CHAPTER 277
FORMERLY
SENATE BILL NO. 162

AN ACT TO AMEND TITLE 16 OF THE DELAWARE CODE RELATING TO SEXUALLY TRANSMITTED DISEASES, INFORMED CONSENT, AND CONFIDENTIALITY.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. Amend Chapter 7 of Title 16 of the Delaware Code by making insertions as shown by underlining as follows:

Chapter 7. Sexually Transmitted Diseases

Subchapter 1 – Sexually Transmitted Disease Prevention and Control

§ 701. Definitions.

Section 2. Amend Chapter 7 of Title 16 of the Delaware Code by making insertions as shown by underlining as follows:

Subchapter 2 – HIV Testing and Counseling

§ 714. Definitions.

For purposes of this Subchapter the following definitions shall apply:

(1) “AIDS” shall mean Acquired Immunodeficiency Syndrome, a stage of HIV illness.

(2) “Approved laboratory” shall mean a laboratory approved by the Department for the purpose of performing standard tests for HIV as recognized as such by the Department.

(3) “Clinical setting” shall mean pre-natal clinics, hospital emergency departments, urgent care clinics, inpatient services, substance abuse treatment clinics, public health clinics, nursing homes, community clinics, correctional health-care facilities, blood banks, blood centers, sperm banks, primary care settings, and other public or private settings as defined by the Division.

(4) “Healthcare provider” shall mean any nurse, physician, dentist or other dental worker, optometrist, podiatrist, chiropractor, laboratory or blood bank technologist or technician, phlebotomist, dialysis personnel, emergency healthcare provider (including any paramedic, emergency medical technician, law enforcement personnel or firefighter), others whose activities involve contact with patients, their blood or corpses, and other public or private providers as defined by the Division.

(5) “Health facility” shall mean a hospital, nursing home, clinic, blood bank, blood center, sperm bank, laboratory, or other healthcare institution.

(6) “HIV” shall mean the Human Immunodeficiency Virus, a virus that can be transmitted sexually and that is identified as the causative agent of AIDS.

(7) “HIV test” shall mean a test to detect HIV infection.

(8) “Informed Consent” means consent of the subject of the test or subject’s legal guardian to the performance of HIV testing by a health care provider who has informed the subject or the subject’s legal guardian both verbally and in writing, to an extent reasonably comprehensive to general lay understanding, of the nature of the proposed testing and of the risks and alternatives to testing which a reasonable person would consider material to the decision whether or not to undergo testing.

(9) “Invasive medical procedure” shall mean any procedure involving surgical entry into tissues, cavities, or organs.

(10) “Legal guardian” shall mean a person appointed by a court to assume legal authority for another who has been found incompetent or, in the case of a minor, a person who has legal custody of the minor.

(11) “Manner known to transmit HIV” shall mean parenteral exposure to blood or blood products including but not limited to injection through the skin, sexual exposure, or exposure as otherwise determined by the Division.

(12) “Non-clinical setting” shall mean community-based organizations (CBO), outreach & education settings, mobile vans, and other settings as defined by the Division.

(13) “Person” shall mean any natural person, partnership, association, joint venture, trust, public, or private corporation, or health facility.

(14) “Prevention Counseling” shall mean an interactive process of assessing risk, recognizing specific behaviors that increase the risk for acquiring or transmitting HIV, and developing a plan to take specific steps to reduce risks.

(15) “Release of test results” shall mean a written authorization for disclosure of test results, which is signed, dated and specifies to whom disclosure is authorized and the time period during which the release is to be effective.

(16) “Routine/Opt-Out Testing” shall mean that the general consent for medical care shall encompass testing for HIV and that testing may be performed as a part of routine care unless it is declined and that declination is noted in the medical record. A separate consent for HIV testing is not required.

(17) “Test Counseling” shall include information that includes an explanation of the testing process/procedure, the meaning of possible test results, and provision of resources for additional information about relevant infections. The information may be provided orally or in writing and the subject of the counseling given the opportunity to ask questions.

(18) “HIV related tests” shall mean HIV tests, CD4 cell count tests, viral load tests, or any other rests related to HIV.

§ 715. Consent for HIV testing

(a) A healthcare provider or other person who performs HIV testing services in a clinical setting may provide Routine/Opt-Out testing provided that the following occurs:

(1) The subject is informed, orally or in writing, that Routine/Opt-Out HIV testing is encompassed by the general consent for medical services.

(2) The subject is given the opportunity to refuse consent to HIV testing at each instance of testing. Documentation of such refusal shall be noted in the subject’s medical record.

(3) The subject is provided HIV Test Counseling, orally or in writing, at the first instance of testing and by request thereafter.

(b) The healthcare provider or other person who performs HIV testing services in a non-clinical setting must obtain written documentation of informed consent at each instance of HIV screening.

