

THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 1207 Session of
1997

INTRODUCED BY EARLL, MURPHY, BRIGHTBILL, SALVATORE, WHITE,
KUKOVICH, STOUT, RHOADES, O'PAKE, GERLACH, HART, BODACK,
AFFLERBACH AND WILLIAMS, NOVEMBER 24, 1997

REFERRED TO JUDICIARY, NOVEMBER 24, 1997

AN ACT

1 Ensuring the confidentiality of information obtained from a
2 genetic test and regulating its collection, retention, use
3 and dissemination.

4 The General Assembly of the Commonwealth of Pennsylvania
5 hereby enacts as follows:

6 Section 1. Short title.

7 This act shall be known and may be cited as the Genetic
8 Testing Confidentiality Act.

9 Section 2. Legislative intent.

10 (a) Finding.--The General Assembly finds that the
11 collection, retention, use and dissemination of genetic
12 information can threaten an individual's right to privacy. The
13 increasing use of biotechnology and sophisticated genetic
14 screening techniques and the expanded understanding of the
15 genetic links to a variety of physical and psychological
16 diseases have greatly magnified the potential harm to individual
17 privacy that can occur from any collection, retention, use and
18 dissemination of genetic information.

(b) Intent.--It is the intent of the General Assembly to protect the confidentiality of the collection, retention, use or dissemination of information obtained from a genetic test.

Section 3. Definitions.

The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"Confidential genetic information." Genetic information acquired in the course of delivery of health or social services or obtained pursuant to written release.

"Genetic information." Individually identifiable information obtained from a genetic test.

"Genetic test." A laboratory test of human DNA or chromosomes used to identify the presence or absence of inherited alterations in genetic material which are associated with disease or illness, including carrier status. A genetic test is a direct measure of those alterations which does not include a test of indirect manifestations of the alterations.

"Health care provider." An individual or institutional health care provider.

"Home-care agency." Any organization or part of an organization which is staffed and equipped to provide in-home health care services. The term includes, but is not limited to, Commonwealth-licensed home health agencies, home health aide agencies or private-duty care agencies.

"Individual health care provider." A physician, nurse, technician, emergency medical services worker, chiropractor, optometrist, psychologist, nurse-midwife, physician assistant, dentist or other person, including a professional corporation or partnership, or an employee or agent of such an individual or an

1 institutional health care provider, providing medical, nursing,
2 drug or alcohol rehabilitation services, mental health services
3 or other health care services.

4 "Individually identifiable information." Information which
5 identifies or reasonably could identify an individual as
6 possessing inherited alterations in genetic material that are
7 associated with disease or illness, including carrier status.

8 "Institutional health care provider." A hospital, nursing
9 home, hospice, clinic, blood bank, plasmapheresis or other blood
10 product center, organ or tissue bank, sperm bank, clinical
11 laboratory, residential or outpatient drug and alcohol
12 rehabilitation service, mental health facility, mental
13 retardation facility, home-care agency or any health care
14 institution required to be licensed in this Commonwealth,
15 whether privately or publicly operated.

16 Section 4. Informed consent for genetic testing.

17 (a) Consent.--Except as provided for in subsection (b), no
18 genetic test may be obtained from an individual without first
19 securing the informed written consent to the test from that
20 individual or that individual's legal guardian or attorney-in-
21 fact. Any consent shall be preceded by an explanation of the
22 test, including its purpose, potential uses, limitations and
23 interpretation.

24 (b) Exceptions.--The provisions of subsection (a) shall not
25 apply to the use of a genetic test:

26 (1) On a cadaver by a health care provider which
27 procures, processes, distributes or uses a human body or a
28 human body part, tissue or bodily fluids for use in medical
29 research and education, therapy or transplantation.

30 (2) To assist in the identification of a dead

1 individual.

2 (3) To identify tissue or bodily fluid collected at a
3 crime scene.

4 (4) To assist in the care and treatment of an individual
5 under circumstances requiring an emergency response when that
6 individual is unable to give informed consent to a genetic
7 test.

8 (5) For research or public health purposes, but only
9 where the identity of the individual providing the sample is
10 not disclosed to the person or group collecting and
11 conducting the research.

12 (6) Pursuant to a court order after there has been a
13 judicial determination that the test will likely produce
14 information that is relevant and material to issues that are
15 properly before the court.

16 Section 5. Confidentiality of genetic information.

17 (a) General rule.--The subject of a genetic test or any
18 personal representative authorized to sign for the subject shall
19 have access to confidential genetic information. Confidential
20 genetic information shall be disclosed to the subject of a
21 genetic test unless the subject indicates otherwise.

22 Confidential genetic information shall only be disclosed to
23 anyone who is not the subject of testing as provided for under
24 this section; provided, however, that nothing in this section is
25 intended to govern disclosure to or by individuals or entities
26 covered by the exemptions in section 4(b).

27 (b) Consent.--Confidential genetic information shall not be
28 disclosed except in accordance with prior written consent
29 executed by the subject, and only to the extent, under the
30 circumstances, and for the purposes expressly allowed by this

1 act.

2 (c) Required elements of written consent to disclosure.--A
3 written consent to disclosure of confidential genetic
4 information shall include:

5 (1) The name of the subject of the genetic information.

6 (2) The specific name or general designation of the
7 person permitted to make the disclosure.

