REPORT OF THE
SPECIAL ADVISORY COMMISSION ON MANDATED
HEALTH INSURANCE BENEFITS

HOUSE BILL 667: MANDATED COVERAGE OF ALTERNATIVES TO SURGERY

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 Sections 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 667 regarding a mandate of coverage of alternatives to surgery.

Respectfully submitted,

Timothy D. Hugo
Chairman
Special Advisory Commission on
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Introduction

House Bill 667 was introduced in the 2008 Session of the General Assembly by Delegate Robert G. Marshall. The bill was referred to the Special Advisory Commission on Mandated Health Insurance Benefits (Advisory Commission) by the House Committee on Commerce and Labor.

The Advisory Commission scheduled a public hearing for September 29, 2008 in Richmond to receive comments on the bill. At the meeting, Delegate Marshall advised the Advisory Commission that it was not necessary to hear House Bill 667 because of the similarity of the intent of the bill with House Bill 669 that would mandate coverage for amino acid-based formulas, and House Bill 615 that would mandate coverage for amino acid-based elemental formulas. No individuals or representatives of any organizations indicated a desire to speak at the meeting. Written comments in opposition to the bill were received from the Virginia Association of Health Plans (VAHP). Written comments in opposition to any new mandated benefits were received from the Virginia Chamber of Commerce (VCC) and comments on the adverse impact of mandated benefits on the number of insureds in small businesses were received from the National Federation of Independent Business (NFIB).

The Joint Legislative Audit and Review Commission (JLARC) provided an assessment on the Evaluation of House Bill 667: Mandated Coverage of Alternatives to Surgery in accordance with s

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 667 would add Section 38.2-3407.9:03 to the Accident and Sickness Provisions of the Code of Virginia. The bill requires insurers to provide coverage for nonsurgical treatment if they cover surgical treatment of a medical condition or disease. The nonsurgical treatment must be less expensive; less dangerous; not experimental or investigational; generally recognized by the regional medical community as appropriate for the condition or disease; and not less efficacious than the surgical treatment. The bill applies to insurers issuing individual or group accident and sickness policies providing hospital, medical and surgical or major medical coverage on an expense incurred basis,

corporations providing individual or group subscription contracts; and health maintenance organizations (HMOs) providing health care plans.

The language of House Bill 667 is very broad. The language "any nonsurgical treatment of a medical condition" could include hundreds of medical situations and numerous treatments. The patron of the legislation informed staff to the Advisory Commission by letter of June 30, 2008 that the intent of House Bill 667 was to address situations where a feeding tube would have to be inserted surgically in a child to obtain coverage for amino acid-based formulas because coverage was not provided for orally-administered formulas.[1] The actual language of the bill is much broader and covers much more than that situation. Amended language was not received from the patron prior to analysis of the bill. Therefore, the analysis prepared for the Advisory Commission review and this report address the broader language of the bill as it was referred to the Advisory Commission.

Previous Legislation

Bills addressing special formulas have been reviewed by the Advisory Commission three times over the past ten years. House Bill 2197 and House Bill 2199 were introduced by then Delegate Robert McDonnell in 1999. The bills required coverage for low-protein foods and formulas for the treatment of inborn errors of metabolism such as phenylketonuria, maple syrup urine disease, and homocystinuria. The Advisory Commission voted to recommend that the bills not be enacted, but that a mechanism to assist individuals and families be provided either through the expansion of the state program at the Virginia Department of Health (VDH) or by a tax credit to families buying the foods and formulas.

In 2002, Delegate Robert Orrock introduced House Bill 84 that would have required coverage for polypeptide or amino-acid based formulas 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 Advisory Commission recommended that the bill not be enacted, but that funding for the VDH program should be increased, and coverage should be expanded to cover individuals needing polypeptide or amino acid-based formulas or with the disorders covered by the bill.

