## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** CS/CS/HB 963 Newborn Screenings
**SPONSOR(S):** Health Quality Subcommittee, Fitzenhagen
**TIED BILLS:** **IDEN./SIM. BILLS:** SB 1124

| REFERENCE | ACTION | ANALYST | STAFF DIRECTOR or BUDGET/POLICY CHIEF |
|---|---|---|---|
| 1) Health Quality Subcommittee | 15 Y, 0 N, As CS | Tuszynski | McElroy |
| 2) Health Care Appropriations Subcommittee | 14 Y, 0 N, As CS | Mielke | Pridgeon |
| 3) Health & Human Services Committee | | | |

## SUMMARY ANALYSIS

Newborn screening is a preventive public health program that is provided in every state in the United States to identify, diagnose, and manage newborns at risk for selected disorders that, without detection and treatment, can lead to permanent developmental and physical damage or death. The United States Department of Health and Human Services (HHS) Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) advises HHS on the most appropriate application of universal newborn screening tests, technologies, policies, guidelines and standards. ACHDNC establishes the heritable disorders listed on the federal Recommended Uniform Screening Panel (RUSP).

In Florida, the Department of Health (DOH) is responsible for administering the statewide Newborn Screening Program (NSP), which conducts screenings for 53 hereditary and congenital disorders. Once a disorder is added to the RUSP, it is reviewed by DOH's Genetic and Newborn Screening Advisory Council (GNSAC) to determine whether to recommend the disorder be added to the NSP panel.

The most recent disorders added to the state's panel were Severe Combined Immunodefiency (SCID) and Critical Congenital Heart Defect (CCHD). SCID was added 1 year and 10 months after recommendation by the GNSAC and CCHD was added 2 years and 6 months after the recommendation by the GNSAC.

CS/CS/HB 963 amends s. 383.14, F.S., to require DOH to adopt rules requiring every newborn in the state, at the appropriate age, to be tested for any condition listed on the federal RUSP that the GNSAC advises should be included in the NSP panel. DOH must adopt the rules to include any condition the GNSAC recommends within 18 months if a FDA-approved test (or a suitable alternative) is available. If no such test exists within the 18-month period, DOH must begin testing as soon as such test becomes available.

The bill also requires DOH to adopt rules requiring the GNSAC to consider addition of a condition in the NSP panel within 1 year of the condition being added to the federal RUSP. After the GNSAC recommends a condition be included, DOH must submit a legislative budget request to seek an appropriation to add testing of the condition to the newborn screening program.

The bill has a significant indeterminate negative fiscal impact on DOH, subject to an appropriation for testing of new conditions, and has no impact on local governments.

The bill provides for an effective date of July 1, 2017.

## FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

**Current Situation**

Federal Recommendations for Newborn Screening

Newborn screening is a preventive public health program that is provided in every state in the United States to identify, diagnose, and manage newborns at risk for selected disorders that, without detection and treatment, can lead to permanent developmental and physical damage or death.

The United States Department of Health and Human Services (HHS) Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC), under the Public Health Service Act,[1] is established to reduce morbidity and mortality in newborns and children who have, or are at risk for, heritable disorders.[2] To that end, the ACHDNC advises the Secretary of HHS on the most appropriate application of universal newborn and child screening tests and technical information for the development of policies and priorities that will enhance the ability of state and local health agencies to provide for screening, counseling, and health care services for newborns and children having, or at risk for, heritable disorders.[3] As part of this process, ACHDNC establishes the list of heritable disorders on the federal Recommended Uniform Screening Panel (RUSP).

The RUSP currently recommends screening for 32 core conditions and 26 secondary conditions.[4]

Florida Newborn Screening Program

Section 383.14(5), F.S., establishes the Florida Genetics and Newborn Screening Advisory Council (GNSAC) to advise the Department of Health (DOH) about which disorders should be added to the Newborn Screening Program (NSP) panel of screened disorders and the procedures for collecting and transmitting specimens.[5] Florida's NSP currently screens for 50 of the 58 disorders recommended by the RUSP, including 31 core conditions and 28 secondary conditions.[6]

