### 26:2-111.6

#### LEGISLATIVE HISTORY CHECKLIST

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**LAWS OF**: 2013 **CHAPTER**: 90

**NJSA:** 26:2-111.6 (Provides for screening newborn infants for adrenoleukodystrophy)

BILL NO: S2137 (Substituted for A3272)

**SPONSOR(S)** Sweeney and others

**DATE INTRODUCED:** July 26, 2012

**COMMITTEE:** ASSEMBLY: Appropriations

**SENATE:** Health, Human Services and Senior Citizens

**Budget and Appropriations** 

AMENDED DURING PASSAGE: Yes

**DATE OF PASSAGE:** ASSEMBLY: June 20, 2013

**SENATE:** May 13, 2013

**DATE OF APPROVAL:** August 7, 2013

FOLLOWING ARE ATTACHED IF AVAILABLE:

FINAL TEXT OF BILL (First reprint enacted)

S2137

SPONSOR'S STATEMENT: (Begins on page 2 of introduced bill)

Yes

COMMITTEE STATEMENT: ASSEMBLY: Yes

SENATE: Yes Health

Budget

. (Audio archived recordings of the committee meetings, corresponding to the date of the committee statement, *may possibly* be found at www.njleg.state.nj.us)

FLOOR AMENDMENT STATEMENT: No

LEGISLATIVE FISCAL ESTIMATE: Yes

A3272

SPONSOR'S STATEMENT (Begins on page 2 of introduced bill)

Yes

COMMITTEE STATEMENT: ASSEMBLY: Yes Health

**Appropriations** 

SENATE: No

FLOOR AMENDMENT STATEMENT: No

LEGISLATIVE FISCAL ESTIMATE: Yes

(continued)

VETO MESSAGE:	No
GOVERNOR'S PRESS RELEASE ON SIGNING:	No
FOLLOWING WERE PRINTED:	
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### P.L.2013, CHAPTER 90, approved August 7, 2013 Senate, No. 2137 (First Reprint)

1 AN ACT concerning screening for adrenoleukodystrophy in 2 newborn infants and supplementing Title 26 of the Revised 3 Statutes

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BE IT ENACTED by the Senate and General Assembly of the State of New Jersey:

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- 1. a. All infants born in this State shall be tested for adrenoleukodystrophy (ALD) beginning six months following the occurrence of all of the following:
- 11 (1) the development of a reliable <sup>1</sup> [methodology] test or series 12 of tests<sup>1</sup> for screening newborns for ALD using dried blood 13 spots<sup>1</sup> [,]<sup>1</sup> and quality assurance testing methodology for <sup>1</sup> [the test] 14 ALD testing<sup>1</sup>;
- 15 (2) <sup>1</sup> [the registration with the federal Food and Drug Administration of any reagents necessary for the test;
- 17 (3) 1 the availability 1 of quality assurance materials for the
  18 ALD test 1 from the federal Centers for Disease Control and
  19 Prevention 1 of any necessary reagents 1: 1 and 1
- Prevention <sup>1</sup> [of any necessary reagents] <sup>1</sup>; <sup>1</sup> [and] 20 (3) the inclusion of newborn screening
- 20 (3) the inclusion of newborn screening for ALD in the
  21 Recommended Uniform Screening Panel of the United States
  22 Secretary of Health and Human Services' Advisory Committee on
  23 Heritable Disorders in Newborns and Children, after the
  24 committee's evidence review of newborn screening for ALD;<sup>1</sup>
- 25 (4) <sup>1</sup> [the acquisition by the Department of Health and Senior 26 Services of ] the review by the Department of Health of the 27 proposed test; and
- 28 (5)<sup>1</sup> the <sup>1</sup>acquisition of <sup>1</sup> equipment necessary to implement the 29 expanded screening tests <sup>1</sup>by the State's Newborn Screening 30 <u>Laboratory.</u> <sup>1</sup>
- b. The Department of Health <sup>1</sup> [and Senior Services] <sup>1</sup> may charge a reasonable fee <sup>1</sup> and any reasonable increase in this fee as necessary, <sup>1</sup> for the test performed pursuant to this section. The amount of the fee and the procedures for collecting the fee shall be determined by the Commissioner of Health <sup>1</sup> [and Senior Services] <sup>1</sup>.

