



GOV. MSG. NO. 1393

EXECUTIVE CHAMBERS
HONOLULU

DAVID Y. IGE
GOVERNOR

July 12, 2022

The Honorable Ronald D. Kouchi,
President
and Members of the Senate
Thirty-First State Legislature
State Capitol, Room 409
Honolulu, Hawai'i 96813

The Honorable Scott K. Saiki,
Speaker and Members of the
House of Representatives
Thirty-First State Legislature
State Capitol, Room 431
Honolulu, Hawai'i 96813

Dear President Kouchi, Speaker Saiki, and Members of the Legislature:

I am transmitting herewith SB2032 SD2 HD2 CD1, without my approval and with the statement of objections relating to the measure.

SB2032 SD2 HD2 CD1

RELATING TO GENETIC INFORMATION
PRIVACY.

Sincerely,

DAVID Y. IGE
Governor, State of Hawai'i

EXECUTIVE CHAMBERS

HONOLULU

July 12, 2022

STATEMENT OF OBJECTIONS TO SENATE BILL NO. 2032

Honorable Members
Thirty-First Legislature
State of Hawai'i

Pursuant to Section 16 of Article III of the Constitution of the State of Hawai'i, I am returning herewith, without my approval, Senate Bill No. 2032, entitled "A Bill for an Act Relating to Genetic Information Privacy."

The purpose of this bill is to regulate direct-to-consumer genetic testing products to protect the privacy and confidentiality of consumers' genetic data. This bill requires direct-to-consumer genetic testing companies to adhere to certain requirements pertaining to the collection, use, and disclosure of genetic data.

This bill is objectionable because while the bill's purpose to protect the consumers' privacy and confidentiality is admirable, the enforcement mechanism provided in the bill appears to be problematic. Specifically, the bill requires the Office of Consumer Protection (OCP) to bring actions to enforce violations through the Attorney General, thereby depriving OCP of its independent authority under section 487-5, Hawaii Revised Statutes (HRS), to initiate actions for the violation of laws enacted for the purpose of consumer protection. In addition, it is not clear whether a consumer would retain the right to file a claim for an unfair and deceptive trade practice under chapter 480, HRS, for a violation of the prohibitions or requirements set forth in the bill. The lack of clarity may inadvertently and undesirably deter consumers from filing their own claims against direct-to-consumer genetic testing companies under chapter 480, HRS.

STATEMENT OF OBJECTIONS
SENATE BILL NO. 2032
Page 2

For the foregoing reasons, I am returning Senate Bill No. 2032 without my approval.

Respectfully,

A handwritten signature in black ink, appearing to read "David Y. Ige". The signature is fluid and cursive, with a large, sweeping flourish at the end.

DAVID Y. IGE
Governor of Hawai'i

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 (iii) Specifies how the genetic data may be
- 2 shared;
- 3 (B) Separate express consent for each of the
- 4 following:
- 5 (i) Transfer or disclosure of the consumer's
- 6 genetic data to any person other than the
- 7 company's vendors and service providers;
- 8 (ii) Use of the consumer's genetic data beyond
- 9 the primary purpose of the direct-to-
- 10 consumer genetic testing product or service
- 11 and inherent contextual uses; and
- 12 (iii) Retention of any biological sample provided
- 13 by the consumer following completion of the
- 14 initial genetic testing service requested by
- 15 the consumer;
- 16 (C) Informed consent in compliance with the federal
- 17 policy for the protection of human research
- 18 subjects prescribed by title 45 Code of Federal
- 19 Regulations part 46, for the transfer or
- 20 disclosure of the consumer's genetic data to
- 21 third-party persons for research purposes or



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.



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

APPROVED this day of , 2022

GOVERNOR OF THE STATE OF HAWAII

THE SENATE OF THE STATE OF HAWAI'I

Date: May 3, 2022
Honolulu, Hawaii 96813

We hereby certify that the foregoing Bill this day passed Final Reading in the Senate of the Thirty-First Legislature of the State of Hawai'i, Regular Session of 2022.


President of the Senate


Clerk of the Senate

SB No. 2032, SD 2, HD 2, CD 1

THE HOUSE OF REPRESENTATIVES OF THE STATE OF HAWAII

Date: May 3, 2022
Honolulu, Hawaii

We hereby certify that the above-referenced Bill on this day passed Final Reading in the House of Representatives of the Thirty-First Legislature of the State of Hawaii, Regular Session of 2022.



Scott K. Saiki
Speaker
House of Representatives



Brian L. Takeshita
Chief Clerk
House of Representatives