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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 may authorize screening tests for
13 congenital anomalies, including, but not limited to, a
14 screening for critical congenital heart defects, to be
15 performed at a health care facility that provides newborn
16 infant care and that complies with the test procedures and the
17 standards of accuracy and precision required by the Department.

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

20 (410 ILCS 240/2) (from Ch. 111 1/2, par. 4904)

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

23 (a) Institute and carry on an intensive educational program
24 among physicians, hospitals, public health nurses and the
25 public concerning disorders included in newborn screening ~~the~~

1 ~~diseases phenylketonuria, hypothyroidism, galactosemia and~~
2 ~~other metabolic diseases.~~ This educational program shall
3 include information about the nature of the diseases and
4 examinations for the detection of the diseases in early infancy
5 in order that measures may be taken to prevent the ~~intellectual~~
6 disabilities resulting from the diseases.

7 (a-5) Require that ~~Beginning July 1, 2002, provide~~ all
8 newborns be screened ~~with expanded screening tests~~ for the
9 presence of genetic, metabolic, and congenital anomalies.

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

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

24 (2) Moneys shall be appropriated from the Fund to the
25 Department solely for the purposes of providing newborn
26 screening, follow-up, and treatment programs. Nothing in

1 this Act shall be construed to prohibit any licensed
2 medical facility from collecting additional specimens for
3 testing for metabolic or neonatal diseases or any other
4 diseases or conditions, as it deems fit. Any person
5 violating the provisions of this subsection (a-5.1) is
6 guilty of a petty offense. ~~endocrine, or other metabolic~~
7 ~~disorders, including phenylketonuria, galactosemia,~~
8 ~~hypothyroidism, congenital adrenal hyperplasia,~~
9 ~~biotinidase deficiency, and sickling disorders, as well as~~
10 ~~other amino acid disorders, organic acid disorders, fatty~~
11 ~~acid oxidation disorders, and other abnormalities~~
12 ~~detectable through the use of a tandem mass spectrometer.~~

13 (3) If ~~by July 1, 2002,~~ the Department is unable to
14 provide the ~~expanded~~ screening using the State Laboratory,
15 it shall temporarily provide such screening through an
16 accredited laboratory selected by the Department until the
17 Department has the capacity to provide screening through
18 the State Laboratory. If ~~expanded~~ screening is provided on
19 a temporary basis through an accredited laboratory, the
20 Department shall substitute the fee charged by the
21 accredited laboratory, plus a 5% surcharge for
22 documentation and handling, for the fee authorized in this
23 subsection (a-5.1) ~~(c) of this Section.~~

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

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

7 (a-5.4) Arrange for or provide public health nursing,
8 nutrition, and social services and clinical consultation as
9 indicated.

10 (a-5.5) The Director shall appoint a Genetic and Metabolic
11 Diseases Advisory Committee to provide guidance and
12 recommendations to the Department's newborn screening program.
13 The Genetic and Metabolic Diseases Advisory Committee shall
14 review the feasibility of including additional metabolic,
15 genetic, and congenital disorders in the newborn screening
16 panel. The Genetic and Metabolic Diseases Advisory Committee
17 shall be comprised of health and medical experts and consumer
18 representatives. The Department shall consider the
19 recommendations of the Genetic and Metabolic Diseases Advisory
20 Committee in determining whether to include an additional
21 disorder in the screening panel prior to adopting
22 administrative rules. Members of the Genetic and Metabolic
23 Diseases Advisory Committee may receive compensation for
24 necessary expenses incurred in the performance of their duties.

25 (a-6) (Blank). In accordance with the timetable specified
26 in this subsection, provide all newborns with expanded

1 ~~screening tests for the presence of certain Lysosomal Storage~~
2 ~~Disorders known as Krabbe, Pompe, Gaucher, Fabry, and~~
3 ~~Niemann-Pick. The testing shall begin within 6 months following~~
4 ~~the occurrence of all of the following:~~

5 ~~(i) 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 Federal Drug~~
9 ~~Administration cleared or in house developed methods,~~
10 ~~performed under an institutional review board approved~~
11 ~~protocol, if required;~~

12 ~~(ii) the availability of quality assurance testing~~
13 ~~methodology for these processes;~~

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

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-6) 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 each milestone described~~
26 ~~in items (i) through (iv) of this subsection (a-6).~~

