SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: Banking and Insurance Committee

BILL: CS/SB 482

INTRODUCER: Banking and Insurance Committee and Senator Bullard

SUBJECT: Congenital Craniofacial Anomalies

DATE: April 20, 2006 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Knudson	Deffenbaugh	BI	**Fav/CS**
2.			HE	
3.			WM	
4.				
5.				
6.				

I. Summary:

Congenital craniofacial anomalies are a diverse group of deformities in the growth of the head and facial bones that are present at birth. The Committee Substitute requires the Agency for Health Care Administration (agency), in consultation with the Office of Insurance Regulation (office), to conduct a study evaluating the medical necessity, efficacy, and costs associated with mandating health insurance coverage for cranial skull molding orthotics and other therapies used in the treatment of certain craniofacial anomalies. The agency is authorized to contract with an actuary and other experts to assist in conducting the study. The agency and office are required to submit a report that includes findings and legislative recommendations to the Legislature by January 1, 2007.

The CS appropriates $25,000 from the Insurance Regulatory Trust Fund to the Office of Insurance Regulation for the purpose of funding the study.

This bill creates an undesignated section of law.

II. Present Situation:

Background on Craniofacial Anomalies

Congenital craniofacial anomalies are a diverse group of deformities in the growth of the head and facial bones that are present at birth. There are numerous types of congenital craniofacial anomalies. The most commonly occurring anomalies are cleft lip and cleft palate. Complex syndromes involving such anomalies may not fully express clinical manifestations or be diagnosed in the first year of life. There are numerous variations in these cases, some are mild; other cases are severe and require surgery.

The cause of craniofacial anomalies is unknown. There is no single factor that causes these abnormalities. There are many factors that may contribute to the occurrence of these abnormalities, including:

- combination of genes received from parents or a change in the genes at the time of conception,
- prenatal environmental exposure,
- premature birth or birth trauma, and
- folic acid deficiency.

The most common types of craniofacial anomalies are cleft palate, cleft lip, craniosynostosis, and hemifacial microsomia, vascular malformation, hemagioma, and deformational or positional plagiocephaly.

- Cleft lip and cleft palate - a separation that occurs in the lip or the roof or the mouth or both. This is the most common anomaly seen at birth.
- Craniosynostosis – a condition in which the sutures or soft spots in the skull close prematurely, resulting in problems with normal brain and skull growth.
- Hemifacial microsomia – a condition in the tissues on one side of the face are underdeveloped, affecting primarily the ear, mouth, and jaw area.
- Vascular malformation – a birthmark or a growth, present at birth, which is composed of blood vessels that cause functional or aesthetic problems.
- Hemangioma – a type of birthmark that may appear at birth or soon thereafter.
- Deformational or positional plagiocephaly – a misshapen or asymmetrical shape of the head from repeated exposure to the same area of the head. This cranial asymmetry may be present at birth or develop during infancy.

The incidence rate of deformational plagiocephaly is estimated to be as low as 1 in 300 live births to as high as 48 percent of infants younger than 1 year-old. Some experts contend that the significantly increasing diagnosis of deformational placgiocephaly is correlated with the recommendation of the American Academy of Pediatrics and others that infants be placed on their backs when sleeping to prevent sudden infant death syndrome.[1] Advocates for the bill provided additional information concerning the incidence rate for deformational plagiocephaly. With 212,243 births per year in Florida in 2003, using the 3 percent incidence rate noted in the Netherlands and New Zealand studies, approximately 6,367 children in Florida will develop a deformity that persists beyond infancy that could require medical intervention. Several studies indicate that deformational plagiocephaly is not a benign condition, and may be linked to medical and developmental problems.

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[1] Persing J, Hector J, et. al. *Prevention and Management of Positional Skull Deformities in Infants.* Pediatrics. 2003;112: 199-202.

Medical Care for Craniofacial Anomalies

The optimal time for the first evaluations of a child with craniofacial anomalies is within the first few days of life.[2] In cases involving deformational plagiocephaly, diagnosis can be determined at birth and up to 1 year of age. Treatment of deformational plagiocephaly and certain other cranial anomalies involves mechanical adjustments, exercises, and surgery in some instances. To decrease the risk of developing deformational plagiocephaly and to minimize the progression of it, experts recommend alternating the sleeping position of an infant.

The use of an orthotic device, such as a skull-molding helmet, can be an option for patients with certain types of severe deformity. These devices apply mild pressure to the protruding areas of deformity and are available only if prescribed by a physician. Generally, molding helmets are used as an alternative to a surgical reshaping of the skull, and can be used when the bones are not yet fused together. Once the bones have fused, however, surgery is needed to allow the bones to be freed up and the skull reshaped. While the use of such molding helmets after surgery is much less common, there are certain cases in which it can be beneficial. There are times when there are limits to the amount of reshaping that can be accomplished surgically, and the helmet serves to help reshape the skull over time due to ongoing head growth. It can also be used to help stabilize the bones and protect the repair after the surgery.

There are drawbacks to helmet therapy as well. The devices are made to be worn up to 23 hours per day. It needs to be form fitted to the child, so a mold is made to insure a good fit. The course of therapy will vary depending on the age of the child and the growth of the skull, but is usually in the range of a few months. If the device needs to be in place for a longer time, a new one may be needed to accommodate for head growth, which would then require additional molding and additional costs. The frequency of follow-up visits is contingent upon the severity of the initial head shape, age of the infant, and the individual treatment protocol.

