

SENATE BILL 766

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CF HB 866

By: **Senator Sydnor**

Introduced and read first time: February 7, 2022

Assigned to: Finance

A BILL ENTITLED

1 AN ACT concerning

2 **Commercial Law – Consumer Protection – Genetic Information Privacy**

3 FOR the purpose of regulating the use of genetic data by direct-to-consumer genetic testing
4 companies, including by requiring a direct-to-consumer genetic testing company to
5 provide consumers with certain information regarding the company's policies and
6 procedures, obtain certain consents from consumers before collecting, using, or
7 disclosing the consumer's genetic data, and develop and implement certain policies
8 and procedures to protect genetic data and provide for certain disclosures to law
9 enforcement and other government agencies; and generally relating to genetic
10 information privacy.

11 BY repealing and reenacting, with amendments,
12 Article – Commercial Law
13 Section 13–301(14)(xxxiv) and (xxxv)
14 Annotated Code of Maryland
15 (2013 Replacement Volume and 2021 Supplement)

16 BY adding to
17 Article – Commercial Law
18 Section 13–301(14)(xxxvi); and 14–4401 through 14–4408 to be under the new
19 subtitle “Subtitle 44. Genetic Information Privacy Act”
20 Annotated Code of Maryland
21 (2013 Replacement Volume and 2021 Supplement)

22 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,
23 That the Laws of Maryland read as follows:

24 **Article – Commercial Law**

25 13–301.

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 Unfair, abusive, or deceptive trade practices include any:

2 (14) Violation of a provision of:

3 (xxxiv) The federal Servicemembers Civil Relief Act; [or]

4 (xxxv) [§] SECTION 11–210 of the Education Article; or

5 (XXXVI) TITLE 14, SUBTITLE 44 OF THIS ARTICLE; OR

6 SUBTITLE 44. GENETIC INFORMATION PRIVACY ACT.

7 14–4401.

8 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS
9 INDICATED.

10 (B) (1) “BIOLOGICAL SAMPLE” MEANS A MATERIAL PART OR A
11 DERIVATIVE OF OR DISCHARGE FROM A MATERIAL PART OF A HUMAN KNOWN TO
12 CONTAIN DNA.

13 (2) “BIOLOGICAL SAMPLE” INCLUDES HUMAN TISSUE, BLOOD,
14 URINE, AND SALIVA.

15 (C) (1) “DEIDENTIFIED DATA” MEANS DATA THAT:

16 (I) CANNOT REASONABLY BE:

17 1. USED TO INFER INFORMATION ABOUT A CONSUMER;

18 OR

19 2. LINKED TO AN IDENTIFIABLE CONSUMER; AND

20 (2) IS SUBJECT TO:

21 (I) ADMINISTRATIVE AND TECHNICAL MEASURES TO ENSURE
22 THAT THE DATA CANNOT BE ASSOCIATED WITH A PARTICULAR CONSUMER;

23 (II) PUBLIC COMMITMENT BY THE COMPANY TO MAINTAIN AND
24 USE DATA IN A DEIDENTIFIABLE FORM AND NOT ATTEMPT TO REIDENTIFY DATA;
25 AND

1 **(III) LEGALLY ENFORCEABLE CONTRACTUAL OBLIGATIONS**
2 **THAT PROHIBIT A RECIPIENT OF THE DATA FROM ATTEMPTING TO REIDENTIFY THE**
3 **DATA.**

4 **(D) “DIRECT-TO-CONSUMER GENETIC TESTING COMPANY” MEANS AN**
5 **ENTITY THAT:**

6 **(1) OFFERS GENETIC TESTING PRODUCTS OR SERVICES DIRECTLY TO**
7 **A CONSUMER; OR**

8 **(2) COLLECTS, USES, OR ANALYZES GENETIC DATA PROVIDED TO THE**
9 **COMPANY BY A CONSUMER.**

10 **(E) “DNA” MEANS DEOXYRIBONUCLEIC ACID.**

11 **(F) “EXPRESS CONSENT” MEANS AN AFFIRMATIVE RESPONSE BY A**
12 **CONSUMER TO A SPECIFIC, DISCRETE, FREELY GIVEN, AND UNAMBIGUOUS NOTICE**
13 **REGARDING THE COLLECTION, USE, OR DISCLOSURE OF THE CONSUMER’S GENETIC**
14 **DATA FOR A SPECIFIC PURPOSE.**

15 **(G) (1) “GENETIC DATA” MEANS DATA, IN ANY FORMAT, THAT CONCERNS**
16 **THE GENETIC CHARACTERISTICS OF A CONSUMER.**

17 **(2) “GENETIC DATA” INCLUDES:**

18 **(I) RAW SEQUENCE DATA THAT RESULT FROM SEQUENCING OF**
19 **A CONSUMER’S COMPLETE EXTRACTED DNA OR A PORTION OF THE CONSUMER’S**
20 **COMPLETE EXTRACTED DNA;**

