

THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL**No. 983** Session of
2020

INTRODUCED BY DiSANTO, BROWNE, MENSCH, COLLETT, MARTIN, FONTANA,
MASTRIANO, TARTAGLIONE, PITTMAN, LAUGHLIN, LEACH, STEFANO,
ARNOLD AND PHILLIPS-HILL, JANUARY 15, 2020

SENATOR JUDY WARD, AGING AND YOUTH, AS AMENDED,
SEPTEMBER 21, 2020

AN ACT

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

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

11 Section 1. The definitions of "board" and "disease" in
12 section 2 of the act of September 9, 1965 (P.L.497, No.251),
13 known as the Newborn Child Testing Act, are amended and the
14 section is amended by adding definitions to read:

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

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

1 "Board." The [State Advisory Health] Newborn Screening and
2 Follow-up Technical Advisory Board in the Department of Health.

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

7 * * *

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

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

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

25 * * *

26 "SECRETARY." THE SECRETARY OF HEALTH OF THE COMMONWEALTH. <--

27 * * *

28 "UNLICENSED MIDWIFE." THE TERM INCLUDES NATIONALLY CERTIFIED
29 MIDWIVES, TRADITIONAL MIDWIVES, AMISH, MENNONITE OR PLAIN
30 MIDWIVES AND OTHER SPECIFIC CULTURAL OR SPIRITUAL COMMUNITY-

1 BASED MIDWIVES NOT LICENSED TO PRACTICE MIDWIFERY IN THIS
2 COMMONWEALTH.

3 Section 2. Section 3(a), (b.1), (d) and (e) of the act are
4 amended AND THE SECTION IS AMENDED BY ADDING A SUBSECTION to <--
5 read:

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

7 (a) In order to assist health care providers to determine
8 whether treatment or other services are necessary to avert
9 [mental retardation, permanent disabilities] intellectual
10 disability, physical disability or death, the department, [with <--
11 the approval of the Newborn Screening and Follow-up Technical
12 Advisory Committee] ~~in consultation with the board~~ [COMMITTEE] <--
13 BOARD, shall establish a program providing for:

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

- 16 (i) Phenylketonuria (PKU).
- 17 (ii) Maple syrup urine disease (MSUD).
- 18 (iii) Sickle-cell disease (hemoglobinopathies).
- 19 (iv) Galactosemia.
- 20 (v) Congenital adrenal hyperplasia (CAH).
- 21 (vi) Primary congenital hypothyroidism.

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

- 24 (A) Globoid Cell Leukodystrophy (Krabbe).
- 25 (B) Fabry.
- 26 (C) Pompe.
- 27 (D) Niemann-Pick.
- 28 (E) Gaucher.
- 29 (F) Hurler Syndrome (MPS I).

30 (2) Follow-up services relating to case management,

1 referrals, confirmatory testing, assessment and diagnosis of
2 newborn children with abnormal, inconclusive or unacceptable
3 screening test results for the following diseases:

4 (i) Phenylketonuria (PKU).

5 (ii) Maple syrup urine disease (MSUD).

6 (iii) Sickle-cell disease (hemoglobinopathies).

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

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

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

12 (vii) Multiple carboxylase deficiency (MCD).

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

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

15 (x) 3-Methylcrotonyl-CoA carboxylase deficiency (3MCC).

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

18 (xii) Beta-ketothiolase deficiency (BKT).

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

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

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

25 (xvi) Trifunctional protein deficiency (TFP).

26 (xvii) Carnitine uptake defect (CUD).

27 (xviii) Homocystinuria (HCY).

28 (xix) Tyrosinemia type I (TYR I).

29 (xx) Argininosuccinic acidemia (ASA).

30 (xxi) Citrullinemia (CIT).

1 ~~(xxiv) Carnitine uptake defect (CUD).~~
2 ~~(xxv) Homocystinuria (HCY).~~
3 ~~(xxvi) Tyrosinemia type I (TYR I).~~
4 ~~(xxvii) Argininosuccinic acidemia (ASA).~~
5 ~~(xxviii) Citrullinemia (CIT).~~
6 ~~(xxix) Hb S/Beta thalassemia (Hb S/Th).~~
7 ~~(xxx) Hb S/C disease (Hb S/C).~~
8 ~~(xxxi) Congenital hypothyroidism (HYPOTH).~~
9 ~~(xxxii) Biotinidase deficiency (BIOT).~~
10 ~~(xxxiii) Cystic fibrosis (CF).~~
11 ~~(xxxiv) Severe combined immunodeficiency disease (SCID).~~
12 ~~(xxxv) (X) Spinal Muscular Atrophy (SMA).~~ <--
13 (2) ~~(Reserved).~~ A BIRTHING FACILITY, CERTIFIED-NURSE <--
14 MIDWIFE, UNLICENSED MIDWIFE OR HEALTH CARE PRACTITIONER SHALL
15 ORDER THE SCREENING TESTS OF NEW CHILDREN FOR THE FOLLOWING
16 DISEASES:
17 (I) ISOVALERIC ACIDEMIA/ISOVALERY-COA DEHYDROGENASE
18 DEFICIENCY (IVA).
19 (II) GLUTARIC ACIDEMIA TYPE I/GLUTARYL-COA DEHYDROGENASE
20 DEFICIENCY TYPE I (GA I).
21 (III) 3-HYDROXY 3-METHYLGLUTARYL-COA LYASE DEFICIENCY (HMG).
22 (IV) MULTIPLE CARBOXYLASE DEFICIENCY (MCD).
23 (V) METHYLMALONIC ACIDEMIA (MUTASE DEFICIENCY) (MUT).
24 (VI) METHYLMALONIC ACIDEMIA (CBL A, B).
25 (VII) 3-METHYLCRONTONYL-COA CARBOXYLASE DEFICIENCY (3MCC).
26 (VIII) PROPIONIC ACIDEMIA/PROPIONYL-COA CARBOXYLASE
27 DEFICIENCY (PROP).
28 (IX) BETA-KETOTHIOLASE DEFICIENCY (BKT).
29 (X) MEDIUM CHAIN ACYL-COA DEHYDROGENASE DEFICIENCY (MCAD).
30 (XI) VERY LONG-CHAIN ACYL-COA DEHYDROGENASE DEFICIENCY

