

STORAGE NAME: h0817s1.hr.doc
DATE: February 6, 2002

**HOUSE OF REPRESENTATIVES
COMMITTEE ON
HEALTH REGULATION
ANALYSIS**

BILL #: CS/HB 817
RELATING TO: Newborn Infant Screening
SPONSOR(S): Committee on Health Regulation and Representative Sobel and others
TIED BILL(S): None.

ORIGINATING COMMITTEE(S)/COUNCIL(S)/COMMITTEE(S) OF REFERENCE:

- (1) HEALTH REGULATION YEAS 7 NAYS 1
 - (2) JUDICIAL OVERSIGHT
 - (3) COUNCIL FOR HEALTHY COMMUNITIES
 - (4)
 - (5)
-

I. SUMMARY:

THIS DOCUMENT IS NOT INTENDED TO BE USED FOR THE PURPOSE OF CONSTRUING STATUTES, OR TO BE CONSTRUED AS AFFECTING, DEFINING, LIMITING, CONTROLLING, SPECIFYING, CLARIFYING, OR MODIFYING ANY LEGISLATION OR STATUTE.

This bill requires the Secretary of the Department of Health to designate members of the Genetics and Infant Screening Advisory Council, which is part of the Children's Medical Services program in the Department of Health, to serve as members of a study group to conduct comparative research regarding expanding the metabolic infant screening program including the use of tandem mass spectrometry. Additional members of the study groups shall include a representative designated by the Florida Hospital Association and a representative from the Florida chapter of the March of Dimes. The study work group shall make recommendations and develop a plan for expansion of Florida's Infant Screening Program tailored to the needs of Florida's population. The study group shall also 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 is to complete its research by August 1, 2002, and submit its recommendations and plan to the Legislature by September 1, 2002.

Florida's Infant Screening program is a statewide program through which all newborns are screened for five metabolic, congenital, hereditary disorders prior to discharge from a hospital or other birthing facility. One of the primary consequences of failure of early detection and treatment of the five disorders is death or severe mental retardation.

Based on information provided by the Department of Health, cost for participation of the Genetics and Infant Screening Program Advisory Council members will be covered by Children's Medical Services. The Florida Hospital Association and the March of Dimes are expected to pay travel/meeting expenses for its representatives. Any additional costs associated with invited participants will have to be covered by their respective agencies or entities or other funding sources.

II. SUBSTANTIVE ANALYSIS:

A. DOES THE BILL SUPPORT THE FOLLOWING PRINCIPLES:

- | | | | |
|-----------------------------------|------------------------------|-----------------------------|---|
| 1. <u>Less Government</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 2. <u>Lower Taxes</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 3. <u>Individual Freedom</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 4. <u>Personal Responsibility</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 5. <u>Family Empowerment</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |

For any principle that received a “no” above, please explain:

B. PRESENT SITUATION:

Florida’s Infant Screening program is a statewide program through which all newborns are screened for five metabolic, congenital, hereditary disorders prior to discharge from a hospital or other birthing facility. One of the primary consequences of failure of early detection and treatment of the five disorders is death or severe mental retardation.

The Infant Screening Program began in 1965 with the screening for a single disorder, phenylketonuria (PKU), and has been expanded to include galactosemia, congenital hypothyroidism, congenital adrenal hyperplasia, and hemoglobinopathies, primarily sickle cell disease.

Once a newborn's blood specimen is collected, it is mailed to the State Laboratory in Jacksonville where all infant screening specimens are processed. 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. CMS has the responsibility for follow-up of infants with abnormal screening tests. CMS refers newborns with presumptive abnormal tests for medical evaluations, 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. CMS 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.

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 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 yearly and advises the department 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.

With the development of tandem mass spectrometry during the late 1990's for early detection of metabolic disorders of newborns, it is possible to screen for up to 30 disorders. To date, nine states have included tandem mass screening in their newborn screening programs and 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 U.S. receive, at a minimum, the same core group of nine screening tests for metabolic disorders. These disorders include the five metabolic disorders that 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.