(1) Informed consent to an HIV test in a non-clinical setting shall consist of a voluntary agreement executed by the subject of the test or the subject's legal guardian.

(2) At each instance of testing, the subject of the test must be offered HIV Test Counseling and Prevention Counseling prior to consent for HIV testing.

(c) Notwithstanding any other provision of law, a minor 12 years of age or older may consent or refuse consent to be a subject of HIV-related testing and to counseling relevant to the test. The consent or refusal of the minor shall be valid and binding as if the minor had achieved majority, and shall not be voidable, nor subject to later disaffirmance, because of minority.

(d) Notwithstanding subsection (a) of this Section the provisions of subsections (b), (c) and of this Section do not apply when:

(1) Knowledge of such test results is necessary for medical diagnostic purposes to provide appropriate emergency care or treatment and the subject of the test is unable to grant or withhold consent.

(2) The testing is done for the purposes of research; provided that the test is performed in a manner by which the identity of the test subject is not known and may not be retrieved by the researcher.

(3) A health care provider or health care facility procures, processes, distributes or uses (i) blood, (ii) a human body part donated for a purpose specified under the Uniform Anatomical Gift Act [Chapter 27 of this Title] or (iii) semen provided prior to July 11, 1988, for the purpose of artificial insemination, and such test is necessary to assure the medical acceptability of such gift or semen for the purposes intended.

(4) The health of a health care worker has been threatened during the course of a health care worker's duties, as a result of exposure to blood or body fluids of the patient in a manner known to transmit HIV.

(5) It is necessary to control the transmission of HIV infection as may be allowed pursuant to Chapter 7 of this Title as it relates to sexually transmitted diseases, or § 6523(b) of Title 11 as it relates to the Department of Correction.

(6) Testing is ordered by a court of competent jurisdiction within the confines of civil or criminal litigation where the results of an HIV-related test of a party, or a person in the custody or under the legal control of another party, is relevant to the ultimate issue of culpability and/or liability. Said order must be issued in compliance with the following provisions:

a. No court of this State shall issue such order unless the court finds that there is a compelling need for such test results, which cannot be accommodated by other means. In assessing compelling need, the court shall weigh the need for testing and disclosure of the test results against the privacy interest of the test subject and the public interest, which may be disserved, by disclosure which deters future testing or which may lead to discrimination.

b. Pleadings pertaining to ordering of an HIV-related test shall substitute a pseudonym for the true name of the subject of the test. The true name shall be communicated confidentially, in documents not filed with the court.

c. Before granting any such order, the court shall provide the subject of the test with notice and a reasonable opportunity to participate in the proceedings if the individual is not already a party.

d. Court proceedings as to disclosure of test results so ordered shall be conducted in camera unless the subject of the test agrees to a hearing in open court or unless the court determines that a public hearing is necessary to the public interest and the proper administration of justice.

(e) Any person on whom an HIV-related test was performed without first having obtained informed consent pursuant to subsections (d)(1), (4) and (5) of this Section shall be given notice promptly, personally and confidentially that a test sample was taken and the results of such test may be obtained upon request.

(f) At the time of learning the test result, the subject of the test or the subject's legal guardian shall be provided with counseling for coping with the emotional consequences of learning the result, for understanding the interpretation of the test result, for understanding measures for preventing infection to others, to urge the voluntary notification of sexual and needle-sharing partners of the risk of infection and the availability of any appropriate health care services, including mental health care and appropriate social and supportive services.

§ 716. HIV testing of pregnant women.

(a) A perinatal care provider may provide Routine/Opt-Out testing pursuant to § 715(a) of this Subchapter.

(1) In addition to the provisions of subsection (a) of this Section, a licensed health care provider who renders the primary prenatal care for a pregnant woman must offer HIV testing upon intake to perinatal services, during the third trimester, and at intake into labor and delivery if the result of previous test are not available or documented in the patient's chart.

(2) In addition to the provisions of subsection (a) of this Section, a licensed health care provider who renders the primary prenatal care for a pregnant woman must also counsel a pregnant woman that is found to be HIV infected, orally or in writing, about the dangers to her fetus and about the treatment options for maintaining her health and reducing chances of transmission of HIV to her fetus.

(b) A pregnant woman shall have the right to refuse consent to testing HIV infection at any instance of testing and to refuse any recommended treatment. Documentation of such refusal shall be maintained in the patient's medical record. All other provisions of this Subchapter shall apply to such counseling, testing, and disclosure, which take place pursuant to this Section.

§ 717. Confidentiality.

(a) No person may disclose or be compelled to disclose the identity of any person upon whom an HIV-related test is performed, or the results of such test in a manner which permits identification of the subject of the test, except to the following person:

(1) The subject of the test or the subject's legal guardian.

(2) Any person who secures a legally effective release of test results executed by the subject of the test or the subject's legal guardian.