Delegate R. Steven Landes introduced House Bill 1216 in 2004. The bill would have required 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. The Advisory Commission again voted to

recommend against enactment of the legislation and recommended that the VDH program be expanded.[2]

Two bills were introduced in the 2008 Session of the General Assembly to address special formula needs. Both bills were referred to the Advisory Commission for review. House Bill 615 was introduced by Delegate Kristen J. Amundson to require insurers to provide coverage for 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 would apply to insurers issuing individual or group accident and sickness policies providing hospital, medical, and surgical or major medical coverage on an expense incurred basis; corporations providing individual or group subscription contracts, and HMOs providing health care plans.

House Bill 669 was introduced by Delegate Robert G. Marshall and applies to insurers issuing individual or group accident and sickness policies providing hospital, medical and surgical, or major medical coverage on an expense incurred basis, corporations providing subscription contracts, and HMOs providing health care plans. The insurers, corporations, and HMOs must include coverage for the expense of amino acid-based formulas whose protein source has been extensively or completely hydrolyzed.

Nonsurgical Treatment Alternatives

Internet searches for nonsurgical treatments for medical conditions and illnesses produced a broad spectrum of conditions, including conditions such as low back pain, malignant mesothelioma (cancer of the protective lining that covers most of the body's internal organs), carpal tunnel syndrome, peptic ulcer disease, aortic dissection, rosacea, chronic sinusitis, epilepsy, and hyperparathyroidism.

Four types of conditions were included on the survey that was sent to insurers regarding this bill in an attempt to obtain information about the current coverage of alternative treatments, the cost associated with that coverage, and the premium impact of House Bill 667. The conditions listed on the survey were disc herniation; severe coronary disease, fibroid tumors; and gastrointestinal disorders.

A disc is a small spongy cushion that protects the vertebrae in the spine of the back. When a disc is damaged, it can break open or bulge. This is called a slipped, ruptured, or herniated disc. Treatments for a herniated disc can include rest, physical therapy, and medications.[3] Other treatment alternatives include chiropractic treatments, acupuncture and chemonucleolysis. [4] The herniated disc may heal over a period of time. One source estimated that after six weeks, one in ten people experience pain to the extent that they consider surgery.

Coronary artery disease is caused by the build-up of plaque inside of arteries. Plaque is composed of fat, cholesterol, calcium, and other substances in the blood. The build up of plaque in the arteries is known as atherosclerosis. The plaque reduces the flow of blood into the heart by narrowing the arteries.[5] Treatments for coronary artery disease may include lifestyle changes, increase in physical activity and smoking cessation. Medications used in treatment include anticoagulants, aspirin, ace inhibitors, beta blockers, calcium channel blockers, nitroglycerin, glycoprotein, llb-llla, statins, and fish oil and other supplements that are high in omega-3 fatty acids. Cardiac rehabilitation may also be prescribed. The rehabilitation has two parts – exercise training and education, counseling and training.[6] Other treatment alternatives include vitamins, minerals and herbs.[7]

Fibroid tumors are tumors, usually non-cancerous or benign, that are often found in the uterus of women in their thirties or forties.[8] The tumors are solid and made of fibrous tissue. Different medical treatments are used for fibroid tumors that do not involve surgery. Medications can be used to shrink the tumors in the short-term. Uterine artery embolization is a nonsurgical procedure that can be used to treat fibroids. The procedure leaves the uterine intact. The embolization places polyvinyl particles in the uterine arteries before the nexis of vessels spread into the uterine tissue. The particles then move into the vessels and clog them, cutting the blood supply to the fibroids. The fibroids shrink over a period of time.[9]

Gastrointestinal disorders relate to the digestive system. The digestive system is a series of hollow organs that is joined in a tube. The system includes the esophagus, stomach, small and large intestines. The liver, gall bladder, and pancreas are also involved.[10] There are many kinds of digestive disorders. Just some of the disorders include gallstone disease; peptic ulcer disease; circulatory disorders of the GI tract; irritable bowel syndrome, inflammatory bowel syndrome; and diverticular disease.[11] Some of the nonsurgical treatments for gastrointestinal disorders include diet changes; medications that strengthen the resistance of the stomach and duodenum and antibiotics (for ulcers); oral bile acid therapy (for gall stones); antibiotics and bowel rest (for

circulatory disorders of the GI tract); bulk fiber products, antispasmodics, and antidiarrheals (for irritable bowel syndrome); medications or an elemental formula diet (for inflammatory bowel disease).[12]

