

SENATE, No. 1259

STATE OF NEW JERSEY 214th LEGISLATURE

INTRODUCED FEBRUARY 8, 2010

Sponsored by:

Senator FRED H. MADDEN, JR.
District 4 (Camden and Gloucester)
Senator JOSEPH F. VITALE
District 19 (Middlesex)

Co-Sponsored by:

Senators S.Kean and Weinberg

SYNOPSIS

Revises Newborn Screening program in DHSS.

CURRENT VERSION OF TEXT

As introduced.



(Sponsorship Updated As Of: 9/14/2010)

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
10 as follows:

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

17 The Legislature finds and declares that:

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

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

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

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

41
42 2. Section 2 of P.L.1977, c.321 (C.26:2-111) is amended to
43 read as follows:

44 2. **【All】** There is established the Newborn Screening program

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 in the Department of Health and Senior Services. Under this
2 program, all infants born in this State shall be [tested] screened for
3 [hypothyroidism, galactosemia and phenylketonuria] the list of
4 disorders promulgated by the Newborn Screening Advisory
5 Committee and approved by the Commissioner of Health and
6 Senior Services, pursuant to section 3 of P.L. , c. (C.) (pending
7 before the Legislature as this bill). This list shall be reviewed and
8 revised annually. The Commissioner of Health and Senior Services
9 shall issue regulations to assure that newborns are [so tested]
10 screened in a manner approved by the commissioner. The
11 commissioner shall ensure that treatment services are available to
12 all identified individuals.

13 The [State] Department of Health and Senior Services [may]
14 shall charge a [reasonable] fee of at least \$100 for the [tests]
15 screening, follow-up, treatment, and education performed pursuant
16 to this act. The amount of the fee [and the] shall be adjusted by
17 the commissioner as necessary to support the screening, follow-up,
18 and treatment of newborn infants, and the education of physicians,
19 hospital staffs, nurses, and the public as required by this act. The
20 procedures for collecting the fee shall be determined by the
21 commissioner. The commissioner shall apply all revenues collected
22 from the fees to the [testing] screening, follow-up, education, and
23 treatment procedures performed pursuant to this act. A portion of
24 the fee shall be earmarked for ongoing infrastructure upgrades,
25 including providing electronic access to physicians to obtain
26 screening results, follow-up recommendations, and information on
27 the treatment provided by the Newborn Screening program.

28 [The] Based on the recommendations of the Newborn Screening
29 Advisory Committee established pursuant to section 3 of P.L. ,
30 c. (C.) (pending before the Legislature as this bill), the
31 commissioner may also require [testing] the screening of newborn
32 infants for other [preventable biochemical] disorders if reliable and
33 efficient [testing] screening techniques are available. If the
34 commissioner determines that an additional test shall be required,
35 the commissioner, at least [90] 60 days prior to requiring the test
36 [he], shall so advise the President of the Senate [,] and the Speaker
37 of the General Assembly [and chairmen of the standing reference
38 committees on Revenue, Finance and Appropriations and
39 Institutions, Health and Welfare of his determination].

40 The commissioner shall provide a program of reviewing and
41 following up on positive cases in order that measures may be taken
42 to prevent death, mental retardation, or other permanent disabilities.
43 The program shall provide timely intervention and referral to
44 specialists and treatment centers for newborn infants with
45 confirmed positive diagnoses of disorders screened for pursuant to
46 this section. The commissioner shall adopt regulations establishing

1 criteria for qualification as a treatment center, including, but not
2 limited to, specific services that each center shall offer to affected
3 newborn infants. The commissioner shall also adopt regulations
4 establishing qualifications for medical staff employed by such
5 centers.

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

21 The department shall conduct an intensive educational and
22 training program among physicians, **[hospitals]** hospital staffs,
23 **[public health]** nurses, and the public concerning **[those**
24 **biochemical disorders]** newborn screening. This program shall
25 include, but need not be limited to, the following:

26 a. information concerning the nature of the disorders, **[testing]**
27 screening for the detection of these disorders and treatment
28 modalities for these disorders;

29 b. the distribution of educational materials prepared by the
30 department which explain the purposes of newborn screening and
31 the possible disorders for which a newborn infant can be screened;
32 and

33 c. information on follow-up, rehabilitative, medical, and early
34 intervention services available for newborn infants with confirmed
35 positive diagnoses of disorders.

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

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

41

42 3. (New section) The Commissioner of Health and Senior
43 Services shall establish a Newborn Screening Advisory Committee
44 and convene a meeting of the committee at least once a year to
45 review the disorders included in the Newborn Screening program,
46 screening technologies, treatment options, and educational and
47 follow-up procedures. The committee shall include, but need not be

1 limited to, medical, hospital, and public health professionals,
2 scientific experts, and consumer representatives and advocates. The
3 committee shall allow for public input in the course of conducting
4 its review and issue recommendations to the commissioner on the
5 improvement of the Newborn Screening program.

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

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

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17

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STATEMENT

19

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

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

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

- 37 • the commissioner is directed to establish a Newborn Screening
38 Advisory Committee consisting of medical, hospital, and public
39 health professionals, as well as scientific experts and consumer
40 representatives, and convene a meeting of the committee at least
41 once a year to make recommendations on the disorders screened
42 for, screening technologies, treatment options, and educational
43 and follow-up procedures;
- 44 • the commissioner is required to annually review a list of
45 disorders promulgated by the advisory committee and to
46 determine, based on the list, the disorders for which newborn
47 infants will be screened;

- 1 • the commissioner, within 60 days of adding a new disorder to
2 the program, must advise the President of the Senate and the
3 Speaker of the General Assembly;
- 4 • the commissioner is required to provide timely intervention and
5 referral to specialists and treatment centers for newborn infants
6 with confirmed positive diagnoses of the disorders screened for
7 pursuant to the bill;
- 8 • the commissioner is required to adopt regulations establishing
9 qualifications for centers that receive grants to provide treatment
10 for newborns that are diagnosed with certain disorders through
11 the program, and to establish qualifications for medical
12 personnel working at the centers;
- 13 • the commissioner is required to systematically collect data to
14 track and monitor newborns and children with confirmed
15 positive diagnoses of disorders screened for through the
16 program until they reach 21 years of age, and evaluate the long-
17 term outcomes of treatment;
- 18 • the educational program on newborn screening shall provide
19 materials and information on follow-up, rehabilitative, medical,
20 and early intervention services for newborn infants with
21 confirmed positive diagnoses of disorders;
- 22 • the fee charged to hospitals by the department is increased from
23 \$71 to a minimum of \$100, to support the screening, follow-up,
24 and treatment of newborns, and the education of physicians,
25 nurses, and the public;
- 26 • a portion of the fee charged to hospitals by the department is to
27 be used for infrastructure upgrades, including providing
28 electronic access to physicians to obtain screening results,
29 follow-up recommendations, and information on the treatment
30 provided by the Newborn Screening program; and
- 31 • parents of newborn infants are required to provide notice in
32 writing if they object to screening on the grounds that it would
33 conflict with their religious tenets or practices.