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 changing Section 2 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; however, additional fees may be levied no sooner than 6 months prior to the beginning of testing for a new genetic, metabolic, or congenital disorder. 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 Universal Newborn Screening ~~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 Universal Newborn Screening ~~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. Beginning January 1, 2027, the Universal Newborn Screening Advisory Committee shall review all new conditions added to the federal Recommended Uniform Screening Panel within 12 months of the condition being added to the Recommended Uniform Screening Panel, as long as the condition meets the requirements of this Section. If the Recommended Uniform Screening Panel includes conditions not screened by the State on the effective date of this amendatory Act of the 104th General Assembly, the Universal Newborn Screening Advisory Committee shall begin review of the condition no later than one year after the effective date of this amendatory Act of the 104th General Assembly. Nothing in this Section shall be construed to prevent the review and recommendation of additional conditions not on the Recommended Uniform Screening Panel on the effective date of this amendatory Act of the 104th General Assembly, as long as they meet the requirements for review. The Department shall consider the recommendations of the Universal Newborn Screening ~~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. 98-440, eff. 8-16-13; 98-756, eff. 7-16-14; 99-403, eff. 8-19-15.)

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

(410 ILCS 265/5)

Sec. 5. Universal Newborn Screening ~~Genetic and Metabolic Diseases~~ Advisory Committee.

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

(b) The Universal Newborn Screening Advisory Committee shall ~~purposes of Metabolic Diseases Advisory Committee are all of the following~~:

(1) Conduct reviews of any condition added to the federal Recommended Uniform Screening Panel pursuant to Section 2 of the Newborn Metabolic Screening Act within

one year of addition to the Recommended Uniform Screening Panel.

(2) Conduct reviews within one year of any condition that meets the following criteria once both criteria have been met:

(A) has a newborn screening assay available; and

(B) for which there is a therapeutic intervention, or for which there is a treatment approved by the United States Food and Drug Administration.

(3) Following review of each condition, make a formal recommendation to the Department of Public Health on whether to add the condition to the newborn screening panel. If the Department recommends the addition of the condition, the Department must inform the State Laboratory within 60 days of making the decision. If the Department does not recommend the condition, the Department must provide information as to why the decision was made and what gaps of information are needed for reconsideration.

(4) Write and submit to the Governor's Office and the General Assembly by January 1, 2028, and every 3 years thereafter, listing the conditions the Committee reviewed, the Committee's recommendations, the Department of Public Health's decisions, and the status of implementation in the lab. Any recommendations not to add a condition shall include information from the Committee as to why the decision was made, what gaps of information need to be met

for reconsideration along with processes to initiate reconsideration.

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

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

(7) ~~(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.

(8) ~~(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.

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

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

(11) ~~(7)~~ Address any other matters ~~Any other matter~~ deemed appropriate by the Committee and the Director.

(b-5) Nothing in this Section shall be construed to prevent the review and recommendation of additional conditions not currently on the Recommended Uniform Screening Panel.

(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. 98-440, eff. 8-16-13.)