
A BILL FOR AN ACT

RELATING TO GENETIC INFORMATION PRIVACY.

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

1 SECTION 1. The legislature finds that the number of
2 companies offering direct-to-consumer genetic tests, otherwise
3 known as ancestry tests, at-home genetic tests, direct-access
4 genetic tests, genealogy tests, and home deoxyribonucleic acid
5 (DNA) tests, has been growing, along with the range of
6 information on the health conditions and traits covered by the
7 tests.

8 Direct-to-consumer genetic tests provide consumers with
9 direct access to their genetic information without the
10 involvement of health care providers and health plans. As the
11 name suggests, the tests are marketed directly to consumers
12 through the media, print advertisements, or the Internet, and
13 purchased by consumers online or in stores. The consumers
14 collect and mail their DNA samples pursuant to instructions
15 provided by the direct-to-consumer genetic testing company, and
16 a laboratory analyzes the DNA samples for genetic variations
17 that fit the purpose of the test. The method by which the test



1 results are communicated to the consumer varies by company; some
2 post the results on a secure website and provide the consumer
3 with access thereto, some mail a written report to the consumer,
4 and some share the results over the telephone.

5 While direct-to-consumer genetic testing promotes awareness
6 of genetic diseases and can assist consumers in taking a
7 proactive role in maintaining or improving their health and
8 wellness, the legislature is concerned that there is currently
9 little oversight or regulation of direct-to-consumer genetic
10 testing companies, especially in terms of how the privacy and
11 confidentiality of a consumer's genetic information are
12 protected. The legislature acknowledges that the Health
13 Insurance Portability and Accountability Act of 1996 (HIPAA)
14 established national standards to protect an individual's
15 medical records and other personal health information, including
16 genetic information. However, HIPAA applies only to health
17 plans, health care clearinghouses, and certain health care
18 providers; it does not apply to direct-to-consumer genetic
19 testing companies.

20 Accordingly, the purpose of this Act is to protect the
21 privacy and confidentiality of genetic data of consumers who



1 order or purchase a genetic testing product or service and
2 submit their biological samples to direct-to-consumer genetic
3 testing companies, by requiring direct-to-consumer genetic
4 testing companies to adhere to certain requirements pertaining
5 to its collection, use, and disclosure of genetic data.

6 SECTION 2. The Hawaii Revised Statutes is amended by
7 adding a new chapter to be appropriately designated and to read
8 as follows:

9 "CHAPTER

10 HAWAII GENETIC INFORMATION PRIVACY ACT

11 § -1 Short title. This chapter shall be known and may
12 be cited as the Hawaii Genetic Information Privacy Act.

13 § -2 Definitions. As used in this chapter, unless the
14 context clearly requires otherwise:

15 "Biological sample" means any material part of a human
16 being, discharge from a human being, or derivative of a human
17 being that is known to contain the DNA of the human being.

18 "Biological sample" includes the tissue, blood, urine, and
19 saliva of a human being.

20 "Consumer" means any individual who is a resident of the
21 State.



1 "De-identified data" means data that has been de-identified
2 in accordance with title 45 Code of Federal Regulations
3 section 164.514(b).

4 "Direct-to-consumer genetic testing company" or "company"
5 means any person that provides directly to consumers, direct-to-
6 consumer genetic testing products or services related to direct-
7 to-consumer genetic testing products. Services related to
8 direct-to-consumer genetic testing products include:

9 (1) Collecting or receiving biological samples or genetic

10 data from a consumer;

11 (2) Analyzing the genetic data derived from the biological
12 samples or genetic data of a consumer; and

13 (3) Communicating the results of the genetic testing to
14 the consumer.

15 "Direct-to-consumer genetic testing product" means genetic
16 tests that are marketed directly to consumers and purchased by
17 the consumer online or in stores. "Direct-to-consumer genetic
18 testing product" includes ancestry tests, at-home genetic tests,
19 direct-access genetic tests, genealogy tests, and home DNA
20 tests.



1 "Disclose" or "disclosure" means to release, transfer, or
2 otherwise divulge a consumer's genetic data to any person other
3 than the consumer who ordered the genetic testing.

4 "DNA" means deoxyribonucleic acid.

5 "Express consent" means a statement of permission given by
6 a consumer that is positive, direct, and unequivocal, requiring
7 no inference or implication to supply its meaning, regarding the
8 collection, use, or disclosure of genetic data for a specific
9 purpose.

10 "Genetic data" means data in any format that contain
11 information relating to a consumer's genetic characteristics.

12 "Genetic data" includes:

- 13 (1) Raw sequence data that result from the sequencing of a
14 consumer's complete extracted DNA or a portion of the
15 extracted DNA;
- 16 (2) Genotypic and phenotypic information that results from
17 analyzing the raw sequence data; and
- 18 (3) Self-reported health information regarding a
19 consumer's health conditions that the consumer submits
20 to a direct-to-consumer genetic testing company that
21 is:



1 (A) Analyzed in connection with the consumer's raw
2 sequence data; or

3 (B) Used for scientific research or product
4 development.

5 "Genetic data" does not include de-identified data.

6 "Genetic test" or "genetic testing" means any laboratory
7 test of a consumer's complete DNA, regions of DNA, chromosomes,
8 genes, or gene products to determine the presence of a
9 consumer's genetic characteristics.

10 "Individual" means a natural person.

