REPORT OF THE
SPECIAL ADVISORY COMMISSION ON
MANDATED HEALTH INSURANCE BENEFITS

MANDATED COVERAGE FOR PHENYLKETONURIA, MAPLE SYRUP URINE DISEASE, AND HOMOCYSTINURIA

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

HOUSE DOCUMENT NO. 67

COMMONWEALTH OF VIRGINIA
RICHMOND
2000

COMMONWEALTH OF VIRGINIA

STEPHEN H. MARTIN
11TH SENATORIAL DISTRICT
PART OF CHESTERFIELD AND DINWIDDIE COUNTIES;
AMELIA COUNTY; CITY OF COLONIAL HEIGHTS;
POST OFFICE BOX 36147
RICHMOND, VIRGINIA 23235

COMMITTEE ASSIGNMENTS:
EDUCATION AND HEALTH
GENERAL LAWS
LOCAL GOVERNMENT
PRIVILEGES AND ELECTIONS

SENATE

January 10, 2000

To: The Honorable James S. Gilmore, III
Governor of Virginia
and
The General Assembly of Virginia

The report contained herein has been prepared pursuant to §§ 9-298 and 9-299 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 2197 and House Bill 2199 regarding mandatory coverage of low-protein foods and medical formulas for inborn errors of metabolism, such as phenylketonuria, maple syrup urine disease, and homocystinuria.

Respectfully submitted,

Stephen H. Martin
Chairman
Special Advisory Commission on
Mandated Health Insurance Benefits

SPECIAL ADVISORY COMMISSION ON
MANDATED HEALTH INSURANCE BENEFITS

Stephen H. Martin, Chairman
James M. Shuler, Vice Chairman

Thomas K. Norment, Jr.
Vivian E. Watts
Johanna B. Chase
R. DuVal Dickinson
Charles B. Garber
Dao Huynh
Matthew D. Jenkins
Stephen P. Long, M.D.
James F. McIntyre, III
Virginia Norton, Ph.D.
Fred M. Rankin, III
John L. Roper, IV
Alfred W. Gross
E. Anne Peterson, M.D., M.P.H.

TABLE OF CONTENTS

INTRODUCTION

During the 1999 Session of the General Assembly, the House Committee on Corporations, Insurance and Banking referred House Bill 2197 and House Bill 2199 to the Special Advisory Commission on Mandated Health Insurance Benefits (Advisory Commission). House Bill 2197 and House Bill 2199 were patroned by Delegate Robert F. McDonnell.

The Advisory Commission received public comments on House Bill 2197 and House Bill 2199 at the June 1, 1999 meeting in Richmond. Representatives from the Medical College of Virginia/Virginia Commonwealth University's Department of Pediatrics, Division of Metabolism, and four concerned citizens spoke in favor of the bills. In addition, written comments in support of the bills were provided by Medical College of Virginia/Virginia Commonwealth University's Department of Pediatrics, Division of Metabolism Program, and two concerned citizens. The Virginia Manufacturers Association submitted comments in opposition to the bills. On August 24, 1999, representatives from the Medical College of Virginia/Virginia Commonwealth University's Department of Pediatrics, Division of Metabolism, and seven concerned citizens spoke again in support of the bills and representatives of the Health Insurance Association of America (HIAA) and the Virginia Association of Health Plans spoke in opposition. The HIAA provided written comments on House Bill 2197.

The Advisory Commission held a public hearing at the August 24, 1999 meeting and the patron of the bills, Delegate Robert F. McDonnell, submitted amendments to House Bill 2197 and House Bill 2199. The amended bills would be mandated benefits as opposed to mandated offers of coverage for food and formulas for the treatment of inborn errors of metabolism. Delegate Robert F. McDonnell stated that other states require coverage as mandated benefits; the total cost of these mandated benefits is nominal; the number of families needing coverage is small; and the insurance premiums would remain the same given the fact that only 86 patients are currently diagnosed with a metabolic disorder.

SUMMARY OF PROPOSED LEGISLATION

House Bill 2197 and House Bill 2199 add § 38.2-3407.5:2 to the Code of Virginia. House Bill 2197 relates 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 relates to coverage for any medical formula that eliminates specific amino acids for the treatment of an inborn error of metabolism, such as having PKU, MSUD, and HCU.

The bills would require each insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and

surgical, or major medical coverage on an expense incurred basis; each corporation providing individual or group subscription contracts; and each health maintenance organization providing a health care plan for health care services, whose policy contract or plan, including any certificate or evidence of coverage issued in connection with such policy, contract or plan, that includes coverage for prescription drugs on an outpatient basis to offer and make available coverage for any low-protein foods (House Bill 2197) and any medical formulas (House Bill 2199) prescribed for treatment of inborn errors of amino acid metabolism, such as PKU, MSUD, and HCU, which are approved by the United States Food and Drug Administration (FDA). The bills apply to contracts, policies, and plans delivered or issued for delivery or renewed after July 1, 1999. The bills do not apply to short-term travel, accident only, limited or specified disease policies, or contracts designed for issuance to persons eligible for coverage under Medicare, or any other similar coverage under state or federal governmental plans, or to short-term nonrenewable policies of not more than six months' duration.

House Bill 2197 provides that "prescription drugs" includes low-protein foods prescribed for the treatment of inborn errors of amino acid metabolism, such as PKU, MSUD, and HCU. Low-protein foods shall not include commercial food products that may be naturally low in protein, but have not been developed for the treatment of an inborn error of amino acid metabolism.

House Bill 2199 provides that "prescription drugs" includes metabolic or medical formulas classified by the FDA as a medical food and defined as foods that are formulated to be consumed or administered entirely under the supervision of a physician. The medical formulas are intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements are based on recognized scientific principles established by medical evaluation. Medical formulas do not include commercial products that may be low in protein, but have not been developed for the treatment of an inborn error of metabolism.

The bills provide that no insurer, corporation or health maintenance organization shall impose upon any person receiving benefits for any low-protein foods pursuant to this section any (i) copayment, coinsurance payment or fee that is not equally imposed for other prescription drugs upon all individuals in the same benefit category, class, coinsurance level or copayment level receiving benefits for prescription drugs or (ii) reduction in allowable reimbursement for prescription drug benefits.

The bills are not to be construed to require coverage for prescription coverage benefits in any contract, policy or plan that does not otherwise provide coverage for prescription drugs or preclude the use of closed formularies. However, such formularies shall include low protein foods for the treatment of individuals diagnosed with an inborn error of metabolism. The bills do not require

coverage for experimental drugs for the treatment of inborn errors of metabolism that are not approved by the FDA.

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 PKU, MSUD, and HCU. These three disorders require a special medical formula and medical food for treatment.

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. People with PKU can avoid irreversible mental retardation with a carefully controlled diet.

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.

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.

PKU, MSUD, and HCU are inherited as an autosomal recessive genetic trait. Human traits, including the classic genetic diseases, are the product of the interaction of two genes, one received from the father and one from the mother. In recessive disorders, the condition does not appear unless a person inherits the same defective gene for the same trait from each parent. If an individual receives one normal gene and one gene for the disease, the person will be a carrier for the disease, but usually will not show symptoms. There is 25% risk of transmitting the disease to a child whose parents are carriers for a recessive disorder. Fifty percent of their children risk being carriers of the disease, but generally will not show symptoms of the disorder. Twenty-five percent of the children may receive both normal genes, one from each parent, and will be genetically normal (for that particular trait). The risk is the same for each pregnancy.

According to the NORD, infants with PKU may appear normal at birth. Phenylpyruvic acid, a by-product of phenylalanine metabolism, may not be found in the urine during the first days of life. Some newborns (neonates) with this disorder may be weak and feed poorly. Other symptoms of PKU in infants may include vomiting, irritability, or a red skin rash with small pimples (eczematoid). Infants with this disorder generally have a musty or "mousy" body odor caused by phenylacetic acid in the urine or perspiration.

Infants with MSUD begin to develop symptoms several days after birth. Symptoms may include poor feeding habits, vomiting, irregular pattern of breathing, extreme lethargy, convulsive seizures, or coma. Most infants with this disease have episodes of abnormal muscle rigidity (hypertonia) alternating with periods of extreme floppiness (hypotonia). Mental retardation may be apparent in infants who are a few months old.

The NORD stated that HCU is a genetic disorder characterized by developmental and mental retardation, dislocated lenses, sparse hair, chronic flushing of the face (malar flush), and relaxation of ligaments.

SOCIAL IMPACT

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 in 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.

The VDH, Division of Women's and Infants' Health, reported that 86 patients are currently diagnosed with a metabolic disorder. Of the 86 patients, there are currently 77 individuals that have PKU, six individuals diagnosed with MSUD, and three children are diagnosed with HCU. Of those 86 patients, 67 children and ten adults with PKU, three children and three adults with MSUD, and one child and two adults with HCU are currently in the Virginia Metabolic Treatment Program. The only food supplement that the program participants currently receive is the metabolic formula. The VDH reported that 42 children were diagnosed with PKU, two children with MSUD, and one child with HCU within a ten-year range (1987-1997) with a birth population of 1,835,651.

FINANCIAL IMPACT

Proponents representing the Virginia Metabolic Treatment Program stated that a person with a metabolic defect eats many fruits, vegetables, very small amounts of starchy foods (bread, rice, and crackers), and the medical formulas. They noted that the low protein foods described in the House Bill 2197 are foods that are specifically designed to be lower in total protein than regular foods.

The Virginia Metabolic Treatment Program stated that some families have ordered low protein foods on an individual basis from several different private manufacturers. The low protein foods are generally not available in grocery stores. The VDH buys in bulk and provides families with special formulas. Families are then charged 2% of their income to help cover the cost to the VDH.

A recent study was done of families in Virginia receiving metabolic formula from the VDH. The study reported that 58.8% received no insurance reimbursement for medically necessary formulas and 92% received no insurance coverage for low protein foods. Families that have one member with a metabolic defect paid an average of $925 per year out-of-pocket costs and families with two members paid an average of $1,686 per year out-of-pocket costs for the metabolic formula. The average amount paid by all families for medical foods was $1,048 per year out-of-pocket costs. The average amount of money spent on low-protein foods was $519 per year out-of-pocket costs.

MEDICAL EFFICACY

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. 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 phenlalanine 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 50 of the top writers of accident and sickness insurance in Virginia regarding each of the bills to be reviewed by the Advisory Commission this year. Twenty-nine companies responded by April 9, 1999. Five 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 24 respondents that completed the survey, six reported that they currently provide the coverage required by House Bill 2197 and House Bill 2199.

Respondents to the Bureau of Insurance survey provided cost figures that ranged from less than $.01 to $2.00 per month per standard individual policyholder and from $.01 to $2.00 per month per standard group certificate to provide the coverage required by House Bill 2197 and House Bill 2199. Insurers providing coverage on an optional basis provided cost figures of $.01 to $4.00 per month per individual policyholder and from $.02 to $4.00 per month per group certificate holder for the coverage required by each bill. Two companies reported

cost figures of $11.25 and $15.00 per month for individual coverage on an optional basis required by House Bill 2197, and $11.70 and 15.60 per month for individual coverage on an optional basis required by House Bill 2199.

SIMILAR LEGISLATION IN OTHER STATES

According to information published by the National Association of Insurance Commissioners and the National Insurance Law Service, there are 16 states that mandate coverage for low protein foods for the treatment of inherited metabolic disease similar to House Bill 2197. There are 23 states that mandate coverage for medical formulas for the treatment of inherited metabolic disease similar to House Bill 2199. Of those 23 states, only one state requires mandatory offering of coverage for testing and treatment, and 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.

The VDH, Division of Women's and Infants' Health reported that 86 patients are currently diagnosed with a metabolic disorder. Of the 86 patients, there are currently 77 individuals that have PKU, six individuals diagnosed with MSUD, and three children are diagnosed with HCU. Of those 86 patients, 67 children and ten adults with PKU, three children and three adults with MSUD, and one child and two adults with HCU are currently in the Virginia Metabolic Treatment Program. The only food supplement these program participants currently receive is the metabolic formula. The VDH reported that 42 children were diagnosed with PKU, two children with MSUD, and one child with HCU within a ten-year range (1987-1997) with a birth population of 1,835,651.

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

In a 1999 State Corporation Commission Bureau of Insurance survey of the fifty top writers of accident and sickness insurance in Virginia, twenty-four companies currently writing applicable business in Virginia responded. Of that number, six (25%) reported that they currently provide the coverage required by House Bill 2197 and House Bill 2199.

In written comments, VMA noted that § 32.1-67 requires the Board of Health to provide the parents of any child who is a legal resident of the Commonwealth and who is diagnosed as requiring treatment for PKU, the special food products required in the management of that condition. The VDH is allowed at its discretion to require reimbursement from the parents or guardian of the child, not to exceed 2% of annual gross income. This section applies whether or not the child is covered by health insurance.

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 Virginia Metabolic Treatment Program stated that some families have ordered low protein foods on an individual basis from several different private manufacturers. The low protein foods are generally not available in grocery stores. The VDH provides families with special formulas that it buys in bulk. Families are then charged 2% of their income to help cover the cost to the VDH.

The VDH provided sources of payment for the metabolic formula. They stated that two children are covered by a special supplemental Nutrition Program for Women, Infants, and Children (WIC). WIC covers the full cost of formula to five years of age for those children that meet the eligibility criteria. The federal guidelines permit WIC agencies to provide specialized formulas. VDH reported that thirty-three children are covered by insurance. The amount of payment varies by the insurance company. Insurance companies will usually pay 80% after yearly deductibles. Families are currently billed up to 2% of their annual gross income. VDH reported that one child is covered by Champus. Champus covers the full cost of formula for military families. VDH reported that four children are covered by Medicaid. Medicaid pays the full cost of formula to age 21 for eligible clients, if pre-authorized. VDH reported that five children actually pay the full costs of formula.

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.*

A recent study was done of families in Virginia receiving metabolic formula from the VDH. The study reported that 58.8% received no insurance reimbursement for medically necessary formula. Families that have one member with a metabolic defect paid an average of $925 per year out-of-pocket costs and families with two members paid an average of $1,686 per year out-of-pocket costs for the metabolic formula. The average amount paid by all families for medical foods was $1,048 per year out-of-pocket costs. The average amount of money spent on low-protein foods was $519 per year out-of-pocket costs.

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

The VDH, Division of Women's and Infant's Health reported that 86 patients are currently diagnosed with a metabolic disorder. Of the 86 patients there are currently 77 individuals that have PKU, six individuals diagnosed with MSUD, and three children are diagnosed with HCU. Of those 86 patients, 67 children and ten adults with PKU, three children and three adults with MSUD, and one child and two adults with HCU are currently in the Virginia Metabolic Treatment Program. The only food supplement these program participants currently receive is the metabolic formula. The VDH reported that 42 children were diagnosed with PKU, two children with MSUD, and one child with HCU within a ten-year range (1987-1997) with a birth population of 1,835,651.

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

Five families testified in favor of the bills at the public hearing. They stated that people with this disorder are unable to buy anything to correct this disability because it is a lifelong disease. They noted that without proper management, they would suffer cognitive damage.

A registered dietician and a medical consultant for the Medical College of Virginia Hospital testified in favor of the bills at the public hearing. They noted that some of the specific consequences for this disorder include mental retardation, seizures, visual problems, scoliosis, and in the case of MSUD, death. They explained that the available treatment for these metabolic disorders is a low-protein diet. The only permitted foods are fruits and vegetables. The other main component of the dietary therapy is medical formula. They noted that these medical formulas are not nutrition supplements and provide necessary nutrition for children. One of the proponents estimated that approximately ten to fifteen

individuals with PKU are institutionalized in Virginia because they were not diagnosed with PKU by appropriate screenings.

In written comments, VMA stated that some policies do not include prescription drugs (still an optional feature in health insurance policies) and that special formula and foods are considered prescription drugs. The bills would not change the situation since the bills deem the formula and food to be prescription drugs, and coverage for prescription drugs remains optional in some policies.

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 tot he 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 treatment for low-protein foods and medical 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.*

Proponents of the House Bill 2197 and House Bill 2199 make the argument that mandated treatment might serve as an alternative for less expensive treatment such as providing early intervention services. If individuals do not properly maintain their diet, they might develop poor visual-motor coordination, poor problem-solving skills, and mental retardation.