Amino acid-based formulas can be consumed by infants that do not tolerate formulas based on cow milk proteins, soy protein isolate, or casein hydrolysates. Metabolic infant formulas are formulated for use by infants with disorders of amino acid metabolism such as phenylketonuria, maple syrup urine disease, tyrosinemia, or other inherited metabolic disorders.[13] Metabolic disorders occur when a cellular enzyme is limited in its function or missing. If the work of the enzyme is not done, chemical substances can accumulate in the tissues or the chemicals the enzyme makes can be missing. This can cause damage to the individual with the metabolic disorder. The Virginia Newborn Screening program requires the testing of all children born in Virginia for metabolic or endocrine disorders. The program was established to treat children with the disorders early before symptoms of a condition appear.[14] According to information from the Virginia Commonwealth University Metabolic Treatment Center, at least ten of the twenty-eight disorders and diseases that are screened for in Virginia require treatment by formulated nutritional supplements.[15]

Enteral nutrition is a means of providing food through a tube. The tube can be placed in the nose, stomach or the small intestine. A nasogastric tube is one that is placed in the nose. A gastrostomy or percutaneous endoscopic gastrostomy is a tube that goes through the skin and into the stomach. A percutaneous enoscopic jejunostomy tube is one that goes into the small intestine.[16] The gastric feeding tube is the means often used to supply nutrition to those needing amino acid-based elemental formulas. [17]

Tube feedings can be administered in various ways. Bolus feeds nutrition is supplied several times through the day. It can be accomplished using a large syringe, that allows the formulas to drip in or a pump that would supply formula faster. Continuous feeds use a pump with the formula administered slowly over the day. Night feeds supply a continuous feed and are usually used to supplement other feedings.[18]

Social Impact

The social impact of House Bill 667 varies with the number of people that need treatment for each condition that could be covered by the bill. It is very difficult to determine the social impact of House Bill 667 as it was introduced. One insurance company representative remarked that the bill could possibly cover over one hundred diagnosis codes. The bill could apply to many types of cancer, heart disease, problems with the body's circulatory system, orthopedic concerns, as well as problems with the digestion of foods and regular infant formulas.

The age-adjusted rate for heart disease in the United States in 2002 was 241 per 100,000 population. The deaths represented 29% of all the deaths in the United States. According to the Centers for Disease Control, heart disease has been the leading cause of death for the past eighty years.[19] The article "Spinal Decompression Back Pain Relief from Disc Herniation" notes that epidemiologic studies suggest that at some point over 80% of the population will experience low back pain.[20] One source estimates that as many as 30% of women age 40 to 60 may develop fibroid tumors.[21]

There are many types of gastrointestinal disorders. However, the number of people with some of the disorders previously noted ulcers, gall stones, irritable bowel syndrome, and diverticular disease provide some idea of the number of people that could be affected by the bill. Approximately 2% of the adult population has gastric ulcers.[22] It has been estimated that as many as 10% of the American population has gallstones and as many as one million Americans have some type of inflammatory bowel disease.[23] Diverticular disease is experienced by up to 65% of people at least 85 years old and 5% of people under the age of 40.[24] The social impact of the bill as introduced is therefore significant in a state the size of Virginia with a population of approximately 7,600,000.

