

26:2-110a
LEGISLATIVE HISTORY CHECKLIST
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LAWS OF: 2019 **CHAPTER:** 296

NJSA: 26:2-110a (Revises Newborn Screening program in DOH.)

BILL NO: S484 (Substituted for A2705)

SPONSOR(S) Joseph F. Vitale and others

DATE INTRODUCED: 1/9/2018

COMMITTEE: **ASSEMBLY:** Women & Children

SENATE: Health, Human Services & Senior Citizens
Budget & Appropriations

AMENDED DURING PASSAGE: Yes

DATE OF PASSAGE: **ASSEMBLY:** 12/16/2019

SENATE: 1/31/2019

DATE OF APPROVAL: 1/13/2020

FOLLOWING ARE ATTACHED IF AVAILABLE:

FINAL TEXT OF BILL (First Reprint enacted) Yes

S484

SPONSOR'S STATEMENT: (Begins on page 5 of introduced bill) Yes

COMMITTEE STATEMENT: **ASSEMBLY:** Yes Women & Children

SENATE: Yes Health, Human Services & Senior Citizens

Budget & Appro.

(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: Yes

LEGISLATIVE FISCAL ESTIMATE: Yes 5/21/2018
2/5/2019

A2705

SPONSOR'S STATEMENT: (Begins on page 5 of introduced bill) Yes

COMMITTEE STATEMENT:

ASSEMBLY: Yes Women &
Children

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 12/18/2019

VETO MESSAGE:

No

GOVERNOR'S PRESS RELEASE ON SIGNING:

Yes

FOLLOWING WERE PRINTED:

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REPORTS:

No

HEARINGS:

No

NEWSPAPER ARTICLES:

No

RWH/JA

P.L. 2019, CHAPTER 296, *approved January 13, 2020*

Senate, No. 484 (*First Reprint*)

1 AN ACT concerning screening for disorders in newborn infants and
2 amending and supplementing P.L.1977, c.321.

3

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

6

7 1. Section 1 of P.L.1977, c.321 (C.26:2-110) is amended to
8 read as follows:

9 1. **【It is hereby declared to be the public policy of this State**
10 **that in the interests of public health every effort should be made to**
11 **detect in newborn infants, hypothyroidism, galactosemia,**
12 **phenylketonuria, and other preventable biochemical disorders**
13 **which may cause mental retardation or other permanent disabilities**
14 **and to treat affected individuals.】**

15 The Legislature finds and declares that:

16 a. Newborn screening is an essential public health activity that
17 strives to screen every newborn infant for a variety of congenital
18 disorders, which, if not detected and managed early, can result in
19 significant morbidity, mortality, and disability. The State’s newborn
20 screening system ¹**【must provide the infrastructure for universal**
21 access and rapid and effective follow-up】 shall be a coordinated and
22 comprehensive effort to provide education, screening, follow-up,
23 diagnosis, treatment and management, and program evaluation
24 activities¹ ;

25 b. Ongoing advances in technologies and treatment modalities
26 make it possible to screen newborn infants for a wide array of
27 ¹biochemical¹ disorders. It is imperative that the State adjust its
28 ¹**【newborn screening program】 Newborn Screening Program¹ to**
29 incorporate these ¹biochemical¹ disorders to ensure that the
30 program remains at the forefront of these advances; and

31 c. It is the intent of this act to protect the health and quality of
32 life of newborn infants born in this State by enhancing the capacity
33 to screen for congenital disorders and by providing: all newborn
34 infants with screens for certain conditions and with appropriate
35 referrals and early medical intervention when warranted; and
36 newborn data collection is standardized, and conditions detected by
37 newborn screening are tracked and monitored. Further, information
38 on newborn screening and conditions for which a newborn can be
39 screened should be readily accessible, current, and understandable

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.

Matter enclosed in superscript numerals has been adopted as follows:

¹Senate floor amendments adopted December 17, 2018.

1 to both health care providers and parents or guardians.
2 (cf: P.L.1988, c.24, s.2)

3
4 2. (New section) The Commissioner of Health shall establish
5 a Newborn Screening Advisory Review Committee to annually
6 review the disorders included in the Newborn Screening
7 **'[program] Program'**, screening technologies, treatment options,
8 and educational and follow-up procedures. The committee shall
9 include, but need not be limited to, medical, hospital, and public
10 health professionals, scientific experts, and consumer
11 representatives and advocates. The committee shall meet annually
12 to review and revise the list of disorders recommended for inclusion
13 in the Newborn Screening **'[program] Program'**. The committee
14 shall allow for public input in the course of conducting its review
15 and issue recommendations to the commissioner on the
16 improvement of the Newborn Screening **'[program] Program'**.

17
18 3. Section 2 of P.L.1977, c.321 (C.26:2-111) is amended to
19 read as follows:

20 2. **[All]** The Newborn Screening Program in the Department of
21 Health shall screen all infants born in this State **[shall be tested for**
22 **hypothyroidism, galactosemia and phenylketonuria]** based on the
23 list of disorders that is recommended by the Newborn Screening
24 Advisory Review Committee and approved by the Commissioner of
25 Health, **'[consistent]'** with **'consideration of'** the Recommended
26 Uniform Screening Panel of the United States Secretary of Health
27 and Human Services. The Commissioner of Health **[shall]** may
28 issue regulations to assure that newborns are **[so tested]** screened in
29 a manner approved by the commissioner. **[The commissioner shall**
30 **ensure that treatment services are available to all identified**
31 **individuals.]**

32 The **[State]** Department of Health **[may]** shall charge a
33 reasonable fee for the **[tests]** screening, follow-up, treatment, and
34 education performed pursuant to this act. The amount of the fee
35 **[and the]** shall be adjusted by the commissioner as necessary to
36 support the screening, follow-up, and treatment of newborn infants,
37 and the education of physicians, hospital staffs, nurses, and the
38 public as required by this act. The procedures for collecting the fee
39 shall be determined by the commissioner. The commissioner shall
40 apply all revenues collected from the fees to the **[testing]**
41 screening, follow-up, education, and treatment procedures
42 performed pursuant to this act. The fee shall be used to support the
43 program, including, but not limited to, ongoing infrastructure
44 upgrades, including provides electronic access to physicians to
45 obtain screening results, and follow-up recommendations.

46 **[The]** Based on the recommendations of the Newborn Screening
47 Advisory Review Committee established pursuant to section 2 of

1 P.L. , c. (C.) (pending before the Legislature as this bill),
2 the commissioner may also require [testing] the screening of
3 newborn infants for other [preventable biochemical] disorders if
4 reliable and efficient [testing] screening techniques are available.
5 If the commissioner determines that an additional test shall be
6 required, [90] the commissioner, at least 60 days prior to requiring
7 the test [he], shall so advise the President of the Senate [.] and the
8 Speaker of the General Assembly [and chairmen of the standing
9 reference committees on Revenue, Finance and Appropriations and
10 Institutions, Health and Welfare of his determination].

11 The commissioner shall provide 'laboratory services and' a
12 follow-up program [of reviewing and following up] on positive
13 screen cases in order that measures may be taken to prevent [mental
14 retardation] death or intellectual or other permanent disabilities.
15 The program shall provide timely 'intervention and, as
16 appropriate, referrals] information and recommendations for
17 referral' to specialist treatment centers for newborn infants who
18 screen positive for disorders pursuant to this section.