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38 2. This act shall take effect immediately.

EXPLANATION – Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.

Matter underlined  $\underline{thus}$  is new matter.

Matter enclosed in superscript numerals has been adopted as follows:

<sup>&</sup>lt;sup>1</sup>Senate SHH committee amendments adopted September 20, 2012.

**S2137** [1R] 2

Provides for screening newborn infants for adrenoleukodystrophy.

## SENATE, No. 2137

# **STATE OF NEW JERSEY**

### 215th LEGISLATURE

INTRODUCED JULY 26, 2012

Sponsored by: Senator STEPHEN M. SWEENEY District 3 (Cumberland, Gloucester and Salem)

### **SYNOPSIS**

Provides for screening newborn infants for adrenoleukodystrophy.

### **CURRENT VERSION OF TEXT**

As introduced.



#### S2137 SWEENEY

1	AN ACT	concernii	ng	screening	for	adren	oleu	kod	lystr	ophy	in
2	newborn	infants	and	suppleme	nting	Title	26	of	the	Revi	sed
3	Statutes										

**BE IT ENACTED** by the Senate and General Assembly of the State of New Jersey:

- 1. a. All infants born in this State shall be tested for adrenoleukodystrophy (ALD) beginning six months following the occurrence of all of the following:
- (1) the development of a reliable methodology for screening newborns for ALD using dried blood spots, and quality assurance testing methodology for the test;
- (2) the registration with the federal Food and Drug Administration of any reagents necessary for the test;
- (3) the availability from the federal Centers for Disease Control and Prevention of any necessary reagents; and
- (4) the acquisition by the Department of Health and Senior Services of the equipment necessary to implement the expanded screening tests.
- b. The Department of Health and Senior Services may charge a reasonable fee for the test performed pursuant to this section. The amount of the fee and the procedures for collecting the fee shall be determined by the Commissioner of Health and Senior Services.

2. This act shall take effect immediately.

### **STATEMENT**

This bill requires that infants born in the State be screened for adrenoleukodystrophy (ALD) beginning six months following the occurrence of all of the following: (1) the development of a reliable methodology for screening newborns for ALD using dried blood spots, and quality assurance testing methodology for the test; (2) the registration with the federal Food and Drug Administration of any necessary reagents; (3) the availability of the necessary reagents from the federal Centers for Disease Control and Prevention; and (4) the acquisition by the Department of Health and Senior Services (DHSS) of the equipment necessary to implement the expanded screening tests. The bill also authorizes DHSS to charge a reasonable fee for the testing.

Adrenoleukodystrophy is a rare, inherited disorder that can lead to damage to the brain and adrenal glands, and in its most aggressive form can lead to death in two to five years after the age of onset. ALD affects between one in 15,000 and one in 20,000 children worldwide. Recent research has shown promising results in the development of a newborn screening test for ALD, but a

### S2137 SWEENEY

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widely accepted methodology is not yet available. Although there 1 is no cure for ALD, several treatments, including dietary treatments 2 3 combined with Lorenzo's oil and bone transplantation have been 4 used with some success, but treatments are most effective before or 5 shortly after the onset of symptoms. Early detection of the disease 6 may help affected individuals to seek treatment sooner, thereby 7 possibly delaying the onset of symptoms and slowing their 8 progression.

# SENATE HEALTH, HUMAN SERVICES AND SENIOR CITIZENS COMMITTEE

### STATEMENT TO

### **SENATE, No. 2137**

with committee amendments

### STATE OF NEW JERSEY

DATED: SEPTEMBER 20, 2012

The Senate Health, Human Services and Senior Citizens Committee reports favorably and with amendments Senate Bill No. 2137.