- 1 (VLCAD).
- 2 (XII) LONG-CHAIN L-3-OH ACYL-COA DEHYDROGENASE DEFICIENCY
- 3 (LCHAD).
- 4 (XIII) TRIFUNCTIONAL PROTEIN DEFICIENCY (TFP).
- 5 (XIV) CARNITINE UPTAKE DEFECT (CUD).
- 6 (XV) HOMOCYSTINURIA (HCY).
- 7 (XVI) TYROSINEMIA TYPE I (TYR I).
- 8 (XVII) ARGININOSUCCINIC ACIDEMIA (ASA).
- 9 (XVIII) CITRULLINEMIA (CIT).
- 10 (XIX) HB S/BETA-THALASSEMIA (HB S/TH).
- 11 (XX) HB S/C DISEASE (HB S/C).
- 12 (XXI) BIOTINIDASE DEFICIENCY (BIOT).
- 13 (XXII) CYSTIC FIBROSIS (CF).
- 14 (XXIII) SEVERE COMBINED IMMUNODEFICIENCY DISEASE (SCID).
- 15 (XXIV) GLOBOID CELL LEUKODYSTROPHY (KRABBE).

16 (b.1) All laboratories performing the screening tests for
 17 newborn children shall report the results to the department for
 18 follow-up activities. ~~Follow up services provided by THE~~ <--
 19 DEPARTMENT SHALL PROVIDE FOLLOW-UP SERVICES THROUGH the program
 20 ~~shall include~~ RELATING TO case management, referrals, <--
 21 confirmatory testing, assessment and diagnosis of newborn
 22 children with abnormal, inconclusive or unacceptable screening
 23 test results up to a newborn child's first year of life.

24 * * *

25 (d) The department, {with the approval of the Newborn <--
 26 Screening and Follow-up Technical Advisory Committee} ~~in~~ <--
 27 ~~consultation with the board~~ [COMMITTEE] BOARD, shall establish, <--
 28 by transmitting notice to the Legislative Reference Bureau for
 29 periodic publication in the Pennsylvania Bulletin, {changes} <--
 30 additions to the {lists} list under subsection (a) (1) {and (2)} <--

1 of those diseases for which newborn children shall be screened
2 and laboratory screening results reported. PRIOR TO MAKING ANY <--
3 CHANGE, THE DEPARTMENT AND BOARD SHALL JOINTLY TRANSMIT A NOTICE
4 TO THE LEGISLATIVE REFERENCE BUREAU FOR PUBLICATION IN THE
5 PENNSYLVANIA BULLETIN THAT ESTABLISHES A PUBLIC COMMENT PERIOD
6 OF AT LEAST 30 DAYS.

7 (D.1) THE BOARD SHALL CONSIST OF MULTIDISCIPLINARY MEMBERS
8 APPOINTED BY THE SECRETARY. THE BOARD SHALL INCLUDE AT LEAST THE
9 FOLLOWING:

10 (1) AN ETHICIST.

11 (2) THREE PEDIATRIC PHYSICIANS.

12 (3) A NEONATOLOGIST.

13 (4) A GENETIC COUNSELOR.

14 (5) A HEMATOLOGIST.

15 (6) TWO CLINICAL GENETICISTS.

16 (7) A NURSE MIDWIFE.

17 (8) A PARENT ADVOCATE.

18 (9) A REPRESENTATIVE RECOMMENDED BY A HOSPITAL ASSOCIATION.

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

28 * * *

29 Section 3. The act is amended by adding ~~sections~~ A SECTION <--
30 to read:

1 ~~Section 3.1. Newborn Child Screening Program Account. (a) <--~~

2 ~~There is established a special restricted account within the~~
3 ~~State Treasury to be known as the Newborn Child Screening~~
4 ~~Program Account, which shall receive money from the fee~~
5 ~~established under section 3.2 and any other money from any~~
6 ~~source designated for deposit in the account.~~

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

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

15 ~~(d) Unexpended money and interest earned on the money in the~~
16 ~~account shall not lapse to the General Fund, but shall remain in~~
17 ~~the account to be used by the department for purposes specified~~
18 ~~in this act.~~

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

22 ~~Section 3.2. Newborn Child Screening Fee. (a) In order to~~
23 ~~safeguard newborn health and appropriately fund the screening of~~
24 ~~newborns, tracking of screening outcomes, follow up services and~~
25 ~~referrals for treatment, the department shall impose a fee on~~
26 ~~birthing facilities, certified nurse midwives, direct entry~~
27 ~~midwives and health care practitioners for each newborn child~~
28 ~~screened.~~

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

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

5 ~~(d) At least annually the department shall transmit notice~~
6 ~~of the amount of the fee to the Legislative Reference Bureau for~~
7 ~~publication in the Pennsylvania Bulletin.~~

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

11 (1) diseases listed under section 3(a)(1) 3(A); <--

12 (2) diseases added by the board under section 3(d) to the
13 list of diseases under section 3(a)(1) 3(A); and <--

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

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