The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Health Policy Committee

BILL:	SB 2370
INTRODUCER:	Senator Rich
SUBJECT:	Newborn Screening Program Task Force
DATE:	March 29, 2008 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Garner	Wilson	HP	**Pre-meeting**
2.			GO	
3.			HA	
4.				
5.				
6.				

I. Summary:

The bill creates the Newborn Screening Program Task Force within the Division of Children's Medical Services Network (CMSN) of the Department of Health (DOH) to conduct a study that identifies strengths and weaknesses and provides a strategic planning component of the Newborn Screening Laboratory and follow-up programs. The bill specifies membership, voting procedures, meeting and records requirements, compensation, and staffing for the task force.

The bill requires the task force to review the Newborn Screening Laboratory and follow-up programs for strengths and weaknesses. All necessary research must be completed by October 31, 2008. Based on the research, the task force shall prepare a gap analysis study that includes, but need not be limited to, service delivery on a disease-specific basis, provider availability, information technology, management and care, and quality assurance of diagnostic and follow-up systems. The task force must submit the study and its review and recommended plan to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the State Surgeon General by December 1, 2008.

The task force must hold its initial meeting by August 1, 2008, and shall terminate upon the submission of its final study.

This bill creates an undesignated section of law.

II. Present Situation:

Newborn Screening for Genetic Medical Conditions

Each year newborn screening programs in all the states test 4 million newborns to identify those who may have specific genetic and metabolic disorders that could threaten their life or long-term health. Early detection, diagnosis, and treatment of these disorders may prevent a child's death, serious illness, or disability. For example, children with the metabolic disorder phenylketonuria (commonly referred to as PKU) cannot properly metabolize common foods, including milk and meat, and need to be placed on a special diet to avoid mental retardation. Children with sickle cell diseases, which are genetic blood disorders, can receive antibiotic treatment to reduce the risk of bacterial infections.

All newborn screening begins with a health care provider collecting a blood specimen during a newborn's first few days of life. The baby's heel is pricked to obtain a few drops of blood. The blood is placed on a specimen collection card and sent to a laboratory for analysis. State departments of health may use their own laboratory to test samples from the dried blood spots or may have a contract with a private laboratory, a laboratory at a university medical school, or another state's public laboratory.

While the number of genetic and metabolic disorders included in state newborn screening programs ranges from 4 to 36, most states screen for 8 or fewer disorders.[1] Authority for deciding which disorders to include in programs often rests with state health departments or boards of health, which generally receive input from advisory committees. Screening for certain disorders may also be mandated by state law. In deciding which disorders to include in their programs, states generally consider similar criteria, such as how often the disorder occurs in the population, whether an effective screening test exists, and whether the disorder is treatable.

With the exception of federal recommendations that newborns be screened for PKU, congenital hypothyroidism, and sickle cell diseases, there are no federal guidelines on the set of disorders that should be included in state screening programs.

Florida Newborn Screening Program

Under Florida law,[2] the DOH is required to promote the screening of all newborns born in Florida for metabolic, hereditary, and congenital disorders known to result in significant impairment of health or intellect, as screening programs accepted by current medical practice become available and practical in the judgment of the DOH. The DOH is also responsible for promoting the identification and screening of all newborns and their families for environmental risk factors such as low income, poor education, maternal and family stress, emotional instability, substance abuse, and other high-risk conditions.

[1] U.S. Government Accountability Office. *Newborn Screening: Characteristics of State Programs*. March 2003. Found at: http://www.gao.gov/new.items/d03449.pdf (last visited on March 29, 2008).
[2] S. 383.14, F.S.

The goals of these efforts are to identify those children with increased risk of infant mortality and morbidity to provide early intervention, remediation, and prevention services, including, but not limited to, parent support and training programs, home visitation, and case management.

Finally, the law requires that identification, perinatal screening, and intervention efforts shall begin prior to and immediately following the birth of the child by the attending health care provider. Screenings are conducted in hospitals, perinatal centers, county health departments, school health programs that provide prenatal care, and birthing centers. Screenings are reported to the Office of Vital Statistics.

Florida's newborn screening program has a long history. The Florida Newborn Screening Program began in 1965 with the screening of a single disorder, Phenylketonuria (PKU). A major expansion in the number of conditions screened occurred in 2006, when Florida began testing all newborns using a new method called tandem mass spectrometry, which added 24 disorders. With the addition of Cystic Fibrosis in 2007, the number of conditions screened for through the panel has expanded to 35 disorders.[3]

Newborn screening begins at the time the specimen is collected by the birthing facility and continues all the way through confirmation of diagnosis. All newborns born in the state of Florida are mandated to be screened for the current panel of 35 disorders unless the parent objects in writing. The state laboratory in Jacksonville tests all specimens and the CSMN provides follow-up for all abnormal screening results. Specialists from three genetic centers, three endocrine centers, eleven hematology centers and ten cystic fibrosis centers provide evaluation and diagnostic services for infants with presumptive positive test results.

