

26:2-111.7

LEGISLATIVE HISTORY CHECKLIST

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LAWS OF: 2014 **CHAPTER:** 44

NJSA: 26:2-111.7 ("Let Them Be Little Act"; provides for screening newborn infants for MPS I and MPS II)

BILL NO: A1101 (Substituted for S668)

SPONSOR(S) Vainieri Huttle and others

DATE INTRODUCED: January 16, 2014

COMMITTEE: **ASSEMBLY:** Women and Children

SENATE: ---

AMENDED DURING PASSAGE: No

DATE OF PASSAGE: **ASSEMBLY:** May 22, 2014

SENATE: June 26, 2014

DATE OF APPROVAL: September 10, 2014

FOLLOWING ARE ATTACHED IF AVAILABLE:

FINAL TEXT OF BILL (Assembly Committee Substitute enacted) Yes

A1101

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

COMMITTEE STATEMENT: **ASSEMBLY:** Yes

SENATE: No

(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

S668

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

COMMITTEE STATEMENT: **ASSEMBLY:** No

SENATE: Yes Health
Budget

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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REPORTS: No

HEARINGS: No

NEWSPAPER ARTICLES: No

LAW/RWH

P.L.2014, CHAPTER 44, *approved September 10, 2014*
Assembly Committee Substitute for
Assembly, No. 1101

1 AN ACT concerning screening for mucopolysaccharidosis I and II in
2 newborn infants and supplementing Title 26 of the Revised
3 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
9 mucopolysaccharidosis I (MPS I), also known as Hurler syndrome,
10 Hurler-Scheie syndrome, or Scheie syndrome, beginning six months
11 following the occurrence of all of the following:

12 (1) the development of a reliable test or series of tests for
13 screening newborns for MPS I using dried blood spots and quality
14 assurance testing methodology for Hunter syndrome testing;

15 (2) the availability of quality assurance materials for the MPS I
16 test from the federal Centers for Disease Control and Prevention;

17 (3) the inclusion of newborn screening for MPS I in the
18 Recommended Uniform Screening Panel of the United States
19 Secretary of Health and Human Services' Advisory Committee on
20 Heritable Disorders in Newborns and Children, after the
21 committee's evidence review of newborn screening for MPS I;

22 (4) the review by the Department of Health of the proposed test;
23 and

24 (5) the acquisition of equipment necessary to implement the
25 expanded screening tests by the State's Newborn Screening
26 Laboratory.

27 b. All infants born in this State shall be tested for
28 mucopolysaccharidosis II (MPS II), also called Hunter syndrome,
29 beginning six months following the occurrence of all of the
30 following:

31 (1) the development of a reliable test or series of tests for
32 screening newborns for MPS II using dried blood spots and quality
33 assurance testing methodology for Hunter syndrome testing;

34 (2) the availability of quality assurance materials for the MPS II
35 test from the federal Centers for Disease Control and Prevention;

36 (3) the inclusion of newborn screening for MPS II in the
37 Recommended Uniform Screening Panel of the United States
38 Secretary of Health and Human Services' Advisory Committee on
39 Heritable Disorders in Newborns and Children, after the
40 committee's evidence review of newborn screening for MPS II;

41 (4) the review by the Department of Health of the proposed test;
42 and

1 (5) the acquisition of equipment necessary to implement the
2 expanded screening tests by the State's Newborn Screening
3 Laboratory.

4 c. The Department of Health may charge a reasonable fee and
5 any reasonable increase in this fee as necessary, for the tests
6 performed pursuant to this section. The amount of the fee and the
7 procedures for collecting the fee shall be determined by the
8 Commissioner of Health.

9

10 2. This act shall take effect immediately.

11

12

13

14

15 "Let Them Be Little Act"; provides for screening newborn
16 infants for MPS I and MPS II.

