

Senate Engrossed House Bill

~~genetic testing; private property~~
(now: genetic testing; requirements; data; enforcement)

State of Arizona
House of Representatives
Fifty-fifth Legislature
First Regular Session
2021

CHAPTER 254
HOUSE BILL 2069

AN ACT

AMENDING TITLE 44, ARIZONA REVISED STATUTES, BY ADDING CHAPTER 38;
RELATING TO GENETIC TESTING COMPANIES.

(TEXT OF BILL BEGINS ON NEXT PAGE)

1 Be it enacted by the Legislature of the State of Arizona:

2 Section 1. Title 44, Arizona Revised Statutes, is amended by adding
3 chapter 38, to read:

4 CHAPTER 38

5 GENETIC TESTING COMPANIES

6 ARTICLE 1. GENERAL PROVISIONS

7 44-7921. Definitions

8 IN THIS CHAPTER, UNLESS THE CONTEXT OTHERWISE REQUIRES:

9 1. "BIOLOGICAL SAMPLE" MEANS ANY MATERIAL PART OF A HUMAN,
10 DISCHARGE FROM A HUMAN OR DERIVATIVE OF A HUMAN, INCLUDING TISSUE, BLOOD,
11 URINE OR SALIVA, THAT IS KNOWN TO CONTAIN DNA.

12 2. "CONSUMER" MEANS AN INDIVIDUAL WHO IS A RESIDENT OF THIS STATE.

13 3. "DE-IDENTIFIED DATA" MEANS DATA THAT HAS BEEN DE-IDENTIFIED IN
14 ACCORDANCE WITH 45 CODE OF FEDERAL REGULATIONS SECTION 164.514(b).

15 4. "DIRECT-TO-CONSUMER GENETIC TESTING COMPANY" OR "COMPANY" MEANS
16 AN ENTITY THAT OFFERS GENETIC TESTING PRODUCTS OR SERVICES DIRECTLY TO
17 CONSUMERS THAT INVOLVE COLLECTING FROM A CONSUMER OF EITHER GENETIC DATA
18 OR BIOLOGICAL SAMPLES AND FROM WHICH THE COMPANY DERIVES GENETIC DATA FOR
19 ANALYSIS.

20 5. "EXPRESS CONSENT" MEANS A CONSUMER'S AFFIRMATIVE RESPONSE TO A
21 CLEAR AND PROMINENT NOTICE REGARDING COLLECTING, USING OR DISCLOSING
22 GENETIC DATA FOR A SPECIFIC PURPOSE.

23 6. "GENETIC DATA":

24 (a) MEANS ANY DATA, REGARDLESS OF ITS FORMAT, THAT CONCERNS A
25 CONSUMER'S GENETIC CHARACTERISTICS.

26 (b) INCLUDES:

27 (i) RAW SEQUENCE DATA THAT RESULTS FROM SEQUENCING OF A CONSUMER'S
28 COMPLETE EXTRACTED DNA OR A PORTION OF THE CONSUMER'S EXTRACTED DNA.

29 (ii) GENOTYPIC AND PHENOTYPIC INFORMATION THAT RESULTS FROM
30 ANALYZING THE RAW SEQUENCE DATA.

31 (iii) SELF-REPORTED HEALTH INFORMATION THAT A CONSUMER SUBMITS TO A
32 COMPANY REGARDING THE CONSUMER'S HEALTH CONDITIONS AND THAT IS USED FOR
33 SCIENTIFIC RESEARCH OR PRODUCT DEVELOPMENT AND ANALYZED IN CONNECTION WITH
34 THE CONSUMER'S RAW SEQUENCE DATA.

35 (c) DOES NOT INCLUDE DE-IDENTIFIED DATA.

36 7. "GENETIC TESTING" MEANS ANY LABORATORY TEST OF A CONSUMER'S
37 COMPLETE DNA, REGIONS OF DNA, CHROMOSOMES, GENES OR GENE PRODUCTS TO
38 DETERMINE THE PRESENCE OF A CONSUMER'S GENETIC CHARACTERISTICS.