The intent of the NSP is to screen all newborns for hearing impairment and to identify, diagnose, and manage newborns at risk for selected disorders that, without detection and treatment, can lead to permanent developmental and physical damage or death.[7] The NSP involves coordination among several entities, including the Bureau of Public Health Laboratories Newborn Screening Laboratory in

[1] 42 U.S.C. s. 300b-10; 42 U.S.C. s. 217a: Advisory councils or committees (2016).
[2] U.S. Department of Health and Human Services, *Advisory Committee on Heritable Disorders in Newborns and Children*, http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/index.html (last accessed March 11, 2017).
[3] Secretary of Health and Human Services, *Charter Discretionary Advisory Committee on Heritable Disorders in Newborns and Children*, April 24, 2013, available at: http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/about/charterdachdnc.pdf (last accessed March 11, 2017).
[4] Advisory Committee on Heritable Disorders in Newborns and Children, *Recommended Uniform Screening Panel (as of November 2016)*, *available at*: http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendedpanel/uniformscreeningpanel.pdf (last visited March 11, 2017).
[5] S. 383.14(5), F.S.
[6] Florida Department of Health, *Disorder List*, available at: http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/_documents/newborn-screening-disorders.pdf (last accessed March 11, 2017); this list is also maintained by DOH in Rule Rule 64C-7.002, F.A.C.
[7] Florida Department of Health, Florida Newborn Screening Guidelines, 2012, available at: https://www.peds.ufl.edu/divisions/genetics/programs/newborn_screening/2012%20newborn%20screening%20quidelines%20FL.pdf (last accessed March 11, 217).

Jacksonville (State Laboratory), DOH Children's Medical Services (CMS) Newborn Screening Follow-up Program in Tallahassee, and referral centers, birthing centers, and physicians throughout the state.[8]

To administer the NSP, DOH is authorized to charge and collect a fee not to exceed $15 per live birth occurring in a hospital or birth center.[9] DOH must calculate the annual assessment for each hospital and birth center, and then quarterly generate and mail each hospital and birth center a statement of the amount due.[10] Statute authorizes DOH to bill third-party payers for the NSP tests, DOH bills these insurers directly for the cost of the screening.[11] DOH does not bill families that do not have insurance coverage.[12]

The screening process involves collecting a few drops of blood from the newborn's heel.[13] Parents and guardians may decline the screening in writing, which must be placed in the medical record.[14] After a specimen is collected, the specimen card is sent to the State Laboratory in Jacksonville for testing.[15] The State Laboratory receives about 1,000 specimens per day from births in Florida.[16] In the event that a newborn screen has an abnormal result, the CMS program provides follow-up services for the child and his or her family.[17]

*Adding Conditions to the NSP Panel*

Before a disorder is added to the NSP panel, the GNSAC considers the recommendations of the ACHDNC and evaluates whether:[18]

- The disorder is known to result in significant impairment in health, intellect, or functional ability, if not treated before clinical signs appear.
- The disorder can be detected using screening methods which are accepted by current medical practice.
- The disorder can be detected prior to the infant's becoming two weeks of age, or at the appropriate age as accepted medical practice indicates.
- After screening for the disorder, reasonable cost benefits can be anticipated through a comparison of tangible program costs with those medical, institutional, and special educational costs likely to be incurred by an undetected population.

If the GNSAC recommends the inclusion of a disorder to the NSP panel, DOH assesses the availability of funding, staff, the availability of a federally approved test, and treatment options required to add the disorder to the NSP panel.[19] To prepare for the addition of a disorder to the NSP panel, DOH must:[20]

- Obtain budget authority for expenditures for reagents, equipment, data system modifications, staffing, second tier testing, and contracting with referral centers for diagnostic services; testing and validation of the screening test;
- Develop follow-up policies;
- Establish referral center contracts;

[8] Infra, FN 15.
[9] S. 383.14(3)(g)1., F.S.
[10] Id.
[11] S. 383.14(3)(h), F.S.
[12] Florida Department of Health, Bureau of Public Health Laboratories Newborn Screening, http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/BPHL/index.html (last accessed March 15, 2017).
[13] Florida Department of Health, Newborn Screening, http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/ (last accessed March 11, 2017).
[14] S. 383.14(4), F.S.; Rule 64C-7.008, F.A.C.
[15] Supra, FN 13.
[16] Id.
[17] Id.
[18] Rule 64C-7.007, F.A.C. (2014) (repealed in 2015).
[19] Florida Department of Health, *Agency Analysis of 2017 House Bill 963*, February 22, 2017 (on file with Health Quality Subcommittee).
[20] Supra, FN 19 at pg. 3.

