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THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 983 Session of 2020

INTRODUCED BY DiSANTO, BROWNE, MENSCH, COLLETT, MARTIN, FONTANA, MASTRIANO, TARTAGLIONE AND PITTMAN, JANUARY 15, 2020

REFERRED TO AGING AND YOUTH, JANUARY 15, 2020

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 genetic diseases upon infants in certain cases," further providing for definitions and 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. The definitions of "board" and "disease" in section 2 of the act of September 9, 1965 (P.L.497, No.251), known as the Newborn Child Testing Act, are amended and the section is amended by adding definitions 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:

"Birthing facilities." An inpatient or ambulatory health care facility licensed by the department that provides birthing and newborn care services.

"Board." The [State Advisory Health] Newborn Screening and

Follow-up Technical Advisory Board in the Department of Health.

"Certified-nurse midwife." An individual licensed by the State Board of Medicine to practice midwifery under section 35 of the act of December 20, 1985 (P.L.457, No.112), known as the Medical Practice Act of 1985.

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"Direct-entry midwife." An independent practitioner educated in the discipline of midwifery through self-study, apprenticeship, a midwifery school or a college or university-based program distinct from the discipline of nursing. The term includes certified professional midwives, traditional midwives, Amish, Mennonite or Plain midwives and other specific cultural or spiritual community-based midwives not licensed by the State Board of Medicine as a certified-nurse midwife.

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

"Health care practitioner." As the term is defined in section 103 of the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act.

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Section 2. Section 3(a), (b.1), (d) and (e) of the act are 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] intellectual

disability, physical disability or death, the department, [with the approval of the Newborn Screening and Follow-up Technical Advisory Committee] in consultation with the board, shall establish a program providing for:

(1) The screening tests of newborn children and follow-up services for the following diseases:

(i) Phenylketonuria (PKU).

(ii) Maple syrup urine disease (MSUD).

(iii) Sickle-cell disease (hemoglobinopathies).

(iv) Galactosemia.

(v) Congenital adrenal hyperplasia (CAH).

(vi) 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).]

(vii) Globoid Cell Leukodystrophy (Krabbe).

(viii) Pompe.

(ix) Hurler Syndrome (MPS I).

(x) Adrenoleukodystrophy (ALD).

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

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

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

(xiv) Multiple carboxylase deficiency (MCD).

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

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

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

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

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(xxv) Homocystinuria (HCY).

(xxvi) Tyrosinemia type I (TYR I).

(xxvii) Argininosuccinic acidemia (ASA).

(xxviii) Citrullinemia (CIT).

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

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

(xxxi) Congenital hypothyroidism (HYPOTH).

(xxxii) Biotinidase deficiency (BIOT).

(xxxiii) Cystic fibrosis (CF).

(xxxiv) Severe combined immunodeficiency disease (SCID).

(xxxv) Spinal Muscular Atrophy (SMA).

(2) (Reserved).

(b.1) All laboratories performing the screening tests for newborn children shall report the results to the department for follow-up activities. Follow-up services provided by the program shall include case management, referrals, confirmatory testing, assessment and diagnosis of newborn children with abnormal, inconclusive or unacceptable screening test results up to a newborn child's first year of life.

* * *

(d) The department, [with the approval of the Newborn Screening and Follow-up Technical Advisory Committee] in consultation with the board, shall establish, by transmitting notice to the Legislative Reference Bureau for periodic publication in the Pennsylvania Bulletin, [changes] additions to the [lists] list under subsection (a)(1) [and (2)] 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 transmitting notice to the Legislative Reference Bureau for periodic publication in the Pennsylvania Bulletin, the method for reporting test results to the department.

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Section 3. 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 any other money from any source designated for deposit in the account.

(b) The fees deposited in the account are hereby appropriated, upon approval of the Governor, to the department for the use of screening newborn children, tracking screening outcomes, follow-up services and referrals for treatment for up to the first year of life as described in section 3(b.1).

(c) All earnings received from the investment or deposit of the money in the account shall be paid into the account for purposes authorized under this act.

(d) Unexpended money and interest earned on the money in the 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 act.

(e) As used in this section the term "account" shall mean the Newborn Child Screening Program Account established under subsection (a).

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, certified-nurse midwives, direct-entry midwives and health care practitioners 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) At least annually the department shall transmit notice of the amount of the fee to the Legislative Reference Bureau for publication in the Pennsylvania Bulletin.

Section 3.3. Mandated Screening and Follow-up.--Diseases and conditions mandated for screenings and follow-up services shall, at a minimum, include:

(1) diseases listed under section 3(a)(1);

(2) diseases added by the board under section 3(d) to the list of diseases under section 3(a)(1); and

(3) conditions listed in the Recommended Uniform Screening Panel by the United States Department of Health and Human Services.

Section 4. This act shall take effect in 180 days.