

1 AN ACT concerning health.

2 **Be it enacted by the People of the State of Illinois,**
3 **represented in the General Assembly:**

4 Section 5. The Newborn Metabolic Screening Act is amended
5 by changing Section 2 as follows:

6 (410 ILCS 240/2) (from Ch. 111 1/2, par. 4904)

7 Sec. 2. General provisions. The Department of Public
8 Health shall administer the provisions of this Act and shall:

9 (a) Institute and carry on an intensive educational
10 program among physicians, hospitals, public health nurses, and
11 the public concerning disorders included in newborn screening.
12 This educational program shall include information about the
13 nature of the diseases and examinations for the detection of
14 the diseases in early infancy in order that measures may be
15 taken to prevent the disabilities resulting from the diseases.

16 (a-5) Require that all newborns be screened for the
17 presence of certain genetic, metabolic, and congenital
18 anomalies as determined by the Department, by rule.

19 (a-5.1) Require that all blood and biological specimens
20 collected pursuant to this Act or the rules adopted under this
21 Act be submitted for testing to the nearest Department
22 laboratory designated to perform such tests. The following
23 provisions shall apply concerning testing:

1 (1) Beginning July 1, 2015, the base fee for newborn
2 screening services shall be \$118. The Department may
3 develop a reasonable fee structure and may levy additional
4 fees according to such structure to cover the cost of
5 providing this testing service and for the follow-up of
6 infants with an abnormal screening test; however,
7 additional fees may be levied no sooner than 6 months
8 prior to the beginning of testing for a new genetic,
9 metabolic, or congenital disorder. Fees collected from the
10 provision of this testing service shall be placed in the
11 Metabolic Screening and Treatment Fund. Other State and
12 federal funds for expenses related to metabolic screening,
13 follow-up, and treatment programs may also be placed in
14 the Fund.

15 (2) Moneys shall be appropriated from the Fund to the
16 Department solely for the purposes of providing newborn
17 screening, follow-up, and treatment programs. Nothing in
18 this Act shall be construed to prohibit any licensed
19 medical facility from collecting additional specimens for
20 testing for metabolic or neonatal diseases or any other
21 diseases or conditions, as it deems fit. Any person
22 violating the provisions of this subsection (a-5.1) is
23 guilty of a petty offense.

24 (3) If the Department is unable to provide the
25 screening using the State Laboratory, it shall temporarily
26 provide such screening through an accredited laboratory

1 selected by the Department until the Department has the
2 capacity to provide screening through the State
3 Laboratory. If screening is provided on a temporary basis
4 through an accredited laboratory, the Department shall
5 substitute the fee charged by the accredited laboratory,
6 plus a 5% surcharge for documentation and handling, for
7 the fee authorized in this subsection (a-5.1).

8 (a-5.2) Maintain a registry of cases, including
9 information of importance for the purpose of follow-up
10 services to assess long-term outcomes.

11 (a-5.3) Supply the necessary metabolic treatment formulas
12 where practicable for diagnosed cases of amino acid metabolism
13 disorders, including phenylketonuria, organic acid disorders,
14 and fatty acid oxidation disorders for as long as medically
15 indicated, when the product is not available through other
16 State agencies.

17 (a-5.4) Arrange for or provide public health nursing,
18 nutrition, and social services and clinical consultation as
19 indicated.

20 (a-5.5) Utilize the Universal Newborn Screening ~~Genetic~~
21 ~~and Metabolic Diseases~~ Advisory Committee established under
22 the Genetic and Metabolic Diseases Advisory Committee Act to
23 provide guidance and recommendations to the Department's
24 newborn screening program. The Universal Newborn Screening
25 ~~Genetic and Metabolic Diseases~~ Advisory Committee shall review
26 the feasibility and advisability of including additional

1 metabolic, genetic, and congenital disorders in the newborn
2 screening panel, according to a review protocol applied to
3 each suggested addition to the screening panel. Beginning
4 January 1, 2027, the Universal Newborn Screening Advisory
5 Committee shall review all new conditions added to the federal
6 Recommended Uniform Screening Panel within 12 months of the
7 condition being added to the Recommended Uniform Screening
8 Panel, as long as the condition meets the requirements of this
9 Section. If the Recommended Uniform Screening Panel includes
10 conditions not screened by the State on the effective date of
11 this amendatory Act of the 104th General Assembly, the
12 Universal Newborn Screening Advisory Committee shall begin
13 review of the condition no later than one year after the
14 effective date of this amendatory Act of the 104th General
15 Assembly. Nothing in this Section shall be construed to
16 prevent the review and recommendation of additional conditions
17 not on the Recommended Uniform Screening Panel on the
18 effective date of this amendatory Act of the 104th General
19 Assembly, as long as they meet the requirements for review.
20 The Department shall consider the recommendations of the
21 Universal Newborn Screening ~~Genetic and Metabolic Diseases~~
22 Advisory Committee in determining whether to include an
23 additional disorder in the screening panel prior to proposing
24 an administrative rule concerning inclusion of an additional
25 disorder in the newborn screening panel. Notwithstanding any
26 other provision of law, no new screening may begin prior to the

1 occurrence of all the following:

