

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 403 Newborn Adrenoleukodystrophy Screening/Gabriel's Law

SPONSOR(S): La Rosa

TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Langston	O'Callaghan
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Newborn screening is a preventive public health program that is provided in every state in the United States 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 Department of Health (DOH) is responsible for administering the statewide Newborn Screening Program, which conducts screenings for 53 disorders.

Adrenoleukodystrophy (ALD) is a genetically determined neurological disorder that affects 1 in every 17,900 boys worldwide. ALD strips away of the fatty coating that keeps nerve pulses confined and maintains the integrity of nerve signals. This process causes neurological deficits, including visual disturbances, auditory discrimination, impaired coordination, dementia, and seizures.

The bill creates s. 383.147, F.S., for the purpose of directing the Department of Health to establish requirements and adopt rules for screening for ALD as part of the Florida Newborn Screening Program (NSP). Currently, screening for ALD is not included in the mandatory list of conditions that are required for newborn screening.

The bill requires that providers of maternity and newborn services including hospitals, birth centers, and health care providers who perform home births perform the screening or refer newborns for ALD screening within 24 hours after birth. The bill requires that each hospital designate a lead physician to oversee ALD screening, and that birth centers must designate a licensed health care provider to oversee referrals for ALD screening. The ALD screening is required to be covered or reimbursed by most insurance plans and Medicaid.

The bill also provides that parents may opt-out of an ALD screening for their child by filing out a written objection.

The bill will have a significant negative fiscal impact on DOH and no fiscal impact on local government.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Adrenoleukodystrophy (ALD)

Adrenoleukodystrophy (ALD) is a genetically determined neurological disorder that affects 1 in every 17,900 boys worldwide. The presentation of symptoms occurs somewhere between the ages of 4 and 10, and affects the brain with demyelination. Demyelination is the stripping away of the fatty coating that keeps nerve pulses confined and maintains the integrity of nerve signals. This process inhibits the nerves ability to conduct properly, thereby causing neurological deficits, including visual disturbances, auditory discrimination, impaired coordination, dementia, and seizures. Demyelination is an inflammatory response and nerve cells throughout the brain are destroyed.¹

Screening for ALD

ALD was first nominated to the United States Department of Health and Human Services (HHS) Secretary's Advisory Committee on Heritable Disorders and Children (SACHDNC) in 2012. The Discretionary Advisory Committee on Heritable Disorders in Newborns and Children (DACHDNC) was established under the Public Health Service Act² and will fulfill the functions previously undertaken by the former SACHDNC.³ The mission of the DACHDNC is to reduce morbidity and mortality in newborns and children who have, or are at risk for, heritable disorders.⁴ To that end, the DACHDNC provides advice to the Secretary of HHS about aspects of newborn and childhood screening and technical information for the development of policies and priorities that will enhance 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.⁵

When ALD was initially referred, the SACHDNC's decision after a formal review process was to not send the nomination forward to the external condition review group because sufficient prospective data was not yet available from a large pilot study at the Mayo Biochemical Genetics Laboratory.⁶

ALD was again nominated for consideration in September 2013. Then at a January 2014 meeting of the SACHDNC, the Advisory Committee then recommended a full evidence review of ALD and requested the External Evidence Review Group to present a full report to the DACHDNC. There was a preliminary report presented on February 12, 2015, however a recommendation was not made at that time.⁷ If the Advisory Committee recommends ALD to be added to the Recommended Uniform

¹ Adrenoleukodystrophy Foundation, *ALD Information*, http://aldfoundation.org/ald_info.html (last visited March 13, 2015).

² 42 U.S.C. 217a: Advisory councils or committees (2014).

³ U.S. Department of Health and Human Services, *Discretionary Advisory Committee on Heritable Disorders in Newborns and Children*, <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/index.html> (last visited March 13, 2015)

⁴ Id.

