the principles of proportional representation contained in the Rules of the House of Delegates; 10 nonlegislative citizen members appointed by the Governor that include one physician, one chief executive officer of a general acute care hospital, one allied health professional, one representative of small business, one representative of a major industry, one expert in the field of medical ethics, two representatives of the accident and health insurance industry, and two nonlegislative citizen members; and the State Commissioner of Health and the State Commissioner of Insurance, or their designees, who shall serve as ex officio nonvoting members.

C. All nonlegislative citizen members shall be appointed for terms of four years. Legislative and ex officio members shall serve terms coincident with their terms of office. All members may be reappointed. However, no House member shall serve more than four consecutive two-year terms, no Senate member shall serve more than two consecutive four-year terms, and no nonlegislative citizen member shall serve more than two consecutive four-year terms. Vacancies occurring other than by expiration of a term shall be filled for the unexpired term. Vacancies shall be filled in the manner as the original appointments. The remainder of any term to which a member is appointed to fill a vacancy shall not constitute a term in determining the member's eligibility for reappointment.

D. The Commission shall meet at the request of the chairman, the majority of the voting members or the Governor. The Commission shall elect a chairman and a vice-chairman, as determined by the membership. A majority of the members of the Commission shall constitute a quorum.

E. Legislative members of the Commission shall receive such compensation as provided in § [30-19.12](#), and nonlegislative citizen members shall receive such compensation for the performance of their duties as provided in § [2.2-2813](#). All members shall be reimbursed for all reasonable and

necessary expenses incurred in the performance of their duties as provided in §§ [2.2-2813](#) and [2.2-2825](#). Funding for the compensation and costs of expenses of the members shall be provided by the State Corporation Commission.

F. The Bureau of Insurance, the State Health Department, and the Joint Legislative Audit and Review Commission and such other state agencies as may be considered appropriate by the Commission shall provide staff assistance to the Commission. The Joint Legislative Audit and Review Commission shall conduct assessments, analyses, and evaluations of proposed mandated health insurance benefits and mandated providers as provided in subsection D of § [30-58.1](#), and report its findings with respect to the proposed mandates to the Commission.

G. The chairman of the Commission shall submit to the Governor and the General Assembly an annual executive summary of the interim activity and work of the Commission no later than the first day of each regular session of the General Assembly. The executive summary shall be submitted as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents and reports and shall be posted on the General Assembly's website.

§ [30-58.1](#). Powers and duties of Commission.

The Commission shall have the following powers and duties:

- A. Make performance reviews of operations of state agencies to ascertain that sums appropriated have been, or are being expended for the purposes for which such appropriations were made and to evaluate the effectiveness of programs in accomplishing legislative intent;
- B. Study on a continuing basis the operations, practices and duties of state agencies, as they relate to efficiency in the utilization of space, personnel, equipment and facilities;
- C. Make such special studies and reports of the operations and functions of state agencies as it deems appropriate and as may be requested by the General Assembly;
- D. Assess, analyze, and evaluate the social and economic costs and benefits of any proposed mandated health insurance benefit or mandated provider, including, but not limited to, the mandate's predicted effect on health care coverage premiums and related costs, net costs or savings to the health care system, and other relevant issues, and report its findings with respect to the proposed mandate to the Special Advisory Commission on Mandated Health Insurance Benefits; and
- E. Make such reports on its findings and recommendations at such time and in such manner as the Commission deems proper submitting same to the agencies concerned, to the Governor and to the General Assembly. Such reports as are submitted shall relate to the following matters:
 - 1. Ways in which the agencies may operate more economically and efficiently;
 - 2. Ways in which agencies can provide better services to the Commonwealth and to the people; and
 - 3. Areas in which functions of state agencies are duplicative, overlapping, or failing to accomplish legislative objectives or for any other reason should be redefined or redistributed.

Proposed Mandated Benefit Requiring Coverage of Amino Acid-Based Formulas

HOUSE BILL NO. 615

Offered January 9, 2008

Prefiled January 8, 2008

A BILL to amend and reenact § 38.2-4319 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 38.2-3418.15, relating to health insurance coverage for amino acid-based elemental formulas.