- Ensure the availability of the appropriate pediatric specialists and developing standard procedures for diagnostic services for infants with critical values; and
- Develop disorder specific educational materials for physicians and birthing facilities to include the interpretation of lab results, appropriate actions by physicians and facilities upon diagnosis, and information for families.

The most recent disorders added to the NSP panel were Severe Combined Immunodeficiency in 2012 (1 year and 10 months after recommendation by the GNSAC) and Critical Congenital Heart Defect in 2013 (2 years and 6 months after the recommendation by the GNSAC).[21]

Currently, three disorders on the RUSP are not on the NSP panel:[22]

- X-linked ALD (ALD)[23]
- Glycogen Storage Disease Type II (Pompe)[24]
- Mucupolysacharidosis Type I (MPS I)[25]

The GNSAC recommended the addition of ALD to the NSP panel on February 19, 2016. DOH has requested a $1.3 million recurring appropriation in the department's FY 2017-18 Legislative Budget Request to implement screening for ALD.[26] The RUSP added Pompe and MPS I in March 2, 2015 and February 15, 2016, respectively.[27] The GNASC has not recommended either for addition to the NSP panel.

**Effect of Proposed Changes**

CS/CS/HB 963 amends s. 383.14, F.S., to require DOH to adopt rules requiring every newborn in the state, at the appropriate age, to be tested for any condition listed on the federal RUSP which the

[21] Florida Department of Health, Bureau of Public Health Laboratories Newborn Screening, *Conditions Newborn Screening Detects*, available at: http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/BPHL/_documents/nbs-screened-disorders.pdf (last accessed March 11, 2017).; Supra, FN 19 at pg. 2.

[22] *See* United States Department of Health and Human Services, Advisory Committee on Heritable Disorders in Newborns and Children, *Recommended Uniform Screening Panel*, available at: https://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendedpanel/index.html (last accessed March 11, 2017); Florida Department of Health, Bureau of Public Health Laboratories Newborn Screening, *Conditions Newborn Screening Detects*, available at: http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/BPHL/_documents/nbs-screened-disorders.pdf (last accessed March 11, 2017).

[23] X-Linked ALD is a genetic disorder that occurs primarily in males with an incidence rate of approximately 1 in 20,000-50,000. It mainly affects the nervous system and the adrenal glands, which are small glands located on top of each kidney. In this disorder, the fatty covering (myelin) that insulates nerves in the brain and spinal cord is prone to deterioration (demyelination), which reduces the ability of the nerves to relay information to the brain. In addition, damage to the outer layer of the adrenal glands (adrenal cortex) causes a shortage of certain hormones (adrenocortical insufficiency). Adrenocortical insufficiency may cause weakness, weight loss, skin changes, vomiting, and coma. There are three distinct types of X-linked adrenoleukodystrophy: a childhood cerebral form, an adrenomyeloneuropathy type, and a form called Addison disease only; https://ghr.nlm.nih.gov/condition/x-linked-adrenoleukodystrophy (last accessed March 13, 2017).

[24] Pompe is an inherited disorder with an incidence rate of approximately 1 in 40,000. It is caused by the buildup of a complex sugar called glycogen in the body's cells. The accumulation of glycogen in certain organs and tissues, especially muscles, impairs their ability to function normally; https://ghr.nlm.nih.gov/condition/pompe-disease (last accessed March 13, 2017)>

[25] MPS I is a genetic disorder with two presentations. Severe MPS 1 has an incidence rate of approximately 1 in 100,000 and Attenuated MPS 1 – approximately 1 in 500,000. The disorder causes molecules to build up inside lysomes, which causes tissue and organ enlargement as well as interference with the function of proteins inside the lysomes; https://ghr.nlm.nih.gov/condition/mucopolysaccharidosis-type-i# (last accessed March 13, 2017).

[26] Florida Department of Health, Legislative Budget Request for FY 2017-2018, *D-3A Expenditures by Issue and Appropriation Category*, 2017, pg. 88, available at: http://floridafiscalportal.state.fl.us/Document.aspx?ID=14707&DocType=PDF (last accessed March 11, 2017).

