

Amendment - Reference - white - Requested by: Daniel Zolnikov - Free Conference
Committee on SB 351

- 2023

68th Legislature 2023

Drafter: Erin Sullivan, 406-444-3594

SB0351.003.001

1 SENATE BILL NO. 351
2 INTRODUCED BY D. ZOLNIKOV

3
4 A BILL FOR AN ACT ENTITLED: "AN ACT REVISING LAWS RELATED TO BIOMETRIC PRIVACY;
5 CREATING THE GENETIC INFORMATION PRIVACY ACT; REQUIRING ~~A COMPANY~~ AN ENTITY TO
6 PROVIDE CONSUMER INFORMATION REGARDING THE COLLECTION, USE, AND DISCLOSURE OF
7 GENETIC DATA; PROVIDING FOR LIMITATIONS AND EXCLUSIONS; PROVIDING FOR ENFORCEMENT
8 AUTHORITY; AND PROVIDING DEFINITIONS."

9
10 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

11
12 NEW SECTION. Section 1. Short title. [Sections 1 through 6] may be cited as the "Genetic
13 Information Privacy Act".

14
15 NEW SECTION. Section 2. Definitions. As used in [sections 1 through 6], unless the context clearly
16 indicates otherwise, the following definitions apply:

17 (1) "Biological sample" means any human material known to contain DNA, including tissue, blood,
18 urine, or saliva.

19 ~~(2) (a) "Company" means an entity that:~~

20 ~~(i) offers consumer genetic testing products or services directly to a consumer; or~~

21 ~~(ii) collects, uses, or analyzes genetic data that resulted from a direct to consumer genetic testing~~
22 ~~product or service and was provided to the company by a consumer FOR A COMMERCIAL PURPOSE.~~

23 ~~(b) The term does not include an entity when it is engaged only in collecting, using, or analyzing~~
24 ~~genetic data or biological samples in the context of research as defined in 45 CFR 164.501 conducted in~~
25 ~~accordance with the federal policy for the protection of human research subjects under 45 CFR, part 46, the~~
26 ~~good clinical practice guideline issued by the international council for harmonisation of technical requirements~~
27 ~~for pharmaceuticals for human use, or the United States food and drug administration policy for the protection~~

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1 ~~of human subjects under 21 CFR, parts 50 and 56.~~

2 ~~(3)(2)~~ "Consumer" means an individual who is a resident of this state.

3 ~~(4)(3)~~ "Deidentified data" means data that:

4 (a) cannot be reasonably linked to an identifiable individual; and

5 (b) is possessed by ~~a company an entity~~ that:

6 (i) takes administrative and technical measures to ensure that the data cannot be associated with

7 a particular consumer;

8 (ii) makes a public commitment to maintain and use data in deidentified form and to not attempt to

9 reidentify data; and

10 (iii) enters a legally enforceable contractual obligation that prohibits a recipient of the data from

11 attempting to reidentify the data.

12 ~~(5)(4)~~ "DNA" means deoxyribonucleic acid.

13 ~~(5)~~ "Entity" means a partnership, corporation, association, or public or private organization of any

14 character that:

15 (a) offers consumer genetic testing products or services directly to a consumer; or

16 (b) collects, uses, or analyzes genetic data.

17 (6) "Express consent" means a consumer's affirmative response to a clear, meaningful, and

18 prominent notice regarding the collection, use, or disclosure of genetic data for a specific purpose.

19 (7) (a) "Genetic data" means any data, regardless of format, concerning a consumer's genetic

20 characteristics.

21 (b) The term includes but is not limited to:

22 (i) raw sequence data that result from sequencing all or a portion of a consumer's extracted DNA;

23 (ii) genotypic and phenotypic information obtained from analyzing a consumer's raw sequence

24 data; and

25 (iii) self-reported health information regarding a consumer's health conditions that the consumer

26 provides to ~~a company an entity~~ that the ~~company entity~~:

27 (A) uses for scientific research or product development; and

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1 (B) analyzes in connection with the consumer's raw sequence data.

2 ~~(c) The term does not include deidentified data.~~

3 (8) "Genetic testing" means:

4 (a) a laboratory test of a consumer's complete DNA, regions of DNA, chromosomes, genes, or
5 gene products to determine the presence of genetic characteristics of a consumer; or

6 (b) an interpretation of a consumer's genetic data.

7 ~~(9) "Governmental agency" means an executive, legislative, or judicial agency, department, board,
8 commission, authority, institution, or instrumentality of the federal government or of a state or of a county,
9 municipality, or other political subdivision of a state.~~

10 ~~(9)(10)~~ "Person" means an individual, partnership, corporation, association, business, business trust,
11 or legal representative of an organization.

12

13 **NEW SECTION. Section 3. Limitations Exceptions.** (1) [Sections 1 through 6] do not apply to:

14 (a) protected health information that is collected by a covered entity or business associate as
15 those terms are defined in 45 CFR, parts 160 and 164, ~~if separate informed consent related to the collection,
16 use, and dissemination of genetic data is obtained from the consumer, parent, guardian, or power of attorney,
17 and the covered entity or business associate follows the policies under [sections 4(6)(a) through (6)(d)];~~

18 (b) ~~an entity when it is engaged only in collecting, using, or analyzing genetic data or biological
19 samples in the context of research as defined in 45 CFR 164.501 conducted with the express consent of an
20 individual and in accordance with:~~

21 (i) ~~the federal policy for the protection of human research subjects under 45 CFR, part 46, the
22 good clinical practice guideline issued by the international council for harmonisation of technical requirements
23 for pharmaceuticals for human use; or~~

24 (ii) ~~the United States food and drug administration policy for the protection of human subjects
25 under 21 CFR, parts 50 and 56; or~~

26 (c) ~~uses by a governmental agency.~~

27 (2) ~~Beginning June 1, 2025, any collection, storage, use, or dissemination of genetic data by a~~

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1 governmental agency must be performed in accordance with a specific state law or executed through a search
2 warrant.

