

26:2-111.5

LEGISLATIVE HISTORY CHECKLIST

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LAWS OF: 2011 **CHAPTER:** 175

NJSA: 26:2-111.5 ("Emma's Law")

BILL NO: S1999 (Substituted for A2708)

SPONSOR(S) Bucco and others

DATE INTRODUCED: May 27, 2010

COMMITTEE: **ASSEMBLY:** ---

SENATE: Health, Human Services and Senior Citizens

AMENDED DURING PASSAGE: No

DATE OF PASSAGE: **ASSEMBLY:** December 15, 2011

SENATE: December 15, 2011

DATE OF APPROVAL: January 6, 2012

FOLLOWING ARE ATTACHED IF AVAILABLE:

FINAL TEXT OF BILL (Introduced version of bill enacted)

S1999

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

COMMITTEE STATEMENT: **ASSEMBLY:** No

SENATE: Yes

(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: No

A2708

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

COMMITTEE STATEMENT: **ASSEMBLY:** Yes

SENATE: No

FLOOR AMENDMENT STATEMENT: No

LEGISLATIVE FISCAL ESTIMATE: Yes

(continued)

VETO MESSAGE:

No

GOVERNOR'S PRESS RELEASE ON SIGNING:

No

FOLLOWING WERE PRINTED:

To check for circulating copies, contact New Jersey State Government Publications at the State Library (609) 278-2640 ext.103 or <mailto:refdesk@njstatelib.org>

REPORTS:

No

HEARINGS:

No

NEWSPAPER ARTICLES:

No

LAW/KR

P.L.2011, CHAPTER 175, *approved January 6, 2012*
Senate, No. 1999

1 AN ACT concerning screening for certain disorders in newborn
2 infants, designated as Emma's Law, and supplementing Title 26
3 of the Revised Statutes.

4

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

7

8 1. a. All infants born in this State shall be tested for the
9 lysosomal storage disorders known as Krabbe, Pompe, Gaucher,
10 Fabry, and Niemann-Pick diseases within six months following the
11 occurrence of all of the following:

12 (1) the registration with the federal Food and Drug
13 Administration of the necessary reagents;

14 (2) the availability of the necessary reagents from the federal
15 Centers for Disease Control and Prevention;

16 (3) the availability of quality assurance testing methodology for
17 these processes; and

18 (4) the acquisition by the Department of Health and Senior
19 Services of the equipment necessary to implement the expanded
20 screening tests.

21 b. The Department of Health and Senior Services may charge a
22 reasonable fee for the tests performed pursuant to this section. The
23 amount of the fee and the procedures for collecting the fee shall be
24 determined by the Commissioner of Health and Senior Services.

25

26 2. This act shall take effect immediately.

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STATEMENT

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31 This bill requires that infants born in the State be screened for the
32 following lysosomal storage disorders: Krabbe, Pompe, Gaucher,
33 Fabry, and Niemann-Pick diseases, within six months after the
34 following occur:

35 • registration with the FDA of the necessary reagents (substances
36 that would enable detection of the disorders);

37 • availability of the necessary reagents from the federal Centers
38 for Disease Control and Prevention;

39 • availability of quality assurance testing methodology; and

40 • acquisition by the Department of Health and Senior Services
41 (DHSS) of the equipment necessary to implement the screening
42 tests.

S1999

1 The bill also authorizes DHSS to charge a reasonable fee for the
2 testing.

3 This bill is based on Illinois law. Lysosomal storage disorders
4 are rare, inherited disorders that primarily affect children. They
5 cause a range of devastating symptoms, which, depending on the
6 disorder, include developmental delays, movement disorders,
7 seizures, dementia, deafness, blindness, enlarged livers or spleens,
8 bones that grow abnormally, and pulmonary and cardiac problems.
9 Research is underway to find reliable cures and treatments for these
10 diseases. To date, it is believed that the success of treatments that
11 are available depends upon how early children receive them, and
12 thus the critical need to detect these disorders as early as possible.

13 This bill is designated as “Emma’s Law,” after Emma Daniels,
14 who was born in the State in 2009 and diagnosed with Krabbe
15 disease.

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20 “Emma’s Law”; provides for screening newborn infants for
21 lysosomal storage disorders.

