REPORT OF THE
SPECIAL ADVISORY COMMISSION ON MANDATED
HEALTH INSURANCE BENEFITS

HOUSE BILL 615: COVERAGE FOR THE EXPENSE OF AMINO ACID-BASED ELEMENTAL FORMULAS and HOUSE BILL 669: COVERAGE FOR THE EXPENSE OF AMINO ACID-BASED FORMULAS

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

COMMONWEALTH OF VIRGINIA
RICHMOND
2009

January 12, 2009

To: The Honorable Timothy M. Kaine
Governor of Virginia
and
The General Assembly of Virginia

The report contained herein has been prepared pursuant to §§ 2.2-2504 and 2.2-2505 of the Code of Virginia.

This report documents a study conducted by the Special Advisory Commission on Mandated Health Insurance Benefits to assess the social and financial impact and the medical efficacy of House Bill 615 regarding the proposed mandated coverage for the expense of amino acid-based elemental formulas and House Bill 669 regarding proposed mandated coverage for the expense of amino acid-based formulas.

Respectfully submitted,

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INTRODUCTION

The House Committee on Commerce and Labor referred House Bill 615 and House Bill 669 to the Special Advisory Commission on Mandated Health Insurance Benefits (Advisory Commission) during the 2008 Session of the General Assembly. House Bill 615 was introduced by Delegate Kristen J. Amundson and House Bill 669 was introduced by Delegate Robert G. Marshall.

The Advisory Commission held a hearing on September 29, 2008 in Richmond to receive public comments on House Bill 615 and House Bill 669**.** In addition to the patrons**,** a dietitian and four concerned citizens spoke in favor of House Bill 669. A doctor and a concerned citizen spoke in favor of House Bill 615. A representative of the Virginia Association of Health Plans (VAHP) spoke in opposition to House Bill 615 and House Bill 669. Children's Milk Allergy and Gastrointestinal Coalition (MAGIC) provided written comments in support of the bills. Written comments in opposition to the bills were provided by the VAHP and the Virginia Chamber of Commerce. The National Federation of Independent Business (NFIB) also provided written comments on House Bill 615 and House Bill 669.

The Joint Legislative Audit and Review Commission (JLARC) provided an assessment on the Evaluation of House Bill 615 and House Bill 669: *Mandated Coverage of Amino Acid-Based Formulas in accordance with Sections 2.2-2503 and 30-58.1 of the Code of Virginia.* The report is available on the JLARC website at http://jlarc.state.va.us.

SUMMARY OF PROPOSED LEGISLATION

House Bill 615 and House Bill 669 would amend Section 38.2-4319 and add Section 38.2-3418.15 of the Code of Virginia.

House Bill 615 requires insurers to 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. The bill applies to insurers 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; corporations providing individual or group accident and sickness subscription contracts; and health maintenance organizations (HMOs) providing health care plans for health care services.

House Bill 615 requires coverage for the amino acid-based elemental formulas when the prescribing or ordering physician has issued a written order that the formula is medically necessary for the treatment, regardless of the delivery method. House Bill 615 prohibits insurers, corporations or HMOs from imposing any co-payment, fee, policy year or calendar year, or durational benefit limitation or maximum for benefits or services that is not equally imposed on all individuals in the same benefit category.

House Bill 669 requires insurers to provide coverage for the expense of amino-acid-based formulas whose protein source has been extensively or completely hydrolyzed. The bill applies to insurers 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; corporations providing individual or group accident and sickness subscription contracts; and HMOs providing health care plans for health care services.

House Bill 669 only applies if the formula is prescribed by a licensed physician. A managed care health insurance plan may require the physician to be a member of the plan's network. The physician must supply supporting documentation that the formula is required to treat a diagnosed inborn error of amino 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. The formula must be the primary source of nutrition.

House Bill 669 prohibits insurers, corporations or HMOs from imposing any co-payment, coinsurance, deductible amounts, policy year, calendar year, lifetime, or durational benefit limitation or maximum for benefits or services that is not equally imposed on all terms and services covered under the policy, contract, or plan. The bills apply to policies, contracts and plans delivered, issued for delivery, reissued, or extended in the Commonwealth on or after January 1, 2009, or any time thereafter when any term of the policy, contract, or plan is changed or premium is adjusted. The bills do not apply to short-term travel, accident only, limited or specified disease policies, or individual conversion policies or contracts, nor to policies designed for issuance to person eligible for Medicare, or similar coverage under state or federal government plans.

PRIOR REVIEW

Similar bills addressing formulas have been reviewed by the Advisory Commission three times during the past ten years. The members of the Advisory Commission agreed that mandated coverage for medicated formulas was not necessary and recommended that other action be taken.

During the 1999 Session of the General Assembly, The House Committee on Corporations, Insurance and Banking referred two similar bills to the Advisory Commission. House Bill 2197 and House Bill 2199 were introduced by Delegate Robert F. McDonnell. House Bill 2197 related to coverage for any low protein foods prescribed for treatment of inborn errors of amino acid metabolism, such as phenylketonuria (PKU), maple syrup urine disease (MSUD), and homocystinuria (HCU). House Bill 2199 related to coverage for any medical formula that eliminates specific amino acids for the treatment of inborn errors of metabolism, such as having PKU, MSUD, and HCU. On November 22, 1999, the Advisory Commission voted unanimously to recommend that House Bill 2197 and House Bill 2199 not be enacted. During that time, the Virginia Department of Health (VDH) was charging families no more than 2% of their gross income for medical formulas. The Advisory Commission recommended that a mechanism for payment of the formulas or foods be provided either through expansion of the VDH program to include food or a tax credit. The 2000 report of the study was printed as House Document No. 67.

During the 2002 Session of the General Assembly, the House Committee on Commerce and Labor referred a similar bill to the Advisory Commission. House Bill 84 was introduced by Delegate Robert D. Orrock, Sr. House Bill 84 related to coverage for the expense of polypeptide-based or amino acid-based formulas whose protein source has been extensively or completely hydrolyzed. On January 8, 2003, the Advisory Commission voted (9-1) to recommend that House Bill 84 not be enacted. The Advisory Commission believed that the need for assistance for persons requiring polypeptide-based or amino-acid based formulas was significant, but thought that it should not be a mandated insurance benefit. The Advisory Commission believed that the funding for the then current Virginia Department of Health program for individuals with metabolic disorders should be increased and the program should be expanded to cover persons requiring polypeptide-based or amino-acid based formulas. The Advisory Commission recognized that due to the economic environment at the time, the funding for program expansion might not be available. The Advisory Commission believed, however, that expansion of the program to include the additional disorders was the best alternative and that it should be pursued.

