



Sen. Heather A. Steans

Filed: 4/29/2013

09800HB2661sam001

LRB098 09098 RPM 45063 a

1 AMENDMENT TO HOUSE BILL 2661

2 AMENDMENT NO. _____. Amend House Bill 2661 by replacing
3 everything after the enacting clause with the following:

4 "Section 5. The Newborn Metabolic Screening Act is amended
5 by changing Sections 1, 1.5, and 2 and by adding Sections 1.10,
6 3.1, 3.2, and 3.3 as follows:

7 (410 ILCS 240/1) (from Ch. 111 1/2, par. 4903)

8 Sec. 1. The Illinois Department of Public Health shall
9 promulgate and enforce rules and regulations requiring that
10 every newborn be subjected to tests for genetic,
11 ~~phenylketonuria, hypothyroidism, galactosemia and such other~~
12 metabolic, and congenital anomalies ~~diseases~~ as the Department
13 may deem necessary ~~from time to time~~. The Department is
14 empowered to promulgate such additional rules and regulations
15 as are found necessary for the administration of this Act,
16 including mandatory reporting of the results of all tests for

1 these conditions to the Illinois Department of Public Health.

2 (Source: P.A. 83-87.)

3 (410 ILCS 240/1.5)

4 Sec. 1.5. Definitions. In this Act:

5 "Accredited laboratory" means any laboratory that holds a
6 valid certificate issued under the Clinical Laboratory
7 Improvement Amendments of 1988, 102 Stat. 2903, 42 U.S.C. 263a,
8 as amended, and that reports its screening results by using
9 normal pediatric reference ranges.

10 "Department" means the Department of Public Health.

11 ~~"Expanded screening" means screening for genetic and~~
12 ~~metabolic disorders, including but not limited to amino acid~~
13 ~~disorders, organic acid disorders, fatty acid oxidation~~
14 ~~disorders, and other abnormal profiles, in newborn infants that~~
15 ~~can be detected through the use of a tandem mass spectrometer.~~

16 ~~"Tandem mass spectrometer" means an analytical instrument~~
17 ~~used to detect numerous genetic and metabolic disorders at one~~
18 ~~time.~~

19 (Source: P.A. 92-701, eff. 7-19-02.)

20 (410 ILCS 240/1.10 new)

21 Sec. 1.10. Critical congenital heart disease.

22 (a) The General Assembly finds as follows:

23 (1) According to the United States Secretary of Health
24 and Human Services Advisory Committee on Heritable

1 Disorders in Newborns and Children, congenital heart
2 disease affects approximately 7 to 9 of every 1,000 live
3 births in the United States and Europe. The federal Centers
4 for Disease Control and Prevention state that critical
5 congenital heart disease is the leading cause of infant
6 death due to birth defects.

7 (2) Many newborn lives could potentially be saved by
8 earlier detection and treatment of critical congenital
9 heart disease if health care facilities in the State were
10 required to perform a simple, non-invasive newborn
11 screening in conjunction with current screening methods.

12 (b) The Department shall require that screening tests for
13 critical congenital heart defects be performed at birthing
14 hospitals and birth centers in accordance with a testing
15 protocol adopted by the Department, by rule, in line with
16 current standards of care, such as pulse oximetry screening,
17 and may authorize screening tests for additional congenital
18 anomalies to be performed at birthing hospitals and birth
19 centers in accordance with a testing protocol adopted by the
20 Department, by rule.

21 (c) The Department may authorize health care facilities to
22 report screening test results and follow-up information.

23 (410 ILCS 240/2) (from Ch. 111 1/2, par. 4904)

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

1 (a) Institute and carry on an intensive educational program
2 among physicians, hospitals, public health nurses and the
3 public concerning disorders included in newborn screening ~~the~~
4 ~~diseases phenylketonuria, hypothyroidism, galactosemia and~~
5 ~~other metabolic diseases~~. This educational program shall
6 include information about the nature of the diseases and
7 examinations for the detection of the diseases in early infancy
8 in order that measures may be taken to prevent the ~~intellectual~~
9 disabilities resulting from the diseases.

