
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 that the consumer can
3 access, some mail a written report to the consumer, and some
4 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 the 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 direct-to-consumer genetic
6 testing products or services related to direct-to-consumer
7 genetic testing products directly to consumers. For purposes of
8 this definition, services related to direct-to-consumer genetic
9 testing products include:

- 10 (1) Collecting or receiving biological samples or genetic
11 data from a consumer;
- 12 (2) Analyzing the genetic data derived from the biological
13 samples or genetic data of a consumer; and
- 14 (3) Communicating the results of the genetic testing to
15 the consumer.

16 "Direct-to-consumer genetic testing company" does not include
17 any covered entity as defined under title 45 Code of Federal
18 Regulations section 106.103, established pursuant to the Health
19 Insurance Portability and Accountability Act of 1996.

20 "Direct-to-consumer genetic testing product" means genetic
21 tests that are marketed directly to consumers and purchased by



1 the consumer online or in stores. "Direct-to-consumer genetic
2 testing product" includes ancestry tests, at-home genetic tests,
3 direct-access genetic tests, genealogy tests, and home DNA
4 tests.

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

8 "DNA" means deoxyribonucleic acid.

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

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

16 "Genetic data" includes:

- 17 (1) Raw sequence data that result from the sequencing of a
18 consumer's complete extracted DNA or a portion of the
19 extracted DNA;
- 20 (2) Genotypic and phenotypic information that results from
21 analyzing the raw sequence data; and



1 (3) Self-reported health information regarding a
2 consumer's health conditions that the consumer submits
3 to a direct-to-consumer genetic testing company that
4 is:

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

7 (B) Used for scientific research or product
8 development.

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

10 "Genetic test" or "genetic testing" means any laboratory
11 test of a consumer's complete DNA, regions of DNA, chromosomes,
12 genes, or gene products to determine the presence of a
13 consumer's genetic characteristics.

14 "Individual" means a natural person.

15 "Person" means any individual, group, partnership, firm,
16 association, corporation, trust, business trust, estate,
17 cooperative, consortium, joint venture, or any other form of
18 business or legal entity, and the legal representative of the
19 entity.



1 § -3 Direct-to-consumer genetic testing company;
2 requirements; prohibition. (a) A direct-to-consumer genetic
3 testing company shall:
4 (1) Provide consumers with a clear and complete written
5 notice regarding the company's policies and procedures
6 for the collection, use, and disclosure of genetic
7 data, by making available to the consumer the
8 following:
9 (A) A high-level privacy policy overview that
10 includes basic essential information about the
11 company's collection, use, or disclosure of
12 genetic data; and
13 (B) A prominent, publicly available written privacy
14 notice that describes the company's practice
15 relating to biological samples and genetic data,
16 including genetic data collection, consumer
17 consent, use of genetic data, access to genetic
18 data, disclosure of genetic data, transfer of
19 genetic data, security protocols, and retention
20 and deletion of genetic data;

- 1 (2) Obtain the consumer's consent for the collection, use,
2 or disclosure of the consumer's genetic data,
3 including:
- 4 (A) Initial express consent that:
- 5 (i) Clearly describes how the company will use
6 the consumer's genetic data collected
7 through the direct-to-consumer genetic
8 testing product or service;
- 9 (ii) Specifies who has access to the consumer's
10 genetic test results; and
- 11 (iii) Specifies how the genetic data may be
12 shared;
- 13 (B) Separate express consent for each of the
14 following:
- 15 (i) Transfer or disclosure of the consumer's
16 genetic data to any person other than the
17 company's vendors and service providers;
- 18 (ii) Use of the consumer's genetic data beyond
19 the primary purpose of the direct-to-
20 consumer genetic testing product or service
21 and inherent contextual uses; and



- 1 (iii) Retention of any biological sample provided
- 2 by the consumer following completion of the
- 3 initial genetic testing service requested by
- 4 the consumer;
- 5 (C) Informed consent in compliance with the federal
- 6 policy for the protection of human research
- 7 subjects prescribed by title 45 Code of Federal
- 8 Regulations part 46, for the transfer or
- 9 disclosure of the consumer's genetic data to
- 10 third-party persons for research purposes or
- 11 research conducted under the control of the
- 12 company for the purpose of publication or
- 13 generalizable knowledge; and
- 14 (D) Express consent for the consumer to receive:
- 15 (i) Marketing of products and services based on
- 16 the consumer's genetic data; or
- 17 (ii) Marketing of products and services by a
- 18 third-party person based on the consumer
- 19 having ordered or purchased a direct-to-
- 20 consumer genetic testing product or service.



- 1 For the purposes of this subparagraph,
2 "marketing" does not include the provision of
3 customized content or offers on websites or
4 through applications or services provided by the
5 direct-to-consumer genetic testing company that
6 has a first-party relationship with the consumer;
- 7 (3) Not disclose a consumer's genetic data to law
8 enforcement or any other government agency except when
9 required under court order or pursuant to subpoena
10 issued by the department of the attorney general, or
11 with the prior express consent of the consumer;
- 12 (4) Develop, implement, and maintain a comprehensive
13 security program to protect a consumer's genetic data
14 against unauthorized access, use, or disclosure; and
- 15 (5) Provide a process that allows a consumer to:
- 16 (A) Access the consumer's genetic data;
17 (B) Delete the consumer's account and genetic data;
18 and
19 (C) Request and obtain the destruction of the
20 consumer's biological sample.



1 (b) Notwithstanding any other provision in this section to
2 the contrary, a direct-to-consumer genetic testing company shall
3 not disclose a consumer's genetic data to any person offering
4 health insurance, life insurance, or long-term care insurance,
5 or to any employer of the consumer without the prior express
6 consent of the consumer.

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

12 § -4 **Exceptions.** This chapter shall not apply to:

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

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



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

4 § -5 **Violations; penalties.** (a) Any person who
5 violates any provision of this chapter shall be deemed to have
6 engaged in an unfair or deceptive act or practice in the conduct
7 of any trade or commerce within the meaning of section 480-2 and
8 shall be subject to the penalties under chapter 480.

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

12 SECTION 3. If any provision of this Act, or the
13 application thereof to any person or circumstance, is held
14 invalid, the invalidity does not affect other provisions or
15 applications of the Act that can be given effect without the
16 invalid provision or application, and to this end the provisions
17 of this Act are severable.

18 SECTION 4. This Act shall take effect on July 1, 2060.



S.B. NO. 2032
S.D. 2
H.D. 1

Report Title:

Genetic Information Privacy Act; Direct-to-Consumer Genetic Testing Company; Genetic Data; Unfair or Deceptive Acts or Practices; Penalty

Description:

Establishes the Hawaii Genetic Information Privacy Act. Requires direct-to-consumer genetic testing companies to adhere to certain requirements pertaining to the collection, use, and disclosure of genetic data. Deems any violation as an unfair or deceptive trade practice subject to associated penalties. Effective 7/1/2060. (HD1)

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