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S.49

Introduced by Senators Lyons, Chittenden, Clarkson, Gulick, Hardy, Harrison  
and Watson

Referred to Committee on

Date:

Subject: Commerce and trade; consumer protection; data privacy

Statement of purpose of bill as introduced: This bill proposes to protect  
genetic information privacy and consumer health information.

An act relating to protecting genetic information privacy and consumer  
health information

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

Sec. 1. SHORT TITLE

This act shall be known and may be cited as the Genetic Information  
Privacy Act.

Sec. 2. 9 V.S.A. § 2432 is added to read:

§ 2432. GENETIC INFORMATION PRIVACY

(a) Definitions. As used in this section:

(1) “Biological sample” means any material part of the human,  
discharge therefrom, or derivative thereof, such as tissue, blood, urine, or  
saliva, known to contain deoxyribonucleic acid (DNA).

1           (2)(A) “Direct-to-consumer genetic testing company” means an entity

2           that:

3                   (i) offers genetic testing products or services directly to a  
4           consumer; or

5                   (ii) collects, uses, or analyzes genetic data that resulted from a  
6           direct-to-consumer product or service and that was provided to the company by  
7           a consumer;

8                   (B) “Direct-to-consumer genetic testing company” does not include  
9           an entity when engaged only in collecting, using, or analyzing genetic data or  
10           biological samples in the context of research, as defined in 45 C.F.R. §  
11           164.501, conducted in accordance with the Federal Policy for the Protection of  
12           Human Subjects, 45 C.F.R. part 46; the Good Clinical Practice Guideline  
13           issued by the International Council for Harmonisation; or the U.S. Food and  
14           Drug Administration Policy for the Protection of Human Subjects under 21  
15           C.F.R. parts 50 and 56.

16                   (3) “Express consent” means a consumer’s affirmative response to a  
17           clear, meaningful, and prominent notice regarding the collection, use,  
18           maintenance, or disclosure of genetic data for a specific purpose.

19                   (4)(A) “Genetic data” means any data, regardless of its format, that  
20           concerns a consumer’s genetic characteristics, and includes:

1           (i) raw sequence data that result from sequencing of a consumer’s  
2           complete extracted or a portion of the extracted DNA;

3           (ii) genotypic and phenotypic information that results from  
4           analyzing the raw sequence data; and

5           (iii) self-reported health information that a consumer submits to a  
6           company regarding the consumer’s health conditions and that is used for  
7           scientific research or product development and analyzed in connection with the  
8           consumer’s raw sequence data.

9           (B) “Genetic data” does not include deidentified data, which means  
10          data that cannot be used to infer information about, or otherwise be linked to,  
11          an identifiable consumer, and that is subject to:

12           (i) administrative and technical measures to ensure that the data  
13           cannot be associated with a consumer;

14           (ii) public commitment by the company to maintain and use data  
15           in deidentified form and not attempt to reidentify data; and

16           (iii) legally enforceable contractual obligations that prohibit any  
17           recipients of the data from attempting to reidentify the data.

18           (5) “Genetic testing” means any laboratory test of a consumer’s  
19           complete DNA, regions of DNA, chromosomes, genes, or gene products to  
20           determine the presence of genetic characteristics of a consumer.

1        (b) Duties. To safeguard the privacy, confidentiality, security, and integrity  
2        of a consumer's genetic data, a direct-to-consumer genetic testing company  
3        shall do all of the following:

4            (1) Provide clear and complete information regarding the company's  
5        policies and procedures for the collection, use, or disclosure of genetic data by  
6        making available to a consumer:

7            (A) a high-level privacy policy overview that includes basic, essential  
8        information about the company's collection, use, or disclosure of genetic data;  
9        and

10          (B) a prominent, publicly available privacy notice that includes, at a  
11        minimum, information about the company's data collection, consent, use,  
12        access, disclosure, transfer, security, and retention and deletion practices.

13          (2) Obtain a consumer's consent for collection, use, or disclosure of the  
14        consumer's genetic data, including, at a minimum:

15            (A) Initial express consent that clearly describes the uses of the  
16        genetic data collected through the genetic testing product or service and  
17        specifies who has access to test results and how genetic data may be shared.

18            (B) Separate express consent for transferring or disclosing the  
19        consumer's genetic data to any person other than the company's vendors and  
20        service providers or for using genetic data beyond the primary purpose of the  
21        genetic testing product or service and inherent contextual uses.

1           (C) Separate express consent for the retention of any biological  
2           sample provided by the consumer following completion of the initial testing  
3           service requested by the consumer.

4           (D) Informed consent in compliance with the federal policy for the  
5           protection of human research subjects, 45 C.F.R § 46, for transfer or disclosure  
6           of the consumer’s genetic data to third-party persons for research purposes or  
7           research conducted under the control of the company for the purpose of  
8           publication or generalizable knowledge.

9           (E) Express consent for marketing to a consumer based on the  
10           consumer’s genetic data or for marketing by a third-party person to a consumer  
11           based on the consumer having ordered or purchased a genetic testing product  
12           or service. Marketing does not include the provision of customized content or  
13           offers on the websites or through the applications or services provided by the  
14           direct-to-consumer genetic testing company with the first-party relationship to  
15           the customer.

16           (3) Require valid legal process for disclosing genetic data to law  
17           enforcement or any other government agency without a consumer’s express  
18           written consent.

19           (4) Develop, implement, and maintain a comprehensive security  
20           program to protect a consumer’s genetic data against unauthorized access, use,  
21           or disclosure.

1           (5) Provide a process for a consumer to:

2                   (A) access the consumer's genetic data;

3                   (B) delete the consumer's account and genetic data; and

4                   (C) request and obtain the destruction of the consumer's biological  
5 sample.

6           (c) Nondisclosure. Notwithstanding any provision in this section, a direct-  
7 to-consumer genetic testing company shall not disclose a consumer's genetic  
8 data to any entity offering health insurance, life insurance, or long-term care  
9 insurance, or to any employer of the consumer without the consumer's written  
10 consent.

11           (d) Enforcement. A person who violates a provision of this section  
12 commits and unfair and deceptive act in commerce in violation of section 2453  
13 of this title.

14           (e) Limitations. This section does not apply to protected health information  
15 that is collected by a covered entity or business associate, as those terms are  
16 defined in 45 C.F.R. parts 160 and 164, governed by the privacy, security, and  
17 breach notification rules adopted pursuant to the Health Insurance Portability  
18 and Accountability Act of 1996, P.L. 104-191, and the Health Information  
19 Technology for Economic and Clinical Health Act, P.L. 111-5.

20           Sec. 3. EFFECTIVE DATE

21           This act shall take effect on July 1, 2023.