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H.368

Introduced by Representatives Pearson of Burlington and Wizowaty of

Burlington

Referred to Committee on

Date:

Subject: Health; privacy; genetic information

Statement of purpose: This bill proposes to protect the privacy of genetic
information.

An act relating to privacy of genetic information

It is hereby enacted by the General Assembly of the State of Vermont:

Sec. 1. 18 V.S.A. § 9330 is added to chapter 217 to read:

§ 9330. INTENT; PURPOSE

(a) The general assembly recognizes that genetic information is a unique product of an individual's body, the unauthorized use of which interferes with both privacy rights and property interests of that individual. It is the intent of the general assembly to declare genetic information the exclusive property of the individual from whom the information is obtained. It is further the intent of the general assembly to maintain an individual's privacy by prohibiting the disclosure of genetic information without the informed written consent of the person to whom the information pertains.

1 (b) It is the purpose of this chapter to identify an individual’s rights with
2 respect to his or her own genetic material and genetic information.

3 Sec. 2. 18 V.S.A. § 9331 is amended to read:

4 § 9331. DEFINITIONS

5 For purposes of this chapter:

6 (1) “Commissioner” means the commissioner of banking, insurance,
7 securities, and health care administration.

8 (2) “Confidential research information” means any results of a genetic
9 test maintained pursuant to pharmacological or clinical research protocols
10 which are subject to and conducted in accordance with the review and approval
11 of an Institutional Review Board established pursuant to the provisions of
12 45 C.F.R. § 46 and 21 C.F.R. §§ 50 and 56 and which, through encryption,
13 encoding, or other means consistent with the requirements of said federal
14 regulations, either protect the confidentiality of the individual who is the
15 subject of the genetic test or keep the identity of the individual unknown or
16 protected from disclosure.

17 ~~(2)~~(3) “DNA” means deoxyribonucleic acid and “RNA” means
18 ribonucleic acid.

19 ~~(3)~~(4) “Employee” has the same meaning as in 21 V.S.A. § 495d.

20 ~~(4)~~(5) “Employer” has the same meaning as in 21 V.S.A. § 495d.

1 ~~(5)~~(6) “Employment agency” has the same meaning as in 21 V.S.A.
2 § 495d.

3 (7) “Family member” means an individual’s dependent and any other
4 first-degree, second-degree, third-degree, or fourth-degree relative of an
5 individual or of the dependent.

6 (8) “Genetic goods, products, or services” means goods, products, or
7 services that materially rely on genetic information or genetic material by
8 altering or adapting such information or material in a way that is novel or
9 unique.

10 ~~(6)~~(9) “Genetic information” means, ~~the results of “genetic testing”~~
11 ~~contained in any report, interpretation, evaluation, or other record thereof~~ with
12 respect to any individual, information about such individual’s genetic tests, the
13 genetic tests of members of the individual’s family, and the manifestation of a
14 disease or disorder in members of the individual’s family. The term includes
15 any request for or receipt of genetic services by or on behalf of an individual
16 and any participation by an individual or his or her family member in clinical
17 research that includes genetic services. The term does not include information
18 about the sex or age of an individual.

19 ~~(7)~~(10)(A) “Genetic testing” means a test, examination or analysis that
20 is diagnostic or predictive of a particular heritable disease or disorder and is of:

21 (i) a human chromosome or gene;

1 (ii) human DNA or RNA; or

2 (iii) a human genetically encoded protein.

3 (B) The test for human genetically encoded protein referred to in
4 subdivision (A)(iii) of this subdivision shall be generally accepted in the
5 scientific and medical communities as being specifically determinative for the
6 presence or absence of a mutation, alteration, or deletion of a gene or
7 chromosome.

