JOINT LEGISLATIVE AUDIT AND REVIEW COMMISSION
OF THE VIRGINIA GENERAL ASSEMBLY

EVALUATION OF PROPOSED MANDATED HEALTH INSURANCE BENEFITS

Evaluation of House Bill 2337: Addendum to 2008 *Evaluation of House Bill 615 and House Bill 669, Mandated Coverage of Amino Acid-Based Formulas*

June 2009

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JLARC Staff for This Evaluation

Hal Greer, Division Chief
Kimberly Sarte, Principal Fiscal Analyst
Jenny Breidenbaugh, Senior Associate Legislative 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.virginia.gov

Evaluation of House Bill 2337: Addendum to 2008 *Evaluation of House Bill 615 and House Bill 669, Mandated Coverage of Amino Acid-Based Formulas*

House Bill (HB) 2337 proposes mandated health insurance coverage of amino acid-based elemental formula for certain gastrointestinal and hypersensitivity diseases and disorders regardless of delivery method. HB 2337 was introduced in the 2009 General Assembly as a follow-up to HB 615 of the 2008 General Assembly. This document serves as an addendum to the 2008 JLARC Report, *Evaluation of House Bill 615 and House Bill 669: Mandated Coverage of Amino Acid-Based Formulas*, which reviewed two separate bills proposing coverage of amino acid-based formulas. HB 615 was very similar to the current HB 2337 in that it proposed mandated coverage of amino acid-based elemental formulas for certain gastrointestinal and hypersensitivity conditions. HB 669 proposed mandated coverage of amino acid-based metabolic formula for inborn errors of metabolism as well as elemental formula for certain gastrointestinal conditions. No follow-up to HB 669 was introduced in the 2009 General Assembly and therefore, will not be discussed in this addendum. For a more extensive review of both HB 615 and HB 669, please see the 2008 JLARC report.

The differences between HB 615 (2008) and HB 2337 (2009) are minor (Table 1). Changes were made to four of the five classes of medical conditions listed for which the formula would be covered. Coverage of the elemental formula for IgE and non-IgE mediated allergies was limited to children under age ten. Food protein induced enterocolitis syndrome was modified by adding the term severe. Additionally, eosinophilic disorders would have to be diagnosed using the results of a biopsy pursuant to HB 2337. Finally, HB 2337 added a provision allowing for a private review to determine the medical necessity by an agent acting on behalf of the insurer. However, according to the health insurance industry, this language is not needed because they already have the ability to review requests for coverage.

Table 1: Comparison of Conditions: House Bill 615 (2008) and House Bill 2337 (2009)

House Bill 615	House Bill 2337
Immunoglobulin-E (IgE) mediated allergy to multiple food proteins	Immunoglobulin-E (IgE) mediated allergy to multiple food proteins *for enrollees under age 10*
Non-Immunoglobulin-E (non-IgE) mediated allergy to multiple food proteins	Non-Immunoglobulin-E (non-IgE) mediated allergy to multiple food proteins *for enrollees under age 10*
Food protein-induced enterocolitis syndrome	*Severe* food protein-induced enterocolitis syndrome
Eosinophilic disorders	Eosinophilic disorders *as evidenced by the results of a biopsy*
Impaired absorption of nutrients caused by disorders affecting the absorptive surface, functional length, and motility of the GI tract	Impaired absorption of nutrients caused by disorders affecting the absorptive surface, functional length, and motility of the GI tract

Note: Changes identified in *italics.*

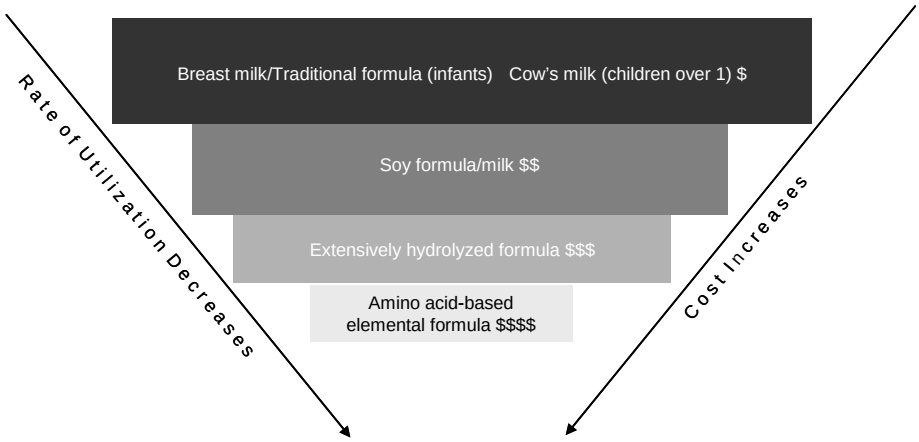
Source: House Bill 615 (2008 General Assembly) and House Bill 2337 (2009 General Assembly).

