



Senate

General Assembly

File No. 107

January Session, 2013

Senate Bill No. 465

Senate, March 25, 2013

The Committee on Public Health reported through SEN. GERRATANA of the 6th Dist., Chairperson of the Committee on the part of the Senate, that the bill ought to pass.

AN ACT REQUIRING NEWBORN SCREENING FOR ADRENOLEUKODYSTROPHY.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1 Section 1. Subsection (a) of section 19a-55 of the general statutes is
2 repealed and the following is substituted in lieu thereof (*Effective*
3 *October 1, 2013*):

4 (a) The administrative officer or other person in charge of each
5 institution caring for newborn infants shall cause to have administered
6 to every such infant in its care an HIV-related test, as defined in section
7 19a-581, a test for phenylketonuria and other metabolic diseases,
8 hypothyroidism, galactosemia, sickle cell disease, maple syrup urine
9 disease, homocystinuria, biotinidase deficiency, congenital adrenal
10 hyperplasia, adrenoleukodystrophy and such other tests for inborn
11 errors of metabolism as shall be prescribed by the Department of
12 Public Health. The tests shall be administered as soon after birth as is
13 medically appropriate. If the mother has had an HIV-related test
14 pursuant to section 19a-90 or 19a-593, the person responsible for

15 testing under this section may omit an HIV-related test. The
16 Commissioner of Public Health shall (1) administer the newborn
17 screening program, (2) direct persons identified through the screening
18 program to appropriate specialty centers for treatments, consistent
19 with any applicable confidentiality requirements, and (3) set the fees to
20 be charged to institutions to cover all expenses of the comprehensive
21 screening program including testing, tracking and treatment. The fees
22 to be charged pursuant to subdivision (3) of this subsection shall be set
23 at a minimum of fifty-six dollars. The Commissioner of Public Health
24 shall publish a list of all the abnormal conditions for which the
25 department screens newborns under the newborn screening program,
26 which shall include screening for amino acid disorders, organic acid
27 disorders and fatty acid oxidation disorders, including, but not limited
28 to, long-chain 3-hydroxyacyl CoA dehydrogenase (L-CHAD) and
29 medium-chain acyl-CoA dehydrogenase (MCAD).

This act shall take effect as follows and shall amend the following sections:		
Section 1	October 1, 2013	19a-55(a)

PH *Joint Favorable*

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 14 \$	FY 15 \$
Public Health, Dept.	GF - Cost	392,551	190,068
State Comptroller - Fringe Benefits ¹	GF - Cost	31,104	41,471
General Fund - TOTAL COST		423,655	231,539
Public Health, Dept.	GF - Potential Revenue Gain	423,655	231,539
POTENTIAL STATE FISCAL IMPACT		0	0

Municipal Impact: None

Explanation

The bill results in a state cost of \$423,655 in FY 14 and \$231,539 in FY 15 associated with testing Connecticut newborns for adrenoleukodystrophy and may also result in a potential General Fund revenue gain of the same amount in each fiscal year from increased newborn screening fees.

There are currently no states carrying out routine newborn screening for adrenoleukodystrophy and there is no uniform method for sample preparation and analysis. As a separate analysis, sample preparation method and quality assurance process must be developed for adrenoleukodystrophy, two Chemists and associated costs are anticipated for the Department of Public Health (DPH), along with costs for testing supplies and equipment. Fringe benefits costs for these two positions are included under the State Comptroller - Fringe Benefits. Revenue is indicated as "potential" as the bill does not

¹The fringe benefit costs for most state employees are budgeted centrally in accounts administered by the Comptroller. The estimated active employee fringe benefit cost associated with most personnel changes is 34.54% of payroll in FY 14 and FY 15.

require DPH to increase the newborn screening fee to cover costs associated with the screening. It is assumed that the agency would choose to do so. Details on these costs and potential General Fund revenue follows.

As the bill is effective 10/1/13, anticipated FY 14 costs to the Department of Public Health (DPH) include nine months of salary expenses for two Chemists of \$90,051, nine months of testing supply expenses of \$52,500 and a one-time instrumentation expense of \$250,000. FY 15 costs reflect annualized expenses for wages of \$120,068 and testing supplies of \$70,000. Added to the DPH costs are fringe benefit costs under the State Comptroller - Fringe Benefits of \$31,104 in FY 14 and \$41,471 in FY 15, resulting in a total state cost of \$423,655 in FY 14 and \$231,539 in FY 15. Per CGS Sec. 19a-55, DPH has the authority to set the fee associated with newborn screening (currently \$56 per infant).² DPH could choose to recoup estimated state costs by increasing the newborn screening fee by \$10.09 in FY 14 and \$5.51 in FY 15.