Patrons—Amundson and Scott, J.M.; Senator: Whipple

Referred to Committee on Commerce and Labor

1 Be it enacted by the General Assembly of Virginia:

1. That § 38.2-4319 of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding a section numbered 38.2-3418.15 as follows:

§ 38.2-3418.15. Coverage for amino acid-based elemental formulas.

A. Notwithstanding the provisions of § 38.2-4319, each insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis; each corporation providing individual or group accident and sickness subscription contracts; and each health maintenance organization providing a healthcare plan for healthcare services shall provide coverage for the provision of amino acid-based elemental formulas for the diagnosis and treatment of Immunoglobulin E and non-Immunoglobulin E mediated allergies to multiple food proteins, food protein-induced enterocolitis syndrome, eosinophilic disorders, and impaired absorption of nutrients caused by disorders affecting the absorptive surface, functional length, and motility of the gastrointestinal tract. However, coverage for the provision of amino acid-based elemental formulas, regardless of delivery method, shall be provided when the prescribing or ordering physician has issued a written order stating that the formula is medically necessary for the treatment thereof.

B. No insurer, corporation, or health maintenance organization shall impose upon any person receiving benefits pursuant to this section any copayment, fee, policy year or calendar year, or durational benefit limitation or maximum for benefits or services that is not equally imposed upon all individuals in the same benefit category.

C. The requirements of this section shall apply to all insurance policies, contracts, and plans delivered, issued for delivery, reissued, or extended in the Commonwealth on and after January 1, 2009, or at any time thereafter when any term of the policy, contract, or plan is changed or any premium adjustment is made.

D. This section shall not apply to short-term travel, accident-only, limited or specified disease, or individual conversion policies or contracts, or to policies or contracts designed for issuance to persons eligi-

ble for coverage under Title XVIII of the Social Security Act, known as Medicare, or any other similar coverage under state or federal governmental plans.

§ 38.2-4319. Statutory construction and relationship to other laws.

A. No provisions of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-100, 38.2-136, 38.2-200, 38.2-203, 38.2-209 through 38.2-213, 38.2-216, 38.2-218 through 38.2-225, 38.2-229, 38.2-232, 38.2-305, 38.2-316, 38.2-322, 38.2-400, 38.2-402 through 38.2-413, 38.2-500 through 38.2-515, 38.2-600 through 38.2-620, Chapter 9 (§ 38.2-900 et seq.), §§ 38.2-1016.1 through 38.2-1023, 38.2-1057, Article 2 (§ 38.2-1306.2 et seq.), § 38.2-1306.1, § 38.2-1315.1, Articles 3.1 (§ 38.2-1316.1 et seq.), 4 (§ 38.2-1317 et seq.) and 5 (§ 38.2-1322 et seq.) of Chapter 13, Articles 1 (§ 38.2-1400 et seq.) and 2 (§ 38.2-1412 et seq.) of Chapter 14, §§ 38.2-1800 through 38.2-1836, 38.2-3401, 38.2-3405, 38.2-3405.1, 38.2-3407.2 through 38.2-3407.6:1, 38.2-3407.9 through 38.2-3407.16, 38.2-3411.2, 38.2-3411.3, 38.2-3411.4, 38.2-3412.1:01, 38.2-3414.1, 38.2-3418.1 through 38.2-3418.14 38.2-3418.15, 38.2-3419.1, 38.2-3430.1 through 38.2-3437, 38.2-3500, subdivision 13 of § 38.2-3503, subdivision 8 of § 38.2-3504, §§ 38.2-3514.1, 38.2-3514.2, 38.2-3522.1 through 38.2-3523.4, 38.2-3525, 38.2-3540.1, 38.2-3542, 38.2-3543.2, Article 5 (§ 38.2-3551 et seq.) of Chapter 35, Chapter 52 (§ 38.2-5200 et seq.), Chapter 55 (§ 38.2-5500 et seq.), Chapter 58 (§ 38.2-5800 et seq.) and § 38.2-5903 of this title shall be applicable to any health maintenance organization granted a license under this chapter. This chapter shall not apply to an insurer or health services plan licensed and regulated in conformance with the insurance laws or Chapter 42 (§ 38.2-4200 et seq.) of this title except with respect to the activities of its health maintenance organization.