39 8. "PERSON" MEANS AN INDIVIDUAL, PARTNERSHIP, CORPORATION,
40 ASSOCIATION, BUSINESS, BUSINESS TRUST OR LEGAL REPRESENTATIVE OF AN
41 ORGANIZATION.

1 44-7922. Direct-to-consumer genetic testing company
2 requirements; prohibition

3 A. A DIRECT-TO-CONSUMER GENETIC TESTING COMPANY SHALL:

4 1. PROVIDE CLEAR AND COMPLETE INFORMATION REGARDING THE COMPANY'S
5 POLICIES AND PROCEDURES FOR COLLECTING, USING OR DISCLOSING GENETIC DATA
6 BY MAKING AVAILABLE TO A CONSUMER BOTH OF THE FOLLOWING:

7 (a) A HIGH-LEVEL PRIVACY POLICY OVERVIEW THAT INCLUDES BASIC,
8 ESSENTIAL INFORMATION ABOUT THE COMPANY'S COLLECTION, USE OR DISCLOSURE OF
9 GENETIC DATA.

10 (b) A PROMINENT, PUBLICLY AVAILABLE PRIVACY NOTICE THAT INCLUDES
11 INFORMATION ABOUT THE COMPANY'S DATA COLLECTION, CONSENT, USE, ACCESS,
12 DISCLOSURE, TRANSFER, SECURITY AND RETENTION AND DELETION PRACTICES.

13 2. OBTAIN A CONSUMER'S CONSENT FOR COLLECTING, USING OR DISCLOSING
14 THE CONSUMER'S GENETIC DATA, INCLUDING:

15 (a) INITIAL EXPRESS CONSENT THAT CLEARLY DESCRIBES THE USES OF THE
16 GENETIC DATA COLLECTED THROUGH THE GENETIC TESTING PRODUCT OR SERVICE AND
17 THAT SPECIFIES WHO HAS ACCESS TO TEST RESULTS AND HOW THE GENETIC DATA MAY
18 BE SHARED.

19 (b) SEPARATE EXPRESS CONSENT FOR ANY OF THE FOLLOWING:

20 (i) TRANSFERRING OR DISCLOSING THE CONSUMER'S GENETIC DATA TO ANY
21 PERSON OTHER THAN THE COMPANY'S VENDORS AND SERVICE PROVIDERS.

22 (ii) USING GENETIC DATA BEYOND THE PRIMARY PURPOSE OF THE GENETIC
23 TESTING PRODUCT OR SERVICE AND INHERENT CONTEXTUAL USES.

24 (iii) RETAINING ANY BIOLOGICAL SAMPLE PROVIDED BY THE CONSUMER
25 FOLLOWING COMPLETION OF THE INITIAL TESTING SERVICE REQUESTED BY THE
26 CONSUMER.

27 (c) INFORMED CONSENT IN COMPLIANCE WITH THE FEDERAL POLICY FOR THE
28 PROTECTION OF HUMAN RESEARCH SUBJECTS PRESCRIBED BY 45 CODE OF FEDERAL
29 REGULATIONS PART 46 FOR TRANSFERRING OR DISCLOSING THE CONSUMER'S GENETIC
30 DATA TO THIRD-PARTY PERSONS FOR RESEARCH PURPOSES OR RESEARCH CONDUCTED
31 UNDER THE CONTROL OF THE COMPANY FOR THE PURPOSE OF PUBLICATION OR
32 GENERALIZABLE KNOWLEDGE.

33 (d) EXPRESS CONSENT FOR MARKETING TO A CONSUMER BASED ON THE
34 CONSUMER'S GENETIC DATA OR FOR MARKETING BY A THIRD-PARTY PERSON TO A
35 CONSUMER BASED ON THE CONSUMER HAVING ORDERED OR PURCHASED A GENETIC
36 TESTING PRODUCT OR SERVICE. FOR THE PURPOSES OF THIS SUBDIVISION,
37 MARKETING DOES NOT INCLUDE PROVIDING CUSTOMIZED CONTENT OR OFFERS ON
38 WEBSITES OR THROUGH APPLICATIONS OR SERVICES PROVIDED BY THE
39 DIRECT-TO-CONSUMER GENETIC TESTING COMPANY WITH THE FIRST-PARTY
40 RELATIONSHIP TO THE CONSUMER.

