



Rep. JoAnn D. Osmond

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09700SB1761ham001

LRB097 10043 RPM 55667 a

1 AMENDMENT TO SENATE BILL 1761

2 AMENDMENT NO. _____. Amend Senate Bill 1761 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. The Department of Public Health shall administer
8 the provisions of this Act and shall:

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

1 diseases.

2 (a-5) Beginning July 1, 2002, provide all newborns with
3 expanded screening tests for the presence of genetic,
4 endocrine, or other metabolic disorders, including
5 phenylketonuria, galactosemia, hypothyroidism, congenital
6 adrenal hyperplasia, biotinidase deficiency, and sickling
7 disorders, as well as other amino acid disorders, organic acid
8 disorders, fatty acid oxidation disorders, and other
9 abnormalities detectable through the use of a tandem mass
10 spectrometer. If by July 1, 2002, the Department is unable to
11 provide expanded screening using the State Laboratory, it shall
12 temporarily provide such screening through an accredited
13 laboratory selected by the Department until the Department has
14 the capacity to provide screening through the State Laboratory.
15 If expanded screening is provided on a temporary basis through
16 an accredited laboratory, the Department shall substitute the
17 fee charged by the accredited laboratory, plus a 5% surcharge
18 for documentation and handling, for the fee authorized in
19 subsection (e) of this Section.

20 (a-6) In accordance with the timetable specified in this
21 subsection, provide all newborns with expanded screening tests
22 for the presence of certain Lysosomal Storage Disorders known
23 as Krabbe, Pompe, Gaucher, Fabry, and Niemann-Pick. The testing
24 shall begin within 6 months following the occurrence of all of
25 the following:

26 (i) the establishment and verification of relevant and

1 appropriate performance specifications as defined under
2 the federal Clinical Laboratory Improvement Amendments and
3 regulations thereunder for Federal Drug
4 Administration-cleared or in-house developed methods,
5 performed under an institutional review board approved
6 protocol, if required ~~the registration with the federal~~
7 ~~Food and Drug Administration of the necessary reagents;~~

8 ~~(ii) the availability of the necessary reagents from~~
9 ~~the Centers for Disease Control and Prevention;~~

10 (ii) ~~(iii)~~ the availability of quality assurance
11 testing methodology for these processes; ~~and~~

12 (iii) ~~(iv)~~ the acquisition and installment by the
13 Department of the equipment necessary to implement the
14 expanded screening tests; ~~and~~

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

18 (v) authentication of pilot testing achieving each
19 milestone described in items (i) through (iv) of this
20 subsection (a-6) for each disorder screening test; and

21 (vi) authentication achieving potentiality of high
22 throughput standards for statewide volume of each disorder
23 screening test concomitant with each milestone described
24 in items (i) through (iv) of the subsection (a-6).

25 It is the goal of this amendatory Act of the 97th ~~95th~~
26 General Assembly that the expanded screening for the specified

1 Lysosomal Storage Disorders begins within 2 3 years after the
2 effective date of this amendatory Act of the 97th General
3 Assembly. The Department is authorized to implement an
4 additional fee for the screening prior to beginning the testing
5 in order to accumulate the resources for start-up and other
6 costs associated with implementation of the screening and
7 thereafter to support the costs associated with screening and
8 follow-up programs for the specified Lysosomal Storage
9 Disorders.

10 (a-7) In accordance with the timetable specified in this
11 subsection (a-7), provide all newborns with expanded screening
12 tests for the presence of Severe Combined Immunodeficiency
13 Disease (SCID). The testing shall begin within 12 months
14 following the occurrence of all of the following:

15 (i) the establishment and verification of relevant and
16 appropriate performance specifications as defined under
17 the federal Clinical Laboratory Improvement Amendments and
18 regulations thereunder for Federal Drug
19 Administration-cleared or in-house developed methods,
20 performed under an institutional review board approved
21 protocol, if required;

22 (ii) the availability of quality assurance testing and
23 comparative threshold values for SCID;

24 (iii) the acquisition and installment by the
25 Department of the equipment necessary to implement the
26 initial pilot and expanded statewide volume of screening

1 tests for SCID;

2 (iv) establishment of precise threshold values
3 ensuring defined disorder identification for SCID;

4 (v) authentication of pilot testing achieving each
5 milestone described in items (i) through (iv) of this
6 subsection (a-7) for SCID; and

7 (vi) authentication achieving potentiality of high
8 throughput standards for statewide volume of the SCID
9 screening test concomitant with each milestone described
10 in items (i) through (iv) of this subsection (a-7).