19 The commissioner shall collect screening information on
20 newborn infants in a standardized manner and develop a system for
21 quality assurance which includes the periodic assessment of
22 indicators that are measurable, functional, and appropriate to the
23 conditions for which newborn infants are screened pursuant to this
24 section. The commissioner shall have the authority to use the
25 information collected to provide follow-up to newborn infants
26 '[and children]' with screened positive diagnoses to provide
27 '[appropriate] information and recommendations for' referral.
28 Information on newborn infants [and their families] compiled
29 pursuant to this section [may] shall be used by the department and
30 agencies designated by the commissioner for the purposes of
31 carrying out this act, but otherwise the information shall be
32 confidential and not divulged or made public so as to disclose the
33 identity of any person to which it relates, except as provided by law.

34 The department shall [conduct an intensive educational and]
35 provide education or training on the Newborn Screening
36 '[program] Program' [among] to physicians, [hospitals] hospital
37 staffs, [public health] nurses, and the public concerning [those
38 biochemical disorders] newborn screening. [This program shall
39 include information concerning the nature of the disorders, testing
40 for the detection of these disorders and treatment modalities for
41 these disorders.]

42 The provisions of this section shall not apply if the parents of a
43 newborn infant 'provide written notice to the hospital or birthing
44 facility where the newborn infant was delivered, in a manner
45 designated by the commissioner, that they' object '[in writing]' to

1 the **[testing]** screening on the grounds that it would conflict with
2 their religious tenets or practices.
3 (cf: P.L.1988, c.24, s.3)

4
5 4. The Department of Health may adopt, pursuant to the
6 "Administrative Procedure Act," P.L.1968 c.410 (C.52:14B-
7 1 et seq.), rules and regulations necessary to implement the
8 provisions of this act.

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10 5. This act shall take effect on the 180th day following
11 enactment, except that the Commissioner of Health may take such
12 anticipatory action in advance as shall be necessary for its
13 implementation.

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18 _____
Revises Newborn Screening program in DOH.

SENATE, No. 484

STATE OF NEW JERSEY
218th LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2018 SESSION

Sponsored by:

Senator JOSEPH F. VITALE

District 19 (Middlesex)

SYNOPSIS

Revises Newborn Screening program in DOH.

CURRENT VERSION OF TEXT

Introduced Pending Technical Review by Legislative Counsel.



1 AN ACT concerning screening for disorders in newborn infants and
2 amending and supplementing P.L.1977, c.321.

3

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

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7 1. Section 1 of P.L.1977, c.321 (C.26:2-110) is amended to
8 read as follows:

9 1. **【It is hereby declared to be the public policy of this State**
10 **that in the interests of public health every effort should be made to**
11 **detect in newborn infants, hypothyroidism, galactosemia,**
12 **phenylketonuria, and other preventable biochemical disorders**
13 **which may cause mental retardation or other permanent disabilities**
14 **and to treat affected individuals.】**

15 The Legislature finds and declares that:

16 a. Newborn screening is an essential public health activity that
17 strives to screen every newborn infant for a variety of congenital
18 disorders, which, if not detected and managed early, can result in
19 significant morbidity, mortality, and disability. The State's newborn
20 screening system must provide the infrastructure for universal
21 access and rapid and effective follow-up;

22 b. Ongoing advances in technologies and treatment modalities
23 make it possible to screen newborn infants for a wide array of
24 disorders. It is imperative that the State adjust its newborn
25 screening program to incorporate these disorders to ensure that the
26 program remains at the forefront of these advances; and

27 c. It is the intent of this act to protect the health and quality of
28 life of newborn infants born in this State by enhancing the capacity
29 to screen for congenital disorders and by providing: all newborn
30 infants with screens for certain conditions and with appropriate
31 referrals and early medical intervention when warranted; and
32 newborn data collection is standardized, and conditions detected by
33 newborn screening are tracked and monitored. Further, information
34 on newborn screening and conditions for which a newborn can be
35 screened should be readily accessible, current, and understandable
36 to both health care providers and parents or guardians.

37 (cf: P.L.1988, c.24, s.2)

38

39 2. (New section) The Commissioner of Health shall establish a
40 Newborn Screening Advisory Review Committee to annually
41 review the disorders included in the Newborn Screening program,
42 screening technologies, treatment options, and educational and
43 follow-up procedures. The committee shall include, but need not be
44 limited to, medical, hospital, and public health professionals,
45 scientific experts, and consumer representatives and advocates. The
46 committee shall meet annually to review and revise the list of

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 disorders recommended for inclusion in the Newborn Screening
2 program. The committee shall allow for public input in the course
3 of conducting its review and issue recommendations to the
4 commissioner on the improvement of the Newborn Screening
5 program.

6

7 3. Section 2 of P.L.1977, c.321 (C.26:2-111) is amended to
8 read as follows:

9 2. **【All】** The Newborn Screening Program in the Department of
10 Health shall screen all infants born in this State **【shall be tested for**
11 **hypothyroidism, galactosemia and phenylketonuria】** based on the
12 list of disorders that is recommended by the Newborn Screening
13 Advisory Review Committee and approved by the Commissioner of
14 Health, consistent with the Recommended Uniform Screening Panel
15 of the United States Secretary of Health and Human Services. The
16 Commissioner of Health **【shall】** may issue regulations to assure
17 that newborns are **【so tested】** screened in a manner approved by the
18 commissioner. **【The commissioner shall ensure that treatment**
19 **services are available to all identified individuals.】**

20 The **【State】** Department of Health **【may】** shall charge a
21 reasonable fee for the **【tests】** screening, follow-up, treatment, and
22 education performed pursuant to this act. The amount of the fee
23 **【and the】** shall be adjusted by the commissioner as necessary to
24 support the screening, follow-up, and treatment of newborn infants,
25 and the education of physicians, hospital staffs, nurses, and the
26 public as required by this act. The procedures for collecting the fee
27 shall be determined by the commissioner. The commissioner shall
28 apply all revenues collected from the fees to the 【testing】
29 screening, follow-up, education, and treatment procedures
30 performed pursuant to this act. The fee shall be used to support the
31 program, including, but not limited to, ongoing infrastructure
32 upgrades, including provides electronic access to physicians to
33 obtain screening results, and follow-up recommendations.

34 **【The】** Based on the recommendations of the Newborn Screening
35 Advisory Review Committee established pursuant to section 2 of
36 P.L. , c. (C.) (pending before the Legislature as this bill),
37 the commissioner may also require 【testing】 the screening
38 of newborn infants for other 【preventable biochemical】 disorders if
39 reliable and efficient 【testing】 screening techniques are available.
40 If the commissioner determines that an additional test shall be
41 required, **【90】** the commissioner, at least 60 days prior to requiring
42 the test 【he】₂ shall so advise the President of the Senate 【,】 and the
43 Speaker of the General Assembly 【and chairmen of the standing
44 reference committees on Revenue, Finance and Appropriations and
45 Institutions, Health and Welfare of his determination】.

1 The commissioner shall provide a follow-up program **[of**
2 reviewing and following up**]** on positive screen cases in order that
3 measures may be taken to prevent **[mental retardation]** death or
4 intellectual or other permanent disabilities. The program shall
5 provide timely intervention and, as appropriate, referrals to
6 specialist treatment centers for newborn infants who screen positive
7 for disorders pursuant to this section.

8 The commissioner shall collect screening information on
9 newborn infants in a standardized manner and develop a system for
10 quality assurance which includes the periodic assessment of
11 indicators that are measurable, functional, and appropriate to the
12 conditions for which newborn infants are screened pursuant to this
13 section. The commissioner shall have the authority to use the
14 information collected to provide follow-up to newborn infants and
15 children with screened positive diagnoses to provide appropriate
16 referral. Information on newborn infants **[and their families]**
17 compiled pursuant to this section **[may]** shall be used by the
18 department and agencies designated by the commissioner for the
19 purposes of carrying out this act, but otherwise the information
20 shall be confidential and not divulged or made public so as to
21 disclose the identity of any person to which it relates, except as
22 provided by law.

