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THE GENERAL ASSEMBLY OF PENNSYLVANIA

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HOUSE BILL

No. 2627 Session of  
2024

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INTRODUCED BY MATZIE, McNEILL, HARKINS, PIELLI, RABB,  
PISCIOTTANO, DONAHUE, HILL-EVANS, HADDOCK, KHAN, KENYATTA,  
GALLAGHER, SANCHEZ, SCHLOSSBERG AND BOROWSKI, OCTOBER 9, 2024

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REFERRED TO COMMITTEE ON CONSUMER PROTECTION, TECHNOLOGY AND  
UTILITIES, OCTOBER 9, 2024

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AN ACT

1 Providing for duties of direct-to-consumer genetic testing  
2 companies and for prohibition on disclosure of genetic data  
3 of consumers; and imposing civil penalties.

4 The General Assembly of the Commonwealth of Pennsylvania  
5 hereby enacts as follows:

6 Section 1. Short title.

7 This act shall be known and may be cited as the Genetic  
8 Information Privacy Act.

9 Section 2. Definitions.

10 The following words and phrases when used in this act shall  
11 have the meanings given to them in this section unless the  
12 context clearly indicates otherwise:

13 "Biological sample." A material part of, or discharge from,  
14 a human being or a derivative of a material part of, or  
15 discharge from, a human being, including tissue, blood, urine or  
16 saliva, known to contain DNA.

17 "Consumer." An individual who is a resident of this

1 Commonwealth.

2 "Deidentified data." Data that cannot reasonably be used to  
3 infer information about, or otherwise be linked to, an  
4 identifiable consumer, which is subject to all of the following:

5 (1) Administrative and technical measures to ensure that  
6 the data cannot be associated with a particular consumer.

7 (2) A public commitment by a direct-to-consumer genetic  
8 testing company to maintain and use the data in a  
9 deidentified form and to not attempt to reidentify the data.

10 (3) Legally enforceable contractual obligations that  
11 prohibit a recipient of the data from attempting to  
12 reidentify the data.

13 "Direct-to-consumer genetic testing company" or "company."

14 As follows:

15 (1) An entity that:

16 (i) offers a direct-to-consumer genetic testing  
17 product or service; or

18 (ii) collects, uses or analyzes genetic data  
19 provided to the entity by a consumer as a result of a  
20 direct-to-consumer genetic testing product or service.

21 (2) The term does not include an entity that is only  
22 engaged in collecting, using or analyzing genetic data or  
23 biological samples in the context of research as defined in  
24 45 CFR 164.501 (relating to definitions), which is conducted  
25 in accordance with 21 CFR Ch. I Subch. A Pts. 50 (relating to  
26 protection of human subjects) and 56 (relating to  
27 institutional review boards), 45 CFR Subch. A Pt. 46  
28 (relating to protection of human subjects) and the Good  
29 Clinical Practice Guideline issued by the International  
30 Council for Harmonisation.

1 "Express consent." A consumer's affirmative response to a  
2 clear, meaningful and prominent notice regarding the collection,  
3 use or disclosure of genetic data for a specific purpose.

4 "Genetic data." Any data, regardless of the format of the  
5 data, that concerns a consumer's genetic characteristics. The  
6 term does not include deidentified data. The term includes any  
7 of the following:

8 (1) Raw sequence data that results from sequencing of a  
9 consumer's complete extracted or a portion of the extracted  
10 DNA.

11 (2) Genotypic and phenotypic information that results  
12 from analyzing the raw sequence data.

13 (3) Self-reported health information that a consumer  
14 submits to a direct-to-consumer genetic testing company  
15 regarding the consumer's health conditions, which is used for  
16 scientific research or product development and analyzed in  
17 connection with the consumer's raw sequence data.

18 "Genetic testing." A laboratory test of a consumer's  
19 complete DNA, regions of DNA, chromosomes, genes or gene  
20 products to determine the presence of genetic characteristics of  
21 the consumer.

22 "Person." An individual, partnership, corporation,  
23 association, business, business trust or legal representative of  
24 an organization.

25 Section 3. Duties of direct-to-consumer genetic testing  
26 companies.

27 In order to safeguard the privacy, confidentiality, security  
28 and integrity of a consumer's genetic data, a direct-to-consumer  
29 genetic testing company shall have the following duties:

30 (1) Provide clear and complete information regarding the

1 company's policies and procedures for the collection, use or  
2 disclosure of genetic data by making all of the following  
3 available to a consumer:

4 (i) A high-level privacy policy overview that  
5 includes basic, essential information about the  
6 company's collection, use or disclosure of genetic data.

