

HOUSE BILL 866

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2lr2894
CF SB 766

By: **Delegate Qi**

Introduced and read first time: February 7, 2022

Assigned to: Economic Matters

Committee Report: Favorable with amendments

House action: Adopted

Read second time: March 10, 2022

CHAPTER _____

1 AN ACT concerning

2 ~~Commercial Law – Consumer Protection – Genetic Information Privacy~~
3 – Consumer Protection and Forensic Genealogy

4 FOR the purpose of regulating the use of genetic data by direct-to-consumer genetic testing
5 companies, including by requiring a direct-to-consumer genetic testing company to
6 provide consumers with certain information regarding the company’s policies and
7 procedures, obtain certain consents from consumers before collecting, using, or
8 disclosing the consumer’s genetic data, and develop and implement certain policies
9 and procedures to protect genetic data and provide for certain disclosures to law
10 enforcement and other government agencies; altering the direct-to-consumer or
11 publicly available open-data personal genomics databases that may be used to
12 conduct forensic genetic genealogical DNA analysis and search to require that the
13 databases seek express consent from their service users regarding the substance of
14 a certain notice; and generally relating to genetic information privacy.

15 BY repealing and reenacting, with amendments,
16 Article – Commercial Law
17 Section 13–301(14)(xxxiv) and (xxxv)
18 Annotated Code of Maryland
19 (2013 Replacement Volume and 2021 Supplement)

20 BY adding to
21 Article – Commercial Law
22 Section 13–301(14)(xxxvi); and 14–4401 through 14–4408 to be under the new
23 subtitle “Subtitle 44. Genetic Information Privacy Act”

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.



1 Annotated Code of Maryland
2 (2013 Replacement Volume and 2021 Supplement)

3 BY repealing and reenacting, without amendments,
4 Article – Criminal Procedure
5 Section 17–101(a), (c), (e), and (g) and 17–102(a)
6 Annotated Code of Maryland
7 (2018 Replacement Volume and 2021 Supplement)

8 BY adding to
9 Article – Criminal Procedure
10 Section 17–101(c–1)
11 Annotated Code of Maryland
12 (2018 Replacement Volume and 2021 Supplement)

13 BY repealing and reenacting, with amendments,
14 Article – Criminal Procedure
15 Section 17–102(d) and 17–103(a)(4)
16 Annotated Code of Maryland
17 (2018 Replacement Volume and 2021 Supplement)

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

20 **Article – Commercial Law**

21 13–301.

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

23 (14) Violation of a provision of:

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

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

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

27 SUBTITLE 44. GENETIC INFORMATION PRIVACY ACT.

28 14–4401.

29 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS
30 INDICATED.

1 **(B) (1) “BIOLOGICAL SAMPLE” MEANS A MATERIAL PART OR A**
2 **DERIVATIVE OF OR DISCHARGE FROM A MATERIAL PART OF A HUMAN KNOWN TO**
3 **CONTAIN DNA.**

4 **(2) “BIOLOGICAL SAMPLE” INCLUDES HUMAN TISSUE, BLOOD,**
5 **URINE, AND SALIVA.**

6 **(C) (1) “DEIDENTIFIED DATA” MEANS DATA THAT:**

7 **(I) CANNOT REASONABLY BE:**

8 1. **USED TO INFER INFORMATION ABOUT A CONSUMER;**

9 **OR**

10 2. **LINKED TO AN IDENTIFIABLE CONSUMER; AND**

11 **(2) IS SUBJECT TO:**

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

14 **(II) PUBLIC COMMITMENT BY THE COMPANY TO MAINTAIN AND**
15 **USE DATA IN A DEIDENTIFIABLE FORM AND NOT ATTEMPT TO REIDENTIFY DATA;**
16 **AND**

17 **(III) LEGALLY ENFORCEABLE CONTRACTUAL OBLIGATIONS**
18 **THAT PROHIBIT A RECIPIENT OF THE DATA FROM ATTEMPTING TO REIDENTIFY THE**
19 **DATA.**