10 (a-5) Require that ~~Beginning July 1, 2002, provide~~ all
11 newborns be screened ~~with expanded screening tests~~ for the
12 presence of certain genetic, metabolic, and congenital
13 anomalies as determined by the Department, by rule.

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

19 (1) The Department may develop a reasonable fee
20 structure and may levy fees according to such structure to
21 cover the cost of providing this testing service and for
22 the follow-up of infants with an abnormal screening test.
23 Fees collected from the provision of this testing service
24 shall be placed in the Metabolic Screening and Treatment
25 Fund. Other State and federal funds for expenses related to
26 metabolic screening, follow-up, and treatment programs may

1 also be placed in the Fund.

2 (2) Moneys shall be appropriated from the Fund to the
3 Department solely for the purposes of providing newborn
4 screening, follow-up, and treatment programs. Nothing in
5 this Act shall be construed to prohibit any licensed
6 medical facility from collecting additional specimens for
7 testing for metabolic or neonatal diseases or any other
8 diseases or conditions, as it deems fit. Any person
9 violating the provisions of this subsection (a-5.1) is
10 guilty of a petty offense. ~~endocrine, or other metabolic~~
11 ~~disorders, including phenylketonuria, galactosemia,~~
12 ~~hypothyroidism, congenital adrenal hyperplasia,~~
13 ~~biotinidase deficiency, and sickling disorders, as well as~~
14 ~~other amino acid disorders, organic acid disorders, fatty~~
15 ~~acid oxidation disorders, and other abnormalities~~
16 ~~detectable through the use of a tandem mass spectrometer.~~

17 (3) If ~~by July 1, 2002,~~ the Department is unable to
18 provide ~~the expanded~~ screening using the State Laboratory,
19 it shall temporarily provide such screening through an
20 accredited laboratory selected by the Department until the
21 Department has the capacity to provide screening through
22 the State Laboratory. If ~~expanded~~ screening is provided on
23 a temporary basis through an accredited laboratory, the
24 Department shall substitute the fee charged by the
25 accredited laboratory, plus a 5% surcharge for
26 documentation and handling, for the fee authorized in this

1 subsection (a-5.1) ~~(c) of this Section.~~

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

5 (a-5.3) Supply the necessary metabolic treatment formulas
6 where practicable for diagnosed cases of amino acid metabolism
7 disorders, including phenylketonuria, organic acid disorders,
8 and fatty acid oxidation disorders for as long as medically
9 indicated, when the product is not available through other
10 State agencies.

11 (a-5.4) Arrange for or provide public health nursing,
12 nutrition, and social services and clinical consultation as
13 indicated.

14 (a-5.5) The Department shall utilize the Genetic and
15 Metabolic Diseases Advisory Committee established under the
16 Genetic and Metabolic Diseases Advisory Committee Act to
17 provide guidance and recommendations to the Department's
18 newborn screening program. The Genetic and Metabolic Diseases
19 Advisory Committee shall review the feasibility and
20 advisability of including additional metabolic, genetic, and
21 congenital disorders in the newborn screening panel, according
22 to a review protocol applied to each suggested addition to the
23 screening panel. The Department shall consider the
24 recommendations of the Genetic and Metabolic Diseases Advisory
25 Committee in determining whether to include an additional
26 disorder in the screening panel prior to proposing an

1 administrative rule concerning inclusion of an additional
2 disorder in the newborn screening panel. Notwithstanding any
3 other provision of law, no new screening may begin prior to the
4 occurrence of all the following:

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

12 (2) the availability of quality assurance testing
13 methodology for the processes set forth in item (1) of this
14 subsection (a-5.5);

15 (3) the acquisition and installment by the Department
16 of the equipment necessary to implement the screening
17 tests;

18 (4) the establishment of precise threshold values
19 ensuring defined disorder identification for each
20 screening test;

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

24 (6) the authentication of achieving the potential of
25 high throughput standards for statewide volume of each
26 disorder screening test concomitant with each milestone

1 described in items (1) through (4) of this subsection
2 (a-5.5).