Genetics and Newborn Screening Advisory Council

The Genetics and Newborn Screening Advisory Council (or Council) is established in s. 383.14(5), F.S., and consists of 15 members specified in law. The Council membership is composed of the following:

- Two consumer members;
- Three practicing pediatricians, at least one of whom must be a pediatric hematologist;
- One representative from each of the four medical schools in the state;
- The State Surgeon General or his or her designee;
- One representative from the DOH representing the CMSN;
- One representative from the Florida Hospital Association;
- One individual with experience in newborn screening programs;
- One individual representing audiologists; and
- One representative from the Agency for Persons with Disabilities.

[3] The Florida Newborn Panel screens for the following conditions: Biotinidase Deficiency; Congenital Adrenal Hyperplasia; Congenital Hypothyroidism; Cystic Fibrosis; Galactosemia; Homocystinuria; Maple Syrup Urine Disease; Medium Chain Acyl-CoA Dehydrogenase (MCADD) Deficiency; Phenylketonuria (PKU); Sickle Cell Diseases; Other Fatty Acid Oxidation Disorders; Organic Acid Disorders; and Urea Cycle Disorders.

The Council meets twice yearly and advises the DOH on: conditions for which testing should be included under the screening program and the genetics program; procedures for collection and transmission of specimens and recording of results; and methods whereby screening programs and genetic services for children currently provided or proposed to be offered in the state may be more effectively evaluated, coordinated, and consolidated.

Florida Newborn Screening Laboratory

The newborn screening panel testing is performed at the Bureau of Laboratories in Jacksonville, also known as the Florida Newborn Screening Laboratory. The laboratory screens over 1,000 specimens per day. This process begins with specimen collection. Once a satisfactory specimen is collected, there must be no delay in sending the specimen to the laboratory to insure the integrity of the specimen.

The metabolic screening results medical professionals receive are only the first part of the identification of affected individuals. If the results are normal, the state mandated screen has been performed and any further testing on the patient is done by an outside agency. If the result is abnormal or meets certain criteria in the borderline range, a repeat test is run and in some instances another analyte is checked within the Jacksonville facility. Further confirmatory testing and diagnosis is performed by an outside agency.

III. Effect of Proposed Changes:

The bill creates the Newborn Screening Program Task Force within the CMSN of the DOH to conduct a study that identifies strengths and weaknesses and provides a strategic planning component of the Newborn Screening Laboratory and follow-up programs.

The bill specifies that the task force shall consist of all members of the Genetics and Newborn Screening Advisory Council and invited consultants. The chair of the Genetics and Newborn Screening Advisory Council shall serve as the chair of the task force and staff of the CSMN shall be assigned by the director to provide support to the task force. All decisions of the task force shall be by majority vote of the members present at a duly convened meeting of the task force. Members of the task force shall serve without compensation, but are entitled to receive reimbursement for travel and per diem expenses as provided in s. 112.061, F.S., and all meetings and records of the task force are subject to the requirements of s. 24(a), Art. I of the State Constitution.

The bill requires the task force to review the Newborn Screening Laboratory and follow-up programs for strengths and weaknesses. All necessary research must be completed by October 31, 2008.

Based on the research, the task force shall prepare a gap analysis study that includes, but need not be limited to, service delivery on a disease-specific basis, provider availability, information technology, management and care, and quality assurance of diagnostic and follow-up systems. The gap analysis study shall define the ideal program. The task force shall submit the gap analysis study and its review and recommended plan to the Governor, the President of the

Senate, the Speaker of the House of Representatives, and the State Surgeon General by December 1, 2008.

The task force must hold its initial meeting by August 1, 2008, and shall terminate upon the submission of the final study.

The bill specifies this act shall take effect July 1, 2008.

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 Article VII, Section 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 Article I, Section 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 Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The CMSN will be required to provide staff support and travel reimbursement for the Newborn Screening Program Task Force. According to the DOH, the exact fiscal impact cannot currently be determined. However, other fiscal analyses for similar task forces suggest that travel and other expenses would equal approximately $500 per task force member per meeting where travel was involved.

VI. Technical Deficiencies:

Line 30 should refer to s. 24(a) and (b), since both records and meetings of the task force must be open to the public.

VII. Related Issues:

Page 2, lines 50-51. The bill requires a study to be submitted by December 1, 2008. The DOH recommends that the due date to complete the research for the study be extended to January 1, 2009, and that the final study report due date be extended to March 1, 2009, in order to allow sufficient time to gather the necessary information for the study required in the bill.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.