⁵ 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>

⁶ U.S. Department of Health and Human Services, *Letter of Secretary's Advisory Committee on Heritable Disorders in Newborns and Children*, October 1, 2012, available at

<http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/nominatecondition/reviews/alddecisionletter.pdf>

⁷ Alex R. Kemper, *Newborn Screening for X-linked Adrenoleukodystrophy (X-ALD): Preliminary Report from the Condition Review Workgroup (CRW)*, February 12, 2015, available at

<http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/meetings/2015/sixth/crupdatealdkemper2.pdf> (PowerPoint on file with Health Quality Subcommittee)

Screening Panel (RUSP), their recommendation will be submitted in writing to the HHS Secretary who will have final approval before the condition is added to the RUSP.⁸

As of January 2015, ALD has not been recommended to the Florida Genetics and Newborn Screening Advisory Council for consideration to be added to the Florida Newborn Screening panel of disorders. ALD is currently screened for in Connecticut, New Jersey, and New York, and in 2014 legislation was proposed in California and Maryland.⁹

Florida Newborn Screening Program

Newborn screening is a preventive public health program that is provided in every state in the United States. Florida's Newborn Screening Program (NSP) currently screens for all disorders recommended by the SACHDNC that have been added to the RUSP by the Secretary for HHS.¹⁰

Section 383.14 (5), F.S., establishes the Florida Genetics and Newborn Screening Advisory Council with the purpose to advise the Department of Health (DOH) about conditions for which testing should be included for the NSP and the procedures for collection and transmission of specimens.

The intent of the NSP is 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 development and physical damage or death.¹¹ The NSP is a comprehensive system involving coordination among several entities, including the Bureau of Laboratories Newborn Screening Laboratory in Jacksonville, Children's Medical Services (CMS) Newborn Screening Follow-up Program in Tallahassee, and referral centers throughout the state. The NSP screens for 31 core conditions and 22 secondary conditions (a total of 53 conditions), 50 of which are included in the Recommended Uniform Screening Panel that is recommended by the SACHDNC.¹²

In Florida, the specimen card is sent to the DOH Newborn Screening Laboratory (DOH State Laboratory) in Jacksonville for testing. The DOH State Laboratory receives about 250,000 specimens annually from babies born in Florida. The majority of the test results are reported within 24 to 48 hours. The CMS program, within DOH, provides follow-up services for all abnormal screening results.

Medicaid Reimbursement for Screening

Medicaid is required, under s. 383.14, F.S., to reimburse costs associated with this screening.¹³ For newborns who receive Medicaid services through a fee-for-service system, Medicaid reimburses the hospital on a Diagnosis Related Group methodology (DRG), and the cost for blood collection for the newborn screening is included in the DRG reimbursement.¹⁴ Medicaid reimburses the DOH State Laboratory for the blood tests as fee-for-service.¹⁵ For newborns enrolled in a Statewide Medicaid Managed Care Managed Medical Assistance (MMA) plan, the cost of this newborn screening is included in the health plans' capitation rate, and the health plan reimburses the hospital and the DOH

⁸ Florida Department of Health, *2015 Agency Legislative Bill Analysis HB 403*, January 28, 2015 (on file with Health Quality Subcommittee).

⁹ Alex R. Kemper, *Newborn Screening for X-linked Adrenoleukodystrophy (X-ALD): Preliminary Report from the Condition Review Workgroup (CRW)*, February 12, 2015, available at <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/meetings/2015/sixth/crupupdatealdkemper2.pdf> (PowerPoint on file with Health Quality Subcommittee).

¹⁰ Id.

¹¹ Florida Department of Health, *2014 Agency Legislative Bill Analysis HB 591*, January 14, 2014 (on file with Health Quality Subcommittee).

¹² Florida Department of Health, *Disorder List*, available at http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/_documents/newborn-screening-disorders.pdf; this list is also maintained by DOH in Rule Rule 64C-7.002, F.A.C.

¹³ Florida Agency for Health Care Administration, *2015 Agency Legislative Bill Analysis HB 403*, January 22, 2015 (on file with Health Quality Subcommittee).

¹⁴ Id.

¹⁵ Id.