(3) An authorized agent or employee of a health facility or health care provider if the health facility or health care provider itself is authorized to obtain the test results, the agent or employee provides patient care or handles or processes specimens of body fluids or tissues, and the agent or employee has a medical need to know such information to provide health care to the patient.

(4) Health care providers providing medical care to the subject of the test, when knowledge of the test results is necessary to provide appropriate emergency care or treatment.

(5) When part of an official report to the Division as may be required by law or regulation.

(6) A health facility or health care provider which procures, processes, distributes or uses: (i) blood; (ii) a human body part from a deceased person donated for a purpose specified under the Uniform Anatomical Gift Act; or (iii) semen provided prior to July 11, 1988, for the purpose of artificial insemination.

(7) Health facility staff committees or accreditation or oversight review organizations which are conducting program monitoring, program evaluation or service reviews, including the Child Death, Near Death and Still Birth Commission conducting reviews pursuant to Title 31.

(8) Pursuant to Chapter 9 of this Title as it relates to investigation of child abuse.

(9) Pursuant to Subchapter 1 of this Chapter as it relates to sexually transmitted diseases and their control.

(10) A person allowed access to said record by a court order which is issued in compliance with § 715(d)(6) of this Subchapter. Upon the issuance of an order to disclose test results, the court shall impose appropriate safeguards against unauthorized disclosure, which shall specify the persons who may have access to the information, the purposes for which the information shall be used and appropriate prohibitions on future disclosures.

(11) Pursuant to Chapter 12A of this Title as it relates to notification of emergency medical care providers.

(b) No person to whom the results of an HIV-related test have been disclosed pursuant to subsection (a) of this Section shall disclose the test results to another person except as authorized by subsection (a) of this Section.

(c) The provisions in this Section shall not interfere with the transmission of information as may be necessary to obtain third-party payment for medical care related to HIV infection or with the documentation of cause of death on death certificates.

§ 718. Enforcement of Subchapter.

(a) Any person aggrieved by a violation of this Subchapter shall have a right of action in the Superior Court and may recover for each violation:

(1) Against any person who negligently violates a provision of this Subchapter, damages of $1,000 or actual damages, whichever is greater.

(2) Against any person who intentionally or recklessly violates a provision of this Subchapter, damages of $5,000 or actual damages, whichever is greater.

(3) Reasonable attorneys' fees.

(4) Such other relief, including an injunction, as a court may deem appropriate.

(b) Any action under this Subchapter is barred unless the action is commenced within 3 years after the cause of action accrues. A cause of action will accrue when the injured party becomes aware of an unauthorized disclosure pursuant to § 717 of this Title, or that an HIV-related test has been conducted without informed consent pursuant to § 715 of this Title.

(c) The Attorney General may maintain a civil action to enforce this Subchapter in which a court may order any relief authorized by subsection (a) of this Section.

(d) Nothing in this Subchapter shall be construed to impose civil liability or criminal sanction for disclosure of an HIV-related test result in accordance with any reporting requirement by the Division.

Section 3. Amend Chapter 12, Title 16, of the Delaware Code by making insertions as shown by underlining and deletions as shown by strike through as follows:

Chapter 12. Informed Consent and Confidentiality

~~Subchapter I. HIV-Related Tests~~

~~§ 1201. Definitions.~~

~~For purposes of this subchapter the following definitions shall apply:~~

~~(1) "Aids" shall mean Acquired Immunodeficiency Syndrome.~~

~~(2) "Health care provider" shall mean any nurse, physician, dentist or other dental worker, optometrist, podiatrist, chiropractor, laboratory and blood bank technologist and technician, phlebotomist, dialysis personnel, emergency health care provider (including any paramedic, emergency medical technician, law enforcement personnel or firefighter) or others whose activities involve contact with patients, their blood or corpses.~~

~~(3) "Health facility" shall mean a hospital, nursing home, clinic, blood bank, blood center, sperm bank, laboratory or other health care institution.~~

~~(4) "HIV" shall mean the human immunodeficiency virus identified as the causative agent of AIDS.~~

~~(5) "HIV related test" shall mean a test for the antibody or antigen to HIV.~~

~~(6) "Legal guardian" shall mean a person appointed by a court to assume legal authority for another who has been found incompetent or, in the case of a minor, a person who has legal custody of the child.~~

~~(7) "Manner known to transmit HIV" shall mean parenteral exposure to blood or blood products including but not limited to injection through the skin; or as otherwise determined by the Division of Public Health.~~

~~(8) "Person" shall mean any natural person, partnership, association, joint venture, trust, public or private corporation or health facility.~~

~~(9) "Release of test results" shall mean a written authorization for disclosure of HIV related test results which is signed, dated and which specifies to whom disclosure is authorized and the time period during which the release is to be effective.~~

~~§ 1202. Informed consent.~~

~~(a) No health facility, health care provider or other person shall test or shall cause by any means to have tested, any specimen of any patient for HIV related tests, without the informed consent of the subject of the test or the subject's legal guardian. A health care provider shall ensure that informed consent has been received prior to ordering testing by a laboratory or other facility.~~

