

House Research Act Summary

CHAPTER: 203

SESSION: 2014 Regular Session

TOPIC: Newborn Screening

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Overview

This act modifies requirements related to the testing done on newborns and storage of the blood samples and tests results. The act adds, among other things, the ability of the parent or legal guardian to elect to have the newborn screening performed but not to have blood samples or test results stored. This act also repeals the retention limit for blood samples and test results

Section

1 Information provided to parents and legal guardians. Amends § 144.125, subdivision 3.

(a) Adds to the requirement that requires the commissioner make information regarding newborn screening be available to childbirth education programs, in addition to health care providers who provide prenatal care as already required by this section. Requires the department to promote the materials and encourage providers and educations programs to thoroughly discuss the program with parents.

(b)(1) Adds requirements for information that must be given to parents or legal guardians prior to testing being performed, including:

- ▶ benefits associated with storage of blood samples and test results;
- ▶ that blood samples and test results will be used in accordance with program operations unless the parent or legal guardian elects not to have the samples and results stored;
- ▶ the department may store blood samples unless the parent or legal guardian elects not to have the samples stored
- ▶ legal guardians, in addition to parents already recognized under the section, have

Section

the right to elect no newborn screening be performed;

- ▶ parents and legal guardians have the right to request newborn screening be performed but not have blood samples or test results stored; and
- ▶ parents or legal guardians may consent, in writing, to have blood samples and test results used for public health studies or research

(b)(2) Adds requirement that, upon request, parents or legal guardians be promptly provided with forms to request to have the newborn screening performed but not to have the blood samples and test results stored.

- 2 Parental options.** Amends § 144.125, subdivision 4. Adds that parents or legal guardians may elect to have the newborn screening performed but not to have the blood samples and test results stored. Adds this election by parents and legal guardians to existing procedures relating to obtaining a signed form and storage of that form.
- 3 Newborn screening program operations.** Amends § 144.125, subdivision 5. Adds clauses 7 and 8 to paragraph (a), which add follow-up services for the cases of heritable and congenital disorders identified by newborn screening and utilization of blood samples and test results for studies related to newborn screening to the definition of newborn screening operations (this provision partially reinstates language that was stricken from section 144.125, subd. 9). Modifies paragraph (b) to preclude any research or studies other than those listed in paragraph (a) without written consent. Adds paragraph (c) which strictly prohibits any sale of bloodspots, test results, or other data collected in the newborn screening program.
- 4 Parental options for additional research.** Amends § 144.125, subdivision 7.
- (a) Clarifies that the authorization given by parents or legal guardians to have blood samples and test results researched for public health purposes must be in writing and allows an individual who was tested as an infant if the individual is 18 years of age or older to submit the authorization.
- (b) Removes items from the list of mandatory inclusions on the parental or legal guardian consent form allowing retention and use of blood samples and test results, including removal of:
- ▶ information as to the personal identification and use of samples and test results for studies;
 - ▶ information that explains that the health department will not store blood samples or test results for longer than 18 years from an infant's birth day; and
 - ▶ the benefits and risks associated with storage of blood samples and test results.

Section

- 5** **Storage and use of samples and test results.** Amends § 144.125, subdivision 8. Allows the health department to store blood samples and test rules and use the samples and results in accordance with subdivision 5. Allows the department to use the results in accordance with subdivision 9 (use of samples and tests for public health studies) if written informed consent is obtained from a parent, legal guardian, or individual. Adds that if the parent or legal guardian elected against storage, the blood samples must be destroyed within 30 days of receipt of the request, and test results must be destroyed within 30 days of receipt of the request or at the earliest time allowed under Clinical Laboratory Improvement Amendments regulations, whichever is later. Allows blood samples and test results to be used for certain purposes until destroyed.
- 6** **Written, informed consent for other use of samples and test results.** Amends § 144.125, subdivision 9. Removes the requirement of written consent for the department to store blood samples and test results and use those samples and tests for newborn screening related purposes (this language, absent the requirement for written consent, is moved to section 144.125, subd. 5). Written consent is still required for research related to public health studies or not related to newborn screening.
- 7** **Revoking consent for storage and use.** Amends § 144.125, subdivision 10. Adds individuals 18 years of age or older whose blood was tested to the lists of persons who may revoke approval for storage or use of blood samples or test results. Removes reference to § 144.125, subdivision 6, which is repealed under this act, and cites subdivision 8 for specifications on destruction of blood samples and test results.
- 8** **Repealer.** Repeals § 144.125, subdivision 6, which is related to the standard retention period for samples and test results.
- 9** **Effective date.** States sections 1 to 8 are effective August 1, 2014, and apply to blood samples collected on or after that date, and to the test results obtained from those samples.