

HOUSE OF REPRESENTATIVES

Unofficial Engrossment

House Engrossment of a Senate File

EIGHTY-SEVENTH SESSION

S. F. No. **1212**

Senate Author(s): Brown and Magnus

House Action

03/15/2012 Companion to House File No. 1521. (Authors:Holberg)
Read First Time and Referred to the Committee on Health and Human Services Reform
03/21/2012 Adoption of Report: Pass as Amended and re-referred to the Committee on Civil Law
03/26/2012 Adoption of Report: Pass and Read Second Time
05/03/2012 Calendar for the Day, Amended
Read Third Time as Amended
Passed by the House as Amended and transmitted to the Senate to include Floor Amendments

1.1 A bill for an act
1.2 relating to health; changing provisions of newborn screening program; adding
1.3 surviving adult children of a deceased patient to the definition of patient for
1.4 purpose of health records; regulating public health use of certain genetic
1.5 information; requiring certain medical assistance notices be in plain language;
1.6 requiring a request for information relating to mandated health benefits; requiring
1.7 reports; amending Minnesota Statutes 2010, sections 13.386, by adding a
1.8 subdivision; 144.125, subdivision 3, by adding subdivisions; 144.128; 144.291,
1.9 subdivision 2, as amended; 256B.05, by adding a subdivision.

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

1.11 Section 1. Minnesota Statutes 2010, section 13.386, is amended by adding a
1.12 subdivision to read:

1.13 Subd. 4. **Public health exception.** Notwithstanding subdivisions 1 to 3, the
1.14 commissioner of health may collect, store, use, and disseminate any genetic information,
1.15 which includes biological information or specimens, to the extent required or permitted by
1.16 any statute or rule that exists as of the effective date of this subdivision. This subdivision
1.17 does not apply to newborn screening activities conducted under sections 144.125 to
1.18 144.128.

1.19 This subdivision expires July 1, 2013.

1.20 **EFFECTIVE DATE.** This section is effective the day following final enactment.

1.21 Sec. 2. Minnesota Statutes 2010, section 144.125, subdivision 3, is amended to read:

1.22 Subd. 3. ~~Objection of parents to test~~ Information provided to parents. Persons
1.23 ~~with a duty to perform testing under subdivision 1 shall advise parents of infants (1) that~~
1.24 ~~the blood or tissue samples used to perform testing thereunder as well as the results of~~
1.25 ~~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 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.

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

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

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

3.7 (b) If a parent or legal guardian elects not to have newborn screening performed,
3.8 then the election shall be recorded on a form that is signed by the parent or legal guardian.
3.9 The signed form shall be made part of the infant's medical record and a copy shall be
3.10 provided to the Department of Health. When a parent or legal guardian elects not to
3.11 have newborn screening performed, the person with the duty to perform testing under
3.12 subdivision 1 must follow that election. A written election to decline testing exempts
3.13 persons with a duty to perform testing and the Department of Health from the requirements
3.14 of this section and section 144.128.

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

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

3.20 (1) confirmatory testing;
3.21 (2) laboratory quality control assurance and improvement;
3.22 (3) calibration of equipment;
3.23 (4) evaluating and improving the accuracy of newborn screening tests for conditions
3.24 approved for screening in Minnesota;
3.25 (5) validation of equipment and screening methods; and
3.26 (6) continuity of operations to ensure testing can continue as required by Minnesota
3.27 law in the event of an emergency.

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

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

3.32 Subd. 6. **Standard retention period for samples and test results.** The standard
3.33 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.

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

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 Tennessee 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.

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

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.

Sec. 8. Minnesota Statutes 2010, section 144.125, is amended by adding a subdivision to read:

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.

Sec. 9. Minnesota Statutes 2010, section 144.125, is amended by adding a subdivision to read:

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.

Sec. 10. Minnesota Statutes 2010, section 144.128, is amended to read:

144.128 COMMISSIONER'S DUTIES.

(a) The commissioner shall:

(1) notify the physicians of newborns tested of the results of the tests performed;

(2) make referrals for the necessary treatment of diagnosed cases of heritable and congenital disorders when treatment is indicated;

(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~~ or test results be destroyed;

(5) comply with a destruction request ~~within 45 days after receiving it 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

(7) adopt rules to carry out sections 144.125 to 144.128.

(b) Nothing in sections 144.125 to 144.128 shall exempt the commissioner from the requirements of the Genetic Privacy Act in section 13.386 or from the penalties for a violation of the Genetic Privacy Act as provided in chapter 13.

Sec. 11. Minnesota Statutes 2010, section 144.291, subdivision 2, as amended by Laws 2012, chapter 187, article 1, section 21, is amended to read:

Subd. 2. **Definitions.** For the purposes of sections 144.291 to 144.298, the following terms have the meanings given.

(a) "Group purchaser" has the meaning given in section 62J.03, subdivision 6.

