

## 1 HOUSE BILL NO. 423

2 INTRODUCED BY D. LENZ

3  
 4 A BILL FOR AN ACT ENTITLED: "AN ACT GENERALLY REVISING LAWS RELATED TO SCREENING  
 5 NEWBORNS FOR GENETIC OR METABOLIC DISORDERS; CREATING A NEWBORN SCREENING  
 6 COMMITTEE; REQUIRING THE DEPARTMENT TO ADD NEW CONDITIONS TO THE NEWBORN  
 7 SCREENING PANEL WHEN CERTAIN CONDITIONS ARE MET; PROVIDING RULEMAKING AUTHORITY;  
 8 AND AMENDING SECTION 50-19-203, MCA."  
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10 WHEREAS, the Montana Legislature has become aware that there are newborn screening tests  
 11 available and treatments that can improve quality of life in conjunction with early diagnosis for certain lysosomal  
 12 storage disorders including MPS I, Pompe, Gaucher, Fabry, and Krabbe diseases; and

13 WHEREAS, it is the intent of the Montana Legislature that these disorders be added to the newborn  
 14 screening panel provided for each infant born in the State of Montana and that additional diseases be added to  
 15 the panel in response to technological advancements; and

16 WHEREAS, to ensure that MPS I, Pompe, Gaucher, Fabry, and Krabbe diseases are ~~added~~  
 17 CONSIDERED FOR ADDITION to the newborn screening panel and THAT other diseases are added as new testing  
 18 and treatment methods become available, the creation of an advisory committee and protocols for adding new  
 19 diseases to the newborn screening panel is necessary.  
 20

21 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:  
 22

23 NEW SECTION. Section 1. Newborn screening advisory committee -- membership -- duties. (1)  
 24 There is a newborn screening advisory committee. The committee consists of ~~six EIGHT~~ 12 members appointed  
 25 by the director of the department ~~as follows:~~

26 (2) (A) THE DIRECTOR SHALL APPOINT THE FOLLOWING VOTING MEMBERS:

27 (a)(i) ~~one member who is a person~~ TWO MEMBERS WHO ARE PERSONS affected by or a family member  
 28 FAMILY MEMBERS of a person affected by a disorder tested for pursuant to 50-19-203;

1           ~~(b)(II)~~ ~~one member who is a physician or nurse practitioner~~ TWO MEMBERS WHO ARE PHYSICIANS OR  
 2 NURSE PRACTITIONERS WHO ARE board-certified in obstetrics, pediatrics, FAMILY MEDICINE, or neonatology;

3           ~~(c)(III)~~ one member who is a representative of a birthing center;

4           ~~(d)(IV)~~ one member who is a representative of medicaid or the insurance industry;

5           ~~(e)(V)~~ one member who is a representative of an advocacy association regarding newborns with  
 6 medical conditions or rare disorders; ~~and~~

7           ~~(f)(VI)~~ one member ~~with~~ WHO IS A MEDICAL GENETICIST OR WHO HAS at least 5 years of experience  
 8 working in a testing laboratory; AND

9           (VII) ONE MEMBER WHO WORKS IN A TRIBAL HEALTH CARE SYSTEM.

10           (B) THE DIRECTOR SHALL APPOINT THE FOLLOWING DEPARTMENT EMPLOYEES AS NONVOTING MEMBERS:

11           (I) THE CHIEF MEDICAL DIRECTOR;

12           (II) A REPRESENTATIVE OF THE NEWBORN SCREENING PROGRAM; AND

13           (III) A REPRESENTATIVE OF THE LABORATORY SERVICES BUREAU.

14           ~~(2)(3)~~ (a) Except as provided in subsection ~~(2)(3)(b)~~, each ~~board~~ VOTING COMMITTEE member shall  
 15 serve a staggered 3-year term and is subject to reappointment for one succeeding term.

16           (b) The director shall appoint the first ~~six~~ EIGHT VOTING members to an initial term of 1, 2, ~~or 3, or 4~~ OR  
 17 3 years so that the terms of no more than ~~two~~ FOUR members expire in any given year.

18           ~~(3)(4)~~ The committee shall meet at least two times each year.

19           ~~(4)(5)~~ The committee shall report its findings to the director at least once a year, if applicable,  
 20 including providing recommendations that the department initiate rulemaking to add an additional metabolic or  
 21 genetic disorder to the newborn screening protocol. IN MAKING RECOMMENDATIONS TO THE DEPARTMENT, THE  
 22 COMMITTEE SHALL USE FEDERALLY RECOGNIZED NATIONAL STANDARDS FOR NEWBORN SCREENING, INCLUDING THE  
 23 RECOMMENDED UNIFORM SCREENING PANEL DEVELOPED BY THE HEALTH RESOURCES AND SERVICES ADMINISTRATION  
 24 OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES.

25           ~~(5)(6)~~ Members of the committee are not entitled to compensation for their services, but they are  
 26 entitled to a mileage allowance, as provided in 2-18-503, and travel and meal expenses, as provided in 2-18-  
 27 501 and 2-18-502.

28           ~~(6)(7)~~ The ~~board~~ COMMITTEE shall gather information on recent developments in testing technology,

1 investigate staff and equipment requirements of new tests, and perform other activities related to newborn  
 2 screening. The ~~board~~ COMMITTEE may make recommendations to the director regarding conditions that should  
 3 be added to the newborn screening panel.

4 ~~(7)(8)~~ The ~~board~~ COMMITTEE is attached to the department of public health and human services for  
 5 administrative purposes, and the department shall provide staff support to the ~~board~~ COMMITTEE.

6 ~~(8)(9)~~ THE COMMITTEE SHALL GIVE PRIORITY AT ITS FIRST MEETING TO REVIEWING KRABBE DISEASE AND  
 7 SHALL RECOMMEND THAT THE DISEASE BE ADDED TO THE NEWBORN SCREENING PANEL. IF THE COMMITTEE FAILS TO  
 8 MAKE THE RECOMMENDATION, THE DIRECTOR SHALL DISBAND THE COMMITTEE.

9

10 **Section 2.** Section 50-19-203, MCA, is amended to read:

11 **"50-19-203. Newborn screening and followup for metabolic and genetic disorders.** (1) A person  
 12 in charge of a facility in which a child is born or a facility in which a newborn is provided care or a person  
 13 responsible for the registration of the birth of a newborn shall ensure that each newborn is administered tests  
 14 designed to detect inborn metabolic and genetic disorders as required under rules adopted by the department.  
 15 The department shall initiate rulemaking to add testing for a new metabolic or genetic disorder to the newborn  
 16 screening panel on occurrence of the following:

17 (a) a reliable test or series of tests for screening newborns for a genetic or metabolic condition using  
 18 dried blood spots or other testing is developed and registered with the United States food and drug  
 19 administration;

20 (b) quality assurance testing methodology is available and approved by the United States centers for  
 21 disease control and prevention;

22 (c) necessary materials for the testing and quality assurance testing are commercially available; and

23 (d) the newborn screening advisory committee has recommended that the test be added to the  
 24 newborn screening protocol.

25 (2) The tests must be done by an approved laboratory. An approved laboratory must be the laboratory  
 26 of the department or a laboratory approved by the department.

27 (3) The department shall contract with one or more providers qualified to provide followup services,  
 28 including counseling and education, for children and parents of children identified with metabolic or genetic

1 disorders to ensure the availability of followup services."

2

3 NEW SECTION. Section 3. Codification instruction. [Section 1] is intended to be codified as an  
4 integral part of Title 50, chapter 19, part 2, and the provisions of Title 50, chapter 19, part 2, apply to [section 1].

5 - END -