

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

**EVALUATION OF PROPOSED  
MANDATED HEALTH INSURANCE BENEFITS**

---

**Evaluation of House Bill 667:  
Mandated Coverage of  
Alternatives to Surgery**

---

**September 2008**

---

## **Members of the Joint Legislative Audit and Review Commission**

### **Chairman**

Delegate M. Kirkland Cox

### **Vice-Chairman**

Senator Charles J. Colgan

Delegate H. Morgan Griffith  
Delegate Frank D. Hargrove, Sr.  
Senator Janet D. Howell  
Delegate Dwight C. Jones  
Senator Thomas K. Norment, Jr.  
Delegate Lacey E. Putney

Delegate Phillip A. Hamilton  
Senator R. Edward Houck  
Delegate Johnny S. Joannou  
Delegate Harvey B. Morgan  
Delegate Robert D. Orrock, Sr.  
Senator Walter A. Stosch

Walter J. Kucharski, Auditor of Public Accounts

### **Director**

Philip A. Leone

---

## **Members of the Special Advisory Commission on Mandated Health Insurance Benefits**

Delegate Clifford L. Athey, Jr.  
Delegate Timothy D. Hugo  
Senator Donald A. McEachin

Elnora H. Allen  
Angie Benton  
Dorothea S. Brodersen  
Peter J. Bernard  
Renard A. Charity, M.D.  
James F. Childress, Ph.D.

Senator George Barker  
Delegate Terry G. Kilgore  
Delegate Donald Merricks

Phyllis L. Cothran  
Alfred W. Gross  
Joseph A. Kelliher  
Karen Remley, M.D., M.B.A., FAAP  
Laura Lee O. Viergever

---

## **JLARC Staff for This Evaluation**

Hal Greer, Division Chief  
Kimberly Sarte, Principal Fiscal Analyst

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

**This evaluation is available on the JLARC website at <http://jlarc.state.va.us>**

Copyright 2008, Commonwealth of Virginia.

---



## Evaluation of House Bill 667: Mandated Coverage of Alternatives to Surgery

### JLARC SUMMARY

House Bill 667 of the 2008 General Assembly Session would require that health insurance plans including coverage for surgical treatment of a medical condition or disease also include coverage for any non-surgical treatment for the medical condition or disease that is (a) less expensive, (b) less dangerous, (c) not experimental or investigational, (d) generally recognized by the regional medical community as an appropriate treatment for the condition or disease, and (e) not less efficacious than the surgical treatment. Subsequent to the referral of HB 667 to the Special Advisory Commission on Mandated Health Insurance Benefits, the patron of the bill indicated that HB 667 was introduced only to secure coverage for the oral consumption of amino acid-based formula in light of one insurance company's policy requiring that formula be delivered via a surgically placed tube to obtain coverage (even though medical experts indicate that oral consumption is preferred, when possible). This evaluation comments on the proposed coverage in its entirety and the specific issue relating to the administration of amino acid-based formulas.

#### MEDICAL EFFICACY AND EFFECTIVENESS

Due to the breadth of the medical conditions and treatments covered by HB 667, medical experts indicate that it is difficult to make a meaningful assessment of the medical efficacy or effectiveness of treatments that may be covered by the proposed mandate. Experts indicate that oral consumption of amino acid-based formula is pre-

#### In This Evaluation

Background .....	1
Medical Efficacy and Effectiveness .....	7
Social Impact .....	9
Financial Impact .....	16
Balancing Medical, Social, and Financial Considerations .....	20
Acknowledgments .....	22
<b>Appendixes</b>	
A: Statutory Authority for JLARC Evaluation .....	23
B: Proposed Mandated Benefit .....	25
C: Evaluation Topic Areas and Criteria.....	27
D: Bibliography.....	29
E: Letter from the Patron of HB 667.....	31

ferred when possible due to the risk of complication. However, there may be situations when enteral (tube) feeding is necessary.

## **SOCIAL IMPACT**

The broad nature of the coverage proposed in HB 667 makes it difficult to assess the bill's social impact and challenging for health insurance companies to determine whether they provide the proposed coverage. With regard to amino acid-based formula, most children likely consume the formula orally, but medical experts indicate that some children may require enteral feeding of the formula to adhere to a strict formula diet. Advocates for the proposed mandate and information from another state indicate that some children use feeding tubes solely to receive insurance coverage of the formula, although medical experts consulted for this review were not aware of any cases of this happening. Less than one third of health insurance plans surveyed indicate that they provide coverage of the formula when it is taken orally. Several plans indicated that coverage is only provided if the formula is taken through a feeding tube; some plans further require the patient be hospitalized to receive coverage when taken enterally.

## **FINANCIAL IMPACT**

The premium impact of HB 667 is indeterminate because the scope of the bill is too broad for many insurance companies to develop premium estimates. Some medical experts are concerned that HB 667 could lead to patients not receiving effective and appropriate care for their medical needs, in part because HB 667 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 professionals. The financial impact of requiring coverage of oral consumption of amino acid-based formula when enteral consumption of the formula is already covered is expected to be small.

## **BALANCING MEDICAL, SOCIAL, AND FINANCIAL CONSIDERATIONS**

The impacts of HB 667 could be far reaching, and the breadth of the proposed mandate makes it difficult to assess many of the criteria reviewed by the Special Advisory Commission on Mandated Health Insurance Benefits. If the patron's primary goal is securing insurance coverage for amino acid-based formula, whether taken orally or enterally, then a more direct solution would be to include language in the proposed mandates covering amino acid-based formula (HB 615 and HB 669 of the 2008 General Assembly Session) requiring coverage of the formula regardless of the method of consumption. Also, because not all feeding tubes require surgical placement, it is not clear the extent to which HB 667 would address the patron's concerns.



## **Evaluation of House Bill 667: Mandated Coverage of Alternatives to Surgery**

---

House Bill 667 of the 2008 General Assembly Session would mandate health insurance coverage for alternative treatments to surgery. In particular, HB 667 would require that health insurance plans including coverage for surgical treatment of a medical condition or disease also include coverage for any non-surgical treatment for the medical condition or disease that is (a) less expensive, (b) less dangerous, (c) not experimental or investigational, (d) generally recognized by the regional medical community as an appropriate treatment for the condition or disease, and (e) not less efficacious than the surgical treatment.

Subsequent to the referral of HB 667 to the Special Advisory Commission on Mandated Health Insurance Benefits, the patron of the bill sent a letter to the State Corporation Commission's Bureau of Insurance indicating that the purpose of HB 667 was to address a policy currently in place by one insurance company that requires amino-acid based formulas be delivered via a surgically placed tube instead of orally to obtain coverage. The patron indicated that HB 667 was proposed as a complementary bill to HB 669, which would mandate coverage of amino acid-based formulas. The letter further clarified that HB 667 was only introduced to address amino acid-based formulas and not other conditions. A copy of the patron's letter is provided in Appendix E.