~~(b) Informed consent to an HIV-related test shall consist of a voluntary agreement executed by the subject of the test or the subject's legal guardian. If the agreement is oral, the facts pertaining thereto must be documented by customary practice. Informed consent shall consist of at least the following:~~

~~(1) An explanation of the test, including its purpose, potential uses, limitations and the meaning of its results;~~

~~(2) An explanation of the procedure to be followed, including that the test is voluntary, that consent may be withdrawn and the extent and limitations of the manner in which the results will be confidential;~~

~~(3) An explanation of the nature of AIDS and other manifestations of HIV infection and the relationship between the test result and those diseases; and~~

~~(4) Information about behaviors known to pose risks for transmission of HIV infection.~~

~~(c) Notwithstanding subsection (a) of this section the provisions of subsections (a) and (b) of this section do not apply when:~~

(1) Knowledge of such test results are necessary for medical diagnostic purposes to provide appropriate emergency care or treatment and the subject of the test is unable to grant or withhold consent.

(2) The testing is done for the purposes of research; provided that the test is performed in a manner by which the identity of the test subject is not known and may not be retrieved by the researcher.

(3) A health care provider or health care facility procures, processes, distributes or uses (i) blood, (ii) a human body part donated for a purpose specified under the Uniform Anatomical Gift Act [Chapter 27 of this title] or (iii) semen provided prior to July 11, 1988, for the purpose of artificial insemination, and such test is necessary to assure the medical acceptability of such gift or semen for the purposes intended.

(4) The health of a health care worker has been threatened during the course of a health care worker's duties, as a result of exposure to blood or body fluids of the patient in a manner known to transmit HIV.

(5) Necessary to control the transmission of HIV infection as may be allowed pursuant to Chapter 7 of this title as it relates to sexually transmitted diseases, or § 6523(b) of Title 11 as it relates to the Department of Correction.

(6) Testing is ordered by a court of competent jurisdiction within the confines of civil or criminal litigation where the results of an HIV related test of a party, or a person in the custody or under the legal control of another party, is relevant to the ultimate issue of culpability and/or liability. Said order must be issued in compliance with the following provisions:

a. No court of this State shall issue such order unless the court finds that there is a compelling need for such test results which cannot be accommodated by other means. In assessing compelling need, the court shall weigh the need for testing and disclosure of the test results against the privacy interest of the test subject and the public interest which may be disserved by disclosure which deters future testing or which may lead to discrimination.

b. Pleadings pertaining to ordering of an HIV-related test shall substitute a pseudonym for the true name of the subject of the test. The true name shall be communicated confidentially, in documents not filed with the court.

c. Before granting any such order, the court shall provide the individual whose test result is in question with notice and a reasonable opportunity to participate in the proceedings if the individual is not already a party.

d. Court proceedings as to disclosure of test results so ordered shall be conducted in camera unless the subject of the test agrees to a hearing in open court or unless the court determines that a public hearing is necessary to the public interest and the proper administration of justice.

(7) The testing is done on a pregnant woman as defined in § 1204 of this title.

(d) Any person on whom an HIV related test was performed without first having obtained informed consent pursuant to subsections (c)(1), (4) and (5) of this section shall be given notice promptly, personally and confidentially that a test sample was taken and the results of such test may be obtained upon request.

(e) At the time of learning the test result, the subject of the test or the subject's legal guardian shall be provided with counseling for coping with the emotional consequences of learning the result, for understanding the interpretation of the test result, for understanding measures for preventing infection to others and to urge the voluntary notification of sexual and needle sharing partners of the risk of infection.

(f) Notwithstanding any other provision of law, a minor 12 years of age or older may consent or refuse consent to be a subject of HIV-related testing and to counseling relevant to the test. The consent or refusal of the minor shall be valid and binding as if the minor had achieved majority, and shall not be voidable, nor subject to later disaffirmance, because of minority.

§ 1203. Confidentiality.

(a) No person may disclose or be compelled to disclose the identity of any person upon whom an HIV related test is performed, or the results of such test in a manner which permits identification of the subject of the test, except to the following person:

(1) The subject of the test or the subject's legal guardian.

(2) Any person who secures a legally effective release of test results executed by the subject of the test or the subject's legal guardian.

(3) An authorized agent or employee of a health facility or health care provider if the health facility or health care provider itself is authorized to obtain the test results, the agent or employee provides patient care or handles or processes specimens of body fluids or tissues, and the agent or employee has a medical need to know such information to provide health care to the patient.

(4) Health care providers providing medical care to the subject of the test, when knowledge of the test results is necessary to provide appropriate emergency care or treatment.

(5) When part of an official report to the Division of Public Health as may be required by regulation.

