ILLINOIS HIV/AIDS CONFIDENTIALITY AND TESTING CODE

TITLE 77: PUBLIC HEALTH, CHAPTER I: DEPARTMENT OF PUBLIC HEALTH
SUBCHAPTER k: COMMUNICABLE DISEASE CONTROL AND IMMUNIZATIONS
PART 697 HIV/AIDS CONFIDENTIALITY AND TESTING CODE

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SUBPART A: GENERAL PROVISIONS
Section 697.20 Definitions

"Act" means the AIDS Confidentiality Act.

"AIDS" means acquired immunodeficiency syndrome (Section 3(b) of the Act).

"Blood Bank" means any facility or location at which blood or plasma is procured, furnished, donated, processed, stored or distributed.

"Department" means the Illinois Department of Public Health. (Section 3(a) of the Act)

"Designated Agent" means an organization designated by the Department to conduct public health activities in accordance with a written service agreement with the Department.

"Director" means the Director of the Illinois Department of Public Health.

"Health Care Facility" or "Facility" means any institution, building or agency, or portion of any institution, building or agency, whether public or private (for-profit or nonprofit) that is used, operated or designed to provide health services, medical treatment or nursing, rehabilitative or preventive care to any person or persons.

"Health Care Professional" means any of the following:

\[ \text{a licensed physician;} \]

\[ \text{a physician assistant to whom the physician assistant's supervising physician has delegated the provision of health services;} \]

\[ \text{an advanced practice registered nurse who has a written collaborative agreement with a collaborating physician which authorizes the provision of health services;} \]

\[ \text{a licensed dentist; or a licensed podiatrist. (Section 3(f-5) of the Act)} \]

"Health Care Provider" means any physician, nurse, paramedic, psychologist or other person providing medical, nursing, psychological, or other health care services of any kind. (Section 3(f) of the Act)

"HIV" means the human immunodeficiency virus or any other identified causative agent of AIDS. (Section 3(c) of the Act)

"HIV Infection" means infected with HIV, as evidenced by a positive or reactive supplemental laboratory test result.

"HIV Test" means an HIV test method approved by the federal Food and Drug Administration (FDA) or validated under a laboratory's Clinical Laboratory Improvement Amendments of 1988 (CLIA) certification.
"Informed Consent" means a written or verbal agreement by the subject of a test or the subject's legally authorized representative obtained without undue inducement or any element of force, fraud, deceit, duress or other form of constraint or coercion. (Section 3(d) of the Act)

"Laboratory" means a CLIA approved or licensed facility at which tests are performed to determine the presence of a sexually transmitted infection (STI).

"Legally Authorized Representative" means an individual who is authorized to consent to HIV testing and/or disclosure of HIV test results for an individual who is:

Under the age of 12,

Deceased,

Declared incompetent by a court of law, or

Otherwise not competent to consent (for reasons other than age, such as the apparent inability to understand or communicate with the health care professional) as determined by the health care professional seeking the consent.

The following individuals shall be authorized to consent, in the stated order of priority:

For a living or deceased child under the age of 18:

Parent, except as limited by Section 9(k) of the Act providing limitations on the ability of a parent or legal guardian to receive the child's test results, and Sections 4 and 5 of the Consent by Minors to Medical Procedures Act regarding release of test results involving a sexually transmitted infection,

Legal guardian or other court-appointed personal representative,

Adult next-of-kin.

For a living or deceased adult age 18 or over:

Agent authorized by durable power of attorney for health care,

Legal guardian or other court-appointed personal representative,

Spouse,

Person in a civil union,

Adult children,

Parent,
"Local Health Authority" means the official health department or board of health recognized by the Department as having jurisdiction over a particular area. (Section 3(2) of the Illinois Sexually Transmissible Disease Control Act)

"Opt-Out Testing" means a process in which the test subject is informed that the health care facility or health care professional routinely tests patients for HIV unless the patient refuses, is provided pre-test information as described in this Part, and is given an opportunity to ask questions and told how to decline testing without penalty to his or her ability to receive health care or other services.

"Physician" means a physician licensed to practice medicine under the Medical Practice Act of 1987.

"Rapid HIV Test" means any test approved by the U.S. Food and Drug Administration (FDA) or validated under a laboratory's CLIA certification for the detection of HIV that can be collected and processed within 60 minutes.

"Screening Test" means any HIV test approved by the FDA or validated under a laboratory's CLIA certification that must be followed by a supplemental test to confirm a positive result.

Sexually Transmissible Infection" or "STI" means infection with syphilis, gonorrhea, chlamydia, chancroid or HIV.

"Supplemental Test" means any HIV test approved by the FDA or validated under a laboratory's CLIA certification used to confirm the positive result of a screening test.

"Treatment" means services for prevention, diagnosis and medical management of STIs, including examination, laboratory testing, medication and immunization.