ASSEMBLY, No. 1101

STATE OF NEW JERSEY 216th LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2014 SESSION

Sponsored by:

Assemblywoman VALERIE VAINIERI HUTTLE

District 37 (Bergen)

Assemblyman DAVID P. RIBLE

District 30 (Monmouth and Ocean)

Assemblywoman SHAVONDA E. SUMTER

District 35 (Bergen and Passaic)

SYNOPSIS

"Let Them Be Little Act"; provides for screening newborn infants for Hunter syndrome.

CURRENT VERSION OF TEXT

Introduced Pending Technical Review by Legislative Counsel



(Sponsorship Updated As Of: 2/21/2014)

1 AN ACT concerning screening for Hunter syndrome in newborn
2 infants, designated as the "Let Them Be Little Act," and
3 amending P.L.2011, c.175.
4

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

7
8 1. Section 1 of P.L.2011, c.175 (C.26:2-111.5) is amended to
9 read as follows:

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

14 (1) the registration with the federal Food and Drug
15 Administration of the necessary reagents;

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

18 (3) the availability of quality assurance testing methodology for
19 these processes; and

20 (4) the acquisition by the Department of Health of the
21 equipment necessary to implement the expanded screening tests.

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

26 (cf: 2012, c.17, s.120)
27

28 2. This act shall take effect immediately.
29
30

31 STATEMENT
32

33 This bill, designated as the "Let Them Be Little Act," requires
34 infants born in the State to be screened for Hunter syndrome, a
35 lysosomal disorder, under the same conditions as are required for
36 other lysosomal disorders. Hunter syndrome is a rare genetic
37 disorder which causes permanent, progressive damage affecting
38 appearance, mental development, organ function, and physical
39 abilities.

40 Current law requires newborn screening of other lysosomal
41 disorders known as Krabbe, Pompe, Gaucher, Fabry, and Niemann-
42 Pick diseases, within six months of the occurrence of the following:
43 the registration with the federal Food and Drug Administration of
44 the necessary reagents; the availability of the necessary reagents
45 from the federal Centers for Disease Control and Prevention; the

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 thus is new matter.

1 availability of quality assurance testing methodology for these
2 processes; and the acquisition by the Department of Health of the
3 equipment necessary to implement the expanded screening tests.
4 Newborn screening of Hunter syndrome would be subject to the
5 same requirements.

6 Hunter syndrome occurs mainly among males when an enzyme
7 needed to break down certain complex molecules is missing or
8 malfunctioning. There are two subtypes: early- and late- onset
9 Hunter syndrome. Early-onset Hunter syndrome is more common
10 and severe, and appears usually between two and four years of age.
11 By late childhood, a child may suffer from a severe mental
12 disability and may not live beyond the teenage years. Late-onset
13 Hunter syndrome is milder, and is typically diagnosed after 10 years
14 of age but may not be detected until adulthood. A person with late-
15 onset Hunter syndrome may live into their 50s.

16 It is intended that early screening and diagnosis of Hunter
17 syndrome and appropriate management, through administration of
18 prescription drugs such as ELAPRASE, would enable a child with
19 Hunter Syndrome to live a longer and higher quality of life.

20 The bill is designated as the "Let Them Be Little Act" to
21 recognize that children with Hunter Syndrome are often unable to
22 enjoy the simple pleasures of youth because so much of their lives
23 are occupied with undergoing medical treatments and tests rather
24 than just being kids.

ASSEMBLY WOMEN AND CHILDREN COMMITTEE

STATEMENT TO

ASSEMBLY COMMITTEE SUBSTITUTE FOR ASSEMBLY, No. 1101

STATE OF NEW JERSEY

DATED: FEBRUARY 20, 2014

The Assembly Women and Children Committee reports favorably an Assembly Committee Substitute for Assembly Bill No. 1101.

This committee substitute, designated as the "Let Them Be Little Act," requires infants born in the State to be screened for mucopolysaccharidosis I (MPS I, also known as Hurler syndrome, Hurler-Scheie syndrome, or Scheie syndrome) and mucopolysaccharidosis II (MPS II, also known as Hunter syndrome).

