

WEST VIRGINIA LEGISLATURE

2024 REGULAR SESSION

Introduced

House Bill 5110

By Delegate Young

[Introduced January 25, 2024; Referred to the
Committee on Health and Human Resources then the
Judiciary

1 A BILL to amend the Code of West Virginia, 1931, as amended, by adding thereto a new article,
 2 designated §16-67-1, §16-67-2, §16-67-3, and §16-67-4, all relating to creating the
 3 Genetic Information Privacy Act; and to provide guidelines for the collection, storage, and
 4 protection of privacy with concern to genetic material and information.

Be it enacted by the Legislature of West Virginia:

ARTICLE 67. GENETIC INFORMATION PRIVACY ACT.

§16-67-1. Definitions.

1 (a) This article shall be known, and may be cited, as the Genetic Information Privacy Act.

2 (b) For purposes of this article, the following definitions apply:

3 (1) "Biological sample" means any material part of the human, discharge therefrom, or
 4 derivative thereof, such as tissue, blood, urine, or saliva, known to contain deoxyribonucleic acid
 5 (DNA).

6 (2) "Consumer" means an individual who is a resident of this state.

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

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

9 (B) Collects, uses, or analyzes genetic data that resulted from a direct-to-consumer
 10 genetic testing product or service and was provided to the company by a consumer.

11 (4) "Direct-to-consumer genetic testing company" does not include any entity only when
 12 they are engaged in collecting, using, or analyzing genetic data or biological samples in the
 13 context of research, as defined in 45 C.F.R. sec. 164.501, conducted in accordance with the
 14 Federal Policy for the Protection of Human Subjects, 45 C.F.R. pt. 46, the Good Clinical Practice
 15 Guideline issued by the International Council for Harmonisation, or the United States Food and

16 Drug Administration Policy for the Protection of Human Subjects under 21 C.F.R. pts. 50 and 56;

17 (5) "Express consent" means a consumer's affirmative response to a clear, meaningful,
 18 and prominent notice regarding the collection, use, or disclosure of genetic data for a specific
 19 purpose.

20 (6) "Genetic data" means any data, regardless of its format, that concerns a consumer's
21 genetic characteristics.

22 (A) "Genetic data" includes, but is not limited to:

23 (i) Raw sequence data that result from sequencing of a consumer's complete extracted or
24 a portion of the extracted DNA;

25 (ii) Genotypic and phenotypic information that results from analyzing the raw sequence
26 data; and

27 (iii) Self-reported health information that a consumer submits to a company regarding the
28 consumer's health conditions and that is used for scientific research or product development and
29 analyzed in connection with the consumer's raw sequence data.

30 (B) "Genetic data" does not include deidentified data. For purposes of this subsection,
31 "deidentified data" means data that cannot reasonably be used to infer information about, or
32 otherwise be linked to, an identifiable consumer, and that is subject to:

33 (i) Administrative and technical measures to ensure that the data cannot be associated
34 with a particular consumer;

35 (ii) Public commitment by the company to maintain and use data in deidentified form and
36 not attempt to reidentify data; and

37 (iii) Legally enforceable contractual obligations that prohibit any recipients of the data from
38 attempting to reidentify the data.

39 (7) "Genetic testing" means any laboratory test of a consumer's complete DNA, regions of
40 DNA, chromosomes, genes, or gene products to determine the presence of genetic
41 characteristics of a consumer.

42 (8) "Person" means an individual, partnership, corporation, association, business,
43 business trust, or legal representative of an organization.

§16-67-2. Collection and Use of Genetic Data.

1 (a) To safeguard the privacy, confidentiality, security, and integrity of a consumer's genetic

2 data, a direct-to-consumer genetic testing company shall:

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

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

7 (B) A prominent, publicly available privacy notice that includes, at a minimum, information
8 about the company's data collection, consent, use, access, disclosure, transfer, security, and
9 retention and deletion practices;

10 (2) Obtain a consumer's consent for collection, use, or disclosure of the consumer's
11 genetic data including, at a minimum:

12 (A) Initial express consent that clearly describes the uses of the genetic data collected
13 through the genetic testing product or service, and specifies who has access to test results and
14 how the genetic data may be shared;

15 (B) Separate express consent for transferring or disclosing the consumer's genetic data to
16 any person other than the company's vendors and service providers, or for using genetic data
17 beyond the primary purpose of the genetic testing product or service and inherent contextual uses;

18 (C) Separate express consent for the retention of any biological sample provided by the
19 consumer following completion of the initial testing service requested by the consumer.

20 (D) Informed consent in compliance with the federal policy for the protection of human
21 research subjects, 45 C.F.R. Sec. 46 (2019), for transfer or disclosure of the consumer's genetic
22 data to third party persons for research purposes or research conducted under the control of the
23 company for the purpose of publication or generalizable knowledge; and

24 (E) Express consent for marketing to a consumer based on the consumer's genetic data;
25 or for marketing by a third-party person to a consumer based on the consumer having ordered or
26 purchased a genetic testing product or service. Marketing does not include the provision of
27 customized content or offers on the websites or through the applications or services provided by

28 the direct-to-consumer genetic testing company with the first-party relationship to the customer.

29 (3) Require valid legal process for disclosing genetic data to law enforcement or any other
30 government agency without a consumer's express written consent;

31 (4) Develop, implement, and maintain a comprehensive security program to protect a
32 consumer's genetic data against unauthorized access, use, or disclosure; and

33 (5) Provide a process for a consumer to:

34 (A) Access the consumer's genetic data;

35 (B) Delete the consumer's account and genetic data; and

36 (C) Request and obtain the destruction of the consumer's biological sample.

37 (b) Notwithstanding any other provisions in this section, a direct-to-consumer genetic
38 testing company may not disclose a consumer's genetic data to any entity offering health
39 insurance, life insurance or long-term care insurance, or to any employer of the consumer without
40 the consumer's written consent.

41 (c) The Attorney General may bring an action in the name of the state, or as parens patriae
42 on behalf of Consumers, to enforce this article. In any action brought by the Attorney General to
43 enforce this article, a violation of this article is subject to a civil penalty of \$2,500 for each violation
44 of this article, the recovery of actual damages incurred by Consumers on whose behalf the action
45 was brought, and costs and reasonable attorneys' fees incurred by the office of the Attorney
46 General.

§16-67-3. Limitations.

1 (a) Limitations. This article does not apply to:

2 (1) Protected health information that is collected by a covered entity or business associate
3 as those terms are defined in 45 C.F.R. Parts 160 and 164;

§16-67-4. Application.

1 The disclosure of genetic data pursuant to this article shall comply with all state and federal
2 laws for the protection of privacy and security. This article shall not apply to protected health

3 information that is collected by a covered entity or business associate governed by the privacy,
4 security, and breach notification rules issued by the United States Department of Health and
5 Human Services (Parts Regulations) 160 and 164 of Title 45 of the Code of Federal Services
6 (Parts Regulations) established pursuant to the federal Health Insurance Portability and
7 Accountability Act of 1996 (Public Law 104-191) and the federal Health Information Technology for
8 Economic and Clinical Health Act (Public Law 111-5).

NOTE: The purpose of this bill is to provide guidelines for the collection, storage, and protection of privacy with concern to genetic material and information.

Strike-throughs indicate language that would be stricken from a heading or the present law, and underscoring indicates new language that would be added.