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State of Minnesota
HOUSE OF REPRESENTATIVES

EIGHTY-EIGHTH SESSION

H. F. No. **2526**

02/27/2014 Authored by Norton; Murphy, E.; Huntley and Liebling

The bill was read for the first time and referred to the Committee on Health and Human Services Policy

1.1 A bill for an act
1.2 relating to health; modifying the newborn screening program; amending
1.3 Minnesota Statutes 2012, section 144.125, subdivisions 3, 4, 5, 8, 9, 10;
1.4 Minnesota Statutes 2013 Supplement, section 144.125, subdivision 7; repealing
1.5 Minnesota Statutes 2012, section 144.125, subdivision 6.

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

1.7 Section 1. Minnesota Statutes 2012, section 144.125, subdivision 3, is amended to read:

1.8 Subd. 3. **Information provided to parents.** (a) The department shall make
1.9 information and forms available to childbirth education programs and health care
1.10 providers who provide prenatal care describing the newborn screening program and the
1.11 provisions of this section to be used in a discussion with expectant parents and parents of
1.12 newborns. The department shall make information and forms about newborn screening
1.13 available to the persons with a duty to perform testing under this section and to expectant
1.14 parents and parents of newborns using electronic and other means.

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

1.17 (1) provide parents or legal guardians of infants with a document that provides
1.18 the following information:

1.19 (i) the benefits of newborn screening;

1.20 (ii) that the blood sample will be used to test for heritable and congenital disorders,
1.21 as determined under subdivision 2;

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

1.23 (iv) ~~the standard retention periods for blood samples and test results as provided in~~
1.24 subdivision 6 the benefits associated with the department's storage of an infant's blood
1.25 sample and test results;

2.1 (v) that blood samples and test results will be used for program operations ~~during~~
 2.2 ~~the standard retention period~~ in accordance with subdivision 5, unless the parents or legal
 2.3 guardians elect not to have the blood samples and test results stored;

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

2.6 (vii) that parents or legal guardians have a right to elect not to have newborn
 2.7 screening performed and a right to secure private testing; and

2.8 (viii) that parents or legal guardians have a right to elect to have the newborn
 2.9 screening performed, but not to have the blood samples and test results stored;

2.10 (2) upon request, provide parents or legal guardians of infants with forms necessary
 2.11 to request that the infant not have blood collected for testing or to request to have the
 2.12 newborn screening performed, but not to have the blood samples and test results stored; and

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

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

2.18 Sec. 2. Minnesota Statutes 2012, section 144.125, subdivision 4, is amended to read:

2.19 Subd. 4. **Parental options.** (a) The parent or legal guardian of an infant otherwise
 2.20 subject to testing under this section may elect not to have newborn screening performed,
 2.21 or may elect to have newborn screening tests performed, but not to have the blood samples
 2.22 and test results stored.

2.23 (b) If a parent or legal guardian elects not to have newborn screening performed or
 2.24 elects not to allow the blood samples and test results to be stored, then the election ~~shall~~
 2.25 must be recorded on a form that is signed by the parent or legal guardian. The signed form
 2.26 ~~shall~~ must be made part of the infant's medical record and a copy shall be provided to
 2.27 the Department of Health. When a parent or legal guardian elects not to have newborn
 2.28 screening performed, the person with the duty to perform testing under subdivision 1 must
 2.29 follow that election. A written election to decline testing exempts persons with a duty
 2.30 to perform testing and the Department of Health from the requirements of this section
 2.31 and section 144.128.

2.32 Sec. 3. Minnesota Statutes 2012, section 144.125, subdivision 5, is amended to read:

3.1 Subd. 5. **Newborn screening program operations.** (a) "Newborn screening
3.2 program operations" means actions, testing, and procedures directly related to the
3.3 operation of the newborn screening program, limited to the following:

3.4 (1) confirmatory testing;

3.5 (2) laboratory quality control assurance and improvement;

3.6 (3) calibration of equipment;

3.7 (4) evaluating and improving the accuracy of newborn screening tests for conditions
3.8 approved for screening in Minnesota;

3.9 (5) validation of equipment and screening methods; ~~and~~

3.10 (6) continuity of operations to ensure testing can continue as required by Minnesota
3.11 law in the event of an emergency; and

3.12 (7) utilization of blood samples and test results for studies related to newborn
3.13 screening, including studies used to develop new tests.

