

1 AN ACT relating to genetic information.

2 *Be it enacted by the General Assembly of the Commonwealth of Kentucky:*

3 ➔SECTION 1. A NEW SECTION OF KRS CHAPTER 311 IS CREATED TO
4 READ AS FOLLOWS:

5 *(1) As used in this section:*

6 *(a) "Biological sample" means any material part of the human, discharge*
7 *therefrom, or derivative thereof, such as tissue, blood, urine, or saliva,*
8 *known to contain deoxyribonucleic acid (DNA);*

9 *(b) "Consumer" means an individual who is a resident of the state;*

10 *(c) "Direct-to-consumer genetic testing company" means an entity that offers*
11 *consumer genetic testing products or services directly to consumers or*
12 *collects, uses, or analyzes genetic data provided to them by a consumer;*

13 *(d) "Express consent" means a consumer's affirmative response, or the*
14 *affirmative response of a consumer's legal guardian, attorney-in-fact,*
15 *health care surrogate, or authorized representative, to a clear, meaningful,*
16 *and prominent notice regarding the collection, use, or disclosure of genetic*
17 *data for a specific purpose;*

18 *(e) 1. "Genetic data" means any data, regardless of its format, that concerns*
19 *a consumer's genetic characteristics and includes but is not limited to:*

20 *a. Raw sequence data that result from a sequencing of a*
21 *consumer's complete extracted or a portion of the extracted*
22 *DNA;*

23 *b. Genotypic and phenotypic information that results from*
24 *analyzing the raw sequence data; and*

25 *c. Self-reported health information that a consumer submits to a*
26 *company regarding the consumer's health conditions and that is*
27 *used for scientific research or product development and analyzed*

1 in connection with the consumer's raw sequence data.

2 2. "Genetic data" does not include deidentified data;

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

6 (g) "Person" has the same meaning as KRS 446.010.

7 (2) To safeguard the privacy, confidentiality, security, and integrity of a consumer's
8 genetic data, a direct-to-consumer genetic testing company shall:

9 (a) Provide clear and complete information regarding the company's policies
10 and procedures for collection, use, or disclosure of genetic data by making
11 available to a consumer:

12 1. A high-level privacy policy overview that includes basic, essential
13 information about the company's collection, use, or disclosure of
14 genetic data; and

15 2. A prominent, publicly available privacy notice that includes, at a
16 minimum, information about the company's data collection, consent,
17 use, access, disclosure, transfer, security, and retention and deletion
18 practices;

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

21 1. Initial express consent that clearly describes the uses of the genetic
22 data collected through the genetic testing product or service, and
23 specifies who has access to test results and how the genetic data may
24 be shared;

25 2. Separate express consent for transferring or disclosing the consumer's
26 genetic data to any person other than the company's vendors and
27 service providers, or for using genetic data beyond the primary

- 1 purpose of the genetic testing product or service and inherent
2 contextual uses;
- 3 3. Separate express consent for the retention of any biological sample
4 provided by the consumer following completion of the initial testing
5 service requested by the consumer;
- 6 4. Informed consent in compliance with the federal policy for the
7 protection of human research subjects, 45 C.F.R. pt. 46, for transfer
8 or disclosure of the consumer's genetic data to third party persons for
9 research purposes or research conducted under the control of the
10 company for the purpose of publication or generalizable knowledge;
11 and
- 12 5. a. Express consent for marketing to a consumer based on the
13 consumer's genetic data; or for marketing by a third party
14 person to a consumer based on the consumer having ordered or
15 purchased a genetic testing product or service.
- 16 b. Marketing does not include the provision of customized content
17 or offers on the Web sites or through the applications or services
18 provided by the direct-to-consumer genetic testing company with
19 the first-party relationship to the customer;
- 20 (c) Require valid legal process for disclosing genetic data to law enforcement or
21 any other government agency without a consumer's express written
22 consent;
- 23 (d) Develop, implement, and maintain a comprehensive security program to
24 protect a consumer's genetic data against unauthorized access, use, or
25 disclosure; and
- 26 (e) Provide a process for a consumer to:
- 27 1. Access the consumer's genetic data;

- 1 2. Delete the consumer's account and genetic data; and
- 2 3. Request and obtain the destruction of the consumer's biological
- 3 sample.
- 4 (3) Notwithstanding any other provisions in this section, a direct-to-consumer
- 5 genetic testing company may not disclose a consumer's genetic data to any entity
- 6 offering health insurance, life insurance, or long-term care insurance, or to any
- 7 employer of the consumer without the consumer's written consent.
- 8 (4) The Attorney General may bring an action in the name of the Commonwealth, or
- 9 as parens patriae on behalf of consumers, to enforce this section. In any action
- 10 brought by the Attorney General to enforce this section, a violation of this section
- 11 is subject to a civil penalty of the following:
- 12 (a) Two thousand five hundred dollars (\$2,500) for each violation of this
- 13 section;
- 14 (b) The recovery of actual damages incurred by consumers on whose behalf the
- 15 action was brought; and
- 16 (c) Costs and expenses incurred by the office of the Attorney General.
- 17 (5) This section does not apply to:
- 18 (a) A public or private institution of higher education; or
- 19 (b) An entity owned or operated by a public or private institution of higher
- 20 education.
- 21 (6) The disclosure of genetic data pursuant to this section shall comply with all state
- 22 and federal laws for the protection of privacy and security. This section shall not
- 23 apply to protected health information that is collected by a covered entity or
- 24 business associate governed by the privacy, security, and breach notification rules
- 25 issued by the United States Department of Health and Human Services, 45 C.F.R.
- 26 pts. 160 and 164, established pursuant to the federal Health Insurance Portability
- 27 and Accountability Act of 1996, Pub. L. No. 104-191, and the federal Health

- 1 **Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-**
- 2 **5.**
- 3 ➔ Section 2. This Act may be cited as the Genetic Information Privacy Act.