As amended by the committee, this bill requires that infants born in the State be screened for adrenoleukodystrophy (ALD) beginning six months following the occurrence of all of the following:

- the development of a reliable test or series of tests and quality assurance testing methodology for ALD testing;
- the availability of quality assurance materials for the test from the federal Centers for Disease Control and Prevention;
- the inclusion of ALD in the Recommended Uniform Screening Panel of the federal Advisory Committee on Heritable Disorders in Newborns and Children, following its evidence review;
- the review of the proposed test by the Department of Health; and
- the acquisition of equipment necessary to implement the expanded screening tests has been acquired by the State's Newborn Screening Laboratory.

The bill also authorizes the Department of Health to charge a reasonable fee for testing and any reasonable increase as necessary.

The committee amendments clarify that screening for ALD is to be conditioned upon the development of reliable testing based on accepted methodologies, the availability of quality assurance materials for the test from the federal Centers for Disease Control and Prevention, inclusion of ALD in the Recommended Uniform Screening Panel of the federal Advisory Committee on Heritable Disorders in Newborns and Children, the review of the proposed test by the Department of Health, and the acquisition of equipment necessary to implement the test by the State's Newborn Screening Laboratory. The amendments also provide that the Department of Health may charge any reasonable increased fees for this test as necessary, and update statutory references to the Department of Health to conform to current law.

### LEGISLATIVE FISCAL ESTIMATE

[First Reprint]

### SENATE, No. 2137

### STATE OF NEW JERSEY 215th LEGISLATURE

DATED: JANUARY 14, 2013

#### **SUMMARY**

**Synopsis:** Provides for screening newborn infants for adrenoleukodystrophy.

**Type of Impact:** Minimal or no impact.

**Agencies Affected:** Department of Health.

#### Office of Legislative Services Estimate

Fiscal Impact	<u>Years 1-3</u>
State Cost	Minimal or no impact – See comments below
State Revenue	Minimal or no impact – See comments below

• The bill will likely have no impact for several years, as a newborn screening test for ALD is not currently available.

### **BILL DESCRIPTION**

Senate Bill No. 2137 (1R) of 2012 requires that infants born in the State be screened for adrenoleukodystrophy (ALD) beginning six months after the occurrence of all of the following:

- the development of a reliable test or series of tests and quality assurance testing methodology for ALD testing;
- the availability of quality assurance materials for the test from the federal Centers for Disease Control and Prevention;
- the inclusion of ALD in the Recommended Uniform Screening Panel of the federal Advisory Committee on Heritable Disorders in Newborns and Children, following the committee's evidence review;
- the review of the proposed test by the Department of Health; and
- the acquisition of equipment necessary to implement the ALD screening test by the State's Newborn Screening Laboratory.



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The bill also authorizes the Department of Health to charge a reasonable fee for testing and any reasonable increase as necessary.

#### FISCAL ANALYSIS

#### **EXECUTIVE BRANCH**

None received.

#### OFFICE OF LEGISLATIVE SERVICES

It is not likely that the criteria set forth in the bill will be met for several years, so the bill will not be implemented during that period. Researchers at the Kennedy Krieger Institute have developed a newborn screening method to detect ALD, which is currently being tested in a large pilot study at the Mayo Biochemical Genetics Laboratory. Further research and development will be required before the test will meet the conditions set forth in the bill.

Even if the conditions regarding development and availability of a test are met, the bill effectively grants the Department of Health an option not to add the ALD test to the newborn screening panel if it chooses not to review the test or acquire the necessary equipment. The bill does not provide any new authority, as current law provides the Commissioner of Health with the authority to add additional tests to the newborn screening panel.

If a test for ALD is added to the newborn screening panel State costs may increase, but these costs cannot be determined without knowledge of what such a test would entail. Currently, the Newborn Screening Program screens the approximately 110,000 children born in this State each year for a panel of 54 disorders. Any additional costs could be offset by increasing the charge, currently \$90, which the Department of Health levies on hospitals for each newborn screening panel. If the test can be conducted using the same blood sample that is used for other newborn screening tests, it is likely that additional costs would be minimal.

