REPORT OF THE
SPECIAL ADVISORY COMMISSION ON MANDATED
HEALTH INSURANCE BENEFITS

HOUSE BILL 84 (2002): MANDATED COVERAGE FOR POLYPEPTIDE OR AMINO ACID-BASED FORMULAS

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

COMMONWEALTH OF VIRGINIA
RICHMOND
2003

January 10, 2003

To: The Honorable Mark Warner
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 (Advisory Commission) to assess the social and financial impact and the medical efficacy of House Bill 84 regarding mandatory coverage for the expense of polypeptide-based or amino acid-based formulas whose protein source has been extensively or completely hydrolyzed.

Respectfully submitted,

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Chairman
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INTRODUCTION

The House Committee on Commerce and Labor referred House Bill 84 to the Special Advisory Commission on Mandated Health Insurance Benefits (Advisory Commission) during the 2002 Session of the General Assembly. House Bill 84 was introduced by Delegate Robert D. Orrock, Sr.

The Advisory Commission held a public hearing on November 12, 2002, in Richmond, to receive public comments on House Bill 84. Representatives from the Medical College of Virginia/Virginia Commonwealth University Health Systems Metabolic Diseases Program, the University of Virginia Health Systems Metabolic Diseases Program, Blue Ridge Pediatrics, and four concerned citizens spoke in favor of the bill. A representative from the Virginia Association of Health Plans (VAHP) spoke in opposition to the bill.

In addition, written comments in support of the bill were provided by Medical College of Virginia/Virginia Commonwealth University Health Systems Metabolic Diseases Program, the University of Virginia Health Systems Metabolic Diseases Program, Blue Ridge Pediatrics, Duke University Medical Center Division of Pediatrics, Cincinnati Children's Hospital Medical Center, the University of Virginia Health System Department of Pediatrics, Children's Hospital in Boston, Massachusetts, and three concerned citizens. Written comments in opposition to House Bill 84 were provided by VAHP.

SUMMARY OF PROPOSED LEGISLATION

The bill adds § 38.2-3418.14 to the Code of Virginia to require 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 subscription contracts; and health maintenance organizations (HMOs) providing health care plans to provide coverage for the expense of polypeptide-based or amino acid-based formulas whose protein source has been extensively or completely hydrolyzed.

The bill requires coverage for polypeptide-based or amino acid-based formulas prescribed by a licensed physician. A managed care health insurance plan, as defined in Chapter 58 (§ 38.2-5800 et seq.) of the Insurance Code, may require such physician to be a member of the plan's provider network.

The bill requires that the physician furnish supporting documentation to the insurers, corporations, or HMOs that the polypeptide-based or 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. The polypeptide-based or amino acid-based formula is the primary source of nutrition as certified by the treating physician by diagnosis.

The bill prohibits insurers, corporations, or HMOs from imposing copayments, fees, or conditions on persons for these benefits that are not equally imposed on all individuals in the same benefit category. The bill also prohibits insurers, corporations, or HMOs from imposing any policy-year or calendar-year dollar or durational benefit limitations or maximums for benefits provided under this section.

The bill applies to insurance policies, contracts, and plans delivered, issued for delivery, reissued, renewed or extended in the Commonwealth on or after July 1, 2002, or at any time thereafter when the term is changed or any premium adjustment is made.

The bill does not apply to short-term travel, accident-only, short-term nonrenewable policies of not more than six months' duration, limited or specified disease policies, or policies or contracts for persons eligible for coverage under Title XVIII of the Social Security Act (Medicare), or any other similar coverage under state or federal governmental plans.

Amino acid-based formulas are used to treat various medical conditions including disorders of amino-acid metabolism and intestinal disorders. The treatment of metabolic disorders such as phenylketonuria (PKU), maple syrup urine disease (MSUD), and homocystinuria (HCU) requires the use of amino acid-based formulas. The treatment of intestinal diseases such as food allergies and eosinophilic gastroenteritidies (eosinophilic gastroenteritis (EG), eosinophilic colitis, eosinophilic esophagitis) also requires the use of amino acid-based formulas.

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 patroned by Delegate Robert F. McDonnell. House Bill 2197 required coverage for any low protein foods prescribed for treatment of inborn errors of amino acid metabolism, such as PKU, MSUD, and HCU. House Bill 2199 required coverage for any medical formula that eliminates specific amino acids for the treatment of inborn errors of metabolism, such as 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 the medical formulas. The Advisory Commission recommended that a mechanism for payment be provided either through expansion of the VDH program to include food, or a tax credit for the families with members with these conditions. The 2000 report of the study was printed as House Document No. 67.