BACKGROUND

Amino acid-based elemental formulas are specialized medical formulas used for certain food hypersensitivity and gastrointestinal (GI) conditions. Medical experts noted that the language in HB 2337 covers a broad array of GI and hypersensitivity disorders. With elemental formulas, the proteins are predigested and broken down into smaller pieces for easier digestion and absorption. The determination of the need for elemental formula is made over a period of time after persistent problems, and the formulas are used primarily for treatment or nutrition in children.

According to medical experts, the use of amino acid-based elemental formulas depends in part upon the severity of the hypersensitivity and may be medically necessary on a case-by-case basis. Less expensive and more palatable formulas, such as hydrolyzed formulas, are tried first (Figure 1). (A medical expert interviewed for this study noted that physicians may skip soy milk or formula when the evidence suggests that the condition requires extensively hydrolyzed formula.) If a physician determines that other formulas, including hydrolyzed formulas, are not effective, elemental formula may be prescribed as a last resort. This is with the exception of eosinophilic esophagitis, in which elemental formula is the standard treatment for a child diagnosed with the condition through a biopsy.

Figure 1: Sequence of Formulas Typically Used in Treatment of Most Gastrointestinal and Hypersensitivity Conditions Included in HB 2337



Note: Physicians sometimes prescribe extensively hydrolyzed formula without first trying soy formula/milk when the evidence suggests that it may be necessary. In the case of eosinophilic esophagitis, elemental formula is the standard treatment and it is not necessary to attempt other formulas first.

Source: Medical literature review and medical expert interviews.

In the case of hypersensitivity conditions, elemental formulas are used primarily for infants and young children, and not adults. Food allergies are one type of hypersensitivity. According to Children's Milk Allergy and Gastrointestinal Coalition (MAGIC) and medical experts, children typically need the formulas for a period of two years or less and the majority of children outgrow the hypersensitivity (allergic) conditions by age five.

Since common GI disorders such as Crohn's disease and short bowel syndrome (SBS) are not curable, elemental formulas are used to alleviate severe symptoms. Conditions with impaired digestion and absorption, such as SBS, may affect individuals of any age. In children, especially when digestion and absorption are compromised, amino acid-based formulas are more commonly delivered through a feeding tube but may also be administered orally. According to medical practice guidelines, the formulas are only recommended for children. In rare cases medical experts indicate that formula may be used by adults. The duration of the formulas' use is uncertain and varies from weeks to years depending on the conditions and the individual.

For the small proportion of children with hypersensitivity and GI conditions who need elemental formula, adverse health consequences may result when elemental formulas are not utilized. These consequences may include deteriorating overall

health, poor nutrition, failure to thrive, physical growth failure, and poor weight gain. In rare cases, the lack of elemental formula for GI disorders may result in small intestine failure in which the body cannot digest food and lead to death.

More background on amino acid-based elemental formula and the diseases and disorders for which coverage would be mandated is available in the 2008 JLARC report.

MEDICAL EFFICACY AND EFFECTIVENESS

The medical efficacy and effectiveness of amino acid-based elemental formulas are well established as a treatment of last resort for certain conditions listed in HB 2337 and a standard treatment for eosinophilic esophagitis (Table 2); however, the bill also would cover conditions for which the use of formula is not standard medical practice. As previously indicated, in order to establish the need for elemental formula, less expensive and more palatable formulas are tried first (Figure 1). However, physicians note that for some children with certain disorders, elemental formula is the only formula that will allow them to meet their nutritional needs. For children diagnosed with eosinophilic esophagitis as evidenced by the result of a biopsy, elemental formula is the standard treatment. Medical practice guidelines and physicians interviewed for this study do not support the use of elemental formulas as a treatment for adults for any of the GI or hypersensitivity conditions listed in HB 2337. (Table 2 modifies information presented in last year's report to clarify that elemental formula is only used as a treatment of last resort for most conditions.)

For more detailed information and analysis on the diseases and disorders included in HB 2337, please see the 2008 JLARC report on this topic.