State Laboratory for the newborn screening in accordance with the contracts it has with those providers.¹⁶

Effect of Proposed Changes

The bill creates s. 383.147, F.S., entitled “Gabriel’s Law.” It defines “adrenoleukodystrophy (ALD) screening” as a test administered to newborns to identify the presence of ALD.

The bill requires that the ALD screening must be administered by hospitals within 24 hours after birth. The bill also requires that a licensed birth center or a health care provider responsible for home births refer the newborn to a physician within 24 hours after birth. It also requires that the results be reported to the newborn’s primary care physician.

Newborn screening usually takes place before a newborn leaves the hospital. Most tests use a few drops of blood from pricking the baby’s heel. The bloodspot specimen is placed on a special filter paper then sent off for testing. ALD would be screened for in this manner.¹⁷ However, all other diseases that are currently screened in this manner are collected after the newborn is 24 hours of age and has been on protein feed for 24 hours.¹⁸ Requiring the ALD screening completed before the others would result in duplicative testing for the newborn. Currently, only the hearing screening test is recommended to be administered to a newborn prior to 24 hours of age.¹⁹

The bill also requires designated staff within the hospital and birthing center to be responsible for oversight and monitoring; a physician must be designated at each hospital and a licensed health care provider must be designated at each birthing center.

Additionally, the bill requires insurance coverage of ALD screening. It requires the ALD screening to be covered or reimbursed by most insurance plans, with a few exceptions, and Medicaid. 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 would result in two separate payments.²⁰

The bill also establishes coverage and reimbursement requirements for Medicaid recipients enrolled in a managed care plan. For this screening test, health care providers would be reimbursed directly by Medicaid on a fee-for-service basis and the test would not be covered by the MMA plans. The DOH Newborn Screening Laboratory in Jacksonville would have a bifurcated billing process; it would bill the Medicaid health plan for screening for the 53 conditions currently required by law and would bill Medicaid directly for the ALD screening.²¹

The bill permits the parent or legal guardian of the newborn to decline the screening test for their newborn by filing out a written objection, which must be maintained by the physician or other individual attending the newborn.

The effective date of the bill is July 1, 2015.

B. SECTION DIRECTORY:

¹⁶ Id.

¹⁷ Alex R. Kemper, *Newborn Screening for X-linked Adrenoleukodystrophy (X-ALD): Preliminary Report from the Condition Review Workgroup (CRW)*, February 12, 2015, available at <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/meetings/2015/sixth/crupdatealdkemper2.pdf> (PowerPoint on file with Health Quality Subcommittee).

¹⁸ Florida Department of Health, *2015 Agency Legislative Bill Analysis HB 403*, January 28, 2015 (on file with Health Quality Subcommittee).

¹⁹ Id.

²⁰ Florida Agency for Health Care Administration, *2015 Agency Legislative Bill Analysis HB 403*, January 22, 2015 (on file with Health Quality Subcommittee).

²¹ Id.

Section 1: Creates s. 383.147, F.S., relating to newborn adrenoleukodystrophy screening and insurance coverage thereof.

Section 2: Provides an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill will have a significant negative fiscal impact on AHCA for newborns covered under Florida Medicaid:

Fiscal Year	Medicaid Newborns	Increased Cost
2015-2016	130,081	\$2,146,344
2016-2017	131,669	\$2,182,531
2017-2018	133,275	\$2,199,029

Annual screening costs were determined by multiplying the unit cost per the CPT Code of \$16.50 and the estimated number of Medicaid newborns each year. The estimated annual total number of newborns based on the Florida Vital Statistics Annual Report 2013 was 215,194, of which 59% was Medicaid newborns (126,964) and increases by 1.22% each year.²²

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Individuals who only maintain a supplemental health policy would be required to pay for the ALD screening out-of-pocket, unless they opt out of the screening.

D. FISCAL COMMENTS:

None.

²² Id.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to affect county or municipal governments

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill requires DOH to adopt rules related to newborn screening requirements for this disease. DOH maintains Rule 64C-7.002, F.A.C., which includes the list of congenital conditions/diseases for which newborns are screened and when the blood specimen is to be collected; this rule would need to be amended to include screening for ALD.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES