

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL: CS/SB 1124

INTRODUCER: Health Policy Committee and Senator Book

SUBJECT: Newborn Screenings

DATE: March 28, 2017

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	Fav/CS
2.			AHS	
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1124 amends s. 383.17, F.S., modifying the Newborn Screening Program to require testing for any condition included in the federal Recommended Uniform Screening Panel (RUSP) and which the Genetics and Newborn Screening Advisory Council (GNSAC) has recommended for inclusion in the state's screening program.

The Department of Health (DOH) is required to expand testing statewide to include newborn screenings for any new conditions within 18 months after the council has made its recommendation for inclusion and if an approved test is available that meets state guidelines. If such a test is not available within 18 months after the council's recommendation, the DOH shall implement the screening as soon as a test offered by the FDA or an alternative vendor is available.

The bill also requires the GNSAC to consider whether a condition should be added to the state's screening program within 1 year after a condition is added to the RUSP.

The immediate fiscal impact to the DOH is \$1,331,492. For the implementation of future disorders, the DOH estimates a cost of \$850,000 to \$3 million per disorder.

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

II. Present Situation:

According to the Association of Maternal and Child Health Programs, nearly all infants born in the United States are screened by state Newborn Screening programs.¹ From these screening programs, approximately 12,500 newborns are diagnosed annually with detectable, treatable disorders.²

Advisory Committee on Heritable Disorders in Children and Newborns

At the federal level, the Secretary of the Department of Health and Human Services' Committee on Heritable Disorders in Children and Newborns (SACHDNC) is tasked with providing the Secretary with recommendations, advice, and technical information on the most appropriate use of technologies, policies, guidelines, and standards for two objectives:

- Effectively reducing morbidity and mortality in newborns and children having or at risk for, heritable disorders; and
- Enhancing the ability of the state and local health agencies to provide for newborn and child screening, counseling, and health care services for newborns and children having, or at risk for, heritable disorders.³

The SACHDNC was re-established in federal law in 2014⁴ and the committee was chartered on May 7, 2015.⁵ The committee is authorized to operate through the end of the 2019 fiscal year.⁶ Up to 15 individuals may serve as an organizational representative on the committee. These organizations represent broad health care interests in public health, primary care, specialty care, consumer and family organizations, and professional societies.⁷ The committee must meet at least four times per year.⁸

The SACHDNC's Nomination and Prioritization Workgroup reviews nominated conditions to decide if sufficient evidence is available for an external evidence review by the Condition Review Workgroup (CRW). The CRW performs an independent, evidence-based review of the

¹ Kate Taft, Association of Maternal and Child Health Programs, *National Newborn Screening Contingency Plan Update* (Presentation to Advisory Committee on Heritable Disorders in Newborns and Children Meeting (Feb. 9, 2017), <https://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/meetings/2017/0209/newbornscreeningconplan.PDF> (last visited Mar. 21, 2017).

² Association of Maternal and Child Health Programs, *Issue Brief: State Newborn Screening and Birth Defects Program Roles in Screening for Critical Congenital Heart Defects (CCHD)* (October 2013), pg. 2, http://www.amchp.org/programsandtopics/CHILD-HEALTH/projects/newborn-screening/Documents/AMCHP_Screening_for_CCHD_Issue_Brief_FINAL-Oct2013.pdf#search=newborn%20screening%20programs%20detectable%20diseases, (last visited Mar. 22, 2017).

³ Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, *2013 Annual Report*, <https://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/reportsrecommendations/reports/heritdisordersnewbornschildrenannualrpt13.pdf> (last visited Mar. 21, 2017).

⁴ Public Health Service Act, Title XI, s. 1111 (42 U.S.C. 300b-10), as amended by P.L. 113-240.

⁵ Advisory Committee on Heritable Disorders in Newborns and Children, <https://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/index.html>, (last visited Mar. 21, 2017).

⁶ Advisory Committee on Heritable Disorders in Newborns and Children, *Charter*, <https://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/about/charterdachdnc.pdf>, (last visited Mar. 21, 2017).

⁷ Advisory Committee on Heritable Disorders in Newborns and Children, *About the Committee*, <https://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/about/index.html>, (last visited Mar. 21, 2017).