Table 2: Use of Amino Acid-Based Elemental Formulas to Treat Gastrointestinal and Hypersensitivity Diseases and Disorders in Children and Adults

	Child		Adult	
Condition	**Standard Treatment**	**Last Resort Treatment**	**Standard Treatment**	**Last Resort Treatment**
Immunoglobulin-E (IgE) mediated allergy to multiple food proteins	X	✓	X	X
Non-Immunoglobulin-E (non-IgE) mediated allergy to multiple food proteins	X	X	X	X
Food protein-induced enterocolitis syndrome	X	✓	X	X
Eosinophilic esophagitis	✓	X	X	X
Eosinophilic gastroenteritis	X	✓	X	X
Crohn's disease	X	✓	X	X
Short bowel syndrome	X	✓	X	X
Other disorders of impaired absorption of nutrients caused by disorders affecting the absorptive surface, functional length, and motility of the GI tract	X	X	X	X

✓= Indicates the recommendations of medical practice guidelines. X= Not supported by medical practice guidelines.

Note: Determination of formulas as standard or last resort treatment is based on medical literature and medical expert reviews; however, treatment with amino acid-based formulas should be made on an individual basis by a physician.

Source: Medical literature and medical expert review.

SOCIAL IMPACT

Conditions that require the use of amino acid-based formulas are relatively rare. An estimated less than one percent of individuals diagnosed with the hypersensitivity and GI conditions listed in HB 2337 utilize amino acid-based elemental formulas, and changes to HB 2337 from the 2008 bill do not significantly change the affected population. The majority of health insurance companies do not provide coverage of amino acid-based elemental formulas. This may present a financial hardship because the cost of formulas could range from approximately five to ten percent of median household income in 2009. Therefore, some individuals may not be receiving the necessary formula due to the cost.

Prevalence of Condition and Utilization of Treatment

The differences from HB 615 (2008) to HB 2337 (2009) do not substantially change the population affected by mandated coverage of elemental formulas. The first and most significant change to the legislation is limiting coverage of formulas for IgE and non-IgE mediated allergies to children under age ten. As mentioned, the majority of children with severe IgE and non-IgE mediated allergies that require the use of elemental formulas are

less than ten years of age (though it is not recommended for non-IgE). However, according to medical experts consulted for this study, this age appears arbitrary and would deny coverage for a proportion of adolescents who need the formula. In FY 2008, 89 percent of children on Medicaid who used elemental or hydrolyzed formula for IgE and non-IgE mediated allergies were under age ten. Therefore, this change would potentially eliminate coverage for the 11 percent who are ten to 18 years. However, medical procedure codes used to identify formulas do not distinguish between elemental formulas and other formulas, like extensively hydrolyzed formula; therefore, the proportion of children under and over age ten may not accurately portray the use of elemental formula, in particular.

Second, the addition of the term "severe" to modify food protein induced enterocolitis syndrome is unnecessary and somewhat confusing, according to medical experts. It does not effectively identify the population in need of elemental formula and enterocolitis already implies a severe condition.

Third, the use of elemental formula to treat eosinophilic disorders is commonly determined by the results of a biopsy. Therefore, the addition of the phrase "as evidenced by the results of a biopsy" in HB 2337 is appropriate, but does not narrow the population further than the previous bill.

Current prevalence and utilization rates can be used to provide an estimate of the number of children who need amino acid-based elemental formulas in Virginia; however, the precise number of children who need the formula is not known. National prevalence rates for the GI and hypersensitivity disorders listed in HB 2337 range from 100 per 100,000 individuals for eosinophilic esophagitis to 8,000 per 100,000 children under five years of age for food allergies. However, since elemental formula is used for only the most severe cases of these disorders, the formula use would be substantially less than the prevalence rate.

Analysis of the number of children and adults using elemental formulas is significantly less than one percent of Virginia's population based on data from the State employee health plan and State Medicaid. Since extensively hydrolyzed formulas are tried before prescribing elemental formulas, an accurate utilization rate for elemental formula is difficult to calculate because most data sources do not distinguish between the formula types. An estimated 374 Virginia children under age five may use amino acid-based elemental formula based on analysis using 2008 WIC data. (WIC data does distinguish between hydrolyzed and elemental formula.) No data source is available to show the use of elemental formula for all ages and conditions listed in HB 2337,

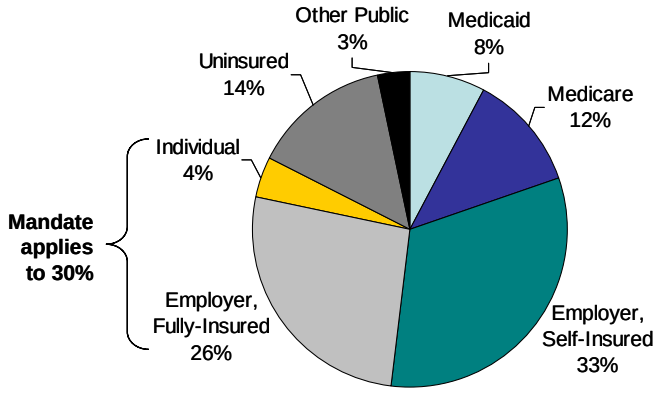
though Children's MAGIC and medical experts indicate that the majority of individuals using elemental formula are young children. For more analysis on utilization rates, refer to the 2008 JLARC report.