3 (a-6) (Blank). ~~In accordance with the timetable specified~~
4 ~~in this subsection, provide all newborns with expanded~~
5 ~~screening tests for the presence of certain Lysosomal Storage~~
6 ~~Disorders known as Krabbe, Pompe, Gaucher, Fabry, and~~
7 ~~Niemann Pick. The testing shall begin within 6 months following~~
8 ~~the occurrence of all of the following:~~

9 ~~(i) 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 Federal Drug~~
13 ~~Administration cleared or in-house developed methods,~~
14 ~~performed under an institutional review board approved~~
15 ~~protocol, if required;~~

16 ~~(ii) the availability of quality assurance testing~~
17 ~~methodology for these processes;~~

18 ~~(iii) the acquisition and installment by the~~
19 ~~Department of the equipment necessary to implement the~~
20 ~~expanded screening tests;~~

21 ~~(iv) establishment of precise threshold values~~
22 ~~ensuring defined disorder identification for each~~
23 ~~screening test;~~

24 ~~(v) authentication of pilot testing achieving each~~
25 ~~milestone described in items (i) through (iv) of this~~
26 ~~subsection (a-6) for each disorder screening test; and~~

1 ~~(vi) authentication achieving potentiality of high~~
2 ~~throughput standards for statewide volume of each disorder~~
3 ~~screening test concomitant with each milestone described~~
4 ~~in items (i) through (iv) of this subsection (a-6).~~

5 ~~It is the goal of Public Act 97 532 that the expanded~~
6 ~~screening for the specified Lysosomal Storage Disorders begins~~
7 ~~within 2 years after August 23, 2011 (the effective date of~~
8 ~~Public Act 97 532). The Department is authorized to implement~~
9 ~~an additional fee for the screening prior to beginning the~~
10 ~~testing in order to accumulate the resources for start-up and~~
11 ~~other costs associated with implementation of the screening and~~
12 ~~thereafter to support the costs associated with screening and~~
13 ~~follow-up programs for the specified Lysosomal Storage~~
14 ~~Disorders.~~

15 ~~(a-7) (Blank). In accordance with the timetable specified~~
16 ~~in this subsection (a-7), provide all newborns with expanded~~
17 ~~screening tests for the presence of Severe Combined~~
18 ~~Immunodeficiency Disease (SCID). The testing shall begin~~
19 ~~within 12 months following the occurrence of all of the~~
20 ~~following:~~

21 ~~(i) the establishment and verification of relevant and~~
22 ~~appropriate performance specifications as defined under~~
23 ~~the federal Clinical Laboratory Improvement Amendments and~~
24 ~~regulations thereunder for Federal Drug~~
25 ~~Administration cleared or in house developed methods,~~
26 ~~performed under an institutional review board approved~~

1 ~~protocol, if required;~~

2 ~~(ii) the availability of quality assurance testing and~~
3 ~~comparative threshold values for SCID;~~

4 ~~(iii) the acquisition and installment by the~~
5 ~~Department of the equipment necessary to implement the~~
6 ~~initial pilot and expanded statewide volume of screening~~
7 ~~tests for SCID;~~

8 ~~(iv) establishment of precise threshold values~~
9 ~~ensuring defined disorder identification for SCID;~~

10 ~~(v) authentication of pilot testing achieving each~~
11 ~~milestone described in items (i) through (iv) of this~~
12 ~~subsection (a-7) for SCID; and~~

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

17 ~~It is the goal of Public Act 97-532 that the expanded~~
18 ~~screening for Severe Combined Immunodeficiency Disease begins~~
19 ~~within 2 years after August 23, 2011 (the effective date of~~
20 ~~Public Act 97-532). The Department is authorized to implement~~
21 ~~an additional fee for the screening prior to beginning the~~
22 ~~testing in order to accumulate the resources for start-up and~~
23 ~~other costs associated with implementation of the screening and~~
24 ~~thereafter to support the costs associated with screening and~~
25 ~~follow up programs for Severe Combined Immunodeficiency~~
26 ~~Disease.~~