8 (C) For the purposes of sections 9332 and 9333 of this title, as they
9 apply to insurers, section 9334 of this title, and ~~section 8~~ V.S.A. § 4727 of
10 ~~Title 8~~, and notwithstanding any language in this section to the contrary,
11 “genetic testing” does not include:

12 (i) a test, examination or analysis which reports on an individual’s
13 current condition unless such a test, examination, or analysis is designed or
14 intended to be specifically determinative for the presence or absence of a
15 mutation, alteration, or deletion of a gene or chromosome; or

16 (ii) a test, examination or analysis of a human chromosome or
17 gene, of human DNA or RNA, or of a human genetically encoded protein that
18 is diagnostic or predictive of a particular heritable disease or disorder, if, in
19 accordance with generally accepted standards in the medical community, the
20 potential presence or absence of a mutation, alteration, or deletion of a gene or
21 chromosome has already manifested itself by causing a disease, disorder or

1 medical condition or by symptoms highly predictive of the disease, disorder or
2 medical condition.

3 (11) “Informed written consent” means a written consent form for the
4 requested release of a person’s genetic information, or the release of genetic
5 information, or for the release of medical records containing such information.
6 The form shall state the purpose for which the information is being requested
7 and shall be distinguished from written consent for the release of any other
8 medical information.

9 ~~(8)~~(12) “Insurance” means a policy of insurance regulated under Title 8,
10 offered or issued in this state, including health, life, disability, and long-term
11 care insurance policies, hospital and medical service corporation service
12 contracts, and health maintenance organization benefit plans. The term also
13 includes a workers’ compensation policy regulated under chapter 9 of Title 21.

14 ~~(9)~~(13) “Labor organization” has the same meaning as in 21 V.S.A.
15 § 495d.

16 ~~(40)~~(14) “Licensing agency” means a unit of state government
17 authorized to grant, deny, renew, revoke, suspend, annul, withdraw, or amend
18 a professional license, certification, or registration.

19 (15) “Prior written consent” means a written consent form signed by the
20 person who is the subject of the test or, if that person lacks capacity to consent,
21 signed by the person authorized to consent for such person. The form must

1 allow for amendment or revocation at any time and shall not be a general
2 waiver or consent for genetic testing or a general authorization for the release
3 of medical records or medical information. The form shall include:

4 (A) a statement of the purpose of the test;

5 (B) a statement that prior to signing the consent form, the consenting
6 person discussed with the medical practitioner ordering the test the reliability
7 of positive or negative test results and the level of certainty that a positive test
8 result for that disease or condition serves as a predictor of such disease;

9 (C) a statement that the consenting person was informed about the
10 availability and importance of genetic counseling and provided with written
11 information identifying a genetic counselor or medical geneticist from whom
12 the consenting person might obtain such counseling;

13 (D) a general description of each specific disease or condition tested
14 for; and

15 (E) the name of the person or persons to whom the test results may be
16 disclosed.

17 Sec. 3. 18 V.S.A. § 9332 is amended to read:

18 § 9332. GENETIC TESTING; LIMITATIONS; PRIOR WRITTEN

19 CONSENT

20 (a) No person shall be required to undergo genetic testing, except as
21 provided in this chapter.

1 (b) A person may be required to undergo genetic testing ~~in connection with~~
2 ~~insurance subject to the limitations imposed under section 9334 of this title or~~
3 if otherwise required by law for the following reasons:

4 (1) To establish parentage.

5 (2) To determine the presence of metabolic disorders in a newborn by
6 testing conducted pursuant to newborn screening and protocols.

7 (3) In connection with a criminal investigation or prosecution.

8 (4) For remains identification by the chief medical examiner or
9 designee.

10 (5) For purposes of the state DNA data bank, the state DNA database
11 and CODIS pursuant to subchapter 4 of chapter 113 of Title 20.

12 (c) Samples collected pursuant to ~~subdivisions (1), (2), (3) or (4) of~~
13 ~~subsection (b)~~ subdivision (b)(1), (2), (3), or (4) of this section or collected
14 voluntarily pursuant to an agreement shall not be utilized for any purpose in
15 connection with the state DNA data bank, the state DNA database and CODIS
16 unless specifically authorized by subchapter 4 of chapter 113 of Title 20.