(6) A health facility or health care provider which procures, processes, distributes or uses: (i) blood; (ii) a human body part from a deceased person donated for a purpose specified under the Uniform Anatomical Gift Act; or (iii) semen provided prior to July 11, 1988, for the purpose of artificial insemination.

(7) Health facility staff committees or accreditation or oversight review organizations which are conducting program monitoring, program evaluation or service reviews, including the Child Death, Near Death and Still Birth Commission conducting reviews pursuant to Title 31.

(8) Pursuant to Chapter 9 of this title as it relates to investigation of child abuse.

(9) Pursuant to Chapter 7 of this title as it relates to sexually transmitted diseases and their control.

(10) A person allowed access to said record by a court order which is issued in compliance with the following provisions:

a. No court of this State shall issue such order unless the court finds that the person seeking the test results has demonstrated a compelling need for the test results which cannot be accommodated by other means. In assessing compelling need, the court shall weigh the need for disclosure against the privacy interest of the test subject and the public interest which may be disserved by disclosure which deters future testing or which may lead to discrimination.

b. Pleadings pertaining to disclosure of test results shall substitute a pseudonym for the true name of the subject of the test. The disclosure to the parties of the subject's true name shall be communicated confidentially, in documents not filed with the court.

c. Before granting any such order, the court shall provide the individual whose test result is in question with notice and a reasonable opportunity to participate in the proceedings if the individual is not already a party.

d. Court proceedings as to disclosure of test results shall be conducted in camera unless the subject of the test agrees to a hearing in open court or unless the court determines that a public hearing is necessary to the public interest and the proper administration of justice.

e. Upon the issuance of an order to disclose test results, the court shall impose appropriate safeguards against unauthorized disclosure, which shall specify the persons who may have access to the information, the purposes for which the information shall be used and appropriate prohibitions on future disclosures.

(11) Pursuant to Chapter 12A of this title as it relates to notification of emergency medical care providers.

(b) No person to whom the results of an HIV-related test have been disclosed pursuant to subsection (a) of this section shall disclose the test results to another person except as authorized by subsection (a) of this section.

(c) The provisions in this section shall not interfere with the transmission of information as may be necessary to obtain 3rd party payment for medical care related to HIV infection or with the documentation of cause of death on death certificates.

§ 1204. Counseling of all pregnant women.

(a) As a routine component of prenatal care, every licensed health care provider who renders the primary prenatal care, regardless of the site of such practice, shall advise every pregnant woman who is that provider's patient of the value of testing for Human Immunodeficiency Virus (HIV) infection and shall include a test for HIV infection among the standard battery of prenatal tests administered to each such pregnant woman, unless such pregnant woman opts out. Practitioners shall also counsel all pregnant women who are found to be HIV positive about the dangers to her fetus and the advisability of receiving treatment in accordance with the then current Centers for Disease Control and Prevention recommendations for HIV positive pregnant women.

(b) In addition to the provisions of subsection (a) of this section, a licensed health care provider who renders the primary prenatal care for a pregnant woman must offer HIV testing in the third trimester if she is at high risk for acquiring HIV. A woman is at high risk if 1 or more of the following applies:

(1) A history of a sexually transmitted disease; or

(2) During the pregnancy:

a. Illicit drug use or the exchange of sex for money or drugs;

b. Multiple sex partners or a sex partner known to be HIV positive or at high risk of acquiring HIV; or

c. Signs or symptoms suggestive of acute HIV infection.

(c) Any pregnant woman shall have the right to refuse consent to testing HIV infection and any recommended treatment. Documentation of such refusal shall be maintained in the patient's medical record. All other provisions of this subchapter shall apply to such counseling, testing and disclosure which takes places pursuant to this section.

§ 1205. Enforcement of subchapter.

(a) Any person aggrieved by a violation of this subchapter shall have a right of action in the Superior Court and may recover for each violation:

(1) Against any person who negligently violates a provision of this subchapter, damages of $1,000 or actual damages, whichever is greater.

(2) Against any person who intentionally or recklessly violates a provision of this subchapter, damages of $5,000 or actual damages, whichever is greater.

(3) Reasonable attorneys' fees.

(4) Such other relief, including an injunction, as the court may deem appropriate.

(5) Any action under this subchapter is barred unless the action is commenced within 3 years after the cause of action accrues. A cause of action will accrue when the injured party becomes aware of an unauthorized disclosure pursuant to § 1203 of this title, or that an HIV-related test has been conducted without informed consent pursuant to § 1202 of this title.

~~(b) The Attorney General may maintain a civil action to enforce this subchapter in which the court may order any relief authorized by subsection (a) of this section.~~

~~(c) Nothing in this subchapter shall be construed to impose civil liability or criminal sanction for disclosure of an HIV-related test result in accordance with any reporting requirement by the Division of Public Health.~~

Subchapter ~~II.~~ I. Genetic Information

§ ~~1220~~. 1201. Definitions.