Availability of Coverage

Among the top insurance carriers surveyed by the Bureau of Insurance (BOI), nine of the responding carriers (25 percent) indicated that the benefit called for by HB 2337 is available as part of the standard insurance package. Five of these insurers also report that medical necessity for their company is determined based on the proportion of daily caloric intake that the formula represents, which is not a criterion in HB 2337. These insurers indicated that they will provide coverage if the formula constitutes greater than 50 percent of the individual's daily calories.

Health insurance mandates apply to approximately 30 percent of Virginia's population (Figure 2)—those covered by individual policies (4 percent) or fully-insured employer-based coverage (26 percent). However, legislation passed by the 2009 General Assembly allows insurers to sell policies to employers with 50 or fewer employees that do not include State mandates. As a result, HB 2337 would provide health insurance coverage for elemental formulas for some proportion less than 30 percent of children in need.

Figure 2: Health Insurance Mandates Apply to an Estimated 30 Percent of Virginians (2008)



Source: Kaiser statehealthfacts.org for Virginia (2008) and Kaiser Employer Health Benefits Survey 2008.

During the 2009 session, the General Assembly also added §2.2-2818.2 to the *Code of Virginia* which requires health insurance mandates be applied to the State employee health plan. In this case, the impact on coverage may be minimal because the State

already covers elemental formula for certain GI and hypersensitivity disorders. However, due to the broad nature of the bill, mandated coverage may require that conditions be added to the State's current coverage of amino acid-based elemental formulas.

Availability of Treatment Without Coverage

Two Virginia Department of Health (VDH) programs as well as Medicaid cover amino acid-based elemental formulas for GI and hypersensitivity disorders. However, due to the income requirements of these programs, many children with private insurance may be ineligible for the programs.

Care Connection for Children provides free amino acid-based formulas for low-income children at or below 300 percent FPL with a physical condition lasting longer than 12 months. The formulas must be medically necessary and have a physician's prescription. Children with GI or hypersensitivity disorders may qualify for the program; however, no amino acid-based elemental formulas are currently distributed through this program. VDH program staff report that they do not know why families have not received coverage for elemental formula through this program. However, Care Connection is a payer of last resort; therefore, if the child is eligible and able to receive coverage through another program or private insurance, they are ineligible for the program.

Children under five years of age at or below 185 percent FPL with GI and hypersensitivity disorders may be eligible to receive amino acid-based elemental formulas from the Women, Infants, and Children (WIC) program through VDH. In December 2008, 80 children in Virginia received amino acid-based elemental formulas through WIC.

In addition to the VDH programs, Medicaid covers elemental formulas for certain conditions. Medicaid provides formulas for individuals with GI and hypersensitivity conditions when the use is adequately justified by a physician. In FY 2007, Medicaid provided coverage for amino acid-based or extensively hydrolyzed formulas for approximately 3,750 children and 16 adults with GI and hypersensitivity disorders. However, elemental formula use covered by Medicaid is likely substantially less because this figure includes those receiving hydrolyzed formulas.

Those individuals who do not qualify for a State program and whose insurance plans do not provide coverage of the formula would have to pay for it out of pocket. As discussed below, for some families the out-of-pocket cost of the formula could be prohibitively high. As a result, individuals may not receive the needed amount

of formula and some may incur debt in order to pay for the formula using credit cards and private loans.

Financial Hardship

Amino acid-based formulas are widely available for purchase; however, elemental formulas are substantially more expensive than traditional baby formulas. Based on Virginia's median household income in 2009 ($59,064), the annual cost could range from 5.1 to 9.6 percent of household income for elemental formulas ($3,024-$5,676 annually). This is more than double the cost of traditional baby formulas, which annually cost from 2.3 to 4.3 percent of median household income. These cost figures reflect only the cost of the formulas and do not include other medical treatments that may be necessary as a result of the disorders. Further, health-care costs are estimated to be approximately 5.7 percent of total annual household expenditures. Therefore, the cost of elemental formulas could be nearly double what households typically spend on health-care costs nationally and in some cases may be cost prohibitive. In most cases, these costs would persist for two years or less, according to Children's MAGIC.