⁸ *Supra* note 6.

condition if received to determine the suitability and potential net benefit of screening for the condition.⁹ The review process includes a review of the results of controlled trials, observational studies, case studies, expert opinions, focus groups, cost-effectiveness analysis, policy analysis, and an ethical analysis.

After the CRW completes its review, the SACHDNC votes on whether to recommend the addition of a condition to recommended uniform screening panel (RUSP) to the Secretary. The Secretary makes the final decision on whether or not to add a condition to the RUSP.¹⁰ States make their own determination as to which conditions they will add to their own screening programs.

Currently, the RUSP recommends screening for 32 core disorders and 26 secondary disorders.¹¹ The most recently added disorder to the RUSP was in February 2016, when the Secretary approved the committee's recommendation to add Adrenoleukodystrophy (X-ALD).¹²

Florida Newborn Screening Program

Florida has had a newborn screening program since 1965¹³ and currently screens for 31 core disorders and 22 secondary disorders unless a parent objects in writing. Of these disorders, 50 are included on the RUSP.¹⁴ In Florida, the state's Genetics and Newborn Screening and Advisory Council (GNSAC) advises the DOH on which disorders to include under Florida's screening program.

Before leaving the hospital, a few drops of blood are taken from a baby's heel and the ears are also tested for hearing. Results are sent back to the hospital and then forwarded to the baby's doctor or the doctor can retrieve the results from a provider portal.¹⁵ Children's Medical Services will contact parents for additional testing when there is an abnormal test result.¹⁶

Newborn screenings are funded by billing Medicaid and private insurance for the screening tests and a \$15 fee paid by birthing facilities.¹⁷ Families without insurance or Medicaid coverage are not billed.

⁹ *Id.*

¹⁰ *Id.*

¹¹ Advisory Committee on Heritable Disorders in Newborns and Children, *Recommended Uniform Screening Panel*, <https://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendedpanel/uniformscreeningpanel.pdf> (last visited Mar. 21, 2017).

¹² Letter from Sylvia M. Burwell, Secretary, Health and Human Services, to Joseph A. Bocchini, Jr., M.D., Committee Chairperson, Advisory Committee on Heritable Disorders in Newborns and Children (February 16, 2016), <https://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendations/secretary-final-response-x-ald.pdf>, (last visited Mar. 21, 2017).

¹³ Rick Scott, Proclamation, *Florida's 50th Anniversary of Newborn Screening*, (June 25, 2015) (on file with the Senate Committee on Health Policy).

¹⁴ Department of Health, *Senate Bill 1124 Analysis* (Feb. 22, 2017) (on file with the Senate Committee on Health Policy).

¹⁵ Department of Health, *Newborn Screening* <http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/index.html> (last visited Mar. 21, 2017).

¹⁶ *Id.*

¹⁷ 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 visited Mar. 21, 2017).

The 15-member GNSAC is established within the DOH.¹⁸ The council includes consumer members, pediatricians, medical school representatives, the State Surgeon General, a Florida Hospital Association representative, an individual with experience in newborn screening programs, an individual who represents audiologists, and a representative from the Agency for Persons with Disabilities. The council is directed to meet at least twice per year.

The GNSAC is given three purposes under the statute. The council is to advise the DOH about:

- Conditions for which testing should be included under the screening program and the genetics program;
- Procedures for collecting and transmitting specimens and recording results; and
- Methods to more effectively evaluate, coordinate, and consolidate screening programs and genetics services for children.¹⁹

When the SACHDNC makes a recommendation and adds a disorder to the RUSP, the GNSAC carefully reviews the recommendation to ensure:

- 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 2 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; and
- When screening for a disorder, sufficient pediatric medical infrastructure is available to provide continued services for patients' diagnostic services and medical maintenance.²⁰

Historically, it has taken the DOH a minimum of a year and half to implement a new disorder to the screening panel.²¹ The most recently added disorders, Severe Combined Immunodeficiency and Critical Congenital Heart Defect, took 1 year and 10 months and 2 years and 6 months respectively to add in Florida.²² Currently, there are three disorders on the RUSP that are not on Florida's panel: X-ALD, Pompe, and Muccupolysachariidosis Type I.²³

When the GNSAC recommends adding a new disorder to the state's screening panel, the DOH's newborn screening laboratory prepares a fiscal impact analysis and requests a specific legislative appropriation if funding is needed. When all of the criteria is met, the condition is then added to the screening program.

