

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 632

INTRODUCER: Health Policy Committee and Senator Garcia

SUBJECT: Newborn Adrenoleukodystrophy Screening

DATE: March 23, 2015 REVISED: _____

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 632 directs the Department of Health (department) to adopt rules to require newborns to be tested for adrenoleukodystrophy (ALD) as soon as ALD is adopted on the federal Recommended Uniform Screening Panel.

Once ADL screening is added by rule, the Agency for Health Care Administration (agency) reports a negative first year fiscal impact of \$2,146,344 and the department an additional negative impact of \$2,683,100 to implement the screening.

II. Present Situation:

What is Adrenoleukodystrophy?

Adrenoleukodystrophy (ALD) is a genetic disorder that damages myelin, the sheath that surrounds the brain's neurons. The disorder affects approximately 1 in 18,000 people with the most devastating form appearing in childhood.¹ Women have two X chromosomes and are the carriers of the disease, but since men only have one X chromosome, they are more severely affected by the disorder.² While nearly all patients with the disorder suffer from adrenal

¹ The Stop ALD Foundation, *What is ALD?* <http://www.stopald.org/what-is-ald/> (last visited: Mar. 19, 2015).

² The Cleveland Clinic, *Diseases and Conditions - Adrenoleukodystrophy (ALD)*, http://my.clevelandclinic.org/health/diseases_conditions/hic_What_is_Adrenoleukodystrophy (last visited Mar. 19, 2015).

insufficiency, also known as Addison's disease,³ the neurological symptoms can begin in either childhood or in adulthood.⁴ The most common symptoms for children include behavioral changes such as abnormal withdrawal or aggression, memory loss, and drops in school performance.⁵ Later symptoms might include: visual loss, learning disabilities, seizures, speech problems, swallowing difficulties, deafness, coordination issues, fatigue, and progressive dementia. Women may develop symptoms, but they usually experience milder forms of the disorder than those seen in boys and men.⁶

Federal Recommendations for Newborn Screening

The United States Department of Health and Human Services Advisory Committee on Heritable Disorders in Newborns and Children (DACHDNC) develops recommendations on the most appropriate policies, guidelines and standards for universal newborn screening tests. The Secretary of the Department of Health and Human Services (HHS) established the Secretary's Advisory Committee (committee) to reduce morbidity and mortality in newborns who have, or are at risk, for heritable diseases.⁷

The committee has established a Uniform Screening Panel that screens for 31 core disorders and 26 secondary disorders and recommends every state incorporate this panel into their screening program.⁸ Additional conditions may be nominated for inclusion on the Recommended Uniform Screening Panel (RUSP). A Nomination and Prioritization Workgroup reviews the nomination and decides if there is sufficient information for the condition to move on to the Condition Review Workgroup which is responsible for the final report to the DACHDNC.

ALD was nominated in 2012 for inclusion on the RUSP, but was not forwarded to the Condition Review Workgroup based on lack of sufficient data.⁹ At the January 2014 meeting, ALD was again nominated and a preliminary report from the Condition Review Workgroup was presented on February 12, 2015.¹⁰ A decision from that meeting is not yet available.

The HHS Secretary makes the final decision as to whether or not a condition is added to the RUSP.¹¹

³ Addison's disease is a disorder of the adrenal glands. In Addison's, the glands produce an insufficient level of the hormone which controls the body's levels of sugar, sodium, and potassium. *see Supra* note 1.

⁴ *Supra*, note 2.

⁵ *Id.*

⁶ *Id.*

⁷ U.S. Department of Health and Human Services, *Advisory Committee on Heritable Disorders in Newborns and Children*, <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/> (last visited Mar. 19, 2015).

⁸ *Id.*

⁹ U.S. Department of Health and Human Services, *Letter to Charles Peters, M.D. and Amber Salzman, Ph.D.*, (October 1, 2012), <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/nominatecondition/reviews/alddecisionletter.pdf> (last visited Mar. 19, 2015).

¹⁰ Alex R. Kemper, M.D., M.P.H., M.S., Duke Clinical Research Institute, *Newborn Screening for X-Linked Adrenoleukodystrophy (X-ALD): Preliminary Report from the Condition Review Workgroup*, (February 12, 2015) <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/meetings/2015/sixth/crupdatealdkemper2.pdf> (last visited Mar. 19, 2015).