The social impact of mandating coverage for amino acid-based formulas is significantly smaller. Children's Magic (Milk Allergy and GastroIntestinal Coalition) estimates the total number of children in Virginia needing the formulas to range from 327 to 503. Children's Magic estimates the number of those children covered by private insurance to be from 209 to 322.[25] The VDH reported that in 2007, 27 children and 8 adults received formulas from the Virginia Metabolic Program.[26]

Financial Impact

It is extremely difficult to address the financial impact of House Bill 667 as it was introduced. The bill is very broad and could possibly address hundreds of treatments. The bill language, however, does require that a treatment would have to be less costly than the surgical alternative for the provision to be applied. However, there is a financial impact for services provided to individuals who have not utilized any treatment that is covered by insurance. Some of those individuals have paid for other treatments using resources other than insurance.

One example of the financial impact for a treatment that could be covered by House Bill 667 relates to treatment for fibroid tumors. One of the reports relating to cost of treatment of pelvic disorders determined that the "episode of care" cost for hysterectomy was standardized at a value of $5,145 based on the 2007 Medicare reimbursement rate for hysterectomy (combining surgeon and facility reimbursement). The relative costs of treatments were $4,116 for oral medications, and $2,830 for endometrial ablation.[27]

The cost of providing amino acid-based formulas can be significant for some families. The median income in Virginia for 2006 inflation adjusted dollars was $56,277.[28] One proponent of House Bill 669 indicated that her family pays approximately $600 per month or $7,200 annually for a formula prescribed by a physician for her child.[29] Another family has been reported to spend approximately $500 per month for formula for a child with eosinophilic esophagitis.[30] Children's Magic stated that the average cost of specialized formulas is over $5,000 per year for oral consumption and that the cost of enteral feeding can be approximately $20,000.[31]

Medical Efficacy

The medical efficacy of the treatments that could be covered by House Bill 667 varies by treatment. The language of the bill requires that the covered treatments be less dangerous; not experimental or investigational; generally recognized by the regional medical community as appropriate for the condition or disease; and not less efficacious than the surgical treatment. The bill language would not require coverage of treatments

that are "not efficacious." The determination of experimental or investigational and "less dangerous" could be the subject of disagreement, and recognition by the regional medical community could be subject to disagreement if there was no consensus on treatment.

One example of the medical efficacy considerations is the treatment of disc (disk) herniation. The Journal of the American Medical Association published the article "Surgical vs. Nonoperative Treatment for Lumbar Disk Herniation" in November of 2006. The article reported on the outcomes of a randomized clinical trial that enrolled patients from March of 2000 to November of 2004. The study abstract noted that the efficacy of lumbar diskectomy was still controversial. The trial interventions were open diskectomy versus nonoperative treatment individualized to the patient. The study concluded that the patients in both the surgery and nonoperative treatment groups showed substantial improvement over a two-year period. No conclusion was reached about the superiority of treatments because of the number of patients receiving both types of care.[32]

The proper treatment of fibroid tumors was discussed in the article "Uterine Fibroid Tumors: Diagnosis and Treatment" published in the journal "American Family Physicians." The article reviewed treatment options for fibroid tumors that included hysterectomy, myolysis, myomectomy, uterine artery embolization, gonadotropin-releasing hormone agonists, hormone therapy and estrogen receptor modulator raloxifene. The article reported that when deciding the treatment of a patient, consideration should be given to they type of symptoms and their severity, the patient's desire for "definitive treatment," the need to preserve childbearing capability, the importance of uterine preservation, infertility due to uterine cavity distortions, and pregnancy complications because of fibroid tumors.[33]

Children's Magic's comments included the statement "Amino acid-based elemental formulas have been found to be an effective treatment." They noted studies published in the Journal of Pediatrics (Volume 141: Number 2) and the American Journal of Gastroenterology (April 2003).[34]

