

**The Florida Senate**  
**PROFESSIONAL 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: Health and Human Services Appropriations Committee

BILL: CS/SB 16

INTRODUCER: Health and Human Services Appropriations Committee and Senator Bullard

SUBJECT: Congenital Craniofacial Anomalies

DATE: April 17, 2007

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Deffenbaugh	BI	<b>Favorable</b>
2.	Bedford	Wilson	HP	<b>Fav/1 amendment</b>
3.	Dull	Peters	HA	<b>Fav/CS</b>
4.				
5.				
6.				

**I. Summary:**

The bill requires the Agency for Health Care Administration (AHCA), in consultation with the Office of Insurance Regulation (OIR), to conduct a study evaluating the medical necessity, efficacy, and costs associated with mandating health insurance and health maintenance organization coverage for cranial skull molding orthotics and other therapies used in the treatment of certain craniofacial anomalies. The AHCA is authorized to contract with an actuary and other experts to assist in conducting the study. The AHCA and the OIR are required to submit a report that includes findings and recommendations to the Legislature by January 1, 2008.

The bill appropriates \$25,000 from the Insurance Regulatory Trust Fund to the OIR for transfer to AHCA. The bill appropriates \$25,000 to the Administrative Trust Fund in AHCA for the purpose of funding the study.

The bill creates two undesignated sections 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. 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, hemifacial microsomia, vascular malformation, hemangioma, and deformational or positional plagiocephaly.

- Cleft lip and cleft palate - a separation that occurs in the lip or the roof of 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 which 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. 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 plagiocephaly 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.<sup>1</sup> Advocates for the bill provided additional information concerning the incidence rate for deformational plagiocephaly. With 226,219 births in Florida in 2005, using the 3 percent incidence rate noted in the Netherlands and New Zealand studies, approximately 6,787 children in Florida would 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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<sup>1</sup> 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.<sup>2</sup> 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. The helmet 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.<sup>3</sup> 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.<sup>4</sup>

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

<sup>3</sup> *Ibid.*

<sup>4</sup> *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. Health maintenance organizations are required to provide the same coverage for treatment of cleft lip or cleft palate for a child under s. 641.31(35), F.S. 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. Section 641.31(34), F.S., imposes the same requirement on health maintenance organizations.

### **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 the \$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.”<sup>5</sup>

### **Subscriber Assistance Program Panel**

The Subscriber Assistance Program (panel) is a State of Florida program designed to assist consumers of managed care entities, such as Health Maintenance Organizations, Prepaid Health Clinics, Prepaid Health Plans, and Exclusive Provider Organizations, with grievances that have not been satisfactorily resolved. The consumer must first complete the entire grievance process of the managed care entity before filing a grievance with the program, unless the grievance is of an urgent nature. If the consumer’s grievance meets the required criteria, the program’s staff will schedule the grievance for a hearing before an independent panel. After the hearing, the panel will make a recommendation based on the finding of fact either to the AHCA or the OIR, to ensure that consumers in the State of Florida receive the appropriate, quality medical services.

The panel reported five disputes related to coverage for orthotic devices (DOC band and STAR band) for the period of 2000-2004. In all five cases, the panel concluded that the HMO was not required to provide coverage for the cost of such equipment because the devices were considered to be experimental by investigative services and not medically necessary. In 2005, the panel reported four disputes related to coverage for orthotic devices (DOC band only). In two of the cases, the panel concluded that the HMO did not have to provide coverage, as the devices were contractually excluded as not medically necessary. In one case, the panel concluded that the subscriber should be reimbursed, as the device was durable medical equipment and therefore not excluded. The final case settled before the hearing was conducted with the subscriber being paid. In 2006, there was one dispute related to coverage for orthotic devices (DOC band only) in which the panel decided that the HMO did not have to provide coverage, as the device was contractually excluded as not medically necessary.

### **Proposals for Mandated Health Benefit Coverage**

Section 624.215, F.S., requires every person or organization seeking consideration of a legislative proposal which would mandate a health coverage or the offering of a health coverage by an insurance carrier, health care service contractor, or health maintenance organization as a component of individual or group policies to submit to the agency and the Legislature a report which assesses the social and financial impacts of the proposed coverage. This section specifies the information that must be included in the report. Prior to the 2005 Session, Orthomerica Products, Inc. provided a response to the questions included in s. 624.215, F.S.

### **III. Effect of Proposed Changes:**

**Section 1.** Creates an undesignated section of law requiring the AHCA, in consultation with the OIR, to conduct a study evaluating the medical necessity, efficacy, and costs associated with mandating health insurance and health maintenance organization coverage for cranial skull molding orthotics and other therapies used in the treatment of deformational or positional

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<sup>5</sup> 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.

plagiocephaly. For purposes of the study, the AHCA and the OIR must evaluate if there are gaps in the coverage between small and large group insurance markets. The AHCA must also provide information concerning the types of benefits, including the costs, provided to Medicaid recipients, and their demographic information. The Department of Health must provide information to the AHCA regarding coverages and costs for children having plagiocephaly who are enrolled in the Children's Medical Services Program. The AHCA is authorized to contract with an actuary and other experts to assist in conducting the study. The AHCA is required to submit a report that includes findings and legislative recommendations to the Legislature by January 1, 2008.

**Section 2.** Appropriates \$25,000 from the Insurance Regulatory Trust Fund to the OIR for transfer to AHCA; and, appropriates \$25,000 to the Administrative Trust Fund in AHCA for the purpose of funding the study.

**Section 3.** Provides that the bill will take effect on July 1, 2007.

#### **IV. Constitutional Issues:**

##### **A. Municipality/County Mandates Restrictions:**

The provisions of this bill have no impact on municipalities and the counties under the requirements of Art. VII, s. 18 of the Florida Constitution.

##### **B. Public Records/Open Meetings Issues:**

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Art. I, s. 24(a) and (b) of the Florida Constitution.

##### **C. Trust Funds Restrictions:**

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Art. III, Subsection 19(f) of the Florida Constitution.

#### **V. Economic Impact and Fiscal Note:**

##### **A. Tax/Fee Issues:**

None.

##### **B. Private Sector Impact:**

The results of the study, prepared by the AHCA and the OIR 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 from the Insurance Regulatory Trust Fund to the OIR for transfer to AHCA. The bill appropriates \$25,000 to the Administrative Trust Fund in AHCA for the purpose of funding the study.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

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This Senate staff analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

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## **VIII. Summary of Amendments:**

None.

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