The substitute would require to begin six months following the occurrence of all the following: the development of a reliable test or series of tests for screening newborns for MPS I and MPS II using dried blood spots and quality assurance testing methodology for Hunter syndrome testing; the availability of quality assurance materials for the MPS I and MPS II tests from the federal Centers for Disease Control and Prevention; the inclusion of newborn screenings for MPS I and MPS II in the Recommended Uniform Screening Panel of the United States Secretary of Health and Human Services' Advisory Committee on Heritable Disorders in Newborns and Children, after the committee's evidence review of newborn screenings for MPS I and MPS II; the review by the Department of Health (DOH) of the proposed tests; and the acquisition of equipment necessary to implement the expanded screening tests by the State's Newborn Screening Laboratory.

The committee substitute also allows DOH to charge a reasonable fee, and increase that fee, as necessary, for the tests performed pursuant to the substitute. The amount of the fee and the procedures for its collection would be determined by the Commissioner of Health.

LEGISLATIVE FISCAL ESTIMATE
ASSEMBLY COMMITTEE SUBSTITUTE FOR
ASSEMBLY, No. 1101
STATE OF NEW JERSEY
216th LEGISLATURE

DATED: MAY 29, 2014

SUMMARY

Synopsis: “Let Them Be Little Act”; provides for screening newborn infants for MPS I and MPS II.

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 substitute stipulates a series of conditions that must be met before any action must be taken by the State. Until all of the conditions are met, the substitute would not be implemented and would have no fiscal impact.
- When implemented, the substitute may generate minimal costs, which may be offset by additional revenues from increased fees charged to hospitals for newborn screening.

BILL DESCRIPTION

The Assembly Committee Substitute for Assembly Bill No. 1101 of 2014 requires that all infants born in New Jersey be tested for mucopolysaccharidosis I (MPS I) and mucopolysaccharidosis II (MPS II), beginning six months following the occurrence of all of the following:

- the development of a reliable test or series of tests for screening newborns for MPS I and MPS II using dried blood spots and quality assurance testing methodology for Hunter syndrome testing;

- the availability of quality assurance materials for the MPS I and MPS II tests from the federal Centers for Disease Control and Prevention;
- the inclusion of newborn screening for MPS I and MPS II in the Recommended Uniform Screening Panel of the United States Secretary of Health and Human Services' Advisory Committee on Heritable Disorders in Newborns and Children, after the committee's evidence review of newborn screening for MPS I and MPS II;
- the review by the Department of Health of the proposed tests; and
- the acquisition of equipment necessary to implement the expanded screening tests by the State's Newborn Screening Laboratory.

The substitute's requirements are separate for MPS I and MPS II, so if the specified conditions are met for only one of the two disorders, testing would be required for only that disorder. The substitute also authorizes the Department of Health to charge a reasonable fee for testing and any reasonable increase in that fee as necessary.

FISCAL ANALYSIS

EXECUTIVE BRANCH

None received.

OFFICE OF LEGISLATIVE SERVICES

The Office of Legislative Services believes it is unlikely that the criteria set forth in the substitute will be met for several years, so the substitute would likely not be implemented during that period. Specifically, inclusion of newborn screening for MPS I and MPS II in the Recommended Uniform Screening Panel may not occur in the near future, if it occurs at all. As of January 2014, MPS I is under review by the Condition Review Workgroup of the Discretionary Advisory Committee on Heritable Disorders in Newborns and Children. Upon release of the workgroup's report, MPS I would have to be approved by the Advisory Committee and the Secretary of Health and Human Services in order to be included in the Recommended Uniform Screening Panel. It is noted that only two of the twelve conditions that have been nominated since 2007 have been fully approved, and three are currently pending. MPS II has not been formally nominated for consideration by the Advisory Committee, but a growing body of scientific research suggests that a viable test for MPS II may be available soon, and so may be nominated for consideration by the Advisory Committee.