Although the patron's letter seeks to clarify the purpose of HB 667 as being specific to the administration of amino acid-based formula, the language in the bill is much broader and covers many more medical conditions and treatments. Therefore, the following evaluation will comment on the proposed coverage in its entirety and the specific issue relating to the administration of amino acid-based formulas.

### **BACKGROUND**

House Bill 667 covers a wide range of medical conditions and diseases, and an equally wide range of treatments that could be considered non-surgical alternatives for treating the conditions and diseases. The proposed mandate's patron has indicated that his in-

tent is to require health insurers to cover amino acid-based formula whether consumed orally or through a feeding tube. However, the bill, as written, would cover much more than this specific condition. Concerns exist over the breadth of the bill. Further, because some feeding tubes do not require surgery for their placement, oral consumption of formulas would not be considered a non-surgical alternative in this case.

#### **a. Description of Medical Condition and Proposed Treatment**

House Bill 667 does not specify the medical conditions or types of surgery to which the proposed mandate applies. Therefore, the mandate, as written, could apply to all medical conditions and surgical procedures. In addition, particular alternatives to surgery are not specified in the bill, other than that health plans must include coverage for any non-surgical treatment for a medical condition or disease if they also include coverage for surgical treatment for the condition or disease. However, any alternative treatments covered by the proposed mandate must meet the following criteria specified in the mandate. Alternatives to surgery must be

- (a) less expensive than the surgical treatment,
- (b) less dangerous than the surgical treatment,
- (c) not experimental or investigational,
- (d) generally recognized by the regional medical community as an appropriate treatment for the condition or disease, and
- (e) not less efficacious than the surgical treatment.

#### ***Surgical Procedures***

There is a vast array of medical conditions that are treated with surgery, and many different types of surgical procedures are used to treat them. Surgery can be defined as a medical technology consisting of a physical intervention on tissues. As a general rule, a procedure is considered surgical when it involves cutting of a patient's tissues or closure of a previously sustained wound. All forms of surgery are considered invasive procedures. Non-invasive surgery usually refers to an excision that does not penetrate the structure being treated, such as laser removal of a cataract from the cornea, or a radiosurgical procedure, such as the irradiation of a tumor.

Surgical procedures are commonly categorized by urgency, type of procedure, body system involved, degree of invasiveness, and special instrumentation. Some types of surgical procedures are inpatient and require a hospital stay; other procedures are outpa-

tient and do not require the patient to remain in the hospital overnight.

Surgical procedures are utilized on all of the organ systems of the human body. The most common in-patient surgical procedures are obstetrical procedures and operations on the cardiovascular system, such as cardiac catheterization. The most common outpatient, ambulatory surgical procedures involve operations on the digestive system and the integumentary system (which includes the skin, hair, and nails).

### ***Alternative to Surgery***

House Bill 667 would cover a wide range of treatments that are considered alternatives to surgery. Any non-surgical alternative could be covered as long as it is provided to treat a medical condition or disease for which a surgical procedure is covered, and it meets the above-mentioned criteria. The mandate does not require that non-surgical alternatives be prescribed by a physician or other licensed medical personnel, and it does not require that the alternative be medically necessary. The mandate also does not require that non-surgical alternatives be provided by certified, registered, or licensed professionals. Therefore, alternative treatments would not need to be administered by medical personnel and could be administered by other providers, such as chiropractors and acupuncturists. In addition, without the requirement of a physician's prescription, treatment alternatives could potentially be identified by providers outside the medical community and possibly by patients themselves.

A vast range of alternatives to surgery could be covered by the bill for treating different medical conditions or diseases. Some alternatives make use of the latest technological advances, while others are more "low-tech." The following are several examples of non-surgical alternatives: The gamma knife and other advanced radiotherapies are non-invasive alternatives used for some types of cancer. A non-invasive alternative to treating uterine fibroids is embolization, a procedure that shrinks the fibroids by restricting their blood supply. Pharmaceuticals are an alternative therapy for many diseases and disorders including coronary disease, gastrointestinal disorders, and cancer to name a few. Alternatives to surgery for treating spinal disc herniation include physical therapy, cortisone injections, and simply bed rest. And, there is some evidence that splinting, laser-acupuncture, yoga, and therapeutic ultrasound may be effective alternatives for treating carpal tunnel syndrome.

While alternatives to surgery exist for many diseases and conditions, there are some conditions for which an alternative treatment may not be recommended or available. This is particularly true for

some of the most common surgical procedures, such as obstetrical procedures. For instance, there is not an alternative for an emergency Cesarean section.

### ***Alternatives to Feeding Tubes for Consumption of Amino Acid-Based Formula***

As stated in the letter from the proposed mandate's patron, the motivation behind the proposed mandate is securing insurance coverage for amino acid-based formula when consumed orally rather than through a feeding tube. Amino acid-based formula is used to treat a variety of conditions, including certain hypersensitivity and gastrointestinal diseases and disorders. Anecdotally, parents and advocates report that some insurance companies will not cover amino acid-based formula unless it is consumed using a feeding tube. As a result, there are reports that some parents have had feeding tubes inserted into their children to obtain coverage for the formula, which is estimated to cost from approximately \$3,000 to \$5,600 annually. (For more information on amino acid-base formulas, see JLARC's *Evaluation of House Bill 615 and House Bill 669: Mandated Coverage of Amino Acid-Based Formulas*.)

Enteral feeding, also known as tube feeding, is generally used to provide nutrition when a patient is unable to swallow and consume adequate calories. It may be temporarily utilized in an acute setting, such as for several days, or it may be used long term for a chronic condition. Two basic types of feeding tubes are used for enteral feeding—nasogastric feeding tubes and gastric feeding tubes. Whether a child would use a nasogastric feeding tube or a gastric feeding tube for purposes of receiving amino acid-based formula depends on how long the child would require enteral feeding of the formula.

Nasogastric feeding tubes are the most common type of feeding tube used for short-term enteral feeding and are typically not used for more than two months. Nasogastric feeding tubes are passed through the nostril down to the stomach or beyond (Figure 1). They can be placed by physicians, or nurses and dietitians trained and certified to place nasogastric feeding tubes. Medical experts indicate that the insertion of nasogastric feeding tubes is not considered surgery. In fact, some parents providing home care are taught to do the tube insertion and retractions.

Gastric feeding tubes are used when enteral feeding is required for a longer period of time. The most common type of gastric feeding tube is a percutaneous endoscopic gastrostomy (PEG) tube (Figure 2). Medical experts indicate that placement of a PEG tube is considered minor surgery. To place a PEG tube, an endoscope is passed into the mouth, down the esophagus, and into the stomach.