7 (ii) A prominent, publicly available privacy notice  
8 with information about the company's data collection,  
9 consent, use, access, disclosure, transfer, security and  
10 retention and deletion practices.

11 (2) Obtain a consumer's consent for the collection, use  
12 or disclosure of the consumer's genetic data, which includes  
13 all of the following:

14 (i) Initial express consent that clearly describes  
15 the uses of the consumer's genetic data collected through  
16 the genetic testing product or service and specifies who  
17 has access to test results and how the genetic data may  
18 be shared.

19 (ii) Separate express consent for transferring or  
20 disclosing the consumer's genetic data to a person other  
21 than the company's vendor or service provider or for  
22 using the consumer's genetic data beyond the primary  
23 purpose of the genetic testing product or service and  
24 inherent contextual uses.

25 (iii) Separate express consent for the retention of  
26 a biological sample provided by the consumer after  
27 completion of the initial testing service requested by  
28 the consumer.

29 (iv) Informed consent in accordance with 45 CFR  
30 Subch. A Pt. 46 (relating to protection of human

1 subjects) for the transfer or disclosure of the  
2 consumer's genetic data to a third-party person for  
3 research purposes or research conducted under the control  
4 of the company for the purpose of publication or  
5 generalizable knowledge.

6 (v) Express consent for marketing to the consumer  
7 based on the consumer's genetic data or for marketing by  
8 a third-party person to the consumer based on the  
9 consumer having ordered or purchased a genetic testing  
10 product or service. As used in this subparagraph, the  
11 term "marketing" does not include the provision of  
12 customized content or offers on an Internet website or  
13 through an application or service provided by a direct-  
14 to-consumer genetic testing company with a first-party  
15 relationship to a consumer.

16 (3) Require a valid legal process for disclosing genetic  
17 data to a law enforcement agency or any other Federal, State  
18 or local government entity without the consumer's express  
19 written consent.

20 (4) Develop, implement and maintain a comprehensive  
21 security program to protect the consumer's genetic data  
22 against unauthorized access, use or disclosure.

23 (5) Provide a process for the consumer to:

24 (i) access the consumer's genetic data;

25 (ii) delete the consumer's account and genetic data;

26 and

27 (iii) request and obtain the destruction of the  
28 consumer's biological sample.

29 (6) Otherwise comply with Federal and State laws  
30 regarding the privacy, confidentiality, security and

1 integrity of the consumer's genetic data.

2 Section 4. Prohibition on disclosure of genetic data of  
3 consumers.

4 Notwithstanding the provisions of section 3, a direct-to-  
5 consumer genetic testing company may not disclose a consumer's  
6 genetic data to any of the following without the consumer's  
7 written consent:

8 (1) An entity offering health insurance, life insurance  
9 or long-term care insurance.

10 (2) An employer of the consumer.

11 Section 5. Civil penalties.

12 The Office of Attorney General may bring a civil action in  
13 the name of the Commonwealth or on behalf of consumers to  
14 enforce the provisions of this act in a court of competent  
15 jurisdiction. In an action brought under this section, the court  
16 may impose a civil penalty of \$2,500 for each violation of this  
17 act, the recovery of actual damages incurred by consumers on  
18 whose behalf the action was brought and the costs and reasonable  
19 attorney fees incurred by the Office of Attorney General.

20 Section 6. Applicability.

21 This act shall not apply to any of the following:

22 (1) Protected health information that is collected by a  
23 covered entity or business associate governed by the privacy,  
24 security and breach notification regulations issued by the  
25 United States Department of Health and Human Services under  
26 45 CFR Subt. A Subch. C Pts. 160 (relating to general  
27 administrative requirements) and 164 (relating to security  
28 and privacy) and established Health Insurance Portability and  
29 Accountability Act of 1996 (Public Law 104-191, 110 Stat.  
30 1936) and Health Information Technology for Economic and

1 Clinical Health Act (Public Law 111-5, 123 Stat. 226-279 and  
2 467-496).

3 (2) Biological samples or genetic data lawfully obtained  
4 by a law enforcement agency from a crime scene reasonably  
5 suspected to belong to a putative suspect in a criminal case.

6 (3) Biological samples or genetic data obtained from a  
7 deceased individual whose identity is unknown solely for the  
8 purposes of identifying the individual.

9 Section 7. Effective date.

10 This act shall take effect in 60 days.