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 (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, including hearing loss detected through the early hearing detection and intervention program under section 144.966. The fee is $101 per specimen. Effective July 1, 2010, the fee shall be increased to $106 per specimen. The increased fee amount shall be deposited in the general fund. Costs associated with capital expenditures and the development of new procedures may be prorated over a three-year period when calculating the amount of the fees.

Subd. 2. **Determination of tests to be administered.** The commissioner shall periodically revise the list of tests to be administered for determining the presence of a heritable or congenital disorder. Revisions to the list shall reflect advances in medical science, new and improved testing methods, or other factors that will improve the public health. In determining whether a test must be administered, the commissioner shall take into consideration the adequacy of analytical methods to detect the heritable or congenital disorder, the ability to treat or prevent medical conditions caused by the heritable or congenital disorder, and the severity of the medical conditions caused by the heritable or congenital disorder. The list of tests to be performed may be revised if the changes are recommended by the advisory committee established under section 144.1255, approved by the commissioner, and published in the State Register. The revision is exempt from the rulemaking requirements in chapter 14, and sections 14.385 and 14.386do not apply.

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 and parents of newborns. The department shall make information and forms about newborn screening available to the persons with a duty to perform testing under this section and 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 that provides the following information:

(i) the benefits of newborn screening;

(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;

(v) that blood samples and test results will be used for program operations during the standard retention period in accordance with subdivision 5;

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

(vii) that parents have a right to elect not to have newborn screening performed and a right to secure private testing;

(2) upon request, provide parents or legal guardians of infants with forms necessary to request that the infant not have blood collected for testing; and

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

(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.

(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. 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 not to have newborn screening performed, the person with the duty to perform testing under subdivision 1 must follow that election. 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. 5. **Newborn screening program operations.** (a) "Newborn screening program operations" means actions, testing, and procedures directly related to the operation of the newborn screening program, limited to the following:

(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 as required by Minnesota law in the event of an emergency.

(b) No research, public health studies, or development of new newborn screening tests shall be conducted under this subdivision.

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 date of receipt of the sample. The standard retention period for all test results is up to 24 months from the last date of reporting. Blood samples with a negative test result will

be destroyed within one week of the 71-day retention period. Blood samples with a positive test result will be destroyed within one week of the 24-month retention period. All test results will be destroyed within one month of the 24-month retention period. 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.

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;

(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;

(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;

(5) information that explains that blood samples contain various components, including deoxyribonucleic acid (DNA); and

(6) the benefits and risks associated with the department's storage of a child's blood sample and test results.

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.

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

(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.

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.

History: *1965 c 205 s 1; 1977 c 305 s 45; 1Sp1981 c 4 art 1 s 75; 1985 c 248 s 70; 1986 c 444; 1988 c 689 art 2 s 31; 1994 c 636 art 2 s 2; 1997 c 203 art 2 s 11; 1997 c 205 s 19; 1Sp2003 c 14 art 7 s 26; 2007 c 147 art 16 s 7; 2009 c 79 art 10 s 5; 2012 c 292 art 4 s 3-10*