JLARC
JOINT LEGISLATIVE AUDIT
AND REVIEW COMMISSION

Mandated Health Benefit Review
JLARC Review of Senate Bill 866 (2013)

SUMMARY OF FINDINGS

Pursuant to § 30-344 of the Code of Virginia, staff of the Joint Legislative Audit and Review Commission (JLARC) have reviewed Senate Bill 866 (2013) for the Health Insurance Reform Commission. SB 866 proposes to mandate health insurance coverage of medically necessary enteral formulas for individuals diagnosed with short bowel syndrome (SBS).

JLARC staff have concluded that (1) enteral formulas are generally accepted as medically effective treatments for SBS; (2) the proposed legislation would have a minimal impact on premiums and administrative costs due to the rarity of SBS; (3) the proposed legislation would have a positive financial impact for those few individuals with SBS who need enteral formulas and do not already have coverage for them; and (4) most plans that are subject to state mandates already provide coverage for the benefits proposed in SB 866.

REVIEW OF SB 866

Overview of short bowel syndrome and its treatments

SBS is a rare disorder in which the human body does not properly absorb nutrients because part of the small intestine is not functional due to disease or surgery. SBS can be caused by a variety of conditions, including Crohn's disease, necrotizing enterocolitis, and congenital intestinal abnormalities. SBS can result in malabsorption, weight loss, dehydration, electrolyte imbalance, and vitamin and mineral deficiencies. In severe cases, SBS can lead to death. The prevalence of SBS is unknown but is generally estimated to be between two and five per million individuals, although some estimates are substantially higher. Treatment of SBS is individualized and depends primarily on what section of the small intestine is missing, the length of the missing section, and the quality of the remaining bowel.

Patients with SBS require special nutritional support, at least initially, to maintain adequate nutrition. Nutritional support for the treatment of SBS can be divided into three general categories: parenteral nutrition (intravenous feeding), enteral nutrition (tube feeding), and oral nutrition (normal feeding). In most cases, a patient is given parenteral nutrition immediately after surgery and gradually transitions to normal feeding as the bowel adapts to a smaller surface area for absorption of

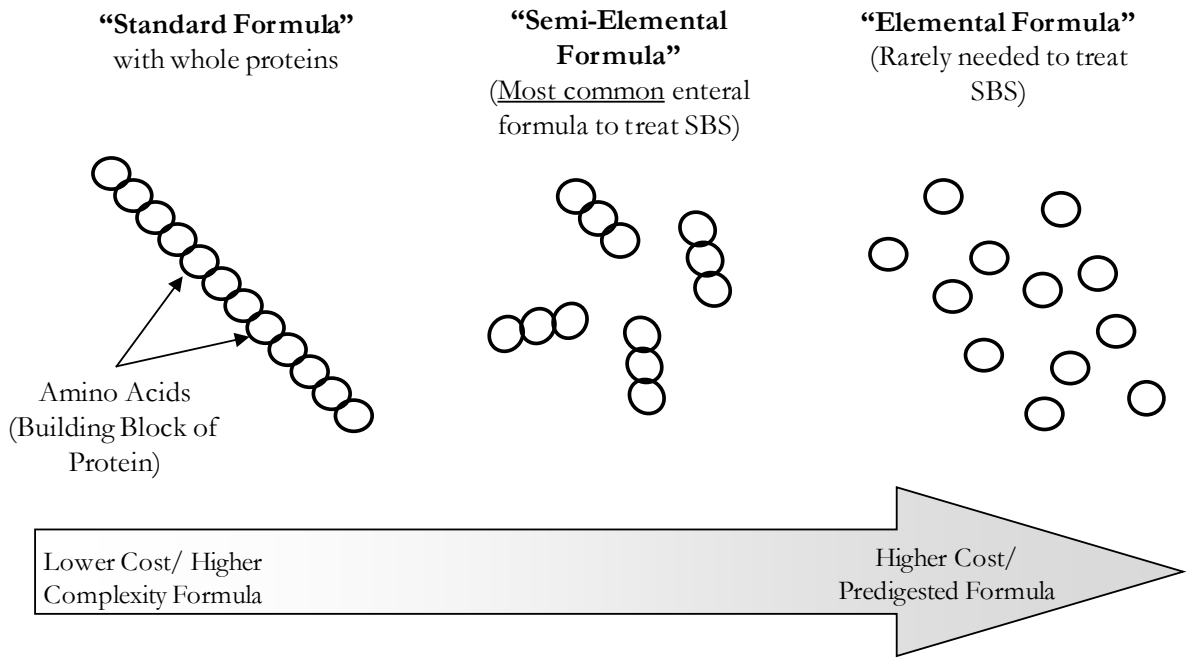
nutrients. However, when a patient is unable to transition directly to normal feeding, the physician may introduce enteral formula, with the goal of weaning the patient from the more risky and expensive intravenous feeding. Depending on the severity of SBS, some patients may eventually transition to normal feeding, and others may require special nutritional support for the rest of their lives.