During the 2004 Session of the General Assembly, the House Committee on Commerce and Labor referred House Bill 1216 to the Advisory Commission. House Bill 1216 was introduced by Delegate R. Steven Landes. House Bill 1216 related to coverage for the treatment of inborn errors of metabolism that involve amino acid, carbohydrate, and fat metabolism and for which medically standard methods of diagnosis, treatment, and monitoring exist. On November 16, 2004, the Advisory Commission voted unanimously (9 to 0) to recommend that House Bill 1216 not be enacted. The Advisory Commission recognized the need for assistance for individuals with inborn errors of metabolism and their families. The members acknowledged the relatively small number of individuals affected with these disorders and suggested that increased funding for the conditions be directed to the VDH.

Inborn Errors of Metabolism

In an article appearing in the Diseases and Conditions Encyclopedia entitled “Inborn Errors of Metabolism,” Dr. Ronald J. Jorgenson describes inborn errors of metabolism as inherited disorders caused by a deficiency in a single gene. Enzymes help the body by stimulating biological reactions inside cells that help the body use and produce energy. [1]

Enzyme defects that lead to inborn errors of metabolism are caused by abnormal genes. Genetic abnormalities are present at the time of conception. An abnormal gene is autosomal recessive in character. According to an article by the University of Pennsylvania Health System, entitled “Medical Genetics,” autosomal diseases are inherited through 1 of the 22 non-sex chromosomes. Recessive inheritance occurs when both genes are inherited from each parent. If only one gene in the pair is abnormal, the disease does not occur or is only mildly present. However, a person with a single defective gene is a carrier, meaning the disease can be passed on to their children. [2]

People born with inborn errors of metabolism carry genetic disorders that hinder their ability to digest foods and metabolize nutrients. For every disorder, enzymes that are supposed to digest food or metabolize nutrients become deficient. Deficient enzymes will result in malnourishment that is very harmful to the body. If the disorders are left untreated, some patients may experience developmental delays, seizures, mental retardation, coma, or death. [3]

The symptoms of inborn errors of metabolism vary from person to person. Some disorders produce relatively unimportant features. Others may produce malformations of the skeleton, abnormal hair, serious diseases, or even death. Some infants demonstrate signs of failure to thrive including being unable to gain weight and grow at the expected rate, and show developmental delays. Others symptoms, including vomiting and diarrhea, may be a signal to a health care provider to test for inborn errors of metabolism. A diagnosis is confirmed by testing the blood, the urine, or administering a Deoxyribonucleic Acid (DNA) test. [4]

Section 32.1-65 of the Code of Virginia requires that every infant born in the Commonwealth be screened for various disorders in order to prevent mental retardation, permanent disability or death. The Division of Consolidated Laboratory Services or any other laboratory that the Virginia Department of Health (VDH) has contracted with can provide the screening tests. Section 32.1-67 of the Code of Virginia provides that infants identified with any condition or disorder should be eligible for services under the Children with Special Health Care Needs Program administered by the VDH. [5]

The Virginia Newborn Screening Program requires all infants born in Virginia to be tested to determine if they have specified metabolic or endocrine disorders. The program, which is funded by the VDH, was established to treat affected children early in life, before symptoms of a particular condition occur. The VDH reported that there are twenty-eight heritable disorders and genetic diseases that infants are currently being screened for in Virginia. According to the VDH and the Virginia Commonwealth University Metabolic Treatment Center, at least ten of those disorders require treatment by medical formulated nutritional supplements. [6]

Metabolic Disorders

House Bill 669 requires coverage for the expense of amino acid-based formulas for the treatment of metabolic disorders including amino acid, urea cycle, and organic acid disorders.

1. Amino Acid Disorders

According to information provided by the Virginia Chapter of the March of Dimes, metabolism is

> the means by which the body derives energy and synthesizes the other molecules it needs from the fats, carbohydrates, and proteins that the body consumes as food, by enzymatic reactions helped by minerals and vitamins. Disease will only occur if a critical enzyme is disabled or if a control mechanism for a metabolic pathway is affected. [7]

Metabolic disorders occur when a specific cellular enzyme is missing or limited in function. When the task of this enzyme is not performed, chemical substances accumulate in the tissues, or chemicals made by the enzyme are missing, and can cause damage to the person. [8]

The Virginia Newborn Screening Services Program currently screens for four amino acid metabolic disorders including phenylketonuria (PKU), maple syrup urine disease (MSUD), homocystinuria (HCU), and Tyrosinemia Type 1 (TYRO). [9]

- According to the National Organization for Rare Disorders (NORD), PKU is a rare metabolic disorder of infancy caused by a deficiency of the liver enzyme phenylalanine hydroxylase. Impairment in the metabolism of the amino acid phenylalanine results in excess accumulation of phenylalanine in the fluids of the body. PKU is a severe progressive disorder that can produce mental retardation if not treated early. The VDH stated that PKU can be treated by changing the patient’s milk to a phenylalainine free formula. [10]

- HCU is a rare hereditary error of metabolism. The amino acid methionine is not properly metabolized due to a defect in the enzyme cystathionine synthetase. Symptoms associated with HCU include mental retardation; delays in reaching developmental milestones (crawling, walking, and sitting); displacement of the lens of the eye (ectopia lentis); abnormal thinning and weakness of the bones (osteoporosis); or the formation of blood clots (thrombi) in various veins and arteries that may lead to life-threatening complications. The VDH stated that patients diagnosed with HCU can be treated with medication and by changing their milk to a methionine free formula.[11]

- MSUD is an extremely rare inherited metabolic disorder characterized by a distinctive sweet odor of the urine and perspiration. Symptoms develop because of the body's inability to properly break down (metabolize) leucine, isoleucine, and valine, organic substances found in proteins (branched chain amino acids). Life-threatening complications of MSUD that may occur in a newborn include the abnormal accumulation of acid in the blood and other tissues of the body (metabolic acidosis) and seizures. If left untreated, MSUD may progress to coma. The VDH stated that patients diagnosed with MSUD can be treated with medication and special formulas not containing certain amino acids. [12]