¹¹ U.S. Department of Health and Human Services, *Advisory Committee on Heritable Disorders in Newborns and Children, Nominate a Condition*,

Florida Newborn Screening Program

Section 383.14, F.S., directs the department to conduct newborn screenings for metabolic, hereditary, and congenital disorders that result in the significant impairment of health or intellect, as programs that are accepted by current medical practice become available. Today, the Florida Newborn Screening Program screens for 31 core conditions and 22 secondary conditions, including all disorders recommended by committee and that have been added to the RUSP.¹² For the month of January 2015 only, more than 21,000 newborns were screened under the current program, with the majority of those occurring in a hospital setting.¹³ For non-newborn intensive care patients, the age requirement for the screening collection is at least 24 hours of age.¹⁴ Any parent's refusal to screening must be in writing and noted in the record. The screenings are funded through the billing of Medicaid and private insurance and a \$15 fee paid by birthing facilities for each live birth. Uninsured families are not billed.

The Florida Genetics and Newborn Screening Advisory Council (advisory council) is established under s. 383.14, F.S., and its responsibilities include advising the department about:

- 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 now provided or proposed to be offered in this state may be more efficiently evaluated, coordinated, and consolidated.¹⁵

According to the department, the advisory council reviews each DACHDNC recommendation using its own criteria before adding a new screening to Florida's program. Those considerations include:

- 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 infants' becoming 2 weeks of age, or at the appropriate age as accepted medical practice indicates; or
- 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.¹⁶

<http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/nominatecondition/index.html> (last visited Mar. 19, 2015).

¹² Department of Health, *Disorder List*, <http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/nbs-disorder.html> (last visited Mar. 19, 2015).

¹³ Department of Health, *Newborn Screening Program Profile Data*, <http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/documents/jan15infprof.pdf> (last visited Mar. 19, 2015).

¹⁴ Department of Health, *Hospitals*, <http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/nbs-hosp.html> (last viewed Mar. 19, 2015).

¹⁵ Section 318.14(5), F.S.

¹⁶ Department of Health, *Senate Bill 632 Analysis* (January 28, 2015) pg. 3, (on file with Senate Committee on Health Policy).

As of January 2015, ALD has not been added to the Florida Newborn Screening panel of disorders.

III. Effect of Proposed Changes:

CS/SB 632 amends s. 383.14, F.S., to direct the department to adopt rules to require newborns to be screened before one week of age for adrenoleukodystrophy (ALD), a genetic disorder, as soon as ALD is adopted for inclusion on the federal Recommended Uniform Screening Panel. This disorder is not currently screened.

It is uncertain when ALD will be included on the federal Recommended Uniform Screening Panel. When the department does add ALD screening to the list of disorders or diseases for which newborns must be screened, budget authority to cover the costs of conducting additional tests would be required. If the Legislature does not provide this budget authority, it is unlikely that the act can be implemented.

The bill provides an effective date of July 1, 2015.

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.

B. Private Sector Impact:

The cost to the private sector is indeterminate. Those that are insured and have coverage for the current newborn screenings may or may not see an increase related to the additional screening once implemented. As initially filed, the agency estimated the cost of the screening to be \$16.50 per newborn at the current Medicaid rate and the

department estimated the cost at \$18.91 at the current Medicare rate.^{17,18} Over 21,000 births were recorded in Florida in January 2015 and of those approximately 50 percent were likely covered under Medicaid and the remainder through either the private sector or uninsured.¹⁹

Depending on when the ALD is added to the RUSP, the fiscal impact could be higher or lower to the private sector.

C. Government Sector Impact:

The Legislature must decide whether to fund the fiscal impact related to the implementation of CS/SB 632 once the ALD screening is added to the RUSP. The following estimates assume an appropriation has been provided.

Agency for Health Care Administration²⁰

The agency will incur on-going costs to add the ALD screening for Medicaid newborns once it is added to the RUSP.