The results of some studies of mild and moderate deformities indicate that repositioning infants may produce similar results as orthotic devices. Some studies indicate that the best results from the use of such devices occur in the age range of 4-12 months of age.[3] The overall efficacy of such orthotic devices versus other treatments is inconclusive, and some experts contend additional studies are necessary to evaluate outcomes with and without helmets due to the significant costs of such devices.[4]

Advocates for mandated coverage for craniofacial anomalies indicated that it is the consensus of the American Academy of Orthotists and Prosthetists that the use of such devices are most effective when it is completed by 12 months of age although some change is possible up to 18 months of age. If delays in treatment occur due to lack of insurance coverage or denial of coverage, the child can miss the optimal treatment period when the head is rapidly growing between 4 months and 1 year of age, resulting in the reduction of correction potential and poor treatment outcomes.

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[2] *Parameters for Evaluation and Treatment of Patients with Cleft Lip/Palate or Other Craniofacial Anomalies,* American Cleft Palate-Craniofacial Association. April 2003.

[3] Ibid.

[4] Ibid.

Advocates also note that the long-term medical issues associated with deformational plagiocephaly, brachycephaly, or scaphocephaly have not been thoroughly documented. As more medical literature is published that links deformational plagiocephaly with mandibular deformities, visual-motor problems, developmental issues, ocular disturbances, and the need for more special services at school, it is anticipated that referrals will increase for cranial remolding devices.

Physicians may also refer children for early intervention services, such as physical, occupational, and speech therapy to improve developmental skills. Pediatricians are already referring more infants for monitoring and treatment than they referred a few years ago, and craniofacial specialists continue to see increasing numbers of children with deformational plagiocephaly in their clinics. However, early intervention may prove to be cost-effective not only to insurers but to society as a whole since treatment may prevent the onset of other more costly medical conditions later in life.

Craniofacial Anomalies-Related Statutory Coverage

Currently, health insurers are required to provide individual and group coverage for cleft lip and cleft palate under s. 627.64193, F.S., and s. 627.66911, F.S., respectively. This coverage must include medical, dental, speech therapy, audiology, and nutritional services if such services are medically necessary. Section 627.65755, F.S., requires insurers to provide group coverage for dental procedures, anesthesia, and hospitalization coverage if such dental condition is likely to result in a medical condition if left untreated and other conditions are met.

Insurance Coverage

Advocates for mandated coverage for craniofacial anomalies provided committee staff with information concerning the availability of insurance coverage for cranial remolding orthotics. About 50-75 percent of all insurance companies are presently paying for cranial remolding orthotics. Of the companies that pay for cranial orthotics, the coverage ranges from full payment for services, to lump sum partial payments, to out-of-network payments in the range of 40-80 percent. Many parents cannot afford to pay $2,500-$3,500 out-of- pocket costs for a cranial remolding device. Manufacturers of this device indicate that some insurers will cover this device under the category of durable medical equipment.

The Division of State Group Insurance of the Department of Management Services contracts with Blue Cross Blue Shield of Florida to administer the state employees’ Preferred Provider Organization (PPO) plan. The PPO does not cover the use of skull-molding helmets for infants to correct an asymmetrical shaped head because the device fails to meet the definition of “medically necessary” under the state plan. In addition, the use of such devices meets the definition of “experimental or investigational services” because “no functional defects have been conclusively associated with positional plagiocephaly and skull-molding devices are not regularly used for the treatment of positional plagiocephaly nor are they more efficacious than the standard treatment of active repositioning for positional plagiocephaly.”[5]

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[5] Letter, dated May 28, 2004, from Dr. Daniel B. Lestage, Vice President of Health Care Programs for Blue Cross Blue Shield of Florida to John Matthews, Director of the Division of State Group Insurance.

The Subscriber Assistance Panel (panel) of the Agency for Health Care Administration (AHCA), which handles coverage disputes between subscribers and health maintenance organizations, reported five disputes related to coverage for orthotic devices (DOC band and STARband) for the period of 2000-2004. In all five cases, the panel concluded that the HMO did not have to provide coverage for the cost of such equipment because the devices were considered to be experimental by investigative services and not medically necessary.

III. Effect of Proposed Changes:

Section 1. Requires the agency, in consultation with the office, to conduct a study evaluating the medical necessity, efficacy, and costs associated with mandating health insurance coverage for cranial skull molding orthotics and other therapies used in the treatment of deformational or positional plagiocephaly. The Department of Health must provide information to the agency regarding coverages and costs for children having plagiocephaly who are enrolled in the Children's Medical Services Program. The agency is authorized to contract with an actuary and other experts to assist in conducting the study. The agency and office are required to submit a report that includes findings and legislative recommendations to the Legislature by January 1, 2007.

Section 2. Appropriates $25,000 from the Insurance Regulatory Trust Fund to the Office of Insurance Regulation for the purpose of funding the study.

Section 3. Provides that the bill will take effect on July 1, 2006.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The results of the study prepared by the agency and the office will provide insights regarding the medical necessity, costs, and efficacy of mandating coverage of various therapies and treatments for certain craniofacial anomalies.

C. Government Sector Impact:

The bill appropriates $25,000 in non-recurring revenue from the Insurance Regulatory Trust Fund to the Office of Insurance Regulation to fund the study that is to be conducted by the agency in consultation with the office.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Summary of Amendments:

None.