- According to the National Organization for Rare Disorder (NORD), TYRO I is a rare genetic metabolic disorder characterized by the lack of the enzyme fumarylacetoacetate hydrolase (FAH), that is needed to break down the amino acid tyrosine. Individuals diagnosed with TYRO are unable to properly break down tyrosine which leads to abnormal accumulation of tyrosine and its metabolites in the liver, potentially resulting in severe liver disease. Tyrosine may also build up in the kidneys and central nervous system. Symptoms associated with TYRO I include failure to thrive, fever, diarrhea, vomiting, an abnormally enlarged liver (hepatomegaly), and yellowing of the skin and the whites of the eyes (jaundice). [13]

2. Urea Cycle Disorders

The National Urea Cycle Disorders Foundation stated that a urea cycle is an inherited disorder caused by the lack of one of the enzymes in the urea cycle that is responsible for removing ammonia from the blood stream. Routinely, the urea is transferred into the urine and removed from the body. However, a disorder occurs when the nitrogen builds up in the form of ammonia (toxic) and the toxic is not removed from the body resulting in hyperammonemia. When ammonia reaches the brain through the blood, it may cause brain damage, coma or death. [14]

The Virginia Newborn Screening Services Program currently screens for two urea cycle disorders: Argininosuccinic acidemia (ASA) and Citrullinemia (CIT).[15]

- ASA is an inherited disorder that causes ammonia to build up in the blood. Build up of ammonia is toxic and can cause brain damage. Infants with ASA may have less energy and a reluctance to eat. Some babies may experience seizures, unusual body movements, or coma. Mental retardation and developmental delay may also occur. Progressive complications may include liver damage and skin lesions. [16]

- CIT is an inherited disorder that occurs when ammonia and other toxic substances build up in the blood. Some infants diagnosed with this disorder may experience a progressive lack of energy, poor feeding, vomiting, seizures, and loss of consciousness. Adults may experience intense headaches, partial loss of vision, lethargy, and problems with their balance and muscle coordination. [17]

3. Organic Acid Disorders

The 2007 California Health Benefits Review Program (CHBRP) Analysis of Assembly 30: Health Coverage: Inborn Errors of Metabolism stated:

> Organic acid disorders occur when deficient enzyme function leads to the accumulation of intermediate metabolites that are not usually present in appreciable amounts in healthy people. Accumulation of the metabolites causes metabolic acidosis (excessive acidity of the blood), which threatens the body's pH balance. Unlike amino acid metabolism disorders, the defective enzyme is several steps removed from the beginning of the protein metabolism pathway. [18]

The Virginia Newborn Screening Services Program currently screens for the following organic acid disorders: Glutaric acidemia Type I (GA-I), Isovaleric acidemia (IVA), Methylmalonic acidemia: mutase deficiency (MUT), and Propionic acidemia (PROP). [19]

- According to the U.S. National Library of Medicine, GA-I is an inherited disorder in which the body has inadequate levels of enzymes to help break down the amino acids lysine, hydroxylsine, and tryptophan, the building blocks of protein. Some babies with GA-I are born with unusually large heads. Mental retardation may also occur. Individuals diagnosed with this disorder may have difficulty in moving, and experience spasms, jerking, rigidity, or decreased muscle tone. [20]

- IVA is a rare disorder characterized by a distinctive odor of sweaty feet during acute illness. The initial symptoms may include poor feeding, vomiting, seizures, and lack of energy. Sometimes these symptoms may progress to more serious medical problems, including seizures, coma, or death. [21]

- MUT is an inherited disorder in that the body is unable to correctly process certain proteins and fats. Some infants with this disorder may experience vomiting, dehydration, weak muscle tone, excessive tiredness, and the failure to gain weight at their expected rate. Long-term complications may include mental retardation, chronic kidney disease, and inflammation. In some cases, without the proper treatment, this disorder can lead to coma or death. [22]

- PROP is an inherited disorder that leads to abnormal level of organic acids in the blood, urine, and tissues that may be very toxic. Symptoms for infants may include poor feeding, vomiting, loss of appetite, weak muscle tone, and lack of energy. Some of these symptoms may progress to more serious medical problems including heart abnormalities, seizures, coma, or death. [23]

Allergic and Gastrointestinal Disorders

House Bill 615 requires coverage for amino acid-based elemental formulas for the treatment of individuals diagnosed with allergic and gastrointestinal disorders including Immunoglobulin E, 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.

The 2008 California Health Benefits Review Program (CHBRP) assessment of the medical, financial, and public health impacts of Assembly Bill 2174 regarding coverage for amino acid-based elemental formula. The CHBPR stated:

> Amino acid-based elemental formulas are complete nutrition formulas designed for individuals who have a dysfunctional or shortened gastrointestinal tract and are unable to tolerate and absorb whole foods or formulas composed of whole proteins, fats, and/or carbohydrates. [24]

The CHBRP stated that short bowel syndrome (SBS) is a malabsorption disorder due to congenital defects of the gut or surgery to treat acquired diseases. If malabsorption becomes severe, an individual is unable to maintain hydration or nutrient balance and may require the assistance of supplemental parenteral nutrition (the practice of feeding a person intravenously).[25]

A dietitian from the Virginia Commonwealth University Metabolic Treatment Center explained that the protein in the elemental formulas is broken down into a smaller biochemical form. Amino acid-based elemental formulas are used for infants with severe allergies and individuals that have intestinal problems that reduce the gastrointestinal tract’s ability to absorb nutrition. The dietician clarified that metabolic formulas are also elemental in nature; however, the additional step of removing part of the biochemical form is performed in elemental formulas. [25]

The Act Against Allergy web site, stated that food allergic diseases can cause frustration and distress, both for the children that suffer from the condition and the parents that take care of them. [26]

Information is provided by the Department of Agronomy and Horticulture at the University of Nebraska-Lincoln USA website. Two authors discussed some of the issues that consumers experience following exposure to certain foods. Module 5: Allergenicity explained that the immune responses of a true food allergy include two categories, the Immunoglobulin E (IgE) and non-Immunoglobulin E mediated.[27]

Module 5 document stated:

> The more common allergic response, IgE-mediated, also referred to as an immediate hypersensitivity reaction, involves the rapid onset of symptoms, and is mediated by IgE antibodies. The non-IgE-cell-mediated response, also referred to as a delayed hypersensitivity reaction, involves the delayed onset of symptoms, usually 24 hours or longer after exposure or ingestion of the food. [28]