1 (a-8) (Blank). ~~In accordance with the timetable specified~~
2 ~~in this subsection (a-8), provide all newborns with expanded~~
3 ~~screening tests for the presence of certain Lysosomal Storage~~
4 ~~Disorders known as Mucopolysaccharidosis I (Hurlers) and~~
5 ~~Mucopolysaccharidosis II (Hunters). The testing shall begin~~
6 ~~within 12 months following the occurrence of all of the~~
7 ~~following:~~

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

15 ~~(ii) the availability of quality assurance testing and~~
16 ~~comparative threshold values for each screening test and~~
17 ~~accompanying disorder;~~

18 ~~(iii) the acquisition and installment by the~~
19 ~~Department of the equipment necessary to implement the~~
20 ~~initial pilot and expanded statewide volume of screening~~
21 ~~tests for each disorder;~~

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

25 ~~(v) authentication of pilot testing achieving each~~
26 ~~milestone described in items (i) through (iv) of this~~

1 ~~subsection (a 8) for each disorder screening test; and~~
2 ~~(vi) authentication achieving potentiality of high~~
3 ~~throughput standards for statewide volume of each disorder~~
4 ~~screening test concomitant with each milestone described~~
5 ~~in items (i) through (iv) of this subsection (a 8).~~

6 ~~It is the goal of Public Act 97 532 that the expanded~~
7 ~~screening for the specified Lysosomal Storage Disorders begins~~
8 ~~within 3 years after August 23, 2011 (the effective date of~~
9 ~~Public Act 97 532). The Department is authorized to implement~~
10 ~~an additional fee for the screening prior to beginning the~~
11 ~~testing in order to accumulate the resources for start up and~~
12 ~~other costs associated with implementation of the screening and~~
13 ~~thereafter to support the costs associated with screening and~~
14 ~~follow up programs for the specified Lysosomal Storage~~
15 ~~Disorders.~~

16 (b) (Blank). ~~Maintain a registry of cases including~~
17 ~~information of importance for the purpose of follow up services~~
18 ~~to prevent intellectual disabilities.~~

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

25 (d) (Blank). ~~Arrange for or provide public health nursing,~~
26 ~~nutrition and social services and clinical consultation as~~

1 ~~indicated.~~

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

22 (Source: P.A. 97-227, eff. 1-1-12; 97-532, eff. 8-23-11;
23 97-813, eff. 7-13-12.)

24 (410 ILCS 240/3.1 new)

25 Sec. 3.1. Lysosomal storage disorders. In accordance with

1 the timetable specified in this Section, the Department shall
2 provide all newborns with screening tests for the presence of
3 certain lysosomal storage disorders known as Krabbe, Pompe,
4 Gaucher, Fabry, and Niemann-Pick. The testing shall begin
5 within 6 months following the occurrence of all of the
6 following:

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

14 (2) the availability of quality assurance testing
15 methodology for these processes;

16 (3) the acquisition and installment by the Department
17 of the equipment necessary to implement the screening
18 tests;

19 (4) the establishment of precise threshold values
20 ensuring defined disorder identification for each
21 screening test;

22 (5) the authentication of pilot testing achieving each
23 milestone described in items (1) through (4) of this
24 Section for each disorder screening test; and

25 (6) the authentication of achieving the potential of
26 high throughput standards for statewide volume of each

1 disorder screening test concomitant with each milestone
2 described in items (1) through (4) of this Section.

3 It was the goal of Public Act 97-532 that the screening for
4 the specified lysosomal storage disorders begins within 2 years
5 after August 23, 2011 (the effective date of Public Act
6 97-532). 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 (410 ILCS 240/3.2 new)

14 Sec. 3.2. Severe combined immunodeficiency disease. In
15 accordance with the timetable specified in this Section, the
16 Department shall provide all newborns with screening tests for
17 the presence of severe combined immunodeficiency disease
18 (SCID). The testing shall begin within 12 months following the
19 occurrence of all of the following:

20 (1) the establishment and verification of relevant and
21 appropriate performance specifications as defined under
22 the federal Clinical Laboratory Improvement Amendments and
23 regulations thereunder for Federal Drug
24 Administration-cleared or in-house developed methods,
25 performed under an institutional review board approved

1 protocol, if required;

2 (2) the availability of quality assurance testing and
3 comparative threshold values for SCID;

4 (3) the acquisition and installment by the Department
5 of the equipment necessary to implement the initial pilot
6 and statewide volume of screening tests for SCID;

7 (4) the establishment of precise threshold values
8 ensuring defined disorder identification for SCID;

9 (5) the authentication of pilot testing achieving each
10 milestone described in items (1) through (4) of this
11 Section for SCID; and

12 (6) the authentication of achieving the potential of
13 high throughput standards for statewide volume of the SCID
14 screening test concomitant with each milestone described
15 in items (1) through (4) of this Section.

