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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1081 Session of 2017

INTRODUCED BY CRUZ, DiGIROLAMO, YOUNGBLOOD, MURT, KINSEY, V. BROWN, BULLOCK, FITZGERALD, ROZZI, DRISCOLL AND SCHLOSSBERG, APRIL 7, 2017

REFERRED TO COMMITTEE ON HUMAN SERVICES, APRIL 7, 2017

AN ACT

Amending the act of September 9, 1965 (P.L.497, No.251), entitled, as amended, "An act requiring physicians, hospitals and other institutions to administer or cause to be administered tests for genetic diseases upon infants in certain cases," further providing for Newborn Child Screening and Follow-up Program; and providing for Newborn Child Screening Program Account, for newborn child screening fee and for mandated screening and follow-up.

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

Section 1. Section 3 of the act of September 9, 1965 (P.L.497, No.251), known as the Newborn Child Testing Act, is amended to read:

Section 3. Newborn Child Screening and Follow-up Program.--

(a) In order to assist health care providers to determine whether treatment or other services are necessary to avert mental retardation, permanent disabilities or death, the department, <u>in consultation</u> with [the approval of] the Newborn Screening and Follow-up Technical Advisory Committee, shall establish a program providing for[:

(1) The] the screening tests of newborn children for the following diseases:

[(i)] (1) Phenylketonuria (PKU).

[(ii)] (2) Maple syrup urine disease (MSUD).

[(iii)] (3) Sickle-cell disease (hemoglobinopathies).

[(iv)] (4) Galactosemia.

[(v)] (5) Congenital adrenal hyperplasia (CAH).

[(vi)] (6) Primary congenital hypothyroidism.

[(vii) Certain Lysosomal storage disorders (LSDs), including:

(A) Globoid Cell Leukodystrophy (Krabbe).

(B) Fabry.

(C) Pompe.

(D) Niemann-Pick.

(E) Gaucher.

(F) Hurler Syndrome (MPS I).

(2) Follow-up services relating to case management, referrals, confirmatory testing, assessment and diagnosis of newborn children with abnormal, inconclusive or unacceptable screening test results for the following diseases:

(i) Phenylketonuria (PKU).

(ii) Maple syrup urine disease (MSUD).

(iii) Sickle-cell disease (hemoglobinopathies).

(iv) Isovaleric acidemia/Isovalery-CoA dehydrogenase deficiency (IVA).

(v) Glutaric acidemia Type I/Glutaryl-CoA dehydrogenase deficiency Type I (GA I).

(vi) 3-Hydroxy 3-methylglutaryl-CoA lyase deficiency (HMG).

(vii) Multiple carboxylase deficiency (MCD).

(viii) Methylmalonic acidemia (mutase deficiency) (MUT).

(ix) Methylmalonic acidemia (Cbl A,B).

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

(xi) Propionic acidemia/Propionyl-CoA carboxylase deficiency (PROP).

(xii) Beta-ketothiolase deficiency (BKT).

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

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

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

(xvi) Trifunctional protein deficiency (TFP).

(xvii) Carnitine uptake defect (CUD).

(xviii) Homocystinuria (HCY).

(xix) Tyrosinemia type I (TYR I).

(xx) Argininosuccinic acidemia (ASA).

(xxi) Citrullinemia (CIT).

(xxii) Hb S/Beta-thalassemia (Hb S/Th).

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

(xxiv) Congenital hypothyroidism (HYPOTH).

(xxv) Biotinidase deficiency (BIOT).

(xxvi) Congenital adrenal hyperplasia (CAH).

(xxvii) Galactosemia (GALT).

(xxviii) Cystic fibrosis (CF).

(b.1) All laboratories performing the screening tests for newborn children shall report the results to the department for follow-up activities.]

(7) Globoid Cell Leukodystrophy (Krabbe).

(8) Pompe.

(9) Hurler Syndrome (MPS I).

(10) Adrenoleukodystrophy (ALD).

(11) Isovaleric acidemia/Isovalery-CoA dehydrogenase deficiency (IVA).