The symptoms of IgE may involve various systems of the body including the skin, respiratory tract, and gastrointestinal tract. Symptoms involving the gastrointestinal tract are common with food allergies that include abdominal cramping and pain, diarrhea, vomiting, and nausea. When an allergist uses the proper diagnostic tools and approaches, a correct diagnosis can be made using a skin test that involves pricking or puncturing the skin, and discussing the patient's history. [29]

Food Protein-Induced Entercolitis Syndrome (FPIES) is a non-IgE mediated immune reaction in the gastrointestinal system to specific foods including continuous vomiting and diarrhea. Some children have severe vomiting and diarrhea, they become seriously dehydrated and go into shock. According to Kids With Food Allergy, a child with FPIES may experience what appears to be a severe stomach bug, but the "bug" only starts a couple hours after the allergic food is consumed. It was explained that poor growth weight may occur along with constant ingestion. [30]

Eosinophilic Disorder occurs when there is high number of eosinophils in the blood that may be triggered by certain allergic foods. Eosinophils, a type of white blood cell, are an important part of the immune system that help fight off certain types of infections in the body. Eosinophilic disorders are further defined by the location of the affected area. For example, eosinophilic esophagitis (EE) is coupled with abnormally high numbers of eosinophils in the esophagus.[31] The American Partnership for Eosinophilic Disorders stated:

> Symptoms of EE vary from one individual to the next and may differ depending on age. Vomiting may occur more commonly in young children and difficulty swallowing in older individuals. Common symptoms include reflux that does not respond to usual therapy (which includes proton pump inhibitors, a medicine which stops acid production in the stomach), dysphagia (difficulty swallowing), food impactions (food gets stuck in the throat), nausea and vomiting, failure to thrive (poor growth or weight loss), abdominal or chest pain, poor appetite, malnutrition, and difficulty sleeping. Individuals that display some of the symptoms of EE should have an upper endoscopy biopsy for diagnosis. [32]

Motility of the gastrointestinal tract occurs when the stretching or contractions of the muscles in the esophagus, stomach, small intestine, and large intestine are not functioning properly in a coordinated fashion. Each region of the gastrointestinal tract works with other regions to process the food along the digestive tract absorbing nutrients and eliminating waste products. The International Foundation for Functional Disorders stated that symptoms of motility of gastrointestinal disorders include heartburn, difficulty swallowing, abdominal distention and pain, nausea, vomiting, constipation, and diarrhea. There are different types of gastrointestinal motility tests that provide information to help with diagnosis and treatment. [33]

SOCIAL IMPACT

Children's MAGIC stated that according to information from medical professionals and a number of state health departments, the number of infants and children that rely on amino acid-based elemental formulas is relatively low. Some children will need the formulas for a period of two years or less. The majority of them will outgrow their allergies within five years. Children's MAGIC reported that data from the VDH, Division of WIC (Supplemental Nutrition for Women, Infants and Children) and Community Nutrition Services indicated that in December 2007, elemental formulas were distributed to 68 participants. [34]

According to the information provided by VDH, when a newborn is identified with one of the reportable conditions, the metabolic center will contact the family. Once the diagnosis is confirmed, the metabolic center will refer the infant to the Care Connection for Children Center that will determine the infant's eligibility for the program. Virginia implemented the first screening for PKU in 1966. In 1984, the newborn screening panel added MSUD and HCU to the list of metabolic disorders that are screened to prevent mental retardation, and permanent disability, or death. During a ten-year period from 1997 to 2006, 45 children were diagnosed with PKU and seven patients with MSUD. The number of infants born and screened in Virginia during the ten-year period was 975,010. For calendar year 2007, VDH reported 27 children and eight adults received formulas from the Virginia Metabolic Program. As of June 2008, there were eight children and nine adults in the program. [35]

According to the Save Babies Through Screening Foundation, Inc. (Foundation), studies have shown that 1 of every 70,000 live births will have some form of ASA. The Foundation reported that 1 out of 57,000 people worldwide are diagnosed with CIT. The incidence of IVA is approximately 1 in 50,000 live births and fewer than 100 cases of GA-I are known in the United States. The Foundation reported that MUT occurs in approximately 1 in 50,000 to 100,000 live births and that PA occurs in approximately 1 in 100,000 live births in the United States. [36]

FINANCIAL IMPACT

The VDH operates two metabolic formula programs. One program is for children with a family income of 300% or less of the poverty level. They can receive metabolic formula at no cost through the distribution program. However, if the participants have insurance coverage that pays for all or part of the formula cost, children are not eligible for the program. The other program is for children whose family is without insurance with income above 300%. They can access the Care Connection for Children Program and purchase metabolic formula through the program. The cost is normally less than the retail price because the VDH pharmacy is able to purchase the formula through multi-state contracts. The VDH stated that adults that have been diagnosed with a disorder are also eligible for either the distribution (no cost) or the purchase programs. The eligibility determination for adults is made by the Office of Family Health Services business unit. [37]

According to the VDH, the annual expenditure for metabolic formulas for the calendar year 2007 was $104,010. The metabolic program generated $33,367 from patients. The Maternal and Child Health Block Grant Title V funds pay for most of the formulas that are provided at no cost. The Enterprise Funds that receive revenue from the purchase of newborn screening filter paper collection devices are also used to pay for formulas. The Department of General Services, Division of Consolidated Laboratory Services, used most of these funds to support follow-up services for newborns. [38]

Children's MAGIC reported that according to the 2006 National Average, the median family income in the United States was $58,528 and that the average cost of elemental formulas per year was $5,075. [39] According to the U.S. Census Bureau, 2006 American Community Survey, the median income in Virginia for 2006 inflation-adjusted dollars was $56,277.[40] A constituent of House Bill 669 stated that her daughter was diagnosed with eosinophilic esophagitis. The family reported that the formula costs more than $100 per case, approximately $500 per month, and their insurance company does not provide coverage for the formula. [41]

On November 12, 2002, a public hearing was held on House Bill 84. A dietician testified that some families will go through one or two cases of formula per month, at a cost of $300 to $500 per month. A proponent of House Bill 84, a patient and a parent of four children diagnosed with eosinophilic gastroenteritis (EG), stated that their monthly out-of-pocket cost for medical formulas was approximately $1,000 per month per child. [42]

The 2005 Report of the Advisory Commission, House Bill 1216: Mandated Coverage for Inborn Errors of Metabolism, reported proponents' written comments in support of the bill. The proponents stated that the cost of providing medical formulas, as preventive measures, would be considerably less than the cost of extended hospital stays for gastric tubes, and possibly liver or kidney transplants resulting from the inability to purchase the formula. A mother stated that medical formulas and low-protein medical food products were medically necessary in order for her daughter to function normally. If her daughter's condition had not been diagnosed and treated since birth, she would be so severely retarded that she would be living in a state facility for the mentally retarded for the duration of her life.[43]

MEDICAL EFFICACY

House Bill 615 requires coverage for amino acid-based elemental formulas that have proven to be effective in the treatment for individuals diagnosed with allergic and gastrointestinal disorders. Amino acid-based elemental formulas contain proteins that are broken down into their simplest form making it easier for the body to process and digest. House Bill 669 requires coverage for the expense of amino acid-based formulas proven to be effective for the dietary management of individuals diagnosed with metabolic conditions.