SENATE, No. 1999

STATE OF NEW JERSEY

214th LEGISLATURE

INTRODUCED MAY 27, 2010

Sponsored by:

Senator ANTHONY R. BUCCO

District 25 (Morris)

Senator LORETTA WEINBERG

District 37 (Bergen)

Assemblyman DAVID P. RIBLE

District 11 (Monmouth)

Assemblyman JASON O'DONNELL

District 31 (Hudson)

Assemblyman HERB CONAWAY, JR.

District 7 (Burlington and Camden)

Assemblyman DANIEL R. BENSON

District 14 (Mercer and Middlesex)

Co-Sponsored by:

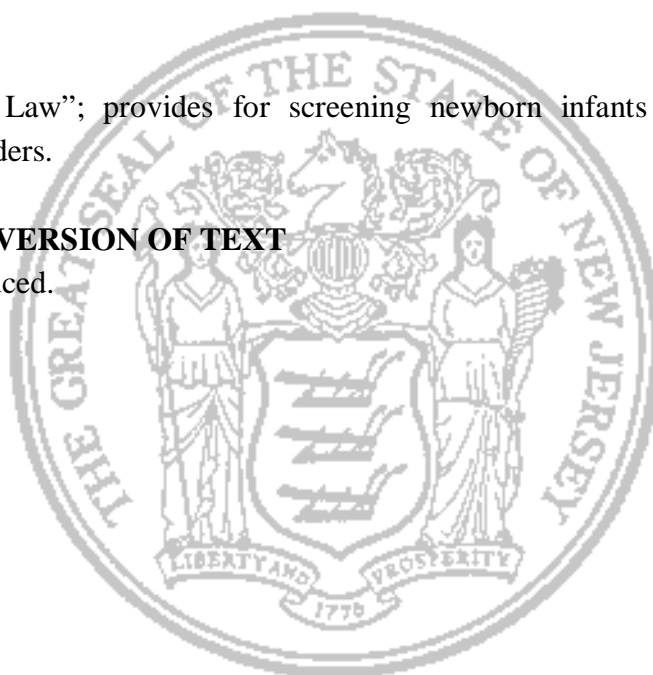
Senators Allen, Van Drew, Assemblymen A.M.Bucco and Diegnan

SYNOPSIS

“Emma’s Law”; provides for screening newborn infants for lysosomal storage disorders.

CURRENT VERSION OF TEXT

As introduced.



(Sponsorship Updated As Of: 12/16/2011)

1 AN ACT concerning screening for certain disorders in newborn
2 infants, designated as Emma's Law, and supplementing Title 26
3 of the Revised Statutes.

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

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19 Services of the equipment necessary to implement the expanded
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21 b. The Department of Health and Senior Services may charge a
22 reasonable fee for the tests performed pursuant to this section. The
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24 determined by the Commissioner of Health and Senior Services.

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40 • acquisition by the Department of Health and Senior Services
41 (DHSS) of the equipment necessary to implement the screening
42 tests.

43 The bill also authorizes DHSS to charge a reasonable fee for the
44 testing.

45 This bill is based on Illinois law. Lysosomal storage disorders
46 are rare, inherited disorders that primarily affect children. They
47 cause a range of devastating symptoms, which, depending on the
48 disorder, include developmental delays, movement disorders,

S1999 A.R.BUCCO, WEINBERG

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1 seizures, dementia, deafness, blindness, enlarged livers or spleens,
2 bones that grow abnormally, and pulmonary and cardiac problems.
3 Research is underway to find reliable cures and treatments for these
4 diseases. To date, it is believed that the success of treatments that
5 are available depends upon how early children receive them, and
6 thus the critical need to detect these disorders as early as possible.

7 This bill is designated as “Emma’s Law,” after Emma Daniels,
8 who was born in the State in 2009 and diagnosed with Krabbe
9 disease.

SENATE HEALTH, HUMAN SERVICES AND SENIOR
CITIZENS COMMITTEE

STATEMENT TO

SENATE, No. 1999

STATE OF NEW JERSEY

DATED: NOVEMBER 21, 2011

The Senate Health, Human Services and Senior Citizens Committee reports favorably Senate Bill No. 1999.

