

# HOUSE BILL 866

I3

(2lr2894)

*ENROLLED BILL*  
— *Economic Matters/Finance* —

Introduced by **Delegate Qi**

Read and Examined by Proofreaders:

\_\_\_\_\_  
Proofreader.

\_\_\_\_\_  
Proofreader.

Sealed with the Great Seal and presented to the Governor, for his approval this

\_\_\_\_\_ day of \_\_\_\_\_ at \_\_\_\_\_ o'clock, \_\_\_\_\_ M.

\_\_\_\_\_  
Speaker.

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.

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**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.

*Italics indicate opposite chamber/conference committee amendments.*



- 1 BY repealing and reenacting, with amendments,  
2 Article – Commercial Law  
3 Section 13–301(14)(xxxiv) and (xxxv)  
4 Annotated Code of Maryland  
5 (2013 Replacement Volume and 2021 Supplement)
- 6 BY adding to  
7 Article – Commercial Law  
8 Section 13–301(14)(xxxvi); and 14–4401 through 14–4408 to be under the new  
9 subtitle “Subtitle 44. Genetic Information Privacy Act”  
10 Annotated Code of Maryland  
11 (2013 Replacement Volume and 2021 Supplement)
- 12 BY repealing and reenacting, without amendments,  
13 Article – Criminal Procedure  
14 Section 17–101(a), (c), (e), and (g) and 17–102(a)  
15 Annotated Code of Maryland  
16 (2018 Replacement Volume and 2021 Supplement)
- 17 BY adding to  
18 Article – Criminal Procedure  
19 Section 17–101(c–1)  
20 Annotated Code of Maryland  
21 (2018 Replacement Volume and 2021 Supplement)
- 22 BY repealing and reenacting, with amendments,  
23 Article – Criminal Procedure  
24 Section 17–102(d) and 17–103(a)(4)  
25 Annotated Code of Maryland  
26 (2018 Replacement Volume and 2021 Supplement)

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

29 **Article – Commercial Law**

30 13–301.

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

32 (14) Violation of a provision of:

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

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

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

2 SUBTITLE 44. GENETIC INFORMATION PRIVACY ACT.

3 14-4401.

4 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS  
5 INDICATED.

6 (B) (1) "BIOLOGICAL SAMPLE" MEANS A MATERIAL PART OR A  
7 DERIVATIVE OF OR DISCHARGE FROM A MATERIAL PART OF A HUMAN KNOWN TO  
8 CONTAIN DNA.

9 (2) "BIOLOGICAL SAMPLE" INCLUDES HUMAN TISSUE, BLOOD,  
10 URINE, AND SALIVA.

11 (C) ~~(1)~~ "DEIDENTIFIED DATA" MEANS DATA THAT:

12 ~~(1)~~ (1) CANNOT REASONABLY BE:

13 ~~(I)~~ (I) USED TO INFER INFORMATION ABOUT A CONSUMER;

14 OR

15 ~~(II)~~ (II) LINKED TO AN IDENTIFIABLE CONSUMER; AND

16 (2) IS SUBJECT TO:

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

19 (II) PUBLIC COMMITMENT BY THE COMPANY TO MAINTAIN AND  
20 USE DATA IN A DEIDENTIFIABLE FORM AND NOT ATTEMPT TO REIDENTIFY DATA;  
21 AND

22 (III) LEGALLY ENFORCEABLE CONTRACTUAL OBLIGATIONS  
23 THAT PROHIBIT A RECIPIENT OF THE DATA FROM ATTEMPTING TO REIDENTIFY THE  
24 DATA.

25 (D) ~~(1)~~ "DIRECT-TO-CONSUMER GENETIC TESTING COMPANY" MEANS  
26 AN ENTITY THAT:

27 ~~(1)~~ ~~(1)~~ OFFERS GENETIC TESTING PRODUCTS OR SERVICES  
28 DIRECTLY TO A CONSUMER; OR

1           ~~(2)~~ ~~(H)~~ (2) COLLECTS, USES, OR ANALYZES GENETIC DATA THAT  
2 RESULTED FROM A DIRECT-TO-CONSUMER GENETIC TESTING PRODUCT OR  
3 SERVICE THAT WAS PROVIDED TO THE COMPANY BY A CONSUMER.

