

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: SB 632

INTRODUCER: Senator Garcia

SUBJECT: Newborn Adrenoleukodystrophy Screening

DATE: March 19, 2015

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	Pre-meeting
2.			BI	
3.			AP	

I. Summary:

SB 632 directs the Department of Health (department) to adopt rules requiring newborns receive adrenoleukodystrophy (ADL) testing effective July 1, 2015. ADL newborn screening is mandated coverage for Medicaid recipients and for those privately insured under ss. 627.6416, 627.6579, and 641.31(30), F.S., with a few exceptions. A newborn's parent or legal guardian may object in writing to the screening.

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.

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 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

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

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.

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

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

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 funding 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

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

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).

III. Effect of Proposed Changes:

SB 632 creates s. 383.147, F.S., which directs the department to adopt rules requiring that newborns be screened for adrenoleukodystrophy (ADL), a genetic disorder that is not currently screened. Definitions specific for this section are also created.

Licensed hospitals, birth centers, or attending health care providers may release the results of the ADL screening directly or through the Children's Medical Services program to the newborn's primary care physician.

A licensed hospital, birth center, or health care provider at a home birth must either provide or refer an ADL screening for a newborn within 24 after birth or admittance to the hospital, but before discharge. Each hospital and birth center is also required to designate a lead physician or health care provider. The individual has programmatic oversight of referrals and completion of the ADL screenings.

The timing of the blood collection under SB 632 may create two separate blood collection schedules with the current newborn screening process. The bloodspot specimen is currently collected for all other disorders after 24 hours of age, not prior to 24 hours of age, according to the department.

The bill mandates insurance coverage for the initial newborn ADL screening under Medicaid and health insurance policies and health maintenance organizations, as provided under ss. 627.6416, 627.6579, and 641.31(30), F.S., with a few exceptions.

Medicaid managed care providers are to be reimbursed directly by the Medicaid program office and would not be covered by the managed care plans for this screening under the bill. However, the cost of collection is already covered by the managed care plans in their capitation rates, so any additional reimbursement would be a duplication of services. It would also mean that the department would have a bifurcated billing process; it would bill the Medicaid health plan for screening the 53 conditions currently required by law and would bill Medicaid directly for the ALD screening.

The bill requires Florida Medicaid to reimburse for this screening separately from the hospital's per diem reimbursement for recipients not enrolled in a Medicaid managed care plan. Since the hospital is already being reimbursed through Medicaid's DRG methodology for the collection of a blood specimen for the existing newborn screening tests, a separate reimbursement for this screening may also result in duplicative payments.

Additionally, the bill references reimbursement for coverage under the Medipass program which no longer exists.

The parent or legal guardian of the newborn may object to the screening. If the parent or legal guardian objects, that objection must be in writing and signed by the parent or guardian with a record maintained.

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. The agency estimated the cost of the screening to be \$16.50 per newborn at the Medicaid rate and the department estimated the cost at \$18.91 at the 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

C. Government Sector Impact:

Agency for Health Care Administration²⁰

The agency will incur on-going costs to add the ADL screening for Medicaid newborns.

Annual screening costs were based on a 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.

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
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 133,275	\$2,199,029

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 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

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

VI. Technical Deficiencies:

On line 63, the bill refers to the Medipass program which is no longer a Medicaid coverage option.

VII. Related Issues:

Unlike other newborn screening requirements in state law, SB 632, makes several references to a newborn's primary care physician or referring a newborn to a physician licensed under ch 458 or ch. 459, F.S. Other newborn screening statutes, such as s. 383.14, F.S., permit release of results to a wider range of primary care providers, including physician assistants, advanced registered nurse practitioners, registered nurses, licensed practical nurses, or midwives.

The department has reported that the July 1, 2015 effective date would be difficult to meet. Two blood collection schedules must be implemented to meet the different time standards and the department must also make database changes, additional time is needed for implementation.

VIII. Statutes Affected:

This bill creates the following section of the Florida Statutes: 383.147, Florida Statutes.

IX. Additional Information:**A. Committee Substitute – Statement of Changes:**

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

None.

B. Amendments:

None.