(Source: Amended at 36 Ill. Reg. 7613, effective May 4, 2012)

Section 697.30 Incorporated and Referenced Materials

a) The following materials are referenced in this Part:

1) Illinois Statutes
   A) AIDS Confidentiality Act [410 ILCS 305]
   B) AIDS Registry Act [410 ILCS 310]
   C) Communicable Disease Prevention Act [410 ILCS 315]
   D) Unified Code of Corrections [730 ILCS 5]
   E) Medical Patient Rights Act [410 ILCS 50]
F) Perinatal HIV Prevention Act [410 ILCS 335]

G) Civil Administrative Code of Illinois [20 ILCS 2310/55 to 55.45].

H) School Code [105 ILCS 5]

I) Abused and Neglected Child Reporting Act [325 ILCS 5]


K) Consent by Minors to Medical Procedures Act [410 ILCS 210]

L) Illinois Sexually Transmissible Disease Control Act [410 ILCS 325]

M) Medical Practice Act of 1987 [225 ILCS 60]

N) Perinatal HIV Prevention Act [410 ILCS 335]


P) Code of Civil Procedure [735 ILCS 5]

Q) Illinois Anatomical Gift Act [755 ILCS 50]

R) Organ Donation Request Act [755 ILCS 60]

S) Communicable Disease Prevention Act [410 ILCS 315]

2) Illinois Rules

A) Control of Communicable Disease Code (77 Ill. Adm. Code 690) (see in particular Section 697.140(a)(4) of this Part)

B) Control of Sexually Transmissible Diseases Code (77 Ill. Adm. Code 693) (see in particular Sections 697.140(a)(4) and 697.210(a) of this Part)

C) Illinois Clinical Laboratories Code (77 Ill. Adm. Code 450) (see in particular Section 697.180(c) and (e))

D) Sperm Bank and Tissue Bank Code (77 Ill. Adm. Code 470) (see in particular Section 697.180(c) and (e))

E) Practice and Procedure in Administrative Hearings (77 Ill. Adm. Code 100) (see in particular Section 697.40 of this Part)

F) Hospital Licensing Requirements (77 Ill. Adm. Code 250)
G) Skilled Nursing and Intermediate Care Facilities Code (77 Ill. Adm. Code 300)

H) Sheltered Care Facilities Code (77 Ill. Adm. Code 330)


L) Community Living Facilities Code (77 Ill. Adm. Code 370)

M) Illinois Health and Hazardous Substances Registry (77 Ill. Adm. Code 840)

3) Federal Statutes

A) Clinical Laboratory Improvement Amendments of 1988 (42 USC 263(a))

B) Education for All Handicapped Children Act (20 USC 921 and 1400)

b) The following materials are incorporated by reference in this Part:

1) Federal Regulations

A) 42 CFR 2a.4(a)-(j), 2a.6(a)-(b), and 2a.7(a)-(b), Protection of Identity – Research Subjects (April 4, 1979)

B) 45 CFR 164.501, Privacy Rule (Standards for Privacy of Individually Identifiable Health Information) of the Health Insurance Portability and Accountability Act of 1996 (October 1, 2007)

2) Other Guidelines


All incorporations by reference of federal regulations or guidelines refer to the regulations or guidelines on the date specified and do not include any amendments or editions subsequent to the date specified.

(Source: Amended at 36 Ill. Reg. 7613, effective May 4, 2012)

Section 697.40 Administrative Hearings

Any administrative hearings conducted by the Department concerning this Part shall be governed by the Department’s Practice and Procedure in Administrative Hearings.

(Source: Amended at 36 Ill. Reg. 7613, effective May 4, 2012)

SUBPART B: HIV TESTING

Section 697.100 Approved HIV Tests and Testing Procedures

a) Any person, laboratory, blood bank, hospital or other entity that conducts laboratory tests to detect the presence of HIV infection shall use an approved HIV test as defined in this Part. (See Section 697.20.)

1) Confirmatory testing shall be completed before HIV test results are released to the health care professional or other individuals authorized to receive the results as described and limited in Section 697.140, except in the following situations:

A) When immediate medical treatment is necessary to prevent further transmission of HIV to a newborn infant in labor, delivery and postpartum settings. For the purposes of this subsection (a)(1), immediate medical treatment, for a newborn infant, means upon delivery or within 48 hours after the infant's birth. (Section 10 of the Perinatal HIV Prevention Act) Treatment shall be conducted as provided by the Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States (see Section 697.30);

B) In instances of occupational exposure, as provided by Section 697.140(a)(8) and (9); or

C) At the time of testing, provided that the subject of the test or the subject’s legally authorized representative has received pre-test information, has been informed of his/her right to refuse testing, and has provided consent to be tested and to receive a preliminary test result in accordance with Sections 697.110 and 697.120, except in the case of a newborn infant as provided in the Perinatal HIV Prevention Act.