¹⁸ Section 383.14, F.S.

¹⁹ Section 383.14(5), F.S.

²⁰ *Supra* note 14.

²¹ *Supra* note 14.

²² *Supra* note 14.

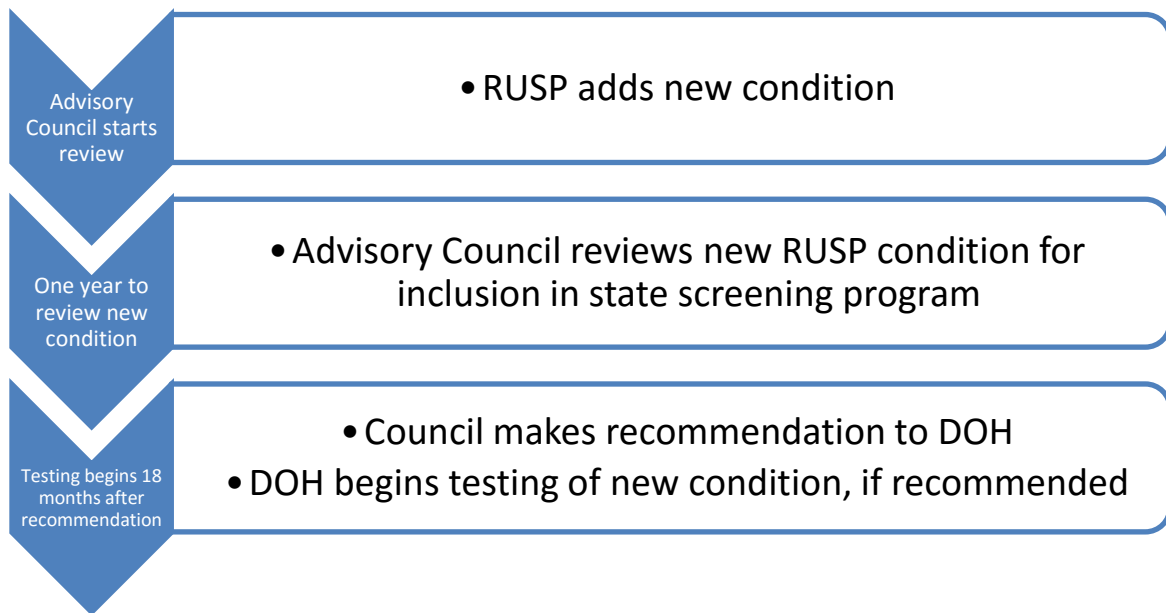
²³ *Supra* note 14.

III. Effect of Proposed Changes:

The bill amends s. 383.14, F.S., modifying the state’s Newborn Screening Program to require the GNSAC to consider conditions included on the federal RUSP and make recommendations to the DOH on which conditions should be included on the state’s Newborn Screening Program. The DOH would also be required to implement any new condition testing within 18 months after the council provides such a recommendation and a test is available that has been approved by the United States Food and Drug Administration (FDA) or an alternative test is offered by an alternative vendor that meets state standards. If such a test is not available within 18 months of a council recommendation, the DOH shall implement the proposed screening as soon as a test is offered by the FDA or by an alternative vendor.

The GNSAC’s mission is updated to include a requirement to review for inclusion in the state’s screening program any new condition that is added to the federal RUSP within 1 year.

The chart below illustrates the review and recommendation process under the bill.