For more detailed information on the social impact of mandated coverage of amino acid-based elemental formulas, see the 2008 JLARC report on this topic.

FINANCIAL IMPACT

The changes from HB 615 to HB 2337 do not substantially change the impact on the total cost of health care discussed in the 2008 JLARC report. The impact of HB 2337 on premiums is expected to be in the range of other health insurance mandates, which is estimated to be from 0.00 to 4.00 percent depending on the mandate and type of contract. The fiscal impact on the State is also expected to be minimal because the State employee health plan and Medicaid already provide coverage of the formula.

Total Cost of Health Care

Mandated coverage of amino acid-based elemental formulas used to treat severe GI and hypersensitivity conditions may reduce the total cost of health care. Medical experts indicate that left untreated, certain severe GI and hypersensitivity conditions may result in increased long-term costs resulting from adverse health consequences.

Similar to the 2008 bill, a concern with HB 2337 is the inclusion of GI and hypersensitivity conditions for which amino acid-based

formulas is not standard medical practice. As written, the mandate may include coverage for elemental formula for certain disorders for which the evidence of its use is inconclusive. Examples include eosinophilic disorders other than eosinophilic esophagitis and gastroenteritis, some non-IgE mediated allergies, and certain GI conditions of impaired absorption. While the use of formula in these cases should be mitigated by the requirement for a physician's written order, the mandates could increase the total cost of health care with little or no health benefits for such conditions. The cost impact of the bill could be modestly reduced (1) if the bill were limited to cover conditions for which elemental formula are used as a standard or last resort treatment, and (2) by requiring evidence that more commonly used, less expensive formulas, such as hydrolyzed, be tried first, except in the case of eosinophilic esophagitis.

Insurance Premium and State Costs

The annual BOI survey of Virginia health insurers also requests information on the premium impact of proposed mandates. While an overall response rate to the survey of 77 percent (36 companies) was achieved, a relatively small number of insurance companies provided estimated monthly premium costs for HB 2337, which may limit the usefulness of the estimates (three companies responded that the mandate would not apply to them). Contributing to the low response rate for individual coverage are those companies that do not serve the individual market. In addition, the estimates varied widely with considerable differences between individual and group policyholders (Table 3).

Table 3: Estimated Monthly Premium Impact Per Policy of HB 2337

	# of Responses	Median Estimate	Highest Estimate	Lowest Estimate
Individual (standard)	10	$0.22	$1.00	$0.02
Individual (optional)	2	2.61	5.00	0.21
Group (standard)	19	0.24	1.08	0.02
Group (optional)	10	2.69	3.00	0.11

Note: Per member per month estimates were converted to per policy estimates for comparison based on an estimate of 2.4 enrollees per policy.

Source: Bureau of Insurance, Survey of Insurance Providers, 2009.

Ten companies provided an estimate for individual policyholders, and 19 companies provided an estimate for group certificate-holders. The median monthly premium estimates for the coverage in HB 2337 as part of a standard individual option is $0.22 per month and the median estimate for standard group coverage is $0.24. The median estimate for optional group coverage is $2.69. No providers indicated that optional individual coverage is available; however, two insurers provided estimates, which results in a median of $2.61 per month.

An individual premium increase of $0.02 to $1.00 (the range of individual standard estimates provided) would result in a monthly premium increase between 0.006 percent and 0.3 percent based on the estimated average monthly premium cost for a single coverage, individual contract, as defined in BOI's 2008 report on the financial impact of mandated health insurance benefits. These compare to the premium impacts of existing mandates, which range from 0.09 to 1.91 percent for single coverage individual contracts and 0.00 to 4.00 percent for group contracts. Data are not available on the monthly premium estimate for group plans, so it is not possible to calculate the percent increase in premium costs estimated from group plans resulting from HB 2337.

Average Individual Insurance Premiums

In October 2008, the Virginia Bureau of Insurance reported an average annual health insurance premium (with current mandated benefits) for an individual contract, single coverage, of $4,124.07 or approximately $344 per month.

The fiscal impact on the State of HB 2337 would be minimal because the State employee health plan and Medicaid already provide coverage of amino acid-based elemental formulas for some of the conditions listed in the bill. However, staff from the Department of Human Resource Management (DHRM) expressed concern that the broad language in the bill would require the State to cover elemental formula for conditions which the State employee health plan does not currently cover, such as lactose intolerance or gluten allergies. The bill's requirement for a physician's written order should help mitigate this impact. Also, adding a requirement that other formulas frequently used for these conditions (except for eosinophilic esophagitis) be tried before prescribing elemental formula would decrease the fiscal impact.