3

4 NEW SECTION. Section 4. Consumer genetic data -- privacy notice -- consent -- access --
5 deletion -- destruction. To safeguard the privacy, confidentiality, security, and integrity of a consumer's
6 genetic data, a company an entity shall:

7 (1) provide clear and complete information regarding the company's entity's policies and
8 procedures for the collection, use, or disclosure of genetic data by making available to a consumer:

9 (a) a high-level privacy policy overview that includes basic, essential information about the
10 company's entity's collection, use, or disclosure of genetic data; and

11 (b) a prominent, publicly available privacy notice that includes, at a minimum, information about the
12 company's entity's data collection, consent, use, access, disclosure, transfer, security, and retention and
13 deletion practices;

14 (2) obtain a consumer's initial express consent from a consumer, parent, guardian, or power of
15 attorney for the collection, use, or disclosure of the consumer's genetic data that:

16 (a) clearly describes the company's entity's use of the genetic data that the company entity collects
17 through the company's entity's genetic testing product or service;

18 (b) specifies who has access to test results; and

19 (c) specifies how the company entity may share the genetic data;

20 (3) if the company entity engages in any of the following, obtain a consumer's:

21 (a) separate express consent for:

22 (i) the transfer or disclosure of the consumer's genetic data to any person other than the

23 company's entity's vendors and service providers, including the name of the third party to which the consumer's
24 genetic data or biological sample will be transferred or disclosed with the consumer's express consent;

25 (ii) the use of genetic data beyond the primary purpose of the company's entity's genetic testing
26 product or service and inherent contextual uses; or

27 (iii) the company's entity's retention of any biological sample provided by the consumer following

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- 1 the ~~company's entity's~~ completion of the initial testing service requested by the consumer;
- 2 (b) informed express consent ~~in accordance with the federal policy for the protection of human~~
- 3 ~~research subjects under 45 CFR, part 46,~~ for transfer or disclosure of the consumer's genetic data to third party
- 4 persons for:
- 5 (i) research purposes; or
- 6 (ii) research conducted under the control of the company entity for the purpose of publication or
- 7 generalizable knowledge; and
- 8 (c) express consent for:
- 9 (i) marketing to a consumer based on the consumer's genetic data; ~~or~~
- 10 (ii) marketing by a third-party person to a consumer based on the consumer having ordered or
- 11 purchased a genetic testing product or service. Marketing does not include the provision of customized content
- 12 or offers on the websites or through the applications or services provided by the company entity with the first-
- 13 party relationship to the customer; ~~;~~ or
- 14 (iii) sale or other valuable consideration of the consumer's genetic data.
- 15 (4) comply with the provisions of 44-6-104 requiring a valid legal process for disclosing genetic
- 16 data to law enforcement or any other government agency without a consumer's express ~~written~~ consent;
- 17 (5) develop, implement, and maintain a comprehensive security program to protect a consumer's
- 18 genetic data against unauthorized access, use, or disclosure; and
- 19 (6) provide a process for a consumer to:
- 20 (a) access the consumer's genetic data;
- 21 (b) delete the consumer's genetic data; ~~and~~
- 22 (c) revoke any consent provided by the consumer; and
- 23 ~~(e)(d)~~ request and obtain the destruction of the consumer's biological sample.
- 24 (7) GENETIC DATA OF MONTANA RESIDENTS OR BIOMETRIC DATA COLLECTED IN THE STATE MUST BE
- 25 STORED WITHIN THE TERRITORIAL BOUNDARIES OF THE UNITED STATES. Genetic data of Montana residents or
- 26 biometric data collected in the state may not be stored within the territorial boundaries of any country currently
- 27 sanctioned in any way by the United States office of foreign asset control or designated as a foreign adversary

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1 under 15 CFR 7.4(a). Genetic data of Montana residents or biometric data collected in the state may only be
2 transferred or stored outside the United States with the consent of the resident.

3
4 **NEW SECTION. Section 5. Disclosure -- when prohibited -- when written express consent**
5 **required.** (1) The disclosure of genetic data pursuant to [sections 1 through 6] must comply with all state and
6 federal laws for the protection of privacy and security.

7 ~~(2) [Sections 1 through 6] may not apply to protected health information that is collected by a~~
8 ~~covered entity or business associate governed by the privacy, security, and breach notification rules issued by~~
9 ~~the:~~

10 ~~(a) United States department of health and human services, 45 CFR, parts 160 and 164,~~
11 ~~established pursuant to the federal Health Insurance Portability and Accountability Act of 1996; and~~

12 ~~(b) federal Health Information Technology for Economic and Clinical Health Act of 2009.~~

13 ~~(3)(2)~~ Notwithstanding any other provisions in [section 4], ~~a company an entity may~~ HAS THE SOLE
14 AUTHORITY TO MAY not disclose a consumer's genetic data to any entity offering health insurance, life insurance,
15 or long-term care insurance, or to any employer of the consumer without the consumer's written express
16 consent.

17
18 **NEW SECTION. Section 6. Enforcement.** (1) The attorney general may has the sole authority to
19 enforce [sections 1 through 6].

20 (2) The attorney general may initiate a civil enforcement action against a person for violation of
21 [sections 1 through 6].

22 (3) In an action to enforce [sections 1 through 6], the attorney general may recover:

23 (a) actual damages to the consumer;

24 (b) costs;

25 (c) reasonable attorney fees; and

26 (d) \$2,500 for each violation of [section 4].

27