(12) Glutaric acidemia Type I/Glutaryl-CoA dehydrogenase deficiency Type I (GA I).

(13) 3-Hydroxy 3-methylglutaryl-CoA lyase deficiency (HMG).

(14) Multiple carboxylase deficiency (MCD).

(15) Methylmalonic acidemia (mutase deficiency) (MUT).

(16) Methylmalonic acidemia (Cbl A, B).

(17) 3-Methylcrontonyl-CoA carboxylase deficiency (3MCC).

(18) Propionic acidemia/Propionyl-CoA carboxylase deficiency (PROP).

(19) Beta-ketothiolase deficiency (BKT).

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

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

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

(23) Trifunctional protein deficiency (TFP).

(24) Carnitine uptake defect (CUD).

(25) Homocystinuria (HCY).

(26) Tyrosinemia type I (TYR I).

(27) Argininosuccinic acidemia (ASA).

(28) Citrullinemia (CIT).

(29) Hb S/Beta-thalassemia (Hb S/Th).

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

(31) Congenital hypothyroidism (HYPOTH).

(32) Biotinidase deficiency (BIOT).

(33) Cystic fibrosis (CF).

(34) Severe combined immunodeficiency disease (SCID).

(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.

(d) The department, in consultation with [the approval of] the Newborn Screening and Follow-up Technical Advisory Committee, shall establish, by periodic publication in the Pennsylvania Bulletin, [changes] additions to the [lists] list under subsection [(a)(1) and (2)] (a) of those diseases for which newborn children shall be screened and laboratory screening results reported.

(e) Notwithstanding any provisions of this act or the act of April 23, 1956 (1955 P.L.1510, No.500), known as the "Disease Prevention and Control Law of 1955," to the contrary, test results and diagnoses based upon screening tests for the diseases listed in this section for newborn children shall be reported to the department. The department shall establish, by periodic publication in the Pennsylvania Bulletin, the method for reporting test results to the department.

(f) Test results for genetic diseases listed in this section and any diseases subsequently added by the department under subsection (d) shall be subject to the confidentiality provisions of the "Disease Prevention and Control Law of 1955."

Section 2. The act is amended by adding sections to read:

Section 3.1. Newborn Child Screening Program Account.--(a) There is established a special restricted account within the State Treasury to be known as the Newborn Child Screening Program Account, which shall receive money from the fee established under section 3.2 and other money from a source designated for deposit in the Newborn Child Screening Program

Account.

(b) The fees deposited in the Newborn Child Screening Program Account are appropriated, upon approval of the Governor, to the department to be used for the screening of newborns, tracking screening outcomes, follow-up services and referrals for treatment for up to the first year of life as described in section 3.

(c) All earnings received from the investment or deposit of the money in the Newborn Child Screening Program Account shall be paid into the account for the purposes authorized under this section.

(d) Any unexpended money and interest earned on the money in the Newborn Child Screening Program Account shall not lapse to the General Fund, but shall remain in the account to be used by the department for purposes specified in this section.

Section 3.2. Newborn Child Screening Fee.--(a) In order to safeguard newborn health and appropriately fund the screening of newborns, tracking of screening outcomes, follow-up services and referrals for treatment, the department shall impose a fee on birthing facilities for each newborn child screened.

(b) The fee shall be deposited in the Newborn Child Screening Program Account established under section 3.1.

(c) The amount of the fee shall be determined by the department and shall not exceed an amount sufficient to cover the administrative, laboratory and follow-up costs associated with the performance of screening tests.

(d) The fee shall be published annually in the Pennsylvania Bulletin.

(e) For the purposes of this section, "birthing facilities" shall be defined as an inpatient or ambulatory health care

facility licensed by the department that provides birthing and newborn care services.

Section 3.3. Mandated Screening and Follow-up.--Conditions mandated for screenings and follow-up services shall include, at a minimum, newborn conditions recommended by the Newborn Screening and Follow-up Technical Advisory Board of the department, after review and consideration of the Recommended Uniform Screening Panel from the United States Department of Health and Human Services.

Section 3. This act shall take effect in 180 days.