4           ~~(2)~~ “DIRECT TO CONSUMER GENETIC TESTING COMPANY” DOES NOT  
5 INCLUDE AN ENTITY ONLY WHEN THE ENTITY IS ENGAGED IN COLLECTING,  
6 ANALYZING, RETAINING, OR DISCLOSING GENETIC DATA OR BIOLOGICAL SAMPLES  
7 IN THE CONTEXT OF RESEARCH, AS DEFINED IN 45 C.F.R. 164.501, CONDUCTED IN  
8 ACCORDANCE WITH:

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

11           ~~(II)~~ THE GOOD CLINICAL PRACTICE GUIDELINES ISSUED BY  
12 THE INTERNATIONAL COUNCIL FOR HARMONISATION; OR

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

15           (E) “DNA” MEANS DEOXYRIBONUCLEIC ACID.

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

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

22           (2) “GENETIC DATA” INCLUDES:

23           (I) RAW SEQUENCE DATA THAT RESULT FROM SEQUENCING OF  
24 A CONSUMER’S COMPLETE EXTRACTED DNA OR A PORTION OF THE CONSUMER’S  
25 COMPLETE EXTRACTED DNA;

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

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

30           ~~(H)~~ (IV) SELF-REPORTED HEALTH INFORMATION SUBMITTED  
31 TO A DIRECT-TO-CONSUMER GENETIC TESTING COMPANY BY A CONSUMER  
32 REGARDING THE CONSUMER’S HEALTH CONDITIONS:

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

3                   2.    ANALYZED IN CONNECTION WITH THE CONSUMER'S  
4 RAW SEQUENCE DATA.

5                   (3)   "GENETIC DATA" DOES NOT INCLUDE DEIDENTIFIED DATA ~~WHEN~~  
6 ~~USED FOR RESEARCH PROJECTS.~~

7                   (H)   "GENETIC TESTING" MEANS A LABORATORY TEST OF THE COMPLETE  
8 DNA, REGIONS OF DNA, CHROMOSOMES, GENES, OR GENE PRODUCTS OF A  
9 CONSUMER TO DETERMINE THE GENETIC CHARACTERISTICS OF THE CONSUMER.

10                  (I)   "MARKETING" DOES NOT INCLUDE THE PROVIDING CUSTOMIZED  
11 CONTENT OR OFFERS ON THE WEBSITES OR THROUGH THE APPLICATIONS OR  
12 SERVICES PROVIDED BY THE DIRECT-TO-CONSUMER GENETIC TESTING COMPANY  
13 WITH THE FIRST-PARTY RELATIONSHIP TO THE CONSUMER.

14 14-4402.

15                  THIS SUBTITLE DOES NOT APPLY TO:‡

16                  (1)   ~~PROTECTED~~ ~~PROTECTED~~ (1) PROTECTED HEALTH INFORMATION  
17 THAT IS COLLECTED BY A COVERED ENTITY OR BUSINESS ASSOCIATE AS DEFINED IN  
18 45 C.F.R. PARTS 160 AND 164‡;

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

21                  (3)   ~~AN ENTITY OWNED OR OPERATED BY AN INSTITUTION OF HIGHER~~  
22 ~~EDUCATION, AS DEFINED IN § 10-101 OF THE EDUCATION ARTICLE; OR~~

23                  (2)   GENETIC DATA OR BIOLOGICAL SAMPLES COLLECTED FOR THE  
24 PURPOSE OF RESEARCH, AS DEFINED IN 45 C.F.R. 164.501, THAT IS CONDUCTED IN  
25 ACCORDANCE WITH:

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

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

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

3 14-4403.

4 (A) A DIRECT-TO-CONSUMER GENETIC TESTING COMPANY SHALL PROVIDE  
5 A CONSUMER WITH CLEAR AND COMPLETE INFORMATION REGARDING THE  
6 COMPANY'S POLICIES AND PROCEDURES FOR COLLECTING, USING, OR DISCLOSING  
7 GENETIC DATA, INCLUDING:

8 (1) A HIGH-LEVEL OVERVIEW OF THE COMPANY'S PRIVACY POLICY  
9 THAT INCLUDES BASIC AND ESSENTIAL INFORMATION ABOUT HOW THE COMPANY  
10 COLLECTS, USES, AND DISCLOSES GENETIC DATA; AND

11 (2) A PRIVACY NOTICE THAT, AT A MINIMUM, INCLUDES  
12 INFORMATION ABOUT THE COMPANY'S DATA COLLECTION, CONSENT, USE, ACCESS,  
13 DISCLOSURE, TRANSFER, SECURITY, AND RETENTION AND DELETION PRACTICES.

14 (B) THE INFORMATION REQUIRED TO BE PROVIDED UNDER SUBSECTION (A)  
15 OF THIS SECTION SHALL BE:

16 (1) MADE PUBLICLY AVAILABLE; AND

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

19 14-4404.

