HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 963 Newborn Screenings
SPONSOR(S): Health Care Appropriations Subcommittee; 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	15 Y, 0 N	Tuszynski	Calamas

SUMMARY ANALYSIS

Newborn screening is a preventive public health program provided in every state 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 U.S. 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. As part of this process, the ACHDNC establishes a list of disorders recommended by the Secretary of HHS for states to screen as part of their state universal newborn screening programs, known as the Recommended Uniform Screening Panel (RUSP).

The Legislature created the Florida Newborn Screening Program (NSP) within the Department of Health (DOH), to promote the screening of all newborns for metabolic, hereditary, and congenital disorders known to result in significant impairment of health or intellect. The NSP currently conducts screenings for 53 disorders. Once a disorder is added to the RUSP, the DOH Genetic and Newborn Screening Advisory Council (GNSAC) reviews the disorder to determine whether to recommend its addition to the NSP panel.

The most recent disorders added to the NSP 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 rules that expand the statewide screening of newborns 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 adopt rules to implement screening 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's inclusion in the federal RUSP. After the GNSAC recommends the addition of a disorder, 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 and Florida Medicaid, 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 provided in every state 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 U.S. 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, the ACHDNC establishes a list of disorders recommended by the Secretary of HHS for states to screen as part of their state universal newborn screening programs, known as the Recommended Uniform Screening Panel (RUSP). Inclusion of a disorder on the RUSP is determined on evidence that supports the potential net benefit of screening, the ability of states to screen for the disorder, and the availability of effective treatments.[4] While the RUSP is a standardized list of disorders supported by the ACHDNC and Secretary of HHS, states ultimately determine what disorders are included in their newborn screening programs.[5]

The RUSP currently recommends screening for 32 core conditions and 26 secondary conditions.[6]

Florida Newborn Screening Program

The Legislature created the Florida Newborn Screening Program (NSP) within the Department of Health (DOH), to promote the screening of all newborns for metabolic, hereditary, and congenital disorders known to result in significant impairment of health or intellect.[7] The NSP also promotes the identification and screening of all newborns in this state and their families for environmental risk factors such as low income, poor education, maternal and family stress, emotional instability, substance

[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] U.S. Department of Health and Human Services, 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 April 14, 2017).
[5] Id.
[6] Id.
[7] S. 383.14(1), F.S.

abuse, and other high-risk conditions associated with increased risk of infant mortality and morbidity to provide early intervention, remediation, and prevention services.[8]

The NSP involves coordination among several entities, including the Bureau of Public Health Laboratories Newborn Screening Laboratory in 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.[9] Health care providers in hospitals, birthing centers, perinatal centers, county health departments, and school health programs provide screening as part of the multilevel NSP screening process that includes a risk assessment for prenatal women, and risk factor analysis and screening for postnatal women and newborns as well as laboratory screening for selected disorders in newborns.[10] The NSP attempts 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.[11] While the NSP attempts to screen all prenatal women and newborns, parents and guardians may decline the screening in writing.[12]

Health care providers perform non-laboratory NSP screening, such as hearing and risk factor analysis, and report the results to the Office of Vital Statistics and, if necessary, make referrals to the appropriate health, education, and social services.[13] Health care providers in hospitals and birthing centers perform specimen collection for laboratory NSP screening by collecting a few drops of blood from the newborn's heel on a standardized specimen collection card.[14] The specimen card is then sent to the state laboratory in Jacksonville for testing, which receives about 1,000 specimens per day from births in Florida.[15] The results of the laboratory test are released to the newborn's healthcare provider. In the event that a newborn screen has an abnormal result, the CMS program provides follow-up services and referrals for the child and his or her family.[16]

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.[17] 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.[18] DOH bills hospitals and birth centers quarterly using vital statistics data to determine the amount to be billed.[19] Statute authorizes DOH to bill third-party payers for the NSP tests; DOH bills

