

HOUSE BILL 1310

By Kumar

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-_____.

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

47-18-_____.

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) Cannot reasonably be linked to an identifiable individual; 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" means an entity that:

(A) Offers consumer genetic testing products or services directly to consumers; or

(B) Collects, uses, or analyzes genetic data that a consumer provides to the entity;

(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-_____.

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; or

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

47-18-_____.

(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, 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-_____.

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-_____.

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.