17 (d) Except for the provisions of subsection (b) of this section, no genetic
18 testing shall be performed on any individual or body parts of any individual
19 nor shall any bodily materials be released for purposes of genetic testing
20 without the prior written authorization and informed consent of the individual
21 to be tested except for medical research where the identity of the subject is

1 unknown or, if the research shall be conducted with anonymized medical
2 information where individual identifiers are encrypted or encoded and the
3 identity of the individual is not disclosed, or if the identity of the individual is
4 known, where standards of protection are equal to those contained in
5 regulations promulgated by the federal Office for ~~Protection from Research~~
6 ~~Risk (OPRR)~~ Human Research Protections.

7 (e) Except for the provisions of subsection (b) of this section, any results of
8 genetic testing or the fact that an individual has requested genetic services or
9 undergone genetic testing shall be disclosed only pursuant to a written
10 authorization executed by the individual tested or by a person authorized by
11 law to act for the individual.

12 (f) A laboratory receiving a request to conduct a genetic test from a health
13 care facility or health care provider, as those terms are defined in section 9402
14 of this title, may conduct the requested test only when the request:

15 (1) authorizes the laboratory to perform the test and disclose the results
16 to the medical practitioner ordering the test; and

17 (2) is accompanied by a signed statement of the medical practitioner
18 ordering the test attesting that the appropriate prior written consent has been
19 obtained from the patient, except when the test is to be conducted as
20 confidential research information for use in epidemiological or clinical
21 research conducted for the purpose of generating scientific knowledge about

1 genes, learning about the genetic basis of disease, or developing
2 pharmaceutical and other treatments of disease.

3 (g) No health care facility or health care provider, as those terms are
4 defined in section 9402 of this title, shall:

5 (1) test any individual for genetic information without first obtaining the
6 subject's prior written consent;

7 (2) disclose the results of a genetic test to anyone other than the subject
8 thereof without first obtaining the subject's informed written consent except
9 when the results will be used only as confidential research information for
10 epidemiological or clinical research conducted for the purpose of generating
11 scientific knowledge about genes, learning about the genetic basis of disease,
12 or developing pharmaceutical and other treatments of disease;

13 (3) disclose the identify of the subject being tested to any other person
14 except with the subject's informed written consent or upon proper judicial
15 order; or

16 (4) deny health care services to an individual solely on the basis of a
17 genetic marker or condition to which an individual's genetic information
18 indicates he or she is predisposed.

19 (h) Except for the provisions of subsection (b) of this section, at the time of
20 suggesting or requesting that an individual consent to genetic testing, the

1 person making the suggestion or request shall advise the individual subject of
2 the test that the results of the test:

3 (1) May become part of the individual's permanent medical record; and

4 (2) May be material to the ability of the individual to obtain certain
5 insurance benefits.

6 Sec. 4. 18 V.S.A. § 9336 is added to read:

7 § 9336. OWNERSHIP OF GENETIC MATERIAL

8 (a) Except as otherwise provided in subsection (e) of this section, genetic
9 material shall be considered real property subject to one's individual control
10 and dominion in accordance with generally held precepts of property law in
11 Vermont. Individuals may make appropriate arrangements to store and
12 maintain their own genetic information and genetic material for future use.

13 (b) A decedent may provide specific authorization in his or her last will or
14 testament to allow a surviving spouse or other family member to use the
15 individual's genetic information after his or her death.

16 (c) Prior to entering into a contract or other agreement to share personal
17 health information, genetic material, or genetic information, the individual
18 providing the genetic material or genetic information must be made aware both
19 orally and in writing that his or her donation is a commodity and is of some
20 material value. If an entity collects genetic material or genetic information
21 with the possible future intent of resale, licensure, or transfer of this material

1 for material gain, the individual who provided the genetic material or
2 information shall be made aware of such possibility and compensated at a fair
3 market value.

4 (d) Any report or record produced by or stored at a hospital; dispensary;
5 laboratory; hospital-affiliated registry; physician; commercial genetic testing
6 company, agency, or association; or insurance institution or its representative
7 pertaining to any genetic information is the exclusive property of the individual
8 sampled or analyzed. Such report or record shall not be considered to be a
9 public record, and the contents thereof shall not be divulged by any person
10 having charge of or access to the report or record without informed written
11 consent, except:

12 (1) upon proper judicial order;

13 (2) to an individual whose official duties, in the sole discretion of the
14 commissioner of health, entitle the individual to receipt of the information
15 contained in such report or record; or

16 (3) as confidential research information for use in epidemiological or
17 clinical research conducted for the purpose of generating scientific knowledge
18 about genes, learning about the genetic basis of disease, or developing
19 pharmaceutical and other treatments of disease.