According to information from the University of Virginia Health System, Division of Pediatric Gastroenterology and Nutrition website, a small group of children are unable to tolerate the hydrolyzed protein contained in the casein formulas and will only tolerate free amino acids, such as those elements contained in Neocate.

Neocate is a hypoallergenic, nutritionally complete powdered infant formula that is especially designed for infants and young children with milk protein allergy. Neocate allows infants and young children to receive all the necessary nutrients for their growth and development. The website stated that:

> Neocate rapidly relieves the diverse symptoms of infant food allergy and can be used for a range of allergy induced conditions such as gastroesophageal reflux disease (GERD) and eosinophilic esophagitis. Neocate is described on the label as:
>
> - Hypoallergenic. Neocate is less likely to cause an allergic response than other formulas.
> - Elemental. The ingredients in Neocate are present in the simplest and purest form so they are easier for the body to process and digest.
> - Amino acid-based. Amino acids are the building block of protein.
> - Nutritionally complete. Neocate provides all of the essential nutrients needed to grow when consumed in adequate amounts. [44]

According to NORD, the goal of treatment for PKU is to keep plasma phenylalanine levels within the normal range. This goal is generally achieved through a carefully planned diet. Limiting the child's intake of phenylalanine must be done cautiously because it is an essential amino acid. A carefully maintained diet can prevent mental retardation and neurological, behavioral, dermatological or brain abnormalities. Treatment must be started at a very young age (under three months) or some degree of mental retardation may be expected. The child's behavior and plasma levels of phenylalanine must be monitored regularly. Studies have demonstrated that children with PKU who are treated with a low-phenylalanine diet before the age of three months do well, with an average intelligence quotient of 100. If treatment is begun after the age of two or three years, only hyperactivity and seizures may be controlled. [45]

Neurological changes usually occur during adolescence and adulthood if people with PKU stop controlling their dietary intake of phenylalanine. Intelligence quotients may decline after a peak at the end of the controlled diet period. Other problems that may appear and become severe once dietary regulation is stopped include difficulties in school, behavioral problems, poor visual-motor coordination, poor problem-solving skills, and abnormalities during brain wave testing. If the intake of phenylalanine is limited too severely in people with PKU, the symptoms of phenylalanine deficiency may develop. These may include fatigue, aggressive behavior, severe loss of appetite (anorexia), and sometimes anemia. [46]

Infants with MSUD must be placed on a diet free of foods that are broken down into branched chain amino acids. The diets are protein restricted. A calorie supplementation is also recommended and may include semi-synthetic dietary supplementation. Children with this disorder must stay on a strict diet established by a physician, in which the intake of branched chain amino acids is omitted. [47]

NORD stated that treatment for HCU consists of controlled supplemental intake of the amino acids methionine, cystine, and folic acid. Massive doses of pyridoxine (a form of Vitamin B 6) may also be prescribed. [48]

Robert Tomaino stated that the three main forms of treatment for TYRO I are devotion to a specialized diet, medication, and liver transplantation. The diet must be low in protein and have low levels of tyrosine and phenylalanine. A strong commitment to this diet may lead to an improvement of symptoms and slow the progression of the disorder. In January 2002, the U.S. Food and Drug Administration approved the orphan medicine, nitisinone (Orfadin) for the treatment of TYRO I. The medicine blocks the metabolism of tyrosine and reduces the accumulation of tyrosine and its metabolites in the body. The drug is used in conjunction with a low protein diet. Some children may receive a liver transplant to treat end stage liver failure or as a preventive measure to avoid the development of liver cancer. It was noted that liver transplantation is considered a last resort in many cases because of the risk of morbidity or mortality associated with the procedure, along with the high cost of surgery and therapy. [49]

According to Children's MAGIC's, 2008 Legislative Brief, *The Fight for Coverage: Elemental Formulas*:

> Amino acid-based elemental formulas are complete nutritional formulas designed for individuals that are unable to tolerate and absorb whole foods or formulas composed of whole proteins, fats, or carbohydrates. Amino acid-based elemental formulas are made from individual (single) non-allergenic amino acids unlike regular dairy (milk or soy based) formulas and foods that contain many complete proteins. Amino acid-based elemental formulas are made of proteins broken down to their elemental level so that they can be easily absorbed and digested. In many cases, amino acid-based elemental formulas are the only thing an infant or child can properly digest and tolerate due to various allergies or gastrointestinal conditions. [49]

Children's MAGIC stated that the medical efficacy of amino acid-based elemental formulas has long been proven. Within two weeks of using amino acid-based elemental formulas or medical foods, hives and rashes clear and diarrhea disappears. After a few months, infants and children returned to their normal weight and continued on a normal growth pattern. Children's MAGIC explained that the formulas help infants and children get back on track towards a healthy existence. [50]

The Journal of Pediatrics 2002 article, entitled *Allergy to Extensively Hydrolyzed Cow's Milk Proteins in Infants: Safety and Duration of Amino Acid-based Formula*, surveyed infants that were allergic to cow's milk protein and extensively hydrolyzed formulas that received an amino acid-based formula. The results indicated that amino acid-based formulas proved to be safe and infants exhibited an overall gain in length and weight. Children that were restricted extensively to hydrolyzed formulas were diagnosed much earlier than children with multiple food allergies.[51]

The American Journal of Gastroenterology 2003 article, entitled *Elemental Diet is an Effective Treatment for Eosinophilic Esophagitis in Children and Adolescents* reported a study of 346 patients with chronic gastroesophageal reflux disease symptoms and eosinophils on esophageal biopsy. Of that number, 51 patients were eventually diagnosed with EE. The study concluded that elemental diets resulted in significant reduction in vomiting, abdominal pain, and dysphagia for children and adolescents with EE. [52]

The Kids With Food Allergy, a national nonprofit food allergy organization, stated that treatment with food protein-induced entercolitis syndrome varies from child to child. Infants that have reacted to both dairy and soy formulas should be placed on hypoallergenic or elemental formulas. Children should be introduced to new foods, one at a time, for an extended period of time. [53]

CURRENT INDUSTRY PRACTICES

The State Corporation Commission Bureau of Insurance surveyed 50 of the top writers of accident and sickness insurance in Virginia regarding each of the bills to be reviewed by the Advisory Commission in 2008. Forty-two companies responded by August 27, 2008. Seven indicated that they have little or no applicable health insurance business in force in Virginia and, therefore, could not provide the information requested. Of the 35 respondents that completed the survey, four reported that they currently provide the coverage required by House Bill 615 and seven reported that they currently provide the coverage as required by House Bill 669.