B. For plans administered by the Department of Medical Assistance Services that provide benefits pursuant to Title XIX or Title XXI of the Social Security Act, as amended, no provisions of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-100, 38.2-136, 38.2-200, 38.2-203, 38.2-209 through 38.2-213, 38.2-216, 38.2-218 through 38.2-225, 38.2-229, 38.2-232, 38.2-322, 38.2-400, 38.2-402 through 38.2-413, 38.2-500 through 38.2-515, 38.2-600 through 38.2-620, Chapter 9 (§ 38.2-900 et seq.), §§ 38.2-1016.1 through 38.2-1023, 38.2-1057, § 38.2-1306.1, Article 2 (§ 38.2-1306.2 et seq.), § 38.2-1315.1, Articles 3.1 (§ 38.2-1316.1 et seq.), 4 (§ 38.2-1317 et seq.) and 5 (§ 38.2-1322 et seq.) of Chapter 13, Articles 1 (§ 38.2-1400 et seq.) and 2 (§ 38.2-1412 et seq.) of Chapter 14, §§ 38.2-3401, 38.2-3405, 38.2-3407.2 through 38.2-3407.5, 38.2-3407.6 and 38.2-3407.6:1, 38.2-3407.9, 38.2-3407.9:01, and 38.2-3407.9:02, subdivisions 1, 2, and 3 of subsection F of § 38.2-3407.10, 38.2-3407.11, 38.2-3407.11:3, 38.2-3407.13, 38.2-3407.13:1, and 38.2-3407.14, 38.2-3411.2, 38.2-3418.1, 38.2-3418.2, 38.2-3419.1, 38.2-3430.1 through 38.2-3437, 38.2-3500, subdivision 13 of § 38.2-3503, subdivision 8 of § 38.2-3504, §§ 38.2-3514.1, 38.2-3514.2, 38.2-3522.1 through 38.2-3523.4, 38.2-3525, 38.2-3540.1, 38.2-3542, 38.2-3543.2, Chapter 52 (§ 38.2-5200 et seq.), Chapter 55 (§ 38.2-5500 et seq.), Chapter 58 (§ 38.2-5800 et seq.) and § 38.2-5903 shall be applicable to any health maintenance organization granted a license under this chapter. This chapter shall not apply to an insurer or health services plan licensed and regulated in conformance with the insurance laws or Chapter 42 (§ 38.2-4200 et seq.) of this title except with respect to the activities of its health maintenance organization.

C. Solicitation of enrollees by a licensed health maintenance organization or by its representatives shall not be construed to violate any provisions of law relating to solicitation or advertising by health professionals.

D. A licensed health maintenance organization shall not be deemed to be engaged in the unlawful practice of medicine. All health care providers associated with a health maintenance organization shall be subject to all provisions of law.

E. Notwithstanding the definition of an eligible employee as set forth in § 38.2-3431, a health maintenance organization providing health care plans pursuant to § 38.2-3431 shall not be required to offer coverage to or accept applications from an employee who does not reside within the health maintenance organization's service area.

F. For purposes of applying this section, "insurer" when used in a section cited in subsections A and B of this section shall be construed to mean and include "health maintenance organizations" unless the section cited clearly applies to health maintenance organizations without such construction.

HOUSE BILL NO. 669

Offered January 9, 2008

Prefiled January 8, 2008

A BILL to amend and reenact § 38.2-4319 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 38.2-3418.15, relating to health insurance coverage for amino acid-based formulas.

Patron—Marshall, R.G.

Referred to Committee on Commerce and Labor

Be it enacted by the General Assembly of Virginia:

1. That § 38.2-4319 of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding a section numbered 38.2-3418.15 as follows:

§ 38.2-3418.15. Coverage for amino-acid-based formulas.

A. Notwithstanding the provisions of § 38.2-3419, each insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical, and surgical, or major medical coverage on an expense-incurred basis; each corporation providing individual or group accident and sickness subscription contracts; and each health maintenance organization providing a health care plan for health care services shall provide coverage for the expense of amino-acid-based formulas whose protein source has been extensively or completely hydrolyzed.

