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H.B. No. 2545

A BILL TO BE ENTITLED

AN ACT

1
2 relating to the use of an individual's genetic data by certain
3 genetic testing companies for commercial purposes; authorizing a
4 civil penalty.

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

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

8 CHAPTER 503A. DIRECT-TO-INDIVIDUAL GENETIC TESTING COMPANIES

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

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

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

16 (3) "Direct-to-individual genetic testing company"
17 means an entity that:

18 (A) offers genetic testing products or services
19 directly to individuals; or

20 (B) collects, uses, or analyzes genetic data that
21 results from a direct-to-individual genetic testing product or
22 service and that an individual provides to the entity.

23 (4) "DNA" means deoxyribonucleic acid.

24 (5) "Express consent" means an individual's

1 affirmative response to a clear and meaningful notice regarding the
2 collection, use, or disclosure of genetic data for a specific
3 purpose.

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

7 (A) includes:

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

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

12 (iii) health information regarding the
13 health conditions that an individual self-reports to a company and
14 that the company:

15 (a) uses for scientific research or
16 product development; and

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

19 (B) does not include deidentified data.

20 (7) "Genetic testing" means a laboratory test of an
21 individual's complete DNA, regions of DNA, chromosomes, genes, or
22 gene products to determine the presence of the individual's genetic
23 characteristics.

24 (8) "Person" means an individual, partnership,
25 corporation, association, business, or business trust or the legal
26 representative of an organization.

27 Sec. 503A.002. APPLICABILITY. (a) This chapter applies to

1 a direct-to-individual genetic testing company that:

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

4 (2) collects, uses, or analyzes genetic data that
5 results from the company's products or services and was provided to
6 the company by an individual who is a resident of this state.

7 (b) This chapter does not apply to:

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

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

14 (B) the good clinical practice guidelines issued
15 by the International Council for Harmonisation of Technical
16 Requirements for Pharmaceuticals for Human Use (ICH); or

17 (C) the United States Food and Drug
18 Administration policy for the protection of human subjects (21
19 C.F.R. Parts 50 and 56);

20 (2) genetic data that is protected health information
21 collected by a covered entity or business associate, as defined by
22 45 C.F.R. Part 160, subject to the privacy, security, and breach
23 notification rules under the Health Insurance Portability and
24 Accountability Act of 1996 (42 U.S.C. Section 1320d et seq.); or

25 (3) an institution of higher education or a private or
26 independent institution of higher education, as those terms are
27 defined by Section 61.003, Education Code.

1 Sec. 503A.003. REQUIREMENTS FOR CERTAIN USES OF
2 DEIDENTIFIED DATA. (a) Except as otherwise provided by this
3 chapter or other law, a direct-to-individual genetic testing
4 company that possesses an individual's deidentified data shall:

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

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

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

16 Sec. 503A.004. REQUIREMENTS FOR CERTAIN USES OR DISCLOSURE
17 OF GENETIC DATA AND BIOLOGICAL SAMPLE. (a) A direct-to-individual
18 genetic testing company shall:

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

22 (2) make publicly available:

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

26 (B) a prominent privacy notice that includes
27 information about the company's data collection, consent, use,

1 access, disclosure, transfer, security, retention, and deletion
2 practices.

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

9 (1) clearly describes the company's use of the genetic
10 data;

11 (2) specifies the persons who have access to test
12 results; and

13 (3) specifies the manner in which the company may
14 share the genetic data.

15 (c) A direct-to-individual genetic testing company shall
16 provide a process for an individual to:

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

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

19 and

20 (3) destroy or require the destruction of the
21 individual's biological sample.

22 Sec. 503A.005. REQUIRED CONSENT. (a) A

23 direct-to-individual genetic testing company engaging in any of the
24 following activities must obtain:

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

26 (A) the transfer or disclosure of the

27 individual's genetic data to any person other than the company's

1 vendors and service providers;

2 (B) the use of genetic data for a purpose other
3 than the primary purpose of the company's genetic testing product
4 or service; or

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

8 (2) an individual's informed consent in accordance
9 with guidelines for the protection of human subjects issued under
10 45 C.F.R. Part 46, for transfer or disclosure of the individual's
11 genetic data to a third party for:

12 (A) research purposes; or

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

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

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

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

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

1 Sec. 503A.006. PROHIBITED DISCLOSURES. (a) A

2 direct-to-individual genetic testing company may not disclose an
3 individual's genetic data to a law enforcement entity or other
4 governmental body unless:

5 (1) the company first obtains the individual's express
6 written consent; or

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

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

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

14 (2) an employer of the individual.

15 Sec. 503A.007. CIVIL PENALTY. (a) A direct-to-individual
16 genetic testing company that violates this chapter is liable to
17 this state for a civil penalty in an amount not to exceed \$2,500 for
18 each violation.

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

24 SECTION 2. The changes in law made by this Act apply only to
25 genetic information obtained by a direct-to-individual genetic
26 testing company on or after the effective date of this Act.

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