20 A DIRECT-TO-CONSUMER GENETIC TESTING COMPANY, AT A MINIMUM,  
21 SHALL OBTAIN THE FOLLOWING CONSENTS FROM A CONSUMER BEFORE  
22 COLLECTING, USING, OR DISCLOSING THE CONSUMER'S GENETIC DATA:

23 (1) INITIAL EXPRESS CONSENT THAT CLEARLY:

24 (I) DESCRIBES THE USES OF THE GENETIC DATA COLLECTED  
25 THROUGH THE GENETIC TESTING PRODUCT OR SERVICE; AND

26 (II) SPECIFIES:

27 1. WHO HAS ACCESS TO THE RESULTS OF THE GENETIC  
28 TESTING; AND

29 2. HOW THE GENETIC DATA MAY BE SHARED;

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

4           **(3) EXPRESS CONSENT FOR USING GENETIC DATA BEYOND THE**  
5 **PRIMARY PURPOSE OF THE GENETIC TESTING PRODUCT OR SERVICE REQUESTED BY**  
6 **THE CONSUMER;**

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

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

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

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

15           **(6) INFORMED CONSENT IN COMPLIANCE WITH THE FEDERAL POLICY**  
16 **FOR THE PROTECTION OF HUMAN RESEARCH SUBJECTS FOR TRANSFER OR**  
17 **DISCLOSURE OF THE CONSUMER'S GENETIC DATA TO THIRD PARTIES FOR**  
18 **RESEARCH PURPOSES OR RESEARCH CONDUCTED UNDER THE CONTROL OF THE**  
19 **COMPANY FOR THE PURPOSE OF PUBLICATION OR GENERALIZABLE KNOWLEDGE.**

20 **14-4405.**

21           **(A) A DIRECT-TO-CONSUMER GENETIC TESTING COMPANY SHALL**  
22 **ESTABLISH LEGAL POLICIES AND PROCESSES FOR DISCLOSING GENETIC DATA TO**  
23 **LAW ENFORCEMENT OR ANOTHER GOVERNMENT AGENCY WITHOUT A CONSUMER'S**  
24 **EXPRESS WRITTEN CONSENT.**

25           **(B) A DIRECT-TO-CONSUMER GENETIC TESTING COMPANY SHALL**  
26 **DEVELOP, IMPLEMENT, AND MAINTAIN A COMPREHENSIVE SECURITY PROGRAM TO**  
27 **PROTECT CONSUMERS' GENETIC DATA AGAINST UNAUTHORIZED ACCESS, USE, OR**  
28 **DISCLOSURE.**

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

31                   **(1) ACCESS THE CONSUMER'S GENETIC DATA;**

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

1           (3)    REQUEST THE DESTRUCTION OF THE CONSUMER'S BIOLOGICAL  
2   SAMPLE.

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

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

8           (2)    AN EMPLOYER OF THE CONSUMER.

9   14-4406.

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

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

16   14-4407.

17          THE DISCLOSURE OF GENETIC DATA IN ACCORDANCE WITH THIS SUBTITLE  
18   SHALL COMPLY WITH ALL STATE AND FEDERAL LAWS FOR THE PROTECTION OF  
19   PRIVACY AND SECURITY.

20   14-4408.

21          THIS SUBTITLE MAY BE KNOWN AND CITED AS THE MARYLAND GENETIC  
22   INFORMATION PRIVACY ACT.

23                                 Article – Criminal Procedure

24   17-101.

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

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



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

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

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

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

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

11 (g) “Publicly available open-data personal genomics database” means a database  
12 in which persons voluntarily submit their genomics data or genetic profiles, typically  
13 processed through direct-to-consumer genetic genealogy services, for the purposes of  
14 comparison or searching against the genetic profiles of other individuals to evaluate  
15 potential familial relationships between the reference sample and other service user  
16 samples.

17 17-102.

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

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

23 (d) FGGS may only be conducted using a direct-to-consumer or publicly available  
24 open-data personal genomics database that:

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

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

30 17-103.

31 (a) A defendant in a criminal case charged with a crime of violence under §  
32 14-101 of the Criminal Law Article or a defendant convicted of a crime of violence under §  
33 14-101 of the Criminal Law Article and seeking postconviction DNA testing is entitled to

1 seek judicial authorization for an FGGS by filing an affidavit with a trial court or  
2 postconviction court certifying that:

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

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

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

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

Approved:

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Governor.

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Speaker of the House of Delegates.

\_\_\_\_\_  
President of the Senate.