[27] United States Department of Health and Human Services, Secretary's Final Response RE: Committee's Recommendation to add Pompe Disease to the RUSP, March 2, 2015, available at: https://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendations/correspondence/secretaryfinalresponse.pdf (last accessed March 11, 2017); United States Department of Health and Human Services, Secretary's Final Response regarding Committee's Recommendation to add MPS I to the RUSP, February 16, 2016, available at: https://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendations/secretary-final-mpsi-rusp.pdf (last accessed March 11, 2017).

GNSAC advises should be included in the state's screening program. The bill also requires DOH to adopt rules that expand the statewide screening of newborns to include any condition the GNSAC recommends within 18 months if a FDA-approved or a suitable alternative vendor test is available. If no such test exists within the 18-month period, DOH must begin testing as soon as such test becomes available.

The bill requires DOH to adopt rules requiring the GNSAC to consider whether to include a condition in the state's screening program within 1 year of the condition being added to the federal RUSP.

The bill requires DOH to submit a legislative budget request to seek an appropriation to add testing of a condition after the GNSAC recommends the condition be included in the newborn screening program.

The effective date of the bill is July 1, 2017.

B. SECTION DIRECTORY:

**Section 1:** Amends s. 383.14, F.S., relating to screening for metabolic disorders, other hereditary and congenital disorders, and environmental risk factors.
**Section 2:** Provides for an effective date of July 1, 2017.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The bill requires DOH, after the GNSAC recommends a condition be included, to submit a legislative budget request to seek an appropriation to add testing of the condition to the newborn screening program. Therefore, the fiscal impact is indeterminate; however, DOH will need to receive an appropriation before testing for new conditions.

   It is unknown what or how many disorders may be added by the RUSP and recommended by the GNSAC in the future. As a comparison, the most recent added test for ALD requires a recurring appropriation of $1,331,492 (with an FDA-approved test) and two FTEs, which is provided in the House's proposed General Appropriations Act for Fiscal Year 2017-2018. Without an FDA-approved test the cost would be nearly $3,000,000.[28]

   The two most recent disorders added to the state's panel, Severe Combined Immunodeficiency and Critical Congenital Heart Defect, required appropriations of $1,961,450 and $204,922, respectively. The Critical Congenital Heart Defect screen does not require a laboratory component.[29]

   Laboratory fiscal impact can range from $850,000 to $3,000,000 depending on multiple factors, including whether there is an FDA-approved test kit, whether the test will be run on existing platforms, whether the test requires additional instrumentation, and how many additional FTEs will be required.[30]

   According to the Agency for Health Care Administration, Florida Medicaid covers required screenings. AHCA will need to monitor the implementation of the bill as well as any

[28] Supra, FN 19 at pg. 5.
[29] Id.
[30] Id.

recommendations by the GNSAC to add conditions to the NSP panel to determine the fiscal impact. Prior AHCA projections indicate there will be 131,669 newborns in the Medicaid program for Fiscal Year 2016-2017 and 133,275 newborns in in Fiscal Year 2016-2017.[31]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

There is an indeterminate negative fiscal impact to insurance carriers that cover newborn screening, depending on which screenings are added.

D. FISCAL COMMENTS:

## III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to effect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Not Applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

## IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 15, 2017, the Health Quality Subcommittee adopted one amendment and reported the bill favorably as a committee substitute. The amendment required DOH to begin testing for any new condition recommended by the GNSAC within 18 months if a FDA-approved or a suitable alternative vendor test is available. If no such test exists within the 18-month period, DOH must begin testing as soon as such test becomes available. The analysis is drafted to the committee substitute as passed by the Health Quality Subcommittee.

On April 4, 2017, the Health Care Appropriations Subcommittee adopted one amendment and reported the bill favorably as a committee substitute. The amendment requires DOH, after the GNSAC recommends a condition be included, to submit a legislative budget request to seek an appropriation to add testing of the condition to the newborn screening program.

[31] Florida Agency for Health Care Administration, *Agency Analysis for 2015 House Bill 403*, January 22, 2015 (on file with Health Quality Subcommittee).