3.14 (b) ~~No research, or public health studies, or development of new newborn screening~~
3.15 ~~tests shall be conducted under this subdivision~~ other than those described in paragraph (a)
3.16 shall be conducted without written consent as described under subdivision 9.

3.17 Sec. 4. Minnesota Statutes 2013 Supplement, section 144.125, subdivision 7, is
3.18 amended to read:

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

3.24 (b) The Department of Health must provide a consent form, with an attached
3.25 Tennessee warning pursuant to section 13.04, subdivision 2. The consent form must
3.26 provide the following:

3.27 ~~(1) information as to the personal identification and use of samples and test results~~
3.28 ~~for studies, including studies used to develop new tests;~~

3.29 ~~(2)~~ (1) information as to the personal identification and use of samples and test
3.30 results for public health studies or research not related to newborn screening;

3.31 ~~(3) information that explains that the Department of Health will not store a blood~~
3.32 ~~sample or test result for longer than 18 years from an infant's birth date;~~

3.33 ~~(4)~~ (2) information that explains that, upon approval by the Department of Health's
3.34 Institutional Review Board, blood samples and test results may be shared with external
3.35 parties for public health studies or research; and

4.1 ~~(5)~~ (3) information that explains that blood samples contain various components,
 4.2 including deoxyribonucleic acid (DNA); ~~and~~

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

4.5 Sec. 5. Minnesota Statutes 2012, section 144.125, subdivision 8, is amended to read:

4.6 Subd. 8. **Extended Storage and use of samples and test results.** ~~When authorized~~
 4.7 ~~in writing by a parent or legal guardian under subdivision 7,~~ The Department of Health
 4.8 may store blood samples and test results ~~for a time period not to exceed 18 years from~~
 4.9 ~~the infant's birth date,~~ and may use the blood samples and test results in accordance with
 4.10 subdivision 9 5, unless a parent or legal guardian elects against the storage of the blood
 4.11 samples and test results, and in accordance with subdivision 9, if written informed consent
 4.12 of a parent or legal guardian is obtained. If a parent or legal guardian has elected against
 4.13 storage, the blood samples must be destroyed within one week of receipt of the request,
 4.14 and test results must be destroyed within one month of receipt of the request.

4.15 Sec. 6. Minnesota Statutes 2012, section 144.125, subdivision 9, is amended to read:

4.16 Subd. 9. **Written, informed consent for other use of samples and test results.**

4.17 With the written, informed consent of a parent or legal guardian, the Department of Health
 4.18 may:

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

4.21 ~~(2) use blood samples and test results for public health studies or research not related~~
 4.22 ~~to newborn screening, and upon approval by the Department of Health's Institutional~~
 4.23 ~~Review Board, share samples and test results with external parties for public health~~
 4.24 ~~studies or research.~~

4.25 Sec. 7. Minnesota Statutes 2012, section 144.125, subdivision 10, is amended to read:

4.26 Subd. 10. **Revoking consent for storage and use.** A parent or legal guardian,
 4.27 or the individual whose blood was tested if the individual is 18 years of age or older,
 4.28 may revoke approval for ~~extended~~ storage or use of blood samples or test results at any
 4.29 time by providing a signed and dated form requesting destruction of the blood samples
 4.30 or test results. The Department of Health shall make necessary forms available on the
 4.31 department's Web site. Blood samples must be destroyed within one week of receipt of a
 4.32 request ~~or within one week of the standard retention period for blood samples provided in~~
 4.33 ~~subdivision 6, whichever is later,~~ and test results must be destroyed within one month of

5.1 receipt of a request ~~or within one month of the standard retention period for test results~~
5.2 ~~provided in subdivision 6, whichever is later.~~

5.3 Sec. 8. **REPEALER.**

5.4 Minnesota Statutes 2012, section 144.125, subdivision 6, is repealed.

144.125 TESTS OF INFANTS FOR HERITABLE AND CONGENITAL DISORDERS.

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.