As reported, this bill requires that infants born in the State be screened for the following lysosomal storage disorders: Krabbe, Pompe, Gaucher, Fabry, and Niemann-Pick diseases, within six months after the following occur:

- registration with the federal Food and Drug Administration of the necessary reagents (substances that would enable detection of the disorders);
- availability of the necessary reagents from the federal Centers for Disease Control and Prevention;
- availability of quality assurance testing methodology; and
- acquisition by the Department of Health and Senior Services (DHSS) of the equipment necessary to implement the screening tests.

The bill also authorizes DHSS to charge a reasonable fee for the testing.

This bill is designated as “Emma’s Law,” after Emma Daniels, who was born in the State in 2009 and diagnosed with Krabbe disease.

ASSEMBLY, No. 2708

STATE OF NEW JERSEY 214th LEGISLATURE

INTRODUCED MAY 13, 2010

Sponsored by:

Assemblyman DAVID P. RIBLE

District 11 (Monmouth)

Assemblyman JASON O'DONNELL

District 31 (Hudson)

Assemblyman HERB CONAWAY, JR.

District 7 (Burlington and Camden)

Assemblyman DANIEL R. BENSON

District 14 (Mercer and Middlesex)

Co-Sponsored by:

Assemblymen A.M.Bucco and Diegnan

SYNOPSIS

“Emma’s Law”; provides for screening newborn infants for lysosomal storage disorders.

CURRENT VERSION OF TEXT

As introduced.



(Sponsorship Updated As Of: 12/16/2011)

1 AN ACT concerning screening for certain disorders in newborn
2 infants, designated as Emma's Law, and supplementing Title 26
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17 these processes; and

18 (4) the acquisition by the Department of Health and Senior
19 Services of the equipment necessary to implement the expanded
20 screening tests.

21 b. The Department of Health and Senior Services may charge a
22 reasonable fee for the tests performed pursuant to this section. The
23 amount of the fee and the procedures for collecting the fee shall be
24 determined by the Commissioner of Health and Senior Services.

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36 that would enable detection of the disorders);
37 • availability of the necessary reagents from the federal Centers
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39 • availability of quality assurance testing methodology; and
40 • acquisition by the Department of Health and Senior Services
41 (DHSS) of the equipment necessary to implement the screening
42 tests.

43 The bill also authorizes DHSS to charge a reasonable fee for the
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45 This bill is based on Illinois law. Lysosomal storage disorders
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48 disorder, include developmental delays, movement disorders,

A2708 RIBLE, O'DONNELL

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2 bones that grow abnormally, and pulmonary and cardiac problems.
3 Research is underway to find reliable cures and treatments for these
4 diseases. To date, it is believed that the success of treatments that
5 are available depends upon how early children receive them, and
6 thus the critical need to detect these disorders as early as possible.

7 This bill is designated as "Emma's Law," after Emma Daniels,
8 who was born in the State in 2009 and diagnosed with Krabbe
9 disease.

ASSEMBLY HEALTH AND SENIOR SERVICES COMMITTEE

STATEMENT TO

ASSEMBLY, No. 2708

STATE OF NEW JERSEY

DATED: DECEMBER 8, 2011

The Assembly Health and Senior Services Committee reports favorably Assembly Bill No. 2708.

This bill, which provides for screening newborn infants for lysosomal storage disorders, is designated as “Emma’s Law” in honor of Emma Daniels.

The bill requires that all infants born in New Jersey be tested for the lysosomal storage disorders known as Krabbe, Pompe, Gaucher, Fabry, and Niemann-Pick diseases within six months after all of the following occur:

- registration with the federal Food and Drug Administration of the necessary reagents (substances that would enable detection of the disorders);
- availability of the necessary reagents from the federal Centers for Disease Control and Prevention;
- availability of quality assurance testing methodology; and
- acquisition by the Department of Health and Senior Services of the equipment necessary to conduct this testing.

The department is authorized to charge a reasonable fee for the screening tests, and the amount of the fee and procedures for its collection are to be determined by the Commissioner of Health and Senior Services.

LEGISLATIVE FISCAL ESTIMATE
ASSEMBLY, No. 2708
STATE OF NEW JERSEY
214th LEGISLATURE

DATED: DECEMBER 21, 2011

SUMMARY

Synopsis: “Emma’s Law”; provides for screening newborn infants for lysosomal storage disorders.