QUESTIONS POSED BY THE PATRON

The patron of HB 2337 requested that this review answer several specific questions. The questions and responses are below.

1. Using the specific diseases and conditions mentioned in HB 2337, what is the total number of children who need this benefit?

   As was addressed under *Social Impact*, an estimated 374 Virginia children under age five need elemental formula. According to Children's MAGIC and medical experts the

majority of individuals utilizing formula are young children. However, it is important to note that the bill's limitation to children under age ten only applies to IgE and non-IgE mediated allergies. As written, HB 2337 would provide coverage of elemental formulas for adults with GI disorders, eosinophilic disorders, and food protein induced enterocolitis syndrome.

2. Of those in need, how many are fully insured, self insured, rely on state/federal programs (ie. WIC, Virginia Department of Health or Medicaid) or have no insurance?

   As stated under *Social Impact*, health mandates apply to less than 30 percent of Virginians. This means that less than approximately 30 percent of those individuals for which elemental formula is needed would likely receive coverage under HB 2337.

3. Do insurers licensed in Virginia currently provide this benefit for both oral and enteral delivery? Which ones? Who does not provide this benefit? What are the specifics of the policies for those that do?

   As stated in the *Financial Impact*, of those who responded to the BOI survey, nine insurers provide coverage of elemental formula regardless of delivery method. Based on data from VDH, these nine insurers tend to be larger companies. Overall, the conditions for which the elemental formula would be covered appear to be similar to those required by HB 2337; however, five of the insurers indicated that they will only provide coverage when the formula constitutes greater than 50 percent of the individual's daily calories.

4. Taking into consideration that WIC and other state programs currently offer this benefit, what is the fiscal impact for the State and for the insurance premiums were this benefit to be mandated?

   For information on the fiscal impact on insurance premiums, see Table 3 in the *Financial Impact* section of this report. As stated, the State does not expect a significant fiscal impact because the State employee health plan, Medicaid, and WIC already cover this benefit when medically necessary and prescribed by a physician.

5. Are the State (ie. WIC, Virginia Department of Health or Medicaid) or insurers providing amino acid-based elemental formulas able to enter into any pricing agreements with the

manufacturers? How do the group prices compare to the prices available directly to the public?

In the 2008 JLARC report, concerns were raised about vendors marking up the price of metabolic formulas charged to health insurance companies so that the patient's cost share is equal to the original price of the formula purchased directly from the manufacturer. Both elemental and metabolic formula manufacturers do not accept health insurance from members of the public purchasing formula directly from them. However, they may offer a discounted rate to institutions such as government programs and pharmacies. The insurer pays a pre-negotiated rate for the formula which may require a co-payment or cost-sharing from the covered individual.

The WIC program does not have a price agreement with the formula manufacturers. Virginia WIC purchases elemental formula through a distribution program run by a community action program in Lancaster, Pennsylvania. The program supports WIC programs in six states, including Virginia. Formula is purchased from the manufacturer at an institutional rate, and the program charges the State WIC program the cost of the formula plus shipping costs and an administrative fee. After the additional shipping and administrative costs are added, the price per can is more than purchasing the elemental formula directly from the manufacturer at the public's cost. However, manufacturers only sell formula in cases of four or six cans directly to the public.

Neither Medicaid nor the State employee health plan has any price agreements with manufacturers of amino acid-based elemental formula.

BALANCING MEDICAL, SOCIAL, AND FINANCIAL CONSIDERATIONS

Medical, social, and financial considerations from the 2008 JLARC evaluation of HB 615 (2008) are not significantly different from considerations for HB 2337 (2009). Based on the premise that the role of health insurance is to promote public health, encourage the use of preventive care, and provide protection from excessive financial expenses for unexpected illness or injury, HB 2337 appears consistent with the role of insurance for certain individuals. Amino acid-based elemental formulas are a standard medical treatment for children with eosinophilic esophagitis and the treatment of last resort for certain severe cases of GI and hypersensitivity conditions. The population that needs elemental

formulas is relatively small, but the formulas are medically necessary for the treatment of these individuals. HB 2337 includes many conditions for which amino acid-based elemental formulas are recommended as a treatment of last resort, but it also includes conditions for which their use is not recommended by medical practice guidelines or medical experts. The mandate specifies that the use of elemental formulas to treat the listed conditions must be medically necessary. In addition, it could specify that more common formulas be tried and eliminated prior to prescribing elemental formulas, with the exception of eosinophilic esophagitis where it is a standard treatment.