20 (e) Information derived from the sequence of the human genome shall be
21 part of the public domain and shall not be considered the property of any

1 individual. Nothing in this chapter shall be construed to grant an ownership
2 right to any individual or entity utilizing the publicly held information from the
3 sequence of the human genome in the furtherance of the creation of a venture
4 or enterprise, including any genetic goods, products, or services.

5 Sec. 5. 18 V.S.A. § 9337 is added to read:

6 § 9337. STORAGE AND DISPOSAL OF GENETIC MATERIAL

7 (a) A person whose genetic material is sampled or analyzed shall be offered
8 options regarding the use of any genetic material remaining after the purpose
9 for which the material was obtained, including storing the material, donating
10 the material to another individual, discarding the material, or donating the
11 material for research. Disclosure of options for the use of the remaining
12 genetic material shall be made at the time written consent is obtained for the
13 testing or use of genetic information.

14 (b) Any entity handling and maintaining genetic information or genetic
15 material shall follow the guidelines for the disposal of genetic information
16 documented in the Centers for Medicare and Medicaid Services Clinical
17 Laboratory Improvement Amendments (CLIA guidelines) or a similar
18 subsequent regulation. Where subsequent regulations are silent on questions of
19 law addressed in the CLIA guidelines, the CLIA guidelines shall be legally
20 controlling.

1 Sec. 6. 18 V.S.A. § 9338 is added to read:

2 § 9338. CONFIDENTIALITY; THIRD PARTIES

3 A laboratory receiving a request to conduct a genetic test from a health care
4 facility or health care provider, as those terms are defined in section 9402 of
5 this title, or any entity which enters into a contract with a third party for
6 analysis of genetic information, genetic material or personal health
7 information, shall be responsible for safeguarding the confidentiality of the
8 materials and resulting data.

9 Sec. 7. 18 V.S.A. § 9339 is added to read:

10 § 9339. RESTRICTIONS ON GENETIC PROFILING FOR MARKETING

11 PURPOSES

12 (a) As used in this section:

13 (1) “Bona-fide clinical trial” means any research project that
14 prospectively assigns human subjects to intervention and comparison groups to
15 study the cause and effect relationship between a medical intervention and a
16 health outcome, that has received approval from an appropriate Institutional
17 Review Board established pursuant to the provisions of 45 C.F.R. § 46 and
18 21 C.F.R. §§ 50 and 56, and that has been registered with the online registry of
19 clinical trials maintained by the U.S. National Institutes of Health.

1 (2) “Genetic profiling” means any effort or intent to attach an
2 individual’s demographic information to his or her genetic information or
3 genetic material for marketing purposes.

4 (3) “Manufacturer” shall have the same meaning as in section 4631a of
5 this title.

6 (4) “Marketing purpose” means any activity by a manufacturer of
7 prescribed products intended to influence choices about purchasing products,
8 including:

9 (A) advertising, publicizing, promoting, or sharing information about
10 a product;

11 (B) identifying individuals to receive a message promoting use of a
12 particular product, including by way of an advertisement, brochure, or contact
13 by a sales representative;

14 (C) planning the substance of a sales representative’s visit or
15 communication or the substance of an advertisement or other promotional
16 message or document;

17 (D) evaluating or compensating sales representatives; and

18 (E) identifying individuals to receive any form of gift, product
19 sample, consultancy, or any other item or service of value, including
20 compensation or employment.

1 (5) “Prescribed products” shall have the same meaning as in section
2 4631a of this title.

3 (b) No person shall license, use, sell, or transfer, for any marketing
4 purpose, prescribed product information related to a regulated transaction that
5 was the result of genetic profiling. A record of a regulated transaction
6 containing genetic information may be transferred to another entity, including
7 to another branch or subsidiary of the same firm, only if it carries satisfactory
8 assurance that the recipient will safeguard the records from being disclosed or
9 used in Vermont for marketing purposes.