23 The department shall **[conduct an intensive educational and]**
24 provide education or training on the Newborn Screening program
25 **[among]** to physicians, **[hospitals]** hospital staffs, **[public health]**
26 nurses, and the public concerning **[those biochemical disorders]**
27 newborn screening. **[This program shall include information**
28 **concerning the nature of the disorders, testing for the detection of**
29 **these disorders and treatment modalities for these disorders.]**

30 The provisions of this section shall not apply if the parents of a
31 newborn infant object in writing to the **[testing]** screening on the
32 grounds that it would conflict with their religious tenets or
33 practices.

34 (cf: P.L.1988, c.24, s.3)

35

36 4. The Department of Health may adopt, pursuant to the
37 "Administrative Procedure Act," P.L.1968 c.410 (C.52:14B-1 et
38 seq.), rules and regulations necessary to implement the provisions
39 of this act.

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41 5. This act shall take effect on the 180th day following
42 enactment, except that the Commissioner of Health may take such
43 anticipatory action in advance as shall be necessary for its
44 implementation.

STATEMENT

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This bill revises the State’s newborn screening program for congenital disorders by requiring the Commissioner of Health to establish a Newborn Screening Advisory Review Committee consisting of medical, hospital, and public health professionals, as well as scientific experts and consumer representatives, which would be authorized to make recommendations on the disorders to be screened for by the department, as well as on screening technologies, treatment options, and educational and follow-up procedures, to be used in the State’s newborn screening program. The committee would be required to meet annually to review and revise the list of disorders that are recommended for inclusion in the program. The bill also makes several other changes to the program, including formally designating it as the “Newborn Screening” program.

Specifically, the bill makes the following changes to the screening, follow-up, treatment, and education components of the Newborn Screening program:

- the commissioner is required to annually review a list of disorders recommended by the advisory committee and approved by the Commissioner, consistent with the Recommended Uniform Screening Panel of the United States Secretary of Health and Human Services, to determine the disorders for which newborn infants will be screened by the department;
- the commissioner, within 60 days of adding a new disorder to the program, must advise the President of the Senate and the Speaker of the General Assembly;
- the commissioner is required to provide timely intervention and appropriate referral to specialist treatment centers for newborn infants who screen positive for disorders pursuant to the bill;
- the commissioner is required to collect screening information on newborn infants in a standardized manner and develop a system for quality assurance which includes the periodic assessment of measurable indicators, and is further authorized to use the collected information to provide follow-up and appropriate referral to newborns and children with screened positive diagnoses, without regard to the age of the infant or child;
- the commissioner is required to provide education or training on the Newborn Screening program to physicians, hospital staffs, nurses, and the public;
- the reasonable fee charged by the department shall be for the screening, follow-up, and treatment of newborns, and the education of physicians, nurses, and the public, as required by the bill, with a portion of the fee to be used for ongoing infrastructure upgrades, including providing electronic access to physicians to obtain screening results and follow-up recommendations; and

S484 VITALE

6

1 • parents of newborn infants are required to provide notice in
2 writing if they object to screening on the grounds that it would
3 conflict with their religious tenets or practices.

4 The Department of Health currently requires that, within 48
5 hours after birth, all newborns shall be screened for 54 disorders.
6 One heel prick of the newborn provides enough blood to test for all
7 54 disorders.

ASSEMBLY WOMEN AND CHILDREN COMMITTEE

STATEMENT TO

[First Reprint]

SENATE, No. 484

STATE OF NEW JERSEY

DATED: MARCH 11, 2019

The Assembly Women and Children Committee reports favorably Senate Bill No. 484 (1R).

This bill revises the State's newborn screening program for congenital disorders by requiring the Commissioner of Health to establish a Newborn Screening Advisory Review Committee, consisting of medical, hospital, and public health professionals, scientific experts and consumer representatives, which would be authorized to make recommendations on the disorders to be screened for by the department, as well as on screening technologies, treatment options, and educational and follow-up procedures, to be used in the State's newborn screening program. The bill requires that the committee meet annually to review and revise the list of disorders that are recommended for inclusion in the program. The bill also makes several other changes to the program, including formally designating it as the "Newborn Screening" program.

Specifically, the bill makes the following changes to the screening, follow-up, treatment, and education components of the Newborn Screening program:

- the Commissioner is required to annually review a list of disorders recommended by the advisory committee and approved by the commissioner, consistent with the Recommended Uniform Screening Panel of the United States Secretary of Health and Human Services, to determine the disorders for which newborn infants will be screened by the department;
- the Commissioner, within 60 days of adding a new disorder to the program, must advise the President of the Senate and the Speaker of the General Assembly;
- the Commissioner is required to provide timely intervention and appropriate referral to specialist treatment centers for newborn infants who screen positive for disorders pursuant to the bill;
- the Commissioner is required to collect screening information on newborn infants in a standardized manner, and develop a system for quality assurance, which includes the periodic assessment of measurable indicators;
- the Commissioner is authorized to use collected screening information to provide follow-up and appropriate referral to newborns

and children with screened positive diagnoses, without regard to the age of the infant or child;

- the Commissioner is required to provide education or training on the Newborn Screening program to physicians, hospital staffs, nurses, and the public;

- the reasonable fee charged by the department shall be for the screening, follow-up, and treatment of newborns, and the education of physicians, nurses, and the public, as required by the bill, with a portion of the fee to be used for ongoing infrastructure upgrades, including providing electronic access to physicians to obtain screening results and follow-up recommendations; and

- parents of newborn infants are required to provide notice in writing if they object to screening on the grounds that it would conflict with their religious tenets or practices.

The Department of Health currently requires all newborns to be screened for 54 disorders within 48 hours after birth. One heel prick of the newborn provides enough blood to test for all 54 disorders.

As reported by the committee, Senate Bill No. 484 (1R) is identical to Assembly Bill No. 2705 (1R) which was also reported by the committee on this date.

SENATE HEALTH, HUMAN SERVICES AND SENIOR
CITIZENS COMMITTEE

STATEMENT TO

SENATE, No. 484

STATE OF NEW JERSEY

DATED: MARCH 5, 2018

The Senate Health, Human Services and Senior Citizens Committee reports favorably Senate Bill No. 484.

This bill revises the State's newborn screening program for congenital disorders by requiring the Commissioner of Health to establish a Newborn Screening Advisory Review Committee consisting of medical, hospital, and public health professionals, as well as scientific experts and consumer representatives, which would be authorized to make recommendations on the disorders to be screened for by the department, as well as on screening technologies, treatment options, and educational and follow-up procedures, to be used in the State's newborn screening program. The committee would be required to meet annually to review and revise the list of disorders that are recommended for inclusion in the program. The bill also makes several other changes to the program, including formally designating it as the "Newborn Screening" program.

Specifically, the bill makes the following changes to the screening, follow-up, treatment, and education components of the Newborn Screening program:

- the commissioner is required to annually review a list of disorders recommended by the advisory committee and approved by the Commissioner, consistent with the Recommended Uniform Screening Panel of the United States Secretary of Health and Human Services, to determine the disorders for which newborn infants will be screened by the department;
- the commissioner, within 60 days of adding a new disorder to the program, must advise the President of the Senate and the Speaker of the General Assembly;
- the commissioner is required to provide timely intervention and appropriate referral to specialist treatment centers for newborn infants who screen positive for disorders pursuant to the bill;
- the commissioner is required to collect screening information on newborn infants in a standardized manner, and develop a system for quality assurance, which includes the periodic assessment of measurable indicators;
- the commissioner is authorized to use collected screening information to provide follow-up and appropriate referral to newborns

and children with screened positive diagnoses, without regard to the age of the infant or child;

- the commissioner is required to provide education or training on the Newborn Screening program to physicians, hospital staffs, nurses, and the public;

- the reasonable fee charged by the department shall be for the screening, follow-up, and treatment of newborns, and the education of physicians, nurses, and the public, as required by the bill, with a portion of the fee to be used for ongoing infrastructure upgrades, including providing electronic access to physicians to obtain screening results and follow-up recommendations; and

- parents of newborn infants are required to provide notice in writing if they object to screening on the grounds that it would conflict with their religious tenets or practices.

