Rep. JoAnn D. Osmond

Filed: 5/17/2011

AMENDMENT TO SENATE BILL 1761

AMENDMENT NO. _____. Amend Senate Bill 1761 by replacing everything after the enacting clause with the following:

"Section 5. The Newborn Metabolic Screening Act is amended by changing Section 2 as follows:

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

Sec. 2. 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 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 mental retardation resulting from the

diseases.

(a-5) Beginning July 1, 2002, provide all newborns with expanded screening tests for the presence of genetic, 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. If by July 1, 2002, the Department is unable to provide 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 subsection (e) of this Section.

(a-6) 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) <u>the establishment and verification of relevant and</u>

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 ~~the registration with the federal Food and Drug Administration of the necessary reagents~~;

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

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

(iii) ~~(iv)~~ 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 the subsection (a-6).

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

Lysosomal Storage Disorders begins within 2 ~~3~~ years after the effective date of this amendatory Act of the 97th General Assembly. 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) 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 this amendatory Act of the 97th General Assembly that the expanded screening for Severe Combined Immunodeficiency Disease begins within 2 years after the effective date of this amendatory Act of the 97th General Assembly. 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) 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 with each milestone described in items (i) through (iv) of this subsection

(a-8).

It is the goal of this amendatory Act of the 97th General Assembly that the expanded screening for the specified Lysosomal Storage Disorders begins within 3 years after the effective date of this amendatory Act of the 97th General Assembly. 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) Maintain a registry of cases including information of importance for the purpose of follow-up services to prevent mental retardation.

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

(e) 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. 95-695, eff. 11-5-07.)

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