Four insurers reported cost figures that ranged from $.21 to $ 1.00 per month per individual policy to provide coverage required by House Bill 615. Fifteen insurers provided cost figures that ranged from $.05 to $1.46 per month per standard group certificate to provide the coverage required by House Bill 615. Two insurers provided cost figures of $.21 and $5.00 per month per individual policyholder for coverage required by House Bill 615 on an optional basis. Fifteen insurers provided cost figures of $.05 to $3.00 per month per group certificateholder for coverage as required by the bill on an optional basis. One respondent reported $313.50 for the monthly cost of its total policy premium and did not supply an estimate or cost for the coverage required by House Bill 615.

Five insurers reported cost figures that ranged from $.14 to $ 9.90 per month per individual policy to provide coverage required by House Bill 669. Sixteen insurers provided cost figures that ranged from $.05 to $12.40 per month per standard group certificate to provide the coverage required by House Bill 669. Two insurers provided cost figures of $.21 and $3.00 per month per individual policyholder for coverage as required by House Bill 669 on an optional basis. Fifteen insurers provided cost figures of $.05 to $2.00 per month per group certificateholder to provide coverage as required by the bill as an option. One respondent reported $313.50 for the monthly cost of its total policy premium and did not supply an estimate or cost for the coverage required by House Bill 669.

SIMILAR LEGISLATION IN OTHER STATES

According to the information published by the National Association of Insurance Commissioners, there are thirty-one states that mandate coverage for medical formulas for the treatment of metabolic diseases. Of those thirty-one, only one state requires a mandated offer of coverage.

Children's MAGIC stated that eight states (Arizona, Connecticut, Illinois, Massachusetts, Minnesota, New Hampshire, New Jersey, and New York) have legislative mandates for coverage of amino acid-based elemental formulas.

REVIEW CRITERIA

SOCIAL IMPACT

a. *The extent to which the treatment or service is generally utilized by a significant portion of the population.*

Children's MAGIC stated that according to the advice of medical professionals and a number of state health departments, the number of infants and children that rely on amino acid-based elemental formulas is relatively low. Children's MAGIC reported that data from the VDH, Division of WIC and Community Nutrition Services indicated that in December 2007, elemental formulas were distributed to 68 participants. [54]

According to the information provided by VDH, during a ten-year period from 1997 to 2006, 45 children were diagnosed with PKU and seven patients with MSUD. The number of infants born and screened in Virginia during the ten-year period was 975,010. For calendar year 2007, VDH reported 27 children and eight adults received formulas from the Virginia Metabolic Program. As of June 2008, there were eight children and nine adults in the program. [55]

b. *The extent to which insurance coverage for the treatment or service is already available.*

In a 2008 State Corporation Commission Bureau of Insurance survey of the 50 top writers of accident and sickness insurance in Virginia, 35 companies currently writing applicable business in Virginia responded. Of the 35 respondents that completed the survey, four (11%) reported that they currently provide the coverage required by House Bill 615 and seven (20%) reported that they currently provide the coverage as required by House Bill 669.

c. *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.*

The VDH operates two metabolic formula programs. One program is for children with a family income of 300% or less of the poverty level. They can receive metabolic formula at no cost through the distribution program. However, if the participants have insurance coverage that pays for all or part of the formula cost, children are not eligible for the program. The other program is for children whose family is without insurance with income above 300%. They can access the Care Connection for Children Program and purchase metabolic formula through the program. The cost is normally less than the retail price because the VDH pharmacy is able to purchase the formula through multi-state contracts. The VDH stated that adults that have been diagnosed with a disorder are also eligible for either the distribution (no cost) or the purchase programs. The eligibility determination for adults is made by the Office of Family Health Services business unit. [56]

d. If the coverage is not generally available, the extent to which the lack of coverage results in unreasonable financial hardship on those persons needing treatment.

Children's MAGIC explained that families are suffering from a lack of coverage and facing an extreme financial burden. It was reported that a year's supply of elemental formulas costs approximately $5,100, which is 10% of the median household income in Virginia. Children's MAGIC stated that according to the Kaiser Family Foundation, the average employee contributes $2,723 a year in premiums for family health insurance which is 5% of their income. The combined out-of-pocket cost for elemental formulas and health insurance is nearly $8,000.[57]

e. The level of public demand for the treatment or service.

Five families testified in favor of House Bill 615 and House Bill 669 at the public hearing. They testified that the formulas are medically necessary and needed for the rest of their children's lives. Mental retardation could result from lack of formula. The costs of the formulas ranged from $ 340 to $1,000 per month. One parent testified that an insurer informed the parent that it would pay for the formula if a feeding tube was inserted in the child to provide the formula. One parent provided written comments that stated two of her four children are dependent on these formulas. One of the children is diagnosed with IVA that ultimately left him with severe brain damage. He receives all of his nutrition via a tube in his stomach. She reported that they pay $1,500 per month out-of-pocket for formula and related supplies for the two children.

Children's MAGIC stated that the level of public demand for House Bill 615 and House Bill 669 is quite low because very few individuals utilize amino acid-based elemental formulas. The bills will affect a tiny segment of the population and the level of demand will be miniscule. The majority of children will use these formulas for a short period of time, on the average, two years or less.

A registered dietitian with the metabolism program in the Department of Human and Molecular Genetics at Virginia Commonwealth University spoke in favor of House Bill 669 at the public hearing. The program works with families and physicians to provide medical services and the necessary treatments for individuals diagnosed with a metabolic condition as long as they reside in this geographic area.