The Department of Health currently requires all newborns to be screened for 54 disorders within 48 hours after birth. One heel prick of the newborn provides enough blood to test for all 54 disorders.

This bill was pre-filed for introduction in the 2018-2019 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, No. 484

STATE OF NEW JERSEY

DATED: DECEMBER 3, 2018

The Senate Budget and Appropriations Committee reports favorably Senate Bill No. 484.

This bill revises the State's newborn screening program for congenital disorders by requiring the Commissioner of Health to establish a Newborn Screening Advisory Review Committee, consisting of medical, hospital, and public health professionals, scientific experts and consumer representatives, which would be authorized to make recommendations on the disorders to be screened for by the department, as well as on screening technologies, treatment options, and educational and follow-up procedures, to be used in the State's newborn screening program. The bill requires that the committee meet annually to review and revise the list of disorders that are recommended for inclusion in the program. The bill also makes several other changes to the program, including formally designating it as the "Newborn Screening" program.

Specifically, the bill makes the following changes to the screening, follow-up, treatment, and education components of the Newborn Screening program:

- the Commissioner is required to annually review a list of disorders recommended by the advisory committee and approved by the commissioner, consistent with the Recommended Uniform Screening Panel of the United States Secretary of Health and Human Services, to determine the disorders for which newborn infants will be screened by the department;
- the Commissioner, within 60 days of adding a new disorder to the program, must advise the President of the Senate and the Speaker of the General Assembly;
- the Commissioner is required to provide timely intervention and appropriate referral to specialist treatment centers for newborn infants who screen positive for disorders pursuant to the bill;
- the Commissioner is required to collect screening information on newborn infants in a standardized manner, and develop a system for quality assurance, which includes the periodic assessment of measurable indicators;
- the Commissioner is authorized to use collected screening information to provide follow-up and appropriate referral to newborns and children with screened positive diagnoses, without regard to the age of the infant or child;

- the Commissioner is required to provide education or training on the Newborn Screening program to physicians, hospital staffs, nurses, and the public;
- the reasonable fee charged by the department shall be for the screening, follow-up, and treatment of newborns, and the education of physicians, nurses, and the public, as required by the bill, with a portion of the fee to be used for ongoing infrastructure upgrades, including providing electronic access to physicians to obtain screening results and follow-up recommendations; and
- parents of newborn infants are required to provide notice in writing if they object to screening on the grounds that it would conflict with their religious tenets or practices.

The Department of Health currently requires all newborns to be screened for 54 disorders within 48 hours after birth. One heel prick of the newborn provides enough blood to test for all 54 disorders.

FISCAL IMPACT:

The Office of Legislative Services (OLS) concludes the bill will have an insignificant net fiscal impact on the State because the bill requires the Commissioner of Health to adjust the fee for all services provided under the Newborn Screening Program in order to support all the expenses incurred by those services. The OLS, however, is unable to determine the costs incurred by the Department of Health (DOH) pursuant to the bill due to the expansion of certain services within the program and whether a fee increase would be necessary to support those services.

The bill generally codifies the existing duties of the Newborn Screening Advisory Review Committee, established by Executive Order and formerly known as the New Jersey Newborn Screening Annual Review Committee. Assuming that the existing operational structure of the committee is maintained, the OLS estimates that this provision of the bill will not generate any additional State expenses.

STATEMENT TO

SENATE, No. 484

with Assembly Floor Amendments
(Proposed by Senator VITALE)

ADOPTED: DECEMBER 17, 2018

These Senate floor amendments revise the findings and declarations section to provide additional details concerning the nature and purpose of the Newborn Screening Program.

The Senate floor amendments clarify that the disorders screened for under the Newborn Screening Program are biochemical disorders.

The Senate floor amendments provide that the list of disorders screened under the program is to be established “with consideration of” the Recommended Uniform Screening Panel of the United States Secretary of Health and Human Services; as introduced, the bill provided that the list was to be “consistent with” the Recommended Uniform Screening Panel.

The Senate floor amendments provide that the Commissioner of Health is to provide laboratory services as well as a follow up program for positive screen cases.

The Senate floor amendments delete language requiring the Newborn Screening Program to provide timely interventions and appropriate referrals to specialist services for newborns with a positive screen, and instead provide that the program will provide timely information and recommendations for referral to specialist services, which better reflects that the program does not provide medical interventions, but facilitates access to medical providers who do provide the services.

The Senate floor amendments remove a reference to follow up care for children, as the services provided by the Newborn Screening Program are limited to newborns and do not extend to older children.

The Senate floor amendments revise the current statutory provisions allowing parents to opt out of newborn screening when it would conflict with their religious beliefs or practices, to specify that written notice of the parents’ objections to the screening is to be provided to the hospital or birthing facility that delivered the newborn in a manner designated by the Commissioner of Health.

LEGISLATIVE FISCAL ESTIMATE
SENATE, No. 484
STATE OF NEW JERSEY
218th LEGISLATURE

DATED: MAY 21, 2018

SUMMARY

Synopsis: Revises Newborn Screening program in DOH.

Type of Impact: Indeterminate expenditure increase offset by indeterminate revenue increase; Insignificant net fiscal impact; General Fund.

Agencies Affected: Department of Health.

Office of Legislative Services Estimate

Fiscal Impact	<u>Annual</u>
State Cost and Revenue	Indeterminate expenditure increase offset by indeterminate revenue increase.

- The Office of Legislative Services (OLS) concludes the bill will have an insignificant net fiscal impact on the State because the bill requires the Commissioner of Health to adjust the fee for all services provided under the Newborn Screening Program in order to support all the expenses incurred by those services. The OLS, however, is unable to determine the costs incurred by the Department of Health (DOH) under the bill due to the expansion of certain services within the program and if a fee increase would be necessary to support those services.
- The establishment of a Newborn Screening Advisory Review Committee under the bill generally codifies the existing duties of the New Jersey Newborn Screening Advisory and Review Committee (currently called the Newborn Screening Advisory Review Committee) established under Executive Order No. 126 in 2001. Assuming that the existing operational structure of the committee is maintained, the OLS estimates that this provision of the bill will not generate any additional State expenses.

BILL DESCRIPTION

This bill revises the law regarding the State's newborn screening program for congenital disorders and formally designates the program as the Newborn Screening Program. Under the bill, the commissioner is required to establish a Newborn Screening Advisory Review

Committee, which would be authorized to make recommendations on the disorders to be screened for by the department, as well as on screening technologies, treatment options, and educational and follow-up procedures, to be used in the State's Newborn Screening Program. The committee would be required to meet annually to review and revise the list of disorders that are recommended for inclusion in the program. Currently, the department requires that within 48 hours of birth all newborns are screened for 55 disorders.

Under the bill, the commissioner is required to: (1) provide timely intervention and appropriate referral to specialist treatment centers for newborn infants who screen positive for disorders pursuant to the bill; and (2) collect screening information on newborn infants in a standardized manner, and develop a system for quality assurance. Furthermore, the commissioner is authorized to use collected screening information to provide follow-up and appropriate referral to newborns and children with screened positive diagnoses, without regard to the age of the infant or child. These responsibilities are added to those currently required under existing law, such as providing a follow-up program on positive screen cases and education or training on the Newborn Screening Program to the medical community and the public.

