

AN ACT

relating to an individual's genetic data, including the use of that data by certain genetic testing companies for commercial purposes and the individual's property right in DNA; authorizing a civil penalty.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subtitle A, Title 11, Business & Commerce Code, is amended by adding Chapter 503A to read as follows:

CHAPTER 503A. DIRECT-TO-CONSUMER GENETIC TESTING COMPANIES; RIGHTS

REGARDING DNA

Sec. 503A.001. DEFINITIONS. In this chapter:

(1) "Biological sample" means a material part of the human body, or a discharge or derivative part of the body, including tissue, blood, urine, or saliva that is known to contain DNA.

(2) "Deidentified data" means data not reasonably linked to and that cannot reasonably be used to infer information about an identifiable individual.

(3) "Direct-to-consumer genetic testing company" means an entity that:

(A) offers genetic testing products or services directly to individuals as consumers of those products or services;  
or

(B) collects, uses, or analyzes genetic data that:

1                   (i) results from a direct-to-consumer  
2 genetic testing product or service; and

3                   (ii) an individual rather than a health  
4 care provider provides to the entity.

5                   (4) "DNA" means deoxyribonucleic acid.

6                   (5) "Express consent" means an individual's  
7 affirmative response to a clear and meaningful notice regarding the  
8 collection, use, or disclosure of genetic data for a specific  
9 purpose.

10                   (6) "Genetic data" means any data, regardless of  
11 format, concerning an individual's genetic characteristics. The  
12 term:

13                   (A) includes:

14                   (i) raw sequence data derived from  
15 sequencing all or a portion of an individual's extracted DNA;

16                   (ii) genotypic and phenotypic information  
17 obtained from analyzing an individual's raw sequence data; and

18                   (iii) health information regarding the  
19 health conditions that an individual self-reports to a company and  
20 that the company:

21                   (a) uses for scientific research or  
22 product development; and

23                   (b) analyzes in connection with the  
24 individual's raw sequence data; and

25                   (B) does not include deidentified data.

26                   (7) "Genetic testing" means a laboratory test of an  
27 individual's complete DNA, regions of DNA, chromosomes, genes, or

1 gene products to determine the presence of the individual's genetic  
2 characteristics.

3 (8) "Person" means an individual, partnership,  
4 corporation, association, business, or business trust or the legal  
5 representative of an organization.

6 Sec. 503A.002. APPLICABILITY. (a) This chapter applies to  
7 a direct-to-consumer genetic testing company that:

8 (1) offers its products or services to individuals who  
9 are residents of this state; or

10 (2) collects, uses, or analyzes genetic data that:

11 (A) results from the company's products or  
12 services; and

13 (B) was provided to the company by an individual  
14 who is a resident of this state rather than by or at the direction of  
15 a health care provider.

16 (b) This chapter does not apply to:

17 (1) an entity only when they are engaged in  
18 collecting, using, or analyzing genetic data or biological samples  
19 in the context of research, as defined by 45 C.F.R. Section 164.501,  
20 that is conducted in accordance with:

21 (A) the federal policy for the protection of  
22 human subjects (45 C.F.R. Part 46);

23 (B) the good clinical practice guidelines issued  
24 by the International Council for Harmonisation of Technical  
25 Requirements for Pharmaceuticals for Human Use (ICH); or

26 (C) the United States Food and Drug  
27 Administration policy for the protection of human subjects (21

1 C.F.R. Parts 50 and 56);

2 (2) genetic data that is protected health information  
3 collected by a covered entity or business associate, as defined by  
4 45 C.F.R. Part 160, subject to the privacy, security, and breach  
5 notification rules under the Health Insurance Portability and  
6 Accountability Act of 1996 (42 U.S.C. Section 1320d et seq.);

7 (3) an institution of higher education or a private or  
8 independent institution of higher education, as those terms are  
9 defined by Section 61.003, Education Code;

10 (4) an entity when the entity is offering genetic  
11 testing products or services through a health care provider; or

12 (5) the collection, use, or analysis of genetic data  
13 by a health care provider.

14 Sec. 503A.003. EXCLUSIVE PROPERTY RIGHT IN DNA;  
15 CONFIDENTIALITY. An individual has a property right in, and  
16 retains the right to exercise exclusive control over, the  
17 individual's biological sample that is provided to or used by a  
18 direct-to-consumer genetic testing company and the results of  
19 genetic testing or analysis conducted on the individual's DNA by a  
20 direct-to-consumer genetic testing company, including to the  
21 collection, use, retention, maintenance, disclosure, or  
22 destruction of the sample or results. The results of the genetic  
23 testing of an individual's DNA are confidential and may not be  
24 disclosed to another person without the individual's express  
25 consent.

26 Sec. 503A.004. REQUIREMENTS FOR CERTAIN USES OF  
27 DEIDENTIFIED DATA. (a) Except as otherwise provided by this

1 chapter or other law, a direct-to-consumer genetic testing company  
2 that possesses an individual's deidentified data shall:

3 (1) implement administrative and technical measures  
4 to ensure the data is not associated with a particular individual;  
5 and

6 (2) publicly commit to maintaining and using data in  
7 deidentified form and refraining from making any attempt to  
8 identify an individual using the individual's deidentified data.