The NFIB provided written comments on House Bill 615 and House Bill 669. The NFIB stated:

> "Small business owners want to and do offer healthcare plans that cover a wide variety of benefits such as preventive care and cancer screenings. Providing these types of benefits is important to the productivity of NFIB members and their employees. However, NFIB continues to be greatly concerned by government imposed mandates that discourage consumer control and innovative health plan design. While mandates make small business health insurance more comprehensive, they also make it more expensive. In some markets, mandated benefits increase the cost of health insurance by as much as 45 percent." [58]

f. The level of public demand and the level of demand from providers for individual and group insurance coverage of the treatment or service.

A pediatric gastroenterologist spoke in favor of House Bill 615 at the public hearing. The doctor testified that elemental formulas are necessary for individuals that are diagnosed with gastrointestinal disorders to restore children to good health. She explained that in her own professional experience, one child died as a result of not receiving the proper treatment and formula.

The VAHP stated that House Bill 615 and House Bill 669 go far beyond the typical scope of formula mandates in other states and that coverage is currently available in the private market. VAHP noted that several health plans offer coverage of formulas under certain circumstances, and the benefit may be limited to certain diagnoses, conditions, methods of administration, or inpatient settings. They stated that the variance among plans is in keeping with the larger debate amongst the medical community as to the categorization of formulas as food when delivered orally. [59]

g. The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts.

The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contract is unknown.

h. Any relevant findings of the state health planning agency or the appropriate health system agency relating to the social impact of the mandated benefit.

The Advisory Commission is not aware of any findings of the state health planning agency or health system agency relating to the social impact of treating individuals diagnosed with the disorders as listed in House Bill 615 and House Bill 669.

Similar, but not identical, bills addressing formulas including House Bill 2197, House Bill 2199, House Bill 84, and House Bill 1216 have been reviewed by the Advisory Commission three times during the past ten years. After reviewing those bills, the members of the Advisory Commission recommended no mandate of coverage for medicated formulas because it was not necessary and recommended that other action be taken, primarily to expand the VDH program that provides formulas.

FINANCIAL IMPACT

a. *The extent to which the proposed insurance coverage would increase or decrease the cost of treatment or service over the next five years.*

It is not anticipated that House Bill 615 or House Bill 669 would increase the cost of treatment over the next five years. However, Children's MAGIC reported that the cost of formulas could decrease, if insurers choose to enter into agreements with pharmacies, manufacturers, and distributors of these formulas. [60]

b. *The extent to which the proposed insurance coverage might increase the appropriate or inappropriate use of the treatment or service.*

It is unlikely that the proposed mandate would significantly increase the inappropriate use of treatment because House Bill 615 requires coverage for amino acid-based elemental formulas when the prescribing or ordering physician has issued a written order stating that the formulas is medically necessary for the treatment. House Bill 669 requires coverage for amino acid-based formulas when it is the primary source of nutrition and prescribed by the treating licensed physician.

It is also unlikely that the proposed mandate would significantly increase the appropriate use of treatment because of the small population that will need treatment.

c. *The extent to which the mandated treatment or service might serve as an alternative for more expensive or less expensive treatment or service.*

Children's MAGIC stated that House Bill 615 and House Bill 669 would serve as an alternative for less expensive treatment. The proposed bills would provide coverage regardless of the delivery method. It was stated that the alternative to oral feeding is enteral feeding, a costly surgery that requires invasive tube feeding. The difference between consuming the formulas orally rather than through a feeding tube is approximately $20,000. [61]

The JLARC assessment reported that in some cases, amino acid-based elemental formulas are used as a second or alternative treatment to other formulas**:**

- Extensive hydrolyzed formulas are the first choice for children with food protein-induced entercolitis 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 bowl 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. [62]

d. 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.

It is unlikely that the proposed mandate would significantly affect the number and types of providers in the next five years because the number of insureds needing such treatment is relatively small.

e. 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.

Four insurers reported cost figures that ranged from $.21 to $ 1.00 per month per individual policy to provide coverage required by House Bill 615. Fifteen insurers provided cost figures that ranged from $.05 to $1.46 per month per standard group certificate to provide the coverage required by House Bill 615. Two insurers provided cost figures of $.21 and $5.00 per month per individual policyholder for coverage required by House Bill 615 on an optional basis. Fifteen insurers provided cost figures of $.05 to $3.00 per month per group certificateholder for coverage as required by the bill on an optional basis. One respondent reported $313.50 for the monthly cost of its total policy premium and did not supply an estimate or cost for the coverage required by House Bill 615.

Five insurers reported cost figures that ranged from $.14 to $ 9.90 per month per individual policy to provide coverage required by House Bill 669. Sixteen insurers provided cost figures that ranged from $.05 to $12.40 per month per standard group certificate to provide the coverage required by House Bill

669. Two insurers provided cost figures of $.21 and $3.00 per month per individual policyholder for coverage as required by House Bill 669 on an optional basis**.** Fifteen insurers provided cost figures of $.05 to $2.00 per month per group certificateholder to provide coverage as required by the bill as an option. One respondent reported $313.50 for the monthly cost of its total policy premium and did not supply an estimate or cost for the coverage required by House Bill 669.

f. *The impact of coverage on the total cost of health care.*

Children's MAGIC stated that amino acid-based elemental formulas are essential and life-saving to individuals that need the coverage to grow into healthier adults. Coverage for the formulas will improve the quality and value of health care. The consequences of denying coverage will result in deteriorating health and costly medical conditions that will have a significant impact on the total cost of health care. [63]

MEDICAL EFFICACY

a. *The contribution of the benefit to the quality of patient care and the health status of the population, including the results of any research demonstrating the medical efficacy of the treatment or service compared to alternatives or not providing the treatment or service.*

A registered dietitian spoke in support of House Bill 669 at the public hearing. She stated that each amino acid-based metabolic formula has a reduced amount of specific amino acid and is designed for a specific diagnosis. The dietitian's written testimony stated that the consequences of individuals going without metabolic formulas may include impaired cognitive development, seizures, skeletal abnormalities, defects in vision, stroke and even death. Amino acid-based formulas designed for specific diagnoses are the foundation of treatment for certain disorders. The role of special formulas mandated in House Bill 669 is to limit the person's intake of those specific amino-acids that they are unable to metabolize and also provide the protein that individuals need to keep their bodies in good working condition. [64]

