

# **Mandated Health Benefit Review**

## **JLARC Review of Senate Bill 867 (2013)**

### **SUMMARY OF FINDINGS**

Pursuant to § 30-344 of the Code of Virginia, staff of the Joint Legislative Audit and Review Commission (JLARC) have completed a review of Senate Bill 867 (2013) for the Health Insurance Reform Commission. SB 867 proposes to mandate health insurance coverage of low-protein foods prescribed for the treatment of phenylketonuria (PKU).

JLARC staff have concluded that, as written, the proposed legislation would have no effect on insurance policies in Virginia. SB 867 refers to low-protein foods that are approved by the U.S. Food and Drug Administration (FDA), but the FDA is not involved in the approval of foods for the treatment of PKU. It appears this reference would ultimately preclude the legislation from having any effect. Further, part of the coverage proposed in SB 867 is already addressed under the Affordable Care Act, through the “essential health benefits” coverage requirement, which applies to non-grandfathered small group and individual plans offered inside and outside of the health exchange.

### **REVIEW OF SB 867**

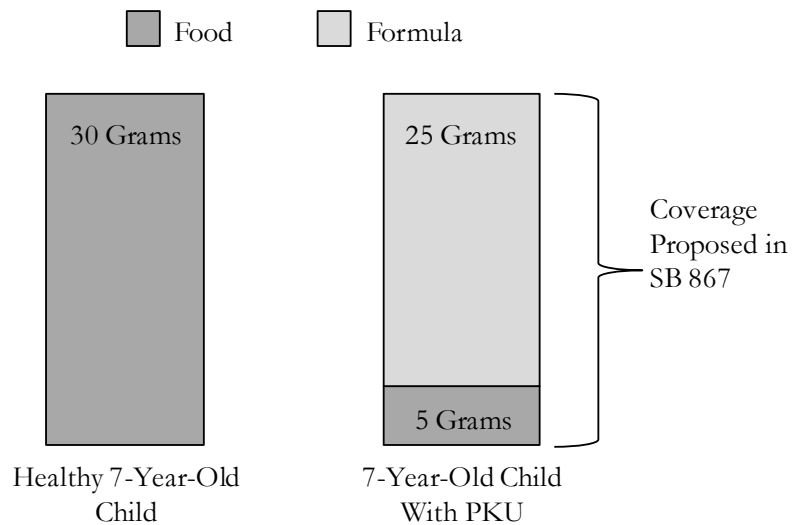
#### **Overview of phenylketonuria (PKU) and its treatments**

Phenylketonuria (PKU) is a rare congenital genetic disorder that prevents the body from processing phenylalanine, an essential building block of protein that is commonly present in foods. When individuals with PKU consume a typical diet, phenylalanine accumulates in the blood, becomes toxic to the body, and causes a variety of physiological and neurological issues, including seizures and intellectual disabilities. PKU is diagnosed as part of the Virginia Newborn Screening Program and is estimated to occur in approximately one in 25,000 newborns.

Treatment of PKU requires a modified diet that is very low in phenylalanine. Because individuals with PKU also need protein to grow and develop normally, they must consume a form of protein that has been altered to remove or reduce the phenylalanine. This altered protein is typically provided through medical formulas and low-protein foods that have been developed to treat PKU. A combination of medical formula and low-protein foods is needed for complete nutrition, and the

exact ratio varies by individual. (See Figure 1 for an example of how medical formulas may be combined with low-protein food to achieve complete nutrition for a 7-year-old child with PKU.)

**Figure 1 – Sources and amounts of protein needed by healthy 7-year-old child compared to 7-year-old child with PKU**



Source: Virginia Commonwealth University Metabolic Treatment Center.

## Summary of SB 867

SB 867 proposes that certain insurers be required to cover medically necessary low-protein (low-phenylalanine) foods prescribed for the treatment of PKU and approved by the U.S. Food and Drug Administration (FDA) for such purpose. Coverage would not extend to foods that are low in protein but have not been developed specifically for the treatment of PKU, such as naturally low-protein foods that can be purchased in grocery stores.

Among those low-protein foods that are developed specifically for the treatment of PKU, it is not clear which forms SB 867 intends to cover. When consulted by JLARC staff, medical experts at UVA and VCU differed in their interpretations of whether the required coverage would extend to formulas, modified low-protein foods, or both. The use of more precise language, such as “medical formulas,” “medical foods,” and “modified low-protein food products” would better ensure that the intended coverage is provided by insurers.

## Impact of SB 867

JLARC staff have concluded that, if enacted, SB 867 would have no impact on health care coverage in Virginia. After a review of FDA documents and interviews with an FDA representative and medical experts at UVA and VCU, JLARC staff determined that the FDA is not involved in the

approval of foods for the treatment of PKU (Figure 2). There appear to be no low-protein foods (formulas or modified low-protein foods) that would meet the FDA approval requirements in SB 867. The requirement that the foods be approved by the FDA would ultimately preclude the legislation from having any effect.

**Figure 2 –The FDA cites foods for PKU as example of foods it does not approve**

**FDA does not approve medical foods.**

A medical food is used for the dietary management of a disease or health condition that requires special nutrient needs. An example of a medical food is a food for use by persons with phenylketonuria, a genetic disorder. A person with this disorder may need medical foods that are formulated to be free of the amino acid phenylalanine. A medical food is intended for use under the supervision of a physician.

Medical foods do not have to undergo premarket approval by FDA. But medical food firms must comply with other requirements, such as good manufacturing practices and registration of food facilities. Medical foods do not have to include nutrition information on their labels, and any claims in their labeling must be truthful and non-misleading.


Source: Source: "Is It Really FDA Approved?" U.S. Food and Drug Administration. Published September 30, 2008. Website. Accessed September 26, 2013. <<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm047470.htm>>

**SB 867 and health care reform**

As of January 1, 2014, all non-grandfathered individual and small group health insurance plans offered in Virginia are required to cover part of the mandated benefits contemplated in SB 867. Specifically, Virginia's essential health benefits package requires coverage of special medical formulas for inborn errors of metabolism, such as PKU (Figure 3). However, the essential health benefits package does not explicitly require coverage of modified low-protein foods that have been developed for the treatment of PKU. The essential health benefits package also does not apply to large group fully-insured plans, which are subject to mandated health benefit requirements.

**Figure 3 – Essential health benefit package includes coverage for PKU formulas**

**Medical formulas**



*Your health plan* covers special medical formulas which are the primary source of nutrition for covered persons with inborn errors of amino acid or organic acid metabolism, metabolic abnormality or severe protein or soy allergies. These formulas must be prescribed by a physician and required to maintain adequate nutritional status.

Source: Anthem KeyCare 30 Plan Document (2013).

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