9 (b) If a direct-to-consumer genetic testing company shares  
10 an individual's deidentified data with another person, the company  
11 shall enter into a legally enforceable contractual obligation  
12 prohibiting the person from attempting to identify an individual  
13 using the individual's deidentified data.

14 Sec. 503A.005. REQUIREMENTS FOR CERTAIN USES OR DISCLOSURE  
15 OF GENETIC DATA AND BIOLOGICAL SAMPLE. (a) A direct-to-consumer  
16 genetic testing company shall:

17 (1) develop, implement, and maintain a comprehensive  
18 security program to protect an individual's genetic data against  
19 unauthorized access, use, or disclosure; and

20 (2) make publicly available:

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

24 (B) a prominent privacy notice that includes  
25 information about the company's data collection, consent, use,  
26 access, disclosure, transfer, security, retention, and deletion  
27 practices.

1        (b) Before collecting, using, or disclosing an individual's  
2 genetic data, a direct-to-consumer genetic testing company shall  
3 provide to the individual information about the company's  
4 collection, use, and disclosure of genetic data the company  
5 collects through a genetic testing product or service, including  
6 information that:

7            (1) clearly describes the company's use of the genetic  
8 data;

9            (2) specifies the persons who have access to test  
10 results; and

11           (3) specifies the manner in which the company may  
12 share the genetic data.

13        (c) A direct-to-consumer genetic testing company shall  
14 provide a process for an individual to:

15           (1) access the individual's genetic data;

16           (2) delete the individual's account and genetic data;  
17 and

18           (3) destroy or require the destruction of the  
19 individual's biological sample.

20        Sec. 503A.006. REQUIRED CONSENT. (a) A direct-to-consumer  
21 genetic testing company engaging in any of the following activities  
22 must obtain:

23           (1) an individual's separate express consent for:

24                (A) the transfer or disclosure of the  
25 individual's genetic data to any person other than the company's  
26 vendors and service providers;

27                (B) the use of genetic data for a purpose other

1 than the primary purpose of the company's genetic testing product  
2 or service; or

3 (C) the retention of any biological sample  
4 provided by the individual following the company's completion of  
5 the initial testing service requested by the individual;

6 (2) an individual's informed consent in accordance  
7 with guidelines for the protection of human subjects issued under  
8 45 C.F.R. Part 46, for transfer or disclosure of the individual's  
9 genetic data to a third party for:

10 (A) research purposes; or

11 (B) research conducted under the control of the  
12 company for the purpose of publication or generalizable knowledge;  
13 and

14 (3) an individual's express consent for:

15 (A) marketing by the company to the individual  
16 based on the individual's genetic data; or

17 (B) marketing by a third party to the individual  
18 based on the individual's ordering or purchasing of a genetic  
19 testing product or service.

20 (b) For purposes of Subsection (a), "marketing" does not  
21 include providing customized content or offers to an individual  
22 with whom a direct-to-consumer genetic testing company has a  
23 first-party relationship on the company's Internet website or  
24 through an application or service provided by the company to the  
25 individual.

26 Sec. 503A.007. PROHIBITED DISCLOSURES. (a) A  
27 direct-to-consumer genetic testing company may not disclose an

1 individual's genetic data to a law enforcement entity or other  
2 governmental body unless:

3 (1) the company first obtains the individual's express  
4 written consent; or

5 (2) the entity or body obtains a warrant or complies  
6 with another valid legal process required by the company.

7 (b) A direct-to-consumer genetic testing company may not  
8 disclose, without first obtaining an individual's written consent,  
9 the individual's genetic data to:

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

12 (2) an employer of the individual.

13 Sec. 503A.008. CIVIL PENALTY. (a) A direct-to-consumer  
14 genetic testing company that violates this chapter is liable to  
15 this state for a civil penalty in an amount not to exceed \$2,500 for  
16 each violation.

17 (b) The attorney general may bring an action to recover a  
18 civil penalty imposed under Subsection (a) and to restrain and  
19 enjoin a violation of this chapter. The attorney general may  
20 recover reasonable attorney's fees and court costs incurred in  
21 bringing the action.

22 SECTION 2. The changes in law made by this Act apply only to  
23 genetic information obtained on or after the effective date of this  
24 Act.

25 SECTION 3. This Act takes effect September 1, 2023.



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President of the Senate

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Speaker of the House

I certify that H.B. No. 2545 was passed by the House on April 28, 2023, by the following vote: Yeas 144, Nays 0, 2 present, not voting; and that the House concurred in Senate amendments to H.B. No. 2545 on May 17, 2023, by the following vote: Yeas 146, Nays 0, 1 present, not voting.

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Chief Clerk of the House

I certify that H.B. No. 2545 was passed by the Senate, with amendments, on May 15, 2023, by the following vote: Yeas 31, Nays 0.

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Secretary of the Senate

APPROVED: \_\_\_\_\_

Date

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Governor