Under existing law, a reasonable fee must be charged by the department for the screening of newborns. The bill provides that the reasonable fee also account for the follow-up and treatment of newborns, and any educational initiatives of the Newborn Screening Program. Furthermore, existing law provides that the revenue generated from this fee is dedicated for the screening and treatment of newborns. The bill also applies this revenue to support the follow-up of newborns, and the education of the medical community and the public, as required by the bill, with a portion of the fee to be used for ongoing infrastructure upgrades, including providing electronic access to physicians to obtain screening results and follow-up recommendations. Under the bill, the commissioner is required to adjust the fee for all services provided under the Newborn Screening Program to support all required expenses.

FISCAL ANALYSIS

EXECUTIVE BRANCH

None received.

OFFICE OF LEGISLATIVE SERVICES

The OLS concludes the bill will have an insignificant net fiscal impact on the State because the bill requires the commissioner to adjust the fee for all services provided under the Newborn Screening Program in order to support all the expenses incurred by those services. Therefore, any expenditures incurred under the bill by the DOH due to the expansion of certain services regarding the department's administration of the program will be offset by the collection of fees applied to services associated with the program. The OLS, however, is unable to determine the cost of the Newborn Screening Program under the provisions of the bill and if a fee increase would be necessary to support the expanded services of the program.

The OLS notes that it is possible that in the initial year of implementation, the department may incur certain expenses before a fee adjustment can be made; however, the bill provides the commissioner with 180 days following enactment to make any necessary action, such as a fee increase, in advance of the bill's implementation. Furthermore, the commissioner is currently responsible for a similar determination, pursuant to N.J.A.C.8:18-1.11, regarding the existing laboratory fee and the appropriate funding the DOH requires to administer the program.

The establishment of a Newborn Screening Advisory Review Committee generally codifies the existing duties of the New Jersey Newborn Screening Advisory and Review Committee (currently called the Newborn Screening Advisory Review Committee) established under Executive Order No. 126 in 2001. Unlike the Executive Order, the bill directs the committee to make recommendations on educational and follow-up procedures. Assuming that the existing operational structure of the committee is maintained, the OLS estimates that this provision of the bill will not generate any additional State expenses.

According to the Governor's FY 2019 Budget, the Executive anticipates the department collecting \$3.3 million in revenue for newborn screenings, follow-up, and treatment in FY 2019. A total of 116,000 infants are expected to be screened. Currently, pursuant to N.J.A.C.8:45-2.1, the fee for a newborn screening is \$150.00. The DOH increased the fee from \$90 to the current rate in April 2017.

Section: Human Services

*Analyst: Sarah Schmidt
Associate Research Analyst*

*Approved: Frank W. Haines III
Legislative Budget and Finance Officer*

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

LEGISLATIVE FISCAL ESTIMATE

[First Reprint]

SENATE, No. 484

STATE OF NEW JERSEY 218th LEGISLATURE

DATED: FEBRUARY 5, 2019

SUMMARY

- Synopsis:** Revises Newborn Screening program in DOH.
- Type of Impact:** Potential annual State expenditure and revenue increases; General Fund.
- Agencies Affected:** Department of Health.

Office of Legislative Services Estimate

Fiscal Impact	<u>Annual</u>
Potential State Expenditure Increase	Indeterminate
Potential State Revenue Increase	Indeterminate

- The Office of Legislative Services (OLS) concludes the bill may potentially increase annual State expenditures and revenues to the extent that the bill expands the responsibilities of the Department of Health (DOH) to provide services under the Newborn Screening Program. The provisions of the bill, however, appear to largely codify existing practice so that any fiscal impact may be relatively minor.

BILL DESCRIPTION

This bill revises statutory law regarding the State's newborn screening program for congenital disorders to make it largely consistent with current practice.

The bill establishes in statutory law the existing Newborn Screening Advisory Review Committee. The committee would be authorized to make recommendations on the biochemical disorders to be screened for by the DOH, as well as on screening technologies, treatment options, and educational and follow-up procedures, to be used in the State's Newborn Screening Program. The committee would be required to meet annually to review and revise the list of disorders that are recommended for inclusion in the program.

The bill updates statutory law to require the department to: (1) provide laboratory services on positive screen cases; (2) provide timely information and recommendations for referral to specialist treatment centers for newborn infants who screen positive for disorders; and (3) collect

screening information on newborn infants in a standardized manner, and develop a system for quality assurance. Furthermore, the DOH is authorized to use collected screening information to provide follow-up to newborns with screened positive diagnoses to provide information and recommendation for referral. These responsibilities are added to those required under existing statutory law, such as providing a follow-up program on positive screen cases and education or training on the Newborn Screening Program to the medical community and the public.

Under existing statutory law, the department is to charge a reasonable, dedicated fee that is to cover the expenditures of the Newborn Screening Program.

FISCAL ANALYSIS

EXECUTIVE BRANCH

None received.

OFFICE OF LEGISLATIVE SERVICES

The OLS concludes the bill may potentially increase annual State expenditures and revenues to the extent that the bill expands the responsibilities of the DOH to provide services under the Newborn Screening Program. The provisions of the bill, however, appear to largely codify existing practice so that any fiscal impact may be relatively minor.

For example, the bill establishes in statutory law the existing Newborn Screening Advisory Review Committee and generally codifies the committee's existing duties. Assuming that the existing operational structure of the committee is maintained, the OLS estimates that this provision of the bill will not generate any additional State expenses.

If the bill were to increase the annual operating expenditures of the DOH, it may be possible that the department may raise the fee whose collections are to fund the program. The OLS, however, is unable to determine the added cost of the Newborn Screening Program under the bill and if a fee increase would be necessary.

The OLS notes that it is possible that in the initial year of implementation, the department may incur certain expenses before a fee adjustment can be made; however, the bill provides the department with 180 days following enactment to make any necessary action, such as a fee increase, in advance of the bill's implementation.

According to the Governor's FY 2019 Budget, the department's Newborn Screening Laboratory is expected to screen 116,000 infants for 55 disorders in FY 2019. Currently, the fee for a newborn screening is \$150, which the DOH increased from \$90 in April 2017. Although the fee is initially charged to hospitals, it is typically shifted to third-party insurance providers.

Section: Human Services

*Analyst: Sarah Schmidt
Senior Research Analyst*

*Approved: Frank W. Haines III
Legislative Budget and Finance Officer*

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

ASSEMBLY, No. 2705

STATE OF NEW JERSEY 218th LEGISLATURE

INTRODUCED FEBRUARY 1, 2018

Sponsored by:

Assemblyman JOHN F. MCKEON
District 27 (Essex and Morris)

Co-Sponsored by:

Assemblywoman McKnight

SYNOPSIS

Revises Newborn Screening program in DHSS.

CURRENT VERSION OF TEXT

As introduced.



(Sponsorship Updated As Of: 3/8/2019)

1 AN ACT concerning screening for disorders in newborn infants,
2 amending P.L.1977, c.321, and supplementing Title 26 of the
3 Revised Statutes.

