

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1293 Newborn Adrenoleukodystrophy Screening

SPONSOR(S): Health Quality Subcommittee, La Rosa and others

TIED BILLS: **IDEN./SIM. BILLS:** SB 1640

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	9 Y, 0 N, As CS	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 United States Department of Health and Human Services (HHS) Discretionary Advisory Committee on Heritable Disorders in Newborns and Children (DACHDNC) advises HHS on the most appropriate application of universal newborn screening tests, technologies, policies, guidelines and standards. DACHDNC establishes the heritable disorders listed on the federal Recommended Uniform Screening Panel (RUSP).

In Florida, the Department of Health (DOH) is responsible for administering the statewide Newborn Screening Program (NSP), which conducts screenings for 53 disorders. Once a heritable disorder is added to the RUSP, it is reviewed by the DOH Newborn Screening Advisory Council, which recommends to DOH whether the disorder should be added to the NSP panel of disorders to be screened for in Florida.

Adrenoleukodystrophy (ALD) is a genetically determined neurological disorder that affects one in every 17,900 boys worldwide. ALD strips away 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. To date, ALD has not been added to the RUSP and is not on the NSP's panel of disorders that are required for newborn screening.

HB 1293 requires DOH to expand statewide newborn screening to include screening for ALD within one year after it is added to the RUSP.

The bill will have a significant negative fiscal impact on DOH and the Agency for Health Care Administration if screening for ALD is added to the RUSP, and no fiscal impact on local government.

The bill provides an effective date of July 1, 2016.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Federal Recommendations for Newborn Screening

The United States Department of Health and Human Services (HHS) Discretionary Advisory Committee on Heritable Disorders in Newborns and Children (DACHDNC), under the Public Health Service Act,¹ fulfills the functions previously undertaken by the former Secretary's Advisory Committee on Heritable Disorders and Children (SACHDNC),² to reduce morbidity and mortality in newborns and children who have, or are at risk for, heritable disorders.³ To that end, the DACHDNC advises the Secretary of HHS the most appropriate application of universal newborn and child screening tests and technical information for the development of policies and priorities that will enhance the ability of state and local health agencies to provide for screening, counseling, and health care services for newborns and children having, or at risk for, heritable disorders.⁴ If the DACHDNC recommends the inclusion of a screening to the RUSP, its recommendation must be submitted in writing to the HHS Secretary, who will have final approval before the condition is added to the RUSP.

As part of this process, DACHDNC establishes the heritable disorders listed on the federal Recommended Uniform Screening Panel (RUSP). The RUSP currently provides 32 core conditions and 26 secondary conditions.⁵

Florida Newborn Screening Program

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 which disorders should be screened for under the Newborn Screening Program (NSP) and the procedures for collection and transmission of specimens. Florida's NSP currently screens for all disorders that are included on the RUSP.⁶

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 developmental and physical damage or death.⁷ Before a disorder is added to the NSP, the Genetics and Newborn Screening Advisory Council considers the SACHDNC's recommendation to ensure that the disorder would meet the following criteria:

- The disorder causes significant impairment in health, intellect, or functional ability, if not treated before clinical signs appear;
- The disorder can be detected using accepted screening methods;
- The disorder can be detected prior to two weeks of age, or at the appropriate age as accepted medical practice indicates; and
- After screening for the disorder, reasonable cost benefits can be anticipated.⁸

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

² 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 January 28, 2016).

³ Id.

⁴ 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> (last visited January 28, 2016).

⁵ Discretionary Advisory Committee on Heritable Disorders in Newborns and Children, *Recommended Uniform Screening Panel (as of March 2015)*, available at <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendedpanel/uniformscreeningpanel.pdf> (last visited January 28, 2016).

⁶ Id.

⁷ Florida Department of Health, *Agency Analysis of 2014 House Bill 591*, January 14, 2014 (on file with Health Quality Subcommittee).

⁸ S. 383.14(5), F.S.

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 all core conditions and 22 secondary conditions (a total of 53 conditions); this includes all of the core conditions recommended by the RUSP and 50 of their recommendations overall.⁹

In Florida, once the screening takes place, 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.

Adrenoleukodystrophy (ALD)

Adrenoleukodystrophy (ALD) is a genetically determined neurological disorder that affects one in every 17,900 boys worldwide¹⁰. The presentation of symptoms occurs somewhere between the ages of 4 and 10, and affects the brain with demyelination.¹¹ Demyelination is the stripping away of the fatty coating that keeps nerve pulses confined and maintains the integrity of nerve signals.¹² This process inhibits the nerves ability to conduct properly, thereby causing neurological deficits, including visual disturbances, auditory discrimination, impaired coordination, dementia, and seizures.¹³ Demyelination is an inflammatory response and nerve cells throughout the brain are destroyed.¹⁴

Screening for ALD

The SACHDNC first nominated ALD to be included in RUSP to in 2012.¹⁵ At that time, the nomination did not progress and SACHDNC did not recommend a full evidence review because sufficient prospective data was not yet available from a large pilot study at the Mayo Biochemical Genetics Laboratory.¹⁶ In September 2013, ALD was again nominated for consideration. Following that nomination, at a January 2014 meeting of the SACHDNC, the Advisory Committee recommended a full evidence review of ALD and requested the External Evidence Review Group to present a full report to the SACHDNC.¹⁷ The preliminary report was presented to the DACHDNC Advisory Committee on February 12, 2015;¹⁸ following the report, the Advisory Committee submitted a recommendation that ALD be included in the RUSP to the HHS Secretary on September 25, 2015.¹⁹ The HHS Secretary has indicated that she will respond in mid-February 2016, to the DACHDNC's recommendation.²⁰

⁹ Florida Department of Health, *Disorder List*, available at <http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/documents/newborn-screening-disorders.pdf> (last visited January 28, 2016); this list is also maintained by DOH in Rule Rule 64C-7.002, F.A.C.