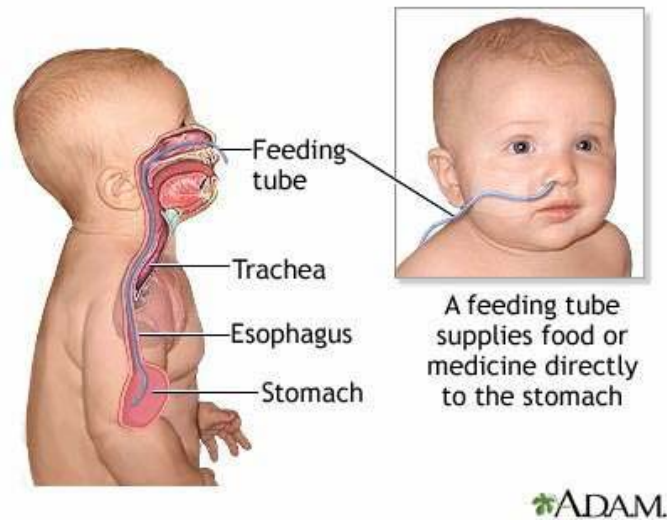


The surgeon can then visualize the stomach wall through which the PEG tube will pass. Under visualization with the endoscope, a PEG tube passes through the skin of the abdomen through a small incision and into the stomach. A balloon is blown up on the end of the tube, holding it in place. For adults, PEG tubes can be inserted under local anesthesia as an outpatient procedure. However, children are usually sedated and require a three-day hospital admission.

---

**Figure 1: Example of a Nasoenteric Feeding Tube**

---



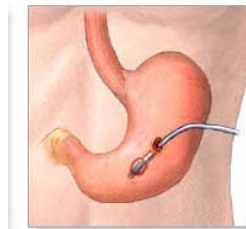
Source: A.D.A.M.

---

---

**Figure 2: Example of a Percutaneous Endoscopic Gastrostomy (PEG) Feeding Tube**

---



ADAM

Source: A.D.A.M.

---

The stated intention of the patron of HB 667 is to require insurers to cover oral consumption of amino acid-based formula as an alternative to receiving it through a feeding tube. In the case of a PEG feeding tube, this would be an alternative to surgery. In the case of a nasogastric feeding tube, oral consumption of the formula would not be an alternative to surgery.

### **b. History of Proposed Mandate**

House Bill 667, as introduced, would mandate health insurance coverage for alternatives to surgery. Specific types of surgery, medical conditions, and non-surgical treatments are not defined. However, covered non-surgical treatments are subject to certain stipulations in the bill.

According to the patron of HB 667, the bill was motivated by the concern that some families are unable to receive insurance coverage for amino acid-based formulas for children with severe food protein hypersensitivities or digestive disorders unless the formula is administered through a feeding tube. As mentioned previously, subsequent to the referral of HB 667 to the Special Advisory Commission on Mandated Health Insurance Benefits, the patron of the proposed mandate sent a letter to the Bureau of Insurance clarifying that HB 667 was only introduced to address amino acid-based formulas and not other conditions. A copy of the patron's letter is in Appendix E.

Although the patron has indicated his intent by letter, the bill as written would provide much broader coverage than the patron intended and would be much broader than existing health insurance mandates. In addition, several technical differences exist between HB 667 and most other health insurance mandates. House Bill 667 does not include the following requirements and exclusions:

- Usual language indicating that the coverage shall have durational limits, dollar limits, deductibles, and copayments and coinsurance factors that are no less favorable than for physical illness generally.
- Usual exclusions stating that the mandate does not apply to short-term travel, accident only, limited or specified disease, or individual conversion policies or contracts, or to policies or contracts designed for issuance to persons eligible for Medicare or any other similar coverage under state or federal government plans;
- Any requirements that the treatment be medically necessary, prescribed by an authorized health care professional,

or provided by certified, registered, or licensed health care professionals.

### **c. Proponents and Opponents of Proposed Mandate**

Proponents and opponents of HB 667 will have the opportunity to officially express their views at the public hearing on September 29, 2008, conducted by the Special Advisory Commission on Mandated Health Insurance Benefits. Proponents of the bill appear to be families of children who use amino acid-based formulas but are unable to receive insurance coverage of the formulas unless they are administered through a feeding tube. These families advocate receiving insurance coverage of the formula whether it is administered orally or through a feeding tube. The Children's Milk Allergy and Gastrointestinal Coalition (Children's MAGIC) also supports health insurance coverage of amino acid-based formulas when administered orally.

Opponents of HB 667 include the health insurance industry and others concerned about the breadth of the bill. Health insurers indicate that surgery, in general, is often a last resort, and insurance often covers evidence-based, medically-necessary treatments. Individuals in the medical community have expressed concern that the mandate could contravene good medical practice due to the breadth of potential treatment that could be covered and because treatments do not need to be overseen by medical professionals or administered by licensed providers. There is also concern that the mandate could give health insurance plans, rather than medical providers, the right to decide a patient's treatment and thereby encourage health insurance plans to push patients towards alternative treatments. Further, there is concern that the proposed mandate could be in conflict with the clinical trials for cancer mandate because HB 667 excludes experimental and investigational treatments.

#### **Medical Efficacy**

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

### **MEDICAL EFFICACY AND EFFECTIVENESS**

Due to the breadth of the medical conditions and treatments covered by HB 667, medical experts indicate that it is difficult to make a meaningful assessment or comment on the medical efficacy or effectiveness of treatments that may be covered by the proposed mandate. Experts indicate that oral consumption of amino acid-based formula is preferred when possible due to the risk of complication related to the placement and use of both nasogastric and PEG feeding tubes. However, there may be situations when enteral feeding of the formula is necessary.

### a. Medical Efficacy of Benefit

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. Medical Effectiveness of Benefit

#### Medical Effectiveness

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

Medical experts consulted for this review indicate that the breadth of the medical conditions and treatments covered by HB 667 make it very difficult to comment on the efficacy and effectiveness of treatments covered by the bill. As discussed above, for some medical conditions, there is evidence supporting the effectiveness of certain alternative treatments in lieu of surgery, whereas for other conditions, evidence is not yet available to support the effectiveness of alternative treatments. In still other circumstances, for example situations requiring a C-section delivery of babies, alternatives to surgery do not exist. Without specification in the bill indicating the diagnosed conditions or treatments covered, it is difficult to make a meaningful assessment of medical efficacy or effectiveness.

With regard to amino acid-based formula, no studies were found addressing the effectiveness of oral consumption of amino acid-based formulas compared to enteral feeding of the formula. However, medical experts indicate that oral consumption of formulas is always preferred to enteral feeding when possible due to the potential complications or increased risk that can arise from the placement and use of feeding tubes.