FORMULAS

Casein Hydrolysate Formulas. According to information provided by the University of Virginia Health System, Division of Pediatric Gastroenterology and Nutrition, children with extreme sensitivity or allergy and who are exposed to intact or whole proteins may experience rectal bleeding, vomiting or diarrhea. Many of these children will tolerate casein hydrolysate formulas. According to the information provided by the Virginia Commonwealth University Health System, The Department of Clinical Nutrition, Nutramigen, Pregestimil, and Alimentum are casein hydrolysate formulas based on a hypoallergenic protein source consisting of amino acids and small peptides (see Appendix B). These products are helpful when there has been damage to an infant's gastrointestinal (GI) tract from a viral or bacterial infection. If an infant has significant fat malabsorption, Pregestimil or Alimentum may be the products of selection because about half of the fat is provided by medium chain triglycerides (MCT) that do not require the normal fat digestive pathways. The casein hydrolysate formulas may also be helpful during times of acute GI infection. A damaged GI tract is permeable to foreign products, disposing an infant to an allergic condition. The usage of casein hydrolysate formulas may improve digestion and allow for mucosal healing and recovery of function. It would also provide an opportunity for a progressive return to more standard formulas.

According to meadjohnson.com, Mead Johnson Nutritionals, the maker of Enfamil's Nutramigen and Pregestimil formulas, stated that Nutramigen is a hypoallergenic formula and is effective in supplying protein in a hydrolyzed form for infants and children sensitive to intact proteins of milk and other foods. The protein of Nutramigen is supplied as hydrolyzed casein specially processed to be essentially non-antigenic. Pregestimil is a hypoallergenic and virtually isotonic, nutritionally complete infant formula that contains MCT oil as 55% of its fat blend, a protein hydrolysate, and a readily digestible carbohydrates blend. Pregestimil is specifically designed for the dietary management of infants with severe malabsorption disorders, including intractable diarrhea, short gut syndrome, steatorrhea, cystic fibrosis, and severe protein-calorie malnutrition.

Ross Products, a division of Abbott Laboratories, is a United States market leader in pediatric nutritionals and a world leader in adult nutritionals. Alimentum is a nutritionally complete hypoallergenic formula for infants and can be used as a supplemental beverage for children with severe food allergies, sensitivity to intact protein, protein maldigestion or fat malabsorption. Alimentum contains predigested protein (casein hydrolysate) to minimize allergenicity and is easily digested with absorbed fat blend.

Amino Acid-Based Formulas. According to information provided by the University of Virginia Health System, Division of Pediatric Gastroenterology and Nutrition, 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. According to the web site: staff.washington.edu, Neocate is the only infant formula of this type currently on the market. The Department of Clinical Nutrition provided a list of several specialized formulas for infants from the Pediatric Nutrition Reference Guide 2002, 6th edition that also contained free amino acids, such as EleCare, Neocate One +, and Vivonex Pediatric that are designed for children over one year of age (see Appendix B).

Information provided by a manufacturer, SHS North America, stated that Neocate is specifically designed to meet the nutritional needs of infants with severe cow milk protein allergy or multiple food protein intolerance. Neocate One + Powder is intended to meet the nutritional needs for one to ten-year olds that are unable to ingest a normal diet or other hypoallergenic products. Neocate and Neocate One + Powder's sole ingredients (100% free amino acids, milk free, gluten free, and soy protein free) provide complete nutrition and may be the only source of nutrition for some children. Neocate and Neocate One + Powder have an elemental composition that requires minimal digestion and are more suitable for patients with compromised GI function.

According to ross.com, EleCare is used to meet the nutritional needs of children 1 year of age and older that require an amino acid-based medical food. Elecare is designed for children that are unable to tolerate intact protein, for the dietary management of maldigestion, severe food allergies, GI tract impairment, or other conditions in which an elemental (amino acid-based) diet is required.

According to novartisnutrition.com, Vivonex Pediatric is a nutritionally-complete elemental (100% free amino acids) formula designed specifically for children ages 1-10. Vivonex Pediatric can be used for tube feeding or consumed orally and is available in flavored packets. Vivonex Pediatric is considered a medical food and consumers should consult with their physician on the use of this product. Vivonex Pediatric is recommended for patients that are diagnosed with short bowel syndrome, malabsorption syndrome, GI enterocutaneous fistula, and intractable diarrhea.

METABOLIC DISORDERS

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.

