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# 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  
18 results are communicated to the consumer varies by company; some



1 post the results on a secure website that the consumer can  
2 access, some mail a written report to the consumer, and some  
3 share the results over the telephone.

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

19       Accordingly, the purpose of this Act is to protect the  
20 privacy and confidentiality of genetic data of consumers who  
21 order or purchase a genetic testing product or service and



1 submit their biological samples to direct-to-consumer genetic  
2 testing companies by requiring direct-to-consumer genetic  
3 testing companies to adhere to certain requirements pertaining  
4 to the collection, use, and disclosure of genetic data.

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

8 "CHAPTER

9 HAWAII GENETIC INFORMATION PRIVACY ACT

10 § -1 Short title. This chapter shall be known and may  
11 be cited as the Hawaii Genetic Information Privacy Act.

12 § -2 Definitions. As used in this chapter, unless the  
13 context clearly requires otherwise:

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

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

19 "Consumer" means any individual who is a resident of the  
20 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 160.103, 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 "DNA" means deoxyribonucleic acid.

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

8 "Genetic data" includes:

- 9 (1) Raw sequence data that result from the sequencing of a  
10 consumer's complete extracted DNA or a portion of the  
11 extracted DNA;
- 12 (2) Genotypic and phenotypic information that results from  
13 analyzing the raw sequence data; and
- 14 (3) Self-reported health information regarding a  
15 consumer's health conditions that the consumer submits  
16 to a direct-to-consumer genetic testing company that  
17 is:
- 18 (A) Analyzed in connection with the consumer's raw  
19 sequence data; or
- 20 (B) Used for scientific research or product  
21 development.



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

2 "Genetic test" or "genetic testing" means any laboratory  
3 test of a consumer's complete DNA, regions of DNA, chromosomes,  
4 genes, or gene products to determine the presence of a  
5 consumer's genetic characteristics.

6 "Individual" means a natural person.

7 "Person" means any individual, group, partnership, firm,  
8 association, corporation, trust, business trust, estate,  
9 cooperative, consortium, joint venture, or any other form of  
10 business or legal entity, and the legal representative of the  
11 entity.

12 § -3 Direct-to-consumer genetic testing company;  
13 requirements; prohibition. (a) A direct-to-consumer genetic  
14 testing company shall:

15 (1) Provide consumers with a clear and complete written  
16 notice regarding the company's policies and procedures  
17 for the collection, use, and disclosure of genetic  
18 data by making available to the consumer the  
19 following:

20 (A) A high-level privacy policy overview that  
21 includes basic essential information about the



- 1            company's collection, use, and disclosure of  
2            genetic data; and
- 3            (B) A prominent, publicly available written privacy  
4            notice that describes the company's practice  
5            relating to biological samples and genetic data,  
6            including genetic data collection, consumer  
7            consent, use of genetic data, access to genetic  
8            data, disclosure of genetic data, transfer of  
9            genetic data, security protocols, and retention  
10           and deletion of genetic data;
- 11           (2) Obtain the consumer's consent for the collection, use,  
12           or disclosure of the consumer's genetic data,  
13           including:
- 14           (A) Initial express consent that:
- 15                   (i) Clearly describes how the company will use  
16                   the consumer's genetic data collected  
17                   through the direct-to-consumer genetic  
18                   testing product or service;
- 19                   (ii) Specifies who has access to the consumer's  
20                   genetic test results; and







1 research conducted under the control of the  
2 company for the purpose of publication or  
3 generalizable knowledge; and

4 (D) Express consent for the consumer to receive  
5 marketing of products and services:

6 (i) Based on the consumer's genetic data; or

7 (ii) By a third-party person based on the  
8 consumer having ordered or purchased a  
9 direct-to-consumer genetic testing product  
10 or service.

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

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



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

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

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

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

8                 (C) Request and obtain the destruction of the  
9                         consumer's biological sample.

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

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

21           (d) As used in this section:



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

9 **§ -4 Exceptions.** This chapter shall not apply to:

- 10 (1) Protected health information that is collected by a  
11 covered entity or business associate governed by the  
12 privacy, security, and breach notification rules  
13 issued by the United States Department of Health and  
14 Human Services under title 45 Code of Federal  
15 Regulations parts 160 and 164;
- 16 (2) Biological samples that are obtained or genetic data  
17 that is generated for the purposes of an individual's  
18 medical screening, treatment, or diagnosis; and
- 19 (3) A public or private institution of higher education or  
20 an entity owned or operated by a public or private  
21 institution of higher education.



1           §   -5   Violations; civil penalties. Any person who  
2 violates any provision of this chapter shall be assessed a civil  
3 penalty of not less than \$2,500 for each violation in addition  
4 to any other applicable penalties.

5           §   -6   Enforcement; civil action; damages; costs;  
6 attorneys' fees. (a) The director of the office of consumer  
7 protection shall have concurrent jurisdiction with the attorney  
8 general to enforce the provisions of this chapter.

9           (b) The director of the office of consumer protection, by  
10 and through the attorney general, may bring an action in any  
11 court of competent jurisdiction on behalf of the State or as  
12 parens patriae on behalf of consumers to:

- 13           (1) Enjoin any violation of this chapter;  
14           (2) Enjoin any person from continuing to engage in acts in  
15 violation of this chapter or acts in furtherance  
16 thereof;  
17           (3) Collect the penalties provided by section   -5; or  
18           (4) Recover any damages sustained by any person injured by  
19 a violation of this chapter, on whose behalf the  
20 action was brought.



1           In any such action, the State shall also be entitled to  
2 recover the costs of suit together with reasonable attorneys'  
3 fees."

4           SECTION 3. This Act does not affect rights and duties that  
5 matured, penalties that were incurred, and proceedings that were  
6 begun before its effective date.

7           SECTION 4. If any provision of this Act, or the  
8 application thereof to any person or circumstance, is held  
9 invalid, the invalidity does not affect other provisions or  
10 applications of the Act that can be given effect without the  
11 invalid provision or application, and to this end the provisions  
12 of this Act are severable.

13           SECTION 5. This Act shall take effect upon its approval.



**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. Establishes fines for violations. Allows the Office of Consumer Protection to bring civil action against violators. (CD1)

*The summary description of legislation appearing on this page is for informational purposes only and is not legislation or evidence of legislative intent.*