A table of these costs and potential revenue is provided below.

**Estimated Costs to Screen CT Newborns for
Adrenoleukodystrophy & Potential Fee Increase**

Item	FY 14 \$ ¹	FY 15 \$
2 Chemists	90,051	120,068
Other Expenses (testing supplies)	52,500	70,000
Equipment (instrumentation)	250,000	-
Department of Public Health Costs	392,551	190,068
State Comptroller - Fringe Benefits Costs	31,104	41,471
STATE TOTAL	423,655	231,539
Possible newborn screening fee increase ²	10.09	5.51
Potential General Fund revenue ³	423,655	231,539

²Total revenue generated from the newborn screening fee was \$2.5 million in FY 12. Of this, per Sec. 39 of PA 11-48, \$1.1 million was authorized for use by DPH to pay for expenses incurred to perform the testing. The remainder (\$1.4 million) was deposited into the General Fund as unrestricted revenue.

Item	FY 14 \$ ¹	FY 15 \$
POTENTIAL STATE FISCAL IMPACT	-	-

¹SB 465 is effective 10/1/13. Position and testing supply costs reflect nine months of the fiscal year.

²Per CGS Sec. 19a-55, DPH has the authority to set the fee associated with newborn screening. This increase would raise the fee to \$66.09 in FY 14 and \$61.51 in FY 15 per newborn.

³Assumes 42,000 newborns born in Connecticut annually.

The Out Years

Should adrenoleukodystrophy be included in the Recommended Uniform Screening Panel by the U.S. Department of Health and Human Services (HHS) Secretary's Advisory Committee on Heritable Disorders in Newborns and Children,³ it is anticipated that two full-time Chemist positions within DPH would not be needed to perform this screening. Furthermore, it is unknown whether existing equipment could be utilized to perform a standardized test for adrenoleukodystrophy once it is developed. If so, costs may be significantly lower in the future and the potential increase to the newborn screening fee by DPH would likewise be less.

It should be noted that fringe benefit costs estimated at 34.54% of payroll in FY 14 and FY 15 would also include normal annual pension costs (currently estimated at 7.5% of payroll) in the out years. These costs will be recognized in the state's annual required pension contribution in future actuarial valuations.

Sources: 2/27/13 Public Health Committee Testimony
State of New Jersey's Office of Legislative Services 1/14/13 fiscal estimate on screening newborn infants for adrenoleukodystrophy

³<http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendedpanel/index.html>

OLR Bill Analysis**SB 465*****AN ACT REQUIRING NEWBORN SCREENING FOR ADRENOLEUKODYSTROPHY.*****SUMMARY:**

This bill adds adrenoleukodystrophy to the list of genetic and metabolic diseases for which hospitals and other institutions must test newborns under the Department of Public Health's (DPH) newborn screening program. The law requires such testing to be performed as soon as medically appropriate, unless a parent objects on religious grounds. In addition to the initial screening test, the program directs parents of identified infants to appropriate counseling and treatment.

EFFECTIVE DATE: October 1, 2013

BACKGROUND***Adrenoleukodystrophy (ALD)***

ALD is a genetic disorder that causes the accumulation of very-long-chain fatty acids in the nervous system, adrenal gland, and testes, which causes a range of neurological, physical, and behavioral symptoms. While females are genetic carriers for the disease, it primarily affects males.

Generally, the disorder appears between ages four and eight, although milder forms can occur in adulthood. Childhood onset results in a long-term coma approximately two years after the development of neurological symptoms. The child can live in this coma for as long as 10 years until he or she dies.

There is no specific treatment for ALD, but eating a diet low in very-long-chain fatty acids and taking special oils (called Lorenzo's oil) can

lower blood levels of these fatty acids.

Newborn Screening Program

DPH's newborn screening program requires all health care institutions caring for newborn infants to test them for:

1. phenylketonuria and other metabolic diseases,
2. HIV,
3. hypothyroidism,
4. galactosemia,
5. sickle cell disease,
6. maple syrup urine disease,
7. homocystinuria,
8. biotinidase deficiency,
9. congenital adrenal hyperplasia, and
10. other tests for inborn metabolic errors DPH prescribes.

Separate from the newborn screening program, the law also requires these institutions to test infants for critical congenital heart disease, cystic fibrosis, and severe combined immunodeficiency disease.

Related Law

The law requires individual and group health insurance policies to cover certain food products (e.g., acid modified preparations and low protein modified food products) used to treat inherited metabolic diseases (CGS §§ 38a-518c and 38a-429c).

COMMITTEE ACTION

Public Health Committee

Joint Favorable

Yea 28 Nay 0 (03/11/2013)