2) Before testing is conducted under subsection (a)(1)(A) or (B) (C), the subject of the test or the subject’s legally authorized representative shall receive pre-test information and shall have provided specific written or verbal informed consent to be tested and to receive a preliminary test result in accordance with Sections 697.110 and 697.120, except in the case of a newborn infant as provided in the
Perinatal HIV Prevention Act. The provision of pre-test information and informed consent shall be documented in the patient's medical record or as part of the consent form for medical care or HIV testing completed by the patient.

3) In the exceptions described in subsection (a)(1)(A) or (B), a preliminary test result may be released to persons specified in Section 697.140(a)(1), (2), (3), (8), or (9).

4) Any release of preliminary positive results from HIV tests shall include a disclaimer that an HIV infection has not been diagnosed and cannot be diagnosed without supplemental testing.

b) HIV testing shall be a routine part of general medical care, as recommended by the United States Centers for Disease Control and Prevention, Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings.

c) The Department will conduct training, technical assistance, and outreach activities, as needed, to encourage routine opt-out HIV testing in health care settings.

(Source: Amended at 36 Ill. Reg. 7613, effective May 4, 2012)

Section 697.110 HIV Pre-Test Information

a) No health care professional may order an HIV test without making available to the person tested pre-test information, except as provided in subsection (b). (Section 5 of the Act) Pre-test information may be provided in writing, verbally, or by video, electronic, or other means. The subject must be offered an opportunity to ask questions about the HIV test and decline testing. (Section (3)(d) of the Act) The health care professional may delegate the responsibility of providing pre-test information only to another individual who is knowledgeable about HIV infection, including possible medical and psychosocial aspects of the infection. Pre-test information may be included along with other medical information generally provided to a subject. The required pre-test information consists of the following information:

1) The meaning of the test results, including the purpose, potential uses, and limitations of the test and test results, and procedures to be followed;

2) That testing for HIV is voluntary, and consent to be tested may be withdrawn at any time before testing of the specimen has been initiated;

3) The availability of referrals for further information or counseling (Section 5 of the Act);

4) The subject's right to be tested anonymously at a site that offers anonymous testing, and a referral to a site at the request of the patient; and

5) The right to confidentiality, including nondisclosure of information identifying the subject of the test and the results of the test, to the extent provided by law.

b) Pre-test information when ordering an HIV test is not required in the situations listed in Section 697.120 (b)(1), (2), (5) and (7).
Section 697.120 Informed Consent

a) No person may order an HIV test without first receiving the documented informed consent of the subject of the test or the subject's legally authorized representative, except as provided in subsection (b). A health care facility or provider may offer opt-out HIV testing where the subject or the subject's legally authorized representative is informed that the subject will be tested for HIV unless he or she refuses. The health care facility or professional must document the provision of informed consent, including pre-test information, and whether the subject or the subject's legally authorized representative declined the offer of HIV testing. (Section 4 of the Act)

1) The health care professional ordering the test or another health care professional involved in the patient's care shall obtain the informed consent.

2) The health care professional may delegate the responsibility of obtaining informed consent only to another individual who is knowledgeable about HIV infection, including possible medical and psychosocial aspects of that infection.

3) A health care professional may combine a form used to obtain informed consent for HIV testing with forms used to obtain written consent for general medical care or any other medical test or procedure, provided that the forms make it clear that the subject may consent to general medical care, tests, or medical procedures without being required to consent to HIV testing and clearly explain how the subject may opt-out of HIV testing. (Section 3(d)(2) of the Act)

4) The person obtaining the informed consent shall document receipt of consent in the subject's medical record or as part of the consent form for medical care or HIV testing completed by the patient.

b) Informed consent to perform an HIV test is not required in the following situations:

1) When the health care professional or health care facility procures, processes, distributes or uses a human body part donated for purposes specified under the Illinois Anatomical Gift Act or the Organ Donation Request Act and the test is necessary to assure the medical acceptability of the human body part. (Section 7 of the Act)

2) When the health care professional or health care facility procures, processes, distributes or uses semen provided prior to September 21, 1987, for the purpose of artificial insemination and the test is necessary to assure medical acceptability of the semen. (Section 7 of the Act)

3) When the testing is for the purpose of research and performed in such a way that the identity of the test subject is not known and may not be retrieved by the researcher, and in such a way that the test subject is not informed of the results of the testing. (Section 8 of the Act)
4) When an HIV test is performed upon a person who is specifically required by state or federal law to be tested, such as blood, plasma, semen and human tissue donors and persons required to be tested pursuant to Section 5-5-3 of the Unified Code of Corrections. (Section 11 of the Act)

5) When an insurance company, fraternal benefit society, health services corporation, health maintenance organization, or any other insurer subject to regulation under the Illinois Insurance Code requires any insured patient or applicant for new or continued insurance or coverage to be tested for infection with HIV or any other identified causative agent of AIDS. (Section 3 of the Medical Patient Rights Act) (See Section 697.160.)

