## Minnesota

### Newborn Genetic Testing & Surveillance System

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<td>MN</td>
<td>STATUTE: M.S. 144.125 – 144.128</td>
<td>144.125 TESTS OF INFANTS FOR HERITABLE AND CONGENITAL DISORDERS. Subdivision 1. Duty to perform testing. It is the duty of (1) the administrative officer or other person in charge of each institution caring for infants 28 days or less of age, (2) the person required in pursuance of the provisions of section 144.215, to register the birth of a child, or</td>
<td>144.125. Subd. 3. Information provided to parents. (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</td>
<td>M.S. 144.125. Subd. 5. Newborn screening program operations…(b) No research, public health studies, or development of new newborn screening tests shall be conducted under this subdivision.</td>
<td>YES</td>
<td>YES</td>
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Updated August 2012. All state statutes and department rules originally accessed online July/Aug 2008. Statute/Rule data not inclusive. For comprehensive or updated language, access complete statute and rules online, at local library or through the state legislature.
(3) the nurse midwife or midwife in attendance at the birth, to arrange to have administered to every infant or child in its care tests for heritable and congenital disorders according to subdivision 2 and rules prescribed by the state commissioner of health. Testing and the recording and reporting of test results shall be performed at the times and in the manner prescribed by the commissioner of health. The commissioner shall charge a fee so that the total of fees collected will approximate the costs of conducting the tests and implementing and maintaining a system to follow-up infants with heritable or congenital disorders…

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 that provides the following information:

(i) the benefits of newborn screening;

Subd. 6. Standard retention period for samples and test results. The standard retention period for blood samples with a negative test result is up to 71 days from the date of receipt of the sample. The standard retention period for blood samples with a positive test result is up to 24 months from the last date of reporting…During the standard retention period, the Department of Health may use blood samples and test results for newborn screening program operations in accordance with subdivision 5.
### 144.128 COMMISSIONER'S DUTIES.
The commissioner shall:…

- (3) maintain a registry of the cases of heritable and congenital disorders detected by the screening program for the purpose of follow-up services;
- (4) prepare a separate form for use by parents or by adults who were tested as minors to direct that blood samples and test results be destroyed;
- (5) comply with a destruction request as described in section 144.125;
- (6) notify individuals who request destruction of samples and test results that the samples and test results have been destroyed and the date of destruction; and ..

(ii) that the blood sample will be used to test for heritable and congenital disorders, as determined under subdivision 2;
(iii) the data that will be collected as part of the testing;
(iv) the standard retention periods for blood samples and test results as provided in subdivision 6;

### Subd. 7. Parental options for extended storage and use. (a)
The parent or legal guardian of an infant otherwise subject to testing under this section may authorize that the infant's blood sample and test results be retained and used by the Department of Health beyond the standard retention periods provided in subdivision 6 or the purposes described in subdivision 9.

- (b) The Department of Health must provide a consent form, with an attached Tennessen warning pursuant to section 13.04, subdivision 2. The consent form must provide the following: (1) information as to the personal identification and use of samples and test results for studies, including studies used to develop new tests; (2) information as to the personal identification and use of samples and test results for public health studies or research not related to newborn screening;
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<td>(b) Nothing in section 144.125 to 144.128 shall exempt the commissioner from the requirement of the genetic privacy act in section 13.386 or from the penalties for violation of the geneti privacy act as provided in chapter 13.</td>
<td>(v) that blood samples and test results will be used for program operations during the standard retention period in accordance with subdivision 5;</td>
<td>(3) information that explains that the Department of Health will not store a blood sample or test result for longer than 18 years from an infant's birth date;</td>
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<td>4615.0750 PURPOSE AND SCOPE. The purpose and scope of parts 4615.0750 to 4615.0760 is to describe the responsibilities of the Minnesota Department of Health to assure that persons diagnosed as having hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia will:</td>
<td>(vi) the Department of Health’s Web site address where more information and forms may be obtained; and</td>
<td>(4) information that explains that, upon approval by the Department of Health's Institutional Review Board, blood samples and test results may be shared with external parties for public health studies or research;</td>
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<td>(vii) that parents have a right to elect not to have newborn screening performed and a right to secure private testing;</td>
<td>(5) information that explains that blood samples contain various components, including deoxyribonucleic acid (DNA); and</td>
<td>(6) the benefits and risks associated with the department's storage of a child's blood sample and test results.</td>
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(1) Have access to approved laboratory treatment control tests when available;  
(2) Have necessary financial assistance for treatment of diagnosed cases when indicated; and  
(3) Be included in a registry of cases for the purpose of coordinating follow-up services.

| Subd. 8. Extended storage and use of samples and test results.  
When authorized in writing by a parent or legal guardian under subdivision 7, the Department of Health may store blood samples and test results for a time period not to exceed 18 years from the infant's birth date, and may use the blood samples and test results in accordance with subdivision 9. |
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| Subd. 9. Written informed consent for other use of samples and test results.  
With the written, informed consent of a parent or legal guardian, the Department of Health may:  
(1) Use blood samples and test results for studies related to newborn screening, including studies used to develop new tests; and |
|---|
4615.0755 DEFINITIONS. Subp. 8. Registry.
"Registry" means a permanent record maintained by the department on each patient diagnosed by a physician and reported to the department as having hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia.

(c) Nothing in this section prohibits a parent or legal guardian of an infant from having newborn screening performed by a private entity.

Subd. 4. Parental options.
(a) The parent or legal guardian of an infant otherwise subject to testing under this section may elect not to have newborn screening performed.

(2) Use blood samples and test results for public health studies or research not related to newborn screening, and upon approval by the Department of Health's Institutional Review Board, share samples and test results with external parties for public health studies or research.
4615.0760 RESPONSIBILITIES OF DEPARTMENT OF HEALTH. …

Subp. 4. Registry of cases. The department shall maintain a registry of all diagnosed cases of hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and congenital adrenal hyperplasia reported to the department. The registry shall be updated not more often than annually by direct contact with the patient to determine their address and their need for medical treatment services, educational materials, and counseling related to their metabolic disease. The registry shall include the following minimum data on each patient:

(b) If a parent or legal guardian elects not to have newborn screening performed, then the election shall be recorded on a form that is signed by the parent or legal guardian…A written election to decline testing exempts persons with a duty to perform testing and the Department of Health from the requirements of this section and section 144.128.

Subd. 10. Revoking consent for storage and use. A parent or legal guardian may revoke approval for extended storage or use of blood samples or test results at any time by providing a signed and dated form requesting destruction of the blood samples or test results. The Department of Health shall make necessary forms available on the department's Web site. Blood samples must be destroyed within one week of receipt of a request or within one week of the standard retention period for blood samples provided in subdivision 6, whichever is later. Test results must be destroyed within one month of receipt of a request or within one month of the standard retention period for test results provided in subdivision 6, whichever is later.
| A. name of patient; | **13.386 Subd. 3. Collection, storage, use, and dissemination of genetic information.** 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:

(1) with the individual's written informed consent... Consent to disseminate genetic information under item (i) must be signed and dated. |

| B. gender; | |
| C. date of birth; | |
| D. place of birth; | |
| E. parents' names; | |
| F. current address of patient; | |
| G. diagnosis; | |
| H. name and address of physician; and | |
| I. other data the commissioner deems necessary for follow-up services. | |