

HOUSE RESEARCH

Bill Summary

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Overview

This bill provides that the samples and data collected under MDH's newborn screening program is not subject to the general genetic information provision of the Data Practices Act, and establishes new requirements for informing parents about the screening process and options related to the collection and use of their infants' genetic data.

Section

- 1** **Collection, storage, use and dissemination of genetic information.** Amends § 13.386, subd. 3. Provides that the Minnesota Department of Health's (MDH) use of genetic information and blood specimens for testing infants for heritable and congenital disorders is governed by the provisions of the newborn screening program.

Provides an immediate effective date.
- 2** **Information provided to parents.** Amends § 144.125, subd. 3. Modifies the requirements for providing information to parents and parents' rights to object to testing and storage of an infant's information and samples.
 - (a) Requires persons with the duty to perform testing under the newborn screening program to provide a document with certain information to parents prior to testing, including, but not limited to, the following:
 - blood samples will be used to test for heritable and congenital disorders, the samples will be retained by MDH for 2 years and the samples may be used for operation of the newborn screening program;
 - alternatives available to parents and the availability of a form to exercise those alternatives;
 - benefits and consequences of testing, refusing to test, and of retaining samples or

choosing to destroy the samples;

- how the samples and data collected will be stored and used by MDH;
- MDH's website where certain related forms can be obtained;

Provides that this document satisfies the requirements of a Tennessee warning.

- (b) Requires the person with the duty to perform testing under the newborn screening program to record that the parents have received the required information and have had the opportunity to ask questions.
- (c) Gives parents and legal guardians of an infant to object to testing, to the storage of the infant's blood sample, to the storage of the infant's test results for more than 24 months, and to the use of the infant's blood sample or test results for newborn screening program operations. Specifies the procedure that must be followed if a parent or guardian objects to any of the stated options.

Provides an immediate effective date.

3 Storage and use of samples for newborn screening program operations. Amends § 144.125 by adding subd. 4.

- (a) Permits MDH to store and use blood samples for up to 24 months for operations of the program.
- (b) Permits MDH to use and store samples for individual health-related studies, or for another purpose, with written informed consent.

Provides an immediate effective date.

4 Newborn screening program operations. Amends § 145.125, by adding subd. 5. Defines "newborn screening program operations."

Provides an immediate effective date.

5 Development of new screening tests. Amends § 144.125, by adding subd. 6. Requires MDH to remove identifying information from samples when using samples to develop new screening tests. Permits use of serial numbers to relink a sample to an infant in the event of the discovery of a serious issue that needs to be communicated to an infant's parents. Requires that such a relinkage may only be done after consultation with an ethics committee and an institutional review board.

Provides an immediate effective date.

6 Destruction of samples within 25 months. Amends § 144.125 by adding subd. 7.

- (a) Requires MDH to destroy all newborn screening samples within 25 months of the infant's birth, unless a parent or guardian has given written, informed consent.
- (b) Requires MDH to implement this subdivision by July 1, 2010.

Provides an immediate effective date.

- 7 Records retention requirements.** Amends § 144.125 by adding subd. 8. Requires MDH to retain test results in compliance with Minnesota Statutes, section 138.17 (which governs destruction, preservation, and reproduction of records by the government).

Provides an immediate effective date.

- 8 Destruction of existing samples.** Requires MDH to destroy all samples retained by the department as of June 1, 2009, within 25 months of that date, unless a parent or guardian gives written informed consent.

- 9 Newborn screening report.** Requires MDH to report and make recommendations to the legislature, by January 15, 2010, as to current efforts for ensuring and enhancing methods for informing parents about newborn screening and their rights and options under the program.

Provides an immediate effective date.