6) When a health care provider or employee of a health facility, or a firefighter or an EMT-B, EMT-I or EMT-P, is involved in an accidental direct skin or mucous membrane contact with the blood or bodily fluids of an individual which is of a nature that may transmit HIV, as determined by a physician in his or her medical judgment. Should such test prove to be positive, the patient and the health care provider, health facility employee, firefighter, EMT-B, EMT-I, or EMT-P shall be provided appropriate counseling consistent with the Act. (Section 7 of the Act)

7) When in the judgment of the physician, such testing is medically indicated to provide appropriate diagnosis and treatment to the subject of the test, provided that the subject of the test has otherwise provided his or her consent to such physician for medical treatment. (Section 8 of the Act)

8) For a health care professional or health care facility to perform a test when a law enforcement officer is involved in the line of duty in a direct skin or mucous membrane contact with the blood or bodily fluids of an individual which is of a nature that may transmit HIV, as determined by a physician in his or her medical judgment. Should such test prove to be positive, the patient shall be provided appropriate counseling consistent with the Act. For purposes of Section 7(c) of the Act, "law enforcement officer" means any person employed by the State, a county or a municipality as a policeman, peace officer, auxiliary-policeman, correctional officer or in some like position involving the enforcement of the law and protection of the public interest at the risk of that person's life. (Section 7 of the Act)

9) When an individual is charged with a sex crime in accordance with the Criminal Code of 1961.

(Source: Amended at 36 Ill. Reg. 7613, effective May 4, 2012)

Section 697.130 Anonymous Testing

Any individual seeking an HIV test shall have the right to anonymous testing, unless identification of the test subject is otherwise required. Anonymous testing shall be performed after pre-test information is provided and informed consent is obtained, using a coded system that does not link individual identity with the request or result. A health care facility or health care professional that does not provide anonymous testing shall refer an individual requesting an anonymous test to a site where it is available. (Section 6 of the Act) Any anonymous testing system adopted by the health care professional ordering the test shall ensure that the persons conducting the laboratory tests transmit the correct test results to the
proper health care professional, and that the correct test results are given to the correct patient. When a test subject does not have the right to request anonymity, the test subject may request that the blood sample be labeled so as to prevent any person from learning the identity of the test subject, unless the person is authorized to receive the information pursuant to Section 697.140 of this Part.

a) If anonymous testing is requested, the health care professional shall assign to the person a unique number or notation, which shall be used in lieu of the person's name. The specimen for testing shall be labeled with the name of the health care professional or health care facility and the unique number or notation assigned to the patient for the purpose of receiving the test results. Unless otherwise authorized by the patient, any record of the test result shall be maintained in a manner identifying the record only by its unique number or notation.

b) Anonymous testing shall not be permitted under the following circumstances:

1) When identification of the test subject is permitted or required to comply with Section 697.140(a)(3) or (6) of this Part; or

2) If the test is performed to determine eligibility as a donor or acceptability of a donation of blood, plasma, semen, oocytes or other human tissue.

(Source: Amended at 36 Ill. Reg. 7613, effective May 4, 2012)

Section 697.140 Nondisclosure of the Identity of a Person Tested or Test Results

a) No person may disclose or be compelled to disclose the identity of any person upon whom a test is performed, or the results of such a test in a manner which permits identification of the subject of the test, except to the following persons. (Section 9 of the Act) The term "disclose" as used in this subsection (a) shall not prohibit internal use by a person, or a person's agents or employees, for the purposes of treatment, payment and health care operations, as those terms are defined in 45 CFR 164.501. Any internal use shall be limited to those agents or employees, and the minimum necessary information, needed to accomplish the intended purposes of treatment, payment or health care operations.

1) The subject of the test or the subject's legally authorized representative (Section 9(a) of the Act).

2) Any person designated in a legally effective release of the test results executed by the subject of the test or the subject's legally authorized representative. (Section 9(b) of the Act) A legally effective release means a time-limited written release of medical information signed by the test subject.

3) An authorized agent or employee of a health care facility or health care professional or referring, treating or consulting health care professional of the test subject, if:

A) The health care facility or health care professional is authorized to obtain the test results. Health care facility or health care professional, for the purposes of this subsection (a)(3)(A), includes personnel who handle and
process medical records for that health care facility or health care professional;

B) The agent or employee or referring, treating or consulting health care professional of the test subject provides patient care or handles or processes specimens of body fluids or tissues;

C) The agent or employee or the test subject's referring, treating or consulting health care professional has a need to know such information. (Section 9(c) of the Act); or

D) The agent or employee when involved in an accidental direct skin or mucous membrane contact with the blood or bodily fluids of a patient that is of a nature likely to transmit HIV, such as needle stick or percutaneous exposure, as certified by a health care professional.

