Legislative Council,
General Assembly
State of Delaware

LAWS OF DELAWARE
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CHAPTER 167
151st GENERAL ASSEMBLY
FORMERLY
HOUSE BILL NO. 184

AN ACT TO AMEND TITLE 16 OF THE DELAWARE CODE RELATING TO THE NEWBORN SCREENING PROGRAM.

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

Section 1. Amend Chapter 8C, Title 16 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 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 chapter. All prior regulations and rules promulgated by the Delaware Division of Public Health in ~~regards~~ regard to the screening of newborn infants for diseases shall remain in full force and effect until amended or repealed by the Department.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~~ within 24 to 48 hours of age and shall perform, or arrange for, screening for critical congenital heart defects.

(c) The Division of Public Health shall provide results to the ~~parent or legal guardian and~~ ~~physician of record~~ physician on 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, and immunologic ~~and certain structural~~ disorders will be ~~retained for a period of 3 years~~ destroyed after screening and testing is complete. Screening and testing includes confirmation of any diagnosis.

(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 are hereby appropriated to, and shall be retained ~~by~~ by, the Newborn Screening Program ~~and used~~ ~~for~~ to defray operating expenses associated with this chapter, operation of the ~~program,~~ Program, and programming to ensure the optimal health and development across the lifespan of the maternal and child health population.

(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 specimen taken ~~prior to 72~~ within 24 to 48 hours of age and shall ~~been~~ be 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 the Division of Public Health for any~~ ~~other purpose authorized by law~~ removed.

§ 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 search reviews, including the Child Death Review Commission conducting reviews pursuant to Title 31.

(7) Individuals who have access to an electronic medical record (EMR), in which the information is retained pursuant to §1203(a)(6) of this title, or a health information exchange.

(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~~ a 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.

Approved September 15, 2021