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.1977, c.321 (C.26:2-110) is amended to
9 read as follows:

10 1. **【It is hereby declared to be the public policy of this State**
11 **that in the interests of public health every effort should be made to**
12 **detect in newborn infants, hypothyroidism, galactosemia,**
13 **phenylketonuria, and other preventable biochemical disorders**
14 **which may cause mental retardation or other permanent disabilities**
15 **and to treat affected individuals.】**

16 The Legislature finds and declares that:

17 a. Newborn screening is an essential public health activity that
18 strives to screen every newborn infant for a variety of congenital
19 disorders, which, if not detected and managed early, can result in
20 significant morbidity, mortality, and disability. The State's newborn
21 screening system must provide the infrastructure for universal
22 access and rapid and effective follow-up;

23 b. Ongoing advances in technologies and treatment modalities
24 make it possible to screen newborn infants for a wide array of
25 disorders. It is imperative that the State adjust its newborn
26 screening program to incorporate these disorders to ensure that the
27 program remains at the forefront of these advances; and

28 c. It is the intent of this act to protect the health and quality of
29 life of newborn infants born in this State by enhancing the capacity
30 to screen for congenital disorders and by providing: all newborn
31 infants **【are screened】** with screens for certain conditions and with
32 appropriate referrals and early medical intervention when
33 warranted; and newborn data collection is standardized, and
34 conditions detected by newborn screening are tracked and
35 monitored. Further, information on newborn screening and
36 conditions for which a newborn can be screened should be readily
37 accessible, current, and understandable to both health care providers
38 and parents or guardians.

39 (cf: P.L.1988, c.24, s.2)

40
41 2. (New section) The Commissioner of Health shall establish a
42 Newborn Screening Advisory Review Committee to annually
43 review the disorders included in the Newborn Screening program,
44 screening technologies, treatment options, and educational and
45 follow-up procedures. The committee shall include, but need not be

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 limited to, medical, hospital, and public health professionals,
2 scientific experts, and consumer representatives and advocates. The
3 committee shall meet annually to review and revise the list of
4 disorders recommended for inclusion in the Newborn Screening
5 program. The committee shall allow for public input in the course
6 of conducting its review and issue recommendations to the
7 commissioner on the improvement of the Newborn Screening
8 program.

9

10 3. Section 2 of P.L.1977, c.321 (C.26:2-111) is amended to
11 read as follows:

12 **【All】** The Newborn Screening program in the Department of
13 Health shall screen all infants born in this State **【shall be】** **【tested】**
14 **【screened for】** based on **【hypothyroidism, galactosemia and**
15 **phenylketonuria】** the list of disorders that is recommended by the
16 Newborn Screening Advisory Review Committee and approved by
17 the Commissioner of Health, consistent with the Recommended
18 Uniform Screening Panel of the United States Secretary of Health
19 and Human Services. The Commissioner of Health shall may issue
20 regulations to assure that newborns are **【so tested】** screened in a
21 manner approved by the commissioner. **【The commissioner shall**
22 **ensure that treatment services are available to all identified**
23 **individuals.】**

24 The **【State】** Department of Health **【may】** shall charge a
25 **【reasonable】** reasonable fee for the **【tests】** screening, follow-up,
26 treatment, and education performed pursuant to this act. The
27 amount of the fee **【and the】** shall be adjusted by the commissioner
28 as necessary to support the screening, follow-up, and treatment of
29 newborn infants, and the education of physicians, hospital staffs,
30 nurses, and the public as required by this act. The procedures for
31 collecting the fee shall be determined by the commissioner. The
32 commissioner shall apply all revenues collected from the fees to the
33 **【testing】** screening, follow-up, education, and treatment procedures
34 performed pursuant to this act. The fee shall be used to support the
35 program, including, but not limited to, ongoing infrastructure
36 upgrades, including providing electronic access to physicians to
37 obtain screening results, and follow-up recommendations.

38 **【The】** Based on the recommendations of the Newborn Screening
39 Advisory Review Committee established pursuant to section 2 of
40 P.L. , c. (C.) (pending before the Legislature as this bill),
41 the commissioner may also require **【testing】** the screening of
42 newborn infants for other **【preventable biochemical】** disorders if
43 reliable and efficient **【testing】** screening techniques are available.
44 If the commissioner determines that an additional test shall be
45 required, the commissioner, at least **【90】** 60 days prior to requiring
46 the test **【he】**, shall so advise the President of the Senate **【.】** and the

1 Speaker of the General Assembly **[**and chairmen of the standing
2 reference committees on Revenue, Finance and Appropriations and
3 Institutions, Health and Welfare of his determination**]**.

4 The commissioner shall provide a follow-up program **[**of
5 reviewing and following up**]** on positive screen cases in order that
6 measures may be taken to prevent death **[**, mental retardation,**]** or
7 intellectual or other permanent disabilities. The program shall
8 provide timely intervention and, as appropriate, referrals to
9 specialist treatment centers for newborn infants who screen positive
10 for disorders pursuant to this section.

11 The commissioner shall collect screening information on
12 newborn infants in a standardized manner and develop a system for
13 quality assurance which includes the periodic assessment of
14 indicators that are measurable, functional, and appropriate to the
15 conditions for which newborn infants are screened pursuant to this
16 section. The commissioner shall have the authority to use the
17 information collected to provide follow-up to newborn infants and
18 children with screened positive diagnoses to provide appropriate
19 referral. Information on newborn infants **[**and their families**]**
20 compiled pursuant to this section **[**may**]** shall be used by the
21 department and agencies designated by the commissioner for the
22 purposes of carrying out this act, but otherwise the information
23 shall be confidential and not divulged or made public so as to
24 disclose the identity of any person to which it relates, except as
25 provided by law.

26 The department shall **[**conduct an intensive educational and**]**
27 provide education or training on the Newborn Screening program
28 **[**among**]** to physicians, **[**hospitals**]** hospital staffs, **[**public health**]**
29 nurses, and the public concerning **[**those biochemical disorders**]**
30 newborn screening. **[**This program shall include information
31 concerning the nature of the disorders, testing for the detection of
32 these disorders and treatment modalities for these disorders.**]**

33 The provisions of this section shall not apply if the parents of a
34 newborn infant object in writing to the **[**testing**]** screening on the
35 grounds that it would conflict with their religious tenets or
36 practices.

37 (cf: P.L.1988, c.24, s.3)

38

39 4. The Department of Health may adopt, pursuant to the
40 "Administrative Procedure Act," P.L.1968 c.410 (C.52:14B-1 et
41 seq.), rules and regulations necessary to implement the provisions
42 of this act.

43

44 5. This act shall take effect on the 180th day following
45 enactment, except that the Commissioner of Health may take such
46 anticipatory action in advance as shall be necessary for its
47 implementation.

STATEMENT

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This bill revises the State’s newborn screening program for congenital disorders by requiring the Commissioner of Health and Senior Services to annually review a list of disorders recommended by an advisory committee (established in the bill) to determine the disorders for which newborn infants will be screened by the department. The bill also makes several other changes to the program, including formally designating it as the “Newborn Screening” program.

According to information from the March of Dimes and the CARES Foundation, Inc., the State is currently screening newborns for 50 disorders. This legislation ensures that the disorders included in the Newborn Screening program will be evaluated on a yearly basis and that the program will expand to include more disorders as technology and State resources allow.

