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LEGISLATIVE BILL 308

Approved by the Governor February 13, 2024

Introduced by Bostar, 29.

A BILL FOR AN ACT relating to public health and welfare; to adopt the Genetic Information Privacy Act.
Be it enacted by the people of the State of Nebraska,

Section 1. Sections 1 to 4 of this act shall be known and may be cited as the Genetic Information Privacy Act.

Sec. 2. For purposes of the Genetic Information Privacy Act:

(1) Biological sample means any material part of a human being, discharge therefrom, or derivative thereof, such as tissue, blood, urine, or saliva, known to contain DNA;

(2) Consumer means an individual who is a resident of Nebraska;

(3) Direct-to-consumer genetic testing company or company means an entity that (a) offers consumer genetic testing products or services directly to a consumer, or (b) collects, uses, or analyzes genetic data that resulted from a direct-to-consumer genetic testing product or service and was provided to the company by a consumer. Direct-to-consumer genetic testing company does not include any entity that is solely engaged in collecting, using, or analyzing genetic data or biological samples in the context of research, as defined in 45 C.F.R. 164.501, conducted in accordance with the Federal Policy for the Protection of Human Subjects, 45 C.F.R. part 46, the Good Clinical Practice Guideline issued by the International Council for Harmonisation, or the United States Food and Drug Administration Policy for the Protection of Human Subjects under 21 C.F.R. parts 50 and 56;

(4) DNA means deoxyribonucleic acid;

(5) Express consent means a consumer's affirmative response to a clear, meaningful, and prominent notice regarding the collection, use, or disclosure of genetic data for a specific purpose;

(6)(a) Genetic data means any data, regardless of its format, that concerns a consumer's genetic characteristics. Genetic data includes, but is not limited to: (i) Raw sequence data that results from sequencing of a consumer's complete extracted DNA or a portion of the extracted DNA; (ii) genotypic and phenotypic information that results from analyzing the raw sequence data; and (iii) self-reported health information that a consumer submits to a company regarding the consumer's health conditions and that is used for scientific research or product development and analyzed in connection with the consumer's raw sequence data.

(b) Genetic data does not include de-identified data. For purposes of this subdivision, de-identified data means data that cannot reasonably be used to infer information about, or otherwise be linked to, an identifiable consumer, and that is subject to: (i) Administrative and technical measures to ensure that the data cannot be associated with an identifiable consumer; (ii) public commitment by the company to maintain and use data in de-identified form and not attempt to reidentify data; and (iii) legally enforceable contractual obligations that prohibit any recipients of the data from attempting to reidentify the data;

(7) Genetic testing means any laboratory test of a consumer's complete DNA, regions of DNA, chromosomes, genes, or gene products to determine the presence of genetic characteristics of a consumer; and

(8) Person means an individual, partnership, corporation, association, business, business trust, or legal representative of an organization.

Sec. 3. (1) In order to safeguard the privacy, confidentiality, security, and integrity of a consumer's genetic data, a direct-to-consumer genetic testing company shall:

(a) Provide clear and complete information regarding the company's policies and procedures for collection, use, or disclosure of genetic data by making available to a consumer: (i) A high-level privacy policy overview that includes basic information about the company's collection, use, or disclosure of genetic data; and (ii) a prominent, publicly available privacy notice that includes, at a minimum, information about the company's data collection, consent, use, access, disclosure, transfer, security, and retention and deletion practices;

(b) Obtain a consumer's consent for collection, use, or disclosure of the consumer's genetic data, including:

(i) Initial express consent that clearly states the uses for which the genetic data collected through the genetic testing product or service is intended, specifies the parties who have access to test results, and the means by which such genetic data may be shared;

(ii) Separate express consent for transferring or disclosing the consumer's genetic data to any person other than the company's vendors and service providers, or for using genetic data for purposes not stated in subdivision (1)(b)(i) of this section and inherent contextual uses;

(iii) Separate express consent for the retention of any biological sample provided by the consumer following completion of the initial testing service

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requested by the consumer;

(iv) Informed consent in compliance with the Federal Policy for the Protection of Human Research Subjects, as described in 45 C.F.R. part 46, for transfer or disclosure of the consumer's genetic data to third-party persons for research purposes or research conducted under the control of the company for the purpose of publication or generalizable knowledge; and

(v) Express consent for marketing to a consumer based on the consumer's genetic data or for marketing by a third-party person to a consumer based on the order or purchase by a consumer of a genetic testing product or service. For purposes of this subdivision, marketing does not include the provision of customized content or offers on websites or through applications or services provided by the direct-to-consumer genetic testing company having the first-party relationship to the consumer;

(c) Require a court order before disclosing genetic data to any government agency, including law enforcement, without the consumer's express written consent;

(d) Develop, implement, and maintain a comprehensive security program to protect a consumer's genetic data from unauthorized access, use, or disclosure; and

(e) Provide a process for a consumer to (i) access the consumer's genetic data, (ii) delete the consumer's account and genetic data, and (iii) request and obtain written documentation verifying the destruction of the consumer's biological sample.

(2) A direct-to-consumer genetic testing company shall not disclose a consumer's genetic data to any entity offering health insurance, life insurance, or long-term care insurance or to any employer of the consumer without the consumer's written consent.

(3) The Attorney General may bring an action to enforce the provisions of the Genetic Information Privacy Act. A violation of the act is subject to a civil penalty of two thousand five hundred dollars for each violation, in addition to actual damages incurred by the consumer, and costs and reasonable attorney's fees incurred by the Attorney General. Within thirty days after receipt of any civil penalty amount, the Attorney General shall remit such amount to the State Treasurer to be distributed in accordance with Article VII, section 5, of the Constitution of Nebraska.

Sec. 4. (1) The Genetic Information Privacy Act does not apply to protected health information collected by a covered entity or business associate as those terms are defined in 45 C.F.R. parts 160 and 164.

(2) The disclosure of genetic data pursuant to the Genetic Information Privacy Act shall comply with all state and federal laws for the protection of privacy and security. The act shall not apply to protected health information collected by a covered entity or business associate governed by the privacy, security, and breach notification rules issued by the federal Department of Health and Human Services, 45 C.F.R. parts 160 and 164, established pursuant to the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, and the Health Information Technology for Economic and Clinical Health Act, enacted as part of the American Recovery and Reinvestment Act of 2009, Public Law 111-5.