In written comments, HIAA expressed concern about House Bill 2197 regarding coverage for certain low protein foods for individuals diagnosed with inborn errors of amino acid metabolism. HIAA stated that the bill exempts commercial food products that are naturally low in protein, but the language is unclear as to the fact that other items are not included in the coverage unless they can be obtained by prescription.

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 policyholder is anticipated because of the expenses associated with such 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 providing medical formulas and low-protein foods for individuals diagnosed with PKU, MSUD, and HCU. Proponents believe that failing to recognize the importance of the treatments and their benefits may result in higher costs to insurers in the long run in providing early intervention services, physician services, medications, and institutional care.

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.

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 periods. 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 phenlalanine 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.

One proponent stated 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 an individual diagnosed with MSUD are mental retardation, seizures, coma, and death. HCU consisted of 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.*

The proponents believe that House Bill 2197 and House Bill 2199 address the medical need of treating individuals with inborn errors in metabolism such as PKU, MSUD, and HCU. The benefit is consistent with the role of health insurance. However, some opponents believe that coverage for low-protein foods is not consistent with the role of health insurance.

In written comments, HIAA expressed concerned that this legislation is a dangerous precedent that could lead to similar proposals for other specialty foods. HIAA stated that most Virginians face limitations in their diet in order to maintain their health because of medical condition, food allergy, or general health concerns. HIAA noted that health insurance should not be the vehicle for paying for such products. They believe that concern over the price of various food products should not be addressed through health insurance.

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 $.01 to $2.00 per month per standard individual policyholder and from $.01 to $2.00 per month per standard group certificate to provide the coverage required by House Bill 2197 and House Bill 2199. Insurers providing coverage on an optional basis provided cost figures of $.01 to $4.00 per month for individual policies and from $.02 to $4.00 per month per group certificate holder for the coverage required by each bill. Two companies reported cost figures of $11.25 and $15.00 per month for individual policies on an optional basis required by House Bill 2197, and $11.70 and 15.60 per month for individual policies on an optional basis required by House Bill 2199.

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

House Bill 2197 and House Bill 2199 were amended to make it a mandated benefit. 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 requested the VDH to perform analysis regarding the fiscal impact of expanding the current state program to include food. The VDH estimated that in Year 1 (FY 1999-2000), it would cost VDH $286,160 to implement the program and $277,129 for Year 2 (FY 2000-2001). They concluded that in order to implement the full cost of the program, VDH would require additional staff and funding to support the expanded program.

The Advisory Commission voted unanimously on November 22, 1999 to recommend that House Bill 2197 and House Bill 2199 not be enacted. They recommended that a mechanism for payment be provided either through expansion of the VDH program to include food or a tax credit.

CONCLUSION

The Advisory Commission believes that based on the information presented, the VDH is currently charging families no more than 2% of their gross annual income for medical formulas, and a mandate for treatment is not necessary at this time. They also believe that there should be a strong consideration of other alternatives such as requiring the VDH to expand their current program to include food or a possible tax credit.

999049350

HOUSE BILL NO. 2197

Offered January 20, 1999

A BILL to amend the Code of Virginia by adding a section numbered 38.2-3407.5:2, relating to coverage for certain low protein foods for individuals diagnosed with an inborn error of amino acid metabolism.

Patron—McDonnell

Referred to Committee on Corporations, Insurance and Banking

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding a section numbered 38.2-3407.5:2 as follows:

§ 38.2-3407.5:2. Coverage for certain low protein foods for individuals diagnosed with an inborn error of amino acid metabolism.

A. Each (i) insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical or major medical coverage on an expense-incurred basis; (ii) corporation providing individual or group accident and sickness subscription contracts; and (iii) health maintenance organization providing a health care plan for health care services, whose policy, contract or plan, including any certificate or evidence of coverage issued in connection with such policy, contract or plan, includes coverage for prescription drugs on an outpatient basis, shall offer and make available coverage thereunder for any low protein foods prescribed for treatment of inborn errors of amino acid metabolism, such as phenylketonuria, maple syrup urine disease, and homocystinuria, which are approved by the United States Food and Drug Administration for such purpose.