4) The Department or the local health authority, in accordance with rules for reporting and controlling the spread of disease, or as otherwise provided by State law. (See 77 Ill. Adm. Code 690, 693, 250, 300, 330, 340, 350, 370, 390, and 840.) The Department, local health department or designated agent shall not disclose information and records held by them relating to known or suspected cases of AIDS or HIV infection, publicly or in any action of any kind in any court or before any tribunal, board or agency. AIDS and HIV Infection shall be protected from disclosure in accordance with the provisions of Sections 8-2101 through 8-2105 of the Code of Civil Procedure. (Section 9(d) of the Act)

5) A health care facility or health care professional which procures, processes, distributes or uses:

A) A human body part from a deceased person with respect to medical information regarding the person; or

B) Semen provided prior to September 21, 1987, for the purpose of artificial insemination. (Section 9(e) of the Act)

6) Health care facility staff committees for the purpose of conducting program monitoring, program evaluation or service reviews conducted by, but not limited to, the Department, local health authority or designated agent. (Section 9(f) of the Act)

7) A school principal in accordance with Section 697.400 of this Part.

8) Any health care professional or employee of a health care facility, and any firefighter or any EMT-B, EMT-I, EMT-P involved in an accidental direct skin or mucous membrane contact with the blood or bodily fluids of an individual which is of a nature that may transmit HIV, as determined by a physician in his or her medical judgment. (Section 9(h) of the Act)

9) Any law enforcement officer, as defined in subsection (c) of Section 7 of the Act, involved in the line of duty in a direct skin or mucous membrane contact with the
blood or bodily fluids of an individual which is of a nature that may transmit HIV, as determined by a physician in his or her medical judgment. (Section 9(i) of the Act)

10) A temporary caretaker of a child taken into temporary protective custody by the Department of Children and Family Services pursuant to Section 5 of the Abused and Neglected Child Reporting Act. (Section 9(j) of the Act)

b) HIV test results may be disclosed to researchers when done in a manner that does not reveal the identity of the subject of the test. The de-identification of test results may be performed by an authorized agent or employee of a health facility or health care professional. Any test results that cannot be revealed without identifying the subject of the test shall be disclosed only in accordance with subsection (a). The Department shall disclose test results and demographic data without identifying information to researchers, in accordance with Section 697.220.

c) No person may disclose unconfirmed HIV test results in a manner that permits the identification of the subject of the test, except in accordance with Section 697.100(a)(1).

d) Documentation of informed consent, including written forms, if any, and HIV test results may be maintained, documented, and transmitted in a confidential manner in an electronic medical record system, medical record or confidential fax that allows disclosure only to persons authorized to receive the information under subsection (a).

e) Liability and Sanctions

1) Nothing in the Act or this Part shall be construed to impose civil liability or criminal sanction for disclosure of a test result in accordance with any reporting requirement of the Department for a diagnosed case of HIV infection, AIDS or a related condition. (Section 15 of the Act)

2) Nothing in the Act or this Part shall be construed to impose civil or criminal sanction for performing a test without informed consent pursuant to the provisions of Section 7(b) or (c) of the Act. (Section 15 of the Act)

3) The intentional or reckless violation of the Act or this Part shall constitute a Class A misdemeanor. (Section 12 of the Act)

f) Sections 697.110, 697.120, 697.130 and 697.140 shall not apply to eligibility and coverage requirements established by a health maintenance organization nor to any insurance company, fraternal benefit society, or other insurer regulated under the Illinois Insurance Code. (Section 15.1 of the Act)

(Source: Amended at 36 Ill. Reg. 7613, effective May 4, 2012)

Section 697.155 Delivery of HIV Test Results

a) The subject of the test or the subject’s legally authorized representative shall be notified in person whenever possible of the confirmed positive result of an HIV test. (Section 9.5(b) of the Act) If the results are provided over the phone, the health care professional shall
ensure that results are delivered to the test subject or the legally authorized representative only through methods such as verifying the subject's date of birth or other confidential information known only to the subject.

1) A health care professional shall make at least two attempts to deliver a positive test result to the subject or the subject's legally authorized representative.