16 It was the goal of Public Act 97-532 that the screening for
17 severe combined immunodeficiency disease begins within 2 years
18 after August 23, 2011 (the effective date of Public Act
19 97-532). The Department is authorized to implement an
20 additional fee for the screening prior to beginning the testing
21 in order to accumulate the resources for start-up and other
22 costs associated with implementation of the screening and
23 thereafter to support the costs associated with screening and
24 follow-up programs for severe combined immunodeficiency
25 disease.

1 (410 ILCS 240/3.3 new)

2 Sec. 3.3. Mucopolysaccharidosis disorders. In accordance
3 with the timetable specified in this Section, the Department
4 shall provide all newborns with screening tests for the
5 presence of certain lysosomal storage disorders known as
6 mucopolysaccharidosis I (Hurlers) and mucopolysaccharidosis II
7 (Hunters). The testing shall begin within 12 months following
8 the occurrence of all of 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 Federal 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 and
17 comparative threshold values for each screening test and
18 accompanying disorder;

19 (3) the acquisition and installment by the Department
20 of the equipment necessary to implement the initial pilot
21 and statewide volume of screening tests for each disorder;

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

1 Section for each disorder screening test; and

2 (6) the authentication of achieving the potential of
3 high throughput standards for statewide volume of each
4 disorder screening test concomitant with each milestone
5 described in items (1) through (4) of this Section.

6 It was the goal of Public Act 97-532 that the screening for
7 the specified lysosomal storage disorders begins within 3 years
8 after August 23, 2011 (the effective date of Public Act
9 97-532). The Department is authorized to implement an
10 additional fee for the screening prior to beginning the testing
11 in order to accumulate the resources for start-up and other
12 costs associated with implementation of the screening and
13 thereafter to support the costs associated with screening and
14 follow-up programs for the specified lysosomal storage
15 disorders.

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

18 (410 ILCS 265/5)

19 Sec. 5. Genetic and Metabolic Diseases Advisory Committee.

20 (a) The Director of Public Health shall create the Genetic
21 and Metabolic Diseases Advisory Committee to advise the
22 Department of Public Health regarding issues relevant to
23 newborn screenings of metabolic diseases.

24 (b) The purposes of Metabolic Diseases Advisory Committee

1 are all of the following:

2 (1) Advise the Department regarding issues relevant to
3 its Genetics Program.

4 (2) Advise the Department regarding optimal laboratory
5 methodologies for screening of the targeted conditions.

6 (3) Recommend to the Department consultants who are
7 qualified to diagnose a condition detected by screening,
8 provide management of care, and genetic counseling for the
9 family.

10 (4) Monitor the incidence of each condition for which
11 newborn screening is done, evaluate the effects of
12 treatment and genetic counseling, and provide advice on
13 disorders to be included in newborn screening panel.

14 (5) Advise the Department on educational programs for
15 professionals and the general public.

16 (6) Advise the Department on new developments and areas
17 of interest in relation to the Genetics Program.

18 (7) Any other matter deemed appropriate by the
19 Committee and the Director.

20 (c) The Committee shall consist of 20 members appointed by
21 the Director of Public Health. Membership shall include
22 physicians, geneticists, nurses, nutritionists, and other
23 allied health professionals, as well as patients and parents.
24 Ex-officio members may be appointed, but shall not have voting
25 privileges.

26 (d) Members of the Committee may receive compensation for

1 necessary expenses incurred in the performance of their duties.

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

3 Section 99. Effective date. This Act takes effect upon
4 becoming law.".