***Medical experts indicate that oral consumption of formulas is always preferred to enteral feeding when possible.***

Complications can occur from both the placement and use of nasogastric feeding tubes. More serious complications related to tube placement include inadvertent placement of the tube in the respiratory tract and pulmonary/pharyngeal perforation. One expert indicated that tube malposition in the airway, pharynx, and esophagus occurs in 4.4 percent of all cases. Once in place, several complications can occur. One study found that migration of the tube out of the small bowel occurs in 12.5 to 16 percent of cases, and inadvertent dislodgement occurs in 25 to 41 percent of cases. (These statistics may be different for pediatric patients.) Use of a

nasal bridle can reduce the frequency of inadvertent displacement, but persistent use of the bridle presents a risk of erosion of the nasal septum. Other complications that can arise with nasoenteric feeding tubes include clogging of the tube, cracking or breaking of the tubing, kinking of tubes, difficulty swallowing, aspiration, rupture of the tube's mercury capsule within the gastrointestinal tract, and sinus infection. To reduce the risk of sinus infections, nasoenteric tubes must be rotated every three weeks to the alternate nostril.

Complications related to placement of PEG tubes are less common than those related to nasoenteric tube placement, although a reaction to the sedation can occur. However, once in place, a number of complications can occur with PEG tubes, with infection at the PEG site being the most common. Excessive leakage around the PEG site and gastrointestinal bleeding can also occur. One study found that complications were more common among patients who underwent the placement of a PEG tube on an outpatient basis compared with patients for whom the PEG procedure was performed while in the hospital.

Although oral consumption of amino acid-based formulas is preferred due to the risks above, medical experts indicated that there may be situations where enteral feeding of the formula is medically necessary. Also, due to the unpalatable nature of amino acid-based formulas, a feeding tube is needed for many patients to maintain compliance with a formula-restricted diet.

## **SOCIAL IMPACT**

The broad nature of the coverage provided under HB 667 makes it difficult to assess many of the criteria under Social Impact. For example, assessing the utilization of the treatment is problematic due to the wide range of treatments that could be covered. Even where statistics are available, it is impossible to know whether non-surgical treatments were used as an alternative to surgery. The breadth of coverage in the proposed mandate also makes it challenging for health insurance companies to accurately determine whether they provide the coverage in the proposed mandate. Further, some medical experts have expressed concern that the broad language in the bill could result in patients receiving inappropriate or inadequate care, which could negatively impact public health.

With regard to amino acid-based formula, most children likely consume the formula orally. However, medical experts indicate that, due to the unpalatable nature of the formula, some children may require enteral feeding of the formula to adhere to a strict formula diet. Advocates for the proposed mandate indicate that there are

children who use feeding tubes for the formula solely to receive insurance coverage. A review in California also found that some individuals may keep a feeding tube in place longer than medically necessary to obtain insurance coverage. However, medical experts consulted for this review were not aware of any cases of children receiving formula enterally to obtain health insurance coverage. Less than one third of health insurance plans surveyed by Virginia's Bureau of Insurance indicate that they provide coverage of the formula when it is taken orally, and several plans indicate that coverage is only provided if the formula is taken through a feeding tube. Some plans also require the patient to be hospitalized to obtain coverage. If amino acid-based formula is not covered by insurance, it may present a financial hardship for some families.

#### **a. Utilization of Treatment**

Due to the wide range of treatments that are covered by the proposed mandate and the varying circumstances in which they are used, it is difficult to comment on the utilization of treatments that are covered by the proposed mandate. Even where statistics are available, it is impossible to know whether the treatments were used as an alternative to surgery per se.

Many medical alternatives to surgery may already be covered by health insurance. However, one area where insurance typically provides less coverage is complementary and alternative medicine (CAM). CAM is a group of diverse medical and health care systems, therapies, and products that is not presently considered to be part of conventional medicine. Chiropractors, acupuncturists, and massage therapists are among the many different types of CAM providers. In some states, CAM providers' scope of practice is prescribed by law, and they provide recognized benefits under health plan coverage. In 2002, an estimated 36 percent of adult Americans had used some form of CAM therapy during the past 12 months. CAM was used most often to treat back pain or problems, head or chest colds, neck pain or problems, joint pain or stiffness, and anxiety or depression. Prayer is the most commonly used CAM therapy. However, outside of prayer the next most commonly used therapies were natural products, deep breathing exercises, meditation, chiropractic care, yoga, massage, and diet-based therapies. The extent to which these therapies were used as an alternative to surgery is unknown.

With regard to amino acid-based formula, statistics are unavailable on the proportion of children receiving amino acid-based formula orally versus through a feeding tube. Medical experts indicate that most children would consume the formula orally. However, due to the unpalatable nature of the formula and for medical reasons, some children may require use of a feeding tube



to adhere to the formula diet. A 2008 review by the California Health Benefits Review Program (CHBRP) estimated the proportion of individuals with two disorders—eosinophilic disorders and short bowel syndrome—who consume amino acid-based formula orally versus through a feeding tube. According to the CHBRP estimates, approximately seven percent of individuals with these disorders used a feeding tube to consume the formula.

Even if more detailed data were available on the method of consumption of amino acid-based formula, it would be impossible to determine how many children were using a feeding tube because it is medically necessary versus how many are using one to obtain health insurance coverage of the formula. Also, some individuals may need a feeding tube temporarily and may be able to transition to oral consumption. Advocates for the proposed mandate indicate that there are parents who have had feeding tubes inserted into their children to obtain coverage of the formula. Also, the CHBRP indicated that some individuals would keep a feeding tube in place for as long as a nutritional need for the formula remains to take advantage of insurance coverage. However, medical experts consulted for this review were not aware of any cases of children receiving amino acid-based formulas enterally to obtain health insurance coverage.

#### **b. Availability of Coverage**

Many alternative treatments to surgery are already covered by health insurance companies, for example, pharmaceuticals or radiation therapy. However, the extent to which insurers provide the broad coverage included in HB 667 is more questionable. Based on a Bureau of Insurance (BOI) survey, 15 of 33 insurers responding to the survey indicated that they provide the coverage in the proposed mandate. (An additional seven plans responding to the survey indicated they do not market products to which the mandates would apply.) However, two indicated that alternative treatments would be covered as long as they are standard and not experimental or investigational. Nine companies indicated that they do not provide the coverage in the proposed mandate. However, another nine companies indicated that either the bill was too vague for them to provide a relevant response or they do not include any language in their contracts addressing the issues in the proposed mandate. (An additional 12 plans did not respond to the survey.)

With regard to amino acid-based formula, nine of the 33 companies (27 percent) responding to the survey indicated that they provide coverage of the formula when taken orally, but five of the companies qualified their response, for example, indicating coverage is provided for specific conditions only or on a case-by-case basis. Eight companies indicated that they provide coverage of the for-

mula when taken via a feeding tube, but four of those only provide coverage for hospitalized patients. Of those companies not requiring hospitalization, one responded that coverage is provided only if medically necessary and another responded that coverage is only for specific conditions. The remaining plans did not provide coverage or did not provide a response to this portion of the survey.