B. Coverage under this section shall apply only if:

- 1. The amino-acid-based formula is prescribed by a licensed physician. A managed care health insurance plan, as defined in Chapter 58 (§ 38.2-5800 et seq.) of this title, may require such physician to be a member of the plan's provider network;*
- 2. The physician furnishes supporting documentation to the insurer, corporation, or health maintenance organization that the amino-acid-based formula is required to treat either a diagnosed inborn error of amino acid or organic acid metabolism or a diagnosed disease or disorder of the gastrointestinal tract that leads to malnutrition or malabsorption due to inflammation, protein sensitivity, or inborn errors of digestion; and*
- 3. The amino-acid-based formula is the primary source of nutrition as certified by the treating physician by diagnosis.*

C. No insurer, corporation, or health maintenance organization shall impose upon any person receiving benefits pursuant to this section any copayment, coinsurance, or deductible amounts, or any policy year, calendar year, lifetime, or other durational benefit limitation or maximum for benefits or services, that is not equally imposed upon all terms and services covered under the policy, contract, or plan.

D. The requirements of this section shall apply to all insurance policies, contracts, and plans delivered, issued for delivery, reissued, or extended in the Commonwealth on and after January 1, 2009, or at any time thereafter when any term of the policy, contract, or plan is changed or any premium adjustment is made.

E. This section shall not apply to short-term travel, accident-only, limited or specified disease, or individual conversion policies or contracts, nor to policies or contracts designed for issuance to persons eligible for coverage under Title XVIII of the Social Security Act, known as Medicare, or any other

similar coverage under state or federal governmental plans.

§ 38.2-4319. Statutory construction and relationship to other laws.

A. No provisions of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-100, 38.2-136, 38.2-200, 38.2-203, 38.2-209 through 38.2-213, 38.2-216, 38.2-218 through 38.2-225, 38.2-229, 38.2-232, 38.2-305, 38.2-316, 38.2-322, 38.2-400, 38.2-402 through 38.2-413, 38.2-500 through 38.2-515, 38.2-600 through 38.2-620, Chapter 9 (§ 38.2-900 et seq.), §§ 38.2-1016.1 through 38.2-1023, 38.2-1057, Article 2 (§ 38.2-1306.2 et seq.), § 38.2-1306.1, § 38.2-1315.1, Articles 3.1 (§ 38.2-1316.1 et seq.), 4 (§ 38.2-1317 et seq.) and 5 (§ 38.2-1322 et seq.) of Chapter 13, Articles 1 (§ 38.2-1400 et seq.) and 2 (§ 38.2-1412 et seq.) of Chapter 14, §§ 38.2-1800 through 38.2-1836, 38.2-3401, 38.2-3405, 38.2-3405.1, 38.2-3407.2 through 38.2-3407.6:1, 38.2-3407.9 through 38.2-3407.16, 38.2-3411.2, 38.2-3411.3, 38.2-3411.4, 38.2-3412.1:01, 38.2-3414.1, 38.2-3418.1 through 38.2-3418.14 38.2-3418.15, 38.2-3419.1, 38.2-3430.1 through 38.2-3437, 38.2-3500, subdivision 13 of § 38.2-3503, subdivision 8 of § 38.2-3504, §§ 38.2-3514.1, 38.2-3514.2, 38.2-3522.1 through 38.2-3523.4, 38.2-3525, 38.2-3540.1, 38.2-3542, 38.2-3543.2, Article 5 (§ 38.2-3551 et seq.) of Chapter 35, Chapter 52 (§ 38.2-5200 et seq.), Chapter 55 (§ 38.2-5500 et seq.), Chapter 58 (§ 38.2-5800 et seq.) and § 38.2-5903 of this title shall be applicable to any health maintenance organization granted a license under this chapter. This chapter shall not apply to an insurer or health services plan licensed and regulated in conformance with the insurance laws or Chapter 42 (§ 38.2-4200 et seq.) of this title except with respect to the activities of its health maintenance organization.