Specifically, the bill makes the following changes to the screening, follow-up, treatment, and education components of the Newborn Screening program: the commissioner is directed to establish a Newborn Screening Advisory Committee consisting of medical, hospital, and public health professionals, as well as scientific experts and consumer representatives, and convene a meeting of the committee at least once a year to make recommendations on the disorders screened for, screening technologies, treatment options, and educational and follow-up procedures; the commissioner is required to annually review a list of disorders promulgated by the advisory committee and to determine, based on the list, the disorders for which newborn infants will be screened; the commissioner, within 60 days of adding a new disorder to the program, must advise the President of the Senate and the Speaker of the General Assembly; the commissioner is required to provide timely intervention and referral to specialists and treatment centers for newborn infants with confirmed positive diagnoses of the disorders screened for pursuant to the bill; the commissioner is required to adopt regulations establishing qualifications for centers that receive grants to provide treatment for newborns that are diagnosed with certain disorders through the program, and to establish qualifications for medical personnel working at the centers; the commissioner is required to systematically collect data to track and monitor newborns and children with confirmed positive diagnoses of disorders screened for through the program until they reach 21 years of age, and evaluate the long-term outcomes of treatment; the educational program on newborn screening shall provide materials and information on follow-up, rehabilitative, medical, and early intervention services for newborn infants with confirmed positive diagnoses of disorders; the fee charged to hospitals by the department is increased from \$71 to a minimum of \$100, to support the screening, follow-up, and treatment of newborns, and the education of physicians, nurses, and the public; a portion of the fee charged to hospitals by the department is to be used for infrastructure upgrades, including providing electronic access to physicians to obtain

A2705 MCKEON

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1 screening results, follow-up recommendations, and information on the
2 treatment provided by the Newborn Screening program; and parents of
3 newborn infants are required to provide notice in writing if they object
4 to screening on the grounds that it would conflict with their religious
5 tenets or practices.

ASSEMBLY WOMEN AND CHILDREN COMMITTEE

STATEMENT TO

ASSEMBLY, No. 2705

with committee amendments

STATE OF NEW JERSEY

DATED: MARCH 11, 2019

The Assembly Women and Children Committee reports favorably and with committee amendments Assembly Bill No. 2705.

As amended by the committee, this bill revises the State's newborn screening program for congenital disorders by requiring the Commissioner of Health to establish a Newborn Screening Advisory Review Committee, consisting of medical, hospital, and public health professionals, scientific experts and consumer representatives, which would be authorized to make recommendations on the disorders to be screened for by the department, as well as on screening technologies, treatment options, and educational and follow-up procedures, to be used in the State's newborn screening program. The bill requires that the committee meet annually to review and revise the list of disorders that are recommended for inclusion in the program. The bill also makes several other changes to the program, including formally designating it as the "Newborn Screening" program.

Specifically as amended by the committee, the bill makes the following changes to the screening, follow-up, treatment, and education components of the Newborn Screening program:

- the Commissioner is required to annually review a list of disorders recommended by the advisory committee and approved by the commissioner, consistent with the Recommended Uniform Screening Panel of the United States Secretary of Health and Human Services, to determine the disorders for which newborn infants will be screened by the department;
- the Commissioner, within 60 days of adding a new disorder to the program, must advise the President of the Senate and the Speaker of the General Assembly;
- the Commissioner is required to provide timely intervention and appropriate referral to specialist treatment centers for newborn infants who screen positive for disorders pursuant to the bill;
- the Commissioner is required to collect screening information on newborn infants in a standardized manner, and develop a system for quality assurance, which includes the periodic assessment of measurable indicators;
- the Commissioner is authorized to use collected screening information to provide follow-up and appropriate referral to newborns

and children with screened positive diagnoses, without regard to the age of the infant or child;

- the Commissioner is required to provide education or training on the Newborn Screening program to physicians, hospital staffs, nurses, and the public;

- the reasonable fee charged by the department shall be for the screening, follow-up, and treatment of newborns, and the education of physicians, nurses, and the public, as required by the bill, with a portion of the fee to be used for ongoing infrastructure upgrades, including providing electronic access to physicians to obtain screening results and follow-up recommendations; and

- parents of newborn infants are required to provide notice in writing if they object to screening on the grounds that it would conflict with their religious tenets or practices.

This bill was pre-filed for introduction in the 2018-2019 session pending technical review.

As reported by the committee, Assembly Bill No. 2705 (1R) is identical to Senate Bill No. 484 (1R) which was also reported by the committee on this date.

COMMITTEE AMENDMENTS

The committee amended the bill to revise the findings and declarations section to provide additional details concerning the nature and purpose of the Newborn Screening Program, and to clarify that the disorders screened for under the Newborn Screening Program are biochemical disorders.

The committee amendments provide that the list of disorders screened under the program is to be established “with consideration of” the Recommended Uniform Screening Panel of the United States Secretary of Health and Human Services; as introduced, the bill provided that the list was to be “consistent with” the Recommended Uniform Screening Panel.

The committee amended the bill to provide that the Commissioner of Health is to provide laboratory services as well as a follow up program for positive screen cases.

The committee amendments also delete language requiring the Newborn Screening Program to provide timely interventions and appropriate referrals to specialist services for newborns with a positive screen, and instead provide that the program will provide timely information and recommendations for referral to specialist services, which better reflects that the program does not provide medical interventions, but facilitates access to medical providers who do provide the services.

The committee amendments remove a reference to follow up care for children, as the services provided by the Newborn Screening Program are limited to newborns and do not extend to older children.

The committee also amended the bill to revise the current statutory provisions allowing parents to opt out of newborn screening when it would conflict with their religious beliefs or practices, to specify that written notice of the parents' objections to the screening is to be provided to the hospital or birthing facility that delivered the newborn in a manner designated by the Commissioner of Health.

LEGISLATIVE FISCAL ESTIMATE

[First Reprint]

ASSEMBLY, No. 2705

STATE OF NEW JERSEY 218th LEGISLATURE

DATED: DECEMBER 18, 2019

SUMMARY

Synopsis: Revises Newborn Screening program in DHSS.

Type of Impact: Increase in State expenditures and revenue.

Agencies Affected: Department of Health.

Fiscal Impact	<u>Annual</u>
State Cost Increase	Indeterminate
State Revenue Increase	Indeterminate

- The Office of Legislative Services (OLS) concludes that this legislation will have an insignificant net fiscal impact to the State because the bill requires the Department of Health (DOH) to adjust the fee charged for services provided under the Newborn Screening Program in order to fund the expenses incurred for those services. Therefore, any increased administrative costs incurred by the DOH to expand certain screening, informational, and educational services would be fully offset by the fees collected under the program.
- Without access to specific programmatic information from the Executive Branch, the OLS is unable to determine the cost of the Newborn Screening Program under the provisions of the bill, and whether a fee increase would be needed to support the expanded program services.

BILL DESCRIPTION

The bill revises the State's newborn screening program for congenital disorders by requiring the DOH to establish a Newborn Screening Advisory Review Committee, consisting of medical, hospital, and public health professionals, scientific experts and consumer representatives. The committee would be authorized to make recommendations regarding the disorders to be screened for by the department, as well as the screening technologies, treatment options, and educational and follow-up procedures to be used in the State's newborn screening program. The bill requires that the committee meet annually to review and revise the list of disorders that are recommended for inclusion in the program.

This legislation also makes several other changes to the screening, follow-up, treatment, and

education components of the Newborn Screening Program, as specified in the bill. The reasonable fee charged by the DOH is to be used to finance the cost of the screening, follow-up, and treatment of newborns, and the education of physicians, nurses, and the public, as required by the bill. A portion of the fee is to be used to fund ongoing infrastructure upgrades, including providing physicians with electronic access to obtain screening results and follow-up recommendations. The parents of newborn infants are required to provide written notice if they object to screening on the grounds that it would conflict with their religious tenets or practices.

FISCAL ANALYSIS

EXECUTIVE BRANCH

None received.

OFFICE OF LEGISLATIVE SERVICES

The OLS concludes that this legislation will have an insignificant net fiscal impact to the State because the bill requires the DOH to adjust the fee charged for services provided under the Newborn Screening Program in order to fund the expenses incurred for those services. Therefore, any increased administrative costs incurred by the DOH to expand certain screening, informational, and educational services would be fully offset by the fees collected under the program. Without access to specific programmatic information from the Executive Branch, the OLS is unable to determine the cost of the Newborn Screening Program under the provisions of the bill, and whether a fee increase would be needed to support the expanded program services.