Insurance companies' responses on coverage of amino acid-based formula, whether consumed orally or enterally, may reflect the broad nature of the proposed mandate. Both HB 667 and its companion bill, HB 669, which would require coverage of amino acid-based formula, are broad in the conditions they would cover. Therefore, insurers may be indicating that they do not provide coverage for all the conditions that could be included by the bills. For example, in California, 100 percent of insurance companies indicated they provide coverage for amino acid-based elemental formula when taken enterally by persons with eosinophilic disorders or short bowel syndrome.

### **c. Availability of Treatment/ Benefit**

The availability of various alternatives to surgery likely varies based on the specific alternative. In general, it is expected that there are more alternatives available in urban settings and communities with a medical school than in rural settings. Amino acid-based formula appears to be widely available. For more information on the availability of amino acid-based formula, see JLARC's *Evaluation of House Bill 615 and House Bill 669: Mandated Coverage of Amino Acid-Based Formulas*.

### **d. Availability of Treatment Without Coverage**

The availability of non-surgical treatments without insurance coverage varies based on the treatment. Expensive high tech treatments such as the gamma knife and other advanced radiotherapies are largely unavailable without insurance coverage. Other alternatives such as physical therapy, some pharmaceuticals, and bed rest may be largely available without insurance. However, it is likely that some people do not pursue certain non-surgical treatment alternatives because they do not have insurance coverage.

With regard to amino acid-based formula, a State program is available to assist individuals at or below 300 percent of the federal poverty level (FPL) with certain conditions. However, individuals and families above 300 percent of FPL are required to pay for the formula out-of pocket if they do not have insurance coverage. For some families, the costs of the formula may be prohibitive. For more information on the availability of amino acid-based formula without insurance coverage, see JLARC's *Evaluation of*



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

**e. Financial Hardship**

The financial hardship of non-surgical treatment alternatives varies depending on the particular treatment. Median household income in Virginia is estimated to be \$58,607 in 2008. Very expensive high-tech therapies, such as advanced radiotherapy techniques and pharmaceuticals that could cost in the tens of thousands of dollars, would cause great financial hardship to individuals and families. However, other treatments, such as a limited number of physical therapy or acupuncture sessions, may cost several hundred dollars or less and create only a limited, temporary financial strain on families.

Amino acid-based formula is estimated to cost from \$1,900 to more than \$5,000 annually, constituting about 3.3 to 9.7 percent of median household income. Given that health care costs are estimated to be approximately 5.7 percent of total annual U.S. household expenditures, the cost of the formula could nearly double what a household typically spends on health care costs. For more information on the financial hardship for families paying out of pocket for amino acid-based formula, see JLARC's *Evaluation of House Bill 615 and House Bill 669: Mandated Coverage of Amino Acid-Based Formulas*.

**f. Prevalence/ Incidence of Condition**

The wide range of conditions that would be covered by the proposed mandate makes it difficult to make meaningful estimates of prevalence or incidence. HB 667 would require insurers to cover non-surgical treatments for any medical conditions and diseases for which they cover surgical treatments. One approach could be to look at the incidence of surgical procedures performed in the United States. However, there may not be non-surgical alternatives for some of the most common surgical procedures. Also, for those procedures for which there are alternatives, the alternatives may not be medically advised in every case. In addition, in many cases the alternatives to surgery will have been tried, resulting in surgery as the last best treatment option.

**Prevalence**

Prevalence is defined as the total number of cases of the condition in the population at a specific time.

Table 1 shows the top five surgical procedures performed in hospital and outpatient ambulatory settings. The most common inpatient surgical procedures performed in hospitals were obstetrical and cardiac procedures. Detailed information on the surgical procedures performed in ambulatory settings is not yet available. (The National Center for Health Statistics is in the process of compiling this information through the National Survey of Ambulatory Sur-

gery.) However, information is available on the number of surgical procedures provided in ambulatory centers by system or area of the human body. The greatest number of surgical procedures was performed on the integumentary system, which includes the skin, hair, and nails, followed by the digestive system, the musculoskeletal system, the eye, and the urinary system.

**Table 1: Top Five Surgical Procedures in Hospital and Ambulatory Settings in the United States, 2005**

<b>Procedure Category</b>	<b>Number of Procedures (in thousands)</b>
<b>Short-Stay Hospitals</b>	
Cesarean section	1,262
Repair of current obstetric laceration after Cesarean section	1,259
Cardiac catheterization	1,209
Artificial rupture of membranes to induce labor	928
Balloon angioplasty of coronary artery or coronary atherectomy	645
<b>Ambulatory Medical Centers</b>	
Integumentary system (skin, hair, & nails)	23,392
Digestive system	14,276
Musculoskeletal system	5,717
Eye	5,228
Urinary system	3,174

Source: 2005 National Hospital Discharge Survey; 2005 National Ambulatory Medical Care Survey

Information is not available on the proportion of children using amino acid-based formula who receive it through a feeding tube. However, the California Health Benefits Review Program estimates that approximately seven percent of individuals with eosinophilic disorders and short bowel syndrome, both rare disorders, use feeding tubes to consume amino acid-based formula. Even if insurance coverage were available for oral consumption of the formula, it is unclear what proportion of individuals could stop using feeding tubes to consume the formula because some individuals medically require feeding tubes.

### **g. Demand for Proposed Coverage**

It is impossible to estimate the demand for the coverage in HB 667 due to the broad range of medical conditions and treatment alternatives that could be covered. However, there likely is some demand for treatments and therapies that are not currently covered by insurance plans, particularly complementary and alternative medicine (CAM) therapies. The overall demand for coverage of oral consumption of amino acid-based formulas is estimated to be relatively low because the conditions that require the use of amino

acid-based formulas are quite rare. For more information on the incidence and prevalence of these conditions, see JLARC's *Evaluation of House Bill 615 and House Bill 669: Mandated Coverage of Amino Acid-Based Formulas*.

#### **h. Labor Union Coverage**

Labor unions have not advocated for the coverage similar to that provided in HB 667 in their health benefit packages.

#### **i. State Agency Findings**

There are no state agency reports or findings addressing non-surgical alternatives for medical conditions or diseases where coverage is provided for the surgical treatment of these conditions or disease. In 2000, 2003, and 2005, the Special Advisory Commission reviewed proposals mandating coverage of formulas for the treatment of inborn errors of metabolism and/or gastrointestinal disorders. In 2008, the Special Advisory Commission is reviewing two proposals (HB 615 and HB 669) that would mandate coverage of amino acid-based formulas. The Bureau of Insurance and JLARC conducted reviews of these proposals.