21 **(II) GENOTYPIC AND PHENOTYPIC INFORMATION THAT**
22 **RESULTS FROM ANALYZING RAW SEQUENCE DATA; AND**

23 **(III) SELF-REPORTED HEALTH INFORMATION SUBMITTED TO A**
24 **DIRECT-TO-CONSUMER GENETIC TESTING COMPANY BY A CONSUMER REGARDING**
25 **THE CONSUMER’S HEALTH CONDITIONS:**

26 **1. THAT IS USED FOR SCIENTIFIC RESEARCH OR**
27 **PRODUCT DEVELOPMENT; AND**

28 **2. ANALYZED IN CONNECTION WITH THE CONSUMER’S**
29 **RAW SEQUENCE DATA.**

30 **(3) “GENETIC DATA” DOES NOT INCLUDE DEIDENTIFIED DATA.**

1 **(H) “GENETIC TESTING” MEANS A LABORATORY TEST OF THE COMPLETE**
2 **DNA, REGIONS OF DNA, CHROMOSOMES, GENES, OR GENE PRODUCTS OF A**
3 **CONSUMER TO DETERMINE THE GENETIC CHARACTERISTICS OF THE CONSUMER.**

4 **(I) “MARKETING” DOES NOT INCLUDE THE PROVIDING CUSTOMIZED**
5 **CONTENT OR OFFERS ON THE WEBSITES OR THROUGH THE APPLICATIONS OR**
6 **SERVICES PROVIDED BY THE DIRECT-TO-CONSUMER GENETIC TESTING COMPANY**
7 **WITH THE FIRST-PARTY RELATIONSHIP TO THE CONSUMER.**

8 **14-4402.**

9 **THIS SUBTITLE DOES NOT APPLY TO:**

10 **(1) PROTECTED HEALTH INFORMATION THAT IS COLLECTED BY A**
11 **COVERED ENTITY OR BUSINESS ASSOCIATE AS DEFINED IN 45 C.F.R. PARTS 160**
12 **AND 164;**

13 **(2) AN INSTITUTION OF HIGHER EDUCATION, AS DEFINED IN § 10-101**
14 **OF THE EDUCATION ARTICLE; OR**

15 **(3) AN ENTITY OWNED OR OPERATED BY AN INSTITUTION OF HIGHER**
16 **EDUCATION, AS DEFINED IN § 10-101 OF THE EDUCATION ARTICLE.**

17 **14-4403.**

18 **(A) A DIRECT-TO-CONSUMER GENETIC TESTING COMPANY SHALL PROVIDE**
19 **A CONSUMER WITH CLEAR AND COMPLETE INFORMATION REGARDING THE**
20 **COMPANY’S POLICIES AND PROCEDURES FOR COLLECTING, USING, OR DISCLOSING**
21 **GENETIC DATA, INCLUDING:**

22 **(1) A HIGH-LEVEL OVERVIEW OF THE COMPANY’S PRIVACY POLICY**
23 **THAT INCLUDES BASIC AND ESSENTIAL INFORMATION ABOUT HOW THE COMPANY**
24 **COLLECTS, USES, AND DISCLOSES GENETIC DATA; AND**

25 **(2) A PRIVACY NOTICE THAT, AT A MINIMUM, INCLUDES**
26 **INFORMATION ABOUT THE COMPANY’S DATA COLLECTION, CONSENT, USE, ACCESS,**
27 **DISCLOSURE, TRANSFER, SECURITY, AND RETENTION AND DELETION PRACTICES.**

28 **(B) THE INFORMATION REQUIRED TO BE PROVIDED UNDER SUBSECTION (A)**
29 **OF THIS SECTION SHALL BE:**

30 **(1) MADE PUBLICLY AVAILABLE; AND**

1 **(2) PLACED IN A PROMINENT AREA OF THE DIRECT-TO-CONSUMER**
2 **GENETIC TESTING COMPANY'S WEBSITE.**

3 **14-4404.**

4 **A DIRECT-TO-CONSUMER GENETIC TESTING COMPANY, AT A MINIMUM,**
5 **SHALL OBTAIN THE FOLLOWING CONSENTS FROM A CONSUMER BEFORE**
6 **COLLECTING, USING, OR DISCLOSING THE CONSUMER'S GENETIC DATA:**

7 **(1) INITIAL EXPRESS CONSENT THAT CLEARLY:**

8 **(I) DESCRIBES THE USES OF THE GENETIC DATA COLLECTED**
9 **THROUGH THE GENETIC TESTING PRODUCT OR SERVICE; AND**

10 **(II) SPECIFIES:**

11 **1. WHO HAS ACCESS TO THE RESULTS OF THE GENETIC**
12 **TESTING; AND**

13 **2. HOW THE GENETIC DATA MAY BE SHARED;**

14 **(2) EXPRESS CONSENT FOR TRANSFERRING OR DISCLOSING THE**
15 **CONSUMER'S GENETIC DATA TO A PERSON OTHER THAN THE COMPANY'S VENDORS**
16 **AND SERVICE PROVIDERS;**