Section: Human Services

Analyst: David Drescher

Assistant Fiscal Analyst

Approved: David J. Rosen

Legislative Budget and Finance Officer

This legislative fiscal estimate has been produced by the Office of Legislative Services due to the failure of the Executive Branch to respond to our request for a fiscal note.

This fiscal estimate has been prepared pursuant to P.L.1980, c.67 (C.52:13B-6 et seq.).

### SENATE BUDGET AND APPROPRIATIONS COMMITTEE

### STATEMENT TO

# [First Reprint] **SENATE, No. 2137**

### STATE OF NEW JERSEY

DATED: JANUARY 14, 2013

The Senate Budget and Appropriations Committee reports favorably Senate Bill No. 2137 (1R).

This bill requires that infants born in the State be screened for adrenoleukodystrophy (ALD) beginning six months following the occurrence of all of the following:

- the development of a reliable test or series of tests and quality assurance testing methodology for ALD testing;
- the availability of quality assurance materials for the test from the federal Centers for Disease Control and Prevention;
- the inclusion of ALD in the Recommended Uniform Screening Panel of the federal Advisory Committee on Heritable Disorders in Newborns and Children, following its evidence review;
- the review of the proposed test by the Department of Health; and
- the acquisition of equipment necessary to implement the expanded screening tests has been acquired by the State's Newborn Screening Laboratory.

The bill also authorizes the Department of Health to charge a reasonable fee for testing and any reasonable increase as necessary.

### **FISCAL IMPACT**:

The Office of Legislative Services notes that it is not likely that the criteria set forth in the bill will be met for several years, so the bill will not be implemented during that period. Researchers at the Kennedy Krieger Institute have developed a newborn screening method to detect ALD, which is currently being tested in a large pilot study at the Mayo Biochemical Genetics Laboratory. Further research and development will be required before the test will meet the conditions set forth in the bill.

Even if the conditions regarding development and availability of a test are met, the bill effectively grants the Department of Health an option not to add the ALD test to the newborn screening panel if it chooses not to review the test or acquire the necessary equipment. The bill does not provide any new authority, as current law provides the Commissioner of Health with the authority to add additional tests to the newborn screening panel.

If a test for ALD is added to the newborn screening panel State costs may increase, but these costs cannot be determined without knowledge of what such a test would entail. Currently, the Newborn Screening Program screens the approximately 110,000 children born in this State each year for a panel of 54 disorders. Any additional costs could be offset by increasing the charge, currently \$90, which the Department of Health levies on hospitals for each newborn screening panel. If the test can be conducted using the same blood sample that is used for other newborn screening tests, it is likely that additional costs would be minimal.

### ASSEMBLY APPROPRIATIONS COMMITTEE

### STATEMENT TO

# [First Reprint] **SENATE, No. 2137**

### STATE OF NEW JERSEY

**DATED: JUNE 6, 2013** 

The Assembly Appropriations Committee reports favorably Senate Bill No. 2137 (1R).

The bill requires that all infants born in the State be tested for adrenoleukodystrophy (ALD), a rare genetically determined neurological disorder that affects the brain with demyelination and causes neurological deficits.

The bill provides that the testing of infants for ALD is required to begin six months after the occurrence of each of the following:

- -- the development of a reliable test or series of tests and quality assurance testing methodology for ALD testing;
- -- the availability of quality assurance materials for the test from the federal Centers for Disease Control and Prevention:
- -- the inclusion of ALD in the Recommended Uniform Screening Panel of the federal Advisory Committee on Heritable Disorders in Newborns and Children, following its evidence review;
  - -- the review of the proposed test by the Department of Health; and
- -- the acquisition of equipment necessary to implement the expanded screening tests by the State's Newborn Screening Laboratory.

