AN ACT TO AMEND TITLE 16 OF THE DELAWARE CODE RELATING TO THE NEWBORN GENETIC TESTING PANEL

WHEREAS, more than 6000 rare diseases, each affecting less than 200,000 patients in the United States, cumulatively impact 30 million people in the United States; and

WHEREAS, Delawareans with rare diseases and their families face great obstacles in obtaining diagnoses, seeking treatment, and paying for care; and

WHEREAS, newborn genetic testing plays a key role in obtaining early diagnoses; and

WHEREAS, the current Delaware genetic testing panel does not align with the federal recommended uniform screening panel.

NOW, THEREFORE:
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:

(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in regard to the screening of newborn infants for diseases shall remain in full force and effect until amended or repealed by the Department.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 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 physician on record.

~~(d) The Director of the Division of Public Health or, if the Director is not a licensed physician or advanced practice registered nurse, a licensed physician or advanced practice registered nurse designated by the Director and employed by the Division, with advice from the Committee, will determine which disorders shall be on the screening panel.~~

(d) The Director of the Division of Public Health or, if the Director is not a licensed physician or advanced practice registered nurse, a licensed physician or advanced practice registered nurse designated by the Director and employed by the Division, with advice from the Committee, will determine which disorders shall be on the screening panel by holding triennial meetings open to the public

I. The Director shall ensure that any disorder that is included on the RUSP as of January 1, 2027, is included in the testing required under this section if determined appropriate by the Committee within six months. For any disorder included on the RUSP, the Committee shall conduct an evaluation to determine whether the disorder should be included on the screening panel.

II. The Director, in consultation with the Committee, shall evaluate all disorders added to the RUSP after January 1, 2027 within 6 months of its addition.

III. For any disorder included on the RUSP that the Director determines should not be included under the state's screening program in consultation with the Committee, the Committee shall determine whether reevaluation is necessary by (i) reviewing the medical literature published on the disorder since the initial evaluation and (ii) allowing for public input. The Committee shall conduct such determination annually. Upon determining that a condition in the RUSP should not be included under the state's screening program, the Committee shall publish a publicly available report to ensure transparency, document the basis for its decision, and provide recommendations for future review of the condition.

(e) Blood specimens for metabolic, hematologic, endocrinologic, and immunologic disorders will be 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, the Newborn Screening Program to defray operating expenses associated with this chapter, operation of the 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.

Section 2. This bill shall take effect on January 1st, 2027.

Synopsis

This bill mandates the Department of Health and Social Services to establish a publicly transparent process for determining the disorders included in the state's newborn genetic screening panel, including but not limited to those promulgated in the federal recommended universal screening panel. The bill mandates review of conditions included in the RUSP within 6 months of their addition to the panel.