2) If a health care professional is unable to notify a subject or the subject's legally authorized representative of a positive test within 14 days after receipt of the test result, the health care professional shall notify the local health department within 21 days after receipt of the test result. The name of the subject (unless testing was anonymous) and his or her locating information shall be included in the notification.

b) When the subject or the subject's legally authorized representative is notified of a confirmed positive test result, the health care professional shall provide the subject or the subject's legally authorized representative with a referral to counseling in connection with the confirmed positive test result and a referral to an appropriate medical facility for the treatment and management of HIV. (Section 9.5(b) of the Act) Any health care professional making a referral to another health care professional shall document consent from the test subject or the test subject's legally authorized representative.

c) A health care professional shall not be in violation of this Section when an attempt to contact the test subject or the subject's legally authorized representative at the address or telephone number provided by the test subject or the subject's legally authorized representative does not result in contact and notification or where an attempt to deliver results by personal contact has not been successful and the Department has been notified in accordance with subsection (a)(2). (Section 9.5(b) of the Act)

d) HIV-negative results shall be delivered to the test subject in person when feasible. It is recommended that post-test information be provided to those with HIV-negative results, including:

1) Risk reduction strategies to prevent transmission;

2) The importance and availability of STI screening;

3) The possibility that a recent infection cannot be detected by standard tests; and

4) The benefits of repeat testing.

(Source: Added at 36 Ill. Reg. 7613, effective May 4, 2012)

Section 697.160 HIV Testing for Insurance Purposes

a) Health maintenance organizations, insurance companies, fraternal benefit societies, health services corporations and other insurers subject to regulation under the Illinois Insurance Code are not required to comply with Sections 697.110, 697.120, 697.130 and 697.140 in establishing eligibility and coverage requirements that include mandatory HIV tests. This exemption also extends to the physician or other health care professional that performs the tests.
b)  Health maintenance organizations, insurance companies, fraternal benefit societies, health services corporations and other insurers subject to the Illinois Insurance Code that require any insured patient or applicant for new or continued insurance or coverage to be tested for HIV shall:

1)  Give the patient or applicant prior written notice of such requirement;

2)  Proceed with such testing only upon the written authorization of the applicant or patient; and

3)  Keep the results of such testing confidential.

c)  Notice of an adverse underwriting or coverage decision may be given to any appropriately interested party, but the insurer may only disclose the test result itself to a physician designated by the applicant or patient, and any such disclosure shall be in a manner that assures confidentiality.  (Section 3(c) of the Medical Patient Rights Act)

(Source: Amended at 36 Ill. Reg. 7613, effective May 4, 2012)

Section 697.170  Enforcement of the AIDS Confidentiality Act

a)  All health care facilities and health care professionals are required to comply with this Part.  Any failure to comply will be addressed in accordance with the following:

1)  Health care facilities and health care professionals that are licensed, certified, permitted or given any other form of recognition by the Department shall comply with the provisions of Sections 697.110, 697.120, 697.130 and 697.140 of this Part that are applicable to the health care facilities and health care professionals as a condition of licensure, certification, permit or any other form of recognition by the Department.  The reckless, deliberate or conscious failure to comply with these provisions shall constitute grounds for suspension, revocation or denial in accordance with the respective licensure, certification, permit and other recognition laws and regulations.

2)  The Department shall forward to the appropriate State, federal or local regulatory agency any complaint that it receives concerning the failure by any health care facility or health care professional that is subject to regulation by that agency to comply with the applicable provisions of Sections 697.110, 697.120, 697.130 and 697.140.

b)  The intentional or reckless violation of the Act or this Part shall constitute a Class A misdemeanor.  (Section 12 of the Act)

c)  Any person aggrieved by a violation of the Act or this Part shall have a right of action in the circuit court and may recover for each violation:

1)  Against any person who negligently violates a provision of the Act or this Part, liquidated damages of $2,000 or actual damages, whichever is greater.
2) Against any person who intentionally or recklessly violates a provision of the Act or this Part, liquidated damages of $10,000 or actual damages, whichever is greater.

3) Reasonable attorney fees.

4) Such other relief, including an injunction, as the court may deem appropriate.
   (Section 13 of the Act)

(Source: Amended at 36 Ill. Reg. 7613, effective May 4, 2012)

Section 697.180 HIV Testing for Blood and Human Tissue Donations

All potential donors of blood, plasma, semen, oocytes, organs, or other tissues shall be tested for HIV infection to determine whether the donated blood, plasma, semen, oocytes, organs, or other human tissue may be infected with HIV.

   a) All potential donors shall receive the HIV pre-test information set forth in Section 697.110(a) of this Part and be given the opportunity to refuse HIV testing. The informed consent provisions of Section 697.120 of this Part are required.

   b) If HIV testing is refused, the person shall not be accepted as a donor.

   c) The results of HIV testing shall be delivered in accordance with Section 697.155 and 77 Ill. Adm. Code 450 and 470.

   d) The results of HIV testing shall be kept confidential in accordance with Section 697.140.

   e) The donated blood, plasma, semen, oocytes, organs or other human tissue shall be handled in accordance with 77 Ill. Adm. Code 450 and 470.