The California Health Benefits Review Program (CHBRP) analyzed a mandate of coverage for amino acid-based elemental formula and reported to the California legislature in April, 2008. The CHBRP report "Analysis of Assembly Bill 2174: Coverage for Amino Acid-Based Elemental Formula" included information of the effectiveness of amino acid-based formulas for the diagnosis and treatment of eosinophilic disorders and short bowel syndrome, regardless of the delivery method. The report examined the effectiveness of elemental formula for diagnosis and treatment of two disorders: eosinophilic esophagitis and short bowel syndrome. The program noted that they found no literature on the effectiveness of amino acid-based elemental formula for

any other eosinophilic disorder. The report noted that evidence suggests that elemental formulas improve clinical symptoms and histology associated with the allergic response to EE such as "… resolution of symptoms such as diarrhea, vomiting, poor weight gain, food refusal, and abdominal pain; and improvement of esophageal histology, and defined by the number of eosinophils visible upon endoscopic biopsy of the esophagus." The report noted that findings comparing the use of elemental formulas to an elimination diet were "ambiguous."[35]

The review program also analyzed coverage for inborn errors of metabolism and reported its findings in "Analysis of Assembly Bill 30: Health Coverage: Inborn Errors of Metabolism" in August 2007. The bill required coverage for the testing and treatment of inborn errors of metabolism. In California, the report estimated that 687 persons per year are born with an inborn error of metabolism that does not include phenylketonuria (PKU). The average estimate for PKU births in California was 105. The analysis of Assembly Bill 30 noted that there were no published randomized controlled trials or nonrandomized studies with comparison groups on effectiveness of special formulas or food products for inborn errors of metabolism relative to no medical nutrition therapy. The report noted that the lack of controlled studies is probably due to the "rarity of these disorders and their potentially lethal consequences." The report summarized that their analysis for medical effectiveness relied on treatment guidelines based on expert consensus. The report noted that inborn errors of metabolism are "single-cause conditions for which the scientific basis and rationale for treatment are strong."[36]

Insurance Requirements in Other States

Information from the National Association of Insurance Commissioners was reviewed to determine whether other states have requirements similar to House Bill 667. A survey of state insurance departments was also conducted to determine if similar requirements exist. No state was found to have a requirement similar to House Bill 667.[37]

The NAIC Compendium of State Laws listed thirty-one states as having a requirement for coverage of metabolic disease formulas. Children's Magic submitted information stating that eight states require coverage for amino acid-based elemental formulas.

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Current Insurance Coverage

The Bureau of Insurance surveyed fifty of the top writers of accident and sickness insurance in Virginia regarding the bills referred to the Advisory Commission for review in 2008. Forty-two companies responded to the survey by August 27, 2008. Seven of the companies indicated that they do not write business applicable to House Bill 667. Thirty-three companies responded to the questions on House Bill 667.

Fifteen companies indicated that they provide coverage required by the bill. Nine companies said that they do not provide the coverage House Bill 667 requires. The remaining companies described the bill language as too broad or vague to allow them to provide a response to the question or did not respond to the question in any manner.

Nine companies responded to the question regarding the premium impact of the bill. Six of the nine companies indicated a minimal impact and provide no amount. Three companies provided responses that ranged from zero to $3.00 per month. One company provided the monthly premium amount for a standard contract and did not address the cost of any of the bills referred to the Advisory Commission this year. Two companies provided information about coverage of formulas and did not address the current bill language.

Three of the companies indicated that they do not provide coverage for the nonsurgical treatment for the conditions listed on the survey (disc herniation; severe coronary disease; fibroid tumors; and gastrointestinal disorders). Many of the respondents did not address the questions about the four conditions because the questions or bill were too broad or their company medical policy does not address coverage in that manner. Few companies answered the question regarding the premium impact of medical and surgical coverage for the four conditions listed in the survey. Six companies indicated a minimal impact.

Nine companies indicated that they provide coverage for amino acid-based formulas received orally in their standard contract. Five of the nine modified their response with additional information such as providing coverage only for specified conditions; or providing coverage on a case-by-case basis. Eight companies will pay for formula

received through a feeding tube. Four of the respondents require the person to be hospitalized to provide coverage for the formulas through a feeding tube.