17 **(3) EXPRESS CONSENT FOR USING GENETIC DATA BEYOND THE**
18 **PRIMARY PURPOSE OF THE GENETIC TESTING PRODUCT OR SERVICE REQUESTED BY**
19 **THE CONSUMER;**

20 **(4) EXPRESS CONSENT FOR THE RETENTION OF A BIOLOGICAL**
21 **SAMPLE PROVIDED BY THE CONSUMER AFTER THE INITIAL TESTING SERVICE**
22 **REQUESTED BY THE CONSUMER IS COMPLETED;**

23 **(5) EXPRESS CONSENT TO BE MARKETED TO BY:**

24 **(I) THE DIRECT-TO-CONSUMER GENETIC TESTING COMPANY**
25 **BASED ON THE CONSUMER'S GENETIC DATA; AND**

26 **(II) A THIRD PARTY BASED ON THE CONSUMER HAVING**
27 **ORDERED OR PURCHASED A GENETIC TESTING PRODUCT OR SERVICE; AND**

1 **(6) INFORMED CONSENT IN COMPLIANCE WITH THE FEDERAL POLICY**
2 **FOR THE PROTECTION OF HUMAN RESEARCH SUBJECTS FOR TRANSFER OR**
3 **DISCLOSURE OF THE CONSUMER’S GENETIC DATA TO THIRD PARTIES FOR**
4 **RESEARCH PURPOSES OR RESEARCH CONDUCTED UNDER THE CONTROL OF THE**
5 **COMPANY FOR THE PURPOSE OF PUBLICATION OR GENERALIZABLE KNOWLEDGE.**

6 **14-4405.**

7 **(A) A DIRECT-TO-CONSUMER GENETIC TESTING COMPANY SHALL**
8 **ESTABLISH LEGAL POLICIES AND PROCESSES FOR DISCLOSING GENETIC DATA TO**
9 **LAW ENFORCEMENT OR ANOTHER GOVERNMENT AGENCY WITHOUT A CONSUMER’S**
10 **EXPRESS WRITTEN CONSENT.**

11 **(B) A DIRECT-TO-CONSUMER GENETIC TESTING COMPANY SHALL**
12 **DEVELOP, IMPLEMENT, AND MAINTAIN A COMPREHENSIVE SECURITY PROGRAM TO**
13 **PROTECT CONSUMERS’ GENETIC DATA AGAINST UNAUTHORIZED ACCESS, USE, OR**
14 **DISCLOSURE.**

15 **(C) A DIRECT-TO-CONSUMER GENETIC TESTING COMPANY SHALL**
16 **ESTABLISH A PROCESS FOR A CONSUMER TO:**

17 **(1) ACCESS THE CONSUMER’S GENETIC DATA;**

18 **(2) DELETE THE CONSUMER’S ACCOUNT AND GENETIC DATA; AND**

19 **(3) REQUEST THE DESTRUCTION OF THE CONSUMER’S BIOLOGICAL**
20 **SAMPLE.**

21 **(D) NOTWITHSTANDING ANY OTHER PROVISIONS OF LAW, A**
22 **DIRECT-TO-CONSUMER GENETIC TESTING COMPANY MAY NOT, WITHOUT THE**
23 **CONSUMER’S WRITTEN CONSENT, DISCLOSE A CONSUMER’S GENETIC DATA TO:**

24 **(1) AN ENTITY OFFERING HEALTH INSURANCE, LIFE INSURANCE, OR**
25 **LONG-TERM CARE INSURANCE; OR**

26 **(2) AN EMPLOYER OF THE CONSUMER.**

27 **14-4406.**

28 **(A) A VIOLATION OF THIS SECTION IS AN UNFAIR, ABUSIVE, OR DECEPTIVE**
29 **TRADE PRACTICE WITHIN THE MEANING OF TITLE 13 OF THIS ARTICLE AND IS**
30 **SUBJECT TO THE ENFORCEMENT AND PENALTY PROVISIONS CONTAINED IN TITLE**
31 **13 OF THIS ARTICLE.**

1 **(B) THIS SECTION DOES NOT PREVENT AN INDIVIDUAL FROM PURSUING**
2 **ANY OTHER REMEDY PROVIDED BY LAW.**

3 **14-4407.**

4 **THE DISCLOSURE OF GENETIC DATA IN ACCORDANCE WITH THIS SUBTITLE**
5 **SHALL COMPLY WITH ALL STATE AND FEDERAL LAWS FOR THE PROTECTION OF**
6 **PRIVACY AND SECURITY.**

7 **14-4408.**

8 **THIS SUBTITLE MAY BE KNOWN AND CITED AS THE MARYLAND GENETIC**
9 **INFORMATION PRIVACY ACT.**

10 **SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect**
11 **October 1, 2022.**