20 **(D) (1) “DIRECT-TO-CONSUMER GENETIC TESTING COMPANY” MEANS**
21 **AN ENTITY THAT:**

22 ~~**(1)**~~ **(I) OFFERS GENETIC TESTING PRODUCTS OR SERVICES**
23 **DIRECTLY TO A CONSUMER; OR**

24 ~~**(2)**~~ **(II) COLLECTS, USES, OR ANALYZES GENETIC DATA THAT**
25 **RESULTED FROM A DIRECT-TO-CONSUMER GENETIC TESTING PRODUCT OR**
26 **SERVICE THAT WAS PROVIDED TO THE COMPANY BY A CONSUMER.**

27 **(2) “DIRECT-TO-CONSUMER GENETIC TESTING COMPANY” DOES NOT**
28 **INCLUDE AN ENTITY ONLY WHEN THE ENTITY IS ENGAGED IN COLLECTING,**
29 **ANALYZING, RETAINING, OR DISCLOSING GENETIC DATA OR BIOLOGICAL SAMPLES**

1 IN THE CONTEXT OF RESEARCH, AS DEFINED IN 45 C.F.R. 164.501, CONDUCTED IN
2 ACCORDANCE WITH:

3 (I) THE FEDERAL POLICY FOR THE PROTECTION OF HUMAN
4 SUBJECTS ESTABLISHED IN 45 C.F.R. PART 46;

5 (II) THE GOOD CLINICAL PRACTICE GUIDELINES ISSUED BY
6 THE INTERNATIONAL COUNCIL FOR HARMONISATION; OR

7 (III) THE U.S. FOOD AND DRUG ADMINISTRATION PROTECTION
8 OF HUMAN SUBJECTS UNDER 21 C.F.R. PARTS 50 AND 56.

9 (E) “DNA” MEANS DEOXYRIBONUCLEIC ACID.

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

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

16 (2) “GENETIC DATA” INCLUDES:

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

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

22 (III) INFORMATION EXTRAPOLATED, DERIVED, OR INFERRED
23 FROM THE ANALYSIS OF RAW SEQUENCE DATA; AND

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

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

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

1 **(3) “GENETIC DATA” DOES NOT INCLUDE DEIDENTIFIED DATA WHEN**
2 **USED FOR RESEARCH PROJECTS.**

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

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

10 **14-4402.**

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

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

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

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

19 **14-4403.**

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

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

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

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

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

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

6 **14-4404.**

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

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

11 **(i) DESCRIBES THE USES OF THE GENETIC DATA COLLECTED**
12 **THROUGH THE GENETIC TESTING PRODUCT OR SERVICE; AND**

13 **(ii) SPECIFIES:**

14 **1. WHO HAS ACCESS TO THE RESULTS OF THE GENETIC**
15 **TESTING; AND**

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

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

20 **(3) EXPRESS CONSENT FOR USING GENETIC DATA BEYOND THE**
21 **PRIMARY PURPOSE OF THE GENETIC TESTING PRODUCT OR SERVICE REQUESTED BY**
22 **THE CONSUMER;**

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

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

27 **(i) THE DIRECT-TO-CONSUMER GENETIC TESTING COMPANY**
28 **BASED ON THE CONSUMER'S GENETIC DATA; AND**

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

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

8 14-4405.

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

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

17 (C) A DIRECT-TO-CONSUMER GENETIC TESTING COMPANY SHALL
18 ESTABLISH A PROCESS FOR A CONSUMER TO:

19 (1) ACCESS THE CONSUMER'S GENETIC DATA;

20 (2) DELETE THE CONSUMER'S ACCOUNT AND GENETIC DATA; AND

21 (3) REQUEST THE DESTRUCTION OF THE CONSUMER'S BIOLOGICAL
22 SAMPLE.

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

26 (1) AN ENTITY OFFERING HEALTH INSURANCE, LIFE INSURANCE,
27 DISABILITY INSURANCE, OR LONG-TERM CARE INSURANCE; OR

28 (2) AN EMPLOYER OF THE CONSUMER.