A more limited version of the mandate would more directly meet patients' needs and would reduce the impact on insurance premiums. Mandated coverage of the formulas would help to relieve financial hardship of those self-paying because the financial hardship may be significant, from five percent to almost ten percent of median household income. In comparison, mandating coverage is estimated to have a modest impact on premiums. The impact could be lessened further, however, by (1) limiting the bill to those conditions for which elemental formulas are recommended as a standard or last resort treatment according to medical practice guidelines and medical experts, (2) eliminating coverage for adults, and (3) requiring other potential treatments to be attempted first, with the exception of eosinophilic esophagitis.

ACKNOWLEDGMENTS

JLARC staff would like to acknowledge the expertise, assistance, and information provided by staff at Virginia Commonwealth University and University of Virginia Health System. In addition, JLARC would like to thank the Virginia State Corporation Commission Bureau of Insurance, the Virginia Association of Health Plans, the Department of Human Resource Management, the Department of Medical Assistance Services, and the Department of Health for their assistance.

Appendix A

Proposed Mandated Benefit Requiring Coverage of Amino Acid-Based Elemental Formula

HOUSE BILL NO. 2337
Offered January 14, 2009
Prefiled January 14, 2009

A BILL to amend and reenact § 38.2-4319 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 38.2-3418.15, relating to health insurance coverage for amino acid based elemental formulas.

Patrons—Amundson and Marshall, R.G.

Referred to Committee on Commerce and Labor

Be it enacted by the General Assembly of Virginia:

1. That § 38.2-4319 of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding a section numbered 38.2-3418.15 as follows:

§ 38.2-3418.15. Coverage for amino acid based elemental formulas.

A. Notwithstanding the provisions of § 38.2-3419, each insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense incurred basis; each corporation providing individual or group accident and sickness subscription contracts; and each health maintenance organization providing a health care plan for health care services shall provide coverage for the provision of amino acid based elemental formulas, regardless of the method of intake, for the diagnosis and treatment of Immunoglobulin E and non Immunoglobulin E mediated allergies to multiple food proteins for enrollees under age 10, severe food protein induced enterocolitis syndrome, eosinophilic disorders as evidenced by the results of a biopsy, and impaired absorption of nutrients caused by disorders affecting the absorptive surface, functional length, and motility of the gastrointestinal tract. For coverage, the ordering physician shall issue a written order stating that the amino acid based elemental formula is medically necessary for the treatment of a disease or disorder listed in this section. A private review agent, acting on behalf of an insurer, nonprofit health service plan, or health maintenance organization, may review the ordering physician's determination of the medical necessity of the amino acid based elemental formula for the treatment of the disease or disorder listed in this section.

B. No insurer, corporation, or health maintenance organization shall impose upon any person receiving benefits pursuant to this section any copayment, fee, policy year or calendar year, or durational benefit limitation or maximum for benefits or services that is not equally imposed upon all individuals in the same benefit category.

C. The requirements of this section shall apply to all insurance policies, contracts, and plans delivered, issued for delivery, reissued, or extended in the Commonwealth on and after January 1, 2010, or at any time thereafter when any term of the policy, contract, or plan is changed or any premium adjustment is made.

D. This section shall 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 coverage under Title XVIII of the Social Security Act, known as Medicare, or any other similar coverage under state or federal governmental plans.

§ 38.2-4319. Statutory construction and relationship to other laws.

