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**HOUSE OF REPRESENTATIVES
AS REVISED BY THE COMMITTEE ON
JUDICIAL OVERSIGHT
ANALYSIS**

BILL #: CS/HB 817

RELATING TO: Newborn Infant Screening

SPONSOR(S): Committee on Health Regulation and Representatives Sobel and Siplin

TIED BILL(S): None

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

- (1) HEALTH REGULATION YEAS 7 NAYS 1
- (2) JUDICIAL OVERSIGHT YEAS 9 NAYS 0
- (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.

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. 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 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.

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 their representatives. Any additional costs associated with invited participants will have to be covered by their respective agencies or entities or other funding sources.

On February 21, 2002, the Committee on Judicial Oversight adopted a "strike-everything" amendment to include a designee of the Florida Statutory Teaching Hospital Council on the study group and remove references to an "expansion" of the infant screening program. The amendment is traveling with the bill.

II. SUBSTANTIVE ANALYSIS:

A. DOES THE BILL SUPPORT THE FOLLOWING PRINCIPLES:

- | | | | |
|-----------------------------------|------------------------------|--|---|
| 1. <u>Less Government</u> | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input 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:

This bill creates a study group and requires the study group to prepare a report.

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.¹ 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

¹ See s. 383.14(5), F.S.

- 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.²

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.

C. EFFECT OF PROPOSED CHANGES:

This bill authorizes Children's Medical Services of the Department of Health to convene 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 study group will make recommendations regarding the expansion of the newborn infant screening program tailored to the needs of Florida's population. The research is to be completed by August 1, 2002, and recommendations of the study group shall be submitted to the Legislature by September 1, 2002.

This bill provides that the study group shall consist of members of the Genetics and Infant Screening Advisory Council designated by the Secretary of Health. In addition, a representative designated by the Florida Hospital Association and a representative from the Florida chapter of the March of Dimes will serve on the study group.

This bill takes effect upon becoming law.

D. SECTION-BY-SECTION ANALYSIS:

Section 1. This 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 group shall make recommendations and develop a plan for expansion of Florida's Infant Screening Program tailored to the needs of Florida's population.

² See s. 383.14(5), F.S.

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 associations they represent.

D. FISCAL COMMENTS:

The Department of Health projects no fiscal impact. This estimate is 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 final 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:

This bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

This 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:

This 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:

None.

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 amendment added representatives of the Florida Hospital Association and the Florida chapter of the March of Dimes to the study group. In addition, the amendment required 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.

On February 21, 2002, the Committee on Judicial Oversight adopted a “strike-everything” amendment to include a designee of the Florida Statutory Teaching Hospital Council on the study group and remove references to an “expansion” of the infant screening program. This bill, as amended, was reported favorably.

VII. SIGNATURES:

COMMITTEE ON HEALTH REGULATION:

Prepared by:

Staff Director:

Lucretia Shaw Collins

Lucretia Shaw Collins

AS REVISED BY THE COMMITTEE ON JUDICIAL OVERSIGHT:

Prepared by:

Staff Director:

L. Michael Billmeier, Jr., J.D.

Nathan L. Bond, J.D.