#### **j. Public Payer Coverage**

Medicaid does not have a specific policy to provide coverage of non-surgical treatments for medical conditions or diseases if surgical treatment of the condition or disease is covered. However, the Medicaid State Plan provides coverage for medically necessary services, which may or may not be surgery depending on the condition and treatment required. Medicaid's coverage policy states the following:

“Allowable Medicaid reimbursement is based upon medical necessity. Medicaid defines “medically necessary services” as those services that are covered under the State Plan and are reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body member. Coverage may be denied if the requested service is not medically necessary according to the preceding criteria or is generally regarded by the medical profession as experimental or unacceptable.” *Department of Medical Assistance Services, Physician Manual*

With regard to amino acid-based formula, both Medicaid and the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) cover amino acid-based formula, whether taken orally or enterally, for certain conditions. Medicaid provides coverage for the formula for individuals with inborn errors of metabo-

lism, and individuals with allergic and GI conditions when the use is adequately justified by a physician. WIC provides the formula for children under age five with allergic and GI disorders. In addition, there are two Virginia Department of Health programs that offer amino acid-based formulas. For more information on Medicaid and WIC coverage of the formulas and the VDH programs, see JLARC's *Evaluation of House Bill 615 and House Bill 669: Mandated Coverage of Amino Acid-Based Formulas*.

#### **k. Public Health Impact**

##### **Public Health**

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

Without better defined treatments or conditions that would be covered by the proposed mandate, it is difficult to determine the potential impact on public health. Some medical experts expressed concern over the broad and vague language included in the bill. Although the proposed mandate includes criteria that surgical alternatives must meet to be covered, it appears that alternative treatments could potentially be identified and/or provided by individuals outside of the medical community. Without any oversight or guidance by a physician or medical professional, there is concern that patients may end up receiving inappropriate or inadequate care. With regard to amino acid-based formula, benefits of covering the formula, regardless of the method of consumption, would largely accrue to the patients diagnosed with disorders requiring the formula.

#### **FINANCIAL IMPACT**

The premium impact of HB 667 is indeterminate because the scope of the bill is too broad for many insurance companies to develop premium estimates. The broad nature of the bill also makes it difficult to assess several other criteria under Financial Impact, although the proposed mandate requires that non-surgical treatments must be less expensive than surgical treatments. Some experts are concerned that HB 667 could lead to patients not receiving effective and appropriate care for their medical needs. This is, in part, because HB 667 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 professionals.

The financial impact of requiring coverage of oral consumption of amino acid-based formula when enteral consumption of the formula is covered is expected to be small. However, in addition to being more cost effective, medical experts indicate that oral consumption is preferred, whenever possible, due to the risks and complications that can occur with feeding tubes.

### **a. Effect on Cost of Treatment**

Due to the broad range of treatments that could be covered by the proposed mandate, it is not possible to estimate how the costs of non-surgical treatment in general may be impacted by the proposed mandate. If insurance began covering treatments that were not previously covered, providers may increase their rates. However, as with other services, providers would need to enter into a contractual agreement with insurance companies. This could put pressure on providers to accept a lower reimbursement rate in exchange for a higher volume of patients as a result of being included in a health plan's network. The proposed mandate is not expected to affect the cost of amino acid-based formulas.

### **b. Change in Utilization**

Health insurance companies already cover alternative treatments to surgery for many medical conditions and diseases. However, for non-surgical alternatives that are not currently covered by health insurance, their utilization may increase as a result of the proposed mandate. Some medical experts expressed concern that HB 667 could lead to patients not receiving effective and appropriate care for their medical needs.

Language is included in HB 667 to help guard against health insurance coverage of, and therefore increased use of, inappropriate or unsafe treatments. In particular, non-surgical alternatives covered by the proposed mandate must be (i) less expensive, (ii) less dangerous, (iii) not experimental or investigational, (iv) generally recognized by the regional medical community as an appropriate treatment for the condition or disease, and (v) not less efficacious than the surgical treatment. While some medical experts indicated that the above criteria would mitigate the risks of patients using dangerous or inappropriate treatments, other experts felt that there is a risk for abuse and patients not receiving the appropriate treatment for their condition under the mandate.

The concern of some medical experts is related, in part, to the absence of language in HB 667 addressing several issues that are frequently covered by existing health insurance mandates. The proposed mandate does not require that non-surgical alternatives be prescribed by a physician or other licensed personnel, nor does it require that alternatives be medically necessary. The mandate also does not require that alternative treatments be provided by certified, registered, or licensed professionals. Without these requirements, it appears that non-surgical alternatives could be potentially identified and/or provided by individuals themselves or individuals outside of the medical community. There is also concern that the absence of these requirements could result in health

plans determining treatment rather than medical providers. The proposed mandate may result in more case-by-case assessments of treatment options by insurance companies that could create unintended intrusion in medical care delivery decisions.

Another concern is with the proposed mandate's criterion that non-surgical treatments must be generally recognized by the regional medical community as an appropriate treatment. Medical experts indicate that regional medical groups do not exist to assess the appropriateness of different treatments for various medical conditions or diseases. Experts indicate that national guidelines based on evidence-based research are typically used to determine whether medical treatments are indicated for specific medical diseases and conditions.

With regard to amino acid-based formula, HB 667 could lead to an increase in oral consumption of the formula for those individuals that currently receive it through a PEG feeding tube solely to obtain insurance coverage of the formula. However, this is likely a modest number of individuals. As indicated under Availability of Coverage, only eight insurance companies report covering amino acid-based formulas when taken enterally but not orally. The proposed mandate would not affect individuals whose insurance companies do not cover amino acid-based formula at all, regardless of the method of consumption.

### **c. Serves as an Alternative**

The purpose of HB 667 is to provide coverage of non-surgical alternatives for treating medical conditions or diseases. The bill also requires that non-surgical treatments be less expensive than surgical treatment of a medical condition or disease. So by design, non-surgical treatments covered by the proposed mandate must be more cost effective than surgery. In many cases, it is also likely that non-surgical treatments may have been used or tried prior to the recommendation of surgery, resulting in surgery as the last option available.

With regard to amino acid-based formula, oral consumption of the formula would be a less expensive alternative than administration of the formula through a feeding tube. The Children's Milk Allergy and Gastrointestinal Coalition (MAGIC) estimates the cost of enteral feeding using a PEG tube to be \$20,242 in the first year, not including the cost of formula. Medical experts indicate that oral consumption of the formula is also preferred to enteral feeding when possible due to the risks and complications that can occur with feeding tubes such as perforation of the lung or infection. In addition to affecting the health of the patient, these risks can also drive up the cost of enteral feeding.



### **Average Individual Insurance Premiums**

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

### **Impact of Premiums on Employers' Decisions to Offer Health Insurance**

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

## **d. Effect on Providers**

It is difficult to estimate the effect on providers due to the wide range of treatments that could be covered by the proposed mandate. For those treatments and services that are not currently covered by health insurance, the number of providers would likely increase as a result of the mandate. The scope of providers could be limited by requiring a physician’s prescription for non-surgical alternatives covered by HB 667, and by requiring that any providers must be licensed or certified. However, due to the breadth of providers that are covered, it is unclear whether a general licensure or certification requirement would be meaningful. The proposed mandate is not expected to affect providers of amino acid-based formula, or medical professionals that place feeding tubes.