41 3. REQUIRE A VALID LEGAL PROCESS FOR DISCLOSING GENETIC DATA TO LAW
42 ENFORCEMENT OR ANY OTHER GOVERNMENT AGENCY WITHOUT A CONSUMER'S EXPRESS
43 WRITTEN CONSENT.

1 4. DEVELOP, IMPLEMENT AND MAINTAIN A COMPREHENSIVE SECURITY PROGRAM
2 TO PROTECT A CONSUMER'S GENETIC DATA AGAINST UNAUTHORIZED ACCESS, USE OR
3 DISCLOSURE.

4 5. PROVIDE A PROCESS FOR A CONSUMER TO DO ALL OF THE FOLLOWING:
5 (a) ACCESS THE CONSUMER'S GENETIC DATA.
6 (b) DELETE THE CONSUMER'S ACCOUNT AND GENETIC DATA.
7 (c) REQUEST AND OBTAIN THE DESTRUCTION OF THE CONSUMER'S BIOLOGICAL
8 SAMPLE.

9 6. DISCLOSE GENETIC DATA ONLY IN ACCORDANCE WITH SECTION 12-2802.
10 B. NOTWITHSTANDING ANY OTHER PROVISION IN THIS SECTION, A
11 DIRECT-TO-CONSUMER GENETIC TESTING COMPANY MAY NOT DISCLOSE A CONSUMER'S
12 GENETIC DATA TO ANY ENTITY OFFERING HEALTH INSURANCE, LIFE INSURANCE OR
13 LONG-TERM CARE INSURANCE OR TO ANY EMPLOYER OF THE CONSUMER.

14 44-7923. Exceptions

15 THIS CHAPTER DOES NOT APPLY TO ANY OF THE FOLLOWING:

16 1. PROTECTED HEALTH INFORMATION THAT IS COLLECTED BY A COVERED
17 ENTITY OR BUSINESS ASSOCIATE GOVERNED BY THE PRIVACY, SECURITY AND BREACH
18 NOTIFICATION RULES ISSUED BY THE UNITED STATES DEPARTMENT OF HEALTH AND
19 HUMAN SERVICES UNDER 45 CODE OF FEDERAL REGULATIONS PARTS 160 AND 164.

20 2. BIOLOGICAL SAMPLES THAT ARE OBTAINED OR GENETIC DATA THAT IS
21 GENERATED FOR THE PURPOSES OF AN INDIVIDUAL'S MEDICAL SCREENING, TREATMENT
22 OR DIAGNOSIS.

23 3. GENETIC DATA THAT IS GENERATED BY ANALYSES OR TESTS DESCRIBED IN
24 SECTION 12-2801, PARAGRAPH 1, SUBDIVISION (b).

25 4. A PUBLIC OR PRIVATE INSTITUTION OF HIGHER EDUCATION OR AN ENTITY
26 THAT IS OWNED OR OPERATED BY A PUBLIC OR PRIVATE INSTITUTION OF HIGHER
27 EDUCATION.

28 44-7924. Enforcement; violation; civil penalty; damages;
29 costs; attorney fees

30 THE ATTORNEY GENERAL MAY BRING AN ACTION TO ENFORCE THIS CHAPTER. A
31 PERSON WHO VIOLATES THIS CHAPTER IS SUBJECT TO:

32 1. A CIVIL PENALTY OF UP TO \$2,500 FOR EACH VIOLATION.

33 2. THE PAYMENT OF ACTUAL DAMAGES INCURRED BY CONSUMERS AS A RESULT
34 OF THE VIOLATION.

35 3. COSTS AND REASONABLE ATTORNEY FEES INCURRED BY THE OFFICE OF THE
36 ATTORNEY GENERAL.

37 Sec. 2. Short Title

38 Title 44, chapter 38, Arizona Revised Statutes, as added by this
39 act, may be cited as the "Genetic Information Privacy Act".

APPROVED BY THE GOVERNOR APRIL 20, 2021.

FILED IN THE OFFICE OF THE SECRETARY OF STATE APRIL 20, 2021.