Even if the conditions regarding development and availability of the tests are met, the substitute effectively grants the Department of Health an option not to add the tests to the newborn screening panel if it chooses not to review the test or acquire the necessary equipment. The substitute 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 tests for MPS I or MPS II are 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 60 disorders. Any additional costs could be offset by increasing the charge, currently \$90, which the Department of Health levies on health care facilities for each newborn screened. 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. The substitute specifically does not require that the Department of Health acquire any equipment necessary to conduct the tests.

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.).

SENATE, No. 668

STATE OF NEW JERSEY 216th LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2014 SESSION

Sponsored by:

Senator NELLIE POU

District 35 (Bergen and Passaic)

SYNOPSIS

"Let Them Be Little Act"; provides for screening newborn infants for Hunter syndrome.

CURRENT VERSION OF TEXT

Introduced Pending Technical Review by Legislative Counsel



1 AN ACT concerning screening for Hunter syndrome in newborn
2 infants, designated as the "Let Them Be Little Act," and
3 amending P.L.2011, c.175.
4

5 **BE IT ENACTED** by the Senate and General Assembly of the State
6 of New Jersey:
7

8 1. Section 1 of P.L.2011, c.175 (C.26:2-111.5) is amended to
9 read as follows:

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

14 (1) the registration with the federal Food and Drug
15 Administration of the necessary reagents;

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

18 (3) the availability of quality assurance testing methodology for
19 these processes; and

20 (4) the acquisition by the Department of Health of the
21 equipment necessary to implement the expanded screening tests.

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

26 (cf: P.L.2012, c.17, s.120)
27

28 2. This act shall take effect immediately.
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31 STATEMENT
32

33 This bill, designated as the "Let Them Be Little Act," requires
34 infants born in the State to be screened for Hunter syndrome, a
35 lysosomal disorder, under the same conditions as are required for
36 other lysosomal disorders. Hunter syndrome is a rare genetic
37 disorder which causes permanent, progressive damage affecting
38 appearance, mental development, organ function, and physical
39 abilities.

40 Current law requires newborn screening of other lysosomal
41 disorders known as Krabbe, Pompe, Gaucher, Fabry, and Niemann-
42 Pick diseases, within six months of the occurrence of the following:
43 the registration with the federal Food and Drug Administration of
44 the necessary reagents; the availability of the necessary reagents

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 thus is new matter.

1 from the federal Centers for Disease Control and Prevention; the
2 availability of quality assurance testing methodology for these
3 processes; and the acquisition by the Department of Health of the
4 equipment necessary to implement the expanded screening tests.
5 Newborn screening of Hunter syndrome would be subject to the
6 same requirements.

7 Hunter syndrome occurs mainly among males when an enzyme
8 needed to break down certain complex molecules is missing or
9 malfunctioning. There are two subtypes: early- and late- onset
10 Hunter syndrome. Early-onset Hunter syndrome is more common
11 and severe, and appears usually between two and four years of age.
12 By late childhood, a child may suffer from a severe mental
13 disability and may not live beyond the teenage years. Late-onset
14 Hunter syndrome is milder, and is typically diagnosed after 10 years
15 of age but may not be detected until adulthood. A person with late-
16 onset Hunter syndrome may live into their 50s.

17 It is intended that early screening and diagnosis of Hunter
18 syndrome and appropriate management, through administration of
19 prescription drugs such as ELAPRASE, would enable a child with
20 Hunter Syndrome to live a longer and higher quality of life.

21 The bill is designated as the "Let Them Be Little Act" to
22 recognize that children with Hunter Syndrome are often unable to
23 enjoy the simple pleasures of youth because so much of their lives
24 are occupied with undergoing medical treatments and tests rather
25 than just being kids.