Type of Impact: A possible increase in expenditures and revenues.

Agencies Affected: Department of Health and Senior Services (DHSS), Department of Human Services (DHS).

Office of Legislative Services Estimate

Fiscal Impact	<u>Years 1-3</u>
State Cost	Unable to determine.
State Revenue	Unable to determine.

- Enactment of the legislation may not result in any change in spending or revenue, as it requires that four conditions be met before DHSS must take any action. Three of these conditions are uncertain, but the fourth is under the control of DHSS. If DHSS chooses not to meet the fourth condition, it would not be subject to the requirements of the bill.
- If the conditions are met and State’s newborn screening program is expanded, DHSS will incur costs that cannot be determined at this time.
- The bill authorizes DHSS to offset costs it incurs from the legislation by charging a fee for the screenings in a manner determined by the Commissioner. Depending on how the fee is collected, Medicaid and NJ FamilyCare may be responsible for paying this fee for their respective enrollees.

BILL DESCRIPTION

Assembly Bill No. 2708 of 2010 requires that infants born in the State be screened for the following lysosomal storage disorders: Krabbe, Pompe, Gaucher, Fabry, and Niemann-Pick diseases, within six months after the following occur:

- Registration with the Food and Drug Administration (FDA) of the necessary reagents (substances that would enable detection of the disorders);
- Availability of the necessary reagents from the federal Centers for Disease Control and Prevention (CDC);
- Availability of quality assurance testing methodology; and
- Acquisition by DHSS of the equipment necessary to implement the screening tests.

The bill also authorizes DHSS to charge a reasonable fee for the testing. The amount of the fee and the procedures for collecting the fee are to be determined by the Commissioner of Health and Senior Services.

FISCAL ANALYSIS

EXECUTIVE BRANCH

None received, however, some information described below was provided informally by DHSS.

OFFICE OF LEGISLATIVE SERVICES

The Office of Legislative Services (OLS) is unable to determine what costs, if any, would be generated by this legislation. The DHSS would not be required to take any action until the four conditions set forth in the bill are met. At this time, the OLS has not been able to determine if the first three conditions are met. That is, the OLS does not know the following: 1) if the necessary reagents have been registered with the FDA; 2) if the necessary reagents have been made available by the CDC; or 3) if quality assurance testing methodology has been developed. The DHSS has informally provided information that the fourth condition is not met, as it does not currently possess the equipment necessary to implement the screening tests. The OLS notes that the bill does not direct DHSS to acquire this equipment; it only requires that screening begin once DHSS acquires the equipment and the other three conditions are met. The OLS does not have information regarding the cost to DHSS to acquire the necessary equipment.

Currently, the Newborn Screening Program performs screening tests for 54 disorders on all newborns in the State within 48 hours after birth. These tests are performed at the State-operated Newborn Screening Laboratory. **Information provided informally by DHSS indicates that the tests required by this legislation would be performed as a part of the same panel of tests.** New Jersey State Health Assessment Data indicates that approximately 110,000 children are born in the State each year who would be screened. Some cost would be incurred by performing each test, but a per-capita price cannot be estimated with available information.

The bill authorizes DHSS to levy a reasonable fee to offset costs it incurs as a result of this legislation. The Newborn Screening Program is funded through a fee on hospitals, currently set at \$90 per child. It seems likely that the fee authorized by this legislation would be added to this \$90 fee. Although the fee is initially charged to hospitals, it is typically shifted to third-party payers, including Medicaid and NJ FamilyCare. Assuming that the fee is implemented in this fashion, and that these programs fully cover the additional fee, the Medicaid and NJ FamilyCare programs would bear an additional cost equal to the fee increase, multiplied by the number of

infants born to mothers enrolled in each program, less the federal matching funds. Without further information from DHSS, the OLS cannot determine how much the current \$90 fee would increase as a result of adding tests for these five additional diseases. It is noted that the increased cost would not be paid directly to hospitals for managed care enrollees, but would be incorporated into the capitated fee paid by the State to the managed care organizations that provide insurance to Medicaid and NJ FamilyCare enrollees.

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.).