As used in this subchapter:

(1) "Genetic characteristic" means any inherited gene or chromosome, or alternation thereof, that is scientifically or medically believed to predispose an individual to a disease, disorder or syndrome, or to be associated with a statistically significant increased risk of development of a disease, disorder or syndrome.

This includes, but is not limited to, information regarding carrier status, information regarding an increased likelihood of future disease or increased sensitivity to any substance, information derived from laboratory tests that identify mutations in specific genes or chromosomes, requests for genetic services or counseling, tests of gene products and direct analysis of genes or chromosomes.

(2) "Genetic information" means information about inherited genes or chromosomes, and of alterations thereof, whether obtained from an individual or family member, that is scientifically or medically believed to predispose an individual to disease, disorder or syndrome or believed to be associated with a statistically significant increased risk of development of a disease, disorder or syndrome.

(3) "Genetic test" means a test for determining the presence or absence of an inherited genetic characteristic in an individual, including tests of nucleic acids such as DNA, RNA, and mitochrondrial DNA, chromosomes or proteins in order to identify a predisposing genetic characteristic associated with disease, disorder or syndrome.

(4) "Informed consent"

a. For the purpose of obtaining genetic information, means the signing of a consent form which includes a description of the genetic test(s) to be performed, its purpose(s), potential uses, and limitations and the meaning of its results, and that the individual will receive the results unless the individual directs otherwise;

b. For the purpose of retaining genetic information, means the signing of a consent form which includes a description of the genetic information to be retained, its potential uses and limitations;

c. For the purpose of disclosing genetic information, means the signing of a consent form which includes a description of the genetic information to be disclosed and to whom.

d. For the purpose of obtaining insurance, there may be a single signing which shall allow the obtaining, retaining and disclosure of genetic information, which, in addition to the requirements of paragraphs a. and b. of this subsection, shall:

1. Be written in plain language;

2. Be dated;

3. Name or identify by generic reference the persons authorized to disclose information about the individual;

4. Specify the nature of the information authorized to be disclosed;

5. Name or identify by generic reference the person to whom the individual is authorizing information to be disclosed, or subsequently redisclosed;

6. Describe the purpose for which the information is collected;

7. Specify the length of time such authorization shall remain valid; and,

8. Be signed by:

A. The individual;

B. Such other person authorized to consent for such individual, if such individual lacks the capacity to consent; or;

C. The claimant for the proceeds of an insurance policy.

§ ~~1221.~~ 1202. Informed consent required to obtain genetic information.

(a) No person shall obtain genetic information about an individual without first obtaining informed consent from the individual.

(b) The requirements of this section shall not apply to genetic information obtained:

(1) By a state, county, municipal or federal law enforcement agency for the purposes of establishing the identity of a person in the course of a criminal investigation or prosecution;

(2) To determine paternity;

(3) Pursuant to the DNA analysis and data bank requirements of § 4713 of Title 29;

(4) To determine the identity of deceased individuals;

(5) For anonymous research where the identity of the subject will not be released;

(6) Pursuant to newborn screening requirements established by state or federal law; or

(7) As authorized by federal law for the identification of persons.

§ ~~1222.~~ 1203. Authorization to retain genetic information and samples from which genetic information is derived.

(a) No person shall retain an individual's genetic information without first obtaining informed consent from the individual unless:

(1) Retention is necessary for the purposes of a criminal or death investigation or a criminal or juvenile proceeding;

(2) Retention is necessary to determine paternity;

(3) Retention is authorized by order of a court of competent jurisdiction;

(4) Retention is made pursuant to the DNA analysis and data bank requirements of § 4713 of Title 29; or

(5) Retention of information is for anonymous research where the identity of the subject will not be released.

(b) The sample of an individual from which genetic information has been obtained shall be destroyed promptly unless:

(1) Retention is necessary for the purposes of a criminal or death investigation or a criminal or juvenile proceeding;

(2) Retention is authorized by order of a court of competent jurisdiction; or

(3) Retention is authorized by the individual; or

(4) Retention is for anonymous research where the identity of the subject will not be released.

§ ~~1223~~. 1204. Genetic information access by the subject.

An individual promptly upon request, may inspect, request correction of and obtain genetic information from the records of that individual.

§ ~~1224.~~ 1205. Conditions for disclosure to others of genetic information.