¹⁰ Adrenoleukodystrophy Foundation, *What is ALD?*, <http://www.aldfoundation.org/ald.php> (last visited January 28, 2016).

¹¹ Id.

¹² Id.

¹³ Id.

¹⁴ Id.

¹⁵ 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> (last visited January 28, 2016).

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> (last visited January 28, 2016).

¹⁸ Id.

¹⁹ Florida Department of Health, *Agency Analysis for 2016 House Bill HB 1293*, January 28, 2015 (on file with Health Quality Subcommittee).

²⁰ Id.

ALD is currently screened for in California, Connecticut, New Jersey, and New York.²¹ The Florida Genetics and Newborn Screening Advisory Council has not yet considered whether ALD should be added to Florida's NSP panel of disorders.²² However, the Genetics and Newborn Screening Advisory Council will consider whether ALD should be added at its February 19, 2016, meeting.²³

Effect of Proposed Changes

The bill amends s. 383.14, F.S., to direct DOH to expand statewide newborn screening to include screening for ALD within one year after ALD is added to the RUSP. This will make ALD only the second disease statutorily required to be screened under the NSP.²⁴ The bill also removes DOH's discretion to determine that ALD meets appropriate criteria for screening. Typically, DOH has the discretion to determine which disorders must be screened after consultation with the Genetics and Newborn Screening Advisory Council.

DOH will be required to adopt rules related to newborn screening requirements for ALD if it is added to the RUSP. Specifically, Rule 64C-7.002, F.A.C., which includes the list of congenital conditions/diseases for which newborns are screened and specifies when the blood specimen is to be collected, would need to be amended to include screening for ALD once it is added to the RUSP.

The effective date of the bill is July 1, 2016.

B. SECTION DIRECTORY:

Section 1: Amends s. 383.14, F.S., relating to screening for metabolic disorders, other hereditary and congenital disorders, and environmental risk factors.

Section 2: Provides an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

DOH estimates that the potential revenue collections from third-party insurers could range from \$566,700 to \$850,050; however, it also notes that currently, there is only a 10 to 15 percent collection rate for newborn screening services.²⁵

2. Expenditures:

The bill will have a significant negative fiscal impact on DOH if ALD screening begins. This will include an annual, recurring cost of \$750,000 for the DOH State Laboratory to conduct the screening at a cost \$2.50 per specimen for approximately 300,000 newborns screened.²⁶ In addition, DOH will incur a one-time cost of \$50,000 to modify its current data system to incorporate ALD screening, follow-up, and tracking.²⁷

²¹ *Supra*, note 17.

²² Florida Department of Health, *Agency Analysis for 2015 House Bill HB 403*, January 28, 2015 (on file with Health Quality Subcommittee).

²³ *Supra*, note 19. ALD has been added to the agenda for the February 19, 2016, meeting for discussion and consideration.

²⁴ See, s. 383.14(2), F.S. (stating that DOH "shall adopt and enforce rules requiring that every newborn in this state shall, prior to becoming 1 week of age, be subjected to a test for phenylketonuria" and specifying that DOH "may deem" it necessary to screen for other disorders).

²⁵ *Supra*, note 19. Currently, ALD testing cannot be billed separately because there is no recognized CPT code for ALD screening; however, DOH suggests the code 82016. The Medicare price for 82016 is \$18.89; this is also the amount that would be billed to newborns with commercial third-party insurers.

²⁶ *Id.*

²⁷ *Id.*

The bill will also have a significant negative fiscal impact on the Agency for Health Care Administration for newborns covered under Florida Medicaid.²⁸

Fiscal Year	Medicaid Newborns	Total Increased Cost (Including Federal)	Cost to Florida Medicaid
2016-2017	131,669	\$2,172,531	\$843,376
2017-2018	133,275	\$2,199,029	\$848,605

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.²⁹ The estimated annual total number of newborns increases by 1.22% each year.³⁰

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Private insurance would bear the costs of the confirmatory testing for each covered newborn with a presumptive positive screening result, which may also include molecular testing for all positive confirmatory tests. This impact is indeterminate.³¹

D. FISCAL COMMENTS:

None.

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:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 2, 2016, the Health Quality Subcommittee adopted an amendment to extend the time within which DOH must adopt statewide screening of newborns for adrenoleukodystrophy to require such

²⁸ Florida Agency for Health Care Administration, *Agency Analysis for 2015 House Bill 403*, January 22, 2015 (on file with Health Quality Subcommittee).

²⁹ Email from Orland Pryor, Deputy Director of Legislative Affairs, Agency for Health Care Administration, Re: AHCA Analysis HB 1293, February 2, 2016. (On file with Health Quality Subcommittee staff).

³⁰ Id.

³¹ *Supra*, note 19.

screening within one year after adrenoleukodystrophy is adopted for inclusion on the RUSP, instead of immediately after such adoption. The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute as passed by the Health Quality Subcommittee.