B. For the purposes of this section, prescription drugs shall be deemed to include low protein foods prescribed for the treatment of inborn errors of amino acid metabolism, such as phenylketonuria, maple syrup urine disease and homocystinuria; however, low protein foods shall not include commercial food products which may be naturally low in protein but have not been developed for the treatment of an inborn error of amino acid metabolism.

C. No insurer, corporation or health maintenance organization shall impose upon any person receiving benefits for any low protein food pursuant to this section any (i) copayment, coinsurance payment or fee that is not equally imposed for other prescription drugs upon all individuals in the same benefit category, class, coinsurance level or copayment level receiving benefits for prescription drugs or (ii) reduction in allowable reimbursement for prescription drug benefits.

D. The provisions of subsection A shall not be construed to:

1. Require coverage for prescription coverage benefits in any contract, policy or plan that does not otherwise provide coverage for prescription drugs;

2. Preclude the use of closed formularies; however, such formularies shall include low protein foods for the treatment of individuals diagnosed with an inborn error of amino acid metabolism; or

3. Require coverage for experimental drugs for the treatment of an inborn error of metabolism which are not approved by the United States Food and Drug Administration.

E. The provisions of this section shall not apply to short-term travel, accident-only, limited or specified disease policies, or contracts designed for issuance to persons eligible for coverage under Title XVIII of the Social Security Act, known as Medicare, or any other similar coverage under state or federal governmental plans, or to short-term nonrenewable policies of not more than six months' duration.

F. The provisions of this section shall be applicable to contracts, policies or plans delivered, issued for delivery or renewed in this Commonwealth on and after July 1, 1999.

999048350

HOUSE BILL NO. 2199

Offered January 20, 1999

A BILL to amend the Code of Virginia by adding a section numbered 38.2-3407.5:2, relating to coverage for medical formulas for individuals diagnosed with an inborn error of metabolism.

Patron—McDonnell

Referred to Committee on Corporations, Insurance and Banking

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding a section numbered 38.2-3407.5:2 as follows:

§ 38.2-3407.5:2. Coverage for medical formulas for the treatment of an inborn error of metabolism.

A. Each (i) insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical or major medical coverage on an expense-incurred basis; (ii) corporation providing individual or group accident and sickness subscription contracts; and (iii) health maintenance organization providing a health care plan for health care services, whose policy, contract or plan, including any certificate or evidence of coverage issued in connection with such policy, contract or plan, includes coverage for prescription drugs on an outpatient basis, shall offer and make available coverage thereunder for any medical formula which eliminates specific amino acids for the treatment of an inborn error of metabolism, such as phenylketonuria, maple syrup urine disease or homocystinuria, and is approved by the United States Food and Drug Administration for such purpose.

B. For the purposes of this section, prescription drugs shall include metabolic or medical formulas classified by the United States Food and Drug Administration as a medical food and defined as foods which are formulated to be consumed or administered entirely under the supervision of a physician and which are intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements based on recognized scientific principles are established by medical evaluation. Medical formulas shall not include commercial products which may be low in protein but have not been developed for the treatment of an inborn error of metabolism.

C. No insurer, corporation or health maintenance organization shall impose upon any person receiving benefits for any medical formula pursuant to this section any (i) copayment, coinsurance payment or fee for such medical formula that is not equally imposed for other prescription drugs upon all individuals in the same benefit category, class, coinsurance level or copayment level receiving benefits for prescription drugs or (ii) reduction in allowable reimbursement for prescription drug benefits.

D. The provisions of subsection A shall not be construed to:

1. Require coverage for prescription coverage benefits in any contract, policy or plan that does not otherwise provide coverage for prescription drugs;

2. Preclude the use of closed formularies; however, such formularies shall include medical formulas as defined in this section; or

3. Require coverage for experimental drugs for the treatment of any inborn error of metabolism which are not approved by the United States Food and Drug Administration.

E. The provisions of this section shall not apply to short-term travel, accident-only, limited or specified disease policies, or contracts designed for issuance to persons eligible for coverage under Title XVIII of the Social Security Act, known as Medicare, or any other similar coverage under state or federal governmental plans, or to short-term nonrenewable policies of not more than six months' duration.