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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. Other Constitutional Issues:

Under this bill, the GNSAC will recommend to the DOH new conditions that should be included on the state's Newborn Screening Program as they are added to the federal RUSP. If this advisory panel makes the recommendation to include this new condition, the DOH is required to expand the screening of that new condition statewide within 18 months of receipt of that recommendation. This might violate the non-delegation doctrine in article 2, section 3 of the Florida Constitution because "fundamental and primary policy decisions must be made by the Legislature."²⁴

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

Private health care providers and facilities may be impacted by any change in testing requirements. Tests for additional conditions may result in more results that will need follow-ups with either additional testing or referrals for specialty care. There may be a need for a supplemental pediatric infrastructure to address the needs of infants and children who are identified through the screening process. In the month of January 2017 alone, the DOH reports in excess of 23,000 newborn screenings.²⁵

For some conditions, FDA approved tests have not yet been developed. Laboratories that can conduct this work with non-FDA tests would be in high demand and would make these non-FDA approved tests available at a high cost to the states.

There may be some long-term cost savings to the health care system as health conditions are caught in the earliest of stages allowing for treatment plans, intervention services, and preventive care to begin as soon as possible.

C. Government Sector Impact:

The DOH is not able to provide an exact fiscal impact; however, for the X-ALD condition which has already been approved by the Secretary of Health and Human Services but has not yet been implemented in Florida, the DOH estimates a fiscal impact of \$1,331,492.²⁶

²⁴ See *Askew v. Cross Key Waterways*, 372 So. 2d 913 (Fla. 1978).

²⁵ Department of Health, *Newborn Screening Program Profile Data (Jan. 1, 2017 - Jan. 31, 2017)*, <http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/documents/January17inprof.pdf>, (last visited Mar. 21, 2017).

²⁶ *Supra* note 14, at 5.

The Public Health Laboratory in Jacksonville has estimated a fiscal impact of \$850,000 to \$3,000,000 per disorder that is added to the panel. The cost range is based on:

- Is the testing kit FDA approved?
- Can the test be run on an existing test's platform?
- Will it require additional instrumentation to perform the test?
- How many additional FTEs will be required? The exact number is unknown and is dependent upon the additional labor required to perform the tests and analyze, interpret, record, review, and report the results.²⁷

VI. Technical Deficiencies:

None.

VII. Related Issues:

Advisory Councils

An “advisory council” is defined in state law as an advisory body created by specific statutory enactment and appointed to function on a continuing basis and appointed to function on a continuing basis for the study of the problems arising in a specified functional or program area of state government and to provide recommendations and policy alternatives.²⁸

This bill authorizes the GNSAC, an advisory council comprised of members appointed by the Governor, President of the Senate, and the Speaker of the House of Representatives, to recommend to the DOH new conditions that should be included in the state’s Newborn Screening Program as they are added to the federal RUSP. If this advisory panel makes the recommendation to include a condition for screening, the DOH is required to expand statewide screening of that new condition within 18 months of receiving that recommendation, if a test is available from the FDA or another alternative source which meets state standards. By requiring the DOH to expand its screening program within 18 months of a recommendation, the GNSAC may be acting in more than an advisory capacity.

Non-Binding Authority

This legislation; however, will be “frozen in time” and only those conditions not currently covered by the state as of the date of enactment would be added to Florida’s screening program. The Florida Supreme Court has held that one legislature cannot bind the actions of a future legislature.²⁹ If the RUSP is updated, this statute must be re-enacted for the new conditions to take effect.

Implementation Costs

According to the DOH, adding a condition to the screening program can cost the state anywhere from \$850,000 to \$3 million. The bill does not include any provision for the costs of adding the

²⁷ *Supra* note 14, at 5.

²⁸ Section 20.03(7), F.S.

²⁹ *Scott v. Williams*, 107 So. 3d 379 (Fla. 2013).

new condition if the advisory council makes a positive recommendation or for making the addition of the new condition subject to a specific appropriation.

Additionally, the DOH has indicated that for the last two new conditions, the quickest the DOH has been able to implement a new test has been 22 months. The bill does not address what happens if the DOH is unable to meet the implementation deadline of 18 months.

VIII. Statutes Affected:

This bill substantially amends section 383.14 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on March 27, 2017:

The DOH is required to expand statewide screening for any conditions within 18 months (rather than within one year) after the council renders their advice to the DOH for additions to the screening panel, if a test approved by the United States Food and Drug Administration (FDA) or a compatible alternative test that meets state guidelines is available. If such a test is not available within 18 months of the council's recommendation, the DOH shall implement the new screening as soon as a test approved by the FDA or an alternative vendor is available.

B. Amendments:

None.