2 (1) the establishment and verification of relevant and
3 appropriate performance specifications as defined under
4 the federal Clinical Laboratory Improvement Amendments and
5 regulations thereunder for U.S. Food and Drug
6 Administration-cleared or in-house developed methods,
7 performed under an institutional review board-approved
8 protocol, if required;

9 (2) the availability of quality assurance testing
10 methodology for the processes set forth in item (1) of
11 this subsection (a-5.5);

12 (3) the acquisition and installment by the Department
13 of the equipment necessary to implement the screening
14 tests;

15 (4) the establishment of precise threshold values
16 ensuring defined disorder identification for each
17 screening test;

18 (5) the authentication of pilot testing achieving each
19 milestone described in items (1) through (4) of this
20 subsection (a-5.5) for each disorder screening test; and

21 (6) the authentication of achieving the potential of
22 high throughput standards for statewide volume of each
23 disorder screening test concomitant with each milestone
24 described in items (1) through (4) of this subsection
25 (a-5.5).

26 (a-6) (Blank).

1 (a-7) (Blank).

2 (a-8) (Blank).

3 (b) (Blank).

4 (c) (Blank).

5 (d) (Blank).

6 (e) (Blank).

7 (Source: P.A. 98-440, eff. 8-16-13; 98-756, eff. 7-16-14;
8 99-403, eff. 8-19-15.)

9 Section 10. The Genetic and Metabolic Diseases Advisory
10 Committee Act is amended by changing Section 5 as follows:

11 (410 ILCS 265/5)

12 Sec. 5. Universal Newborn Screening ~~Genetic and Metabolic~~
13 ~~Diseases~~ Advisory Committee.

14 (a) The Director of Public Health shall create the
15 Universal Newborn Screening ~~Genetic and Metabolic Diseases~~
16 Advisory Committee to advise the Department of Public Health
17 regarding issues relevant to newborn screenings of metabolic
18 diseases.

19 (b) The Universal Newborn Screening Advisory Committee
20 shall ~~purposes of Metabolic Diseases Advisory Committee are~~
21 ~~all of the following:~~

22 (1) Conduct reviews of any condition added to the
23 federal Recommended Uniform Screening Panel pursuant to
24 Section 2 of the Newborn Metabolic Screening Act within

1 one year of addition to the Recommended Uniform Screening
2 Panel.

3 (2) Conduct reviews within one year of any condition
4 that meets the following criteria once both criteria have
5 been met:

6 (A) there is a newborn screening assay available
7 for the condition; and

8 (B) there is a therapeutic intervention or
9 treatment approved by the United States Food and Drug
10 Administration for the condition.

11 (3) Following review of each condition, make a formal
12 recommendation to the Department of Public Health on
13 whether to add the condition to the newborn screening
14 panel. If the Department approves the addition of the
15 condition, the Department must inform the State Laboratory
16 within 60 days of receiving the recommendation. The State
17 Laboratory shall implement newborn screening for the
18 approved conditions within 2 years. If the Department does
19 not approve the condition, the Department must provide
20 information as to why the decision was made and what gaps
21 of information are needed for reconsideration.

22 (4) Submit to the Governor's Office and the General
23 Assembly by December 31, 2027 and each year thereafter, a
24 list of the conditions the Committee reviewed, the
25 Committee's recommendations, the Department of Public
26 Health's decisions, and the status of implementation in

1 the lab. Any recommendations not to add a condition shall
2 include information from the Committee as to why the
3 decision was made, what gaps of information need to be met
4 for reconsideration along with processes to initiate
5 reconsideration.

6 (5) ~~(1)~~ Advise the Department regarding issues
7 relevant to its Genetics Program.

8 (6) ~~(2)~~ Advise the Department regarding optimal
9 laboratory methodologies for screening of the targeted
10 conditions.

11 (7) ~~(3)~~ Recommend to the Department consultants who
12 are qualified to diagnose a condition detected by
13 screening, provide management of care, and genetic
14 counseling for the family.

15 (8) ~~(4)~~ Monitor the incidence of each condition for
16 which newborn screening is done, evaluate the effects of
17 treatment and genetic counseling, and provide advice on
18 disorders to be included in newborn screening panel.

19 (9) ~~(5)~~ Advise the Department on educational programs
20 for professionals and the general public.

21 (10) ~~(6)~~ Advise the Department on new developments and
22 areas of interest in relation to the Genetics Program.

23 (11) ~~(7)~~ Address any other matters ~~Any other matter~~
24 deemed appropriate by the Committee and the Director.

25 (b-5) Nothing in this Section shall be construed to
26 prevent the review and recommendation of additional conditions

1 not currently on the Recommended Uniform Screening Panel.

2 (c) The Committee shall consist of 20 members appointed by
3 the Director of Public Health. Membership shall include
4 physicians, geneticists, nurses, nutritionists, and other
5 allied health professionals, as well as patients and parents.
6 Ex officio ~~Ex officio~~ members may be appointed, but shall not
7 have voting privileges.

8 (d) Members of the Committee may receive compensation for
9 necessary expenses incurred in the performance of their
10 duties.

11 (Source: P.A. 98-440, eff. 8-16-13.)

12 Section 99. Effective date. This Act takes effect upon
13 becoming law.