



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, ENDCORINOLOGIC, IMMUNOLOGIC, AND CERTAIN STRUCTURAL DISORDERS.

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

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

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

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

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

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

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

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

16 §801C Short Title

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

18 §802C Definitions

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

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

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

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

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

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

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

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

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

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

45 §803C Advisory Committee

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

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

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

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

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

62 §804C Newborn Screening Program

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

68 b) All hospitals, birthing centers and other birth attendants shall obtain a satisfactory specimen prior to
69 72 hours of age and shall perform, or arrange for, screening for Critical Congenital Heart Defects

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

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

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

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

77 g) Fees

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

81 the Director of the Division of Public Health in consultation with the Advisory Committee and the program staff. The fee
82 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
83 retained by the Newborn Screening Program and used for operation of the program.

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

86 §805C Parental Options

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

90 (1) Screening to be performed;

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

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

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

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

103 § 806C Confidentiality

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

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

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

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

- 111 (4) As authorized by court order;
- 112 (5) To a medical examiner authorized to conduct an autopsy on a child or an inquest on the death of a
113 child.
- 114 (6) Health facility staff committees or accreditation or oversight review organizations which are
115 conducting program monitoring, program evaluation or service reviews, including the Child Death, Near Death
116 and Still Birth Commission conducting reviews pursuant to Title 31 of this code.
- 117 (7) The results of the screen shared electronically through a health information exchange so that health
118 care providers can appropriately access information.
- 119 (8) Pursuant to Chapter 9 of this title as it relates to investigation of child abuse.
- 120 (b) No person to whom the results of an blood specimen for metabolic, hematologic, endocrinologic,
121 immunologic and certain structural disorders screen have been disclosed pursuant to subsection (a) of this section shall
122 disclose the test results to another person except as authorized by subsection (a) of this section.
- 123 (c) The provisions in this section shall not interfere with the transmission of information as may be necessary to
124 obtain third-party payment for medical care related to a metabolic, hematologic, endocrinologic, immunologic, or certain
125 structural disorders or with the documentation of cause of death on death certificates.
- 126 Section 2. Amend § 1203, Title 16 of the Delaware Code by making deletions as shown by strike through and insertions as
127 shown by underline as follows:
- 128 § 1203 Authorization to retain genetic information and samples from which genetic information is derived.
- 129 (a) No person shall retain an individual's genetic information without first obtaining informed consent from the
130 individual unless:
- 131 (1) Retention is necessary for the purposes of a criminal or death investigation or a criminal or juvenile
132 proceeding;
- 133 (2) Retention is necessary to determine paternity;
- 134 (3) Retention is authorized by order of a court of competent jurisdiction;
- 135 (4) Retention is made pursuant to the DNA analysis and data bank requirements of § 4713 of Title 29; ~~or~~
- 136 (5) Retention of information is for anonymous research where the identity of the subject will not be
137 released; or
- 138 (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