HOUSE BILL NO. 423

INTRODUCED BY D. LENZ

A BILL FOR AN ACT ENTITLED: “AN ACT GENERALLY REVISING LAWS RELATED TO SCREENING NEWBORNS FOR GENETIC OR METABOLIC DISORDERS; CREATING A NEWBORN SCREENING COMMITTEE; REQUIRING THE DEPARTMENT TO ADD NEW CONDITIONS TO THE NEWBORN SCREENING PANEL WHEN CERTAIN CONDITIONS ARE MET; PROVIDING RULEMAKING AUTHORITY; AND AMENDING SECTION 50-19-203, MCA.”

WHEREAS, the Montana Legislature has become aware that there are newborn screening tests available and treatments that can improve quality of life in conjunction with early diagnosis for certain lysosomal storage disorders including MPS I, Pompe, Gaucher, Fabry, and Krabbe diseases; and

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

WHEREAS, to ensure that MPS I, Pompe, Gaucher, Fabry, and Krabbe diseases are added to the newborn screening panel and other diseases are added as new testing and treatment methods become available, the creation of an advisory committee and protocols for adding new diseases to the newborn screening panel is necessary.

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

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

(a) one member who is a person affected by or a family member of a person affected by a disorder tested for pursuant to 50-19-203;

(b) one member who is a physician or nurse practitioner board-certified in obstetrics, pediatrics, or

neonatology;

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

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

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

(f) one member with at least 5 years of experience working in a testing laboratory.

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

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

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

(4) The committee shall report its findings to the director at least once a year, if applicable, including providing recommendations that the department initiate rulemaking to add an additional metabolic or genetic disorder to the newborn screening protocol.

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

(6) The board shall gather information on recent developments in testing technology, investigate staff and equipment requirements of new tests, and perform other activities related to newborn screening. The board may make recommendations to the director regarding conditions that should be added to the newborn screening panel.

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

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

"**50-19-203. Newborn screening and followup for metabolic and genetic disorders.** (1) A person in charge of a facility in which a child is born or a facility in which a newborn is provided care or a person responsible for the registration of the birth of a newborn shall ensure that each newborn is administered tests

designed to detect inborn metabolic and genetic disorders as required under rules adopted by the department. The department shall initiate rulemaking to add testing for a new metabolic or genetic disorder to the newborn screening panel on occurrence of the following:

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

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

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

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

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

(3) The department shall contract with one or more providers qualified to provide followup services, including counseling and education, for children and parents of children identified with metabolic or genetic disorders to ensure the availability of followup services."

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

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