PRINTER'S NO. 1017

THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 847 Session of 2007

INTRODUCED BY ORIE, ERICKSON, KITCHEN, STACK, BOSCOLA, COSTA, RAFFERTY, LOGAN, WASHINGTON, PIPPY, O'PAKE, MELLOW, MUSTO AND WONDERLING, MAY 18, 2007

REFERRED TO PUBLIC HEALTH AND WELFARE, MAY 18, 2007

AN ACT

Amending the act of September 9, 1965 (P.L.497, No.251), entitled "An act requiring physicians, hospitals and other institutions to administer or cause to be administered tests for phenylketonuria and other metabolic diseases upon infants in certain cases," further providing for definitions and for newborn screening and follow-up program; providing for a list of diseases and conditions; further providing for procurement of specimens by health care providers and for regulations; and making an appropriation.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. The title of the act of September 9, 1965 (P.L.497, No.251), known as the Newborn Child Testing Act, is amended to read:

AN ACT

Requiring physicians, hospitals and other [institutions] <u>health care providers</u> to administer or cause to be administered tests for [phenylketonuria and other metabolic] <u>genetic, metabolic, hormonal and functional</u> diseases upon infants in certain cases.

Section 2. The definitions of "board" and "disease" in section 2 of the act, added July 9, 1992 (P.L.398, No.86), are amended to read:

Section 2. Definitions.--The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

["Board." The State Advisory Health Board in the Department of Health.]

* * *

["Disease." Diseases listed by the Department of Health by regulation which lead to mental retardation or physical defects, including, without limitation, Phenylketonuria (PKU), maple syrup urine disease (MSUD) and sickle-cell disease (hemoglobinopathies).]

* * *

Section 3. Section 3 of the act, added July 9, 1992 (P.L.398, No.86), is amended to read:

Section 3. [Newborn Child Screening and Follow-up Program] <u>List of Diseases and Conditions</u>.--(a) In order to assist health care providers to determine whether treatment or other services are necessary <u>for a newborn child in order</u> to avert mental retardation, permanent disabilities or death, the department[, with the approval of the board,] shall establish [a program providing for:

(1) The screening tests of newborn children for diseases.

(2) Follow-up services relating to confirmatory testing, assessment and diagnosis of newborn children with abnormal or inconclusive screening test results.

(b) The department, with the approval of the board, shall establish by regulation those diseases, in addition to

phenylketonuria (PKU), maple syrup urine disease (MSUD) and sickle-cell disease (hemoglobinopathies), for which newborn children shall be tested and the methods for testing and disseminating test results.

(c) No screening test shall be performed if a parent or guardian dissents on the ground that the test conflicts with a religious belief or practice.] a list of genetic, metabolic, hormonal and functional diseases or conditions of concern, including, but not limited to:

(1) Phenylketonuria (PKU).

(2) Maple syrup urine disease (MSUD).

(3) Sickle-cell anemia.

(4) Isovaleric acidemia/isovalery-CoA dehydrogenase deficiency (IVA).

(5) Glutaric acidemia type I/glutaryl-CoA dehydrogenase deficiency type I (GA I).

(6) 3-hydroxy-3-methylglutaryl-CoA lyase deficiency (HMG).

(7) Multiple carboxylase deficiency (MCD).

(8) Methylmalonic acidemia mutase deficiency (MUT).

(9) Methylmalonic acidemia (CblA, B).

(10) 3-Methylcrontonyl-CoA carboxylase deficiency (3MCC).

(11) Propionic acidemia/propionyl-CoA carboxylase deficiency (PROP).

(12) Beta-ketothiolase deficiency (BKT).

(13) Medium-chain acyl-CoA dehydrogenase deficiency (MCAD).

(14) Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD).

(15) Long-chain L-3-OH acyl-CoA dehydrogenase deficiency (LCHAD).

(16) Trifunctional protein deficiency (TFP).

(17) Carnitine uptake defect (CUD).

(18) Homocystinuria (HCY).

(19) Tyrosinemia type I (TYR I).

(20) Argininosuccinic acidemia (ASA).

(21) Citrullinemia (CIT).

(22) Hb S/beta-thalassemia (Hb S/Th).

(23) Hb S/C disease (Hb S/C).

(24) Congenital hypothyroidism (CH).

(25) Biotinidase deficiency (BIOT).

(26) Congenital adrenal hyperplasia (CAH).

(27) Galactosemia (GALT).

(28) Cystic fibrosis (CF).

(b) The department shall establish by regulation those conditions and diseases, in addition to those listed in subsection (a), for which newborn children shall be tested.

Section 4. The act is amended by adding sections to read:

Section 3.1. Newborn Child Screening.--(a) The department shall establish a program providing for the reporting of the screening tests of newborn children for the conditions and diseases listed under section 3.

(b) No screening test shall be performed if a parent or guardian dissents on the ground that the test conflicts with a religious belief or practice.

(c) All laboratories performing the screening tests under the program established in subsection (a) shall report all screening test results by the laboratories to the department.

(d) The department shall establish by publication in the Pennsylvania Bulletin the method or methods for reporting all screening test results to the department.

(e) The results of all screening tests performed under the

program established in subsection (a) shall be subject to the confidentiality provisions of section 15 of the act of April 23, 1956 (1955 P.L.1510, No.500), known as the "Disease Prevention and Control Law of 1955."

Section 3.2. Newborn Child Screening Follow-up Program.--The department shall establish a program providing for follow-up services for a newborn child with abnormal or inconclusive screening test results for the condition and diseases listed under section 3. The follow-up services shall include, but not be limited to:

(1) Notifying parents or guardians of test results.

(2) Notifying health care providers of test results.

(3) Arranging for confirmatory screening and testing.

(4) Notifying health care providers of options for a newborn child with the conditions and diseases listed in section 3.

Section 5. Sections 4 and 5 of the act, added July 9, 1992 (P.L.398, No.86), are amended to read:

Section 4. Procurement of Specimens by Health Care Providers.--(a) Health care providers shall cause to be procured blood specimens of newborn children for required screening and confirmatory tests and send such specimens to a testing laboratory designated by the department.

(b) If the initial specimen is an unacceptable specimen [or as otherwise required by the department by regulation, the], a health care provider shall collect a repeat specimen for screening and confirmatory tests.

Section 5. Regulations.--The department[, with the approval of the board,] shall have the authority to promulgate regulations for the implementation and administration of this act.

Section 6. The sum of $2,000,000, or as much thereof as may be necessary, is hereby appropriated to the Department of Health for the fiscal year July 1, 2007, to June 30, 2008, to carry out the purposes of this act.

Section 7. This act shall take effect July 1, 2007, or immediately, whichever is later.