The bill authorizes the Department of Health to charge a reasonable fee for the required ALD testing, allows for reasonable increases in the fee, and permits the Commissioner of Health to determine the amount of the fee and the procedures for its collection.

The bill takes effect immediately upon enactment.

As reported, this bill is identical to Assembly Bill No. 3272 (1R), as also reported by the committee.

### **FISCAL IMPACT**:

The Office of Legislative Services (OLS) expects the bill to have no fiscal impact to the State for several years until a reliable newborn screening test for ALD is developed and made readily available. Researchers have developed a newborn screening method to detect ALD (and are currently testing the method), but further research and development is needed before the test will meet each of the conditions established by the bill.

The OLS notes that even if the conditions regarding the development and availability of a test are met, the bill effectively grants the Department of Health an option not to add the ALD test to the newborn screening panel if it chooses not to review the test or acquire the necessary equipment. The bill does not provide any new authority, as current law authorizes the Commissioner of Health to add additional tests to the newborn screening panel.

The OLS notes that if a test for ALD is added to the newborn screening panel, State costs may increase, but these costs cannot be determined without knowing what a test entails. The Newborn Screening Program currently screens the approximately 110,000 children born in this State each year for a panel of 54 disorders. The additional costs could be offset by increasing the current \$90 charge imposed on hospitals for each newborn screening panel. If the test is conducted using the same blood sample used for other newborn screening tests, it is likely that the additional costs will be minimal.

## ASSEMBLY, No. 3272

## **STATE OF NEW JERSEY**

### 215th LEGISLATURE

INTRODUCED SEPTEMBER 27, 2012

Sponsored by:

Assemblyman JASON O'DONNELL District 31 (Hudson) Assemblyman PATRICK J. DIEGNAN, JR. District 18 (Middlesex) Assemblyman TROY SINGLETON

**District 7 (Burlington)** 

### **SYNOPSIS**

Provides for screening newborn infants for adrenoleukodystrophy.

### **CURRENT VERSION OF TEXT**

As introduced.



(Sponsorship Updated As Of: 10/19/2012)

### A3272 O'DONNELL, DIEGNAN

1	AN ACT	concernin	g screening	for	adren	oleu	koc	lystr	ophy	in
2	newborn	infants a	and suppleme	enting	Title	26	of	the	Revi	sed
3	Statutes									

**BE IT ENACTED** by the Senate and General Assembly of the State of New Jersey:

- 1. a. All infants born in this State shall be tested for adrenoleukodystrophy (ALD) beginning six months following the occurrence of all of the following:
- (1) the development of a reliable methodology for screening newborns for ALD using dried blood spots and quality assurance testing methodology for the test;
- (2) the registration with the federal Food and Drug Administration of any reagents necessary for the test;
- (3) the availability from the federal Centers for Disease Control and Prevention of any necessary reagents; and
- (4) the acquisition by the Department of Health of the equipment necessary to implement the expanded screening tests.
- b. The Department of Health may charge a reasonable fee for the test performed pursuant to this section. The amount of the fee and the procedures for collecting the fee shall be determined by the Commissioner of Health.

2. This act shall take effect immediately.

### **STATEMENT**

This bill requires that infants born in the State be screened for adrenoleukodystrophy (ALD) beginning six months following the occurrence of all of the following: (1) the development of a reliable methodology for screening newborns for ALD using dried blood spots, and quality assurance testing methodology for the test; (2) the registration with the federal Food and Drug Administration of any necessary reagents; (3) the availability of the necessary reagents from the federal Centers for Disease Control and Prevention; and (4) the acquisition by the Department of Health (DOH) of the equipment necessary to implement the expanded screening tests. The bill also authorizes DOH to charge a reasonable fee for the testing.

