

# Joint Legislative Audit and Review Commission

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

Briefing for the Special Advisory Commission on  
Mandated Health Insurance Benefits

September 29, 2008



# HB 615 Would Cover Amino Acid-Based Elemental Formulas for Certain Conditions

- Gastrointestinal (GI) diseases and disorders
  - Inflammation or protein sensitivity resulting in malnutrition or malabsorption
- Hypersensitivity diseases and disorders
  - Food hypersensitivity – abnormal reaction to food protein or carbohydrate

# HB 669 Would Cover Amino Acid-Based Formulas

- Amino acid-based metabolic formulas for
  - Inborn Errors of Metabolism (IEM)
    - Inherited metabolic disorders where the body cannot process substances, such as amino acids: PKU most common
  
- Amino acid-based elemental formulas for
  - GI diseases and disorders

# Proteins in Normal Food and Amino Acid-Based Formulas

**Normal Food With Whole Protein**



**Amino Acid-Based Formulas**

**Metabolic Formula With Missing Protein**



**Elemental Formula With All Proteins**



Source: VCU Metabolic Treatment Center

## Mandates Similar to HB 615 and HB 669

- Four mandates similar to HB 669 proposed since 1999 in Virginia
- Other states
  - Most states cover formulas for IEM
  - Fewer states cover formulas for GI and hypersensitivity conditions

# In This Presentation

- Medical Efficacy and Effectiveness
- Social Impact
- Financial Impact
- Balancing the Medical, Social, and Financial Considerations

# Medical Efficacy and Effectiveness Well Established for Certain Conditions

- Metabolic formulas for IEM strongly supported by medical evidence
  
- Elemental formulas supported by clinical trials and medical practice guidelines for children
  - Eosinophilic esophagitis and Crohn's disease (primary treatment)
  - Other GI and hypersensitivity conditions (alternative treatment)
  
- Elemental formulas **not** recommended for some GI and hypersensitivity conditions covered by HB 615 & 669, particularly in adults

Source: Medical literature and medical experts consulted at two VA medical schools

## Conditions Are Rare and Length of Formula Use Varies

- Most individuals with IEM likely use formulas
  - Metabolic formulas used for the lifetime
  - Adverse consequences of not using formula severe, particularly for children
- Less than 1% of those with GI and hypersensitivity disorders use elemental formulas
  - Children typically use formulas for 2 years or less

## Cost of Formulas a Financial Hardship for Some

- Most health insurance companies do not cover the formulas
- Annual cost of formulas could range from 3 to 10% of median household income
- VDH programs available
  - At or below 300% federal poverty level:  
Free metabolic & elemental formula
  - Above 300% federal poverty level :  
Purchase metabolic formula at cost
- Expansion of VDH programs may not be desirable

## Financial Impact Depends Largely on Covered Conditions

- Premium impact of HB 615 and HB 669 expected to be in the range of other mandates
- Bills include certain GI and hypersensitivity disorders for which the formulas are not standard medical practice
- Increased utilization for these conditions could increase the total cost of health care
- Could reduce total cost of health care if limited to those disorders for which the formulas are medically necessary

## Proposed Mandates Do Not Target Conditions for Which Formulas Are Standard Medical Practice

- HB 615 would cover elemental formulas for GI and hypersensitivity disorders, but not IEM
- HB 669 would cover formulas for IEM and GI disorders, but not certain hypersensitivity conditions
- Formulas for IEM and certain GI and hypersensitivity conditions consistent with the role of insurance
- Limiting coverage to conditions for which formulas are recommended medical practice would more directly meet patients' needs and reduce the impact on insurance premiums
  - For example, for certain disorders only children use formula in treatment

## **JLARC Staff for Mandated Benefit Evaluations**

Hal Greer, Division Chief

Kimberly Sarte, Team Leader

Jenny Breidenbaugh, Senior Associate Legislative Analyst

**This evaluation is available on our website**

<http://jlarc.state.va.us>      (804) 786-1258