(a) Regardless of the manner of receipt or the source of genetic information, including information received from an individual, a person shall not disclose or be compelled, by subpoena or any other means, to disclose the identity of an individual upon whom a genetic test has been performed or to disclose genetic information about the individual in a manner that permits identification of the individual, unless:

(1) Disclosure is necessary for the purposes of a criminal or death investigation or a criminal or juvenile proceeding or to protect the interests of an issuer in the detection or prevention of fraud, material misrepresentation or material non-disclosure;

(2) Disclosure is necessary to determine paternity;

(3) Disclosure is authorized by order of a court of competent jurisdiction;

(4) Disclosure is made pursuant to the DNA analysis and data bank requirements of § 4713 of Title 29;

(5) Disclosure is authorized by obtaining informed consent of the tested individual describing the information to be disclosed and to whom;

(6) Disclosure is for the purpose of furnishing genetic information relating to a decedent for medical diagnosis of blood relatives of the decedent;

(7) Disclosure is for the purpose of identifying bodies;

(8) Disclosure is pursuant to newborn screening requirements established by state or federal law;

(9) Disclosure is authorized by federal law for the identification of persons; or

(10) Disclosure is by an insurer to an insurance regulatory authority;

(11) Disclosure is authorized in accordance with § 1220(4)d. of this title; or

(12) Disclosure is otherwise permitted by law.

(b) This section shall apply to any subsequent disclosure by any person after another person has disclosed genetic information or the identity of an individual upon whom a genetic test has been performed.

§ ~~1225.~~ 1206. Subchapter applicability.

This subchapter applies only to genetic information or samples that can be identified as belonging to an individual or family. This subchapter does not apply to any law, contract or other arrangement that determines a person's rights to compensation relating to substances or information derived from a sample of an individual from which genetic information has been obtained.

§ ~~1226~~. 1207. Parental rights.

This subchapter does not alter any right of parents or guardians to order medical and/or genetic tests of their children.

§ ~~1227.~~ 1208. Violations, penalties for unlawful disclosure of genetic information, jurisdiction.

(a) Any person who willfully retains an individual's genetic information or retains an individual's sample in violation of this subchapter shall be punished by a fine of not less than $1,000 nor more than $10,000.

(b) Any person who willfully obtains or discloses genetic information in violation of this subchapter shall be punished by a fine not less than $5,000 nor more than $50,000.

(c) Any person who willfully discloses an individual's genetic information in violation of this subchapter, shall be liable to the individual for all actual damages, including damages for economic, bodily or emotional harm which is proximately caused by the disclosure.

(d) The Superior Court shall have jurisdiction over all violations of this subchapter.

Subchapter ~~III.~~ II. Confidentiality of Personal Health Information

§ ~~1230.~~ 1210. Definitions.

As used in this subchapter, the following terms shall have the following meanings:

(1) "Expunge" or "expunged" means to permanently destroy, delete or make nonidentifiable.

(2) "Informed consent" means a written authorization for the disclosure of protected health information on a form substantially similar to one promulgated by the Department of Health and Social Services which is signed in writing or electronically by the individual who is the subject of the information. This authorization shall be dated and shall specify to whom the disclosure is authorized, the general purpose for such disclosure, and the time period in which the authorization for the disclosure is effective.

(3) "Legitimate public health purpose" means a population-based activity or individual effort primarily aimed at the prevention of injury, disease or premature mortality or the promotion of health in the community, including:

a. Assessing the health needs of the community through public health surveillance and epidemiological research;

b. Developing public health policy;

c. Responding to public health needs and emergencies;

d. Review by the Child Death, Near Death and Still Birth Commission; and

e. Requests for hospital records by the Division of Long Term Care Residents' Protection pursuant to § 1232 of this title.

(4) "Protected health information" means any information, whether oral, written, electronic, visual, pictorial, physical or any other form, that relates to an individual's past, present or future physical or mental health status, condition, treatment, service, products purchased, or provision of care and that reveals the identity of the individual whose health care is the subject of the information, or about which there is a reasonable basis to believe such information could be utilized (either alone or with other information that is or should reasonably be known to be available to predictable recipients of such information) to reveal the identity of that individual.

(5) "Research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

§ ~~1231.~~ 1211. Use of protected health information.

(a) Protected health information collected by the Department of Health and Social Services and/or its agencies and by the Child Death, Near Death, and Still Birth Commission shall be used solely for legitimate public health purposes.

(b) Nonidentifiable health information shall be used by the Department of Health and Social Services and its agencies whenever possible consistent with the accomplishment of legitimate public health purposes.

(c) Any use of protected health information permitted by this subchapter shall be limited to the minimum amount of information which the official using the information reasonably believes is necessary to accomplish the legitimate public health purpose.

(d) Protected health information shall not be used by the State for commercial purposes.

(e) Protected health information whose use no longer furthers the legitimate public health purpose for which it was acquired shall be expunged.

§ ~~1232~~. 1212. Disclosure of protected health information.

(a) General privacy protection. -- Protected health information is not public information as defined at § 10002 of Title 29 and may not be disclosed without the informed consent of the individual (or the individual's lawful representative) who is the subject of the information except as expressly provided by statute. Whenever disclosure of protected health information is made pursuant to this subchapter, such disclosure shall be accompanied by a statement concerning the Department of Health and Social Services' disclosure policy.

(b) Scope of disclosure. -- Protected health information shall be disclosed with the informed consent of the individual who is the subject of the information to any person and for any purpose for which the disclosure is authorized pursuant to informed consent.

