State of Tennessee

PUBLIC CHAPTER NO. 324

HOUSE BILL NO. 1310

By Representatives Kumar, Vital, Ragan, Moody

Substituted for: Senate Bill No. 1295

By Senators Bailey, Stevens

AN ACT to amend Tennessee Code Annotated, Title 47, relative to genetic information.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 47, Chapter 18, is amended by adding the following as a new part:

47-18-4901.

This part is known as the "Genetic Information Privacy Act."

47-18-4902.

As used in this part:

(1) "Biological sample" means a human material known to contain DNA, including tissue, blood, urine, or saliva;

(2) "Consumer" means an individual who is a resident of the state;

(3) "Deidentified data" means data that:

(A)

(i) Cannot reasonably be linked to an identifiable individual; or

(ii) Meets the standard for deidentification under the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) (42 U.S.C. § 1320d et seq.) and rules promulgated pursuant to that act; and

(B) Is possessed by a company that:

(i) Takes administrative and technical measures to ensure that the data cannot be associated with a particular consumer;

(ii) Makes a public commitment to maintain and use data in deidentified form and not attempt to reidentify data; and

(iii) Enters into a legally enforceable contractual obligation that prohibits a recipient of the data from attempting to reidentify the data;

(4) "Direct-to-consumer genetic testing company" or "company":

(A) Means an entity that:

(i) Offers consumer genetic testing products or services directly to a consumer; or

(ii) 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; and

(B) Does not include:

(i) A law enforcement agency; or

(ii) An entity that is, and only while, engaged in collecting, using, or analyzing genetic data or biological samples in the context of research, as defined in 45 CFR § 164.501, that is conducted in accordance with:

(*a*) The Federal Policy for the Protection of Human Subjects, as described in 45 CFR Part 46;

(*b*) The Good Clinical Practice Guideline issued by the International Council for Harmonization; or

(*c*) The United States Food and Drug Administration Policy for the Protection of Human Subjects under 21 CFR Parts 50 and 56;

(5) "DNA" means deoxyribonucleic acid;

(6) "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;

(7) "First-party relationship" means the relationship between a company and a consumer from which the company has collected genetic data;

(8) "Genetic data" means data, excluding deidentified data, regardless of format, concerning a consumer's genetic characteristics, including:

(A) Raw sequence data that results from sequencing all or a portion of a consumer's extracted DNA;

(B) Genotypic and phenotypic information obtained from analyzing a consumer's raw sequence data; or

(C) Self-reported health information regarding a consumer's health conditions that the consumer provides to a company and that the company:

(i) Uses for scientific research or product development; and

(ii) Analyzes in connection with the consumer's raw sequence data;

(9) "Genetic testing" means:

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

(B) An interpretation of a consumer's genetic data; and

(10) "Person" means an individual, corporation, business, partnership, limited liability company, or other business entity.

47-18-4903.

This part does not apply to:

(1) Protected health information that is collected by a covered entity or business associate as those terms are defined in 45 CFR Parts 160 and 164;

(2) A public or private institution of higher education;

(3) An entity owned or operated by a public or private institution of higher education;

(4) Biomedical or academic research conducted by a research hospital, academic medical center, or other entity affiliated with such hospital or medical center that is not a direct-to-consumer genetic testing company;

(5) Genetic data that is shared with or by a research hospital, academic medical center, or other entity affiliated with such hospital or medical center that is not a direct-to-consumer genetic testing company for the purposes of biomedical or academic research or to find causes of or cures for a disease or medical condition; or

(6) The sharing of genetic data that does not require consent pursuant to the Federal Policy for the Protection of Human Subjects, as described in 45 CFR Part 46.

47-18-4904.

(a) A direct-to-consumer genetic testing company shall:

(1) Provide to a consumer:

(A) Essential information about the company's collection, use, and disclosure of genetic data; and

(B) A prominent, publicly available privacy notice that includes information about the company's data collection, consent, use, access, disclosure, transfer, security, retention, and deletion practices;

(2) Obtain a consumer's initial express consent for collection, use, or disclosure of the consumer's genetic data that:

(A) Clearly describes the company's use of the genetic data that the company collects through the company's genetic testing product or service;

(B) Specifies who has access to test results; and

(C) Specifies how the company may share the genetic data;

(3) If the company engages in the following conduct, obtain a consumer's:

(A) Separate express consent for:

(i) The transfer or disclosure of the consumer's genetic data to a person other than the company's vendors and service providers;

(ii) The use of genetic data beyond the primary purpose of the company's genetic testing product or service; or

(iii) The company's retention of a biological sample provided by the consumer following the company's completion of the initial testing service requested by the consumer;

(B) Informed consent in accordance with the Federal Policy for the Protection of Human Subjects, as described in 45 CFR Part 46, for transfer or disclosure of the consumer's genetic data to a third party for:

(i) Research purposes; or

(ii) Research conducted under the control of the company for the purpose of publication or generalizable knowledge; and

(C) Express consent for:

(i) Marketing to a consumer based on the consumer's genetic data; or

(ii) Marketing by a third-party person to a consumer based on the consumer having ordered or purchased a genetic testing product or service;

(4) Require valid legal process for the company's disclosure of a consumer's genetic data to law enforcement or a government entity without the consumer's express written consent;

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

(6) Provide a process for a consumer to:

(A) Access the consumer's genetic data;

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

(C) Destroy the consumer's biological sample.

(b) Notwithstanding subdivision (a)(3)(C), a direct-to-consumer genetic testing company with a first-party relationship to a consumer may, without obtaining the consumer's express consent, provide customized content or offers on the company's website or through the company's application or service.

47-18-4905.

A direct-to-consumer genetic testing company shall not disclose a consumer's genetic data without first obtaining the consumer's written consent to:

(1) An entity that offers health insurance, life insurance, or long-term care insurance; or

(2) An employer of the consumer.

47-18-4906.

The division of consumer affairs in the office of the attorney general and reporter shall enforce this part. The division shall:

(1) Establish a means by which a consumer can submit a complaint for a violation of this part; and

(2) Promulgate rules to effectuate this part. The rules must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

SECTION 2. This act takes effect July 1, 2023, the public welfare requiring it, and applies to conduct occurring on or after that date.

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PASSED: April 10, 2023

CAMERON SEXTON, SPEAKER
HOUSE OF REPRESENTATIVES

RANDY MCNALLY
SPEAKER OF THE SENATE

APPROVED this 28th day of April 2023

BILL LEE, GOVERNOR