11 "Person" means any individual, group, partnership, firm,
12 association, corporation, trust, business trust, estate,
13 cooperative, consortium, joint venture, or any other form of
14 business or legal entity, and the legal representative of such
15 entity.

16 § -3 Direct-to-consumer genetic testing company;
17 requirements; prohibition. (a) A direct-to-consumer genetic
18 testing company shall:

19 (1) Provide consumers with a clear and complete written
20 notice regarding the company's policies and procedures
21 for the collection, use, and disclosure of genetic



1 data, by making available to the consumer the
2 following:

3 (A) A high-level privacy policy overview that
4 includes basic essential information about the
5 company's collection, use, or disclosure of
6 genetic data; and

7 (B) A prominent, publicly available written privacy
8 notice that describes the company's practice
9 relating to biological samples and genetic data,
10 including genetic data collection, consumer
11 consent, use of genetic data, access to genetic
12 data, disclosure of genetic data, transfer of
13 genetic data, security protocols, and retention
14 and deletion of genetic data;

15 (2) Obtain the consumer's consent for the collection, use,
16 or disclosure of the consumer's genetic data,
17 including:

18 (A) Initial express consent that:

19 (i) Clearly describes how the company will use
20 the consumer's genetic data collected



1 through the direct-to-consumer genetic
2 testing product or service;

3 (ii) Specifies who has access to the consumer's
4 genetic test results; and

5 (iii) Specifies how the genetic data may be
6 shared;

7 (B) Separate express consent for each of the
8 following:

9 (i) Transfer or disclosure of the consumer's
10 genetic data to any person other than the
11 company's vendors and service providers;

12 (ii) Use of the consumer's genetic data beyond
13 the primary purpose of the genetic testing
14 product or service and inherent contextual
15 uses; and

16 (iii) Retention of any biological sample provided
17 by the consumer following completion of the
18 initial testing service requested by the
19 consumer;

20 (C) Informed consent in compliance with the federal
21 policy for the protection of human research



1 subjects prescribed by title 45 Code of Federal
2 Regulations part 46, for the transfer or
3 disclosure of the consumer's genetic data to
4 third-party persons for research purposes or
5 research conducted under the control of the
6 company for the purpose of publication or
7 generalizable knowledge; and

8 (D) Express consent for the consumer to receive:

9 (i) Marketing of products and services based on
10 the consumer's genetic data; or

11 (ii) Marketing of products and services by a
12 third-party person based on the consumer
13 having ordered or purchased a genetic
14 testing product or service.

15 For the purposes of this subparagraph,
16 "marketing" does not include the provision of
17 customized content or offers on websites or
18 through applications or services provided by the
19 direct-to-consumer genetic testing company that
20 has a first-party relationship with the consumer;



1 (3) Not disclose a consumer's genetic data to law
2 enforcement or any other government agency except when
3 required under court order or pursuant to subpoena
4 issued by the department of the attorney general, or
5 with the prior express consent of the consumer;

6 (4) Develop, implement, and maintain a comprehensive
7 security program to protect a consumer's genetic data
8 against unauthorized access, use, or disclosure; and

9 (5) Provide a process that allows a consumer to:

10 (A) Access the consumer's genetic data;

11 (B) Delete the consumer's account and genetic data;

12 and

13 (C) Request and obtain the destruction of the
14 consumer's biological sample.

15 (b) Notwithstanding any other provision in this section to
16 the contrary, a direct-to-consumer genetic testing company shall
17 not disclose a consumer's genetic data to any person offering
18 health insurance, life insurance, or long-term care insurance or
19 to any employer of the consumer without the prior express
20 consent of the consumer.



(c) Notwithstanding any other provision in this section to the contrary, the disclosure of a consumer's genetic data pursuant to this chapter shall comply with all state and federal laws governing the protection of privacy and security of personal information and health information.

§ -4 Exceptions. This chapter shall not apply to:

(1) Protected health information that is collected by a covered entity or business associate governed by the privacy, security, and breach notification rules issued by the United States Department of Health and Human Services under title 45 Code of Federal Regulations parts 160 and 164;

(2) Biological samples that are obtained or genetic data that is generated for the purposes of an individual's medical screening, treatment, or diagnosis; and

(3) A public or private institution of higher education or an entity owned or operated by a public or private institution of higher education.

§ -5 Violations; penalties. (a) Any person who violates any provision of this chapter shall be deemed to have



1 engaged in an unfair or deceptive act or practice in the conduct
2 of any trade or commerce with the meaning of section 480-2.

3 (b) The penalties provided in this section shall be
4 cumulative to the remedies or penalties available under
5 all other laws of this State."

6 SECTION 3. If any provision of this Act, or the
7 application thereof to any person or circumstance, is held
8 invalid, the invalidity does not affect other provisions or
9 applications of the Act that can be given effect without the
10 invalid provision or application, and to this end the provisions
11 of this Act are severable.

12 SECTION 4. This Act shall take effect upon its approval.



Report Title:

Genetic Information Privacy Act; Direct-to-Consumer Genetic Testing Company; Genetic Information; Privacy; Penalty; Civil Action

Description:

Requires direct-to-consumer genetic testing companies to adhere to certain requirements pertaining to its collection, use, and disclosure of genetic data. Provides that any violation of the Act is deemed to be an unfair or deceptive trade practice in violation of section 480-2, Hawaii Revised Statutes. (SD1)

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