B. For plans administered by the Department of Medical Assistance Services that provide benefits pursuant to Title XIX or Title XXI of the Social Security Act, as amended, no provisions of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-100, 38.2-136, 38.2-200, 38.2-203, 38.2-209 through 38.2-213, 38.2-216, 38.2-218 through 38.2-225, 38.2-229, 38.2-232, 38.2-322, 38.2-400, 38.2-402 through 38.2-413, 38.2-500 through 38.2-515, 38.2-600 through 38.2-620, Chapter 9 (§ 38.2-900 et seq.), §§ 38.2-1016.1 through 38.2-1023, 38.2-1057, § 38.2-1306.1, Article 2 (§ 38.2-1306.2 et seq.), § 38.2-1315.1, Articles 3.1 (§ 38.2-1316.1 et seq.), 4 (§ 38.2-1317 et seq.) and 5 (§ 38.2-1322 et seq.) of Chapter 13, Articles 1 (§ 38.2-1400 et seq.) and 2 (§ 38.2-1412 et seq.) of Chapter 14, §§ 38.2-3401, 38.2-3405, 38.2-3407.2 through 38.2-3407.5, 38.2-3407.6 and 38.2-3407.6:1, 38.2-3407.9, 38.2-3407.9:01, and 38.2-3407.9:02, subdivisions 1, 2, and 3 of subsection F of § 38.2-3407.10, 38.2-3407.11, 38.2-3407.11:3, 38.2-3407.13, 38.2-3407.13:1, and 38.2-3407.14, 38.2-3411.2, 38.2-3418.1, 38.2-3418.2, 38.2-3419.1, 38.2-3430.1 through 38.2-3437, 38.2-3500, subdivision 13 of § 38.2-3503, subdivision 8 of § 38.2-3504, §§ 38.2-3514.1, 38.2-3514.2, 38.2-3522.1 through 38.2-3523.4, 38.2-3525, 38.2-3540.1, 38.2-3542, 38.2-3543.2, Chapter 52 (§ 38.2-5200 et seq.), Chapter 55 (§ 38.2-5500 et seq.), Chapter 58 (§ 38.2-5800 et seq.) and § 38.2-5903 shall be applicable to any health maintenance organization granted a license under this chapter. This chapter shall not apply to an insurer or health services plan licensed and regulated in conformance with the insurance laws or Chapter 42 (§ 38.2-4200 et seq.) of this title except with respect to the activities of its health maintenance organization.

C. Solicitation of enrollees by a licensed health maintenance organization or by its representatives shall not be construed to violate any provisions of law relating to solicitation or advertising by health professionals.

D. A licensed health maintenance organization shall not be deemed to be engaged in the unlawful practice of medicine. All health care providers associated with a health maintenance organization shall be subject to all provisions of law.

E. Notwithstanding the definition of an eligible employee as set forth in § 38.2-3431, a health

maintenance organization providing health care plans pursuant to § 38.2-3431 shall not be required to offer coverage to or accept applications from an employee who does not reside within the health maintenance organization's service area.

F. For purposes of applying this section, "insurer" when used in a section cited in subsections A and B of this section shall be construed to mean and include "health maintenance organizations" unless the section cited clearly applies to health maintenance organizations without such construction.

Evaluation Topic Areas and Criteria for Assessing Proposed Mandated Health Insurance Benefits

Topic Area	Criteria
1. Medical Efficacy	
a. Medical Efficacy of Benefit	The contribution of the benefit to the quality of patient care and the health status of the population, including the results of any clinical research, especially randomized clinical trials, demonstrating the medical efficacy of the treatment or service compared to alternatives or not providing the treatment or service.
b. Medical Effectiveness of Benefit <i>JLARC Criteria*</i>	The contribution of the benefit to patient health based on how well the intervention works under the usual conditions of clinical practice. Medical effectiveness is not based on testing in a rigid, optimal protocol, but rather a more flexible intervention that is often used in broader populations.
c. Medical Efficacy of Provider	If the legislation seeks to mandate coverage of an additional class of practitioners: 1) The results of any professionally acceptable research, especially randomized clinical trials, demonstrating the medical results achieved by the additional class of practitioners relative to those already covered. 2) The methods of the appropriate professional organization to assure clinical proficiency.
d. Medical Effectiveness of Provider <i>JLARC Criteria*</i>	The contribution of the practitioner to patient health based on how well the practitioner's interventions work under the usual conditions of clinical practice. Medical effectiveness is not based on testing in a rigid, optimal protocol, but rather more flexible interventions that are often used in broader populations.
2. Social Impact	
a. Utilization of Treatment	The extent to which the treatment or service is generally utilized by a significant portion of the population.
b. Availability of Coverage	The extent to which insurance coverage for the treatment or service is already generally available.
c. Availability of Treatment <i>JLARC Criteria*</i>	The extent to which the treatment or service is generally available to residents throughout the state.
d. Availability of Treatment Without Coverage	If coverage is not generally available, the extent to which the lack of coverage results in persons being unable to obtain necessary health care treatments.
e. Financial Hardship	If the coverage is not generally available, the extent to which the lack of coverage result in unreasonable financial hardship on those persons needing treatment.
f. Prevalence/Incidence of Condition	The level of public demand for the treatment or service.
g. Demand for Coverage	The level of public demand and the level of demand from providers for individual or group insurance coverage of the treatment or service.

