SENATE
STATE OF MINNESOTA
EIGHTY-EIGHTH LEGISLATURE

S.F. No. 1017

(SENATE AUTHORS: MARTY)

DATE	D-PG	OFFICIAL STATUS
03/04/2013	479	Introduction and first reading Referred to Health, Human Services and Housing
03/11/2013	761a	Comm report: To pass as amended and re-refer to Judiciary
03/20/2013	1310	Comm report: To pass
	1352	Second reading
05/19/2013	4974	General Orders: Stricken and returned to author See SF745, Sec. 3, 11, 14, 16, 39

A bill for an act

relating to health; making changes to genetic information provisions; changing newborn screening test results retention period for a certain time frame; requiring an evaluation of the newborn screening program; amending Minnesota Statutes 2012, sections 13.386, subdivision 3; 144.966, subdivision 3, by adding a subdivision; proposing coding for new law in Minnesota Statutes, chapter 144.

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

Section 1. Minnesota Statutes 2012, section 13.386, subdivision 3, is amended to read:

Subd. 3. **Collection, storage, use, and dissemination of genetic information.** (a) 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:

(i) with the individual's written informed consent; or

(ii) if necessary in order to accomplish purposes described by clause (2). A consent to disseminate genetic information under item (i) must be signed and dated. Unless otherwise provided by law, such a consent is valid for one year or for a lesser period specified in the consent.

(b) Newborn screening activities conducted under sections 144.125 to 144.128 are subject to paragraph (a). Other programs and activities governed under section 144.192 are not subject to paragraph (a).

Sec. 2. **[144.192] TREATMENT OF BIOLOGICAL SPECIMENS AND HEALTH DATA HELD BY THE DEPARTMENT OF HEALTH AND HEALTH BOARDS.**

Subdivision 1. **Definitions.** (a) For purposes of this section, the following terms have the meanings given.

(b) "Biological specimen" means tissue, fluids, excretions, or secretions that contain human DNA originating from an identifiable individual, either living or deceased. Biological specimen does not include infectious agents or chemicals that are isolated from a specimen. Nothing in this section or section 13.386 is intended to limit the commissioner's ability to collect, use, store, or disseminate such isolated infectious agents or chemicals.

(c) "Health data" has the meaning given in section 13.3805, subdivision 1, paragraph (a), clause (2).

(d) "Health oversight" means oversight of the health care system for activities authorized by law, limited to the following:

(1) audits;

(2) civil, administrative, or criminal investigations;

(3) inspections;

(4) licensure or disciplinary actions;

(5) civil, administrative, or criminal proceedings or actions; and

(6) other activities necessary for appropriate oversight of the health care system and persons subject to such governmental regulatory programs for which biological specimens or health data are necessary for determining compliance with program standards.

(e) "Individual" has the meaning given in section 13.02, subdivision 8. In addition, for a deceased individual, individual also means the representative of the decedent.

(f) "Person" has the meaning given in section 13.02, subdivision 10.

(g) "Program operations" means actions, testing, and procedures directly related to the operation of department programs, limited to the following:

(1) diagnostic and confirmatory testing;

(2) laboratory quality control assurance and improvement;

(3) calibration of equipment;

(4) evaluation and improvement of test accuracy;

(5) method development and validation;

(6) compliance with regulatory requirements; and

(7) continuity of operations to ensure that testing continues in the event of an emergency.

(h) "Public health practice" means actions related to disease, conditions, injuries, risk factors, or exposures taken to protect public health, limited to the following:

(1) monitoring the health status of a population;

(2) investigating occurrences and outbreaks;

(3) comparing patterns and trends;

(4) implementing prevention and control measures;

(5) conducting program evaluations and making program improvements;

(6) making recommendations concerning health for a population;

(7) preventing or controlling known or suspected diseases and injuries; and

(8) conducting other activities necessary to protect or improve the health of individuals and populations for which biological specimens or health data are necessary.

(i) "Representative of the decedent" has the meaning given in section 13.10, subdivision 1, paragraph (c).

(j) "Research" means activities that are not program operations, public health practice, or health oversight and is otherwise defined in Code of Federal Regulations, title 45, part 46, subpart A, section 46.102(d).

Subd. 2. **Collection, use, storage, and dissemination.** (a) The commissioner may collect, use, store, and disseminate biological specimens and health data, genetic or other, as provided in this section and as authorized under any other provision of applicable law, including any rules adopted on or before June 30, 2013. Any rules adopted after June 30, 2013, must be consistent with the requirements of this section.

(b) The provisions in this section supplement other provisions of law and do not supersede or repeal other provisions of law applying to the collection, use, storage, or dissemination of biological specimens or health data.

(c) For purposes of this section, genetic information is limited to biological specimens and health data.

Subd. 3. **Biological specimens and health data for program operations, public health practice, and health oversight.** (a) The commissioner may collect, use, store, and disseminate biological specimens and health data to conduct program operations activities, public health practice activities, and health oversight activities. Unless required under other applicable law, consent of an individual is not required under this subdivision.

(b) With the approval of the commissioner, biological specimens may be disseminated to establish a diagnosis, to provide treatment, to identify persons at risk of illness, or to conduct an epidemiologic investigation to control or prevent the spread of serious disease, or to diminish an imminent threat to the public health.

