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 Appropriations

BILL:	CS/CS/SB 1124
INTRODUCER:	Appropriations Committee; Health Policy Committee; and Senator Book
SUBJECT:	Newborn Screenings
DATE:	April 14, 2017 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	**Fav/CS**
2.	Loe	Hansen	AP	**Fav/CS**

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/SB 1124 amends section 383.14, Florida Statutes, to require the Department of Health (DOH) to adopt rules requiring every newborn in the state, at the appropriate age, to be tested for any condition included in the federal Recommended Uniform Screening Panel (RUSP) that the Genetics and Newborn Screening Advisory Council (GNSAC) advises should be included in the Newborn Screening Program's (NSP) panel of hereditary and congenital disorders.

The DOH is required to adopt the rules to include any condition the GNSAC recommends within 18 months if a test that has been approved by the United States Food and Drug Administration (FDA), or suitable alternative that meets state guidelines, is available. If such a test is not available within 18 months, the DOH shall implement the screening as soon as such a test becomes available.

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

The bill has no impact on state revenues or expenditures.

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 that meet two objectives:

- Effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders; and
- Enhancing the ability of state and local health agencies to provide 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 2014[4] 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

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[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 to recommend the addition of a condition to the recommended uniform screening panel (RUSP) to the Secretary. The Secretary makes the final decision 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 X-Linked Adrenoleukodystrophy (X-ALD).[12]

Florida Newborn Screening Program

Florida has had a newborn screening program since 1965[13] 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 federal RUSP.[14] In Florida, the state's Genetics and Newborn Screening and Advisory Council (GNSAC) advises the DOH on which disorders to include in Florida's NSP panel.

Before leaving the hospital, a few drops of blood are taken from a baby's heel, and the baby's ears are tested for hearing. Results are sent back to the hospital and forwarded to the baby's doctor, or the doctor can retrieve the results from a provider portal.[15] Children's Medical Services within the DOH 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.

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[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* (Apr. 3, 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 becoming 2 weeks of age, or at the appropriate age as indicated by accepted medical practice;
- 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 one and a half years 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 be included in testing in Florida.[22] Currently, there are three disorders on the RUSP that are not currently screened in Florida: X-ALD, Pompe, and Muccupolysachariidosis Type I.[23]

When the GNSAC recommends adding a new disorder to Florida's NSP 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 are met, the condition is 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.

X-ALD was recommended for inclusion in Florida's NSP panel by the GNSAC on February 19, 2016. Funding to implement screening has been requested through a Legislative Budget Request for Fiscal Year 2017-2018, and statewide screening will commence once a test kit is approved by the FDA that incorporates X-ALD. The test kit has been submitted to the FDA, and the approval is anticipated to be received in early 2018.[24]

III. Effect of Proposed Changes:

The bill amends s. 383.14, F.S., to require the DOH to adopt rules requiring every newborn in the state, at the appropriate age, to be tested for any condition included in the federal RUSP that the GNSAC advises should be included in Florida's NSP panel.

The DOH is required to adopt the rules to include any condition the GNSAC recommends within 18 months if an FDA-approved test, or suitable alternative that meets state guidelines, is available. If such a test is not available within 18 months, the DOH shall implement the proposed screening as soon as a test offered by the FDA or alternative vendor becomes available.

The DOH is also required to adopt rules requiring the GNSAC to consider addition of a condition in the NSP panel within one year after a condition is added to the federal RUSP. After the GNSAC recommends a condition be included, the DOH must submit a legislative budget request to seek an appropriation to add testing of the condition to the NSP panel.

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.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

[24] Department of Health, *Senate Bill 1124 Analysis* (Apr. 3, 2017) (on file with the Senate Committee on Health Policy).

B. Private Sector Impact:

Private health care providers, insurance carriers, and facilities may experience a negative fiscal impact depending on which conditions are added to the NSP panel that may need follow-ups with either additional testing or referrals for specialty care.

C. Government Sector Impact:

The bill has no impact on state revenues or expenditures.

The DOH is required – after receiving a recommendation from the GNSAC to add a new condition to the NSP panel – to submit a legislative budget request to seek an appropriation to add testing of the condition to the NSP panel.

The type or amount of conditions that will be added in the future by the RUSP and recommended by the GNSAC is unknown; however, for the X-ALD condition recently approved by the Secretary of Health and Human Services but awaiting implementation in Florida, the DOH estimates the additional costs to be $1,331,492 annually.[25] SB 2500, the Senate General Appropriations Act for Fiscal Year 2017-2018, includes an appropriation for this purpose. These costs will be funded from amounts appropriated for the Newborn Screening Program within the DOH's Division of Children's Medical Services.

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

- Whether the testing kit has been approved by the FDA;
- Whether the test can be run on an existing test's platform;
- Whether additional instrumentation will be required to perform the test; and
- The additional workload required to implement testing of the new condition. The exact amount is unknown and dependent upon the additional labor required to perform the tests and analyze, interpret, record, review, and report the results.[26]

VI. Technical Deficiencies:

None.

VII. Related Issues:

Implementation

The DOH has indicated that for the last two conditions added to the newborn screening panel, the earliest 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.

[25] *Supra* note 14, at 5.
[26] *Supra* note 14, at 5.

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/CS by Appropriations Committee on April 13, 2017:
After the GNSAC recommends a condition be included, the DOH must submit a legislative budget request to seek an appropriation to add testing of the condition to the NSP panel.

CS by Health Policy on March 27, 2017:
The DOH is required to expand statewide screening for any condition within 18 months (rather than one year) after the council renders its 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.