SENATE HEALTH, HUMAN SERVICES AND SENIOR
CITIZENS COMMITTEE

STATEMENT TO

SENATE, No. 668

STATE OF NEW JERSEY

DATED: JANUARY 27, 2014

The Senate Health, Human Services and Senior Citizens Committee reports favorably Senate Bill No. 668.

This bill, designated as the "Let Them Be Little Act," requires infants born in the State to be screened for Hunter syndrome, a lysosomal disorder, under the same conditions as are required for other lysosomal disorders. Hunter syndrome is a rare genetic disorder which causes permanent, progressive damage affecting appearance, mental development, organ function, and physical abilities.

Current law requires newborn screening of other lysosomal disorders known as Krabbe, Pompe, Gaucher, Fabry, and Niemann-Pick diseases, within six months of the occurrence of the following: the registration with the federal Food and Drug Administration of the necessary reagents; the availability of the necessary reagents from the federal Centers for Disease Control and Prevention; the availability of quality assurance testing methodology for these processes; and the acquisition by the Department of Health of the equipment necessary to implement the expanded screening tests. Newborn screening of Hunter syndrome would be subject to the same requirements.

Hunter syndrome occurs mainly among males when an enzyme needed to break down certain complex molecules is missing or malfunctioning. There are two subtypes: early- and late-onset Hunter syndrome. Early-onset Hunter syndrome is more common and severe, and appears usually between two and four years of age. By late childhood, a child may suffer from a severe mental disability and may not live beyond the teenage years. Late-onset Hunter syndrome is milder, and is typically diagnosed after 10 years of age but may not be detected until adulthood. A person with late-onset Hunter syndrome may live into their 50s.

It is intended that early screening and diagnosis of Hunter syndrome and appropriate management, through administration of prescription drugs such as ELAPRASE, would enable a child with Hunter Syndrome to live a longer and higher quality of life.

The bill is designated as the "Let Them Be Little Act" to recognize that children with Hunter Syndrome are often unable to enjoy the simple pleasures of youth because so much of their lives are occupied

with undergoing medical treatments and tests rather than just being kids.

This bill was pre-filed for introduction in the 2014-2015 session pending technical review. As reported, the bill includes the changes required by technical review, which has been performed.

SENATE BUDGET AND APPROPRIATIONS COMMITTEE

STATEMENT TO

SENATE COMMITTEE SUBSTITUTE FOR **SENATE, No. 668**

STATE OF NEW JERSEY

DATED: MARCH 20, 2014

The Senate Budget and Appropriations Committee reports favorably a Senate Committee Substitute for Senate Bill No. 668.

This committee substitute, designated as the "Let Them Be Little Act," requires infants born in the State to be screened for mucopolysaccharidosis I (MPS I, also known as Hurler syndrome, Hurler-Scheie syndrome, or Scheie syndrome) and mucopolysaccharidosis II (MPS II, also known as Hunter syndrome).

The committee substitute would require screening to begin six months following the occurrence of all the following: (1) the development of a reliable test or series of tests for screening newborns for MPS I and MPS II using dried blood spots and quality assurance testing methodology for Hunter syndrome testing; (2) the availability of quality assurance materials for the MPS I and MPS II tests from the federal Centers for Disease Control and Prevention; (3) the inclusion of newborn screenings for MPS I and MPS II in the Recommended Uniform Screening Panel of the United States Secretary of Health and Human Services' Advisory Committee on Heritable Disorders in Newborns and Children, after the committee's evidence review of newborn screenings for MPS I and MPS II; (4) the review by the Department of Health (DOH) of the proposed tests; and (5) the acquisition of equipment necessary to implement the expanded screening tests by the State's Newborn Screening Laboratory.