The dietitian clarified that these formulas are in fact medically necessary for treating metabolic disorders. The metabolic formulas are available only by prescription and should be supervised by a qualified physician. These formulas are the mainstay of treatment throughout the life an individual with a metabolic disorder. It was stated that metabolic formulas are critical in preventing disabling consequences in the offspring of women with metabolic disorders. When a pregnant woman has PKU, it is crucial that she uses metabolic formula to preserve the health of her unborn child. In most cases, the child may not have PKU. The pregnant woman needs to maintain an adequate blood level with the help of the metabolic formula; if not, there is a 92% chance that her child will be born mentally retarded, a 73% chance the child will be born with a small head size, and a 12% chance the child will have a heart defect. In the long run, health issues in children will result in higher health care costs than providing coverage for metabolic formulas for the mother. [65]

The 2007 CHBRP analysis of Assembly Bill 30 discussed the medical effectiveness of inborn errors of metabolism (IEM) disorders. Even though treatments vary across IEM disorders, one or more of the following treatments may include special formulas that do not contain the nutrients a person cannot metabolize, special foods products, vitamin supplements, amino acid and enzyme supplements, and prescription drugs. CHBRP stated:

> There are no published randomized controlled trials or nonrandomized studies with comparison groups that assess the effectiveness of special formulas or special food products for IEM disorders relative to no medical nutrition therapy. Most studies on treatment for these disorders are case studies of individual patients or small groups of patients, or present findings from surveys of clinicians. The lack of controlled studies is probably due to the rarity of these disorders and their potentially lethal consequences. The lack of controlled studies is not as great a concern for IEM disorders as for many other conditions because IEM disorders are single-cause conditions for which the scientific basis and rationale for treatment are strong. [66]

The 2008 CHBRP Assembly Bill 2174 discussed the medical effectiveness of treatment for short bowel syndrome (SBS). CHBRP stated that for children diagnosed with congenital SBS, a major therapeutic goal is to promote normal growth and development. Intravenous feeding is not a desirable method for treating SBS for extended periods as it can result in further complications. Because of the rarity of these disorders, few research studies have addressed the usage of elemental formulas to treat SBS. CHBRP reported that three uncontrolled studies of children suggested that elemental formula is associated with the following outcomes:

1. Decrease in the duration of parenteral nutrition therapy and successful transition to oral intake of food that can be easily absorbed by the intestinal tract.
2. Decrease in co-morbidities associated with SBS.
3. Decrease in hospitalizations. [67]

The JLARC assessment noted that the medical efficacy and effectiveness of amino acid-based formulas are well established for treating certain conditions listed in House Bill 615 and House Bill 669. However, the bills also cover certain conditions for which the use of those formulas is not considered standard medical practice. They stated that House Bill 615 would mandate coverage for amino acid-based metabolic formulas for GI and hypersensitivity diseases and disorders. House Bill 669 would mandate coverage for amino acid-based metabolic formulas for IEMs and elemental formulas for certain GI conditions. The JLARC assessment stated:

> Few clinical trails 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 treatment 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. [68]

b. *If the legislation seeks to mandate coverage of an additional class of practitioners:*

1) *The results of any professionally acceptable research demonstrating the medical results achieved by the additional class of practitioners relative to those already covered.*

Not applicable.

2) *The methods of the appropriate professional organization that assure clinical proficiency.*

Not applicable.

EFFECTS OF BALANCING THE SOCIAL, FINANCIAL AND MEDICAL EFFICACY CONSIDERATIONS

a. *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.*

Proponents believe that House Bill 615 and House Bill 669 address both the medical and social needs of treating individuals diagnosed with metabolic disorders, allergic and gastrointestinal disorders. The benefit is consistent with the role of health insurance.

The JLARC assessment noted**:**

> For certain medical conditions listed in House Bill 615 and House Bill 669 health insurance coverage appears consistent with the role of insurance. However, House Bill 615 and House Bill 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 not more clearly defined as opposed to including broad categories of GI and hypersensitivity conditions. [69]

b. The extent to which the need for coverage outweighs the costs of mandating the benefit for all policyholders.

Virginia Chamber of Commerce (VCC) testified in opposition to House Bill 615 and House Bill 669. The VCC provided information from the Council for Affordable Health Insurance (Council), and the Kaiser Family Foundation and the Health Research and Education Trust regarding the impacts mandates have on the affordability of health insurance. The Council states:

1. While mandated health benefits make health insurance more comprehensive, they also make it more expensive.
2. While one mandate by itself may not generate a large increase in premium, it is the culmination of many mandates that increase the cost of coverage.
3. Mandates can boost the cost of a policy between 20 to 45 percent.
4. Experience demonstrates that when health insurance costs go up, more people drop or decline coverage, swelling the ranks of the uninsured.
5. The introduction of state-mandated benefits legislation is slowing down. [70]

The Kaiser Family Foundation states the following information about health benefits in its 2008 summary of findings:

1. Employer sponsored health insurance is still the leading source of health insurance for most Americans, covering 158 million nonelderly people.

2. Health insurance premiums continue to increase, as has the use of cost sharing for medical services between employers and employees.
3. 63% of all firms offered health benefits in 2008, down from 66% in 1999.
4. For small firms with 3-9 workers, only 49% offered health benefits in 2008, down from 56% in 1999.
5. Going forward, companies said they were more likely to ask their employees to pay more of the premium cost, increase deductible amounts, increase office visit cost sharing, or increase the amount employees have to pay for prescriptions. Some firms said they would drop coverage. [71]

The JLARC assessment stated that the formulas covered by the bills are medically necessary for the treatment of certain disorders and the population that needs the coverage is relatively small:

> 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% 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 conditions for which amino acid-based formulas are recommended treatment according to medical practice guidelines. [72]

c. The extent to which the need for coverage may be solved by mandating the availability of the coverage as an option for policyholders.

In the case of group coverage, the decision whether to select the optional coverage or not would lie with the master contract holder and not the individual insured.

RECOMMENDATION

Delegate Amundson and Delegate Marshall asked that action on House Bill 615 and House Bill 669 be deferred until 2009. The Advisory Commission agreed to defer the bills until 2009.

CONCLUSION

Delegate Amundson indicated her intention to introduce legislation in the 2009 Session to address concerns raised during the review of House Bill 615 and House Bill 669. She indicated that the revised legislation that she will introduce will be similar to the legislation in effect in Maryland that addresses coverage of foods and food products for the treatment of inherited metabolic diseases.

ENDNOTES

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[71] Virginia Chamber of Commerce, public meeting October 27, 2008.

[72] 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 Offer of Amino Acid-Based Formulas,” September 2008.