SPONSOR: Sen. Hall-Long & Rep. Barbieri & Rep. Q. Johnson & Rep. Heffernan & Rep. Carson
Sens. Ennis, Lavelle, Lopez; Reps. Briggs King, Jaques, Miro, Mitchell, Potter, B. Short, M. Smith, Wilson

DELAWARE STATE SENATE
148th GENERAL ASSEMBLY

SENATE BILL NO. 58

AN ACT TO AMEND TITLE 16 OF THE DELAWARE CODE RELATING TO THE SCREENING OF NEWBORN INFANTS FOR METABOLIC, HEMATOLOGIC, ENCDORINOLOGIC, IMMUNOLOGIC, AND CERTAIN STRUCTURAL DISORDERS.

WHEREAS, each year a number of babies are born in Delaware with metabolic, hematologic, endocrinologic and structural disorders that can be detected by newborn screening procedures prior to having long term effects on health, cognitive development and survival;

WHEREAS, for these disorders to be detected in a comprehensive manner all infants should be screened within the first few days of life;

WHEREAS, there are interventions available for these disorders that are most effective when applied before there is other evidence of the disorder in affected newborn babies;

WHEREAS, newborn babies with such conditions when identified reliably and in a timely manner and appropriately and promptly treated can be expected to have normal growth and development; and

WHEREAS, parents of newborn babies have responsibility for health care decisions involving their children.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. Amend Title 16 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

Chapter 8C. Screening of Newborn Infants for Metabolic, Hematologic, Endocrinologic, Immunologic, and Certain Structural Disorders”

§801C Short Title

This chapter shall be known and may be cited as the "Newborn Screening Program."

§802C Definitions

(a) “Blood Specimen for Metabolic, Hematologic, Endocrinologic, and Immunologic Disorders” means a dried blood spot on a special filter paper utilized for screening (not diagnostic) tests to establish the likely presence of metabolic, hematologic, endocrinologic, or immunologic disorders.

(b) “Certain Structural Disorders” includes critical congenital heart defects and other structural disorders.

(c) “Endocrinologic Disorder” means the absence or deficiency of a hormone resulting in interference with normal health, growth or development. These disorders include, but are not limited to Congenital Hypothyroidism and Congenital Adrenal Hyperplasia.

(d) “Immunologic Disorder” means, a condition in which a variation in the quantity or function of white blood cells results in deficiency of immune function. These disorders include, but are not limited to, Severe Combined Immunodeficiency Disorder.

(e) “Hematologic Disorder” means, a condition in which a variation in one or more of the hemoglobin structural genes or in one or more of the genes involved in hemoglobin synthesis produces a variation in hemoglobin structure or synthesis, which results in variation in hemoglobin function. These disorders include, but are not limited to, sickle cell anemia, sickle beta thalassemia, beta thalassemia, alpha thalassemia, hemoglobin C disease and other clinically important variations in hemoglobin structure or synthesis.

(f) “Kit” means any or all parts of the combined materials, laboratory filter paper specimen forms, Newborn Screening Program brochure, and/or other components provided by the State Newborn Screening Program for the purposes of collection of the blood spot specimen and for submission of the blood spot specimen for laboratory screening.

(g) “Metabolic Disorder” means a disorder caused by a genetic alteration, which results in a defect in the structure or function of a specific enzyme or other protein. These disorders include, but are not limited to, Phenylketonuria (PKU), Galactosemia, Maple Syrup Urine Disease (MSUD), and Medium Chain Acyl-CoA Dehydrogenase (MCAD) Deficiency.

(h) “Newborn Infant” means any infant born in the State who is under 4 weeks of age.

(i) “Satisfactory Specimen” means a blood spot specimen on which an accurate laboratory analysis for the various disorders can be performed.

(j) “The Newborn Screening Advisory Committee” means a committee, established through this chapter, convened to provide advice and guidance to the Director of Public Health.

§803C Advisory Committee

(a) There shall be established Newborn Screening Advisory Committee ("Committee") that will advise the Director of the Division of Public Health on issues relating to the newborn screening program, including intervention, treatment, and follow-up care for infants and children with metabolic, hematologic, endocrinologic, immunologic and certain structural disorders. Members shall be appointed by the Governor and serve 3-year terms that are renewable. The Board shall have 12 members.

(1) The Department of Health and Social Services shall provide administrative support services required for the Board. Members shall receive no compensation for their services as members.

(2) The Board shall act by majority vote and as required by this State's Administrative Procedures Act, Chapter 101 of Title 29. The Board shall meet at least three times annually.

(3) The Board membership shall consist of: 3 individuals, or parents of individuals, affected by disorders identified by the screening panel; an ethicist; an attorney not employed by the State of Delaware; 3 pediatric physicians; the Medical Director for the Division of Public Health, or his or her designee; the Laboratory Director for the Division of Public Health, or his or her designee; a representative from the Department of Services for Children Youth and their Families; and a member of the public.

(4) The Committee shall elect a Chairperson to serve for at least 1 year from those members appointed by the Governor. A majority of the membership of the Committee shall constitute a quorum to transact its business.

