



Rep. Martha Deuter

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10400SB3049ham001

LRB104 16764 BDA 37272 a

1 AMENDMENT TO SENATE BILL 3049

2 AMENDMENT NO. _____. Amend Senate Bill 3049 by replacing
3 everything after the enacting clause with the following:

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

1 presence of certain genetic, metabolic, and congenital
2 anomalies as determined by the Department, by rule.

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

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

22 (2) Moneys shall be appropriated from the Fund to the
23 Department solely for the purposes of providing newborn
24 screening, follow-up, and treatment programs. Nothing in
25 this Act shall be construed to prohibit any licensed
26 medical facility from collecting additional specimens for

1 testing for metabolic or neonatal diseases or any other
2 diseases or conditions, as it deems fit. Any person
3 violating the provisions of this subsection (a-5.1) is
4 guilty of a petty offense.

5 (3) If the Department is unable to provide the
6 screening using the State Laboratory, it shall temporarily
7 provide such screening through an accredited laboratory
8 selected by the Department until the Department has the
9 capacity to provide screening through the State
10 Laboratory. If screening is provided on a temporary basis
11 through an accredited laboratory, the Department shall
12 substitute the fee charged by the accredited laboratory,
13 plus a 5% surcharge for documentation and handling, for
14 the fee authorized in this subsection (a-5.1).

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

18 (a-5.3) Supply the necessary metabolic treatment formulas
19 where practicable for diagnosed cases of amino acid metabolism
20 disorders, including phenylketonuria, organic acid disorders,
21 and fatty acid oxidation disorders for as long as medically
22 indicated, when the product is not available through other
23 State agencies.

24 (a-5.4) Arrange for or provide public health nursing,
25 nutrition, and social services and clinical consultation as
26 indicated.

1 (a-5.5) Utilize the Universal Newborn Screening ~~Genetic~~
2 ~~and Metabolic Diseases~~ Advisory Committee established under
3 the Genetic and Metabolic Diseases Advisory Committee Act to
4 provide guidance and recommendations to the Department's
5 newborn screening program. The Universal Newborn Screening
6 ~~Genetic and Metabolic Diseases~~ Advisory Committee shall review
7 the feasibility and advisability of including additional
8 metabolic, genetic, and congenital disorders in the newborn
9 screening panel, according to a review protocol applied to
10 each suggested addition to the screening panel. Beginning
11 January 1, 2027, the Universal Newborn Screening Advisory
12 Committee shall review all new conditions added to the federal
13 Recommended Uniform Screening Panel within 12 months of the
14 condition being added to the Recommended Uniform Screening
15 Panel, as long as the condition meets the requirements of this
16 Section. If the Recommended Uniform Screening Panel includes
17 conditions not screened by the State on the effective date of
18 this amendatory Act of the 104th General Assembly, the
19 Universal Newborn Screening Advisory Committee shall begin
20 review of the condition no later than one year after the
21 effective date of this amendatory Act of the 104th General
22 Assembly. Nothing in this Section shall be construed to
23 prevent the review and recommendation of additional conditions
24 not on the Recommended Uniform Screening Panel on the
25 effective date of this amendatory Act of the 104th General
26 Assembly, as long as they meet the requirements for review.

1 The Department shall consider the recommendations of the
2 Universal Newborn Screening ~~Genetic and Metabolic Diseases~~
3 Advisory Committee in determining whether to include an
4 additional disorder in the screening panel prior to proposing
5 an administrative rule concerning inclusion of an additional
6 disorder in the newborn screening panel. Notwithstanding any
7 other provision of law, no new screening may begin prior to the
8 occurrence of all the following:

9 (1) the establishment and verification of relevant and
10 appropriate performance specifications as defined under
11 the federal Clinical Laboratory Improvement Amendments and
12 regulations thereunder for U.S. Food and Drug
13 Administration-cleared or in-house developed methods,
14 performed under an institutional review board-approved
15 protocol, if required;

16 (2) the availability of quality assurance testing
17 methodology for the processes set forth in item (1) of
18 this subsection (a-5.5);

19 (3) the acquisition and installment by the Department
20 of the equipment necessary to implement the screening
21 tests;

22 (4) the establishment of precise threshold values
23 ensuring defined disorder identification for each
24 screening test;

25 (5) the authentication of pilot testing achieving each
26 milestone described in items (1) through (4) of this

subsection (a-5.5) for each disorder screening test; and

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

(a-6) (Blank).