It is estimated that very few people in Virginia (possibly as few as one person) would require the coverage that is proposed in this bill. According to the American Gastroenterological Association, "tube feeding should be considered when the patient cannot or will not eat, the patient has a functional gut, and a method of access can be safely obtained." When consulted by JLARC staff, a nutrition expert from UVA Medical Center estimated that approximately five percent of SBS patients who are initially unable to be weaned off of parenteral nutrition will need and are physiologically capable of receiving enteral nutrition for treatment.

Treatment mandated by SB 866

The proposed legislation would cover the three general types of enteral formulas that are used in the treatment of SBS: standard, semi-elemental, and elemental (Figure 1). The choice among formulas is made by a physician and depends on a patient's ability to absorb nutrients and tolerate particular formulations. According to the nutrition expert at UVA, few SBS patients tolerate a standard formula unless it is very low in fat.

Figure 1 – Three types of enteral formulas would qualify under provisions of SB 866



Source: JLARC staff analysis of SBS literature and interview with nutrition expert at UVA Medical Center.

Medical effectiveness of enteral formulas for SBS

No randomized controlled trials have been completed to understand the medical effectiveness of enteral formulas, due to the rarity of SBS and the variety of conditions that can cause SBS. However, observational studies of enteral feeding in SBS patients find their use effective in helping individuals adapt to more efficiently absorb nutrients with a short intestine. A nutrition expert at UVA Medical Center concurred with these findings and added that enteral nutrition, for patients who can tolerate formulas, is preferred over parenteral nutrition because of the high cost and the risk of infection associated with intravenous feedings.

SB 866 and health reform

As of January 1, 2014, all non-grandfathered individual and small group health insurance plans offered in Virginia are already required, under the Affordable Care Act, to provide the benefits that would be mandated by SB 866. Virginia's "essential health benefits" package requires these plans to cover infusion services, which includes enteral nutrition (Figure 2). Staff at the Virginia Bureau of Insurance confirmed that the coverage proposed in SB 866 is required through the essential health benefits package.

Mandated health benefits also apply to large group fully insured plans, which are not required to provide the benefits included in Virginia's essential health benefits package. However, most of these plans appear to provide the benefits proposed in SB 866. In a survey, 13 of the 18 largest large group fully insured plans in Virginia reported that they currently provide the coverage proposed in SB 866 even though they are not required to do so (Virginia Bureau of Insurance survey, 2014). Three of these 18 insurance carriers reported that they do not cover the benefits proposed in SB 866 and two carriers did not respond to the Bureau of Insurance survey.

Figure 2 – Essential health benefit package includes coverage for enteral formulas

Infusion services

Your health plan covers infusion therapy, which is treatment by placing therapeutic agents into the vein, and parenteral administration of medication and nutrients. Infusion services also include enteral nutrition, which is the delivery of nutrients by tube into the gastrointestinal tract. These services include coverage of all medications administered intravenously and/or parenterally.

☞ **Helpful tip:** Infusion services may be received at multiple sites of service, including *facilities*, professional *provider* offices, ambulatory infusion centers and from home infusion *providers*. Benefits may vary by place of service, and where *you* choose to receive covered services may result in a difference in your *copayment* and/or *coinsurance*. Please see the Infusion services section on the **Summary of benefits** for a description of the benefits by place of service.

Source: Anthem KeyCare 30 Plan Document (2013).

Financial impact of SB 866

SB 866 is not expected to have a significant impact on health insurance premiums, due to the rarity of SBS and the low number of SBS patients who can tolerate enteral formulas. This is consistent with findings of two other states regarding the premium impacts of mandating coverage of formulas for gastrointestinal disorders, including SBS. A recent review conducted for Massachusetts' Center for Health Information and Analysis found that a mandate requiring coverage of enteral formulas for the treatment of SBS and related disorders would have a premium impact of $0.02 per member per month (or 0.01% of the total premium) including administrative costs. Similarly, the California Health Benefits Review Program found that coverage for amino-acid-based elemental formulas for the treatment of SBS and related disorders would affect monthly insurance premiums by less than 0.02% in the privately insured market. The coverage mandates considered for the Massachusetts and California reviews were broader in scope than the proposed mandate in SB 866, so the estimates of likely premium impacts should be considered higher than the likely impact of SB 866.

It is possible that coverage for enteral formulas could result in a net decrease in the cost of health care. Parenteral nutrition is substantially more expensive and involves greater health risks than enteral nutrition, but it is typically covered by insurance. It may be that eligible patients are currently receiving nutrition parenterally because it is the only type of medical nutrition that is covered by their insurance.

On the individual level, out-of-pocket costs for enteral formulas can be substantial. Estimates of the out-of-pocket costs for enteral formulas in the Massachusetts and California reviews ranged from $4,000 to $11,500 per year. These cost estimates are for those who use the formula as the only or main source of nutrition for an entire year, which is consistent with the provision of SB 866 that the enteral formulas be the individual's primary source of nutrition. However, these costs could be higher or lower, depending on the type of formula needed and the individual's particular nutrition needs.

It is estimated that very few people in Virginia (possibly as few as one person) would require the coverage that is proposed in this bill. This legislation is therefore not expected to affect the number of formula providers or the total cost of health care. The benefits of SB 866 would be limited to the individuals receiving treatment, for whom it would reduce a substantial financial burden.

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