Adrenoleukodystrophy is a rare, inherited disorder that can lead to damage to the brain and adrenal glands, and in its most aggressive form can lead to death in two to five years after the age of onset. ALD affects between one in 15,000 and one in 20,000 children worldwide. Recent research has shown promising results in the development of a newborn screening test for ALD, but a widely accepted methodology is not yet available. Although there is no cure for ALD, several treatments, including dietary treatments

### A3272 O'DONNELL, DIEGNAN

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- 1 combined with Lorenzo's oil and bone transplantation, have been
- 2 used with some success, but treatments are most effective before or
- 3 shortly after the onset of symptoms. Early detection of the disease
- 4 may help affected individuals to seek treatment sooner, thereby
- 5 possibly delaying the onset of symptoms and slowing their
- 6 progression.

### ASSEMBLY HEALTH AND SENIOR SERVICES COMMITTEE

### STATEMENT TO

### ASSEMBLY, No. 3272

with committee amendments

### STATE OF NEW JERSEY

DATED: FEBRUARY 7, 2013

The Assembly Health and Senior Services Committee reports favorably and with amendments Assembly Bill No. 3272.

As amended by the committee, this bill requires that infants born in the State be screened for adrenoleukodystrophy (ALD) beginning six months following the occurrence of all of the following:

- the development of a reliable test or series of tests and quality assurance testing methodology for ALD testing;
- the availability of quality assurance materials for the test from the federal Centers for Disease Control and Prevention;
- the inclusion of ALD in the Recommended Uniform Screening Panel of the federal Advisory Committee on Heritable Disorders in Newborns and Children, following its evidence review;
- the review of the proposed test by the Department of Health; and
- the acquisition of equipment necessary to implement the expanded screening tests by the State's Newborn Screening Laboratory.

The bill also authorizes the Department of Health to charge a reasonable fee for testing and any reasonable increase as necessary.

### **COMMITTEE AMENDMENTS**

The committee amendments clarify that screening for ALD is to be conditioned upon the development of reliable testing based on accepted methodologies, the availability of quality assurance materials for the test from the federal Centers for Disease Control and Prevention, inclusion of ALD in the Recommended Uniform Screening Panel of the federal Advisory Committee on Heritable Disorders in Newborns and Children, the review of the proposed test by the Department of Health, and the acquisition of equipment necessary to implement the test by the State's Newborn Screening Laboratory. The amendments also provide that the Department of Health may charge any reasonable increased fees for this test as necessary, and update statutory references to the Department of Health to conform to current law.

### ASSEMBLY APPROPRIATIONS COMMITTEE

### STATEMENT TO

# [First Reprint] ASSEMBLY, No. 3272

### STATE OF NEW JERSEY

**DATED: JUNE 6, 2013** 

The Assembly Appropriations Committee reports favorably Assembly Bill No. 3272 (1R).

The bill requires that all infants born in the State be tested for adrenoleukodystrophy (ALD), a rare genetically determined neurological disorder that affects the brain with demyelination and causes neurological deficits.

The bill provides that the testing of infants for ALD is required to begin six months after the occurrence of each of the following:

- -- the development of a reliable test or series of tests and quality assurance testing methodology for ALD testing;
- -- the availability of quality assurance materials for the test from the federal Centers for Disease Control and Prevention:
- -- the inclusion of ALD in the Recommended Uniform Screening Panel of the federal Advisory Committee on Heritable Disorders in Newborns and Children, following its evidence review;
  - -- the review of the proposed test by the Department of Health; and
- -- the acquisition of equipment necessary to implement the expanded screening tests by the State's Newborn Screening Laboratory.

The bill authorizes the Department of Health to charge a reasonable fee for the required ALD testing, allows for reasonable increases in the fee, and permits the Commissioner of Health to determine the amount of the fee and the procedures for its collection.

The bill takes effect immediately upon enactment.

As reported, this bill is identical to Senate Bill No. 2137 (1R), as also reported by the committee.

### **FISCAL IMPACT**:

The Office of Legislative Services (OLS) expects the bill to have no fiscal impact to the State for several years until a reliable newborn screening test for ALD is developed and made readily available. Researchers have developed a newborn screening method to detect ALD (and are currently testing the method), but further research and development is needed before the test will meet each of the conditions established by the bill.