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 is funded by the Virginia Department of Health (VDH) and was established to treat affected children early in life, before symptoms of a particular condition occur. Of the seven conditions screened in Virginia, three are metabolic disorders affecting protein metabolism such as phenylketonuria (PKU), maple syrup urine disease (MSUD), and homocystinuria (HCU).

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.

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. These are 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, people with 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.

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.

SOCIAL IMPACT

As of December 2001, the VDH estimated that there were 176 known cases of PKU in Virginia. Of the 176 patients, 133 patients are currently in the Virginia Metabolic Treatment Program, and 93 patients are active in the formula program. The VDH reported that six patients were diagnosed with MSUD and eight patients were diagnosed with HCU. The VDH reported that no registry exists for malabsorption or GI disorders. Two registered dieticians at the public meeting provided an information sheet on amino acid based metabolic formulas and Virginia's newborn screening program. The information indicates that in Virginia, there are about 120 individuals using amino based formulas to treat a metabolic disorder.

FINANCIAL IMPACT

The cost of Enfamil Nutramigen Hypoallergenic Formula Powder and Enfamil Pregestimil Formula Powder is approximately $22.25 to $22.65 per can. The SHS consumer price list for home delivery of Neocate Infant Formula shows a price of $115.00 per case that includes 4 cans. Unflavored Neocate One+ Formula is shown at a price of $76.00 per case that includes 10 cans.

Ross home delivery for Alimentum Powder cost approximately $146.00 per case that includes 6 cans. Elecare Powder cost approximately $182.00 per case for 6 cans. Vivonex Nutrition Division was contacted and reported that Vivonex Pediatric Powder costs approximately $129.00 for 36 packets.

According to the information provided by the VDH, Code of Virginia § 32.1-67 requires that formulas be provided by the VDH at no cost to indigent families and is funded by the Maternal and Child Health Block Grant Title V and by fees collected from hospitals for the Newborn Screening testing kits. The VDH is currently charging other families no more than 2% of their gross income per dependent with a metabolic disorder.

Military families are covered by the Champus Nutritional Therapy program. The program includes, but is not limited to inborn errors of metabolism such as PKU, medical conditions of malabsorption such as short bowel syndrome and acute ulcerative colitis, and other pathologies of the alimentary or GI tract such as allergic eosinophilic gastroenteritis.

MEDICAL EFFICACY

Based on clinical experience, meadjohnson.com stated that Nutramigen has been known to be of significant value in the dietary management of protein allergic infants. Nutramigen has proven very important for infants with severe and persistent diarrhea when compared to milk and other feedings that will normally aggravate the symptoms. The usage of Nutramigen has been recommended in order to avoid possible GI absorption of intact protein from milk feedings provided in the recovery stages of infant diarrhea. Nutramigen has proven effective in eliminating the symptoms of protein allergy, allowing the sensitive GI tract to recover, and establishing and maintaining a healthy nutritional state during recovery.

Meadjohnson.com stated that Pregestimil has proven useful in the nutritional management of infants with a variety of severe GI abnormalities where poor tolerance to enteral feeding and the malabsorption of conventional forms of protein, fat, and carbohydrates are common. Pregestimil has proven to be effective in the following conditions: massive bowel reaction (short gut syndrome), recovery from severe diarrhea, protein-calorie malnutrition, GI milk and soy protein intolerance, transition from intravenous alimentation, and GI immaturity. Pregestimil has supported sufficient growth in infants with cystic fibrosis. Studies of metabolic balance have shown excellent nitrogen absorption and retention in recovering malnourished infants.

According to Ross.com, Alimentum is clinically shown to reduce the symptoms of colic due to protein sensitivity and to be well tolerated in infants with protein sensitivity. The features of Alimentum include the following: hypoallergenic to minimize potential for allergic reaction, hydrolyzed casein supplemented with free amino acids for infants who are sensitive to or unable to digest intact protein, lactose-free carbohydrate to avoid lactose-associated diarrhea, and contains approximately 33% of fat as MCT, an easily digested and fat source. Alimentum also includes a blend of two carbohydrates, sucrose and modified tapioca starch using two absorptive pathways to maximize absorption and to minimize the risk of malabsorption. EleCare is clinically shown to support growth when used as a primary source of nutrition. Elecare is well tolerated, useful in such conditions as short-bowel syndrome, contains one-third of the fat known as MCT, an easily digested and well-absorbed fat, and stringent manufacturing standards to reduce risk of whole-protein contamination.

According to the NORD, the goal of treatment for PKU is to keep plasma phenylalanine levels within the normal range. This 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.

