AN ACT REVISING LAWS RELATED TO THE COLLECTION OF GENETIC MATERIAL FOR NEWBORN SCREENINGS; LIMITING THE USE OF GENETIC MATERIAL; ALLOWING PARENTS AND GUARDIANS TO REQUEST DESTRUCTION OF SAMPLES COLLECTED FOR TESTING; AMENDING SECTION 50-19-203, MCA; AND PROVIDING AN EFFECTIVE DATE.

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

Section 1. Genetic material related to newborn screening -- limitations -- retention. (1) Genetic material obtained to conduct the newborn screenings required under this part may not be used for any purposes other than the required screenings unless a parent or guardian consents in writing to use of the material for other purposes.

(2) A parent or guardian may request at any time that blood or other samples obtained for the screenings be destroyed:

(a) at any time after the initial test is completed, if the test results are within a normal range; or

(b) no sooner than 30 days after a test is completed, if the test results are outside of a normal range.

(3) The facility in which a child is born or newborn care is provided or the person responsible for registration of the birth of a newborn shall inform parents or guardians in writing of their rights under this section at or before the time of collection of any samples for newborn screenings. The notification must include information on how to submit a request for destruction of the samples.

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) (a) 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.

(b) A laboratory shall destroy any genetic materials submitted for a newborn if requested by a parent or guardian as provided in [section 1].

(c) A facility that collected samples for tests required under this section shall destroy any excess genetic material that was collected and was not sent to an approved laboratory for testing.

(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."

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].

Section 4. Effective date. [This act] is effective July 1, 2023.

- END -

I hereby certify that the within bill,

HB 682, originated in the House.

_____

Chief Clerk of the House

_____

Speaker of the House

Signed this _____day

of_____, 2023.

_____

President of the Senate

Signed this _____day

of_____, 2023.

HOUSE BILL NO. 682

INTRODUCED BY K. ZOLNIKOV, J. SCHILLINGER, J. CARLSON

AN ACT REVISING LAWS RELATED TO THE COLLECTION OF GENETIC MATERIAL FOR NEWBORN SCREENINGS; LIMITING THE USE OF GENETIC MATERIAL; ALLOWING PARENTS AND GUARDIANS TO REQUEST DESTRUCTION OF SAMPLES COLLECTED FOR TESTING; AMENDING SECTION 50-19-203, MCA; AND PROVIDING AN EFFECTIVE DATE.