

A bill for an act

relating to health; changing provisions in the newborn screening program;
amending Minnesota Statutes 2008, sections 13.386, subdivision 3; 144.125,
subdivision 3, by adding subdivisions.

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

Section 1. Minnesota Statutes 2008, section 13.386, subdivision 3, is amended to read:

Subd. 3. **Collection, storage, use, and dissemination of genetic information.** (a)

Unless otherwise expressly provided by law, genetic information about an individual:

(1) may be collected by a government entity, as defined in section 13.02, subdivision
7a, or any other person only with the written informed consent of the individual;

(2) may be used only for purposes to which the individual has given written
informed consent;

(3) may be stored only for a period of time to which the individual has given written
informed consent; and

(4) may be disseminated only:

(i) with the individual's written informed consent; or

(ii) if necessary in order to accomplish purposes described by clause (2). A consent
to disseminate genetic information under item (i) must be signed and dated. Unless
otherwise provided by law, such a consent is valid for one year or for a lesser period
specified in the consent.

(b) Notwithstanding paragraph (a), the Department of Health's collection, storage,
use, and dissemination of genetic information and blood specimens for testing infants for
heritable and congenital disorders are governed by sections 144.125 to 144.128.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 2. Minnesota Statutes 2008, section 144.125, subdivision 3, is amended to read:

Subd. 3. ~~Objection of parents to test~~ Information provided to parents. ~~Persons with a duty to perform testing under subdivision 1 shall advise parents of infants (1) that the blood or tissue samples used to perform testing thereunder as well as the results of such testing may be retained by the Department of Health, (2) the benefit of retaining the blood or tissue sample, and (3) that the following options are available to them with respect to the testing: (i) to decline to have the tests, or (ii) to elect to have the tests but to require that all blood samples and records of test results be destroyed within 24 months of the testing. If the parents of an infant object in writing to testing for heritable and congenital disorders or elect to require that blood samples and test results be destroyed, the objection or election shall be recorded on a form that is signed by a parent or legal guardian and made part of the infant's medical record. A written objection exempts an infant from the requirements of this section and section 144.128. (a) Prior to collecting a sample, persons with a duty to perform testing under subdivision 1 must provide parents or legal guardians of infants with a document that provides the following information:~~

(1) the blood sample will be used to test for heritable and congenital disorders, the blood sample will be retained by the Department of Health for a period of two years, and that blood sample may be used for newborn screening program operations;

(2) the data that will be collected as a result of the testing;

(3) the alternatives available to the parents or legal guardians in paragraph (c) and that a form to exercise the alternatives is available to the parent or legal guardian from the person with a duty to perform testing under subdivision 1;

(4) the benefits of testing and the consequences of a decision to permit or refuse to supply a sample;

(5) the benefits of retaining the blood sample and the consequences of a decision to destroy the blood sample or to permit or decline to have the blood sample used for newborn screening program operations;

(6) the ways in which the samples and data collected will be stored and used at the Department of Health and elsewhere; and

(7) the Department of Health's Web site address where the forms in paragraph (c) may be obtained.

This document satisfies the requirements of section 13.04, subdivision 2.

(b) The person with a duty to perform testing must record that parents or legal guardians of infants have received the information provided under this subdivision and have had an opportunity to ask questions.

(c) The parent or legal guardian of an infant otherwise subject to testing under this section may object to any of the following:

- (1) the testing itself;
- (2) the storage of the infant's blood samples;
- (3) the storage of the infant's test results for a period longer than 24 months; and
- (4) the use of the infant's blood samples and test results for newborn screening program operations.

If a parent or legal guardian elects to object to one or more of the alternatives in this paragraph, the election shall be recorded on a form that is signed by the parent or legal guardian. The signed form shall be made part of the infant's medical record and shall be provided to the Department of Health. The signature of the parent or legal guardian is sufficient and no witness to the signature, photo identification, or notarization shall be required. When a parent or legal guardian elects an alternative under this subdivision, the Department of Health must follow the election and section 144.128, to the extent that section 144.128 pertains to the elected alternative. If the parent or legal guardian objects to the testing itself, section 144.128 does not apply.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 3. Minnesota Statutes 2008, section 144.125, is amended by adding a subdivision to read:

Subd. 4. Storage and use of samples for newborn screening program operations.

(a) The department may store and use the newborn screening program blood samples for up to 24 months for newborn screening program operations and may store samples for an additional month to carry out the destruction of samples required under subdivision 7.

(b) Notwithstanding paragraph (a), the department may use and store the newborn screening samples for individual health-related studies or any other purpose with a written informed consent of the parent or legal guardian.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 4. Minnesota Statutes 2008, section 144.125, is amended by adding a subdivision to read:

Subd. 5. Newborn screening program operations. "Newborn screening program operations" means actions, testing, and procedures directly related to the improvement, implementation, and development of the newborn screening program, such as the testing of the samples, confirmatory testing, laboratory quality control, calibration of equipment,

evaluating and improving the accuracy of newborn screening tests, implementation and validation of equipment and technology, and studies or research related to the development of new newborn screening tests.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 5. Minnesota Statutes 2008, section 144.125, is amended by adding a subdivision to read:

Subd. 6. Development of new screening tests. When samples are used for program operations to develop new newborn screening tests, the department must remove information that directly links infants to samples, but may use serial numbers that would allow a relinkage in case a serious issue is discovered that needs to be communicated to the parent or guardian of an infant. Such a relinkage may only be done after consultation with an ethics committee or an institutional review board.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 6. Minnesota Statutes 2008, section 144.125, is amended by adding a subdivision to read:

Subd. 7. Destruction of samples within 25 months. (a) Unless a parent or legal guardian has given written informed consent, the department must destroy all newborn screening blood samples within 25 months of the month of birth.

(b) The department must implement this subdivision by July 1, 2010.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 7. Minnesota Statutes 2008, section 144.125, is amended by adding a subdivision to read:

Subd. 8. Records retention requirements. The department shall retain test results in compliance with section 138.17.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 8. Minnesota Statutes 2008, section 144.125, is amended by adding a subdivision to read:

Subd. 9. Destruction of existing samples. Unless a parent or legal guardian has given written informed consent, the department must destroy all newborn screening blood samples retained by the department as of June 1, 2009, within 25 months of that date.

5.1 **EFFECTIVE DATE.** This section is effective the day following final enactment.

5.2 Sec. 9. **NEWBORN SCREENING REPORT.**

5.3 By January 15, 2010, the Department of Health shall report and make
5.4 recommendations to the legislature on its current efforts for ensuring and enhancing how
5.5 parents or legal guardians of newborns are fully informed about the newborn screening
5.6 program and of their rights and options regarding: (1) testing; (2) storage; (3) public
5.7 health practices, studies, and research; (4) the ability to opt out of the collection of data
5.8 and specimens related to the testing; and (5) the ability to seek private testing.

5.9 **EFFECTIVE DATE.** This section is effective the day following final enactment.