(a-7) (Blank).

(a-8) (Blank).

(b) (Blank).

(c) (Blank).

(d) (Blank).

(e) (Blank).

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

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

(410 ILCS 265/5)

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

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

1 diseases.

2 (b) The Universal Newborn Screening Advisory Committee
3 shall ~~purposes of Metabolic Diseases Advisory Committee are~~
4 ~~all of the following:~~

5 (1) Conduct reviews of any condition added to the
6 federal Recommended Uniform Screening Panel pursuant to
7 Section 2 of the Newborn Metabolic Screening Act within
8 one year of addition to the Recommended Uniform Screening
9 Panel.

10 (2) Conduct reviews within one year of any condition
11 that meets the following criteria once both criteria have
12 been met:

13 (A) there is a newborn screening assay available
14 for the condition; and

15 (B) there is a therapeutic intervention or
16 treatment approved by the United States Food and Drug
17 Administration for the condition.

18 (3) Following review of each condition, make a formal
19 recommendation to the Department of Public Health on
20 whether to add the condition to the newborn screening
21 panel. If the Department approves the addition of the
22 condition, the Department must inform the State Laboratory
23 within 60 days of receiving the recommendation. The State
24 Laboratory shall implement newborn screening for the
25 approved conditions within 2 years. If the Department does
26 not approve the condition, the Department must provide

1 information as to why the decision was made and what gaps
2 of information are needed for reconsideration.

3 (4) Submit to the Governor's Office and the General
4 Assembly by December 31, 2027 and each year thereafter, a
5 list of the conditions the Committee reviewed, the
6 Committee's recommendations, the Department of Public
7 Health's decisions, and the status of implementation in
8 the lab. Any recommendations not to add a condition shall
9 include information from the Committee as to why the
10 decision was made, what gaps of information need to be met
11 for reconsideration along with processes to initiate
12 reconsideration.

13 (5) ~~(1)~~ Advise the Department regarding issues
14 relevant to its Genetics Program.

15 (6) ~~(2)~~ Advise the Department regarding optimal
16 laboratory methodologies for screening of the targeted
17 conditions.

18 (7) ~~(3)~~ Recommend to the Department consultants who
19 are qualified to diagnose a condition detected by
20 screening, provide management of care, and genetic
21 counseling for the family.

22 (8) ~~(4)~~ Monitor the incidence of each condition for
23 which newborn screening is done, evaluate the effects of
24 treatment and genetic counseling, and provide advice on
25 disorders to be included in newborn screening panel.

26 (9) ~~(5)~~ Advise the Department on educational programs

1 for professionals and the general public.

2 (10) ~~(6)~~ Advise the Department on new developments and
3 areas of interest in relation to the Genetics Program.

4 (11) ~~(7)~~ Address any other matters ~~Any other matter~~
5 deemed appropriate by the Committee and the Director.

6 (b-5) Nothing in this Section shall be construed to
7 prevent the review and recommendation of additional conditions
8 not currently on the Recommended Uniform Screening Panel.

9 (c) The Committee shall consist of 20 members appointed by
10 the Director of Public Health. Membership shall include
11 physicians, geneticists, nurses, nutritionists, and other
12 allied health professionals, as well as patients and parents.
13 Ex officio ~~Ex officio~~ members may be appointed, but shall not
14 have voting privileges.

15 (d) Members of the Committee may receive compensation for
16 necessary expenses incurred in the performance of their
17 duties.

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

19 Section 99. Effective date. This Act takes effect upon
20 becoming law.".