Rep. Laura Fine

Filed: 3/23/2015

AMENDMENT TO HOUSE BILL 2790

AMENDMENT NO. _____. Amend House Bill 2790 by replacing everything after the enacting clause with the following:

"Section 5. The Newborn Metabolic Screening Act is amended by changing Section 2 and by adding Section 3.4 as follows:

(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. 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 disabilities resulting from the diseases.

(a-5) Require that all newborns be screened 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) Beginning July 1, 2015, the base fee for newborn screening services shall be $118. The Department may develop a reasonable fee structure and may levy additional 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.

(3) If the Department is unable to provide the 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 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).

(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) 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).

(a-7) (Blank).

(a-8) (Blank).

(b) (Blank).

(c) (Blank).

(d) (Blank).

(e) (Blank).

(Source: P.A. 97-227, eff. 1-1-12; 97-532, eff. 8-23-11; 97-813, eff. 7-13-12; 98-440, eff. 8-16-13; 98-756, eff. 7-16-14.)

(410 ILCS 240/3.4 new)

Sec. 3.4. Adrenoleukodystrophy. In accordance with the timetable specified in this Section, the Department shall

provide all newborns with screening tests for the presence of adrenoleukodystrophy (ALD). The testing shall begin within 18 months following the occurrence of all of the following:

(1) the development and validation of a reliable methodology for screening newborns for ALD using dried blood spots and quality assurance testing methodology for such test or the approval of a test for ALD using dried blood spots by the federal Food and Drug Administration;

(2) the availability of any necessary reagents for such test;

(3) 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;

(4) the availability of quality assurance testing and comparative threshold values for ALD;

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

(6) the establishment of precise threshold values ensuring defined disorder identification for ALD;

(7) the authentication of pilot testing achieving each milestone described in items (1) through (6) of this

Section for ALD; and

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

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 adrenoleukodystrophy.

Section 99. Effective date. This Act takes effect July 1, 2015.".