Review Criteria

SOCIAL IMPACT

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

It is difficult to determine the social impact of House Bill 667 as it was introduced. The bill could apply to many types of cancer, heart disease, circulatory problems, orthopedic concerns, as well as problems with the digestion of foods and regular infant formulas. The age adjusted rate for heart disease alone was 241 per 100,000 of population in 2002 in the United States.

The social impact of mandated coverage for individuals needing amino acid-based formulas is significantly smaller. Children's Magic (Milk Allergy and GastroIntestinal Coalition) estimates the total number of children in Virginia needing the formulas ranges from 327 to 503. Children's Magic estimated the number of those children covered by private insurance to range from 209 to 322. The Virginia Department of Health reported that in 2007, 27 children and eight adults received formulas from the Virginia Metabolic program.

b. The extent to which insurance coverage for the treatment of service is generally available.

The Bureau of Insurance surveyed fifty of the top writers of accident and sickness insurance in Virginia regarding the bills referred to the Advisory Commission for review in 2008. Forty-two companies responded to the survey by August 27, 2008. Thirty-three companies responded to the questions on House Bill 667.

Fifteen companies indicated that they provide coverage required by the bill. Nine companies said that they do not provide the coverage House Bill 667 requires. The remaining companies described the bill language as too broad or too vague to allow them to provide a response to the question or did not respond to the question in any manner.

Only three of the companies indicated that they do not provide coverage for the nonsurgical treatment for the conditions listed on the survey (disc herniation; severe coronary disease; fibroid tumors; and gastrointestinal disorders). Many of the respondents did not address the questions about the four conditions because the questions or the bill were too broad or their company medical policy does not address coverage in that manner.

Nine companies indicated that they provide coverage for amino acid-based formulas received orally in their standard contract. Five of the nine modified their responses with additional information such as providing coverage only for specified conditions; or providing coverage on a case-by-case basis. Eight companies will pay for formula received through a feeding tube. Four of the respondents require the person to be hospitalized to provide coverage for the formulas through a feeding tube.

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.

Coverage is available for many nonsurgical treatments. However, every procedure that could be covered by House Bill 667 is not currently covered in all contracts. People may be able to obtain some alternative treatments using their own resources. Some treatments could be expensive and would be difficult to obtain without insurance coverage while others, including services such as prescription medications and physical therapy, might be affordable.

Assistance is available for Virginians needing metabolic formula through two state programs. One program is for families with incomes of no more than 300% of the federal poverty level. Families with incomes above that level must pay for the formulas.

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 treatments.

As previously stated, it is difficult to estimate the potential cost of all of the treatments that could by covered by the bill. Some treatments like prescription medications could be relatively inexpensive in the short-term. However, the cost of items like medications or physical therapy sessions over an extended period of time could be a hardship for some families. One family reported the cost of amino acid-based formulas was $600 per month for their child. Children's Magic noted that the average cost for specialized formulas is over $5,000 per year for oral consumption. Annual costs of $5,000 to $6,000 per year can be a hardship on families with income equal to or less than the 2006 median income in Virginia of $56,277.

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

It is difficult to estimate the public demand for the treatments that could be covered by House Bill 667. It is possible that hundreds of conditions could be covered by the bill. The following four conditions were listed on the survey sent to insurers to obtain information for the analysis of the bill: disc herniation; severe coronary disease; fibroid tumors; and gastrointestinal disorders. The demand for treatment for these conditions varies. Sources estimate that 29% of the deaths in the United States in 2002 were related to heart disease; up to 80% of the population will experience low back pain at some point in their lives; 30% of women aged 40 to 60 may develop fibroid tumors, and up to 10% of the American population has gall stones. All four of the conditions could be treated by services that would be covered by the bill.

The level of demand for amino acid-based formulas is estimated by Children's Magic to range from 327 to 503 children in Virginia. The VDH reported that in 2007, 27 children and eight adults received formulas from the Virginia Metabolic Program.

