SB3049

LRB104 16764 BDA 32796 b

104TH GENERAL ASSEMBLY

State of Illinois

2025 and 2026

SB3049

Introduced 1/28/2026, by Sen. Julie A. Morrison

SYNOPSIS AS INTRODUCED:

410 ILCS 240/2	from Ch. 111 1/2, par. 4904
410 ILCS 265/1	
410 ILCS 265/5	
410 ILCS 445/15	

Amends the Genetic and Metabolic Diseases Advisory Committee Act. Changes the name of the Genetic and Metabolic Diseases Advisory Committee to the Universal Newborn Screening Advisory Committee. Adds duties for the Committee, including duties to hold quarterly meetings, review conditions, make recommendations, and prepare reports. Makes conforming changes in the short title of the Act, the Newborn Metabolic Screening Act, and the Rare Disease Commission Act. Effective immediately.

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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 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 Advisory Committee ~~Genetic and Metabolic Diseases Advisory Committee~~ established under the Universal Newborn Screening Advisory Committee Act ~~Genetic and Metabolic Diseases Advisory Committee Act~~ to provide guidance and recommendations to the Department's newborn screening program. The Universal Newborn Screening Advisory Committee ~~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 Universal Newborn Screening Advisory Committee ~~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 Sections 1 and 5 as follows:

(410 ILCS 265/1)

Sec. 1. Short title. This Act may be cited as the Universal Newborn Screening Advisory Committee ~~Genetic and Metabolic Diseases Advisory Committee~~ Act.

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

(410 ILCS 265/5)

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

(a) The Director of Public Health shall create the Universal Newborn Screening Advisory Committee ~~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 the ~~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.

(b-5) The duties of the Committee include all of the following:

(1) The Committee shall meet quarterly beginning July 1, 2026. During its first quarterly meeting after the effective date of this amendatory Act of the 104th General Assembly, the Committee shall propose a timeline for the completion of the review described in paragraph (2). The timeline shall allow for the review to be conducted within 12 months after the effective date of this amendatory Act of the 104th General Assembly.

(2) The Committee shall identify all conditions for which:

(A) the condition has been added to the Recommended Uniform Screening Panel of the United States Department of Health and Human Services;

(B) a newborn screening assay is available; or

(C) there is a treatment that is in Phase III clinical trials or for which there is a treatment or treatment guideline approved by the United States Food

and Drug Administration.

(3) Beginning October 1, 2026, the Committee shall conduct a review to be completed by October 1, 2028 of the following conditions if they meet the criteria in paragraph (2):

(A) Sanfilippo syndrome type A (MPS IIIA);

(B) Morquio syndrome type A (MPS IVA);

(C) Maroteaux Lamy syndrome (MPS VI);

(D) Sly syndrome (MPS VII); and

(E) Batten disease type 2 (CLN2).

(b-10) The Committee shall make recommendations regarding the reviews described in subsection (b-5), and the recommendations shall be implemented according to the following requirements:

(1) After review of each condition, the Committee shall make a recommendation to the Department on whether to add the condition to the newborn screening panel. Upon receipt of the recommendation, the Department shall decide whether to approve the Committee's recommendation. The Department shall notify the State Laboratory of the Department's decision to add the condition to the newborn screening panel within 30 days of the Department's decision.

(2) If the Department approves the recommendation to add the condition to the newborn screening panel, the State Laboratory shall implement newborn screening for the

approved conditions within 12 months of the Department's notification under paragraph (1) of this subsection (b-10).

(3) On an ongoing basis, the Committee shall also consider screening newborn babies for any condition listed on the Recommended Uniform Screening Panel of the United States Department of Health and Human Services subject to the approval of the Secretary of the United States Department of Health and Human Services.

(4) An annual report from the Committee listing the conditions the Committee reviewed, the Committee's recommendations, the Department's decisions, and the status of implementation in the State Laboratory shall be submitted to the General Assembly and the Governor's office no later than December 31, 2027 and each year thereafter. Any recommendation not to add a condition shall include information from the Committee as to (i) why the decision was made, (ii) what gaps of information need to be met for reconsideration, and (iii) processes to initiate reconsideration. Any condition being reconsidered will follow the same timelines as described in this Section. The annual reports under this paragraph (3) shall be posted on the Department's publicly available website.

(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.)

Section 15. The Rare Disease Commission Act is amended by changing Section 15 as follows:

(410 ILCS 445/15)

(Section scheduled to be repealed on January 1, 2027)

Sec. 15. Study; recommendations. The Commission shall make recommendations to the General Assembly, in the form of an annual report through 2026, regarding:

(1) the use of prescription drugs and innovative therapies for children and adults with rare diseases, and specific subpopulations of children or adults with rare diseases, as appropriate, together with recommendations on the ways in which this information should be used in specific State programs that (A) provide assistance or health care coverage to individuals with rare diseases or broader populations that include individuals with rare diseases, or (B) have responsibilities associated with promoting the quality of care for individuals with rare

diseases or broader populations that include individuals with rare diseases;

(2) legislation that could improve the care and treatment of adults or children with rare diseases;

(3) in coordination with the Universal Newborn Screening Advisory Committee ~~Genetic and Metabolic Diseases Advisory Committee~~, the screening of newborn children for the presence of genetic disorders; and

(4) any other issues the Commission considers appropriate.

The Commission shall submit its annual report to the General Assembly no later than December 31 of each year.

(Source: P.A. 101-606, eff. 12-13-19; 102-671, eff. 11-30-21.)

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