

## AN ACT

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

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

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

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

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

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

- 3 [(i)] (1) Phenylketonuria (PKU).
- 4 [(ii)] (2) Maple syrup urine disease (MSUD).
- 5 [(iii)] (3) Sickle-cell disease (hemoglobinopathies).
- 6 [(iv)] (4) Galactosemia.
- 7 [(v)] (5) Congenital adrenal hyperplasia (CAH).
- 8 [(vi)] (6) Primary congenital hypothyroidism.
- 9 [(vii)] Certain Lysosomal storage disorders (LSDs),  
10 including:

- 11 (A) Globoid Cell Leukodystrophy (Krabbe).
- 12 (B) Fabry.
- 13 (C) Pompe.
- 14 (D) Niemann-Pick.
- 15 (E) Gaucher.
- 16 (F) Hurler Syndrome (MPS I).

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

- 21 (i) Phenylketonuria (PKU).
- 22 (ii) Maple syrup urine disease (MSUD).
- 23 (iii) Sickle-cell disease (hemoglobinopathies).
- 24 (iv) Isovaleric acidemia/Isovalery-CoA dehydrogenase  
25 deficiency (IVA).
- 26 (v) Glutaric acidemia Type I/Glutaryl-CoA dehydrogenase  
27 deficiency Type I (GA I).
- 28 (vi) 3-Hydroxy 3-methylglutaryl-CoA lyase deficiency (HMG).
- 29 (vii) Multiple carboxylase deficiency (MCD).
- 30 (viii) Methylmalonic acidemia (mutase deficiency) (MUT).

- 1 (ix) Methylmalonic acidemia (Cbl A,B).  
2 (x) 3-Methylcrotonyl-CoA carboxylase deficiency (3MCC).  
3 (xi) Propionic acidemia/Propionyl-CoA carboxylase deficiency  
4 (PROP).  
5 (xii) Beta-ketothiolase deficiency (BKT).  
6 (xiii) Medium chain acyl-CoA dehydrogenase deficiency  
7 (MCAD).  
8 (xiv) Very long-chain acyl-CoA dehydrogenase deficiency  
9 (VLCAD).  
10 (xv) Long-chain L-3-OH acyl-CoA dehydrogenase deficiency  
11 (LCHAD).  
12 (xvi) Trifunctional protein deficiency (TFP).  
13 (xvii) Carnitine uptake defect (CUD).  
14 (xviii) Homocystinuria (HCY).  
15 (xix) Tyrosinemia type I (TYR I).  
16 (xx) Argininosuccinic acidemia (ASA).  
17 (xxi) Citrullinemia (CIT).  
18 (xxii) Hb S/Beta-thalassemia (Hb S/Th).  
19 (xxiii) Hb S/C disease (Hb S/C).  
20 (xxiv) Congenital hypothyroidism (HYPOTH).  
21 (xxv) Biotinidase deficiency (BIOT).  
22 (xxvi) Congenital adrenal hyperplasia (CAH).  
23 (xxvii) Galactosemia (GALT).  
24 (xxviii) Cystic fibrosis (CF).  
25 (b.1) All laboratories performing the screening tests for  
26 newborn children shall report the results to the department for  
27 follow-up activities.]  
28 (7) Globoid Cell Leukodystrophy (Krabbe).  
29 (8) Pompe.  
30 (9) Hurler Syndrome (MPS I).

- 1     (10) Adrenoleukodystrophy (ALD).
- 2     (11) Isovaleric acidemia/Isovalery-CoA dehydrogenase
- 3     deficiency (IVA).
- 4     (12) Glutaric acidemia Type I/Glutaryl-CoA dehydrogenase
- 5     deficiency Type I (GA I).
- 6     (13) 3-Hydroxy 3-methylglutaryl-CoA lyase deficiency (HMG).
- 7     (14) Multiple carboxylase deficiency (MCD).
- 8     (15) Methylmalonic acidemia (mutase deficiency) (MUT).
- 9     (16) Methylmalonic acidemia (Cbl A, B).
- 10    (17) 3-Methylcrotonyl-CoA carboxylase deficiency (3MCC).
- 11    (18) Propionic acidemia/Propionyl-CoA carboxylase deficiency
- 12    (PROP).
- 13    (19) Beta-ketothiolase deficiency (BKT).
- 14    (20) Medium chain acyl-CoA dehydrogenase deficiency
- 15    (MCAD).
- 16    (21) Very long-chain acyl-CoA dehydrogenase deficiency
- 17    (VLCAD).
- 18    (22) Long-chain L-3-OH acyl-CoA dehydrogenase deficiency
- 19    (LCHAD).
- 20    (23) Trifunctional protein deficiency (TFP).
- 21    (24) Carnitine uptake defect (CUD).
- 22    (25) Homocystinuria (HCY).
- 23    (26) Tyrosinemia type I (TYR I).
- 24    (27) Argininosuccinic acidemia (ASA).
- 25    (28) Citrullinemia (CIT).
- 26    (29) Hb S/Beta-thalassemia (Hb S/Th).
- 27    (30) Hb S/C disease (Hb S/C).
- 28    (31) Congenital hypothyroidism (HYPOTH).
- 29    (32) Biotinidase deficiency (BIOT).
- 30    (33) Cystic fibrosis (CF).

1       (34) Severe combined immunodeficiency disease (SCID).

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

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

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

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

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

25       Section 3.1. Newborn Child Screening Program Account.--(a)

26 There is established a special restricted account within the  
27 State Treasury to be known as the Newborn Child Screening  
28 Program Account, which shall receive money from the fee  
29 established under section 3.2 and other money from a source  
30 designated for deposit in the Newborn Child Screening Program

1 Account.

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

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

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

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

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

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

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

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

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

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

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