F. The provisions of this section shall be applicable to contracts, policies or plans delivered, issued for delivery or renewed in this Commonwealth on and after July 1, 1999.

HOUSE BILL 2197
COVERAGE FOR CERTAIN LOW PROTEIN FOODS FOR AN INBORN ERROR OF METABOLISM IN OTHER STATES

STATE	CITATION	SUMMARY
Connecticut	Public Act 97-167	Individual and group health insurance policies must cover low-protein modified food products intended for the dietary treatment of inherited metabolic disease if administered under the direction of a physician.
Florida	§ 627.42395	Coverage for inherited diseases of amino acids and organic acids shall include food products modified to be low in protein, in an amount not to exceed $2,500 annually for any insured individual, through the age of 24.
Hawaii	House Bill 326	Coverage for medical foods and low-protein modified food products for the treatment of an inborn error of metabolism prescribed as medically necessary for therapeutic treatment and administered under the supervision of a physician.
Maine	24-A § 2745-D (indiv.) 24-A § 2837-D (group) 24-A § 4238 (HMO) 24-A § 2320-D (nonprofits)	Must include coverage for metabolic formula and special modified low-protein foods for inborn error of metabolism.
Maryland	§ 15-807	Group policy shall cover medical foods prescribed by doctor for therapeutic treatment of inherited metabolic disease.
Massachusetts	175:47C 176A:8B (Nonprofits) 176B:4C (Medical Service Corp.)	Coverage of newborns shall include special medical formulas necessary for treatment of PKU.
Minnesota	§ 62.A.26	Must provide dietary treatment for PKU.
Nevada	689A.0423 (Indiv.) 689B.0353 (Group) 695C.1723 (HMO) 695B.1923 (Nonprofit)	Mandated coverage for enteral formulas medically necessary for treatment of inherited metabolic diseases and up to at least $2,500 per year for special food products prescribed by physician.

HOUSE BILL 2197
COVERAGE FOR CERTAIN LOW PROTEIN FOODS FOR AN INBORN ERROR OF METABOLISM IN OTHER STATES

STATE	CITATION	SUMMARY
New Hampshire	§§ 415:6-c (individual) 415:18-e (group) 419:5-f (nonprofits) 420:5-g (nonprofits) 420-A:7-i (nonprofits) 420-B:8-ff (HMOs)	Provide non-prescription enteral formula for treatment of inherited metabolic disease, include food products modified to be low-protein in an amount not to exceed $1,800 annually for any insured individual.
New Jersey	Ch. 338 SB 1887	Provides coverage for the therapeutic treatment of inherited metabolic diseases, including the purchase of medical foods and low-protein modified food products, when diagnosed and determined to be medically necessary by the enrollee's physician.
New York	§ 3216(i)(21) - Indiv 3221(k)(11) – Group 4322 (b)(25) - HMO	Include cost of enteral formulas when prescribed as medically necessary for disorders that will cause the individual to become malnourished. Also, includes modified solid food products that are medically necessary; cost not to exceed $2,500 per 12-month period.
North Dakota	26.1-36-09.7	Cover medical foods and low-protein modified food products for therapeutic treatment of inherited metabolic disease.
Oregon	743.726	Must include coverage for inborn errors of metabolism. Coverage includes diagnosis, monitoring and controlling disorders, including medical foods
Tennessee	§ 56-7-2505	Mandated coverage for dietary formulas for treatment of PKU.
Utah	R590-76-4 (HMOs)	Must include coverage for special diet services provided by HMOs.
Vermont	tit. 8 § 4089d	Must include coverage for medical foods prescribed for medically necessary treatment for an inherited metabolic disease. Coverage for low protein modified food products must be at least $2,500 per 12-month period.

