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.)

BILL: CS/SB 2002

SPONSOR: Health, Aging and Long-Term Care Committee and Senators Wasserman Schultz and Saunders

SUBJECT: Newborn Infant Screening

DATE: February 20, 2002 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HC	Favorable/CS
2.			GO	
3.				
4.				
5.				
6.				

I. Summary:

The bill authorizes Children's Medical Services within the Department of Health to convene a study group to conduct comparative research regarding the infant screening programs currently operating in other states. The study group must make recommendations regarding the State's newborn infant screening requirements and develop a newborn infant screening plan tailored to the needs of Florida's population. The study group must consider the cost of current testing, the cost of expansion, appropriate mechanisms for reimbursing the cost of testing and the appropriate location for such testing. The study group's research must be completed by August 1, 2002, and its recommendations and plan submitted to the Legislature by September 1, 2002.

This bill creates one undesignated section of law.

II. Present Situation:

Florida's Infant Screening program is a statewide program through which all newborns are screened for five metabolic, congenital, or hereditary disorders prior to discharge from a hospital or other birthing facility. One of the primary consequences of failure to detect and treat the five disorders early is death or severe mental retardation. The Infant Screening Program began in 1965 with screening for a single disorder, phenylketonuria (PKU). In addition to PKU, the program, at the appropriate age, screens infants for such other metabolic diseases and hereditary or congenital disorders as the Department of Health deems necessary.[1]

[1] Such disorders include: phenylketonuria, galactosemia, congenital hypothyroidism, congenital adrenal hyperplasia, and hemoglobinopathies, primarily sickle cell disease.

Section 383.14(5), F.S., creates a 12-member Genetics and Infant Screening Program Advisory Council appointed by the Secretary of Health. The membership of the council consists of: two consumers; 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 Secretary of Health or her or his designee; one representative from the Department of Health representing Children's Medical Services; and one representative from the Developmental Disabilities Program Office of the Department of Children and Family Services.

The Council meets twice annually and advises the Department of Health 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 genetics services for children currently provided or proposed to be offered in the state may be more effectively evaluated, coordinated, and consolidated.

Once a newborn's blood specimen is collected, it is mailed to the State Laboratory in Jacksonville where all infant specimens for screening tests are processed.[2] When the State Laboratory receives a presumptive abnormal screening result, the Children's Medical Services (CMS) program office in Tallahassee and the physician of record are immediately contacted. Children's Medical Services has the responsibility for follow-up of infants with abnormal screening tests. Newborns with presumptive abnormal tests are referred by CMS for medical evaluations. Children's Medical Services contacts families and physicians by phone and mail, collects and tracks data, and provides educational information to families, physicians, birthing facilities, and community referral sources. Children's Medical Services contracts with three regional Endocrine Centers, three regional Genetics Centers, and eight regional CMS Hematology/Oncology centers that provide follow-up and confirmatory testing for those infants identified with presumptive abnormal screening results.

Tandem mass spectrometry is a laboratory testing technology that was introduced in the 1990s and is being used for newborn screening because it substantially increases the number of metabolic disorders that can be detected. According to a recent report by the Centers for Disease Control and Prevention, tandem mass spectrometry is relatively new, and scientific data are limited regarding the incorporation of this technology into newborn screening and maternal and child health programs.[3] The Commission on the Study of Children with Developmental Delays recommended that the State of Florida revise its newborn screening program to take advantage of new technologies, such as tandem mass spectrometry, to prevent mental retardation and other disabling conditions.[4] The commission study indicated that tandem mass spectrometry can provide substantial benefits to patients and their families.

CS for SB 1018, "Learning Gateway", which passed during the 2001 Session, called for more effective screening for precursors of learning problems, learning disabilities, and mild

[2] "Screening test" is defined as a non-diagnostic laboratory procedure that is capable of detecting the presumptive presence of PKU, neonatal hypothyroidism, galactosemia, and such other designated disorders by the Department of Health. Rule 64C7.001(20), Florida Administrative Code.

[3] "Using Tandem Mass Spectrometry for Metabolic Disease Screening Among Newborns," A report of a Centers for Disease Control and Prevention Workgroup, April 13, 2001

[4] "Report of the Commission on the Study of Children with Developmental Delays", The Commission on the Study of Children with Developmental Delays, January, 2001.

developmental delays, to be used in local demonstration projects. The Governor stated in his veto message of Committee Substitute for Senate Bill 1018 (2001), that the bill was vetoed, in part, due to the expense associated with the Department of Health's purchase of expensive equipment to process tandem mass spectrometry tests in three demonstration counties.[5] The Governor's message stated that:

> "The addition of the Tandem Mass Spectrometry test is used to test certain metabolic abnormalities that may or may not lead to learning disabilities. Although the test may have merit in identifying additional metabolic abnormalities, direct links between the existence of these additional abnormalities and learning disabilities have not been established with medical certainty. I believe that the addition of such a mandatory test should be approved based on a more thorough and thoughtful analysis of need and benefit by the Department of Health."

According to the Department of Health, to date, nine states have included screening involving tandem mass spectrometry in their newborn screening programs and have expanded the number of screened disorders by one or more.

The March of Dimes, a national non-profit health organization, recommends that every baby born in the United States receive, at a minimum, the same core group of nine screening tests for metabolic disorders. These disorders include the five metabolic disorders for which Florida screens, and Medium-Chain Acyl-coa Dehydrogenase Deficiency (MCAD), Biotinidase Deficiency, Maple Syrup Urine Disease, and Homocystinuria. Parent groups are also advocating national expansion of infant screening metabolic testing.

III. Effect of Proposed Changes:

The bill authorizes Children's Medical Services within the Department of Health to convene a study group for the purpose of conducting comparative research regarding the infant screening programs that currently operate in other states. The study group shall include members of the Genetics and Infant Screening Advisory Council designated by the Secretary of the Department of Health, a representative designated by the Florida Hospital Association, a representative designated by the Florida Statutory Teaching Hospital Council and a representative from the Florida chapter of the March of Dimes. The study group must work under the auspices of Children's Medical Services. The study group must make recommendations regarding newborn infant screening requirements in Florida and must develop a newborn infant screening plan tailored to the needs of Florida's population. The study group must consider the cost of current testing, the cost of expansion, appropriate mechanisms for reimbursing the cost of testing and the appropriate location for such testing. The study group's research must be completed by August 1, 2002, and its recommendations and plan must be submitted to the Legislature by September 1, 2002.

The bill provides an effective date upon becoming a law.

[5] Pursuant to section 62, ch. 2001-277, Laws of Florida, tests and postnatal screenings must be performed by the State Public Health Laboratory, in coordination with Children's Medical Services.

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, s. 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The Department of Health has indicated that the costs for participation of the Genetics and Infant Screening Program Advisory Council members will be covered by CMS.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

None.