HB2790

LRB09903689JLK23700b

99TH GENERAL ASSEMBLY

State of Illinois

2015 and 2016

HB2790

by Rep. Laura Fine

SYNOPSIS AS INTRODUCED:

410 ILCS 240/3.4 new

Amends the Newborn Metabolic Screening Act. Requires the Department of Public Health to provide all newborns with screening tests for the presence of adrenoleukodystrophy (ALD). Provides that testing shall begin within 12 months following the occurrence of various events, including: (1) the development and validation of a reliable methodology; (2) the availability of any necessary reagents; (3) the establishment and verification of relevant and appropriate performance specifications; (4) the availability of quality assurance testing; (5) the acquisition and installment of necessary equipment; (6) the establishment of precise threshold values ensuring defined disorder identification for ALD; (7) the authentication of pilot testing; and (8) the authentication of achieving the potential of high throughput standards. Allows the Department 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.

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A BILL FOR

AN ACT concerning health.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

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

(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 12 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.