(c) Nonidentifiable information. -- Any disclosure of protected health information permitted by this subchapter shall be disclosed in a nonidentifiable form whenever possible, consistent with the accomplishment of legitimate public health purposes, except when the disclosure is authorized through the informed consent of the person who is the subject of the information. Any disclosures of protected health information permitted by this subchapter shall also be limited to the minimum amount of information which the person making the disclosure reasonably believes is necessary to accomplish the purpose of the disclosure, except when the disclosure is authorized through the informed consent of the individual who is the subject of the information.

(d) Disclosure without informed consent. -- Protected health information may be disclosed without the informed consent of the individual who is the subject of the information where such disclosures are made:

(1) Directly to the individual;

(2) To appropriate federal agencies or authorities as required by federal or state law and for law-enforcement purposes in accordance with 45 C.F.R. Parts 160, 162, and 164;

(3) To health care personnel to the extent necessary in an emergency to protect the health or life of the person who is the subject of the information from serious, imminent harm;

(4) To the public safety authority during a public health emergency in accord with the uses described in § 1231 of this subchapter;

(5) In the course of any judicial or administrative proceeding in accordance with 45 C.F.R. Parts 160, 162, and 164, or pursuant to a court order to avert a clear danger to the individual or the public health;

(6) To the Child Death, Near Death and Still Birth Commission;

(7) To the Division of Long Term Care Residents' Protection in cases where the Division is engaged in an investigation or survey involving the care or treatment of an individual at a facility licensed by the Division, and the individual has been admitted to a hospital from the facility or discharged from a hospital to the facility. The Division of Long Term Care Residents Protection is an entity charged with helping to safeguard the health and safety of patients. It shall be recognized as a "public health authority" and as a "health oversight agency," and it shall be recognized in the performance of its functions as a peer review organization or auditor or evaluator with respect to such aspects of health care delivery systems or providers;

(8) Pursuant to § 2005 of this title;

(9) For research, regardless of the source of funding of the research, provided that the researcher provides documentation that an alteration to or waiver, in whole or in part, of the individual authorization required by subsection (a) of this section for use or disclosure of protected health information has been approved by the applicable privacy board in accordance with HIPAA regulations. Said approval shall not be granted until the Board has determined all of the following:

a. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

1. An adequate plan to protect the identifiers from improper use and disclosure;

2. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

3. Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

b. The research could not practicably be conducted without the waiver or alteration; and

c. The research could not practicably be conducted without access to and use of the protected health information;

(10) For patient treatment and care coordination, defined as the provision, coordination, or management of health care and related services by 1 or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from 1 health care provider to another; or

(11) To a health plan, health care clearinghouse, business associate, or health care provider, as each is defined by 45 C.F.R. Part 160, to use only in accordance with federal law for transactions that transmit information between 2 parties to carry out financial or administrative activities related to health care, health care operations, and health insurance, as set forth in 45 C.F.R Parts 160, 162, and 164.

(e) Deceased individuals. -- Nothing in this subchapter shall prohibit the disclosure of protected health information:

(1) In a certificate of death, autopsy report or related documents prepared under applicable laws or regulations;

(2) For the purposes of identifying a deceased individual;

(3) For the purposes of determining a deceased individual's manner of death by a medical examiner; or

(4) To provide necessary information about a deceased individual who is a donor or prospective donor of an anatomical gift.

(f) Informed consent by others. -- When an individual who is the subject of protected health information is not competent or is otherwise legally unable to give informed consent for the disclosure of protected health information, informed consent may be given by the individual's parents, legal guardians or other persons lawfully authorized to make health care decisions for the individual.

(g) Secondary disclosures. -- No person to whom protected health information has been disclosed pursuant to this subchapter shall disclose the information to another person except as authorized by this subchapter. This section shall not apply to:

(1) The individual who is the subject of the information;

(2) The individual's parents, legal guardians or other persons lawfully authorized to make health care decisions for the individual where the individual who is the subject of the information is unable to give legal consent pursuant to subsection (f) of this section; or

(3) Any person who is specifically required by federal or state law to disclose the information.

(h) Upon written request of an individual to a medical laboratory for a copy of the results of a laboratory examination of that individual, the medical laboratory shall provide a copy of those results that are sought to that individual. The medical laboratory may require a reasonable copying fee for copying and transmitting the records.

(i) The Child Death, Near Death and Still Birth Commission is an entity charged with helping to safeguard the health and safety of children. It shall be recognized as a "health oversight agency", and as a "public health authority", and it shall be recognized in the performance of its functions as a peer review organization or auditor or evaluator with respect to any aspect of health care delivery systems or providers.

§ ~~1233.~~ 1213. Regulations.

The Department of Health and Social Services shall enforce this subchapter and shall from time to time promulgate any additional forms and regulations that are necessary for this purpose.

Approved June 27, 2012