(b) "Health information exchange" means a legal arrangement between health care providers and group purchasers to enable and oversee the business and legal issues involved in the electronic exchange of health records between the entities for the delivery of patient care.

(c) "Health record" means any information, whether oral or recorded in any form or medium, that relates to the past, present, or future physical or mental health or condition of a patient; the provision of health care to a patient; or the past, present, or future payment for the provision of health care to a patient.

(d) "Identifying information" means the patient's name, address, date of birth, gender, parent's or guardian's name regardless of the age of the patient, and other nonclinical data which can be used to uniquely identify a patient.

(e) "Individually identifiable form" means a form in which the patient is or can be identified as the subject of the health records.

(f) "Medical emergency" means medically necessary care which is immediately needed to preserve life, prevent serious impairment to bodily functions, organs, or parts, or prevent placing the physical or mental health of the patient in serious jeopardy.

(g) "Patient" means:

(1) a natural person who has received health care services from a provider for treatment or examination of a medical, psychiatric, or mental condition;

(2) the surviving spouse, surviving adult children, and parents of a deceased patient, ~~or unless the authority of a surviving adult child has been limited by the principal in the principal's health care directive;~~

(3) a person the patient appoints in writing as a representative, including a health care agent acting according to chapter 145C, unless the authority of the agent has been limited by the principal in the principal's health care directive; and

(4) except for minors who have received health care services under sections 144.341 to 144.347, in the case of a minor, ~~patient includes~~ a parent or guardian, or a person acting as a parent or guardian in the absence of a parent or guardian.

(h) "Provider" means:

(1) any person who furnishes health care services and is regulated to furnish the services under chapter 147, 147A, 147B, 147C, 147D, 148, 148B, 148C, 148D, 150A, 151, 153, or 153A;

(2) a home care provider licensed under section 144A.46;

(3) a health care facility licensed under this chapter or chapter 144A; and

(4) a physician assistant registered under chapter 147A.

(i) "Record locator service" means an electronic index of patient identifying information that directs providers in a health information exchange to the location of patient health records held by providers and group purchasers.

(j) "Related health care entity" means an affiliate, as defined in section 144.6521, subdivision 3, paragraph (b), of the provider releasing the health records.

EFFECTIVE DATE. This section is effective August 1, 2012, and applies for persons who become deceased on or after that date.

Sec. 12. Minnesota Statutes 2010, section 256B.05, is amended by adding a subdivision to read:

Subd. 6. Notice from lead agency. The notice of the reduction, suspension, denial, or termination of services under section 256B.0659, 256B.0915, 256B.092, or 256B.49, from the lead agency to the applicant or recipient must be made in plain language.

EFFECTIVE DATE. This section is effective for all notices dated on or after January 1, 2013.

Sec. 13. **REPORTS FROM THE COMMISSIONER OF HEALTH.**

By January 15, 2013, the commissioner of health must publish and submit to the chairs and ranking minority members of the legislative committees with jurisdiction over health and data privacy proposed legislation to authorize the commissioner of health to collect, store, use, and disseminate genetic information, which includes biological information or specimens, for existing activities at the Department of Health where the commissioner of health determines express authorization is not already provided in law.

Sec. 14. **NOTIFICATION FROM COMMISSIONER OF HEALTH.**

After destruction of the test results created pursuant to the newborn screening program that were retained for more than two years prior to November 16, 2011, and after destruction of all blood samples collected pursuant to the newborn screening program that were retained prior to November 16, 2011, the commissioner of health must notify the public through a general announcement and must submit a letter of notification to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services.

Sec. 15. **REQUEST FOR INFORMATION; EVALUATION OF MANDATED HEALTH BENEFITS.**

The commissioner of commerce shall issue a request for information regarding the cost and feasibility of a comprehensive evaluation of mandated health benefits required by a Minnesota statute or rule as of June 1, 2012. The commissioner shall issue a written report on the results of the request for information to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services and commerce no later than December 15, 2012. Any such evaluation must include the analysis, data, and information described in Minnesota Statutes, section 62J.26, subdivision 2, paragraph (b), clauses (1) through (6). For purposes of this section, a "mandated health benefit" means a statutory or administrative requirement that a health plan do the following:

(1) provide coverage or increase the amount of coverage for the treatment of a particular disease, condition, or other health care need;

(2) provide coverage or increase the amount of coverage of a particular type of health care treatment or service, or of equipment, supplies, or drugs used in connection with a health care treatment or service; or

(3) provide coverage for care delivered by a specific type of provider.

EFFECTIVE DATE. This section is effective the day following final enactment.

9.1 Sec. 16. **EFFECTIVE DATE.**

9.2 (a) Sections 2 and 6 to 9 are effective August 1, 2012.

9.3 (b) Sections 3 to 5 are effective the day following final enactment and apply to blood
9.4 samples collected and test results created on or after that date.

9.5 (c) Nothing in sections 2 to 10 affect or limit pending legal actions with respect to
9.6 transactions, occurrences, or events that occurred prior to November 16, 2011.