h. Labor Union Coverage	The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts.
i. State Agency Findings	Any relevant findings of the state health planning agency or the appropriate health system agency relating to the social impact of the mandated benefit.
j. Public Payer Coverage <i>JLARC Criteria*</i>	The extent to which the benefit is covered by public payers, in particular Medicaid and Medicare.
k. Public Health Impact <i>JLARC Criteria*</i>	Potential public health impacts of mandating the benefit.
3. Financial Impact	
a. Effect on Cost of Treatment	The extent to which the proposed insurance coverage would increase or decrease the cost of treatment of service over the next five years.
b. Change in Utilization	The extent to which the proposed insurance coverage might increase the appropriate or inappropriate use of the treatment or service.
c. Serves as an Alternative	The extent to which the mandated treatment or service might serve as an alternative for more expensive or less expensive treatment or service.
d. Impact on Providers	The extent to which the insurance coverage may affect the number and types of providers of the mandated treatment or service over the next five years.
e. Administrative and Premium Costs	The extent to which insurance coverage might be expected to increase or decrease the administrative expenses of insurance companies and the premium and administrative expenses of policyholders.
f. Total Cost of Health Care	The impact of coverage on the total cost of health care.
4. Effects of Balancing Medical, Social, and Financial Considerations	
a. Social Need/Consistent with Role of Insurance	The extent to which the benefit addresses a medical or a broader social need and whether it is consistent with the role of health insurance.
b. Need Versus Cost	The extent to which the need for coverage outweighs the costs of mandating the benefit for all policyholders.
c. Mandated Option	The extent to which the need for coverage may be solved by mandating the availability of the coverage as an option for policy holders.

*Denotes additional criteria added by JLARC staff to criteria adopted by the Special Advisory Commission on Mandated Health Insurance Benefits.

Source: Special Advisory Commission on Mandated Health Insurance Benefits and JLARC staff analysis.

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California Health Benefits Review Program (April 2008). Analysis of Assembly Bill 2174: Coverage for Amino Acid-Based Elemental Formula.

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Virginia Newborn Screening Panel

As of March 2006, the *Code of Virginia* requires that infants born in Virginia be screened for 28 disorders included in the newborn screening panel, including:

- 3 Hydroxy 3 Methylglutaryl-CoA Lyase Deficiency (HMG)
- 3-Methylcrotonyl-CoA Carboxylase Deficiency (3MCC)
- Argininosuccinic Acidemia (ASA)
- Beta Ketothiolase Deficiency (BKT)
- Biotinidase Deficiency
- Carnitine Uptake Deficiency (CUD)
- Citrullinemia (CIT)
- Congenital Adrenal Hyperplasia (CAH)
- Congenital Hypothyroidism (CH)
- Cystic Fibrosis (CF)
- Galactosemia (GALT)
- Glutaric Acidemia Type I (GAI)
- Homocystinuria (HCU)
- Isovaleric Acidemia (IVA)
- Long Chain Hydroxy acyl-CoA Dehydrogenase Deficiency (LCHADD)
- Maple Syrup Urine Disease (MSUD)
- Medium chain acyl-CoA dehydrogenase deficiency (MCADD)
- Methylmalonyl Adenosyl- Cabalamine Synthesis Defects (Cbl A& B)
- Methylmalonyl-CoA Mutase Deficiency (MUT)
- Multiple CoA Carboxylase Deficiency (MCCD)
- Phenylketonuria (PKU)
- Propionic Acidemia (PA)
- Sickle Beta Thalassemia (Hb S β Thal)
- Sickle Hemoglobin C Disease (Hb SC)

- Sickle Cell Anemia (Hb SS)
- Trifunctional Protein Deficiency (TFP)
- Tyrosinemia Type I (TYR I)
- Very Long Chain Acyl-CoA Dehydrogenase Deficiency (VLCADD)



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