FISCAL IMPACT:

The committee substitute provides that screening would not begin until six months after a series of conditions are met. When screening is implemented, the substitute may generate minimal costs, which may be offset by revenues from fees charged to hospitals for newborn screening. The substitute requires separate screening for MPS I and MPS II, so if the specified conditions are met for only one of the two disorders, testing would be required for only that disorder. The committee substitute also allows DOH to charge a reasonable fee, and to increase that fee, as necessary, for the screening tests performed pursuant to the substitute. The amount of the fee and the procedures for its collection would be determined by the Commissioner of Health.

LEGISLATIVE FISCAL ESTIMATE
SENATE COMMITTEE SUBSTITUTE FOR
SENATE, No. 668
STATE OF NEW JERSEY
216th LEGISLATURE

DATED: MARCH 26, 2014

SUMMARY

Synopsis: “Let Them Be Little Act”; provides for screening newborn infants for MPS I and MPS II.

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 substitute stipulates a series of conditions that must be met before any action must be taken by the State. Until all of the conditions are met, the substitute would not be implemented and would have no fiscal impact.
- When implemented, the substitute may generate minimal costs, which may be offset by additional revenues from increased fees charged to hospitals for newborn screening.

BILL DESCRIPTION

The Senate Committee Substitute for Senate Bill No. 668 of 2014 requires that all infants born in New Jersey be tested for mucopolysaccharidosis (MPS) I and MPS II, beginning six months following the occurrence of all of the following:

- the development of a reliable test or series of tests for screening newborns for MPS I and MPS II using dried blood spots and quality assurance testing methodology for Hunter syndrome testing;
- the availability of quality assurance materials for the MPS I and MPS II tests from the federal Centers for Disease Control and Prevention;

- the inclusion of newborn screening for MPS I and MPS II in the Recommended Uniform Screening Panel of the United States Secretary of Health and Human Services' Advisory Committee on Heritable Disorders in Newborns and Children, after the committee's evidence review of newborn screening for MPS I and MPS II;
- the review by the Department of Health of the proposed tests; and
- the acquisition of equipment necessary to implement the expanded screening tests by the State's Newborn Screening Laboratory.

The substitute's requirements are separate for MPS I and MPS II, so if the specified conditions are met for only one of the two disorders, testing would be required for only that disorder. The substitute also authorizes the Department of Health to charge a reasonable fee for testing and any reasonable increase in that fee as necessary.

FISCAL ANALYSIS

EXECUTIVE BRANCH

None received.

OFFICE OF LEGISLATIVE SERVICES

The Office of Legislative Services believes it is unlikely that the criteria set forth in the substitute will be met for several years, so the substitute would likely not be implemented during that period. Specifically, inclusion of newborn screening for MPS I and MPS II in the Recommended Uniform Screening Panel may not occur in the near future, if it occurs at all. As of January 2014, MPS I is under review by the Condition Review Workgroup of the Discretionary Advisory Committee on Heritable Disorders in Newborns and Children. Upon release of the workgroup's report, MPS I would have to be approved by the Advisory Committee and the Secretary of Health and Human Services in order to be included in the Recommended Uniform Screening Panel. It is noted that only two of the twelve conditions that have been nominated since 2007 have been fully approved, and three are currently pending. MPS II has not been formally nominated for consideration by the Advisory Committee, but a growing body of scientific research suggests that a viable test for MPS II may be available soon, and so may be nominated for consideration by the Advisory Committee.

Even if the conditions regarding development and availability of the tests are met, the substitute effectively grants the Department of Health an option not to add the tests to the newborn screening panel if it chooses not to review the test or acquire the necessary equipment. The substitute 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 tests for MPS I or MPS II are 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 60 disorders. Any additional costs could be offset by increasing the charge, currently \$90, which the Department of Health levies on health care facilities for each newborn screened. 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.

The substitute specifically does not require that the Department of Health acquire any equipment necessary to conduct the tests.

Section: Human Services

*Analyst: David Drescher
Associate Fiscal Analyst*

*Approved: David J. Rosen
Legislative Budget and Finance Officer*

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