   (Source: Amended at 36 Ill. Reg. 7613, effective May 4, 2012)

SUBPART C: HIV/AIDS REGISTRY SYSTEM

Section 697.200 HIV/AIDS Registry System

The Department's HIV/AIDS Registry System has been created to compile more complete and precise statistical data than is presently available in order to evaluate HIV treatment and prevention measures. The HIV/AIDS Registry System is a compilation of information concerning reported cases of AIDS and HIV.

   (Source: Amended at 36 Ill. Reg. 7613, effective May 4, 2012)

Section 697.210 Reporting Requirements

   a) Local health authorities that receive HIV/AIDS reports from health care professionals, hospitals or laboratories shall report to the Department's HIV/AIDS Registry System within seven days after receiving the HIV/AIDS report.
b) The Department requests, but does not require, hospitals, clinics, military facilities and prisons maintained by the federal government or other governmental agencies within the United States to report HIV/AIDS case information concerning present or past residents of Illinois, using the Adult HIV/AIDS Confidential Case Report, as modified by the Department.

(Source: Amended at 36 Ill. Reg. 7613, effective May 4, 2012)

Section 697.220 Release of HIV/AIDS Registry Data

a) The Department may not release data gathered pursuant to the HIV/AIDS Registry Act unless:

1) It is in a statistical form that does not identify the reporting entity, physician and patient in any way, including by address;

2) The release or transfer is to an Illinois Local Public Health Department or to a registry or health department of another state, and is of data concerning a person who is residing in that jurisdiction. The Department shall disclose individual patient data concerning residents of another state to the Registry in the individual's state of residence if the recipient of reported information about HIV/AIDS is legally required to hold reported information about HIV/AIDS in confidence and provides protection from disclosure of patient identifying information equivalent to the protection afforded by the Illinois law. (Section 7(a) of the AIDS Registry Act)

b) All data obtained directly from medical records of individual patients shall be for the confidential use of the Department and those entities authorized by the Department to view such records in order to carry out the purposes of the HIV/AIDS Registry Act. (Section 7(b) of the HIV/AIDS Registry Act)

c) The identity of any person whose condition or treatment has been studied, or any facts which are likely to reveal the identity of such person, shall be confidential and shall not be revealed in any report or any other matter prepared, released or published. Researchers may, however, use the names of persons when requesting additional information for research studies approved by the Department; provided, however, that when a request for additional information is to be made, the Department shall first obtain authorization from the patient or the patient's legally authorized representative after ascertaining that a test subject's physical and psychological condition is suitable for the request in the opinion of the test subject's health care professional. (Section 7(c) of the HIV/AIDS Registry Act)

1) All requests by medical or epidemiologic researchers for confidential HIV/AIDS Registry data shall be submitted in writing to the Department. The request shall include a study protocol that contains: objectives of the research; rationale for the research, including scientific literature justifying the current proposal; overall study methods, including copies of forms, questionnaires, and consent forms used to contact facilities, health care professionals or study subjects, and including methods for documenting compliance with 42 CFR 2a.4(a)-(j), 2a.6(a)-(b), and 2a. 7(a)-(b)(1); methods for the processing of data; storage and security measures taken to ensure confidentiality of patient identifying information; time frame of the study; a description of the funding source of the study (e.g., federal...
contract); the curriculum vitae of the principal investigator and a list of collaborators. In addition, the research request shall specify what patient or facility identifying information is needed and how the information will be used.

2) All requests to conduct research and modifications to approved research proposals involving the use of data that includes patient or facility identifying information shall be subject to a review to determine compliance with the following conditions. The Department will enter into contracts for research that requires the release of patient or health care facility identifying information when requests meet the following conditions:

A) The request for patient or facility identifying information contains stated goals or objectives;

B) The request documents the feasibility of the study design in achieving the stated goals and objectives;

C) The request documents the need for the requested data to achieve the stated goals and objectives;

D) The requested data can be provided within the time frame set forth in the request;

E) The request documents that the researcher has qualifications relevant to the type of research being conducted;

F) The research will not duplicate other research already underway using the same Registry data; and

G) The request documents other such conditions relevant to the need for the patient or facility identifying information and the patient’s confidentiality rights, because the Department will release only the patient or facility identifying information that is necessary for the research.

3) The Department will enter into research contracts for all approved research requests. These contracts shall specify exactly what information is being released and how it can be used. In addition, the researcher shall include assurances that:

A) The researcher understands that use of data is restricted to the specifications of the research protocol;

B) The researcher understands that any data that may lead to the identity of any patient, research subject, health care professional, other person, or hospital is strictly privileged and confidential and agrees to keep all data strictly confidential at all times;

C) The researcher understands that all officers, agents and employees are to keep all data strictly confidential;
D) The researcher agrees to communicate the requirements of this Section to all officers, agents, and employees, to discipline all persons who may violate the requirements of this Section, and to notify the Department in writing within 48 hours after any violation of this Section, including full details of the violation and corrective actions to be taken;

E) The researcher understands that all data provided by the Department pursuant to this contract may be used only for the purposes named in this contract and that any other or additional use of the data shall result in immediate termination of this contract by the Department; and

F) The researcher understands that all data provided by the Department pursuant to this contract is the sole property of the Department and may not be copied or reproduced in any form or manner and agrees to return all data and all copies and reproduction of the data to the Department upon termination of the contract.