29 14-4406.

1 (A) A VIOLATION OF THIS SECTION IS AN UNFAIR, ABUSIVE, OR DECEPTIVE
2 TRADE PRACTICE WITHIN THE MEANING OF TITLE 13 OF THIS ARTICLE AND IS
3 SUBJECT TO THE ENFORCEMENT AND PENALTY PROVISIONS CONTAINED IN TITLE
4 13 OF THIS ARTICLE.

5 (B) THIS SECTION DOES NOT PREVENT AN INDIVIDUAL FROM PURSUING
6 ANY OTHER REMEDY PROVIDED BY LAW.

7 14-4407.

8 THE DISCLOSURE OF GENETIC DATA IN ACCORDANCE WITH THIS SUBTITLE
9 SHALL COMPLY WITH ALL STATE AND FEDERAL LAWS FOR THE PROTECTION OF
10 PRIVACY AND SECURITY.

11 14-4408.

12 THIS SUBTITLE MAY BE KNOWN AND CITED AS THE MARYLAND GENETIC
13 INFORMATION PRIVACY ACT.

14 Article – Criminal Procedure

15 17-101.

16 (a) In this title the following words have the meanings indicated.

17 (c) “Direct-to-consumer genetic genealogy services” means genetic genealogy
18 services that are offered by private companies directly to members of the public and law
19 enforcement agencies rather than through clinical health care providers, typically via
20 customer access to secure online websites.

21 (C-1) “EXPRESS CONSENT” HAS THE MEANING STATED IN § 14-4401 OF THE
22 COMMERCIAL LAW ARTICLE.

23 (e) “Forensic genetic genealogical DNA analysis and search” or “FGGS” means:

24 (1) the forensic genetic genealogical DNA analysis of biological material
25 using SNP or other sequencing techniques to develop an FGG profile;

26 (2) a subsequent search using the FGG profile in a publicly available
27 open-data personal genomics database or a direct-to-consumer genetic genealogy service
28 to find individuals related to the source of the FGG profile; and

29 (3) a genealogical search using public records and other lawful means to
30 obtain information in accordance with this title.

1 (g) “Publicly available open–data personal genomics database” means a database
2 in which persons voluntarily submit their genomics data or genetic profiles, typically
3 processed through direct–to–consumer genetic genealogy services, for the purposes of
4 comparison or searching against the genetic profiles of other individuals to evaluate
5 potential familial relationships between the reference sample and other service user
6 samples.

7 17–102.

8 (a) (1) FGGS may not be initiated without judicial authorization and without
9 certifying before the court that the forensic sample and the criminal case satisfy the criteria
10 set forth in this section.

11 (2) If an FGGS is certified before a court in accordance with this section,
12 the court shall authorize the initiation of the FGGS.

13 (d) FGGS may only be conducted using a direct–to–consumer or publicly available
14 open–data personal genomics database that:

15 (1) provides explicit notice to its service users and the public that law
16 enforcement may use its service sites to investigate crimes or to identify human remains;
17 and

18 (2) seeks acknowledgement and EXPRESS consent from its service users
19 regarding the substance of the notice described in item (1) of this subsection.

20 17–103.

21 (a) A defendant in a criminal case charged with a crime of violence under §
22 14–101 of the Criminal Law Article or a defendant convicted of a crime of violence under §
23 14–101 of the Criminal Law Article and seeking postconviction DNA testing is entitled to
24 seek judicial authorization for an FGGS by filing an affidavit with a trial court or
25 postconviction court certifying that:

26 (4) an FGGS shall only be conducted using a direct–to–consumer or
27 publicly available open–data personal genomics database that:

28 (i) provides explicit notice to its service users and the public that
29 law enforcement may use its service sites to investigate crimes or to identify human
30 remains; and

31 (ii) seeks acknowledgment and EXPRESS consent from its service
32 users regarding the substance of the notice described in item (i) of this paragraph;

33 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
34 October 1, 2022.