SENATE, No. 1283

STATE OF NEW JERSEY
217th LEGISLATURE

INTRODUCED FEBRUARY 8, 2016

Sponsored by:
Senator JOSEPH F. VITALE
District 19 (Middlesex)

SYNOPSIS
Revises Newborn Screening program in DOH.

CURRENT VERSION OF TEXT
As introduced.

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

1. Section 1 of P.L.1977, c.321 (C.26:2-110) is amended to read as follows:
   1. [It is hereby declared to be the public policy of this State that in the interests of public health every effort should be made to detect in newborn infants, hypothyroidism, galactosemia, phenylketonuria, and other preventable biochemical disorders which may cause mental retardation or other permanent disabilities and to treat affected individuals.]

   The Legislature finds and declares that:
   a. Newborn screening is an essential public health activity that strives to screen every newborn infant for a variety of congenital disorders, which, if not detected and managed early, can result in significant morbidity, mortality, and disability. The State’s newborn screening system must provide the infrastructure for universal access and rapid and effective follow-up;
   b. Ongoing advances in technologies and treatment modalities make it possible to screen newborn infants for a wide array of disorders. It is imperative that the State adjust its newborn screening program to incorporate these disorders to ensure that the program remains at the forefront of these advances; and
   c. It is the intent of this act to protect the health and quality of life of newborn infants born in this State by enhancing the capacity to screen for congenital disorders and by providing: all newborn infants with screens for certain conditions and with appropriate referrals and early medical intervention when warranted; and newborn data collection is standardized, and conditions detected by newborn screening are tracked and monitored. Further, information on newborn screening and conditions for which a newborn can be screened should be readily accessible, current, and understandable to both health care providers and parents or guardians.

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

2. (New section) The Commissioner of Health shall establish a Newborn Screening Advisory Review Committee to annually review the disorders included in the Newborn Screening program, screening technologies, treatment options, and educational and follow-up procedures. The committee shall include, but need not be limited to, medical, hospital, and public health professionals, scientific experts, and consumer representatives and advocates. 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.
committee shall meet annually to review and revise the list of
disorders recommended for inclusion in the Newborn Screening
program. The committee shall allow for public input in the course
of conducting its review and issue recommendations to the
commissioner on the improvement of the Newborn Screening
program.

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

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

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

[The] Based on the recommendations of the Newborn Screening
Advisory Review Committee established pursuant to section 2 of
P.L. , c. (C. ) (pending before the Legislature as this bill),
the commissioner may also require [testing] the screening of
newborn infants for other [preventable biochemical] disorders if
reliable and efficient [testing] screening techniques are available.
If the commissioner determines that an additional test shall be
required, [90] the commissioner, at least 60 days prior to requiring
the test [he], shall [so] advise the President of the Senate [.] and the
Speaker of the General Assembly [and chairmen of the standing
reference committees on Revenue, Finance and Appropriations and
Institutions, Health and Welfare of his determination].
The commissioner shall provide a follow-up program [of reviewing and following up] on positive screen cases in order that measures may be taken to prevent [mental retardation] death or intellectual or other permanent disabilities. The program shall provide timely intervention and, as appropriate, referrals to specialist treatment centers for newborn infants who screen positive for disorders pursuant to this section.

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

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

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

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

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

5. This act shall take effect on the 180th day following enactment, except that the Commissioner of Health may take such anticipatory action in advance as shall be necessary for its implementation.
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 with 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
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 that, within 48 hours after birth, all newborns shall be screened for 54 disorders. One heel prick of the newborn provides enough blood to test for all 54 disorders.