

SENATE
STATE OF MINNESOTA
EIGHTY-SEVENTH LEGISLATURE

S.F. No. 2463

(SENATE AUTHORS: HANN, by request and Sheran)

DATE	D-PG	OFFICIAL STATUS
03/14/2012	4415	Introduction and first reading Referred to Health and Human Services
03/19/2012	4554	Author added Sheran

A bill for an act
relating to health; changing provisions of the newborn screening program;
amending Minnesota Statutes 2010, sections 144.125, subdivision 3, by adding
subdivisions; 144.128.

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

Section 1. Minnesota Statutes 2010, 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) The department shall make information and forms available to health care providers who provide prenatal care describing the newborn screening program and the provisions of this section to be used in a discussion with expectant parents. The department shall make information and forms about newborn screening available to expectant parents and parents of newborns using electronic and other means.

(b) Prior to collecting a sample, persons with a duty to perform testing under subdivision 1 must:

(1) provide parents or legal guardians of infants with a document meeting the requirements of section 13.04, subdivision 2, that provides the following information:

(i) the benefits of testing and the risks of a decision to refuse to supply a blood sample;

(ii) that the blood sample will be used to test for certain heritable and congenital disorders;

(iii) the data that will be collected as part of the testing;

(iv) that the blood sample will be stored for 71 days from the date of sample receipt in order to assure completion of the newborn screening process and the test results will be stored for 24 months from the date of reporting as required by federal law and regulations unless otherwise authorized;

(v) that the blood sample and data for a positive test result will be stored by the Department of Health;

(vi) the use of blood samples and test results for quality assurance and improvement during the standard retention period;

(vii) the benefits for longer storage of blood samples and test results; and

(viii) the Department of Health's Web site address where more information and forms may be obtained;

(2) provide parents or legal guardians of infants with forms to request one or more of the following:

(i) that the infant not have blood collected for testing; and

(ii) that the infant's blood sample and test results be retained by the Department of Health after the standard retention period; and

(3) record in the infant's medical record that a parent or legal guardian of the infant has received the information and the forms required under this subdivision and has had an opportunity to ask questions.

Sec. 2. Minnesota Statutes 2010, section 144.125, is amended by adding a subdivision to read:

Subd. 4. **Parental options.** (a) The parent or legal guardian of an infant otherwise subject to testing under this section may:

(1) choose not to have blood collected for testing; and

(2) authorize the infant's blood sample and test results be retained by the Department of Health after the standard retention period.

(b) If a parent or legal guardian elects an alternative in this subdivision, 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 a copy shall be provided to the Department of Health. When a parent or legal guardian elects an alternative under this subdivision, the Department of Health must follow the election and section 144.128. A written election to decline testing exempts an infant from the requirements of this section and section 144.128.

Sec. 3. Minnesota Statutes 2010, section 144.125, is amended by adding a subdivision to read:

Subd. 5. Newborn screening program operations. (a) "Newborn screening quality assurance and improvement operations" means actions, testing, and procedures directly related to the operation of the newborn screening program, such as:

- (1) confirmatory testing;
- (2) laboratory quality control assurance and improvement;
- (3) calibration of equipment;
- (4) evaluating and improving the accuracy of newborn screening tests for conditions approved for screening in Minnesota;
- (5) validation of equipment and screening methods; and
- (6) continuity of operations to ensure testing can continue in the event of an emergency.

(b) Newborn screening quality assurance and improvement does not include research or the development of new newborn screening tests.

Sec. 4. Minnesota Statutes 2010, section 144.125, is amended by adding a subdivision to read:

Subd. 6. Storage and use of samples and test results for newborn screening quality assurance and improvement. During the standard retention period, the Department of Health may use blood samples and test results for newborn screening quality assurance and improvement. When authorized in writing by a parent or legal guardian under subdivision 4, the department may store blood samples and test results for the time period authorized by the parent or legal guardian. Blood samples and positive test results of infants shall be stored by the Department of Health.

Sec. 5. Minnesota Statutes 2010, section 144.125, is amended by adding a subdivision to read:

Subd. 7. **Standard retention period for samples and test results.** Blood samples without authorization for further storage shall be destroyed within a week of 71 days of the date of sample receipt. Test results without authorization for further storage shall be destroyed within one month of 24 months of the date of reporting.

Sec. 6. Minnesota Statutes 2010, section 144.125, is amended by adding a subdivision to read:

Subd. 8. **Written informed consent for other use of samples and test results.** With written informed consent of the parent or legal guardian, the Department of Health may:

(1) use newborn screening samples and test results for newborn screening related studies including studies used to develop new newborn screening tests;

(2) use newborn screening samples and test results for non-newborn screening public health studies or research;

(3) share the samples and test results with external parties for public health studies or research following approval by the Department of Health's institutional review board; and

(4) allow a parent or legal guardian to authorize ongoing consent for studies and research or authorize consent for a single study.

Sec. 7. Minnesota Statutes 2010, section 144.125, is amended by adding a subdivision to read:

Subd. 9. **Revoking consent for storage and use.** A parent or legal guardian or an adult who was tested as a minor may revoke approval for storage and use for newborn screening quality assurance and improvement or for other uses of samples and test results at any time by providing a signed and dated request for destruction form. The Department of Health shall make the form available on the department's Web site. Blood samples shall be destroyed within one week of receipt of the request or after 71 days from the date of sample receipt, whichever is later. Test results will be destroyed within one month of receipt of the request or after 24 months from the date of reporting, whichever is later.

Sec. 8. Minnesota Statutes 2010, section 144.128, is amended to read:

144.128 COMMISSIONER'S DUTIES.

The commissioner shall:

(1) collect, use, disseminate, and store blood samples and test results in order to administer the newborn screening program for heritable and congenital disorders as described in sections 144.125 to 144.128;

- 5.1 ~~(1)~~ (2) notify the physicians of newborns tested of the results of the tests performed;
- 5.2 ~~(2)~~ (3) make referrals for the necessary treatment of diagnosed cases of heritable and
- 5.3 congenital disorders when treatment is indicated;
- 5.4 ~~(3)~~ (4) maintain a registry of the cases of heritable and congenital disorders detected
- 5.5 by the screening program for the purpose of follow-up services;
- 5.6 ~~(4)~~ (5) prepare a separate form for use by parents or by adults who were tested as
- 5.7 minors to direct that blood samples ~~and~~ or test results be destroyed;
- 5.8 ~~(5)~~ (6) comply with a destruction request ~~within 45 days after receiving it~~ as
- 5.9 described in section 144.125;
- 5.10 ~~(6)~~ (7) notify individuals who request destruction of samples and test results that the
- 5.11 samples and test results have been destroyed; and
- 5.12 ~~(7)~~ (8) adopt rules to carry out sections 144.125 to 144.128.

5.13 Sec. 9. **EFFECTIVE DATE.**

5.14 This act is effective the day following final enactment and applies to blood samples

5.15 and test results collected on or after that date.