The OLS notes that even if the conditions regarding the development and availability of a test are met, the bill effectively grants the Department of Health an option not to add the ALD test to the newborn screening panel if it chooses not to review the test or acquire the necessary equipment. The bill does not provide any new authority, as current law authorizes the Commissioner of Health to add additional tests to the newborn screening panel.

The OLS notes that if a test for ALD is added to the newborn screening panel, State costs may increase, but these costs cannot be determined without knowing what a test entails. The Newborn Screening Program currently screens the approximately 110,000 children born in this State each year for a panel of 54 disorders. The additional costs could be offset by increasing the current \$90 charge imposed on hospitals for each newborn screening panel. If the test is conducted using the same blood sample used for other newborn screening tests, it is likely that the additional costs will be minimal.

### LEGISLATIVE FISCAL ESTIMATE

[First Reprint]

### ASSEMBLY, No. 3272 STATE OF NEW JERSEY 215th LEGISLATURE

**DATED: JUNE 6, 2013** 

### **SUMMARY**

**Synopsis:** Provides for screening newborn infants for adrenoleukodystrophy.

**Type of Impact:** Minimal or no impact.

**Agencies Affected:** Department of Health.

#### Office of Legislative Services Estimate

Fiscal Impact	<u>Years 1-3</u>
State Cost	Minimal or no impact – See comments below
<b>State Revenue</b>	Minimal or no impact – See comments below

• The bill will likely have no impact for several years, as a newborn screening test for adrenoleukodystrophy (ALD) is not currently available.

### **BILL DESCRIPTION**

Assembly Bill No. 3272 (1R) of 2012 requires that infants born in the State be screened for ALD beginning six months after the occurrence of all of the following:

- the development of a reliable test or series of tests and quality assurance testing methodology for ALD testing;
- the availability of quality assurance materials for the test from the federal Centers for Disease Control and Prevention;
- the inclusion of ALD in the Recommended Uniform Screening Panel of the federal Advisory Committee on Heritable Disorders in Newborns and Children, following the committee's evidence review;
- the review of the proposed test by the Department of Health; and
- the acquisition of equipment necessary to implement the ALD screening test by the State's Newborn Screening Laboratory.

The bill also authorizes the Department of Health to charge a reasonable fee for testing and any reasonable increase as necessary.



### FISCAL ANALYSIS

#### **EXECUTIVE BRANCH**

None received.

#### OFFICE OF LEGISLATIVE SERVICES

It is not likely that the criteria set forth in the bill will be met for several years, so the bill will not be implemented during that period. Researchers at the Kennedy Krieger Institute have developed a newborn screening method to detect ALD, which is currently being tested in a large pilot study at the Mayo Biochemical Genetics Laboratory. Further research and development will be required before the test will meet the conditions set forth in the bill.

Even if the conditions regarding development and availability of a test are met, the bill effectively grants the Department of Health an option not to add the ALD test to the newborn screening panel if it chooses not to review the test or acquire the necessary equipment. The bill does not provide any new authority, as current law provides the Commissioner of Health with the authority to add additional tests to the newborn screening panel.

If a test for ALD is added to the newborn screening panel State costs may increase, but these costs cannot be determined without knowledge of what such a test would entail. Currently, the Newborn Screening Program screens the approximately 110,000 children born in this State each year for a panel of 54 disorders. Any additional costs could be offset by increasing the charge, currently \$90, which the Department of Health levies on hospitals for each newborn screening panel. If the test can be conducted using the same blood sample that is used for other newborn screening tests, it is likely that additional costs would be minimal.

Section: Human Services

Analyst: David Drescher

Associate Fiscal Analyst

Approved: David J. Rosen

Legislative Budget and Finance Officer

This legislative fiscal estimate has been produced by the Office of Legislative Services due to the failure of the Executive Branch to respond to our request for a fiscal note.

This fiscal estimate has been prepared pursuant to P.L.1980, c.67 (C.52:13B-6 et seq.).