

1 H.343

2 Introduced by Representatives Rachelson of Burlington, Burditt of West

3 Rutland, Oliver of Sheldon, and Small of Winooski

4 Referred to Committee on

5 Date:

6 Subject: Commerce and trade; consumer protection; data privacy

7 Statement of purpose of bill as introduced: This bill proposes to protect

8 genetic information privacy and consumer health information.

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

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

12 Sec. 1. SHORT TITLE

13 This act shall be known and may be cited as the Genetic Information

14 Privacy Act.

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

16 § 2432. GENETIC INFORMATION PRIVACY

17 (a) Definitions. As used in this section:

18 (1) "Biological sample" means any material part of the human,

19 discharge therefrom, or derivative thereof, such as tissue, blood, urine, or

20 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
12 of 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
15 21 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.