C. EFFECT OF PROPOSED CHANGES:

The bill requires the Secretary of Health to designate members of the Genetics and Infant Screening Advisory Council, along with a representative designated by the Florida Hospital Association and a representative from the Florida chapter of the March of Dimes to serve as a study group to conduct comparative research regarding expanding infant metabolic screening and using tandem mass spectrometry. This study shall include analyzing data available from other states. The recommendations of the study group shall be submitted to the Legislature by September 1, 2002.

D. SECTION-BY-SECTION ANALYSIS:

Section 1. The bill authorizes the formation of a study group consisting of the members of the Genetics and Infant Screening Advisory Council designated by the Secretary of Health, a representative designated by the Florida Hospital Association and a representative from the Florida chapter of the March of Dimes. The study work group shall make recommendations and develop a plan for expansion of Florida's Infant Screening Program tailored to the needs of Florida's population. The study group shall also 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 research shall be completed by August 1, 2002, and the recommendations and plan submitted to the Legislature by September 1, 2002.

Section 2. Provides an effective date of upon becoming law.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

See Fiscal Comments section.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Members of the study group representing an organization or entity will have their expenses paid for by the association they represent.

D. FISCAL COMMENTS:

According to the Department of Health, cost estimates are based on the following assumptions:

1. The full membership of the Genetics and Infant Screening Advisory Council (12 members) will participate in the study group.
2. Additional medical and other interested experts, both in-state and out-of-state, may be requested to advise the study group on the expansion of Florida's program.
3. An initial conference call will be arranged by the Children's Medical Services with the advisory council members to review the workgroup responsibilities, determine action plan steps, recommend other experts for consultation, and establish timelines.
4. After conducting the required comparative research, the working group will convene in Tallahassee for a meeting to address findings, actions, and recommendations to be included in the legislative report. Cost for participation of the Genetics and Infant Screening Program Advisory Council members will be covered by Children's Medical Services. Any additional costs or costs associated with invited participants (outside the membership of the Genetics and Infant Screening Program Advisory Council) will have to be covered by their respective agencies or entities or other funding sources.
5. A draft legislative report will be shared by email with the workgroup members and other interested parties for comment. A conference call to review and finalize the report will follow.

The finalized legislative report with the recommendations and screening plan will be submitted by September 1, 2002.

IV. CONSEQUENCES OF ARTICLE VII, SECTION 18 OF THE FLORIDA CONSTITUTION:

A. APPLICABILITY OF THE MANDATES PROVISION:

The bill does not require counties or municipalities to expend funds or to take any action requiring the expenditure of funds.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

The bill does not reduce the authority that municipalities or counties have to raise revenues in the aggregate.

C. REDUCTION OF STATE TAX SHARED WITH COUNTIES AND MUNICIPALITIES:

The bill does not reduce the percentage of state tax shared with counties or municipalities.

V. COMMENTS:

A. CONSTITUTIONAL ISSUES:

None.

B. RULE-MAKING AUTHORITY:

None.

C. OTHER COMMENTS:

The sponsor introduced HB 1053 for the purpose of including on the advisory council "a representative from the Florida chapter of the March of Dimes." An amendment has been prepared to include that representative in this bill.

In addition, a representative of the Florida Hospital Association has indicated interest in serving on the council in that most infants are born in a hospital setting.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

On January 30, 2002, the Committee on Health Regulation adopted a strike everything amendment and reported the bill favorably as a committee substitute. The original bill did not include on the study group a representative designated by the Florida Hospital Association or a representative from the Florida chapter of the March of Dimes. In addition, the original bill did not require the study group to 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.

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VII. SIGNATURES:

COMMITTEE ON HEALTH REGULATION:

Prepared by:

Staff Director:

Lucretia Shaw Collins

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