A. No provisions of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-100, 38.2-136, 38.2-200, 38.2-203, 38.2-209 through 38.2-213, 38.2-216, 38.2-218 through 38.2-225, 38.2-229, 38.2-232, 38.2-305, 38.2-316, 38.2-322, 38.2-400, 38.2-402 through 38.2-413, 38.2-500 through 38.2-515, 38.2-600 through 38.2-620, Chapter 9 (§ 38.2-900 et seq.), §§ 38.2-1016.1 through 38.2-1023, 38.2-1057, Article 2 (§ 38.2-1306.2 et seq.), § 38.2-1306.1, § 38.2-1315.1, Articles 3.1 (§ 38.2-1316.1 et seq.), 4 (§ 38.2-1317 et seq.) and 5 (§ 38.2-1322 et seq.) of Chapter 13, Articles 1 (§ 38.2-1400 et seq.) and 2 (§ 38.2-1412 et seq.) of Chapter 14, §§ 38.2-1800 through 38.2-1836, 38.2-3401, 38.2-3405, 38.2-3405.1, 38.2-3407.2 through 38.2-3407.6:1, 38.2-3407.9 through 38.2-3407.16, 38.2-3411.2, 38.2-3411.3, 38.2-3411.4, 38.2-3412.1:01, 38.2-3414.1, 38.2-3418.1 through 38.2-3418.14 *38.2-3418.15*, 38.2-3419.1, 38.2-3430.1 through 38.2-3437, 38.2-3500, subdivision 13 of § 38.2-3503, subdivision 8 of § 38.2-3504, §§ 38.2-3514.1, 38.2-3514.2, 38.2-3522.1 through 38.2-3523.4, 38.2-3525, 38.2-3540.1, 38.2-3542, 38.2-3543.2, Article 5 (§ 38.2-3551 et seq.) of Chapter 35, Chapter 52 (§ 38.2-5200 et seq.), Chapter 55 (§ 38.2-5500 et seq.), Chapter 58 (§ 38.2-5800 et seq.) and § 38.2-5903 of this title shall be applicable to any health maintenance organization granted a license under this chapter. This chapter shall not apply to an insurer or health services plan licensed and regulated in conformance with the insurance laws or Chapter 42 (§ 38.2-4200 et seq.) of this title except with respect to the activities of its health maintenance organization.

B. For plans administered by the Department of Medical Assistance Services that provide benefits pursuant to Title XIX or Title XXI of the Social Security Act, as amended, no provisions of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-100, 38.2-136, 38.2-200, 38.2-203, 38.2-209 through 38.2-213, 38.2-216, 38.2-218 through 38.2-225, 38.2-229, 38.2-232, 38.2-322, 38.2-400, 38.2-402 through 38.2-413, 38.2-500 through 38.2-515, 38.2-600 through 38.2-620, Chapter 9 (§ 38.2-900 et seq.), §§ 38.2-1016.1 through 38.2-1023, 38.2-1057, § 38.2-1306.1, Article 2 (§ 38.2-1306.2 et seq.), § 38.2-1315.1, Articles 3.1 (§ 38.2-1316.1 et seq.), 4 (§ 38.2-1317 et seq.) and 5 (§ 38.2-1322 et seq.) of Chapter 13, Articles 1 (§ 38.2-1400 et seq.) and 2 (§ 38.2-1412 et seq.) of Chapter 14, §§ 38.2-3401, 38.2-3405, 38.2-3407.2 through 38.2-3407.5, 38.2-3407.6 and 38.2-3407.6:1, 38.2-3407.9, 38.2-3407.9:01, and 38.2-3407.9:02, subdivisions 1, 2, and 3 of subsection F of § 38.2-3407.10, 38.2-3407.11, 38.2-3407.11:3, 38.2-3407.13, 38.2-3407.13:1, and 38.2-3407.14, 38.2-3411.2, 38.2-3418.1, 38.2-3418.2, 38.2-3419.1, 38.2-3430.1 through 38.2-3437, 38.2-3500, subdivision 13 of § 38.2-3503, subdivision 8 of § 38.2-3504, §§ 38.2-3514.1, 38.2-3514.2, 38.2-3522.1 through 38.2-3523.4, 38.2-3525, 38.2-3540.1, 38.2-3542, 38.2-3543.2, Chapter 52 (§ 38.2-5200 et seq.), Chapter 55 (§ 38.2-5500 et seq.), Chapter 58 (§ 38.2-5800 et seq.) and § 38.2-5903 shall be applicable to any health maintenance organization granted a license under this chapter. This chapter shall not apply to an insurer or health services plan licensed and regulated in conformance with the insurance laws or Chapter 42 (§ 38.2-4200 et seq.) of this title except with respect to the activities of its health maintenance organization.

C. Solicitation of enrollees by a licensed health maintenance organization or by its representatives shall not be construed to violate any provisions of law relating to solicitation or advertising by health professionals.

D. A licensed health maintenance organization shall not be deemed to be engaged in the unlawful practice of medicine. All health care providers associated with a health maintenance organization shall be subject to all provisions of law.

E. Notwithstanding the definition of an eligible employee as set forth in § 38.2-3431, a health maintenance organization providing health care plans pursuant to § 38.2-3431 shall not be required to offer coverage to or accept applications from an employee who does not reside within the health maintenance organization's service area.

F. For purposes of applying this section, "insurer" when used in a section cited in subsections A and B of this section shall be construed to mean and include "health maintenance organizations" unless the section cited clearly applies to health maintenance organizations without such construction.

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.virginia.gov