## **e. Administrative and Premium Costs**

The administrative expenses for insurance companies for the proposed mandate would likely be higher than for other mandates. However, the premium impact of HB 667 is indeterminate because the scope of the bill is too broad for many insurance companies to develop a premium estimate. It is also likely that many alternative non-surgical treatments are already covered under current insurance provisions, so no change in premium would be expected for these treatments.

### ***Administrative Expenses of Insurance Companies.***

The administrative expenses for insurance companies related to HB 667 would likely be higher than other mandates because health insurance plans would need to establish provider networks and negotiate reimbursement rates for services they currently do not cover. The proposed mandate may also require case-by-case assessments of treatment options not previously required under current coverage provisions and lead to more time spent on appeals.

### ***Premium and Administrative Expenses of Policyholders***

The premium impact of HB 667 is indeterminate. Only three health plans provided estimates of the premium impact of HB 667, and monthly premium estimates range from zero to \$3.00. Six plans indicated the premium impact would be minimal. The remaining health plans did not provide a premium estimate, and a number of them indicated that the scope of benefits in the bill is too broad for them to provide a premium estimate. Two plans indicated that the premium impact of covering amino acid-based formulas would be \$0.05 and \$0.08 per member per month for group standard and group optional contracts, respectively.

## **f. Total Cost of Health Care**

Due to the range of medical conditions and alternative treatments covered by the proposed mandate, it is difficult to estimate the impact on the total cost of health care. Because the mandate requires non-surgical alternatives to be less expensive than surgical treatments, in theory HB 667 could reduce the total cost of health care. Also, medical experts indicate there are some medical conditions, such as Crohn's disease, that can be more effectively managed at a cheaper cost using non-surgical approaches. Further, one expert suggested that indirect costs, such as time away from work or school, could be minimized by a reduction in surgery. Decreased surgery leads to less time in the hospital, which positively impacts productivity. However, for other conditions, such as biologic therapy for inflammatory bowel disease, the cost of state-of-the-art non-surgical treatments may not be much cheaper than surgery. Also, some experts indicate that costs could actually increase if medical conditions are not properly managed and individuals do not pursue the appropriate treatment for their conditions or delay surgery.

To the extent that some individuals use feeding tubes to consume amino acid-based formula solely for the purpose of obtaining health insurance coverage, the proposed mandate could reduce the cost of health care for these individuals. However, the impact on the total cost of health care would be minimal.

## **BALANCING MEDICAL, SOCIAL, AND FINANCIAL CONSIDERATIONS**

The impacts of HB 667 could be far reaching, and the breadth of the proposed mandate makes it difficult to assess many of the criteria reviewed by the Special Advisory Commission on Mandated Health Insurance Benefits. The patron of HB 667 has indicated by letter that he is only interested in ensuring that amino acid-based formula is covered whether taken orally or by a feeding tube. Because not all feeding tubes require surgical placement, it is not clear the extent to which HB 667 would address the patron's concerns. If the patron's primary goal is securing insurance coverage for amino acid-based formula, whether taken orally or enterally, then a more direct solution would be to include language in the proposed mandates covering amino acid-based formula (HB 615 and HB 669) that would require coverage of the formula regardless of the method of consumption.

### **a. Social Need/ Consistent With Role of Insurance**

Due to the breadth of medical conditions and non-surgical treatments that could be covered by HB 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 HB 667 is to secure insurance coverage of amino acid-based formula whether 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 a feeding tube. However, the placement of some feeding tubes does not require surgery and therefore would not be affected by the proposed mandate.

#### **b. Need Versus Cost**

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. Mandated Offer**

##### **Mandated Offer**

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

An offer of coverage may be appealing to some individuals and employers due to the broad range of alternatives that could be covered by the bill. However, it is difficult to estimate the extent to which the offer would be purchased without estimates of the potential premium impact of a mandated offer. It is unlikely that individuals or employers would purchase an offer that is restricted to coverage of oral consumption of amino acid-based formula. Conditions that require the use of amino acid-based formula are relatively rare, and most purchasers of health insurance will probably not view their coverage, let alone the distinction of oral versus enteral consumption of the formula, as a critical need.

## **ACKNOWLEDGMENTS**

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

## Statutory Authority for JLARC Evaluation of Proposed Mandated Health Insurance Benefits

---

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

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

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

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

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

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

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

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

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

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

The Commission shall have the following powers and duties:

A. Make performance reviews of operations of state agencies to ascertain that sums appropriated have been, or are being expended for the purposes for which such appropriations were made and to evaluate the effectiveness of programs in accomplishing legislative intent;

B. Study on a continuing basis the operations, practices and duties of state agencies, as they relate to efficiency in the utilization of space, personnel, equipment and facilities;

C. Make such special studies and reports of the operations and functions of state agencies as it deems appropriate and as may be requested by the General Assembly;

D. Assess, analyze, and evaluate the social and economic costs and benefits of any proposed mandated health insurance benefit or mandated provider, including, but not limited to, the mandate's predicted effect on health care coverage premiums and related costs, net costs or savings to the health care system, and other relevant issues, and report its findings with respect to the proposed mandate to the Special Advisory Commission on Mandated Health Insurance Benefits; and

E. Make such reports on its findings and recommendations at such time and in such manner as the Commission deems proper submitting same to the agencies concerned, to the Governor and to the General Assembly. Such reports as are submitted shall relate to the following matters:

1. Ways in which the agencies may operate more economically and efficiently;

2. Ways in which agencies can provide better services to the Commonwealth and to the people; and

3. Areas in which functions of state agencies are duplicative, overlapping, or failing to accomplish legislative objectives or for any other reason should be redefined or redistributed.

## Proposed Mandated Benefit Requiring Coverage of Alternatives to Surgery

---

**HOUSE BILL NO. 667**

Offered January 9, 2008

Prefiled January 8, 2008

*A BILL to amend the Code of Virginia by adding a section numbered [38.2-3407.9:03](#), relating to coverage for less intrusive alternatives to surgery.*

-----  
Patron-- Marshall, R.G.

