Rep. Robyn Gabel

Filed: 4/12/2013

AMENDMENT TO HOUSE BILL 2661

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

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

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

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

these conditions to the Illinois Department of Public Health.
(Source: P.A. 83-87.)

(410 ILCS 240/1.5)

Sec. 1.5. Definitions. In this Act:

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

"Department" means the Department of Public Health.

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

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

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

(410 ILCS 240/1.10 new)

Sec. 1.10. Critical congenital heart disease.

(a) The General Assembly finds as follows:

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

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

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

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

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

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

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

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

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

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

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

also be placed in the Fund.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~protocol, if required;~~

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

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

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

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

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

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

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

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

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

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

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

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

~~subsection (a-8) for each disorder screening test; and~~

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

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

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

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

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

~~indicated.~~

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

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

(410 ILCS 240/3.1 new)

Sec. 3.1. Lysosomal storage disorders. In accordance with

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

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

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

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

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

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

It was the goal of Public Act 97-532 that the screening for the specified lysosomal storage disorders begins within 2 years after August 23, 2011 (the effective date of Public Act 97-532). The Department is authorized to implement an additional fee for the screening prior to beginning the testing in order to accumulate the resources for start-up and other costs associated with implementation of the screening and thereafter to support the costs associated with screening and follow-up programs for the specified lysosomal storage disorders.

(410 ILCS 240/3.2 new)

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

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

protocol, if required;

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

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

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

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

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

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

(410 ILCS 240/3.3 new)

Sec. 3.3. Mucopolysacchardosis disorders. In accordance with the timetable specified in this Section, the Department shall provide all newborns with screening tests for the presence of certain lysosomal storage disorders known as mucopolysaccharidosis I (Hurlers) and mucopolysaccharidosis II (Hunters). The testing shall begin within 12 months following the occurrence of all of the following:

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

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

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

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

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

Section 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 Section.

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

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

(410 ILCS 265/5)

Sec. 5. Genetic and Metabolic Diseases Advisory Committee.

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

(b) The purposes of Metabolic Diseases Advisory Committee

are all of the following:

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

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

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

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

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

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

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

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

(d) Members of the Committee may receive compensation for

necessary expenses incurred in the performance of their duties.

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

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