4) Any departures from the approved protocol shall be submitted in writing and approved by the Director in accordance with subsection (c)(2) prior to initiation. No patient or facility identifying information may be released by a researcher to a third party.

5) The Department shall disclose individual patient or facility information to the reporting facility that originally supplied that information to the Department, upon written request of the facility.

d) HIV/AIDS information may be disclosed in accordance with Sections 697.140 and 697.400.

e) No liability shall attach to any hospital, physician or other facility submitting information pursuant to the Act based upon a claim that such hospital, physician or facility reported information which may be confidential. (Section 7(d) of the HIV/AIDS Registry Act)

(Source: Amended at 36 Ill. Reg. 7613, effective May 4, 2012)

SUBPART E: MISCELLANEOUS PROVISIONS

Section 697.400 Notification of School Principals

a) Whenever a child of school age is reported to the Department or a local health department with a confirmed HIV infection, the Department or local health authority shall give prompt (within three working days) and confidential notice of the identity of the child to the principal of the school in which the child is enrolled. If the child is enrolled in a public school, the principal shall disclose the identity of the child to the superintendent of the school district in which the child resides. (Section 2a of the Communicable Disease Prevention Act) School age is defined as between ages 5 and 21 by Section 10-20.12 of the School Code and between ages 3 and 21 for handicapped children by the Education for All Handicapped Children Act. Diagnosed cases and laboratory results are reported to the Department in accordance with the Control of Sexually Transmissible Infections Code. If the child resides in a county or city governed
by a Local Health authority, notification shall be the responsibility of the Local Health
authority. In all other cases, notification shall be the responsibility of the
Department. The Local Health authority or the Department shall offer assistance to the
principal concerning HIV, the availability of counseling and training, and guidelines for
management of the child in the classroom.

b) Upon receipt of the notice, the principal may, as necessary, such as when a student needs
medical attention or must take medication during school attendance, or when the student’s
clinical condition necessitates other services, disclose the identity of an infected child to
the school nurse at that school, the classroom teachers in whose classes the child is
enrolled, and those persons who, pursuant to federal or State law, are required to decide
the placement or educational program of the child. In addition, the principal may inform
such other persons as may be necessary, in the opinion of the principal, that an infected
child is enrolled at that school so long as the child's identity is not revealed. (Section 2a
of the Communicable Disease Prevention Act)

c) No person to whom the child's identity is disclosed may disclose the information to any
other person except as permitted by law (see Sections 9 and 10 of the Act).

(Source: Amended at 36 Ill. Reg. 7613, effective May 4, 2012)

Section 697.420 Testing, Treatment or Counseling of Minors

Any person 12 years of age or older who may have come in contact with any STI may consent
to testing and to medical care and/or counseling related to the diagnosis and/or treatment of such STI. (Section 4
of the Consent by Minors to Medical Procedure Act)

(Source: Amended at 36 Ill. Reg. 7613, effective May 4, 2012)

AUTHORITY: Implementing and authorized by the AIDS Confidentiality Act [410 ILCS 305]; the AIDS
Registry Act [410 ILCS 310]; the Communicable Disease Prevention Act [410 ILCS 315]; the Perinatal
HIV Prevention Act [410 ILCS 335]; and Sections 2310-10, 2310-315, 2310-325, and 2310-580 of the
Civil Administrative Code of Illinois [20 ILCS 2310/2310-10, 2310-315, 2310-325 and 2310-580].

SOURCE: Emergency rules adopted at 12 Ill. Reg. 1601, effective January 1, 1988, for a maximum of
150 days; adopted at 12 Ill. Reg. 9952, effective May 27, 1988; amended at 13 Ill. Reg. 11544, effective
July 1, 1989; amended at 15 Ill. Reg. 11646, effective August 15, 1991; emergency amendment at 17 Ill.
Reg. 1204, effective January 7, 1993, for a maximum of 150 days; emergency expired on June 7, 1993;
amended at 17 Ill. Reg. 15899, effective September 20, 1993; amended at 19 Ill. Reg. 1117, effective
13905, effective October 8, 2004; emergency amendment at 29 Ill. Reg. 14558, effective September 14,
2005, for a maximum of 150 days; amended at 30 Ill. Reg. 2373, effective February 3, 2006; amended at
36 Ill. Reg. 7613, effective May 4, 2012..