10 (c) Nothing in this section shall prohibit the collection, use, transfer, or sale
11 of prescribed product information for marketing purposes if the data:

12 (1) are aggregated;

13 (2) do not contain identifying information; and

14 (3) cannot be used, directly or indirectly, to obtain identifying
15 information.

16 (d) Nothing in this section shall prohibit the collection, use, transfer, or sale
17 of prescribed product information for nonmarketing purposes, including patient
18 care, patient care management, utilization review, health care research,
19 bona-fide clinical trials, product safety studies, transfer of information to the
20 patient or patient’s authorized representative, and as required by law.

1 elements, when either the name or the data elements are not encrypted or
2 redacted or protected by another method that renders them unreadable or
3 unusable by unauthorized persons:

4 (i) Social Security number;

5 (ii) Motor vehicle operator's license number or nondriver
6 identification card number;

7 (iii) Financial account number or credit or debit card number, if
8 circumstances exist in which the number could be used without additional
9 identifying information, access codes, or passwords;

10 (iv) Account passwords or personal identification numbers or
11 other access codes for a financial account;

12 (v) Genetic information, as defined in 18 V.S.A. § 9331.

13 * * *

14 Sec. 10. 8 V.S.A. § 10403 is amended to read:

15 § 10403. PROHIBITION ON DISCRIMINATION BASED ON SEX,

16 MARITAL STATUS, RACE, COLOR, RELIGION, NATIONAL

17 ORIGIN, AGE, SEXUAL ORIENTATION, GENDER IDENTITY,

18 GENETIC INFORMATION, OR HANDICAPPING CONDITION

19 (a) No financial institution shall discriminate against any applicant for
20 credit services on the basis of the sex, marital status, race, color, religion,
21 national origin, age, sexual orientation, gender identity, genetic information, or

1 handicapping condition of the applicant, provided the applicant has the legal
2 capacity to contract.

3 * * *

4 (c) Definitions. As used in this section:

5 * * *

6 (6) "Genetic information" shall have the same meaning as in 18 V.S.A.
7 § 9331.

8 (7) "Handicapping condition" applied to an applicant means a
9 handicapped individual as defined in ~~subdivision 21 V.S.A. § 495d(5) of Title~~
10 ~~24~~. For the purposes of this section, an applicant with a handicapping
11 condition does not include an alcoholic or drug abuser who, by reason of
12 current alcohol or drug use, constitutes an unacceptable credit risk.

13 (7)(8) "Person" means a natural person, a corporation, government or
14 governmental subdivision or agency, trust, estate, partnership, cooperative,
15 association, or other entity.

16 * * *

17 Sec. 11. 9 V.S.A. § 4501 is amended to read:

18 § 4501. DEFINITIONS

19 As used in this chapter:

20 * * *

1 of an individual employee of any public agency shall be made available to that
2 individual employee or his or her designated representative;

3 * * *

4 Sec. 14. 13 V.S.A. § 15 is added to read:

5 § 15. MISAPPROPRIATION OF GENETIC INFORMATION

6 A person who commits, causes to be committed, or attempts to commit any
7 crime and in furtherance of such crime misappropriates genetic information, as
8 that term is defined in 18 V.S.A. § 9331, or genetic material shall be subject to
9 the following penalties:

10 (1) If the maximum penalty for the underlying crime is one year or less,
11 the penalty for a violation of this section shall be imprisonment for not more
12 than two years or a fine of not more than \$2,000.00 or both.

13 (2) If the maximum penalty for the underlying crime is more than one
14 year but less than five years, the penalty for a violation of this section shall be
15 imprisonment for not more than five years or a fine of not more than
16 \$10,000.00 or both.

17 (3) If the maximum penalty for the underlying crime is five years or more,
18 the penalty for the underlying crime shall apply; however, the court shall
19 consider the defendant's misappropriation of the genetic information or genetic
20 material as a factor in sentencing.

- 1 Sec. 15. EFFECTIVE DATE
- 2 This act shall take effect on passage.