The OLS notes that, in the initial year of the Newborn Screening Program expansion, the department may incur certain expenses before a fee adjustment can be made; however, the bill gives the commissioner 180 days following enactment to take any anticipatory actions, such as a fee increase, needed to implement the program expansion. Furthermore, the commissioner is currently responsible for a similar determination, pursuant to N.J.A.C.8:18-1.11, regarding the existing laboratory fee and the appropriate funding the DOH requires to administer the program.

According to the Governor's Fiscal Year (FY) 2020 Budget, the department's Newborn Screening Laboratory is expected to screen 98,300 infants for 55 disorders in FY 2020. Currently, the newborn screening fee is \$150, which the DOH increased from \$90 in 2017. Although the fee is initially charged to hospitals, it is typically shifted to third-party insurance providers.

The establishment of a Newborn Screening Advisory Review Committee under the bill generally codifies the existing duties of the committee, which was established as the Newborn Screening Annual Review Committee under Executive Order No. 126 in 2001. Assuming that the existing operational structure of the committee is maintained, the OLS estimates that this provision of the bill will not generate any additional State expenses.

Section: Human Services

Analyst: Anne Cappabianca
Assistant Fiscal Analyst

Approved: Frank W. Haines III
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.).

Governor Murphy Signs Legislative Package to Fight New Jersey's Maternal and Infant Health Crisis

01/13/2020

TRENTON - Governor Phil Murphy today signed a legislative package into law to combat New Jersey's maternal and infant health crisis and provide health benefits coverage for fertility preservation services. The series of bills aims to improve health outcomes for New Jersey's mothers and babies and address the racial inequities in maternal and infant health care. The legislation will support the efforts of the Administration's Nurture NJ campaign, which is led by First Lady Tammy Murphy.

"In New Jersey, we are committed to improving the health and safety of every mother and child," **said Governor Murphy**. "By signing today's bills, we are taking another step forward in our effort to eliminate the racial disparities in maternal and infant care. I am proud to sign these bills into law and commend my colleagues in the Legislature for their commitment to improve health outcomes for New Jersey's mothers, babies, and families."

"Our mission is to make New Jersey the safest place in the nation to give birth," **said First Lady Tammy Murphy**. "To achieve this, it is absolutely essential that mothers across all races, ethnicities, social and economic backgrounds are listened to and supported by federal, state and community resources. Today's legislation provides better care and support for our mothers and babies, and moves us closer to improving health outcomes for all of New Jersey's families."

The Governor signed the following four bills into law:

- **A5509 (Mosquera, Timberlake, Mukherji/Ruiz, Pou)** – Requires health benefits and Medicaid coverage for breastfeeding support.
- **S3159 (Weinberg, Greenstein/Vainieri Huttle, Reynolds-Jackson, Mukherji)** - Requires Medicaid coverage for pasteurized donated human breast milk under certain circumstances.
- **S484 (Vitale, Gill/ McKeon, Speight, Vainieri Huttle)** - Revises Newborn Screening program in the Department of Health.
- **S2133 (Cruz-Perez, Ruiz/Lampitt, Timberlake, Mosquera, Sumter, Tucker, Reynolds-Jackson)** - Mandates health benefits coverage for fertility preservation services under certain health insurance plans.

A5509

"As parents of young children, each of us knows first-hand the challenges of raising a child and just how important it is to be able to receive the support you need. Under the ACA, Medicaid currently provides coverage for breastfeeding equipment and services. This new mandate would not only guarantee continued coverage for Medicaid recipients even if the ACA is dismantled at the federal level, but would also require all New Jersey insurers to provide coverage for comprehensive lactation support. We are ensuring the health and well-being of mothers and their babies, while giving New Jersey parents one less expense to worry about as they care for their children," **said Assemblymembers Mosquera, Timberlake, and Mukherji**.

S3159

"The American Academy of Pediatrics recommends breast milk as the exclusive source of nutrition for a child in their first six months of life," **said Assemblywoman Valerie Vainieri Huttle**. "In extending health coverage for donated breast milk, we can ensure it is available and affordable for all mothers seeking to breastfeed and boost positive health outcomes for their babies."

"Low-income families under Medicaid will now have the same access to breast milk as those under all other health coverage policies," **said Assemblywoman Verlina Reynolds-Jackson**. "With breastfeeding shown to have a protective effect against respiratory illnesses, ear infections, allergy development and other diseases, it is important to remove barriers and guarantee quality health care to all mothers and babies in need."

"As my wife and I recently experienced, milk production is not always as seamless post-delivery as you'd hope or expect, nor does it always last as long as desired," **Assemblyman Raj Mukherji**. "The coverage extended under this new law will be particularly important for parents with prematurely born babies or those babies who may

need human breast milk for certain conditions for which formula is insufficient. As outcomes have shown, fortified breast milk can better provide the necessary nutrients for those in the Neonatal Intensive Care Unit to greatly increase healthy growth and development. Income should not determine which New Jersey families can ensure the health of their babies.”

S484

“The importance of this type of advisory committee cannot be emphasized enough,” **said Assemblyman McKeon**. “Its members would have both the experience and authority necessary to make recommendations to the Department of Health on screening technologies, treatment options, follow-up procedures and more. Their advice would help promote the well-being of newborns throughout the state.”

“We must prioritize our children’s health by utilizing the expertise of scientists, doctors and other educated professionals when it comes to congenital disorders,” **said Assemblywoman Speight**. “Maintaining updated methods of screening for a wide array of biochemical disorders can help reduce the amount of morbidity, mortality and disability that would otherwise be caused by undetected health problems.”

“Early diagnosis of a potential congenital disorder and access to early medical interventions can save parents and their children a lifetime of pain,” **said Assemblywoman Vainieri Huttle**. “It’s important for our state to do everything we can to make sure medical practitioners and parents are educated with standardized, up-to-date information on these disorders and how they can be both identified and treated.”

S2133

“Being diagnosed with a serious health condition and deciding to undergo major medical treatment is stressful enough without having to worry about potential infertility as a result of the treatment,” **said Assemblywoman Lampitt**. “Having the option to utilize fertility services helps to provide patients with peace of mind and makes the decision to seek medical treatment a little easier.”

“When someone requires a life-saving treatment, they shouldn’t have to choose between daunting medical bills or never having a family,” **said Assemblywoman Timberlake**. “Guaranteeing insurance coverage is one way we can help alleviate patients’ financial concerns and allow them to make their decision based on what they want rather than what they can afford.”

“As a mother, there is nothing in the world I value more than my children. Raising a child is such a rewarding experience,” **said Assemblywoman Mosquera**. “This law will ensure that no one who dreams of being a parent will be denied that opportunity if there is any way for them to do so, regardless of their current health problems.”

“Advancements in medical technology are providing patients with incredible alternatives they never would have had in the past,” **said Assemblywoman Sumter**. “If someone wants to start a family of their own someday but may soon face infertility, it’s important we help them achieve their dream by guaranteeing coverage of these beneficial fertility preservation services.”

“Everyone deserves the chance to form a family of their own,” **said Assemblywoman Tucker**. “In the past, the kinds of treatment cancer patients receive would have severely limited their ability to do so – but that is no longer the case thanks to modern fertility preservation services. We must ensure their ability to use those services whenever necessary and desired.”

“At a time when patients are coping with serious illnesses that can be both challenging and discouraging, knowing they can still have a family someday gives them hope,” **said Assemblywoman Reynolds-Jackson**. “That kind of hope during such a difficult time is more powerful than many people can comprehend. This law will help patients focus on the possibilities of life.”