(c) For purposes of Clinical Laboratory Improvement Amendments proficiency testing, the commissioner may disseminate de-identified biological specimens to state

public health laboratories that agree, pursuant to contract, not to attempt to re-identify the biological specimens.

(d) Health data may be disseminated as provided in section 13.3805, subdivision 1, paragraph (b).

Subd. 4. **Research.** The commissioner may collect, use, store, and disseminate biological specimens and health data to conduct research in a manner that is consistent with the federal common rule for the protection of human subjects in Code of Federal Regulations, title 45, part 46.

Subd. 5. **Storage of biological specimens and health data according to storage schedules.** (a) The commissioner shall store health data according to section 138.17.

(b) The commissioner shall store biological specimens according to a specimen storage schedule. The commissioner shall develop the storage schedule by July 1, 2013, and post it on the department's Web site.

Subd. 6. **Secure storage of biological specimens.** The commissioner shall establish appropriate security safeguards for the storage of biological specimens, with regard for the privacy of the individuals from whom the biological specimens originated, and store the biological specimens accordingly. When a biological specimen is disposed of, it must be destroyed in a way that prevents determining the identity of the individual from whom it originated.

Subd. 7. **Applicability to health boards.** The provisions of subdivisions 2; 3, paragraphs (a), (c), and (d); and 4 to 6 pertaining to the commissioner also apply to boards of health and community health boards organized under chapter 145A. These boards may also disseminate health data pursuant to section 13.3805, subdivision 1, paragraph (b), clause (2).

Sec. 3. Minnesota Statutes 2012, section 144.966, subdivision 3, is amended to read:

Subd. 3. **Early hearing detection and intervention programs.** All hospitals shall establish an early hearing detection and intervention (EHDI) program. Each EHDI program shall:

(1) in advance of any hearing screening testing, provide to the newborn's or infant's parents or parent information concerning the nature of the screening procedure, applicable costs of the screening procedure, the potential risks and effects of hearing loss, and the benefits of early detection and intervention;

(2) comply with parental consent under section 144.125, subdivision ~~3~~ 4;

(3) develop policies and procedures for screening and rescreening based on Department of Health recommendations;

(4) provide appropriate training and monitoring of individuals responsible for performing hearing screening tests as recommended by the Department of Health;

(5) test the newborn's hearing prior to discharge, or, if the newborn is expected to remain in the hospital for a prolonged period, testing shall be performed prior to three months of age or when medically feasible;

(6) develop and implement procedures for documenting the results of all hearing screening tests;

(7) inform the newborn's or infant's parents or parent, primary care physician, and the Department of Health according to recommendations of the Department of Health of the results of the hearing screening test or rescreening if conducted, or if the newborn or infant was not successfully tested. The hospital that discharges the newborn or infant to home is responsible for the screening; and

(8) collect performance data specified by the Department of Health.

Sec. 4. Minnesota Statutes 2012, section 144.966, is amended by adding a subdivision to read:

Subd. 8. **Construction.** Notwithstanding anything to the contrary, nothing in this section shall be construed as constituting newborn screening activities conducted under sections 144.125 to 144.128.

Sec. 5. **NEWBORN SCREENING TEST RESULTS POSTPONEMENT.**

Notwithstanding Minnesota Statutes, section 144.125, subdivision 6, and section 13.386, and Laws 2012, chapter 292, article 4, section 22, the test results collected on or after November 16, 2011, shall not be destroyed subject to the schedule under Minnesota Statutes, section 144.125, prior to June 1, 2014. A parent or legal guardian may provide a signed and dated form requesting destruction of the test results. The commissioner shall comply with the request within one month of receipt of the request or within one month of the standard retention period for test results, whichever is later.

Sec. 6. **NEWBORN SCREENING PROGRAM STUDY.**

(a) The commissioner of health, in consultation with the medical research and advocacy groups identified in paragraph (b), shall review the newborn screening programs in Minnesota Statutes, section 144.125, and evaluate the scientific and medical validity of a comprehensive and sustainable long-term storage and use plan for the test results under Minnesota Statutes, section 144.125. The commissioner shall consider the following:

(1) peer-reviewed medical research into the diagnosis and treatment of heritable and congenital disease;

(2) strategies for education of parents and families about the utility of advancing new knowledge through research on blood spots and test data made possible by long-term storage and use;

(3) plans and protocols for clinical and research access to test result data;

(4) minimizing the administrative burden on hospitals and health care providers in the operation of the newborn screening program;

(5) the adequacy of current law on the standard retention period for test results under Minnesota Statutes, section 144.125, subdivision 6; and

(6) privacy concerns associated with parental consent options and long-term storage and use of blood samples and test data.

(b) As part of the evaluation, the commissioner shall consult with medical research and data privacy experts, including, but not limited to, specialists in metabolic care, immunology, pediatrics, epidemiology, nutrition, pulmonology, cardiology, endocrinology, hematology, hearing care, and medical genetics, as well as patient advocacy and data privacy groups.

(c) By February 1, 2014, the commissioner shall submit a report to the chairs and ranking minority members of the senate and house of representatives committees and divisions with primary jurisdiction on health and human services and data privacy on comprehensive and sustainable long-term storage and usage of the test results.

(d) The commissioner shall conduct the evaluation required under this section within existing appropriations.

Sec. 7. **EFFECTIVE DATE.**

Sections 1 to 6 are effective July 1, 2013.