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

Five families spoke in support of House Bill 615 and House Bill 669 at the public hearing and a dietician spoke in favor of House Bill 667. No interested parties spoke in favor of House Bill 669 at the hearing. However, prior to the hearing, at least one family discussed their insurer's position of providing coverage of formulas when administered through a feeding tube but not when the formulas are consumed orally.

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

No information was provided to the Advisory Commission regarding collective bargaining organizations' interest in the proposed coverage.

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

No information was received on the findings of a state health planning agency or health system agency on House Bill 667.

The Advisory Commission's previous reviews of bills mandating coverage for specialized formulas resulted in recommendations against the enactment of mandates for coverage. The Advisory Commission did recommend the expansion of the VDH program to provide assistance to more families and consideration of a tax credit for families that purchased the 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 difficult to estimate the financial impact of House Bill 667 as it was introduced. The bill could cover a large number of treatments. The cost of some treatments that are currently not covered could possibly increase if insurance coverage was available, but it is not possible to estimate the cost impact. The cost of specialized formulas is not expected to increase because of the small number of individuals that require the formulas.

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

The appropriate use of nonsurgical treatments could increase if there is currently no insurance coverage for those treatments. Inappropriate use of treatments should be minimal because the language of the bill requires that the treatment be generally recognized by the regional medical community as appropriate for the condition or disease. Appropriate treatment for those needing formulas would possibly increase. However, because of the severe consequences of going without necessary formulas, most individuals needing formulas are receiving them, and the families are paying the costs out-of-pocket.

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 make the point that paying for orally consumed formulas for those that need them is less expensive than paying for the surgical placement of a feeding tube. Proponents also noted that the bill requires coverage for treatments that are "less expensive" than the surgical alternative. Oral feedings are less expensive than tube feedings that are estimated by Children's Magic to cost up to $20,000.

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.

The existing language of the bill could possibly affect the number of providers performing nonsurgical treatments in the next five years. As previously noted, the language could cover hundreds of medical situations and numerous treatments. It is not possible to estimate the impact of the bill on the number of providers.

A bill requiring coverage for medically necessary amino acid-based formulas (House Bill 669) is not expected to increase the number of providers because of the relatively small number of individuals needing the formulas.

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.

Responses to the 2008 survey by the Bureau of Insurance provided limited information on the estimated cost of House Bill 667. Only nine of the 33 survey respondents answered the question about the premium impact of the bill. Six of the nine companies provided responses that ranged from zero to $3.00 per month. The remaining three responses were not specific to the bill. Ten companies did not respond to questions about the impact of the bill because they consider the language of the bill so broad or vague that they were unable to provide a response.

Companies provided responses to premium impact questions for House Bill 669, the bill House Bill 667 was intended to complement. 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 for coverage on an optional basis of $.21 and $3.00 per month per individual policyholder for House Bill 669. Fifteen insurers provided cost figures for coverage on an optional basis of $.05 to $2.00 per month per group certificateholder.

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

The broad language in House Bill 667 makes it difficult to determine the impact of the bill on the total cost of health care. The requirement that treatments provided because of the mandate be “less expensive” than the surgical alternative should result in little or no

actual increase in the total cost of health care. However, if a person is currently going without any type of health care in the absence of this requirement there could be an increase in short-term health care costs. Alternately, someone going without any health care treatment could develop more serious and costly health care needs in the future.

The impact of providing coverage for amino acid-based formulas is not significant because the number of individuals in Virginia in need of formulas is not high.

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.*

The bill language requires treatments to be efficacious. However, the medical efficacy of treatments that could be covered by House Bill 667 varies by treatment. For example, issues could be raised regarding the medical efficacy of treatments for disc herniation. All treatments for disc herniation may not be considered efficacious by all medical practitioners. As newer treatments are developed and studied, the standard medical practice changes for most illnesses and conditions.