11 It is the goal of this amendatory Act of the 97th General
12 Assembly that the expanded screening for Severe Combined
13 Immunodeficiency Disease begins within 2 years after the
14 effective date of this amendatory Act of the 97th General
15 Assembly. The Department is authorized to implement an
16 additional fee for the screening prior to beginning the testing
17 in order to accumulate the resources for start-up and other
18 costs associated with implementation of the screening and
19 thereafter to support the costs associated with screening and
20 follow-up programs for Severe Combined Immunodeficiency
21 Disease.

22 (a-8) In accordance with the timetable specified in this
23 subsection (a-8), provide all newborns with expanded screening
24 tests for the presence of certain Lysosomal Storage Disorders
25 known as Mucopolysaccharidosis I (Hurlers) and
26 Mucopolysaccharidosis II (Hunters). The testing shall begin

1 within 12 months following the occurrence of all of the
2 following:

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

10 (ii) the availability of quality assurance testing and
11 comparative threshold values for each screening test and
12 accompanying disorder;

13 (iii) the acquisition and installment by the
14 Department of the equipment necessary to implement the
15 initial pilot and expanded statewide volume of screening
16 tests for each disorder;

17 (iv) establishment of precise threshold values
18 ensuring defined disorder identification for each
19 screening test;

20 (v) authentication of pilot testing achieving each
21 milestone described in items (i) through (iv) of this
22 subsection (a-8) for each disorder screening test; and

23 (vi) authentication achieving potentiality of high
24 throughput standards for statewide volume of each disorder
25 screening test concomitant with with each milestone
26 described in items (i) through (iv) of this subsection

1 (a-8).

2 It is the goal of this amendatory Act of the 97th General
3 Assembly that the expanded screening for the specified
4 Lysosomal Storage Disorders begins within 3 years after the
5 effective date of this amendatory Act of the 97th General
6 Assembly. The Department is authorized to implement an
7 additional fee for the screening prior to beginning the testing
8 in order to accumulate the resources for start-up and other
9 costs associated with implementation of the screening and
10 thereafter to support the costs associated with screening and
11 follow-up programs for the specified Lysosomal Storage
12 Disorders.

13 (b) Maintain a registry of cases including information of
14 importance for the purpose of follow-up services to prevent
15 mental retardation.

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

22 (d) Arrange for or provide public health nursing, nutrition
23 and social services and clinical consultation as indicated.

24 (e) Require that all specimens collected pursuant to this
25 Act or the rules and regulations promulgated hereunder be
26 submitted for testing to the nearest Department of Public

1 Health laboratory designated to perform such tests. The
2 Department may develop a reasonable fee structure and may levy
3 fees according to such structure to cover the cost of providing
4 this testing service. Fees collected from the provision of this
5 testing service shall be placed in a special fund in the State
6 Treasury, hereafter known as the Metabolic Screening and
7 Treatment Fund. Other State and federal funds for expenses
8 related to metabolic screening, follow-up and treatment
9 programs may also be placed in such Fund. Moneys shall be
10 appropriated from such Fund to the Department of Public Health
11 solely for the purposes of providing metabolic screening,
12 follow-up and treatment programs. Nothing in this Act shall be
13 construed to prohibit any licensed medical facility from
14 collecting additional specimens for testing for metabolic or
15 neonatal diseases or any other diseases or conditions, as it
16 deems fit. Any person violating the provisions of this
17 subsection (e) is guilty of a petty offense.

18 (Source: P.A. 95-695, eff. 11-5-07.)

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