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

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

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

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

26 ~~(iii) the acquisition and installment by the~~

1 ~~Department of the equipment necessary to implement the~~
2 ~~initial pilot and expanded statewide volume of screening~~
3 ~~tests for SCID;~~

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

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

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

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

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

1 ~~Mucopolysaccharidosis II (Hunters). The testing shall begin~~
2 ~~within 12 months following the occurrence of all of the~~
3 ~~following:~~

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

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

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

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

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

24 ~~(vi) authentication achieving potentiality of high~~
25 ~~throughput standards for statewide volume of each disorder~~
26 ~~screening test concomitant with each milestone described~~

1 ~~in items (i) through (iv) of this subsection (a 8).~~

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

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

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

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

24 (e) (Blank). ~~Require that all specimens collected pursuant~~
25 ~~to this Act or the rules and regulations promulgated hereunder~~
26 ~~be 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 (c) is guilty of a petty offense.~~

18 (Source: P.A. 97-227, eff. 1-1-12; 97-532, eff. 8-23-11;
19 97-813, eff. 7-13-12.)

20 (410 ILCS 240/3.1 new)

21 Sec. 3.1. Lysosomal storage disorders. In accordance with
22 the timetable specified in this Section, the Department shall
23 provide all newborns with screening tests for the presence of
24 certain lysosomal storage disorders known as Krabbe, Pompe,
25 Gaucher, Fabry, and Niemann-Pick. The testing shall begin

1 within 6 months following the occurrence of all of the
2 following:

3 (1) 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 (2) the availability of quality assurance testing
11 methodology for these processes;

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

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

17 (5) authentication of pilot testing achieving each
18 milestone described in items (1) through (4) of this
19 Section for each disorder screening test; and

20 (6) authentication achieving potentiality of high
21 throughput standards for statewide volume of each disorder
22 screening test concomitant with each milestone described
23 in items (1) through (4) of this Section.

24 It is the goal of Public Act 97-532 that the screening for
25 the specified lysosomal storage disorders begins within 2 years
26 after August 23, 2011 (the effective date of Public Act

1 97-532). The Department is authorized to implement an
2 additional fee for the screening prior to beginning the testing
3 in order to accumulate the resources for start-up and other
4 costs associated with implementation of the screening and
5 thereafter to support the costs associated with screening and
6 follow-up programs for the specified lysosomal storage
7 disorders.

8 (410 ILCS 240/3.2 new)

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

15 (1) 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 (2) the availability of quality assurance testing and
23 comparative threshold values for SCID;

24 (3) the acquisition and installment by the Department
25 of the equipment necessary to implement the initial pilot

1 and statewide volume of screening tests for SCID;

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

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

7 (6) 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 (1) through (4) of this Section.

11 It is the goal of Public Act 97-532 that the screening for
12 severe combined immunodeficiency disease begins within 2 years
13 after August 23, 2011 (the effective date of Public Act
14 97-532). The Department is authorized to implement an
15 additional fee for the screening prior to beginning the testing
16 in order to accumulate the resources for start-up and other
17 costs associated with implementation of the screening and
18 thereafter to support the costs associated with screening and
19 follow-up programs for severe combined immunodeficiency
20 disease.

21 (410 ILCS 240/3.3 new)

22 Sec. 3.3. Mucopolysaccharidosis disorders. In accordance
23 with the timetable specified in this Section, the Department
24 shall provide all newborns with screening tests for the
25 presence of certain lysosomal storage disorders known as

1 mucopolysaccharidosis I (Hurlers) and mucopolysaccharidosis II
2 (Hunters). The testing shall begin within 12 months following
3 the occurrence of all of the following:

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

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

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

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

19 (5) authentication of pilot testing achieving each
20 milestone described in items (1) through (4) of this
21 Section for each disorder screening test; and

22 (6) authentication achieving potentiality of high
23 throughput standards for statewide volume of each disorder
24 screening test concomitant with each milestone described
25 in items (1) through (4) of this Section.

26 It is the goal of Public Act 97-532 that the screening for

1 the specified lysosomal storage disorders begins within 3 years
2 after August 23, 2011 (the effective date of Public Act
3 97-532). 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 Section 99. Effective date. This Act takes effect upon
11 becoming law.".