Annual screening costs were based on the current unit cost of \$16.50 and the estimated number of Medicaid newborns. The estimated number of Medicaid newborns was increased each year by 1.22 percent which is the most recent increase rate from the Florida Vital Statistics Annual Report.

| Agency for Health Care Administration - Fiscal Impact | | |
|--|------------------------------|--------------------|
| SFY 2015-2016 | FED/STATE | COSTS |
| Federal | 60.51% | \$1,298,753 |
| State | 39.49% | \$847,591 |
| TOTAL: | Medicaid Newborns 131,081 | \$2,146,344 |
| SFY 2016-17 | | |
| | FED/STATE | COSTS |
| Federal | 61.18% | \$1,329,154 |
| State | 38.82% | \$843,376 |
| TOTAL: | Medicaid Newborns 131,669 | \$2,172,531 |
| SFY 2017-18 | | |
| | FED/STATE | COSTS |
| Federal | 61.41% | \$1,350,424 |
| State | 848,605% | \$848,6605 |
| TOTAL: | Medicaid Newborns | \$2,199,029 |

¹⁷ Agency for Health Care Administration, *House Bill 403 Analysis* (January 22, 2015) p.5, (on file with the Senate Committee on Health Policy).

¹⁸ Department of Health, *Senate Bill 632 Analysis* (January 28, 2015) pg. 5, (on file with the Senate Committee on Health Policy).

¹⁹ Department of Health, Division of Public Health Statistics and Performance Management, *Births Covered by Medicaid - 2013*, <http://www.floridacharts.com/charts/DataViewer/BirthViewer/BirthViewer.aspx?cid=595> (last viewed Mar. 19, 2015).

²⁰ Agency for Health Care Administration, *House Bill 403 Analysis*, (January 22, 2015) pg.5, (on file with the Senate Committee on Health Policy).

| Agency for Health Care Administration - Fiscal Impact | | |
|---|-----------|-------|
| SFY 2015-2016 | FED/STATE | COSTS |
| | 133,275 | |

Department of Health²¹

Revenues

The Department of Health projects revenues of \$567,300 to \$850,950 based on collections paid for the additional screening at the current Medicare rate of \$18.91 for CPT code 82016.

| <i>Expenditures</i> | Costs |
|--|-------------|
| Newborn Screening Laboratory 300,000 specimens (\$8.50/specimen) each year <i>The price is based on the analysis being performed using the laboratory set up inside the Bureau of Public Health Laboratories facility. When the test for ALD becomes commercially available (12 to 18 months), it will be added to existing test kits and the ALD marker can be tested with the other disorders.</i> | \$2,550,000 |
| Newborn Screening Follow-Up Program <i>Non-recurring funds needed to incorporate the ALD screening and follow-up actions for handling modifications to the existing data system</i> | \$50,000 |
| Newborn Screening Genetic Centers 3 Genetic Centers (\$27,000/centers/year) <i>The centers are located at the University of Miami, the University of South Florida, and the University of Florida and would handle the presumptively positive results and provide diagnostic evaluation.</i> | \$83,100 |

The fiscal impact amount could increase or decrease based on the actual date that ALD is added to the RUSP.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Under the original bill, the department reported that the July 1, 2015 effective date would be difficult to meet. It is unclear how the department would prepare for an unknown implementation date for which the department has indicated requires significant preparation prior to implementation. The department must also make database changes.

The committee substitute requires an appropriation for increased Medicaid services, implementation and ongoing operations. The bill requires expansion of the screening as soon as the screening is adopted for inclusion on the federal panel. If the adoption occurs during a fiscal

²¹ Department of Health, *Senate Bill 632 Analysis* (January 28, 2015), pgs. 5-6, (on file with the Senate Committee on Health Policy).

year where no funding has been provided for this contingency, it is unclear how the department and the agency would comply with the statutory requirements.

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 23, 2015:

The committee substitute:

- Removed requirement for the department to adopt rules requiring newborns receive ALD testing effective July 1, 2015;
- Removed mandated insurance coverage and Medicaid coverage requirements for ALD newborn screening; and
- Expands statewide screening for ALD as soon as ALD screening is adopted for inclusion on the federal Recommended Uniform Screening Panel.

- B. **Amendments:**

None.