-----  
Referred to Committee on Commerce and Labor  
-----

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding a section numbered [38.2-3407.9:03](#) as follows:

§ [38.2-3407.9:03](#). *Coverage for alternatives to surgery.*

*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 surgical treatment of a medical condition or disease shall also include coverage for any nonsurgical treatment for the medical condition or disease that is (a) less expensive, (b) less dangerous, (c) not experimental or investigational, (d) generally recognized by the regional medical community as an appropriate treatment for the condition or disease, and (e) not less efficacious than the surgical treatment.*



Appendix **C**

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

Topic Area	Criteria
<b>1. Medical Efficacy</b>	
a. Medical Efficacy of Benefit	The contribution of the benefit to the quality of patient care and the health status of the population, including the results of any clinical research, especially randomized clinical trials, demonstrating the medical efficacy of the treatment or service compared to alternatives or not providing the treatment or service.
b. Medical Effectiveness of Benefit <i>JLARC Criteria*</i>	The contribution of the benefit to patient health based on how well the intervention works under the usual conditions of clinical practice. Medical effectiveness is not based on testing in a rigid, optimal protocol, but rather a more flexible intervention that is often used in broader populations.
c. Medical Efficacy of Provider	<p>If the legislation seeks to mandate coverage of an additional class of practitioners:</p> <ol style="list-style-type: none"> <li>1) The results of any professionally acceptable research, especially randomized clinical trials, demonstrating the medical results achieved by the additional class of practitioners relative to those already covered.</li> <li>2) The methods of the appropriate professional organization to assure clinical proficiency.</li> </ol>
d. Medical Effectiveness of Provider <i>JLARC Criteria*</i>	The contribution of the practitioner to patient health based on how well the practitioner's interventions work under the usual conditions of clinical practice. Medical effectiveness is not based on testing in a rigid, optimal protocol, but rather more flexible interventions that are often used in broader populations.
<b>2. Social Impact</b>	
a. Utilization of Treatment	The extent to which the treatment or service is generally utilized by a significant portion of the population.
b. Availability of Coverage	The extent to which insurance coverage for the treatment or service is already generally available.
c. Availability of Treatment <i>JLARC Criteria*</i>	The extent to which the treatment or service is generally available to residents throughout the state.
d. Availability of Treatment Without Coverage	If coverage is not generally available, the extent to which the lack of coverage results in persons being unable to obtain necessary health care treatments.
e. Financial Hardship	If the coverage is not generally available, the extent to which the lack of coverage result in unreasonable financial hardship on those persons needing treatment.
f. Prevalence/Incidence of Condition	The level of public demand for the treatment or service.
g. Demand for Coverage	The level of public demand and the level of demand from providers for individual or group insurance coverage of the treatment or service.

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

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

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



## Bibliography

---

### PEER-REVIEWED RESEARCH

**Andrews DW, Suarez O, Goldman HW, Downes MB, Benarz G, Corn BW, Werner-Wasik M, Rosenstock J, Curran WJ Jr. (2001).** Stereotactic radiosurgery and fractionated stereotactic radiotherapy for the treatment of acoustic schwannomas: comparative observations of 125 patients treated at one institution. *International Journal of Radiation Oncology, Biology, Physics*, 50(5): 1265-1278. *Abstract.*

**Axelrod D, Kazmerski K, Kishore I. (2006).** Pediatric Enteral Nutrition. *Journal of Parenteral and Enteral Nutrition*, 30(1): S21-S26.

**Cresci G, Mellinger J. (2006).** The History of Nonsurgical Enteral Tube Feeding Access. *Nutrition in Clinical Practice*, 21: 522-528.

**Ghahremani GG, Gould RJ. (1986).** Nasoenteric Feeding Tubes: Radiographic Detection of Complications. *Digestive Diseases and Sciences*, 31(6): 574-585.

**Golfieri R, Muzzi C, De Iaco P, Maffei M, Giampalma E, Amore B, Muzzupapa G, Baroncini S, Bovicelli L. (2000).** The percutaneous treatment of uterine fibromas by means of transcatheter arterial embolization. *Radiologia Medica*, 100(1-2):48-55. *Abstract.*

**Goodyear-Smith F, Arroll B. (2004).** What can family physicians offer patients with carpal tunnel syndrome other than surgery? A systematic review of nonsurgical management. *Annals of Family Medicine*, 2(3): 267-273. *Abstract.*

**Lochs H, Dejong C, Hammarqvist F, Hebuterne X, Leon-Sanz M, Schutz T, van Gemert W, von Gossom A, Valentini L, DGEM: Lubke H, Bischoff S, Engelmann N, Thul P. (2006).** ESPEN Guidelines on Enteral Nutrition: Gastroenterology. *Clinical Nutrition*, 25: 260-274.

**McClave SA, Chang W. (2003).** Complications of enteral access. *Gastrointestinal Endoscopy*, 58(5): 739-751.

#### **OTHER RESEARCH**

**California Health Benefits Review Program. (2008).** Analysis of Assembly Bill 2174: Coverage for Amino Acid-Based Elemental Formula. A Report to the 2007-2008 California Legislature, April 8, 2008.

**Center for Disease Control. (2004).** Complementary and Alternative Medicine Use Among Adults: United States, 2002. *Advance Data from Vital and Health Statistics*, 343, May 27, 2004.

**Children's Magic Inc. (2008).** Report to the Legislature of the State of Florida and Florida Agency for Health Care Administration, Mandated Health Coverage of Elemental Formula for Food Protein Allergy in Infants and Children as required by Florida Statute 624.215, March 2008.

**Medscape. (2008).** Biologic Therapy for Inflammatory Bowel Disease. Website.

**University of California San Francisco Today. (2008).** Alternatives to Surgery and Radiation for Prostate Cancer. Website.

# E

## Letter from the Patron of HB 667

---

Attached is a letter from the patron of HB 667





COMMONWEALTH OF VIRGINIA

HOUSE OF DELEGATES

RICHMOND

ROBERT G. MARSHALL  
POST OFFICE BOX 421  
MANASSAS, VIRGINIA 20108-0421

THIRTEENTH DISTRICT

COMMITTEE ASSIGNMENTS:  
PRIVILEGES AND ELECTIONS  
COUNTIES, CITIES AND TOWNS  
SCIENCE AND TECHNOLOGY

June 30, 2008

Ms. Althelia Battle  
State Corporation Commission  
Bureau of Insurance  
P.O. Box 1157  
Richmond, VA 23218  
[Via E-mail]

Dear Ms. Battle,

It has come to my attention that there has been some confusion regarding the intent of HB 667. The bill mandates coverage of alternatives to surgery under certain circumstances. The purpose of this bill was to address a policy currently in place by Aetna that requires amino-acid based formulas be delivered via a surgically placed tube instead or orally. HB 667 was proposed as a complimentary bill to HB 669, which mandates coverage of amino-acid based formulas. This letter seeks to clarify that HB 667 was only introduced to address amino-acid based formulas and not other conditions.

I appreciate your analysis of these bills and look forward to your upcoming presentation at the Special Advisory Commission on Mandated Health Insurance Benefits. If you have any questions please contact me at (703) 895-8423 or (703) 853-4213.

Sincerely,

*Bob Marshall*

Delegate Bob Marshall

RGM/ccg







**Joint Legislative Audit and Review Commission**  
**Suite 1100**  
**General Assembly Building**  
**Capitol Square**  
**Richmond, Virginia 23219**  
804-786-1258 Fax 804-371-0101  
<http://jlarc.state.va.us>