Neurological changes usually occur during adolescence and adulthood. If people with PKU stop controlling their dietary intake of phenylalanine, their 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, low developmental age, 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.

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 that omits the intake of branched chain amino acids.

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 B6) may also be prescribed.

CURRENT INDUSTRY PRACTICES

The State Corporation Commission Bureau of Insurance recently surveyed 60 of the top writers of accident and sickness insurance in Virginia regarding each of the bills to be reviewed by the Advisory Commission in 2002. Fifty companies responded by May 28, 2002. Fourteen 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 36 respondents that completed the survey, 13 reported that they currently provide the coverage required by House Bill 84.

Respondents to the Bureau of Insurance survey provided cost figures that ranged from less than $.55 to $9.00 per month per standard individual policyholder and from $.01 to $6.50 per month per standard group certificate to provide the coverage required by House Bill 84. Insurers providing coverage on an optional basis provided cost figures of $.55 to $9.00 per month per individual policyholder and from $.10 to $6.50 per month per group certificate holder for the coverage required by House Bill 84.

VAHP stated that the formulas are not covered under prescription drug coverage because they are not classified as drugs by the federal Food and Drug Administration.

SIMILAR LEGISLATION IN OTHER STATES

In Ohio, House Bill 318, a carryover bill from the 2001 Session (two-year Session) is still currently pending in the Health and Family Services Committee. If enacted, the bill would require health care policies, certificates, contracts, agreements and plans to provide benefits for polypeptide-based or amino acid-based formulas when prescribed to treat specified disorders.

According to information published by the National Association of Insurance Commissioners, there are 26 states that mandate coverage for metabolic disease formulas for the treatment of inherited metabolic disorders. Of those 26 states, only one state requires a mandated offer of coverage for testing and treatment, including dietary management and formulas.

REVIEW CRITERIA

SOCIAL IMPACT

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

PKU, MSUD, and HCU are rare disorders that affect males and females in equal numbers. It is estimated by NORD that PKU occurs in 1 in 11,600 newborns in the United States. PKU affects people from most ethnic backgrounds, although it is rare among Americans of African descent and Jews of Ashkenazi ancestry. MSUD occurs in approximately 1 in 200,000 births in families of European descent. It is more common among Mennonite populations in the United States. It is estimated that 1,000 individuals in the United States are affected by the HCU disorder. About 2,000 people are affected by this disorder worldwide.

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

In a 2002 State Corporation Commission Bureau of Insurance survey of the sixty top writers of accident and sickness insurance in Virginia, thirty-six companies currently writing applicable business in Virginia responded. Of the thirty-six companies, thirteen companies (36%) reported that they currently provide the coverage required by House Bill 84.

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.*

Some services are available to those without coverage. According to the information provided by the VDH, the Code of Virginia Section 32.1-67 requires that formulas be provided by the VDH at no cost to indigent families. The service is funded by the Maternal and Child Health Block Grant Title V and by fees collected from hospitals for the Newborn Screening testing kits. The VDH is currently charging other families no more than 2% of their gross income per dependent with a metabolic disorder.

Military families may obtain some treatments through the Champus Nutritional Therapy program. The program includes, but is not limited to services for inborn errors of metabolism such as PKU, medical conditions of malabsorption such as short bowel syndrome and acute ulcerative colitis, and other pathologies of the alimentary or GI tract such as allergic EG.

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.*

There is a considerable amount of financial hardship on families that must pay the cost of the formulas out of pocket. A dietician testified at the public meeting that some families will go through a case or two cases of formula per month costing anywhere from $300 to $500 per month. A proponent of House Bill 84, a patient and a parent of four children all diagnosed with EG stated that their monthly out-of-pocket cost for medical formulas is approximately $1,000 per month per child.

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

As of December 2001, the VDH estimated that there were 176 known cases of PKU in Virginia. Of the 176 patients, 133 patients are currently in the Virginia Metabolic Treatment Program, and 93 patients are active in the formula program. The VDH reported that six patients were diagnosed with MSUD and eight patients were diagnosed with HCU. The VDH reported that no registry exists for malabsorption or GI disorders. Two registered dieticians testified in favor of House Bill 84. The dieticians provided an information sheet on amino acid based metabolic formulas and Virginia’s newborn screening program. The information indicates that in Virginia, there are about 120 individuals using amino based formulas to treat a metabolic disorder.

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

Seven families testified in favor of House Bill 84 at the public hearing. A registered dietician stated that amino acid based formulas are the only medical treatment for people that are suffering from metabolic disorders or intestinal diseases. She explained that the medical formulas are not a nutritional supplement because 95% of the person's nutrition comes from these formulas.