HOUSE BILL 2199
COVERAGE FOR MEDICAL FORMULAS FOR AN INBORN ERROR OF METABOLISM IN OTHER STATES

STATE	CITATION	SUMMARY
Alaska	§ 21.42.380	Shall provide coverage for formulas for treatment of PKU, with same copayment and deductible as for other illness.
Connecticut	Public Act 97-167	Individual and group health insurance policies must cover low-protein modified food products intended for the dietary treatment of inherited metabolic disease if administered under the direction of a physician.
Florida	§ 627.42395	Group policy must cover prescription and non-prescription enteral formulas for treatment of diesease of malabsorption.
Hawaii	House Bill 326	Coverage for medical foods and low-protein modified food products for the treatment of an inborn error of metabolism prescribed as medically necessary for therapeutic treatment and administered under the supervision of a physician.
Maine	24-A § 2745-D (indiv.) 24-A § 2837-D (group) 24-A § 4238 (HMO) 24-A § 2320-D (nonprofits)	Must include coverage for metabolic formula and special modified low-protein foods for inborn error of metabolism.
Maryland	§ 15-807	Group policy shall cover medical foods and low-protein modified food products prescribed by doctor for therapeutic treatment of inherited metabolic disease.
Massachusetts	175:47C 176A:8B (Nonprofits) 176B:4C (Medical Service Corp.)	Coverage of newborns shall include special medical formulas necessary for treatment of PKU.
Minnesota	§ 62.A.26	Must provide dietary treatment for PKU.
Missouri	376.1219	Coverage for formula recommended by a physician for the treatment of a patient with PKU or any inherited disease of amino and organic acids.

HOUSE BILL 2199
COVERAGE FOR MEDICAL FORMULAS FOR AN INBORN ERROR OF METABOLISM IN OTHER STATES

STATE	CITATION	SUMMARY
Montana	§ 33-22-131	Mandated coverage for dietary formulas for PKU sufferers.
Nevada	689A.0423 (Indiv) 689B.0353 (Group) 695C.1723 (HMO) 695B.1923 (Nonprofit)	Mandated coverage for enteral formulas medically necessary for treatment of inherited metabolic diseases and up to at least $2,500 per year for special food products prescribed by physician.
New Hampshire	§§ 415:6-c (individual) 415:18-e (group) 419:5-f (nonprofits) 420:5-g (nonprofits) 420-A:7-i (nonprofits) 420-B:8-ff (HMOs)	Provide nonprescription enteral formula for treatment of inherited metabolic disease, include food products modified to be low-protein in an amount not to exceed $1,800 annually for any insured individual.
New Jersey	Ch. 338 SB 1887	Provides coverage for the therapeutic treatment of inherited metabolic diseases, including the purchase of medical foods and low-protein modified food products, when diagnosed and determined to be medically necessary by the enrollee's physician.
New York	§ 3216(i)(21) – Indiv 3221(k)(11) – Group 4322 (b)(25) – HMO	Include cost of enteral formulas when prescribed as medically necessary for disorders that will cause the individual to become malnourished. Also, includes modified solid food products that are medically necessary; cost not to exceed $2,500 per 12-month period.
North Dakota	26.1-36-09.7	Cover medical foods and low-protein modified food products for therapeutic treatment of inherited metabolic disease.
Oregon	743.726	Must include coverage for inborn errors of metabolism. Coverage includes diagnosis, monitoring and controlling disorders, including medical foods
Pennsylvania	40-39-344	Shall provide coverage for formulas for treatment of hereditary genetic metabolic disorders.

HOUSE BILL 2199
COVERAGE FOR MEDICAL FORMULAS FOR AN INBORN ERROR OF METABOLISM IN OTHER STATES

STATE	CITATION	SUMMARY
South Dakota	§ 58-17-62 (individual) 58-18-41 (group) 58-38-23 (nonprofits) 58-40-21 (nonprofits) 58-41-98 (HMOs)	Mandated offer of coverage for testing and treatment, including dietary management and formulas.
Tennessee	§ 56-7-2505	Mandated coverage for dietary formulas for treatment of PKU.
Texas	I.C. Art.3.79	Mandated coverage for formulas necessary for treatment of PKU, same as prescription drugs.
Utah	R590-76-4 (HMOs)	Must include coverage for special diet services provided by HMOs.
Vermont	tit. 8 § 4089d	Must include coverage for medical foods prescribed for medically necessary treatment for an inherited metabolic disease. Coverage for low protein modified food products must be at least $2,500 per 12-month period.
Washington	§§ 48.21.300 (group) 48.46.510 (HMO) 48.44.440 (nonprofits) 48.20.520 (indiv.)	Shall provide coverage for formulas for treatment of PKU.