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[8] Id.
[9] Infra. FN 15
[10] Id.
[11] Florida Department of Health, Florida Newborn Screening Guidelines, 2012, available at: https://www.peds.ufl.edu/divisions/genetics/programs/newborn_screening/2012%20newborn%20screening%20guidelines%20FL.pdf (last accessed April 14, 2017).
[12] S. 383.14(4), F.S.; Rule 64C-7.008, F.A.C.; The health care provider must attempt to get a written statement of objection to be placed in the medical record.
[13] Id.
[14] Florida Department of Health, Newborn Screening, http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/ (last accessed April 13, 2017); *Specimen Collection Card,* available at: http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/_images/NBS-bloodspot-card.png (last accessed April 14, 2017).
[15] Florida Department of Health, Newborn Screening, http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/ (last accessed April 13, 2017).
[16] Id.
[17] S. 383.14(3)(g)1., F.S.
[18] Id.
[19] Email from Bryan Wendel, Government Analyst II - Office of Legislative Planning, Florida Department of Health, RE: HB 963, (March 20, 2017).

these insurers directly for the cost of the screening.[20] DOH does not bill families that do not have insurance coverage.[21]

The Legislature established the Florida Genetics and Newborn Screening Advisory Council (GNSAC) to advise DOH about which disorders to include in the NSP panel of screened disorders and the procedures for collecting and transmitting specimens.[22] Florida's NSP currently screens for 50 of the 58 disorders recommended by the RUSP, including 31 core conditions and 28 secondary conditions.[23]

Adding Conditions to the NSP Panel

Before recommending a disorder be added to the NSP panel, the GNSAC considers the recommendations of the ACHDNC and evaluates whether:[24]

- 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.[25] To prepare for the addition of a disorder to the NSP panel, DOH must:[26]

- 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;
- 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).[27]

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[20] S. 383.14(3)(h), F.S.
[21] 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).
[22] S. 383.14(5), F.S.
[23] 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.
[24] Rule 64C-7.007, F.A.C. (2014) (repealed in 2015).
[25] Florida Department of Health, *Agency Analysis of 2017 House Bill 963*, February 22, 2017 (on file with Health Quality Subcommittee).
[26] Supra, FN 25 at pg. 3.

Currently, three disorders on the RUSP are not on the NSP panel:[28]

- X-linked ALD (ALD)[29]
- Glycogen Storage Disease Type II (Pompe)[30]
- Mucupolysacharidosis Type I (MPS I)[31]

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.[32] The RUSP added Pompe and MPS I in March 2, 2015 and February 15, 2016, respectively.[33] 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 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 an FDA-approved or a suitable alternative vendor test is available. If

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[27] 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 25 at pg. 2.

[28] *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).

[29] 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).

[30] 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)>

[31] 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).

[32] 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).

[33] 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).

no such test exists within the 18-month period, DOH must adopt rules to implement screening 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's inclusion in the federal RUSP.

The bill also requires DOH to submit a legislative budget request to seek an appropriation for the costs associated with testing for an additional condition the GNSAC has recommended adding to the NSP panel.

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 in the NSP, to submit a legislative budget request to seek an appropriation to add testing for the condition to the NSP.

   It is unknown what or how many disorders the RUSP may add and be recommended by the GNSAC in the future, or their cost. Therefore, future fiscal impacts are indeterminate. 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.[34] 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.[35] 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.[36]

   According to the Agency for Health Care Administration (AHCA), Florida Medicaid covers required screenings. AHCA will need to monitor the implementation of the bill as well as any 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.[37]

[34] Id.
[35] Supra, FN 25 at pg. 5.
[36] Id.
[37] Florida Agency for Health Care Administration, *Agency Analysis for 2015 House Bill 403*, January 22, 2015 (on file with Health Quality Subcommittee).

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.

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. The analysis is drafted to the committee substitute as passed by the Health Care Appropriations Subcommittee.