8 (3) The name or title of the individual or the name of
9 the organization to which the disclosure is to be made.

10 (4) The purpose of the disclosure.

11 (5) How much and what kind of information is to be
12 disclosed.

13 (6) The signature of the subject or such person
14 authorized to consent for the subject if such subject lacks
15 its capacity to accept.

16 (7) The date on which the consent is signed.

17 (8) A statement that the consent is subject to
18 revocation at any time.

19 (9) The date, event or condition upon which the consent
20 will expire, if not earlier revoked, but in no event longer
21 than two years from the date the consent form is signed.

22 (d) Further disclosure prohibited.--Each disclosure made
23 with the subject's written consent must be accompanied by the
24 following written statement:

25 This information has been disclosed to you from records
26 protected by Pennsylvania law. Pennsylvania law prohibits
27 you from making any further disclosure of this
28 information unless further disclosure is expressly
29 permitted by the written consent of the person to whom it
30 pertains or is authorized by the Genetic Testing

1 Confidentiality Act. A general authorization for the
2 release of medical or other information is not sufficient
3 for this purpose.

4 (e) Limitations on nonconsensual disclosure.--No person or
5 employee, or agent of such a person, who obtains confidential
6 genetic information in the course of the delivery of health or
7 social services or pursuant to a written release under
8 subsection (b) may disclose the information except to the
9 following:

10 (1) The physician who ordered the test or the
11 physician's designee.

12 (2) An agent, employee or medical staff member of a
13 health care provider, when the health care provider has
14 received confidential genetic information during the course
15 of the subject's diagnosis or treatment by the health care
16 provider, provided that the agent, employee or medical staff
17 member is involved in the medical care or treatment of the
18 subject, and the agent, employee or medical staff member has
19 a legitimate need to know. Nothing in this paragraph shall be
20 construed to require the segregation of confidential genetic
21 information from a subject's medical record.

22 (3) Medical personnel to the extent necessary to meet a
23 bona fide medical emergency.

24 (4) A peer review organization or committee as defined
25 in the act of July 20, 1974 (P.L.564, No.193), known as the
26 Peer Review Protection Act, a nationally recognized
27 accrediting agency or, as otherwise provided by law, any
28 Federal or State Government agency with oversight
29 responsibilities over health care providers.

30 (5) Individual health care providers in clinical care or

1 adoption situations where reasonable efforts to locate an
2 individual or individuals to secure voluntary consent to
3 disclosure have failed and where disclosure of confidential
4 genetic information to identifiable third parties is likely
5 to prevent serious harm to such third parties.

6 (6) The Department of Health and persons authorized to
7 gather, transmit or receive vital statistics under the act of
8 June 29, 1953 (P.L.304, No.66), known as the Vital Statistics
9 Law of 1953.

10 (7) The Department of Health and local boards and
11 departments of health, as authorized by the act of April 23,
12 1956 (1955 P.L.1510, No.500), known as the Disease Prevention
13 and Control Law of 1955.

14 (8) Employees of county mental health and mental
15 retardation agencies, county children and youth agencies,
16 county juvenile probation departments, State or county
17 facilities for delinquent youth and contracted residential
18 providers of these entities receiving or contemplating
19 residential placement of the subject who:

20 (i) generally are authorized to receive medical
21 information;

22 (ii) are responsible for ensuring that the subject
23 receives appropriate health care; and

24 (iii) have a need to know the confidential genetic
25 information in order to ensure such care is provided.

26 The entities enumerated in this paragraph may release the
27 information in a court of a dispositional proceeding under 42
28 Pa.C.S. §§ 6351 (relating to disposition of dependent child)
29 and 6352 (relating to disposition of delinquent child) when
30 it is determined that such information is necessary to meet

1 the medical needs of the subject.

2 (9) Qualified personnel for the purpose of conducting
3 scientific research, if the research is performed in a manner
4 by which the identity of the test subject is not known and
5 may not be retrieved by the researcher.

6 (10) Pursuant to a court order after there has been a
7 judicial determination that the disclosure will likely
8 produce information that is relevant and material to issues
9 that are properly before the court.

10 Section 6. Civil cause of action.

11 Any person aggrieved by a violation of this act shall have a
12 cause of action against the person who committed such violation
13 and may recover compensatory damages.

14 Section 7. Separate violations.

15 Each disclosure of confidential genetic information in
16 violation of this act is separate for purposes of civil
17 liability.

18 Section 8. Written procedures.

19 Any individual or institution not exempted under section 4(b)
20 that has access to or maintains genetic information shall
21 establish written procedures for confidentiality and disclosure
22 of the records which are in accordance with the provisions of
23 this act within six months of the effective date of this act.

24 Section 9. Severability.

25 The provisions of this act are severable. If any provision of
26 this act or its application to any person or circumstance is
27 held invalid, the invalidity shall not affect other provisions
28 or applications of this act which can be given effect without
29 the invalid provision or application.

30 Section 10. Applicability.

1 The provisions of this act shall not apply to the
2 authorization for DNA testing under the act of May 28, 1995 (1st
3 Sp.Sess., P.L.1009, No.14), known as the DNA Detection of Sexual
4 and Violent Offenders Act.

5 Section 11. Effective date.

6 This act shall take effect in 60 days.