§804C Newborn Screening Program

a) The Department of Health and Social Services shall adopt rules and regulations under and pursuant to this State's Administrative Procedures Act, Chapter 101 of Title 29, to carry out the objectives of this subchapter. All prior regulations and rules promulgated by the Delaware Division of Public Health in regards to the screening of newborn infants for diseases shall remain in full force and effect until amended or repealed by the Department.

b) All hospitals, birthing centers and other birth attendants shall obtain a satisfactory specimen prior to 72 hours of age and shall perform, or arrange for, screening for Critical Congenital Heart Defects

c) The Division of Public Health shall provide abnormal results to the parent or legal guardian and physician of record.

d) The Director of the Division of Public Health, with advice from the Committee, will determine which disorders shall be on the screening panel.

e) Blood Specimens for metabolic, hematologic, endocrinologic, immunologic and certain structural disorders will be retained for a period of three years.

f) Records obtained from screenings will be retained by the Division of Public Health.

g) Fees

1) The Newborn Screening Program shall bill the birth facility or individual attending the birth for services provided for each newborn screened under these regulations including but not limited to, the cost of the kits for collection of specimens, the laboratory fee for analysis, and administrative costs. The amount billed will be determined by

the Director of the Division of Public Health in consultation with the Advisory Committee and the program staff. The fee will be determined in July of each year based on the cost of the program. All fees collected as a result of billing shall be retained by the Newborn Screening Program and used for operation of the program.

2) No Delaware newborn shall be denied testing for hereditary disorders because of inability of the newborn's parent or legal guardian to pay the fee.

§805C Parental Options

(a) All newborns in Delaware shall have a satisfactory blood specimen taken prior to 72 hours of age and shall been screened for metabolic, hematologic, endocrinologic, immunologic and certain structural disorders. Parents may elect not to participate in any of the following:

(1) Screening to be performed;

(2) The blood spot to be stored following testing; and/or

(3) The results of the screen to be securely shared electronically through a health information exchange so that health care providers can appropriately access information.

(b) The informed consent process shall assure that the parent or guardian who elects that a newborn shall not be tested understands the consequences of such a decision, including the inability to prevent developmental delay and death. Language conveying such information shall be recommended by the Committee for approval by the Division Director.

(c) There will be no research utilizing the stored blood specimens or the stored data without parental consent, except for population based studies in which all identifying information is removed; the blood spots may be used within the Division of Public Health for quality assurance or performance improvement activities including pilot studies when a new disorder is being considered for addition to the panel, or may be used by Division of Public Health for any other purpose authorized by law.

§ 806C Confidentiality

(a) No person may disclose or be compelled to disclose the identity of any person upon whom a blood specimen for metabolic, hematologic, endocrinologic, immunologic and certain structural disorders screen is performed, or the results of such test in a manner which permits identification of the subject of the test, except to the following person:

(1) The subject of the test or the subject's legal guardian.

(2) Any person who secures a legally effective release of test results executed by the subject of the test or the subject's legal guardian.

(3) For purposes of diagnosis, treatment or follow-up

(4) As authorized by court order;

(5) To a medical examiner authorized to conduct an autopsy on a child or an inquest on the death of a child.

(6) Health facility staff committees or accreditation or oversight review organizations which are conducting program monitoring, program evaluation or service reviews, including the Child Death, Near Death and Still Birth Commission conducting reviews pursuant to Title 31 of this code.

(7) The results of the screen shared electronically through a health information exchange so that health care providers can appropriately access information.

(8) Pursuant to Chapter 9 of this title as it relates to investigation of child abuse.

(b) No person to whom the results of an blood specimen for metabolic, hematologic, endocrinologic, immunologic and certain structural disorders screen have been disclosed pursuant to subsection (a) of this section shall disclose the test results to another person except as authorized by subsection (a) of this section.

(c) The provisions in this section shall not interfere with the transmission of information as may be necessary to obtain third-party payment for medical care related to a metabolic, hematologic, endocrinologic, immunologic, or certain structural disorders or with the documentation of cause of death on death certificates.

Section 2. Amend § 1203, Title 16 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 1203 Authorization to retain genetic information and samples from which genetic information is derived.

(a) No person shall retain an individual's genetic information without first obtaining informed consent from the individual unless:

(1) Retention is necessary for the purposes of a criminal or death investigation or a criminal or juvenile proceeding;

(2) Retention is necessary to determine paternity;

(3) Retention is authorized by order of a court of competent jurisdiction;

(4) Retention is made pursuant to the DNA analysis and data bank requirements of § 4713 of Title 29; ~~or~~

(5) Retention of information is for anonymous research where the identity of the subject will not be released.~~;~~ or

(6) Retention is pursuant to newborn screening requirements established by state or federal law.

SYNOPSIS

The bill will codify the Newborn Screening Program, which screens infants for a number of metabolic, hematologic, endocrinologic, immunologic and certain structural disorders. This bill also clarifies that genetic information

disclosed and obtained pursuant to the Newborn Screening Program may be retained.

Author: Senator Hall-Long