In written comments, VAHP stated that currently, the VDH program is providing formulas to 110 individuals diagnosed with PKU, MSUD, and HCU. VAHP noted that if the Commonwealth of Virginia chooses to provide this coverage, the expansion of the program would serve to guarantee that all individuals with these conditions would have access to the medical formulas and that the cost would be spread across all taxpayers. VAHP also noted that a mandated benefit applies to only 25% of the population and that typically small employers would assume the costs associated with a mandate.

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 and organizations in negotiating privately for inclusion of this coverage in group contracts 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 the appropriate health system agency relating to the social impact of this mandate.

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 the cost of polypeptide-based or amino acid-based formulas would be significantly impacted by the proposed mandate.

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 services because the number of insureds needing such treatment appears to be relatively small.

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

VAHP stated that House Bill 84 is problematic because it creates an unlimited benefit, and prevents health plans from requiring the enrollees to share in the cost of the coverage for these formulas. VAHP noted that in 1999, the Advisory Commission considered similar legislation and unanimously recommended against its passage.

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 of the mandate treatments 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.

An increase in the administrative expenses of insurance companies and the premiums and the administrative expenses for policyholders is anticipated because of the expenses associated with, among other things, are policy redesign, form filing, claims processing systems, and marketing.

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

Proponents believe that the total cost of health care will decrease because of the provision of medical formulas for individuals diagnosed with metabolic disorders. Two registered dieticians at the public meeting submitted a fact sheet on amino acid based formulas. In 1980, a study confirmed that the offspring of a woman with untreated PKU has a 92% chance of mental retardation, a 73% chance of microcephaly (small-head size), a 12% chance of congenital heart disease, and a 40% chance of low birth weight, thus increasing health care costs when treating these children.

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.*

According to the NORD, the goal of treatment for PKU is to keep plasma phenylalanine levels within the normal range. This 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.

Neurological changes usually occur during adolescence and adulthood. If people with PKU stop controlling their dietary intake of phenylalanine, their 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, low developmental age, 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.

House Document No. 67 reported that the consequences of going without treatment vary depending on the specific disorders. Without treatment, an individual diagnosed with PKU would gradually become severally mentally retarded and suffer from seizures. The consequences of going without treatment for an individual diagnosed with MSUD are mental retardation, seizures, coma, and death. HCU can cause visual problems, possible mental retardation, scoliosis (curvature of the spine), and childhood stroke.

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 84 addresses the medical need and social need of treating individuals with inborn errors in metabolism such as PKU, MSUD, and HCU. The bill also addresses the medical need and social need of treating individuals suffering from intestinal diseases such as food allergies and eosinophilic gastroenteritidies. The benefit is consistent with the role of health insurance.

In written comments, VAHP requested the Advisory Commission to retain the position they adopted in 1999. In 1999, the Advisory Commission urged “strong consideration” of expanding an existing program within the VDH to meet the needs of individuals diagnosed with certain metabolic disorders. They reported that currently, the VDH program is providing formulas to 110 individuals diagnosed with PKU, MSUD, and HCU. VAHP believes that if the Commonwealth of Virginia expands the program, it would guarantee that all individuals with these conditions would have access to the medical formulas and that the cost would be spread across all taxpayers. VAHP noted that a mandated benefit applies to only 25% of the population and that typically small employers would assume the costs associated with a mandate. VAHP stated that the formulas are not covered under prescription drug coverage because they are not classified as drugs by the federal Food and Drug Administration.

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

Respondents to the Bureau of Insurance survey provided cost figures that ranged from less than $.55 to $9.00 per month per standard individual policyholder and from $.01 to $6.50 per month per standard group certificate to provide the coverage required by House Bill 84. Insurers providing coverage on an optional basis provided cost figures of $.55 to $9.00 per month per individual policyholder and from $.10 to $6.50 per month per group certificate holder for the coverage required by House Bill 84.

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

The Advisory Commission voted 9 – 1 on January 8, 2003 to recommend that House Bill 84 not be enacted. However, the Advisory Commission recommended that other action be taken.

CONCLUSION

The Advisory Commission believes that the need for assistance for persons requiring polypeptide-based or amino-acid based formulas is significant although it should not be a required insurance benefit. The Advisory Commission believes that the funding for the 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 recognizes that in the current economic environment the funding for program expansion may not be available. The Advisory Commission does believe however, that expansion of the program to include the additional disorders is the best alternative and that it should be pursued in the future.