The CHBRP analyzed coverage for inborn errors of metabolism and reported its findings in "Analysis of Assembly Bill 30: Health Coverage: Inborn Errors of Metabolism". The analysis of Assembly Bill 30 noted that there were no published randomized controlled trials or nonrandomized studies with comparison groups on the effectiveness of special formulas or food products for inborn errors of metabolism relative to no medical nutrition therapy. The report noted that the lack of controlled studies is probably due to the "rarity of these disorders and their potentially lethal consequences". The report summarized that their analysis for medical effectiveness relied on treatment guidelines based on expert consensus. The report noted that inborn errors of metabolism are "single-cause conditions for which the scientific basis and rationale for treatment are strong."

The JLARC assessment stated:

> It is difficult to make an assessment of the medical efficacy of alternative treatments to surgery due to the wide variety of treatments available and conditions for which they can be used. Some alternatives have clinical evidence demonstrating their efficacy for certain conditions, such as the use of embolization

for treating uterine fibroids. However, the efficacy of these alternative treatments may not have been studied for other medical conditions. Also, studies of medical efficacy may not exist for alternative treatments potentially covered by the mandate. For example, no clinical studies were found assessing the efficacy of receiving amino acid-based formulas orally rather than through a feeding tube.

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 to 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 intent of the bill as expressed by the patron addresses a medical need that is consistent with the role of health insurance. The language of the bill requires that coverage for the treatment of a medical condition or disease must not be experimental or investigational, and the treatment must be recognized by the regional medical community as an appropriate treatment for the condition or disease. These requirements would appear to limit the coverage to medical needs.

The JLARC assessment noted:

Due to the breath of medical conditions and non-surgical treatments that could be covered by House Bill 667, it is difficult to determine whether the proposed mandate addresses a broad social need or is consistent with the role of health

insurance. Some medical experts are concerned that the bill could result in patients receiving inappropriate or inadequate health care. This is, in part, because the proposed mandate does not require non-surgical alternatives to be prescribed by a physician or other licensed personnel, and does not require treatments to be provided by certified, registered, or licensed personnel.

The patron of the proposed mandate has indicated that the purpose of House Bill 667 is to secure insurance coverage of amino acid-based formula whether it is consumed orally or through a feeding tube. Medical experts indicate that it is preferable for individuals to consume the formula orally rather than enterally due to the risks involved with placement and use of feeding tubes. However, the placement of some feeding tubes does not require surgery, and, therefore, would not be affected by the proposed mandate.

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

It is difficult to estimate the costs associated with House Bill 667 because of the broad language in the bill. Few insurers were able to provide estimates for the four conditions included on the survey for the bill. It is also difficult to determine the need for the coverage because many of the insurers (15 of the 33 respondents) indicated they provide the coverage the bill requires.

The JLARC assessment stated:

> It is not possible to assess the need versus the cost of the proposed mandate because the premium impact is indeterminate. Most insurance companies did not provide premium estimates for the proposed mandate, and many indicated that the scope of the bill is too broad for them to develop premium estimates. The mandate requires that non-surgical treatments must be less expensive than surgical treatments. However, without a more defined set of medical conditions and alternative treatments, it is not possible to say anything more definitive with regard to the need versus the cost of the treatments covered by the bill. With regard to amino acid-based formula, medical experts indicate that it is more cost effective and preferable for patients to consume the formula orally rather than through a feeding tube when possible.

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. It is difficult to determine the number of groups that would be interested in paying for coverage as broad as the bill language. Most insurers were unable to estimate the cost of such coverage.

Coverage that would be limited to amino acid-based formulas would possibly be selected only by individuals that had reason to believe they would need the coverage, a small number of Virginians.

CONCLUSION

Delegate Marshall asked that House Bill 667 be deferred until 2009 along with House Bill 669. He indicated at the November 19, 2008 meeting that House Bill 667 was intended to complement House Bill 669 that would mandate coverage for amino acid-based formulas. Delegate Marshall asked that House Bill 669 be deferred until 2009 along with legislation introduced by Delegate Amundson (House Bill 615) that would require coverage for amino acid-based elemental formulas.

The Advisory Commission agreed to defer House Bill 667 until 2009.

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